Complications in Gynecological Surgery

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1. Prevention of Infection Following Gynecological Surgery: The Evidence

Ronnie F. Lamont
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Definition of Infection

Terms such as inflammation, contamination, infection, sepsis, and febrile morbidity may mean different things to different clinicians. It is important, therefore, that in audits of surgical outcomes, reports of research findings, and comparisons of studies, terminology is defined; an example of this process is given in Table 1.1. The definitions of various systemic inflammatory responses and their associated clinical findings and laboratory test results are shown in Table 1.2.

Pathogenesis

The vagina contains more microorganisms than any other site in the body except the bowel. Uterine manipulation through the vagina, e.g., surgical termination of pregnancy (TOP), or operations that open the vagina, e.g., hysterectomy, will result in contamination of normally sterile sites by bacteria that are normally resident in the vagina. Whether these organisms become established and cause infection and inflammation depends on a mixture of surgical and host-related factors, including low socioeconomic status, poor nutrition, smoking, or preexisting medical conditions, such as impaired immunocompetence. These risk factors may be interrelated, e.g., diabetes, obesity, increased blood loss, duration of surgery, and prolonged hospital stay, and many of the measures that can be taken to reduce the rate of postoperative infectious morbidity focus on reducing the impact of these risk factors. The risk of postoperative infection also depends on the virulence and size of the bacterial inoculum. Normal vaginal flora is composed mainly of organisms of low virulence, dominated by lactobacilli species, which, by producing lactic acid from glycogen in vaginal secretions, render the pH of the vagina very acid (<4.5), in which milieu the growth of other potentially pathogenic organisms is suppressed.

At this low-acid pH, lactobacilli are particularly efficient at producing H_2O_2, which is toxic to bacteria. Under conditions where there is an increase in the

Table 1.1. Definition of Infection—Terminology

	Definition
Inflammation	Localized protective response elicited by injury or tissue damage
Contamination	Pathogenic microorganism(s) in normally sterile tissue without an inflammatory response
Infection	Pathogenic microorganism(s) in normally sterile tissue with a local inflammatory response
Sepsis	Infection with a local and systemic inflammatory response
Febrile morbidity	Temperature of >38.0°C on 2 occasions at least 6 hours apart, excluding the first 24 hours after the procedure

Source: Adapted from and reproduced with kind permission from Tamussino [1].

alkalinity of the vagina (bleeding, semen, douching) or a change in the delicate vaginal ecosystem (few or poor-quality lactobacilli, antibiotics, changes in endocrine status, or phage virus parasitization of lactobacilli), much less H_2O_2 is produced. This results in a 1000-fold increase in other organisms, particularly anaerobes that produce keto acids such as succinate. Succinate blunts the chemotactic response of neutrophils and reduces their killing ability. This

Table 1.2. Definitions of Systemic Inflammatory Responses

	Definition	Clinical Findings, Laboratory Tests
Systemic inflammatory response	Signs and symptoms of disseminated infection or toxins	Fever, tachypnea, tachycardia, leukocytosis, or leukopenia
Sepsis	Infection with a local and systemic inflammatory response	Tachypnea (>20 breaths/min) Tachycardia (>90 bpm) Hyperthermia or hypothermia (>38.4°C or <35.6°C)
Severe sepsis	Sepsis plus evidence of organ dysfunction	Metabolic acidosis, acute encephalopathy, oliguria, hypoxemia, disseminated intravascular coagulation, hypotension
Septic shock	Infection with an overwhelming systemic inflammatory response leading to shock	Hypotension (<90 mm Hg, or 40 mm Hg below baseline)
Sepsis syndrome or multiple-organ syndrome	Sepsis plus evidence of altered organ perfusion	Hypoxia, increased plasma lactate, altered mental state, oliguria

Source: Reproduced with kind permission from Tamussino [1].

results in a synergistic increase in other organisms such as *Mobiluncus* spp and more anaerobes. The result is a polymicrobial imbalance of large numbers of potentially pathogenic organisms, yet no cellular inflammatory response. This condition is called bacterial vaginosis (BV) [2]. As a result, the causative organisms of postoperative infectious morbidity are rarely unimicrobial or exogenous organisms and are more likely to be polymicrobial and endogenous organisms, such as the polymicrobial condition of BV or BV-related organisms, e.g., anaerobes, *Mobiluncus,* mycoplasmas, and ureaplasmas.

In 2001, the Clinical Effectiveness Group of the Association for Genitourinary Medicine and the Medical Society for the Study of Venereal Diseases produced national guidelines for the management of BV. They listed the complications associated with BV as postabortal sepsis, post-hysterectomy vaginal cuff cellulitis, and abscess post–vaginal hysterectomy. They concluded (level of evidence A) that treatment was indicated for symptomatic women, some pregnant women, and women undergoing some surgical procedures. Most of the evidence pertaining to the use of antibiotics in women undergoing surgery relates to hysterectomy and surgical TOP as an example of transvaginal manipulation of the uterus.

Prophylactic Antibiotics for Hysterectomy

Vaginal Hysterectomy

Hirsch [3] reviewed those studies in which antibiotics were used prophylactically in women undergoing vaginal hysterectomy. As early as 1985, Hirsch was able to find 48 studies of 5524 patients, of whom 3037 had been treated and 2487 were used as controls. Febrile morbidity occurred in 444 (15%) of 3037 women who received antibiotics compared to 988 (40%) of 2487 women who did not receive antibiotics (relative risk [RR] = 0.37; 95% confidence interval [CI] = 0.33–0.41; $P < 0.01$). Similarly, pelvic infections occurred in 105 (5%) of 2099 women who received antibiotics compared to 354 (25%) of 1391 women who did not receive antibiotics (RR = 0.2; CI = 0.16–0.24; $P < 0.01$).

Abdominal Hysterectomy

As part of the same review [3], Hirsch reviewed those studies in which antibiotics were used prophylactically in women undergoing abdominal hysterectomy. Hirsch found 30 studies involving 3752 patients, of whom 2165 had been treated and 1587 were used as controls. Febrile morbidity occurred in 348 (16%) of 2165 women who received antibiotics compared to 444 (28%) of 1587 women who did not receive antibiotics (RR = 0.57; CI = 0.51–0.65; $P < 0.01$). Pelvic infection occurred in 57 (5%) of 1196 women who received

antibiotics compared to 114 (10%) of 1144 women who did not receive antibiotics (RR = 0.48; CI = 0.35–0.65; $P < 0.001$). The nature of the abdominal hysterectomy procedure provided a third outcome category—wound infection—for analysis. In this category, 45 (3%) of 1434 women who received antibiotics developed a wound infection compared to 98 (8%) of 1194 women who did not receive antibiotics (RR = 0.38; CI = 0.27–0.54; $P < 0.01$).

Vaginal Versus Abdominal Hysterectomy

Around the time of the Hirsch review [3], 2 studies [4,5] reported on postoperative complications of vaginal versus abdominal hysterectomy. Shapiro et al. [4] found that a higher incidence of infection at the operation site was associated with increased duration of the procedure, lack of antibiotic prophylaxis, younger age, and an abdominal approach. Correcting for these associations, there was no predictive value of the following: obesity, preoperative functional and anatomical diagnosis, postoperative anatomical and pathological diagnosis, estimated blood loss, menopausal status, or surgeon who performed the procedure. Dicker et al. [5] studied 1851 women from 9 institutions. They found that vaginal hysterectomy when compared to abdominal hysterectomy was associated with significantly fewer complications but more unintended surgical procedures. Vaginal hysterectomy was associated with less febrile morbidity, less bleeding requiring transfusion, and less hospitalization and convalescence. Bearing in mind the results of these studies [4,5] and the review by Hirsch [3], in which there were more studies (48 versus 30) and more patients (5524 versus 3752) in which prophylactic antibiotics were used for vaginal hysterectomy compared to abdominal hysterectomy, it seems likely that up to 1985, antibiotics were used preferentially for vaginal hysterectomy compared to abdominal hysterectomy, though the logic of this choice is unclear. This is emphasized by the conclusion of Dicker et al. [5], who claimed that while vaginal hysterectomy with antibiotics had a better outcome than abdominal hysterectomy, the differences were probably attributable to the prevalence and efficacy of antibiotic usage in vaginal hysterectomy.

Bacterial Vaginosis and Post-hysterectomy Infectious Morbidity

Two studies [6,7], in neither of which antibiotic prophylaxis was used, highlighted the association between BV and post-hysterectomy vaginal cuff cellulitis. Soper et al. [6] found that 11 (34%) of 32 women with BV developed post-hysterectomy vaginal cuff cellulitis compared to only 11 (11%) of 102 of women with normal flora (RR = 3.2; CI = 1.5–6.7; $P < 0.005$). Larsson et al. [7] found that 7 (35%) of 20 women with BV developed post-hysterectomy vaginal

cuff infection compared to 4 (8%) of 50 with normal flora (R = 4.4; CI = 1.4–13.3; $P < 0.01$).

Choice of Antibiotics

With the important association of BV and BV-related organisms and the development of post-hysterectomy infectious morbidity, it is important that the antibiotics used prophylactically are active against those organisms, particularly anaerobes. In a metaanalysis, Mittendorf et al. [8] identified 25 randomized controlled trials of antibiotic prophylaxis that used vigorous protocols. They performed metaanalyses and cumulative metaanalyses for all the trials. Separate metaanalyses were performed for cefazolin, metronidazole, and tinidazole. Overall, 21% (373/1768) of patients who did not receive antibiotic prophylaxis had serious infection after abdominal hysterectomy. In comparison, of women who received any antibiotics, only 9% (166/1836) had serious postoperative infections ($P = 0.00001$). Among those who received cefazolin, metronidazole, or tinidazole, 11.4% (70/615; $P = 0.00021$), 6.3% (17/269; $P = 0.015$), and 5% (5/101; $P = 0.034$), respectively, had serious postoperative morbidity. The metaanalyses for individual studies and a cumulative metaanalysis are shown in Figure 1.1. Mittendorf et al. concluded that randomized controlled trials of antibiotic prophylaxis in abdominal hysterectomy that used controls who received no treatment are no longer justified. Moreover, they concluded, if the results of the various studies had been pooled at an earlier date, the inappropriateness of controls who received no treatment would have been discovered in 1980 for cefazolin, in 1984 for metronidazole, and in 1986 for tinidazole.

The Swedish National Study of Infection after Hysterectomy (1996), which took place before publication of the Mittendorf metaanalysis, involved 1060 women from 42 centers, yet included only 236 women (22%) who were given preoperative or postoperative antibiotics [9]. Not surprisingly, the postoperative infection rate was high, at 23%, 9.4% of whom had an infection that was situated either in the wound, in the vaginal cuff, or deep in the pelvis. Thirteen percent had a urinary tract infection (UTI), and 4% had infections distant from the site. Only 50% of the wound, cuff, and deep-pelvic infections were detected before discharge from the hospital. An increased risk of postoperative infection was associated with Wertheims-Meigs hysterectomy (21.4%; RR = 3.0; $P < 0.03$), intraoperative blood loss of >1000 mL (15%; RR = 2.4; $P < 0.001$), and BV (17%; RR = 2.3; $P > 0.05$). Admitting that the publication of Mittendorf et al. (1993) [8] had not been drawn to their attention until after preparation of their manuscript, Henriksson et al. (1998) [10] reported that 500 mg of metronidazole administered intravenously to 134 women immediately before total abdominal hysterectomy resulted in a significantly lower erythrocyte sedimentation rate on day 6 (50 mm/hr vs 56 mm/hr; $P < 0.05$), rate of infection (9% vs 17%; $P < 0.04$), and duration of postoperative hospitalization (7.9 vs 8.8 days; $P < 0.02$).

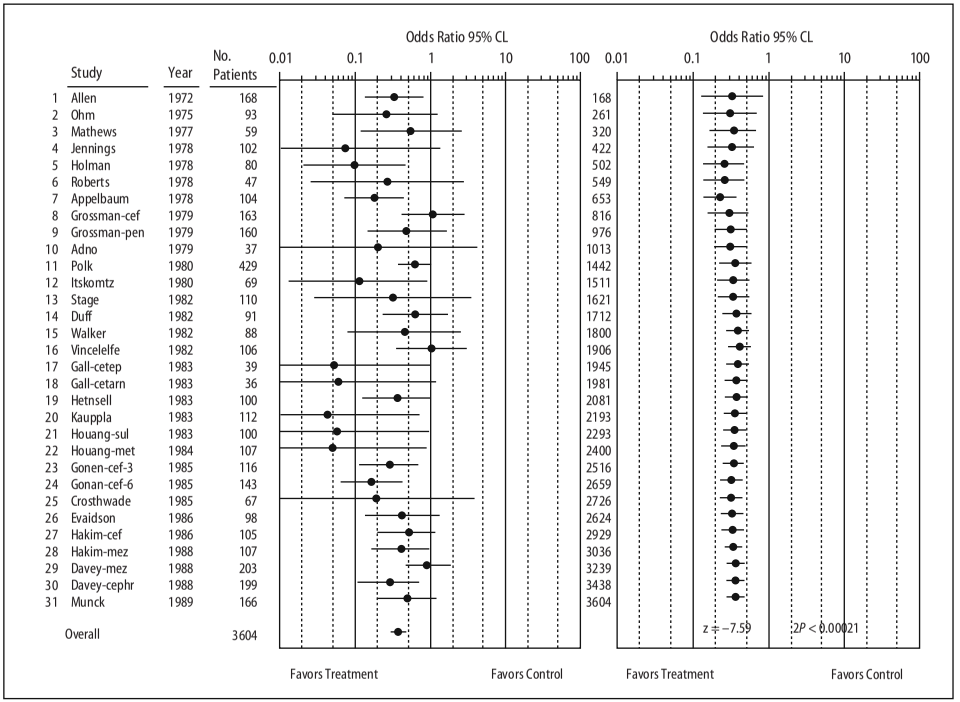

Figure 1.1. All antibiotic prophylaxis studies combined. Odds ratios for occurrence of serious infection after hysterectomy, DerSimonian and Laird random-effects model. In the left-hand graph, point estimates and 95% confidence intervals are given for each individual study, with pooled result at the bottom. On the right-hand side, the same data are presented as a cumulative metaanalysis.

Prevention of Infection Associated with Termination of Pregnancy

Following an unpublished pilot study in Swansea, Wales, in women presenting for TOP, in which the rate of pelvic infection was higher than expected, a larger, more formal study was performed. The study recruited 400 women attending for termination of pregnancy. One hundred twelve women (28%) had BV, 95 (24%) had candida, 3 (0.75%) had *Trichomonas*, and 1 (0.25%) had gonorrhea. Of 32 women (8%) with chlamydia, 63% developed postabortal pelvic infection, requiring 7 to be readmitted to the hospital. As a result, the authors recommended that, since the estimated cost of hospital admission due to chlamydia was twice the estimated cost of screening for and treating chlamydia, screening for chlamydia was essential, and prophylactic antibiotics should cover both chlamydia and BV [11].

The incidence of postabortal sepsis (PAS) is estimated to be between 4% and 12%. Those women with BV have a 3-fold increased risk of PAS compared to women with *Lactobacillus* spp–dominated flora [12]. Prophylactic metronidazole reduces PAS by 66% [13,14]. In a randomized, double-blind, placebo-controlled trial of 231 women attending for TOP who were given either 500 mg of metronidazole or placebo for 10 days starting the week preoperatively, the incidence of PAS was 3.8% in the metronidazole group compared with 12.2% in the placebo group ($P < 0.05$) [13]. The incidence of PAS can also be reduced by the administration of 2% clindamycin vaginal cream preoperatively in women with abnormal flora [15]. Penney et al. [16] found that prophylaxis against PAS was as good as screening and treatment and more cost-effective.

In the summary of recommendations, section 5.5 of the national evidence-based clinical guidelines for the care of women requesting induced abortion, evidence (level A) states that "abortion care should encompass a strategy for minimizing the risk of post abortion infectious morbidity." Level-B evidence states that "appropriate strategies include: antibiotic prophylaxis or screening for lower genital tract organisms with treatment of positive cases." An example of metronidazole 1 g per rectum at the time of TOP plus doxycycline 100 mg twice daily for 7 days commencing post-TOP is given.

Despite this and other recommendations, such as the Government Chief Medical Officer's Expert Advisory Group [17] and the 31st Study Group for the Royal College of Obstetricians and Gynaecologists (RCOG) on the Prevention of Pelvic Infection [18], for the prevention of pelvic infection following TOP and uterine instrumentation there still appears to be lack of uniformity in the United Kingdom. Skinner et al. [19] sent an anonymized questionnaire to gynecologists in the North and South Thames region of the United Kingdom requesting information on case load, screening policies for infection, and the use of prophylactic antibiotics for women undergoing TOP, insertion of intrauterine contraceptive device, laparoscopy, and endometrial sampling and/or hysteroscopy. Respondents were asked about screening procedures for genital infections, antibiotic regimes used, and advice given to women on referral to

genitourinary medicine clinics. Only 55% fulfilled RCOG guidelines for the prevention of chlamydial infection prior to TOP. Only 40% followed guidelines for other uterine instrumentation procedures, and when antibiotics were used, only 42% administered antibiotics that were active against both *Chlamydia trachomatis* and BV. The authors concluded that there were marked inconsistencies and lack of uniformity and that antibiotic regimes were frequently inadequate or inappropriate [19].

Infections Postoperative Hysteroscopy

While accepting the recommendations and guidelines from national bodies, clinical effectiveness groups, professional bodies, RCOG study groups, and expert advisory groups concerning the use of antibiotic prophylaxis to prevent infection when uterine instrumentation is involved, a recent report of 1952 operative hysteroscopies from Marseille, France, recorded a remarkably low incidence of postoperative infection despite the fact that no antibiotic prophylaxis was used. Following 782 resections of leiomyomata, 422 endometrial polypectomies, and 90 uterine septa resections, together with 623 endometrectomies and 199 lyses of intrauterine synechiae, the incidence of endometritis and UTI was extremely low at 18 (0.9%) of 1952 and 12 (0.6%) of 1952, respectively [20].

Conclusion

On July 3, 1909, at the age of 47, Herman Pfannenstiel (1862–1909), the Berlin gynecologist who gave his name to the low transverse incision so commonly used in obstetrics and gynecology, died of septicemia 1 week after a needle-stick injury to his left middle finger, sustained while operating on a patient with a tubo-ovarian abscess. With the introduction of antibiotics, postoperative infections are no longer the danger they were for patients or their surgeons but are still common, potentially life threatening, and a drain on health care. The following bullet points represent the evidence available for the prevention of infection following gynecological surgery.

- Prophylactic antibiotics significantly reduce infectious morbidity following hysterectomy and termination of pregnancy.
- Vaginal hysterectomy is associated with less infectious morbidity than total abdominal hysterectomy, but all hysterectomies should have antibiotic prophylaxis.
- Consensus guidelines also recommend antibiotic prophylaxis for other procedures that involve uterine instrumentation.
- Prophylactic antibiotics for TOP are as good as screening and treatment and probably more cost-effective. The possible exception to this rule is among women under the age of 20 years in whom screen-

ing for sexually transmitted infection such as *Chlamydia trachomatis,* gonococcus, and *Trichomonas* is more likely to result in positive cultures, with the added advantage of genito-urinary medicine (GUM) referral and contact tracing.

- Prophylactic antibiotics for TOP should cover both chlamydia and BV (e.g., doxycycline 200 mg daily plus metronidazole 1 g per rectum twice daily or 400 mg three times daily, or erythromycin 500 mg four times daily and clindamycin 300 mg twice daily).
- Antibiotic prophylaxis for hysterectomy should be broad spectrum as well as antianaerobe to cover wound infection and UTI as well as cuff cellulitis and deep-pelvic infection (e.g., metronidazole 1 g per rectum before surgery plus 750 mg cefuroxime IV with induction of anesthesia or 1.2 g of co-amoxiclav with the induction of anesthesia).
- With the strength of evidence available to show the benefits of antibiotic prophylaxis for hysterectomy and TOP, particularly with respect to covering both chlamydia and BV, together with many other sources of national clinical guidelines and recommendations from government and national expert advisory groups, failure to follow the advice would leave clinicians open to medical litigation.

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2. Complications in Gynecological Oncology

Robin A.F. Crawford

> "*In ten years as a consultant, I have never taken a woman back to theater after my surgery.*"
>
> —Anonymous specialist, eastern region, 2002

This quote provides a very good introduction to this chapter. Complications occur in all forms of gynecological surgery. They can be reduced by a variety of strategies. The view expressed by the consultant quoted above may reflect a number of points. First, the consultant's surgical workload or practice may be too small. Unless complications occur frequently, the practitioner with a small practice will not see many problems within an assessable time frame. Therefore, there will be a lack of insight with regard to these problems or even a selective memory, leading the practitioner to believe that his or her surgeries have few or no complications. This trend has been compounded in the National Health Service (NHS) by poor data collection and no agreement regarding the minimum data set relating to complications. Audit of outcomes and complications is sporadic and usually covers only a short time period. This deficit also leads to complacency with respect to complications.

In gynecological oncology surgery, there are some data relating to complications. Increasingly, we are dealing with a centralized service following the introduction of the Improving Outcomes Guidance in England and Wales [1]. This centralization and the introduction of mandatory minimum data-set collection will lead to more information about complications and should reduce the number of practitioners who subscribe to the opinion voiced in this chapter's opening quote.

Radical Cancer Surgery

The aim of radical cancer surgery is in the first instance curative. In ovarian cancer, surgery is diagnostic (providing histological material), needed for staging, and also therapeutic [2], regardless of the final stage. In endometrial cancer, the surgery is the cornerstone of treatment even with advanced disease, providing information relating to stage as well [3]. In cervical cancer, surgery is reserved for curative intent in patients with early disease. In patients with recurrent cervical disease, surgery may be curative with exenteration [4] but is more often palliative to control symptoms.

Complications of Radical Surgery

Anesthetic and Perioperative Complications

The outcome of surgery depends in part on the patient's fitness (see Figure 2.1). The patients we treat who have gynecological cancer usually comprise an older population than patients with other gynecological conditions. Considerable comorbidity is present in the gynecological cancer population; this comorbidity in itself leads to a higher rate of complication. In comparing outcomes, including hospital stay, these comorbidities should be taken into account. This may be addressed using an evaluation tool such as the "adult comorbidity evaluation-27" sheet [5], which may be used for the minimum cancer data set.

Perioperative death (within 24 hours) was 8.8. per 10,000 anesthesia administrations, with 85% of the deaths related to the patient's comorbidity. Thus, selection of the appropriate operation for each patient is important. In the group of patients who died as a result of anesthetic-related problems, 25% were inadequately prepared for surgery [6].

Appropriate liaison with consultant anesthetists and suitable preoperative preparation of patients with gynecological cancer lead to better outcomes. The primary debulking surgery required for advanced ovarian cancer or the management of the patient for interval debulking surgery is not comparable to routine benign gynecological surgery, and therefore there is an intraoperative requirement for epidural usage, central venous and arterial monitoring, and postoperative high-dependency or intensive-care support.

Risk reduction relating to anesthesia can be achieved by the following practices:

- The use of an appropriately skilled anesthetist providing an apt preoperative assessment
- The use of intraoperative regional anesthesia in addition to general anesthesia, which leads to reduced amount of central sedation,

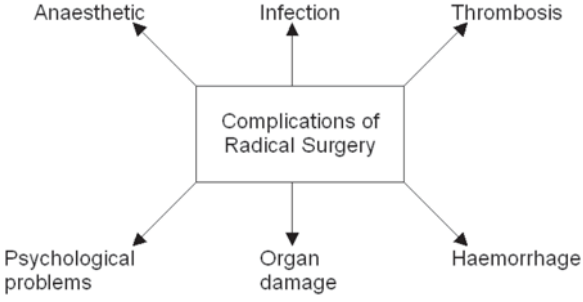

Figure 2.1. Complications of radical surgery.

reduced effect on the gut motility postoperatively, and reduced thrombosis risk, as well as excellent postoperative analgesia
- Good postoperative care, with access to correctly staffed high-dependency and/or intensive care

In the gynecological oncology center, the anesthetist is an integral part of the multidisciplinary team.

Infection

In gynecological oncology, patients are at risk of infection in the chest, in the pelvis/intraabdominal region, in the urinary tract, at the wound site, and at sites of intravenous and arterial lines. Any prophylactic regime is effective in reducing postoperative infective complications [7]. It is important that the regime be given at the appropriate time. We have used a nurse-based "patient group directive" to ensure that all women undergoing surgery, whether elective or emergency, are covered by antibiotic prophylaxis. As the majority of our patients are more than 60 years old, we avoid the use of cephalosporins, as this can predispose toward pseudomembranous colitis [8]. Our patients receive metronidazole (500 mg IV), gentamicin (120 mg IV), and benzyl penicillin (1.2 g IV) with induction of anesthesia. We omit the penicillin if the patient is allergic. We see very few cases of chest infection in our group due to the use of regional anesthesia and active pre- and postoperative physiotherapy.

Thrombosis

Patients with gynecological cancer are at increased risk of thrombosis resulting from the malignancy and the effects of pelvic surgery. Many patients have had decreased mobility prior to surgery as a result of massive ascites. The ascites, combined with a pelvic mass, which can compress the venous return from the legs, causes the woman with gynecological cancer to present a special risk for thromboembolism. In addition, many women with gynecological cancer have a morbidly increased body mass index and thus are at risk of embolism. Following gynecological oncology surgery, the incidence of deep vein thrombosis without prophylaxis is in excess of 40% [9].

Therapeutically, a number of gynecological oncology patients are taking agents that lead to an increased risk of thromboembolism. While conventional hormone replacement therapy (HRT) is well known to predispose to thromboembolism, patients taking tamoxifen have a greater risk of thrombosis and are therefore advised to stop taking it 2 weeks before surgery. This point is important, as there is an increased number of breast cancer patients who opt for surgical ablation of their ovaries as part of their breast cancer management.

We use low-molecular-weight heparin (40 mg subcutaneously) on a daily basis. This regimen is given at 18:00 hours on admission and so will not interfere if an epidural is used the following morning. In addition, patients wear graduated stockings and are well hydrated. We prefer to use regional anesthesia in addition to the general anesthesia, as this has the positive benefit of reducing thrombosis. Calf stimulation is also used in the operating theater, although the evidence for this procedure's benefit is not conclusive. We continue the low-molecular-weight heparin until the patient is discharged from the hospital.

In patients with significant deep vein thrombosis, we also consider using an inferior vena caval umbrella filter inserted under radiological control. Its use greatly reduces the risk of fatal pulmonary embolus, which is especially marked when there is bilateral iliac venous thrombosis associated with a pelvic mass.

Hemorrhage and Transfusion

During extensive surgery for advanced malignancy, patients are at significant risk for intraoperative or primary blood loss. We routinely crossmatch 4 units of blood for patients undergoing ovarian cancer surgery. With patients undergoing interval debulking surgery, we often anticipate an anemia due to the cancer and the effect of chemotherapy. Patients will often be transfused as the operation starts. Our anesthetic team prefers this to transfusion on the day prior to the operation. As these patients are operated on in the window between cycles of chemotherapy, we do not delay the patient as one might do other patients with anemia for a benign operative indication. Secondary hemorrhage occurs rarely and is usually associated with a slipped ligature or unrecognized bleeding point. Often there is a large raw area following tumor resection, and we find that lavage with hot (30°C–40°C) water (not saline) allows identification of bleeding points.

Unfortunately, we do not have easy access to erythropoietin for our chemotherapy patients in the NHS. This subcutaneous treatment can be useful to maintain the hemoglobin during chemotherapy and reduce the need for transfusion prior to interval debulking surgery.

Damage to Organs

Radical gynecological surgery aims to remove as much of the disease as required, including a margin of normal tissue. In cervical cancer surgery, this leads to Wertheim's approach, whereby the ureter, bladder, and bowel are dissected free from the cervical cancer. The incidence of fistula rate is reported as between 1% and 6% for this surgery. During lymphadenectomy, there is a risk of major vessel damage. Vascular injury associated with lymphadenec-

tomy in endometrial cancer occurred in 0.7% of the cases; however, this was satisfactorily managed through adequate surgical training and experience of staff within the unit [10]. During ovarian surgery, the disease is usually confined to the peritoneal cavity, and significant removal of disease can be achieved by peritoneal stripping. Rectal resection with primary anastomosis for clearance of pelvic disease is advocated by some. The acceptable level for anastomotic leak should be equivalent to that for rectal surgery. In the cancer center, we have access to many specialists who can provide intraoperative advice regarding organ injury. This is very helpful when considering injuries, which fortunately are very rare.

Wound dehiscence and hernias are relatively uncommon but are associated with cancer cachexia and midline incisions.

Psychological Complications

The patient diagnosed with gynecological cancer often responds by wanting everything possible done to remove the cancer. While a postmenopausal woman, who has completed her reproductive life, may view a hysterectomy as the removal of an organ that has "turned bad," a young woman may have a very different viewpoint. This is especially marked for those women whose diagnosis is made through screening. The woman diagnosed through screening has never had any symptom or sign of the disease and relies on the medical service for making the diagnosis as well as treating the cancer. The patient then has to live through the life-threatening illness, with major surgery and recovery, never having been "sick" in the first place.

Although the majority of women with gynecological cancer have already completed their families or are postmenopausal, a small group of younger gynecological cancer patients still have fertility needs. This situation is also pertinent for those patients with breast cancer. Preservation of fertility potential can pose a significant problem. Germ cell ovarian cancer can be treated with conservative surgery, as this disease needs treatment with chemotherapy. Recognition of the potential of this condition is imperative, as germ cell ovarian cancer is associated with a young age group and an overall better survival rate. As there has been a tremendous increase in cervical intraepithelial neoplasia (CIN), a number of young women are requiring many cervical treatments. Excisional treatments to the cervix lead to earlier delivery. Consideration must be given to assisted fertility techniques for collection of oocytes or embryos for these young women, although there is often limited time for this treatment.

Radical vulval surgery is associated with severe changes to body image. This has prompted the move to the triple incision, with which we try to reduce the morbidity of the traditional radical en bloc vulvectomy. We aim to perform a wide local excision with a 2 cm macroscopically clear margin from the tumor. This reliably leaves an 8 mm pathologically clear margin, which is associated

with minimal risk of local recurrence. The inguino-femoral lymphadenectomy results in a significant risk of lymphedema, which is ugly and has its associated comorbidity. In the early postoperative period, wound healing is compromised by infection and/or formation of lymphocysts in 20%–30% of patients, while in the long term, lymphedema of the legs with increased risk for cellulitis is reported in 10%–70% of patients.

Sexual dysfunction has been measured in up to 80% of women undergoing gynecological cancer surgery [11].

How to Reduce Complications Further

Complications associated with gynecological cancer surgery can be reduced by addressing several areas of practice, starting with the patient and leading through aspects of the disease, operation, surgeon and his or her team, and therapy.

Through education, patients can be advised about disease-reduction activity. In gynecological cancer, this is the use of the oral contraceptive pill for 5 years, which leads to a 50% reduction in ovarian cancer risk, albeit with an increased risk of cervical cancer. The use of tamoxifen leads to a significant reduction in breast cancer, but its long-term usage is associated with a significant increased risk of endometrial cancer. The move to the aromatase inhibitors for breast cancer will lead to much less endometrial disease. Uptake of appropriate screening methods that have been validated is important. We have seen a significant reduction in cervical cancer since the active call/recall system for cervical screening by primary care was introduced in 1988. Cervical cancer has become a rare cancer in the last decade in the United Kingdom, a situation that has not been mirrored in the rest of Western Europe. The role of laparoscopic prophylactic bilateral oophorectomy for patients at high risk of genetically carried ovarian cancer is important. The use of preadmission assessment is vital to allow the anesthetist to have access to the patient several weeks prior to the operation. The patient's physical state can be optimized before surgery.

The approach to the disease can be modified in several ways. The use of better imaging allows the surgeon to be fully aware of the extent of the disease. This may lead to anticipation of and preparation for bowel surgery by both the surgeon and the patient. It may modify the need to operate, as, if more extensive disease is discovered on imaging, we may consider radiotherapy for cervical cancer or neoadjuvant chemotherapy for patients with extensive ovarian cancer. The use of the "risk-of-malignancy index" [12] has been validated as a method to refer cases of ovarian cancer to a center where there is a survival advantage for the patient. We use a cutoff of 200 for the risk-of-malignancy index and have found it to be very effective. Neoadjuvant chemotherapy may separate out those patients who are chemotherapeutically resistant, and therefore we operate only on those patients who have chemosensitive disease. This again allows for the patient's condition to be optimized. With the effect of chemotherapy, the ascites disappears and the cachexia often improves. We have active input from dieticians, and patients who are having

difficulties with nutrition are given early support, which may include parenteral nutrition for some.

Not operating is perhaps the best way of reducing operative complications. We screen our patients with postmenopausal bleeding with transvaginal ultrasound. Those patients with thin regular endometrium do not undergo any further investigation. This population amounts to more than 40% of the patient group, and we avoid the risk of operative intervention (relating to outpatient hysteroscopy) for these patients. The likelihood of a missed cancer is very small $\ll$1%. The role of lymphadenectomy in endometrial cancer is being addressed by the Medical Research Council, a study in the treatment of endometrial cancer (MRC ASTEC). This randomized study has been reported in abstract form, suggesting that there is no benefit from extended surgery. The use of a second-look procedure in ovarian cancer is not generally recommended, as the results of this operation do not influence the survival [13]. A reduced rate of bowel resection is seen with primary ovarian cancer surgery, as it does not appear to give any survival benefit. This theory, however, has not been subject to a controlled trial. With the increase in more early-stage cervical cancer seen as a result of the screening program, we can perform less radical surgery. Typically, the Rutledge type 2 radical hysterectomy is sufficient for treatment rather than the type 3. The type 2 procedure gives a similar success rate with a lower complication rate. The use of fertility-sparing surgery (radical trachelectomy) is more appropriate with smaller-volume cancers. The role of sentinel-node dissection is of interest for patients with vulval cancer. With only 10%–20% of the patients with apparent stage 1/2 disease having positive nodes, the sentinel-node technique reduces the significant morbidity for those with node-negative disease. In addition, this procedure greatly reduces the length of operation and hospital stay, two parameters that are important for the elderly patient.

The value of the multidisciplinary meeting cannot be overemphasized in the management of reducing complications. An important role in the meeting is that of the specialist pathologist, who provides information leading to either more or less extensive surgery. As well as informing the team about the surgery, the pathological opinion may advise with respect to the need for adjuvant therapy or observation alone without further therapy.

Laparoscopic surgery has not been used widely by oncology centers in the United Kingdom. Our experience is that for endometrial and cervical cancer, there are quite considerable benefits for minimal-access techniques relating to diagnosis and recovery with no adverse effects.

Repair of the midline abdominal incision should use a mass-closure technique with a long-lasting absorbable or nonabsorbable looped suture. Less pain is associated with a long-lasting absorbable suture. Repair of incisional hernia is best achieved with mesh [14].

Having the right surgeon for the operation is very important. The success of the operation is better in centers with a higher frequency of procedure. Surgery in this setting allows the utilization of a surgeon whose is appropriately trained, another factor leading to better outcomes. Junor et al. [15] demonstrated that an operation for ovarian cancer performed by a gynecological oncologist was associated with a 25% better outcome for advanced disease

than an operation performed by the generalist; this translates into a significant survival advantage. This finding is in addition to the patient being managed by the multidisciplinary team and receiving the appropriate chemotherapy.

The use of psychosexual support usually via a specialist nurse who has access to additional expertise is very helpful in alleviating patients' psychological distress.

Return to theater is a problem that occurs but is difficult to quantify. Early return to theater for an appropriate reason can be life saving. It is essential, therefore, that the postoperative care for the patient is of high quality.

In the West Anglia Cancer Network, we are using videoconferencing, which allows for the interaction of the local unit–level team with the specialist multidisciplinary team at the center. This leads to better discussion and management for patients with cancer and precancer without requiring that patients or clinicians travel to the center.

Conclusion

Gynecological cancer surgery is associated with complications, some of which are avoidable by selecting the correct operation, surgeon, and hospital for the procedure. Other complications may be reduced by optimizing the patient's condition before surgery and managing the patient in specialist units.

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3. Laparoscopic Entry Techniques: Consensus

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Once relatively confined to obstetrics and gynecology, laparoscopic procedures that have been developed for all kinds of surgery within the abdomen have increased dramatically over the past decade. The attraction of laparoscopy, as opposed to the "open" operational equivalent, to the gynecologist and general surgeon is the reduced trauma of access. Several very small incisions are utilized rather than one large laparotomy incision. There is clear evidence that laparoscopic surgery provides significant benefits compared with laparotomy for patients, providers, and surgeons. Potential benefits for patients include reduced total operative trauma, reduced incidence of major wound and adhesive complications, more rapid convalescence, and a faster return to work or usual activities. The benefits for healthcare providers include shorter hospital stay with consequent hospital costs and social costs. The benefits for surgeons include an almost-closed and no-touch operative approach with reduced risk of infection, better display of anatomy and pathology, more precise removal of diseased tissue, and more accurate tissue repair [1–4]. As with any surgical procedure, the laparoscopic approach is associated with complications, which must be offset against the expected clinical benefits. The larger medical and surgical community is still evaluating the safety and effectiveness of these laparoscopic procedures in comparison to the traditional open surgical procedures [2,5–7].

George Kelling has been credited with the first laparoscopy as we know it today. In 1901 he used a Fiedler puncture needle to introduce filtered air into the peritoneal cavity (pneumoperitoneum) of a live canine that was locally anesthetized. Kelling then inserted a trocar into the abdomen and used the trocar to advance a Nitze cystoscope (used as an early laparoscope) to visually inspect the canine abdominal cavity [8,9].

Until recently, laparoscopic surgery was conducted primarily in the field of gynecology. Laparoscopic tubal sterilization was first described in the 1930s and 1940s, but it was not until the late 1970s that operative endoscopic techniques were used to treat endometriosis and infertility [10,11]. Progress in the development of new instruments, optics, lasers, and electrosurgery enabled the performance of highly complex and sophisticated laparoscopic surgery [8,10,12].

It was only after the development of computer-chip video/television camera that in 1985 the first laparoscopic cholecystectomy in a human was performed in Germany, succeeded by its independent introduction in France in 1987 [9]. These advances were followed by the rapid expansion of laparoscopy into all areas of general surgery. As Stellato writes, "It can be said without exaggeration that almost any abdominal or retro peritoneal operation performed 'open' has been attempted laparoscopically" [8].

In the United States, 310,756 laparoscopic cholecystectomies were performed in 1997. Diagnostic laparoscopy was estimated to have occurred in 91,170 cases, and laparoscopic sterilization was estimated to have occurred in 317,961 women [13]. In Australian hospitals between July 1999 and June 2000, more than 5.5 million surgical procedures were undertaken. Of these, nearly 3% were estimated to have occurred laparoscopically—a total of 151,501 laparoscopic procedures. These figures suggest that even with small complication rates, large numbers of patients will suffer a complication.

Laparoscopic Entry Technique

The majority of complications associated with laparoscopic surgery occur during access and the creation of artificial pneumoperitoneum [14–18]. The umbilical area is the thinnest portion of the abdominal wall and is therefore the preferred access site [12]. However, immediately below this point are the aortic bifurcation, the bowel, and the omentum. Access-related injuries can occur to these organs as well as to the inferior vena cava, liver, portal vein, cystic artery, ureter, bladder, iliac artery, and epigastric artery [12,19]. Major vascular injuries are rare [11], but once they are inflicted, between 9% and 13% of patients will die, often as a consequence of hemorrhage or gas embolism [20,21]. Access-related bowel or visceral injuries are more common. Reports indicate that between 50% and 66% of bowel or visceral injuries are undiagnosed at the time of primary surgery and can lead to major complications such as sepsis or peritonitis [11].

Classification of Laparoscopic Injuries

Laparoscopic entry-related injuries can be classified into two main groups:

Type 1 injuries—damage by Verres needle or trocar to normally located blood vessels and bowel

Type 2 injuries—damage by Verres needle or trocar to bowel adherent to the abdominal wall

It is recognized that when bowel is firmly adherent to the anterior abdominal wall at the point of entry into the cavity, then bowel damage may occur

whether the mode of access is by laparotomy (open) or laparoscopy (closed).

Despite the rapid evolution in and adoption of laparoscopic surgery in the past decade by general surgeons, most case reports and large series reporting these injuries are derived from older gynecologic literature. Even with newer instrumentation and knowledge, these injuries still occur with great frequency. In part this may relate to a learning curve associated with the adoption of laparoscopic surgery, but additional factors include a lack of understanding of the mechanisms involved in creating these injuries and a lack of appreciation for the proximity of important visceral structures to the anterior abdominal wall.

There are five access methods in three major categories. There is considerable debate as to which of these access methods is the safest and/or most effective.

1. Blind/closed methods
    - Needle (Verres or other) insertion into peritoneum, followed by gas insufflation, insertion of trocar, and insertion of laparoscope. Both insertions are conducted in a blind fashion in closed laparoscopy, usually at an infraumbilical site or in the pit of the umbilicus. This is the most common access method in gynecology.
    - Direct trocar insertion into peritoneum, followed by gas insufflation and insertion of laparoscope. The rationale for the development of this approach was the difficulty associated with grasping the wall of an abdomen distended by pneumoperitoneum, along with the safety issues related to the concomitant increase in force required to insert the primary trocar [22]. A further benefit of this method was the ability to inspect the trocar insertion site for both position of the trocar and damage to internal organs prior to introducing pneumoperitoneum [13]. The Z technique for diagnostic laparoscopy is a variation on the direct trocar technique [12].
2. Visual/open method
    - Hasson technique, including peritoneal cutdown followed by insertion of Hasson trocar under direct visualization, secured with a purse-string suture or stay suture, and then insufflation with carbon dioxide [11,12,23,24].
3. Hybrid visual/closed methods
    - Optical trocar to gain access, followed by gas insufflation and insertion of laparoscope.
    - Optical needle to gain access, followed by gas insufflation, insertion of trocar, and insertion of laparoscope.

Pneumoperitoneum is designed to facilitate better visualization of the abdominal cavity during laparoscopic surgery. It is formed when carbon dioxide gas is introduced into the peritoneum through controlled, automatic insufflation. A large pocket of gas is produced in the greater peritoneal sac, enabling surgical instruments to be advanced without damaging the viscera and vascular structures [12].

Open Versus Closed Laparoscopy

Hasson-Style Access Versus Verres Needle / Trocar Access

Safety

Fourteen studies in the literature provide information on the comparative safety of Hasson-style access versus Verres needle / trocar access [25–37], including 2 abstracts [38,39], 2 series representing the Hasson technique in a total of 2506 patients [40,41], and 8 series using the needle/trocar technique on a total of 80,785 patients [42–49].

A review of worldwide experience related to complications of gynecologic laparoscopic operations involving 1,549,360 patients showed an overall complication rate ranging from 0.2% to 10.3%. Various complications described are detailed in the following paragraphs.

Mortality

No deaths are reported as a consequence of primary-access complications in either the open or closed laparoscopy groups in any of the 4 randomized controlled trials [25–28]. No deaths are reported in open-laparoscopy patients in the nonrandomized controlled trials; however, 1 closed-laparoscopy patient died as a consequence of an unrecognized trocar injury to the bowel, leading to several laparotomies and eventually death by myocardial infarction [33]. In a case series using closed laparoscopy, reporting on predominantly larger sample sizes, 2 deaths were reported in 1 study [43]—due to an epigastric vein injury in one case and an unrecognized gastrointestinal injury in the other case—and a further death was caused by needle injury to the iliac artery in another study [48].

Bowel Injuries

About one third to one half of bowel injuries are related to entry, and the rest are caused during the operative procedure. Although operative bowel injuries are uncommon (0%–0.5%), they occur more frequently than major-vessel injuries. In the United Kingdom, the incidence of bowel injury is on the order of 0.4 per 1000 cases. While this low rate is reassuring, it still implies that about 50 women in the United Kingdom will suffer laparoscopic entry-related bowel damage each year. The colon and small bowel are involved at about the same rate. However, most intestinal injuries are not recognized intraoperatively, and peritonitis or possibly death subsequently occurs. For this reason, bowel injuries are one of the most common causes of postoperative death related to laparoscopy.

A compounding factor in the delayed diagnosis is that most patients with a laparoscopic intestinal injury do not present with the typical features of perforated viscus but present with vague features such as low-grade fever,

leucopenia, or a normal leukocyte count. Nausea, vomiting, ileus, and severe abdominal pain are uncommon features.

Only 1 randomized controlled trial provides data on the risk of bowel injury, and it found no difference between open and closed access [27], but again a wide confidence interval could be a reason for an inconclusive result. Conversely, a metaanalysis of nonrandomized controlled trials demonstrates twice the risk of bowel injury in open laparoscopy compared to closed laparoscopy [29,33–35].

Vascular Injuries

Major vascular injuries that occur after entry are much less frequent than those that occur during the blind-entry phase of the operation. The rate of vascular injury is reported to range from 0.003% to 1.33% when access occurred through the needle/trocar technique [27]. A large Dutch review compared the incidence of vascular injury in the closed technique in 489,335 patients with that of 12,444 patients in whom open laparoscopy was performed [33]. In that cohort, the incidence of major vascular injury using the closed technique was 0.075%, and 0% when open laparoscopy was performed. Catastrophic hemorrhage may occur if the sharp tip or edge of a laparoscopic trocar or insufflation needle injures one of the major vessels, which include the aorta, the inferior vena cava, and the common, internal, and external iliac arteries and veins. In a review of 8 intraoperative major vascular injuries, one half of the patients required laparotomy, but laparoscopic repair was possible in the other half [49]. Major vascular injuries that occur intraoperatively, like those that occur during entry, are associated with a high mortality rate (12.5%), and about one half of the patients require transfusion [49].

Urinary Injuries

Urinary injuries have been observed in 0.02%-1.7% of laparoscopies, which is not different from the number observed in open gynecologic surgery. Bladder injuries are more common than ureteral accidents and also are more commonly recognized intraoperatively than are ureteral lesions. A review of 58 bladder and 47 ureteral injuries showed that bladder injuries were not diagnosed intraoperatively in only 9.2% of laparoscopic operations, but ureteral injuries, like intestinal injuries, were not noticed in 93.7% of cases [50]. In a series of 953 major laparoscopic procedures, 15 urinary injuries (4 ureteral and 11 vesical) were observed, for an overall urinary complication rate of 1.6% [51]. However, in this series, intraoperative diagnosis was established in only 53.3% of patients, and 46.6% of patients required reparative laparotomy.

Careful identification of the ureters in areas where the pelvic ureter is easily exposed should prevent injuries above and near the uterine vessels.

Hematoma

An abdominal wall hematoma may be noted postoperatively in a patient in whom no bleeding occurred intraoperatively; the incidence of this injury ranges from 0.1% to 2.1% with the open technique compared to 0%–0.5% with

the closed technique [29,32,33,41,42,44]. Occasionally, an abscess may develop due to an infected hematoma of the anterior abdominal wall.

Hernia at the Site of Abdominal Wall Trocar

A major advantage of laparoscopic surgery is that the incidence of ventral hernia formation is lower than that with a laparotomy incision. A review of literature suggests that the incidence of incisional hernia associated with laparoscopic gynecologic surgery is 0.06%-1%, and that associated with general surgery is 0.8%-1.2%, both of which are 10 to 100 times lower than the incidence after laparotomy incision [33,45]. Hernias that develop at the trocar site usually result from the lack of closure or improper closure of trocar wounds and, in most instances, are a preventable complication.

Wound Infection

Wound infection at the primary access site is uncommon; most wound infections are minor skin infections that can be treated successfully with expectant management, drainage, or antibiotics. Severe necrotizing fasciitis can occur. Cogliandolo et al. showed higher incidence of wound infection at the primary access site associated with open method compared to closed method [27]. Conversely, Sigman et al. showed higher incidence of wound infection at the primary access site associated with closed method compared to open method [29].

Complications Related to Pneumoperitoneum

Extraperitoneal Insufflation. The most common causes of extraperitoneal insufflation are preperitoneal placement of the insufflating needle or leakage of carbon dioxide around the cannula sites. The amount of retro- or preperitoneal dissection may also be a factor. Usually this condition is mild and is limited to the abdominal wall. Subcutaneous emphysema can become extensive, involving the extremities, the neck, the mediastinum, and even the pericardium, and can result in hypercapnia and cardiovascular collapse. Most studies reporting on needle/trocar laparoscopy have rates of extraperitoneal insufflation ranging from 0.05% to 10.7%. Only 1 study reported the occurrence of extraperitoneal insufflation using the open technique [28].

Gas Embolism. Gas embolism is a complication resulting from the direct entry of the gas into the arterial or venous system. This usually occurs during or shortly after insufflation, but it may result from the direct intravascular insufflation of argon or other gases during the operation. It is an uncommon complication but is associated with high mortality rate. In a recent metaanalysis of nearly 500,000 closed-entry laparoscopies, the incidence of carbon dioxide embolism was 1 (0.0014%) in 71,428 laparoscopies [33]. Two deaths occurred in a series of 7 cases of gas embolism, for a mortality rate of 28.5% [52].

Complications Related to Anesthesia

For laparoscopy, the major complications related to anesthesia are not different from those that occur in open-access cases. Cardiac arrest has been

reported in 0.002%-0.003% of laparoscopies, usually because of a profound vasovagal response to rapid peritoneal distension, the patient's position, increased abdominal pressure, or air embolism [53]. Cardiac arrhythmias have been reported in 27% of patients undergoing laparoscopy [53].

Conversions/Complications Requiring Laparotomy

Two randomized controlled trials suggested an increased risk of laparoscopic cases being converted to laparotomy as a consequence of closed-access complications, demonstrating a 68% protective effect for open laparoscopy [25,27]. In a review of literature comprising 411,139 patients, the overall rate of conversion to laparotomy was 2.1%. For minor laparoscopic procedures, the conversion rate was 1.2%, and for major operations, the rate was 2% [25,35,43,48,54]. The 2 most common reasons for conversion to laparotomy were major vascular injury and major intestinal injury.

Hospital Readmissions

About 0.4%-0.5% of the total number of patients who had laparoscopy were readmitted to the hospital after discharge [55].

Litigation

Where do we stand in relation to complications related to Laparoscopic procedures? Retrospective claim reviews from Canada, the United States, and Australia indicate that the primary port entry leading to bowel injury and delay in its recognition constituted the leading cause of successful claims. Similarly, vascular injuries associated with Verres needle or primary port entry leading to significant morbidity or mortality were another cause of litigation. In all the above cases, the payment ranged between $7,500 and $4,980,086 in the United States and $1,500 and $315,955 outside the United States, depending upon incremental disability or death incurred to the patient [56–58].

How to Minimize the Risk of Complications

Identification of Risk Factors

1. Previous abdominal surgery: The use of an alternative access site should be considered, for example, right upper quadrant.
2. Patient weight: In obese patients it may be more difficult to establish pneumoperitoneum due to the increased distance between the peritoneum and the surface of the abdomen. In very thin patients, the risk of complications is higher due to the reduced distance between the surface of the abdomen and the large blood vessels.

3. Patient position: There is considerable debate whether supine or Trendelenburg position is safe for primary trocar entry. It is possible that Trendelenburg position may cause loss of orientation during needle/trocar insertion and increase the risk of complications. Also, the benefit of having the abdominal organs drop away from the insertion site may reduce the risk of bowel complications but expose the major vessels and therefore increase the risk of vascular injury.
4. Access site: Access in a periumbilical area is more likely to be associated with severe vascular injury (e.g., aorta, vena cava) than access through the upper abdominal quadrants, where pneumothorax or hepatic lesions may be more common.
5. Surgical expertise: Patients of a well-trained and experienced surgeon are likely to have a lower risk of complication.

Use of Newer Instruments

1. Blunt-tipped trocars may provide less risk of injury, although sharp, safety-shielded trocars have not been associated with lower complication rates.
2. Optical trocars and optical Verres needle are also new instruments and are safe and easy to handle. They offer several advantages over the use of the ordinary Verres needle and the minilaparatomy.
3. The single-use Step Radial Expanding System (Innerdyne, Salt Lake City, Utah) should prevent most type 1 injuries. This system may also sometimes displace rather than penetrate tissue when bowel is adherent to the entry site, and thereby also reduce the incidence of type 2 injuries. There is less tissue trauma and less pain. This system uses a Verres needle with a polymeric sleeve. Following insufflation, the needle is removed, leaving the outer sleeve in situ. Direct dilation of the sleeve and therefore the track is obtained by the use of a single appropriately sized dilator (up to 12 mm). This system has a Food & Drug Administration (FDA) approval with regard to its safety.
4. The reusable EndoTIP system (Endoscopic Threaded Imaging Port, Karl Storz Endoscopy, Germany) is designed in such a way that it is inserted without a trocar, allowing the laparoscope to be positioned to give visualization of the layer-by-layer entry into the peritoneal cavity. The potential benefits with this device include no trocar use and endoscopic visualization of the tissue being penetrated. The external threads of the cannula cause the layers of the abdominal wall to be lifted up, rather than pushed down toward the viscera, which limits the risk of visceral or blood vessel injury [59,60]. As the cannula is rotated down to obtain access, it is suggested that injury in the muscle, fascia, and peritoneum is not aligned, thereby reducing the incidence of incisional hernia.

These may be some of the logical benefits of these systems, but large-scale trials would be required to prove their efficiency before widespread use can be recommended. However, the number of procedures required may be prohibitive in the design of such trials.

Recommendations

As with any surgical technique, the laparoscopic approach is associated with complications, which must be offset against the expected clinical benefits. A number of complications of the laparoscopic approach, as described above, either do not occur or occur much less frequently with conventional approaches. These complications are the subject of a consensus document concerning laparoscopic entry techniques: Middlesbrough [61]. They have formulated certain guidelines for closed/open laparoscopy, secondary ports, and proper patient selection and counseling, which could form a basis for safe practice.

In closed laparoscopy, the primary incision should be made in the base of the umbilicus. If there is any suspicion of adhesions, then the alternative entry choice is Palmer's point. The umbilicus should be elevated or stabilized in such a way that the Verres needle can be inserted at a right angle to the skin. A correct positioning of the needle should be checked by either Palmer's aspiration technique or observation of gas-flow pressure rates. The intraabdominal pressure should be up to 25 mm Hg at the time of trocar insertion. This provides a large bubble, and with the tension of the anterior abdominal wall, a greater distance between the anterior abdominal wall and the intraabdominal organs is maintained during trocar insertion, which may reduce type 1 injuries. The primary trocar should be inserted through the thinnest part of the abdominal wall in the base of the umbilicus, and the laparoscope should be rotated through 360° to check visually for any evidence of adhesions, bowel damage, or hemorrhage. At the end of the procedure, the primary trocar should be removed under direct visualization to exclude any previously unnoticed bowel lesions.

Open laparoscopy may reduce or avoid type 1 lesions, but it does not eliminate type 2 bowel lesions. To minimize the risk of damage, the deep fascia should be elevated with suitable clamps to separate the abdominal wall from its contents after the placement of a skin incision at the lower border of the umbilicus. The fascial edges should be tagged with an adequate suture. The entry should be confirmed by visualizing bowel or omentum before inserting the blunt-tipped cannula into the abdomen. The trocar insertion should be guided between thin retractors to prevent displacement of the cannula. Gas should be insufflated directly through the cannula. At the end of the procedure, the fascial defect should be closed to minimize the risk of herniation.

A secondary trocar should be introduced under direct laparoscopic guidance, in order to precisely control the depth and direction of the trocar insertion.

Counseling

As in all surgery, the avoidance of some complications can be achieved by proper patient selection, use of good-quality, well-maintained instruments, and proper technique. Patients should be made aware that not all complica-

tions can be avoided. In counseling for a laparoscopy, all patients should provided with the following information:

1. There is a possibility of injury to bowel, bladder, and blood vessels. The risk of each type of injury is in the range of 1–4 per 1000 cases.
2. There is a possibility that conversion to laparotomy may be required, and on very rare occasions a temporary colostomy may be required.
3. Patients and their doctors should expect a progressive and maintained improvement after laparoscopic surgery. Increasing pain or vomiting should alert the patient or doctor to the risk of complication. Increasing pain should raise the suspicion of bowel damage until proved otherwise.
4. The patient and family should leave the hospital with written information about recognition of complications and the action to be taken in the event of these developing.

Conclusion

The need to perforate the abdominal wall to perform laparoscopic intraabdominal surgery is associated with the risk of damaging the structures beneath. The potential complications associated with peritoneal access are often overlooked, largely because they are relatively uncommon; in fact, most surgeons will see or experience relatively few, if any, of the serious life-threatening varieties in their professional careers. Clearly, vascular and visceral injuries comprise the most sinister of the complications, and the diagnosis of each may not be made until some time after the end of the procedure, a situation that often compounds the severity of the situation. The risk of type 1 injuries may be reduced by use of the Hasson technique, but some type 2 injuries are inevitable, regardless of the method of access. Patients must be fully informed of the nature and extent of these risks and the importance of taking prompt action should a complication arise.

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4. Complications of Laparoscopic Surgery for Endometriosis

Jeremy T. Wright

Complications of laparoscopic surgery are in fact fewer than those reported for laparotomy [1], but their potential severity and the failure to diagnose them quickly and treat them effectively means that the patient can be severely ill before a diagnosis is made, with catastrophic results. Inadvertent bowel injury at laparotomy is regarded as a recognized hazard, particularly during adhesiolysis. Such enterostomies are usually immediately recognized and repaired with minimal postoperative sequelae.

Adhesiolysis at laparoscopy, however, is usually carried out using high-energy sources such as diathermy, laser energy, or ultrasound. These techniques may cause ischemic damage that is not apparent at the time of procedure and may present to another physician some days later. Conservative management will further delay diagnosis, so that the patient becomes gravely ill. Surgery then will usually require fecal diversion, and there will be multisystem failure, a variable stay on an intensive care unit, and possibly even death.

Inevitably, such cases will be subject to critical incident appraisals, potential internal investigations for assessment of safe practice, General Medical Council complaints, and civil litigation for personal injury and negligence [1].

Operative laparoscopy always carries the potential for severe complications. This chapter examines strategies for avoiding and reducing these as much as possible.

Endometriosis Surgery

Endometriosis surgery is associated with a particularly high risk for complications. Superficial peritoneal disease such as powder burn, sago grain, flame hemorrhages, and white scars are frequently found in the ovarian fossae, on the uterosacral ligaments, and in the pouch of Douglas. They overlie the great vessels of the pelvis, the ureter, and possibly the rectum at the peritoneal reflection in the pouch of Douglas. Ovarian involvement may also include the vascular ovarian ligament and the vascular plexus overlying the ureter. Treatment of these areas by ablation, thermocoagulation, or laser vaporization runs the risk of thermal damage to underlying structures, which may not be immediately apparent.

More advanced disease and previous surgery lead to marked anatomical distortion. Adhesive bowel disease frequently involving the sigmoid colon and also small bowel lesions, obliteration of the pelvic cul de sac by uterosacral and rectovaginal endometriosis, and invasion of the muscularis of the rectum, particularly at the peritoneal reflection, add hazard to this already difficult surgery. Management of fibrotic nodular rectovaginal endometriosis can lead to large bowel damage, small bowel damage (as small bowel adhesions to this area are not uncommon), ureteric damage, and significant hemorrhage.

Figure 4.1 shows severe infiltrating nodular endometriosis of the left ultrasound ligament. Medially there is tethering of the rectum to the ligament, the muscularis being involved. Laterally the ureter can be seen drawn medially and caudally by the disease. Lateral to this is the uterine vasculature, the area itself being hemorrhagic and inflamed. Excision requires careful dissection and preservation of the ureters, blood vessels, and rectal wall.

Endometriosis of this nature gives rise to severe symptoms, particularly backache, dyspareunia, and dyschezia. Dyschezia, or painful defecation, is a very important symptom to elicit. It is frequently associated with pain sitting down, particularly during the menses. Inquiry should establish whether this symptom is present throughout the menstrual cycle or only during menses [2]. Pain during menses is likely to be associated with partial rectal involvement, i.e., the rectal mucosa is spared, and only the peritoneal surface and muscularis are involved, whereas continuous rectal pain and dyschezia suggest full thickness involvement, which has obvious significance in planning treatment and counseling for the patient.

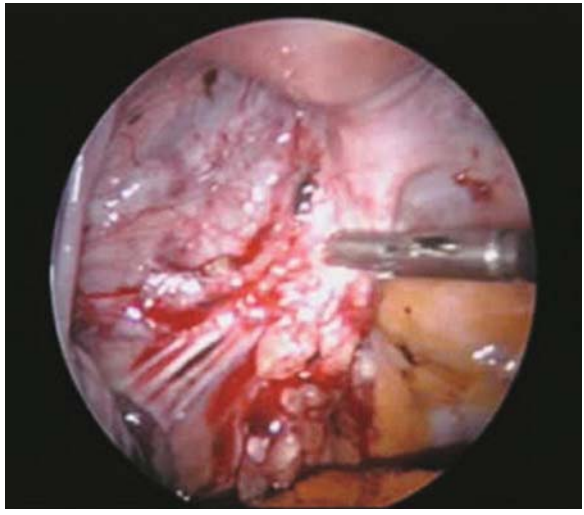

Figure 4.1. Left ultrasound ligament showing a filtrating and nodular endometriosis.

Patient Counseling

Adequate preoperative patient counseling can prevent much needless complaint litigation. Most women with this disease are desperate for help; they have severe symptoms and have usually had multiple diagnostic procedures, trials of hormone manipulation, and possible superficial destructive therapy to the disease using ablative or vaporizing techniques. Both hormonal manipulation and ablative or vaporization therapy cause fibrosis and scarring without fully removing what is often deeply infiltrating disease.

The patient's history has to be taken methodically, and each episode of treatment carefully documented. Questionnaires with structured questions are useful in documenting severity of symptoms and previous interventions and their outcome. Computer programs linked to databases are a very useful data-collection tool, either in real time or subsequent to consultations [3]. The patient history should be supplemented by careful physical examination, with particular reference to noting areas of tenderness and nodularity in the uterosacral ligament and posterior pelvic pouch. All the findings require careful documentation, preferably using a structured approach. Following this, the patient should be given a realistic appraisal of the likely benefits and complications of surgery, including the risks of ureteric or bowel damage, and the possibility of hemorrhage significant enough to require blood transfusion. The need for laparotomy to deal with any of these complications must be stressed.

It should be emphasized that the purpose of surgery is to remove the areas of infiltrating endometriosis and that this will be carried out using the best available means, be it laparoscopy or laparotomy.

All patients should have osmotic and mechanical bowel preparation prior to surgery, supplemented when necessary by on-table rectal lavage prior to the definitive procedure being carried out.

It is wise to document the advice that is given to patients, and the author supplements this with a personal letter to the patient outlining the condition, history, physical findings, proposed surgery, and likely complications. Such explanation, although time-consuming, significantly reduces the risk of patient complaint.

Surgical Techniques

Dissection should start and stay in normal tissue surrounding the endometriotic lesion, aiming to remove the area with a small rim of normal tissue. As the disease is frequently peritoneal, the surgeon should aim to stay as superficial as possible, dissecting away from great vessels. Energy sources such as diathermy or laser vaporization work much better when the tissue is under tension, and the use of probes, such as a rectal probe or vaginal probe, will help considerably both in maintaining tension and keeping these structures away from the area of dissection, and thus inadvertent damage. Hemostasis is sometimes difficult to achieve, but immediate identification and coagulation of small-vessel bleeding will allow dissection to proceed quickly, although

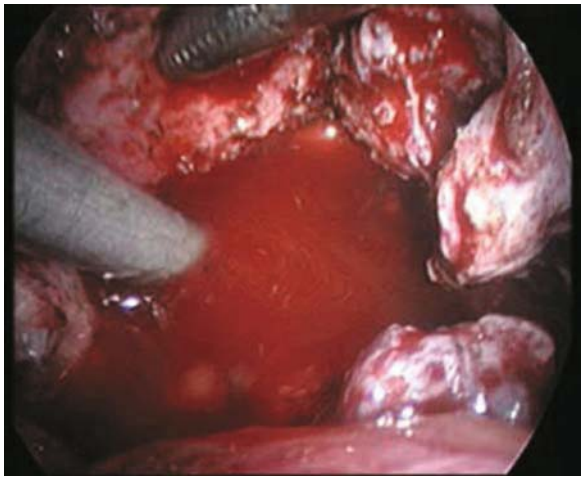

Figure 4.2. Pelvis with perioperative vaginal hemorrhage.

patients who have had multiple surgeries will frequently undergo considerable venous and capillary oozing (Figure 4.2).

Copious suction and irrigation will help to keep the operative field clear, but the steep Trendelenburg position often adopted during this sort of surgery means that considerable volumes of fluid will collect in the abdominal cavity and that bowel will float on this, rising higher in the abdomen and obscuring the view. Regular suction and a continuous check on the volumes infused into and aspirated from the abdominal cavity will help keep the situation under control. During the procedure, rectal integrity should be routinely checked, and this can be quickly and easily carried out by flooding the pelvis with fluid and passing air under pressure into the rectum, which can be simply achieved by using a bladder syringe.

In many centers, this sort of surgery is best carried out using a team approach, as a segmental rectal resection or anterior-wall disc resection may be necessary, and the gynecologist may not have the skills or experience to effect a competent repair. The growth of laparoscopic bowel surgery means that many units will have surgeons with the necessary skills, and a good working partnership can significantly increase patient safety. Particular caution is necessary when a gynecologist is asked to undertake a procedure or give an opinion on a patient who is already anesthetized, which regrettably can be quite commonplace. As experience and skill in laparoscopic procedures grow, particularly among surgeons in training, requests to attend the operating theater when severe endometriosis is unexpectedly confirmed are increasingly common. The surgeon may be invited to undertake a diagnostic or therapeutic procedure on a patient who is poorly prepared, both emotionally and physically. Bowel injury in these circumstances may lead to considerably fecal soiling, and hemorrhage may occur, a situation where only emergency resources rather than previously crossmatched blood are available. A patient

who has been inadequately assessed and counseled will not take kindly to waking up with a laparotomy/fecal diversion and a blood transfusion running. In these circumstances, careful assessment and documentation with a view to undertaking definitive surgery at a later date is far preferable to undertaking an immediate procedure, regardless of how much pressure one is under.

Invitations may also be extended to undertake these procedures on colleagues' patients whom the surgeon has not previously assessed or counseled. However tempting it is to undertake these procedures, either for the privilege of being asked to do so, or for pecuniary advantage, unless the patient has been properly examined and counseled, it is an unwise practice.

Audit

Laparoscopic surgery generally, and for endometriosis in particular, has developed without any formal assessment of efficacy or safety, in either the short or long term. There is little in the way of formal assessment of symptomatology, symptom relief following surgical intervention, or the morbidity associated with such intervention. The recording of physical signs either during clinical assessment or at laparoscopy is poor. The recording systems that do exist, e.g., the r-AFS score, now the r-ASRM score, a scoring system devised by the American Fertility Society, are associated more with evaluating the effects of the disease on fertility than with pain and discomfort.

The conduct of randomized clinical trials in surgery generally, and endometriosis surgery specifically, is very difficult to undertake because of the large number of variables involved and the difficulty of persuading a patient to undergo a sham procedure, even if this was ethically advisable. Inevitably, the only way of assessing the value of this surgery will be in the audit of patient series. This requires the careful documentation of symptoms, physical signs, surgical findings, treatment, morbidity, and subsequent change over time of symptoms and signs. A vast amount of data captured during interactions with patients requires such detailed documentation and recording that a computerized database with a core data set is the only way of assessing this information properly. Such databases now exist commercially or can be easily developed using simple database software.

Individual core data sets can then be held centrally so that the efficacy and the morbidity of various procedures may be assessed, with the greater accuracy and predictability of large numbers. It is only with this sort of data that proper assessment would be possible.

Audit Results

The author's personal data series of surgery for severe rectovaginal endometriosis associated with either partial or complete obliteration of the cul de sac over a 2-year period is shown cumulatively in Table 4.1 and Figure 4.3. The

Table 4.1. Author's Data for Severe Rectovaginal Endometriosis with Cul de Sac Obliteration

	January 2000–April 2000	January 2000–August 2000	January 2000–December 2000	January 2000–April 2001	January 2000–August 2001	January 2000–December 2001	January 2000–April 2002
Total cases	6	24	42	49	59	70	82
% complete obliteration	67	63	67	67	64	69	71
% hemorrhage >500 mL	0	4	5	4	3	6	6
% seromuscular rectal repair	0	0	5	4	3	3	5
% full-thickness rectal repair	0	4	12	10	8	10	10
% ureteric damage	0	4	2	2	2	1	1

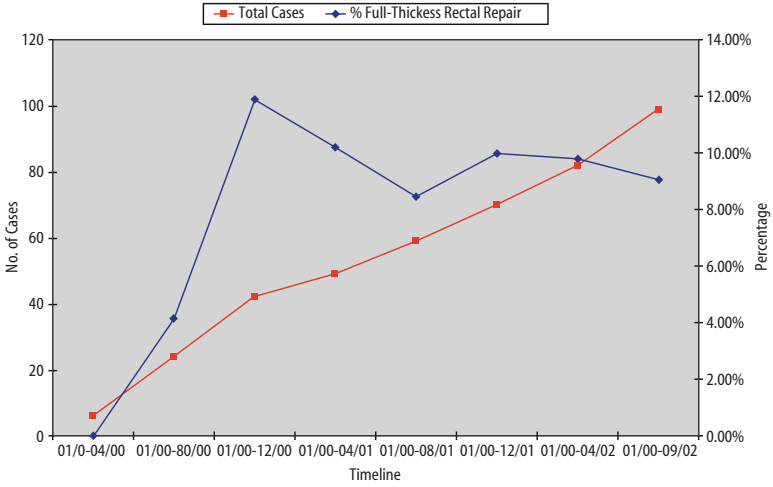

Figure 4.3. Cumulative number of patients with severe rectovaginal endometriosis associated with obliteration of the cul de sac.

number of patients requiring either a seromuscular or full-thickness rectal repair rapidly becomes constant, as does the incidence of significant hemorrhage (Figure 4.4). Increased experience reduces the risk of ureteric damage.

Despite these cases in which the posterior cul de sac is completely obliterated and thus the anatomical distortion greater, increased experience allows a greater chance of successfully dissecting the rectal muscularis away from the mucosa and thus a reduction in the need for a full-thickness rectal repair.

Although there is an understanding by those who handle a large number of cases of severe endometriosis that the likelihood of rectal involvement and a limited rectal resection is high in this disease, for the vast majority of gynecologists and other health professionals, a rectal repair will usually be regarded as a critical incident involving the production of incident reports and an associated, possibly hostile audit, often based on an incomplete understanding of the disease, the surgery, and the long-term outcome, and may result in adverse criticism of the surgeon's work. Adverse-incident reports are not usually measured against a denominator, and personal audit series will go a long way to protecting oneself against such criticisms.

As series grow, surgical risks with 90% confidence intervals (CIs) can be generated, as is shown in Box 4.1, and predictive factors accurately assessed.

This will both improve and give an actuarial base to patient counseling. The predictive factors for full-thickness rectal involvement of endometriosis are shown in Box 4.2.

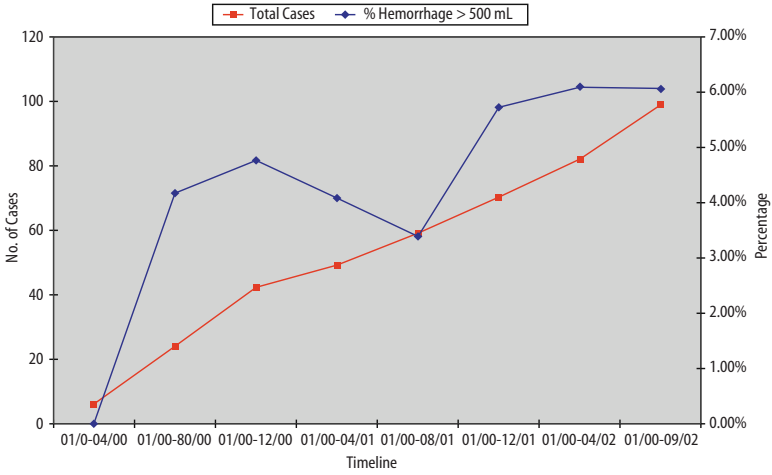

Figure 4.4. Cumulative number of patients with severe rectovaginal endometriosis and percent with significant perioperative hemorrhage.

Box 4.1

Hemorrhage 6% (95% CI 2–13)

Seromuscular repair 6% (95% CI 2–13)

Mucosal repair 9% (95% CI 5–16)

Rectovaginal fistula 1% (95% CI 0.2–6 NS*)

Ureteric fistula 1% (95% CI NS)

*NS, not significant

Box 4.2 Symptoms and Signs Predictive of Severe Rectovaginal Endometriosis

Dyschezia throughout month

Vaginal epithelial involvement

Nodule >4 cm

Rectal fixity

In all branches of surgery, innovation has been associated with an initial increase in morbidity, and indeed mortality, before becoming the accepted method of treatment. Good examples of this progression are laparoscopic cholecystectomy and heart transplantation. To overcome initial prejudice or indeed to properly assess the efficacy and safety of any surgical technique, meticulous audit combined with careful and measurable techniques are the only methods of assessment. Where possible and ethical, of course, these methods should be associated with randomized clinical trials, which are now under way. Surgical treatment of endometriosis currently remains the only effective treatment, but only a few centers are able and willing to carry out these procedures. Adequate training methods would lead to an increase in the number of centers able to provide this surgery.

Experience, training, and audit remain the cornerstones of adequate therapy and are strongly recommended.

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5. Abdominal Wound Closure: How to Avoid Complications

Patrick Hogston

Closing an abdominal incision is one of the commonest and simplest procedures performed by gynecologists and obstetricians. Most wounds heal uneventfully, but failures, particularly in the fascial layer, cause distress to the patient, increase length of hospital stay, and can endanger life. Closure of the abdominal wound is not widely discussed in the gynecological literature, and this chapter aims to provide up-to-date information for the practicing clinician on how to minimize wound failure and how to deal with it when it occurs.

Definition and Incidence of Wound Failure

Most wound failures are superficial separations and should be clearly distinguished from fascial breakdown or wound dehiscence. The latter may present as a burst abdomen where the abdominal contents spill out through both the fascial and skin defect and is associated with high rates of death and complications. Alternatively, the skin may stay intact and the clinical presentation may be as a subsequent incisional hernia.

Superficial separation commonly follows a hematoma or wound infection. With a rising cesarean section rate and most hysterectomies still being performed by the abdominal route, there are more than a million laparotomies for obstetric and gynecologic indications in the United States each year and at least 200,000 in the United Kingdom. Superficial wound separation can be as high as 20%, as this rate depends on the rate of infection. Using the classification of wounds in Table 5.1, emergency cesarean section after prolonged labor with amnionitis will be class 3 or 4 and hence associated with a significant risk of infection.

Fascial dehiscence is the separation of the musculoaponeurotic layer and generally occurs between 3 and 10 days after surgery. However, incisional hernias may present years later. The incidence has remained remarkably stable over the past 50 years at a rate of 0.5% to 3%. This may reflect improved techniques that have overcome the increased comorbidities in patients who would not previously have had surgery performed. However, the overwhelming evidence suggests that fascial dehiscence is nearly always due to a technical error.

Table 5.1. Wound Classification and Risk of Infection

Class	Category	Definition	Wound Infection Rate
1	Clean	Ideal conditions. No entry lumen of GI, GU tract	<5%
2	Clean-contaminated	Wound includes entry in GU tract	2%–10%
3	Contaminated	Open, fresh trauma. Incisions on nonpurulent infection, e.g., amnionitis	15%–20%
4	Dirty	Delayed trauma, foreign body, devitalized tissue	>30%

GI, gastrointestinal tract; GU, urinary tract or vagina.

Risk Factors

Systemic factors that may apply to gynecology patients include obesity, diabetes, older age, pulmonary disease, malignancy, and steroid use. Ensuring correct technique in these patients is particularly important, as the margin for error is small, and if the fascial wound stays intact, any superficial separation can be managed much more easily.

It is widely believed that transverse incisions are associated with a much lower incidence of fascial dehiscence than midline incisions. Greenall et al. [1] showed a lower incidence of incisional hernia (2 vs 9) and no burst abdomens (0 vs 2) in 579 patients randomized to transverse or midline incisions for nongynecological conditions. However, they stated that when controlled for infection, there was no difference in wound failure, which occurred in 2.24% of the patients. Hendrix et al. [2] have performed a case control study of 48 cases of fascial dehiscence complicating 17,995 laparotomies (8950 cesarean sections and 9405 gynecologic procedures) during a 6-year period. This represents an incidence of 0.3%. Of the 48 patients who underwent repair of fascial dehiscence, 27 were after cesarean section (10 vertical, 17 transverse) and 21 after gynecologic surgery (12 vertical, 9 transverse). The risk for dehiscence with vertical incisions was not increased over that with transverse incisions ($P = 0.39$). However, 47 of the 48 cases had documented wound infections compared with 1 of the 144 controls ($P < 0.0001$, odds ratio [OR] 37.8).

Hendrix's study included only patients operated on within 6 days of the initial surgery. This may explain the small number of cases of fascial dehiscence identified as compared to Greenall's study. The rate of incisional hernia at 6 months in the open colposuspension arm of a randomized controlled trial of surgical management of stress incontinence is 10 times that reported by Hendrix, i.e., 3% at 6 months [3].

Luijendijk et al. [4] suggest that laparoscopy followed by transverse laparotomy is associated with a risk of incisional hernia just caudal to the umbilicus (3.5% of 169 cases vs 0 of 177 without laparoscopy). This may be related

to the subsequent dissection of the muscle away from the sheath. However, consideration should be given to closing the sheath of the laparoscopy wound when a subsequent transverse laparotomy incision is made.

Surgical Considerations

Before considering closure of the incision, it is pertinent to consider the opening. There are only 2 types of incision used by the gynecologist, namely, vertical and transverse. There are several variations within this generalization, however, and it is clearly essential that exposure be adequate for the procedure to be performed. The type of incision should be discussed with the patient preoperatively, as the wound will be the only part of the procedure she will see and cosmetic considerations are likely to be important. Transverse incisions are cosmetically more acceptable to most patients but are also less painful and may be less prone to herniation, although this remains unclear (see above). The variations on this type of incision include Pfannenstiel, Joel-Cohen, Maylard's muscle-cutting incision, Cherney's, and Turner-Warwick incisions [5], and hence the gynecologic surgeon should be familiar with these modifications so as to realize that large masses, complex fistula surgery, as well as radical hysterectomy can be performed with adequate access without resorting to a vertical incision. Vertical incisions can be midline or paramedian, with the latter being more likely to damage the nerve supply to the muscle. A midline is easier and quicker and superior for the gynecologist. It is particularly useful in ovarian cancer surgery, where access to the upper abdomen may be required.

Many of the risk factors are difficult to influence. It is important, however, to use proper antisepsis and antimicrobial prophylaxis for all abdominal procedures. Similarly, the avoidance of hypothermia may reduce wound infection rates. There is a trend to use electrocautery to open the abdomen. It is important to use cutting current, as this causes vaporization, whereas coagulation current causes desiccation and a wider path of thermal injury. There is clear evidence from animal studies that coagulation current decreases the abdominal wall bursting strength [6].

Closing the Abdominal Wound

Peritoneum

Traditionally the first layer to be closed is the peritoneum. This is no longer recommended. The presumed benefits (e.g., restoring anatomy, preventing adhesions, preventing herniation, reducing infection) have not been proved in randomized trials. Furthermore, animal studies have shown that the exact opposite may be the case, with increased adhesion formation and infection

due to ischemia and necrosis as well as inflammatory reactions to the sutures themselves. The peritoneum will heal spontaneously within 6 days. The Royal College of Obstetricians and Gynaecologists in the United Kingdom has produced clear recommendations based on review of the literature by a panel of experts [7]. Nonclosure of the peritoneum is quicker and is associated with lower postoperative febrile morbidity, lower requirements for analgesia, quicker return of bowel activity, and a shorter hospital stay. Peritoneum closure is also not cost-effective; costs may be $330 per case. This is especially important in developing countries, where resources are particularly scarce.

There is similar evidence to show that peritoneal closure is not recommended for simple or radical hysterectomy, be it performed vaginally or abdominally.

Fascia

Wound Healing

Surgical wounds are entirely dependent on suture support in the early postsurgery days, as wound strength takes time to develop. Fascial wounds take 3 months to regain 70% of their preoperative strength and probably never regain full strength. It is therefore imperative that the suture retain its strength for 3 months. The skin, in the absence of infection or hematoma, heals much more quickly, particularly with transverse incisions. In the latter circumstance, sutures can be removed after 3 or 4 days.

Suture Material

From the above discussion it will be clear that rapidly absorbable sutures are not suitable for fascial closure of vertical wounds. Experimental animal studies have confirmed that the use of monofilament nylon significantly reduces the rate of wound failure as compared to braided sutures. Bacteria proliferate in the interstices of braided sutures, but this cannot happen with monofilaments. Permanent sutures do have the problem of sinus formation, which is not present with delayed absorbable materials.

Technique

At the end of the nineteenth century, mass-closure techniques were abandoned in favor of layered closure. Mass-closure techniques were reintroduced in the 1940s and have now clearly been shown to be associated with lower rates of wound failure [8]. Hodgson et al. have searched for the ideal method of abdominal fascial closure using MEDLINE and Cochrane Library databases [9]. They did not look only at randomized controlled trials but included comparative studies, provided certain quality criteria were met. The primary outcome was postoperative incisional hernia, and the primary comparisons were between nonabsorbable and absorbable sutures and continuous versus interrupted techniques. When comparing nonabsorbable with absorbable

sutures, the odds of an incisional hernia were significantly lower with nonabsorbable sutures (OR 0.68, confidence interval [CI] 0.52–0.87), although wound pain and suture sinuses were significantly more common (OR 2.18, CI 1.48–3.22, and OR 2.05, CI 1.52–2.77, respectively). The subgroup analysis showed that polydioxanone (PDS) did not have an increased risk of incisional hernia compared with polypropylene (OR 1.53, CI 0.50–4.72).

A randomized study of 225 patients showed no more failures with delayed absorbable polyglyconate (Maxon) as compared to nylon at 2 years [10], and many surgeons favor delayed absorbable sutures, as in low- and medium-risk patients they appear as effective as non-absorbables and do not cause the problems of wound sinus and pain. However, metaanalysis of more than 12,000 cases revealed that permanent sutures result in significantly lower wound disruption. In gynecological surgery using midline incisions, an analysis of risk factors should be made. Surgeons should consider permanent sutures in high-risk patients, but otherwise delayed absorbable sutures appear to be an acceptable alternative.

Sutures should be placed at least 1 cm from the wound edge and less than 1 cm apart. Undue tension should be avoided, and suture length should be 4 times the wound length. VanGeldere [11] showed that with correct attention to technique, the incidence of wound disruption was 0.6% in 2488 cases. Investigation of these 15 failures revealed a suture length of just over 3:1 rather than the recommended ratio of 4:1. The other scenario responsible for wound disruption is running out of suture and managing by using smaller bites and struggling with an unsatisfactory knot.

Alternative Technique

Niggebrugge et al. [12] described a new technique using a continuous double-loop closure (CDLC). Its use in an animal model appeared superior to other techniques and resisted high intraabdominal pressure without strangulation. However, when Niggebrugge et al. performed a randomized controlled trial in 390 patients, they found a significant risk of adverse events including death, so this technique should not be used. The authors postulate that the lessened compliance of the abdominal wall raised the intraabdominal pressure and increased the risk of pulmonary complications and death.

Superficial Fascia

Hematomas and seromas that form in the dead space of the subcutaneous layer can lead to infection and wound breakdown. Del Valle et al. [13] conducted a randomized controlled trial of closure versus nonclosure of Camper's fascia with 3-0 plain catgut. Although they found less wound disruption in the closure group (2.7% vs 7.4%, $P = 0.03$), they did not control for depth of the subcutaneous layer. When patients with a subcutaneous layer of >2 cm are studied, both closure of the superficial fascia [14,15] and suction drainage [16] have been shown to reduce the risk of wound disruption.

Skin

There are many options for closing the skin, and cosmetic results are important in gynecological surgery. Transverse incisions heal well due to lack of tension, and most surgeons use either a subcuticular running stitch or skin staples. Polybutester (Novafil) leaves a better scar than polypropylene or nylon when assessed at 18 months [17,18]. The only benefit of staples shown in randomized studies was speed, as there is more wound pain and a worse cosmetic result compared with subcuticular stitches [19,20]. More recently, skin adhesive (2-octyl cyanoacrylate) has become available to close wounds and is marketed as "an ideal skin closure" for gynecological surgery, despite the lack of clinical studies in this area. It produces appropriate wound strength in minutes, avoids needlestick injury (as do staples) and is claimed to be particularly useful for children. However, a prospective study in children and adolescents suggested a worse cosmetic result [21]. A large multicenter randomized trial of 924 wounds confirmed that octyl cyanoacrylate was faster healing than sutures but cosmetic results were the same [22]. For laparoscopy, adhesive papertape may be faster and more cost-effective than octyl cyanoacrylate or sutures [23].

Management of Acute Wound Failure

Dehiscence of both the fascial and superficial components of abdominal wound with extrusion of bowel is a gynecological emergency. The patient is laid supine, and saline-soaked towels are laid over the abdominal contents. The patient will be distressed and often in pain and will require analgesia. In most cases, preparation for an urgent return to the operating theater should be made. The bowel should be inspected for trauma and the fascia and skin for viability. Necrotic or infected tissue will need debridement back to healthy bleeding edges. Primary repair can then be performed in most cases using a continuous mass-closure technique with a nonabsorbable suture as described above. Cliby [24] has argued for interrupted sutures in this scenario, but a subgroup analysis by Hodgson [9] has shown that incisional hernia is higher with interrupted sutures. There is no need to use deep-tension sutures or plastic bridges.

The biggest problem occurs when closure without undue tension cannot be accomplished [24]. Gynecologists would be advised to call for advice from a general surgeon, who is likely to have more experience with this problem. It may be necessary to use an absorbable mesh such as polyglactin or a nonabsorbable material such as polypropylene. While the latter is widely used in elective hernia repair, there is less experience with acute wound failure. There is a high complication rate due to infection but a risk of enteric fistula of 23%. Delayed absorbable mesh is probably preferable, which can be attached to the circumference of the defect. The wound should then be packed and not closed.

Superficial Wound Breakdown

The mainstay of treatment of superficial wound breakdown is adequate drainage and then care to promote granulation. Healing can take several weeks or months, and consideration can be given to delayed reclosure. Necrotic and infected tissue must first be removed and the presence of healthy granulation tissue observed. Several studies have shown that secondary closure reduces healing time from about 70 to 16 days [25,26]. If the wound is deep, an en bloc closure incorporating the deep and superficial tissues has been described with a 94% success rate [26]. Closure can be performed under local anesthesia, and antibiotics are not required. In cases with large skin loss due to necrosis, it has been shown that wounds heal faster under negative suction pressure, and special pumps are available that can be used in the patient's home [27]. The assistance of a wound-care specialist nurse is particularly helpful.

Management of Late Wound Failure

It is important to realize that even follow-up at 1 year does not reflect the true incidence of incisional hernia. Mudge and Hughes [28] followed a cohort for 10 years and showed that 35% of incisional hernias occurred after 3 years. Repair of incisional hernias in the United Kingdom would usually be done by a general surgeon rather than a gynecologist, if required. Often there is a need to use a mesh material, as closure of the fascia would be under too much tension and further failure likely.

Summary

Wound disruption continues to be a common problem for the obstetric or gynecological patient. Evidence is available for the surgeon to reduce this morbidity. Adequate training in abdominal closure, particularly of vertical incisions, is important. Correct suture choice for fascia and skin can also be evidence based. Management of the superficial layer in obese patients could include closure of Camper's fascia or the use of a suction drain. Further studies should be readily possible to clarify the issues of skin closure and drainage, as disruption of this layer is associated with much medical and nursing time as well as distress and delay in returning to normal activities for the patient.

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6. Recent Advances in Adhesion Prevention

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Use of adhesion prevention adjuvants has become the standard of practice following gynecologic as well as general surgery [1–3]. The frequent occurrence of adhesions after peritoneal cavity surgery and clinical consequences of adhesions, including increased rates of reoperation, postoperative bowel obstruction, infertility, and chronic pelvic pain, which markedly increase healthcare costs, make prevention of adhesions a major contributor to successful postoperative outcome. Devices that reduce postsurgical adhesion formation are a great benefit in reducing postoperative morbidity and failed surgical therapy.

Adhesion prevention adjuvants became available to practicing surgeons in 1990 with the introduction of Interceed Absorbable Adhesion Barrier (Gynecare, Somerville, NJ). Other site-specific barriers soon followed, including Preclude (Gore-Tex, Flagstaff, Ariz) and Seprafilm Bioabsorbable Membrane (Genzyme, Cambridge, Mass). In 1996 an experts' conference was held as part of the International Federation of Fertility and Sterility to evaluate the data supporting the use of barriers and to make recommendations for their application [4]. In general, the guidelines supported prophylactic use of adhesion barriers following adnexal surgery or myomectomy, procedures well known to create adhesions with clinical significance. A recognized limitation of these site-specific barriers was the requirement on the part of the surgeon to predict where adhesions would most likely form and which would cause clinical problems. This limitation was overcome with the availability of intraperitoneal solutions and gels.

Crystalloid

The most popular device used for adhesion prevention is the instillation of salt-containing solutions into the peritoneal cavity at the end of surgery in sufficient volume (300–500 mL) to allow for "flotation" of the adnexal structures [5]. However, in a metaanalysis of 23 clinical trials, hydroflotation with crystalloids was shown not to reduce formation of postsurgical adhesions [6]. These solutions are absorbed from the peritoneal cavity at the rate of 30–60 mL

per hour, so that by 10–12 hours postoperation, little, if any, crystalloid solution would be left in the pelvis [7,8]. Peritoneal healing may take as long as 5–7 days, thereby allowing for an extended period of time for fibrin outpouring from the damaged surfaces to interconnect with adjacent structures in the peritoneal cavity, leading to adhesion formation [9]. Therefore, postsurgical instillates with prolonged peritoneal residence times should theoretically be more successful at preventing adhesions at both surgical and nonsurgical sites.

Intergel

Intergel solution is an aqueous solution of hyaluronic acid (HA) that has been ionically cross-linked by the addition of ferric chloride solution. HA is a linear polysaccharide with repeating disaccharide units composed of sodium D-glucuronate and N-acetyl-D-glucosamine. It is a major component of many body tissues and fluids, where it provides mechanically protective and physically supportive roles. The viscosity and intraperitoneal residence time of an HA solution can be dramatically increased by ionic cross-linking with ferric ion. Ionic cross-linking between the carboxylate groups on the HA and the trivalent iron (Fe^{3+}) results in a significant increase in solution viscosity and intraperitoneal residence compared to the original HA solution. The ionically cross-linked Intergel solution has been found to prevent or reduce adhesion formation in preclinical animal models where HA had little or no effect [10].

Laparotomy Studies

The clinical safety and effectiveness of Intergel solution was initially demonstrated in a single-center pilot study involving 23 patients (Intergel solution group = 13; lactated Ringer's solution group = 10). After laparotomy, 300 mL of study device was instilled [11]. At second-look laparoscopy, 4–12 weeks after laparotomy, patients treated with Intergel solution had significantly fewer adhesions than control patients. Adhesion extent and severity were also significantly reduced. A multicenter study was performed to confirm and extend the results of the pilot study.

Two multicenter studies (one in the United States and one in Europe) to assess the safety and efficacy of Intergel solution to prevent or reduce adhesions in patients undergoing peritoneal cavity surgery by laparotomy have been completed [12,13]. These studies used a third-party blinded, parallel-group, randomized, and controlled design. A statistically significant difference in adhesion burden was found between Intergel solution and control (lactated Ringer's solution). The incidence, severity, and extent of postsurgical adhesions were significantly reduced in the Intergel solution group compared to

the lactated Ringer's solution group. The proportion of sites with re-formed adhesions was reduced by 31%, and the proportion of surgical site adhesions was reduced by 23%. A reduction in adhesions with Intergel solution was also found for subgroups of patients based on the surgical procedure performed: myomectomy, adhesiolysis, tubal procedures, and ovarian procedures.

The effect of Intergel solution on reducing adnexal adhesions was shown by a significant reduction in the American Fertility Society (AFS) score for adnexal adhesions compared to lactated Ringer's solution. The minimum adnexal adhesion score of both the right and left adnexa was reduced by 59% following administration of Intergel solution. In addition, the number of patients who had poor surgical outcomes as evidenced by the presence of moderate or severe adhesion scores at second-look laparoscopy was reduced 5-fold.

Laparoscopy Studies

To evaluate the safety and effectiveness of Intergel administered at the time of laparoscopy, a multicenter randomized, parallel-group, placebo-controlled study was performed to assess the safety, compatibility, and efficacy of Intergel solution compared with lactated Ringer's solution in patients undergoing gynecological surgery by laparoscopy [14]. Intergel solution or lactated Ringer's solution (300 mL) was instilled into the peritoneal cavity of patients immediately prior to termination of laparoscopy. A follow-up laparoscopy was conducted 6–12 weeks later. Videotapes and drawings generated from the laparoscopies were assessed by a masked reviewer. Efficacy was measured by the method of the American Fertility Society, applied to 23 anatomical sites including both pelvic and upper abdominal locations: the modified AFS score (mAFS). Additional variables, including the proportion of sites with adhesions, the extent of adhesions, and the severity of adhesions, were determined. The study evaluated 221 patients (Intergel solution group: 116; lactated Ringer's solution group: 105) in 11 centers throughout the United States. The mAFS adhesion scores at baseline for treated and control groups were significantly different, precluding meaningful analysis of the total study population (1.39 vs 0.98, $P = 0.042$).

Of the surgical subgroups, patients having ovarian or paratubal cystectomies had mAFS adhesion scores that were not significantly different at baseline, allowing for further analysis. For this subgroup, at second-look laparoscopy, mAFS scores were significantly lower in the Intergel solution group than in the control group (Figure 6.1). In addition, there were significant differences in mAFS scores between groups at second-look laparoscopy for de novo adhesions as well as for adhesions at the surgical sites (Figure 6.2). Overall reductions were observed in AFS (62%), mAFS (71%), incidence (61%), extent (60%), and severity (69%) of adhesions (Figure 6.3). The safety profile for the entire study population of patients treated with Intergel solution was

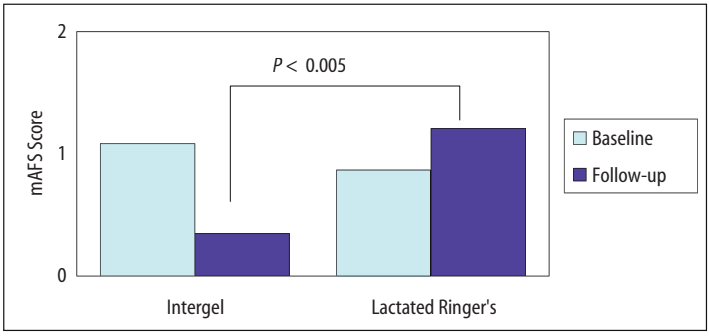

Figure 6.1. Results are shown for patients undergoing ovarian or paratubal cystectomy who received 300 mL of either Intergel Adhesion Prevention Solution or lactated ringer's solution at the end of the laparoscopy (baseline). Six to 12 weeks later the patients had a follow-up laparoscopy. Even though the modified adhesion scores for 23 different anatomical sites throughout the entire pelvis and abdomen (mAFS) were not different at baseline, the mAFS scores were significantly different at follow-up laparoscopy (14).

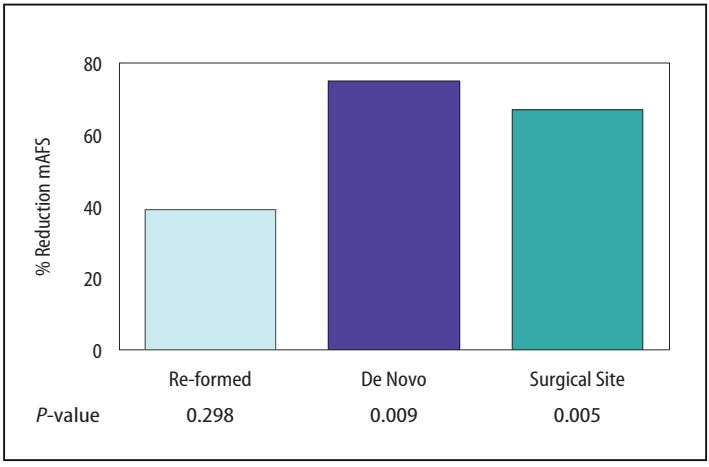

Figure 6.2. Results are shown for patients undergoing ovarian or paratubal cystectomy who received 300 mL of either Intergel Adhesion Prevention Solution at the end of laparoscopy. The patients who received Intergel had a statistically significant reduction in de novo and surgical site adhesions compared to those who received lactated Ringer's solution as measured at 23 different anatomical sites throughout the abdomen and pelvis (14).

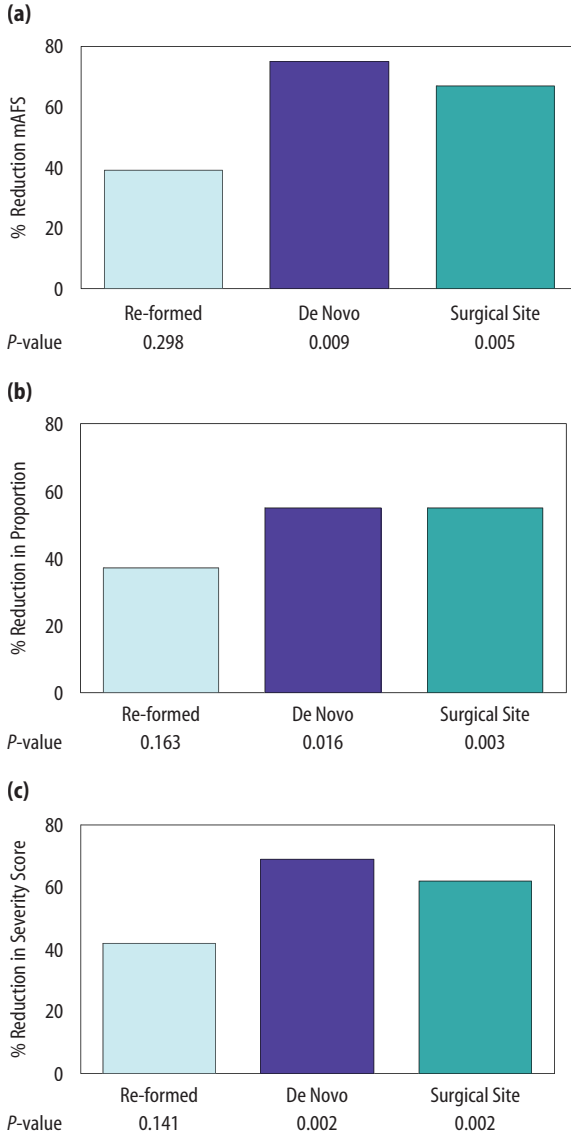

Figure 6.3. Results are shown for patients undergoing ovarian or paratubal cystectomy who received 300 mL of Intergel Adhesion Prevention Solution at the end of the laparoscopic procedure. The incidence (a), extent (b), and severity (c) of de novo and surgical site adhesions were significantly reduced in the patients who received Intergel compared to lactated Ringer's solution (14).

comparable to that of patients treated with lactated Ringer's solution. Intergel solution was safe and compatible with laparoscopy.

Use of Intergel has been associated with rare cases of late-onset (postoperative days ~3–5), nonspecific, diffuse pelvic pain that is self-limited, usually spontaneously resolving in 3 to 5 days. Although typically afebrile, these patients can have elevated temperatures in the presence of a normal white blood cell count, distinguishing from intraperitoneal infection. In the absence of other findings, the pain in these patients usually resolves spontaneously, negating the need for surgical intervention. Due to the above, Intergel was voluntarily withdrawn from the market.

Adept

An iso-osmolar, biodegradable, glucose polymer solution (Adept) containing 4% icodextrin recently became available for adhesion prevention in intraabdominal surgery. Icodextrin is a substrate for amylase, which is widely distributed throughout the body but is not present in the human peritoneal cavity [15]. When given intraperitoneally, icodextrin is largely retained within the peritoneal cavity; absorption of the polymer occurs gradually via the lymphatic system into the systemic circulation. Icodextrin is then readily metabolized by amylase to oligosaccharides, which are cleared by further metabolism to glucose. The intraperitoneal residence time for a 4% icodextrin solution in humans was shown to be at least 72–96 hours, in comparison with saline-based solutions. The fluid dynamics of 4% icodextrin show that a volume placed into the peritoneal cavity after surgery would be present during the time of maximum risk of adhesion formation, up to 3–5 days postsurgery.

Preclinical studies with 4% icodextrin in the rabbit double-uterine-horn model demonstrated that in addition to significant benefits following postoperative instillation, de novo formation of adhesions was significantly reduced by frequent intraoperative irrigation [15]. Adept treatment did not exacerbate the course of induced bacterial peritonitis in rats, supporting the use of 4% icodextrin solution in both gynecological and general abdominal surgery. The reduction of adhesion formation demonstrated in preclinical studies encompassed not only the incidence but also the extent and severity of adhesions. The results of Adept reducing adhesions in animal models were confirmed and extended in a pilot study of patients undergoing laparoscopic gynecological surgery.

In a pilot clinical study, postsurgical instillation of Adept (1 L) was evaluated in a controlled, prospective, assessor-blinded study in female patients undergoing laparoscopic adnexal surgery with a follow-up laparoscopy. Adept or lactated Ringer's solution (control) was used as an intraperitoneal irrigating solution at least every 30 minutes during the surgical procedure [16]. Patients who received Adept had fewer adhesions at second-look laparoscopy 4–6 weeks later (Figure 6.4). Further, patients with at least 1 adhesion at the time of surgery had a significant reduction in adhesions. The results of this pilot study await confirmation in a large pivotal study.

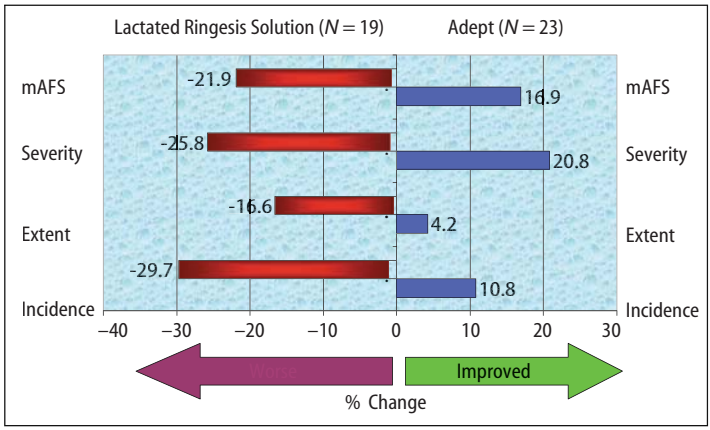

Figure 6.4. Results are shown for patients who underwent laparoscopic adhesiolysis who received 1 liter of either Adept ($N = 23$) or lactated Ringer's solution ($N = 19$) at the end of surgery. All patients underwent rinsing of the pelvic cavity with 100 mL of the respective test solution every 30 minutes throughout the surgical procedure. Patients who received Adept had an improvement in their overall abdominal-pelvic adhesion burden as measured by the mAFS score determined at 23 different anatomical sites, as well as in the incidence, extent, and severity of adhesions compared to the patients who received lactated Ringer's solution.

Intergel Comparison to Interceed

Korell compared the efficacy of Intergel to that of Interceed in the reduction of adhesions following laparoscopic myomectomy [17]. Women of reproductive age ($N = 81$) were randomized to treatment with an adhesion prevention

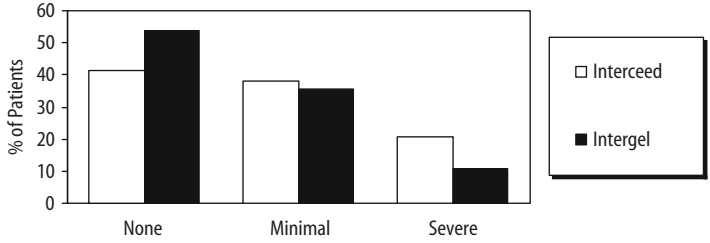

Figure 6.5. Results are shown for patients undergoing myomectomy who received either covering of the uterine surface with Interceed or instillation of Intergel Adhesion Prevention Solution (300 mL) into the pelvis at the end of surgery. About half the patients in both groups had no adhesions at follow-up laparoscopy, while only minimal adhesions were found in most of the other patients. Both devices were effective at reducing adhesions after laparoscopic myomectomy (17).

device following laparoscopic myomectomy, a procedure reported to be associated with up to 90% incidence of severe adhesions [18]. Following the use of adhesion prevention devices, about half the patients were adhesion free, while most of the others had only minimal adhesions (Figure 6.5).

Perspective

While adhesion prevention barriers are safe and effective in all human clinical trials, their use does not eliminate adhesions in all patients. Many investigators are incorporating adhesion prevention barriers into their routine clinical practice and achieving good results, even in difficult clinical settings. As a result of multiple demonstrations of barrier efficacy, adhesion prevention adjuvants have received widespread acceptance. Efficacy of the barriers is limited to surgical situations where the area in question can be completely covered. The instillates Intergel and Adept, which provide generalized peritoneal coverage, can be easily administered via either laparoscopy or laparotomy.

To date no treatment has proven uniformly effective in preventing postoperative adhesion formation. Surgical techniques that limit tissue ischemia, as well as absorbable, nonreactive mechanical barriers, provide clinical benefits to patients today. Ongoing evaluations of drugs that modify the local inflammatory response and agents that reduce fibrin deposition delivered directly into the peritoneal cavity show promise for limiting adhesions tomorrow.

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7. What to Do When the Operation Is Over

Virginia A. Beckett
Derek J. Tuffnell

If you seek advice on to how to get out of a difficult situation, a wise respondent will tell you not to start from where you find yourself. This is particularly the case for operative complications. If you consider how to get out of the problem only once it has occurred, you are going to be faced with significant difficulties. Other chapters deal with the issue of consent, but issues such as training, staffing, and equipment availability all should be considered. However, even with these preparations, all surgeons will have complications. Those who do not fall into the three Ps: *perfect*—there aren't any surgeons we know of in this group; *Pinocchios*—those who are economical with the truth or at best forgetful; and *permanently on holiday*. It is against this background that we consider preventable harm and how it should be addressed.

Vincent et al. report in their retrospective study that 5% of patients admitted to 2 large hospitals in Greater London suffered preventable harm [1]. A subsequent analysis of the causes of errors in clinical practice by the same group [2] suggested that less than 20% of preventable adverse events were directly related to surgical operations or invasive procedures. However, it is highly likely that we will all be involved, either directly or indirectly, in an adverse incident at some point in our careers. The process of risk management aims to proactively identify, assess, and treat risks leading to the prevention of foreseeable adverse events [3]. As a consequence of proactive risk management, unintended harm to patients is reduced and patient safety and care are improved. The Department of Health document *An Organisation with a Memory* recommended a reduction of 25% in the number of cases of negligent harm in obstetrics and gynecology by 2005 [4]. It is not yet clear whether that goal has been achieved. A reactive approach to adverse events would not achieve this type of target. However, as part of a systematic approach to risk assessment, engaging in proactive risk management activity, in addition to the reactive process of incident management, will enable the identification of the many things that could go wrong [5]. Root cause analysis is a structured investigation that aims to establish the underlying cause of serious incidents. In many cases, the root cause of an adverse event lies with the management and organizations that support the delivery of care and not with individual healthcare professionals. The National Patient Safety Agency was set up to run a national system of reporting adverse events and aimed to reduce future harm to patients by identifying and addressing dysfunctional systems. This process

encourages a shift away from a "blame" culture to a "just" culture. By encouraging widespread reporting of near misses and critical incidents, we can use the risk management and patient safety process to identify areas for change and also to lobby for improvement. We should all now be working in environments with robust systems in place to handle the reporting and analysis of adverse events as part of clinical governance. If not, it is in our interests to effect local organizational change.

Preoperative Care

In many cases, intraoperative adverse events can be limited or prevented by careful preoperative preparation of the patient. A root cause analysis may focus on the following points:

1. Consent should be informed, with all reasonable risks discussed with the patient by a staff member who is adequately trained to do so.
2. The correct equipment should be anticipated and available. Theater staff should be familiar with its use.
3. The surgeon should be competent to carry out the planned procedure.
4. Appropriate operative assistance and nursing staff should be available.
5. National Confidential Enquiry into Perioperative Deaths (CEPOD) guidelines, particularly with respect to the preoperative resuscitation of patients and the timing of procedures, should be observed [6].

During the Procedure

Following an adverse event, the optimal response would demonstrate that personnel recognized the event appropriately and acted in a timely way and within their sphere of competence, calling for assistance where necessary. Immediate steps should be taken to investigate the cause and consequences of the event where appropriate.

To demonstrate such an "optimal response," clear and contemporaneous notes are vital. During long procedures, it may be useful to ask one of the theater staff to record the timing of events to improve accuracy. It is particularly important to document who called for help and at what time, and the time that help arrived, while noting any reason for delays. Detail the availability of significant individuals and equipment. Provide a clear description of how the complication was recognized and remedied. Ensure that handwriting is legible and that each entry has a date, time, and signature, with the patient's details on each sheet of paper.

Postoperative Management

In addition to making an accurate record of events at a time when recall is likely to be most accurate, it is imperative that appropriate plans are made for the postoperative care of the patient. Document these plans clearly, but realize that this documentation may need to be backed up verbally. Ensure that the level of care is adequate, whether it be an overnight stay or perhaps transfer to intensive care or a high-dependency unit. It is fundamental to patient safety that once an adverse event has occurred, its consequences be limited. This should encourage a heightened awareness for the subsequent care of the patient.

Patients and Relatives

The General Medical Council states in *Good Medical Practice* that if a patient under one's care has suffered harm, one must explain fully and promptly to the patient what has happened and what long- and short-term side effects are likely to occur [7].

Poor communication accounts for a significant number of complaints against the medical profession [8]. Adopt an open and honest approach and make all effort to maintain lines of communication. Explain the circumstances as fully as possible, using language within the patient's understanding; use an interpreter where necessary. Give the patient the opportunity to ask questions, but recognize that a full analysis of events is unlikely to be helpful until all the facts of the case are established. Apologize that the event has happened. This is not an admission of guilt, and the omission of an apology is often cited in patients' complaints. It is perfectly reasonable for patients to expect acknowledgment that they have been involved in an adverse event together with a verbal expression of empathy.

Relatives must be handled sensitively. They will understandably request information about the incident, but any response should observe patient confidentiality. The duty of care of all staff is to the patient, and information should not be disclosed if one has reason to believe that the patient would object [7].

The Team

The patient is not the only victim when an adverse incident occurs. In a theater setting there is often a well-established team, and few members of that team will be unaffected. This needs to be recognized and the temptation to "just carry on as normal" resisted. It may be appropriate to take a short break, even if this means that some clinical work needs to be delayed. Acknowledge that performance may be affected. If an intraoperative death occurs, the list

should not continue. Even in less serious events, those directly involved in the event should consider stepping down. If an event involves you as the primary surgeon, have the insight to take a break from or stop operating. If one of your trainees is involved in an incident, encourage the same in them.

It is important for the team's psychological well-being to debrief after adverse events. If you were directly involved, try to discuss the incident with an appropriate colleague. This avoids damaging rumination later at home and helps you to clarify your thoughts on the case. Encourage this practice in others, including trainees.

Organize a structured debriefing for the team at a later date, and invite other members of the department where appropriate. Discuss what happened and how the team responded. Use these discussions to formulate lessons to learn and ways to avoid similar events in the future. Consider whether this incident constitutes part of a trend, for example, with a particular piece of equipment. This approach encourages a positive learning culture in the department toward adverse incidents and moves away from the "blame" approach.

Incident Reporting

The National Patient Safety Agency (NPSA) has aimed to ensure reporting of all adverse incidents. Such reporting is essential to good risk management and hence patient safety and clinical governance. Ensure that the correct documents are completed as soon as possible after an adverse event occurs. This is the starting point for follow-up by the risk manager. Since part of the risk management process is to track common events, this will allow the early identification of a serial incident. Where serious harm occurred, the NPSA suggests that a report be filed within 3 working days and a root cause analysis undertaken within 45 working days of the occurrence of the incident [5].

It is important that organizations encourage transparent working practices in which the filing of incident reports is routine and without fear of disciplinary action. In our unit, as in others, the policy on incident reporting states that "disciplinary action should not follow the reporting of an incident except in cases where one or more of the following applies:

- Where there is a second occurrence involving the same individual following education and/or training
- Where the incident has resulted in a police investigation
- Where, in the view of the professional registration body, the action is far removed from acceptable practice
- Failure to report an "incident"

Root Cause Analysis

The aim of any investigation into a serious adverse event or near miss should be to identify underlying deficiencies within the system of working that

may have contributed to the event. It does not seek to expose individual error; indeed, if robust systems are in place, individual errors should rarely result in adverse events. The process should consider all aspects of an event, including the organization as a whole, and encourage the "no blame" or "just" ethos.

All staff involved are asked to provide factual statements of their appreciation of the event, free of conjecture. Factual information regarding the patient's ailment, including local and/or national guidelines and details of the operative procedure, is gathered. Details of staffing rosters are required in order to clarify who was available to provide assistance and whether there were any strains on staffing.

The analysis should consider whether the person who made the decision to take the patient to theater, whether in the acute or outpatient setting, was of appropriate seniority or level of training. Information leaflets are increasingly used to provide patients with information regarding planned procedures, and evidence that these documents were made available would suggest that an attempt was made to provide adequate information for the patient prior to obtaining his or her consent. Documentation of any counseling given at this time is also valuable. The use of guidelines and whether they were adhered to, for example, preablation therapy, would be considered.

On admission, it is clearly important that patients be admitted to the appropriate ward, where staff members are familiar with the planned procedure and any necessary pre- and postoperative care particular to that procedure. "Waiting list initiative" lists require special mention, in that it should be ensured that the team members assembled for the list, both on the ward and in the theater, are adequately familiar with the planned procedures.

In the theater, there should be adequate staffing levels and appropriately trained staff. There should be a nurse available as a runner. A new or unfamiliar anesthetist may have an impact on the dynamics of the team, and this factor may be explored. Evidence that the correct equipment was available and used correctly will be sought. Service records for some equipment may be important.

When the incident occurred, an emergency drill may have been adopted. Any documentation regarding this drill and whether it was regularly practiced would be examined. The panel would look to ensure that any additional equipment, blood, or drugs were available swiftly, and that the support of senior staff members or colleagues from other specialties was available. Time taken to contact such support may be relevant. If the patient was transferred to a high-dependency or intensive care unit, the availability of beds in these facilities would be examined, as would any time taken to transfer the patient to another unit.

Root cause analysis seeks not to apportion blame to individuals but to offer solutions to avoid further adverse events or near misses. It can be used to initiate guidelines and drills and to improve patient information leaflets, for example. It also serves to strengthen cases for increased staffing levels, senior support in the operating theater, and new equipment.

Summary

Risk management is a relatively new process that can sometimes evoke feelings of suspicion among clinicians. However, when used proactively, it offers the opportunity to act at the root cause of an incident to expose deficiencies in the system rather than in individuals. This process encourages a supportive approach to patients, relatives, and staff. The overall aim should be to learn lessons rather than to attribute blame.

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8. Laparoscopic Surgery

Joseph A. Ogah

Severe complications associated with laparoscopy are rare, but as a large number of laparoscopies are carried out each year, the impact and consequence of these complications are considerable. The complications may be life threatening, and the consequences of damage to the bowel, major blood vessels, and urinary tract are potentially catastrophic, leading to considerable physical and emotional suffering as well as significant financial cost.

The overall complication rate of laparoscopy ranges from 0.2% to 10.3 % [1–15], with prospective studies showing higher complication rates [11,14]. The major types of complications that occurred in a series of 236,392 gynecological procedures from different countries are intestinal, urinary tract, and major vascular injuries [5,8–16]. Fifty percent of complications arise from entry technique [11,15], and in 20%–25% of cases, the injury is not recognized intraoperatively [10].

A review of more than 350,000 laparoscopic procedures carried out over more than 20 years using the closed Verres needle entry technique gives a risk of major vascular injuries as 0.02% and that of bowel injury as 0.04% [17–23]. These rates are so low that it would be almost impossible to carry out properly constructed randomized controlled trials to demonstrate the superiority of one entry technique over the other. Garry [24] estimated that to demonstrate a 33% reduction in bowel injury rate from 0.3 in 1000 to 0.2 in 1000 would require 828,204 cases.

Vascular Injury

Vascular injuries can occur at the time of entry into the anterior abdominal wall, before creation of pneumoperitoneum or after the insertion of the primary trocar, or while the laparoscopic operation is being carried out. They can also occur from anterior abdominal wall injuries, particularly involving the inferior epigastric vessels. Secondary ports should be inserted under direct vision so they are less likely to lead to vascular injuries.

Reviews of cases where vascular injuries have been sustained show that an overwhelming majority (>80% in some reviews) occurred at the point of initial entry into the abdominal wall, mainly by the primary trocar; fewer cases occurred during secondary port entry; and even fewer occurred during the operation [17,25–28].

Often when major vascular injuries occur, only minimal free blood is encountered in the peritoneal cavity, contrary to what is expected. Most times,

though, there is a large retroperitoneal hematoma. At other times hemorrhage is obvious. When the anterior abdominal wall vessels are involved, anterior abdominal wall hematoma can occur, which when infected can present as abscess on the abdominal wall.

In more than 50% of cases of vascular injury, repair by laparotomy is needed. For some injuries, depending on the site, extent, and adequate visualization of injury, laparoscopic repair may be carried out [29]. Mortality rates from major vascular injury range from 9% to 22% [17,27,30,31].

Intestinal Injury

Intestinal injury will lead to a laparotomy in 60% of cases [30] and mortality in 2.5%–5% of cases [25,30]. Often mortality occurs because of failure to recognize the bowel injury intraoperatively. The bowel is injured either in its normal anatomical position in the abdomen or when pathologically adherent to the anterior abdominal wall. The risk of bowel injury at laparoscopy is small when compared with other types of abdominal surgery (Table 8.1 [32]), but because at laparoscopy bowel damage is more likely to be undiagnosed intraoperatively, it leads to significant morbidity.

Adhesion of omentum and/or bowel to the anterior abdominal wall puts the bowel at increased risk of injury during laparoscopic surgery. It is important to consider the risk of adhesions prior to embarking on laparoscopic surgery; this risk depends on the method of entry into the abdomen with previous surgery if any. Audebert [33] used a microlaparoscope inserted in the hypochondrium to record the distribution and severity of intraabdominal adhesions and correlated these with past surgical history (Table 8.2).

Between 25% and 50% of bowel injury occurs during entry to the abdominal wall, with 50%–75% occurring during the actual laparoscopic operative procedure [25]. Symptoms of bowel injury following laparoscopy are often atypical. Nausea, vomiting, ileus, and severe pain are uncommon; peritoneal signs are infrequent. More common features include pain at the trocar site near the injured segment of bowel, abdominal distension, and diarrhea with normal bowel sounds. This may be because laparoscopy elicits less inflamma-

Table 8.1. Bowel Injury After Various Methods of Gynecological Surgery

			Entry-Related Injuries	
Type of Surgery	Total Number of Cases	Bowel Injuries	*N*	Rate
Laparotomy	5700	93	48	8.3/1000
Vaginal	965	11	7	7.3/1000
Laparoscopy	3710	13	11	3.0/1000
Dilation and curettage	7575	11	11	1.5/1000

Table 8.2. Rates of Adhesions Related to Surgical History

Surgical History	Total Number of Cases	Adhesions		Severe Adhesions	
		Rate	*N*	Rate	*N*
No previous history	519	8/1000	4	4/1000	2
Previous laparoscopy	140	14/1000	2	7/1000	1
Previous Pfannenstiel	145	214/1000	31	69/1000	10
Previous midline	96	531/1000	51	253/1000	30

tory and immune response than laparotomy. Laparotomy rates following intestinal injury are between 52.4% and 90% [5].

Urinary Tract Injury

Urinary tract injury is observed in 0.02%–2% of laparoscopies. Bladder injuries are more common and are recognized more commonly intraoperatively than ureteric injuries. The most common type of urinary tract injury is bladder perforation (>50%); less common are ureteric ligation, ureteric transaction, and fistula formation. Most injuries to the urinary tract occur during operations for advanced endometriosis, hysterectomy, oophorectomy, pelvic lymphadenectomy, and adhesiolysis.

Repair of injuries to the ureters is mostly accomplished by laparotomy, probably because most cases are diagnosed postoperatively. Diagnosis made intraoperatively increases the chances of laparoscopic repair, depending on the extent of damage.

Prevention of Injuries and Management Strategies

Every method of entering the abdominal cavity has inherent risk of injury to the intraabdominal organs [32]. To reduce the rate of these injuries at laparoscopy, several techniques have been devised, the most popular being the "open" method devised in 1971 by Harrith Hasson, a gynecologist [34,35]. In this method a small incision of 1–2 cm is made just below the umbilicus; then dissection occurs down to the peritoneal cavity. Each suture placed on either side of the rectus sheath is wrapped around pegs on a cannula that has been inserted snugly into the peritoneal cavity. This method is thought to be under direct vision. Some studies confirm the safety of this method and claim reduced risk of major vascular injury. In a series of 10,840 open laparoscopies, no major vascular injuries occurred [36]. A retrospective comparison study [37] documented a statistically significant decreased rate of major vascular injury when the open technique of abdominal entry is compared to a closed technique. A

more recent review of the literature carried out by the Australian College of Surgeons [38] found that even though there seemed to be a trend toward higher risk of vascular injury with the closed Verres needle method, the risk of vascular injury was so low in both groups that there was no statistically significant difference. It also found that the open method had a higher risk of bowel injury (relative risk [RR] = 2.17, 95% confidence interval [CI] = 1.57–4.63).

Irrespective of the method of entry chosen, certain steps can be taken to reduce the risk of injury. Useful steps are outlined in a consensus document [23,39].

The main advantage of locating the primary incision in the depth of the umbilicus rather than the periumbilical area is that this is the thinnest area of the abdominal wall and the only area where the peritoneum is actually attached to the abdominal wall.

The Verres needle should be sharp, with the stylet retracting and springing out briskly; the needle should be checked and replaced frequently, or an appropriate disposable Verres needle should be used. To achieve full control of the needle during insertion, the barrel should be held low down, like a dart. The aim while inserting the Verres needle is to insert it just far enough to penetrate the layers of the abdominal wall and locate the tip just into the peritoneal cavity. Two distinct clicks or pops will be heard or felt as it passes through the sheath and enters the peritoneal cavity. No further advancement of the needle should be made, and checking the location of the tip of the Verres needle by rotatory motion runs the risk of creating injuries as minor as a needle-stick injury of the bowel, which may not need any treatment at all, or as major as a complex bowel tear, which will definitely need surgical treatment. Tests that can be used to check the satisfactory location of the needle are the Palmer's test, the drip test, and the pressure-flow test with the CO_2 insufflator.

With the Palmer's test, a syringe is attached to the end of the Verres needle, and a suction check is done for blood/bowel contents. If there is none, then the fluid is instilled down the Verres needle; the fluid should flow freely into the peritoneal cavity, and suction after this should not lead to return of the fluid back into the syringe from the cavity. With the drip test, fluid in a syringe attached to the Verres needle should flow passively into the abdominal cavity after the plunger is withdrawn. With the pressure-flow test with the CO_2 insufflator, when the needle is correctly situated, the flow of gas when set at 1 L/min should also register 1 L/min combined with an intraabdominal pressure of less than 10 mm Hg. If the needle is inappropriately positioned within the abdominal wall, in adhesions, or in intraabdominal structures, the flow will be low or nothing and the pressure will be high. If bowel contents are obtained at aspiration or instillation and/or insufflation pressures are high, the Verres needle can be removed and an alternative entry site selected [23].

There is some belief that using intraabdominal pressure rather than the volume of gas instilled will lead to a safer distance between the anterior abdominal wall and the abdominal viscera. Reich et al. [40] were the first to describe a high-pressure technique, where, with the patient lying flat, instillation of gas is continued till a pressure of 25 mm Hg is reached. At this pressure,

the distance of the viscera from the anterior abdominal wall is widened; as the wall is stretched, the trocar penetrates the wall more easily, and the greater splinting resists the downward force. This technique does not adversely affect the circulation or the respiratory function of the patient [41]. Once all trocars are in place, the instillation pressure should be reduced to 12–15 mm Hg. Other methods of entry described, including direct trocar insertion, visual access systems, radially expanding trocars, and second-generation endo-tip systems and narrow-diameter laparoscopes inserted down the Verres needle to form an optical Verres system, may be helpful, but as McGurgan and O'Donovan report [42], despite the theoretical advantage, there is as yet no evidence to demonstrate the superiority of this approach over conventional Verres needle. A recent review [38] of all the literature available showed that there was insufficient evidence to indicate a preferred method.

When the umbilicus is not used as site of entry, alternative sites such as the left hypochondrium can be used, as this is statistically the area of the abdomen with the lowest incidence of adhesions. When periumbilical adhesions are suspected, use either the 9th intercostal space, or in the midclavicular line below this point, a rational site is the Palmer's point [43].

If vascular injury occurs and a retroperitoneal hematoma results, it should never simply be observed. When retroperitoneal vessel injury occurs or is suspected, a midline incision to explore and repair the injury is indicated. Evaluating the extent of injury laparoscopically could cause additional damage to the vessel or surrounding structures and lead to loss of time and greater loss of blood. Clamping or clipping major vessels should not be attempted. Frantic clamping and suturing results in further damage to vessels and surrounding structures. Early intervention by a vascular surgeon is recommended.

When bowel injury occurs, the assistance of a bowel surgeon is of utmost importance. Prophylactic colostomy should be restricted to patients with gross fecal contamination.

Careful identification of the ureter at points where it is most exposed is necessary to prevent injury. Laparoscopic ureteric injury can be minimized by using a laparoscopic suturing and tying method, which may be safer than using staples and electrocautery.

When suspicion of ureteric injury exists, cystoscopy with observation of urine jetting through the ureteric orifice is valuable in confirming injury, especially when intravenous indigo carmine is used. Obtaining urology consultation intraoperatively will help to decrease the delay in recognition of ureteric injury and thus increase the likelihood of intraoperative repair.

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9. Urinary Tract Complications

Joseph A. Ogah

Urinary tract injury is a common cause of litigation in gynecology, accounting for about 10% of claims [1]. There is a 91-fold increase in litigation when the urinary tract is injured in comparison to other complications from a hysterectomy [2]. It is a significant cause of morbidity, especially when diagnosis is delayed. Its occurrence and the sequelae can lead to significant personal suffering, anxiety, depression, loss of employment, difficulties in interpersonal relationships, and poor quality of life [2].

The close proximity of the lower urinary tract to the female genital tract puts it at risk of injury during gynecological surgery. Urinary tract injuries complicate between 0.3% and 1% of all gynecological operations and cesarean sections [2–6]. Seventy-four percent of these injuries occur during surgery for benign disease.

Urethra

Iatrogenic injury to the urethra during vaginal or uterine surgery is unusual. It most commonly occurs in association with injury to the sphincter active area of the urethra at the time of urethral diverticulectomy. It occurs in up to 5% of cases of simple diverticulectomy.

Bladder and Ureters

Bladder injuries occur in 1%-5% cases of benign gynecological operations [2,4,6,7]. Most of these injuries are recognized intraoperatively [5,8–11]. More recent studies show rates as high as 3.6%, with vesicovaginal fistula occurring more commonly when the injury is missed [10].

Gynecological surgery is the second commonest cause after primary urological surgery as cause of iatrogenic ureteric injury [12]. Ureteric injuries occur in 0.02%–2.5% of benign pelvic operations, but unlike bladder injuries, in which most cases are recognized intraoperatively, ureteric injuries are often missed intraoperatively [2,4–7,10,13–15]. The true incidence of ureteral injury is likely to be higher with increasing use of electrosurgery and laser surgery, primarily from unrecognized devascularization; higher incidences also occur in surgery for invasive cancer and in some urogynecological surgery.

Causes, Sites, and Types of Injury

The bladder is typically injured at the trigone between the ureteric orifices or on the posterior bladder wall just above the trigone. The injury often occurs while the surgeon is attempting to mobilize the base of the bladder off the cervix or the upper vagina or while closing the vaginal vault and inadvertently catching the posterior wall of the bladder with a suture. Often profuse bleeding makes recognition of surgical planes difficult. Bladder injury also occurs during dissection of the retropubic space and with placement of suspension sutures.

Though the ureter can be injured anywhere along its pelvic course, most injuries during gynecological surgery occur in the distal 3 cm of the ureter [12,16–19] (Figure 9.1). Common sites for injury include the level of the infundibulopelvic ligament, the cardinal ligament at the level of the internal cervical os as the uterine artery crosses over the ureter, and the anterolateral fornix of the vagina as the ureter passes medially to enter the bladder.

The ureter may be injured in many ways: ligated (suture), crushed (clamp), transected, kinked, stretched, lacerated, or devascularized by the effects of thermal, electrical, or laser energy [20].

Risk Factors

Conditions that put the lower urinary tract at risk of injury during gynecological procedures include pelvic masses (e.g., large uterine fibroids, large ovarian masses, tubo-ovarian abscess, pelvic tumor), pregnancy, previous pelvic surgery, endometriosis, pelvic inflammatory disease, pelvic irradiation, complete proccidentia, ovarian remnant, bleeding, and hematoma. Less common risk factors are congenital abnormalities such as mega-ureter, ureteric duplication, and ectopic ureter or kidney.

Goodno et al. and Liapis et al. in their reviews identified some of these risk factors, but it is important to note that in more than 50% of cases no risk factor was identified [21,22].

Prevention

Awareness of the anatomical relations of the urinary tract is of paramount importance, as is knowledge of the risk factors for injury, as outlined previously (Figure 9.2). To avoid injury to the bladder, preoperative bladder drainage with a urethral catheter should be the norm.

Sharp dissection with countertraction on the bladder to separate it from the lower uterine segment and cervix is less likely to cause injury than blunt dissection. Retropubic dissection in the face of previous pelvic surgery is

A. At the pelvic brim over bifurcation of common iliac artery
    1. Oophorectomy
    2. Lymphadenectomy
    3. Hypogastric artery ligation
B. In the cardinal ligament, lateral to the cervix and lower uterine segment
    1. Abdominal hysterectomy
    2. Vaginal hysterectomy
    3. Intraligamentary myomectomy
C. At vaginal fornices just before entry of ureter into the trigone
    1. Retropubic bladder neck suspension
    2. Anterior colporrhaphy
    3. Paravaginal defect repair
D. At the level of the uterosacral ligaments
    1. Excision of pelvic mass
    2. Culdoplasty
    3. LUNA procedure
    4. Ablation of endometriosis
    5. Excision of ovarian remnant

Figure 9.1. Common location of ureteric injury and procedures most commonly associated with injury [18].

hazardous. It may be better to open the bladder dome (where it is most easily repairable after dissection) to aid dissection from the symphysis. Avoid blind clamping in order to achieve hemostasis when there's excessive bleeding.

Use of preoperative intravenous pyelogram (IVP) or contrast-enhanced computed tomography (CT) when distortion of anatomy is suspected may be useful, but Piscitelli et al. [23] reviewed 493 cases of hysterectomy for benign disease and found that 60% received preoperative IVP. Twenty-seven percent of those who received preoperative IVP had abnormal IVP findings, and the factors shown to be most closely associated with abnormal IVP were uterine size 12 weeks and above or an adnexal mass of 4 cm or more. There was no statistically significant difference in the incidence of ureteric injury between

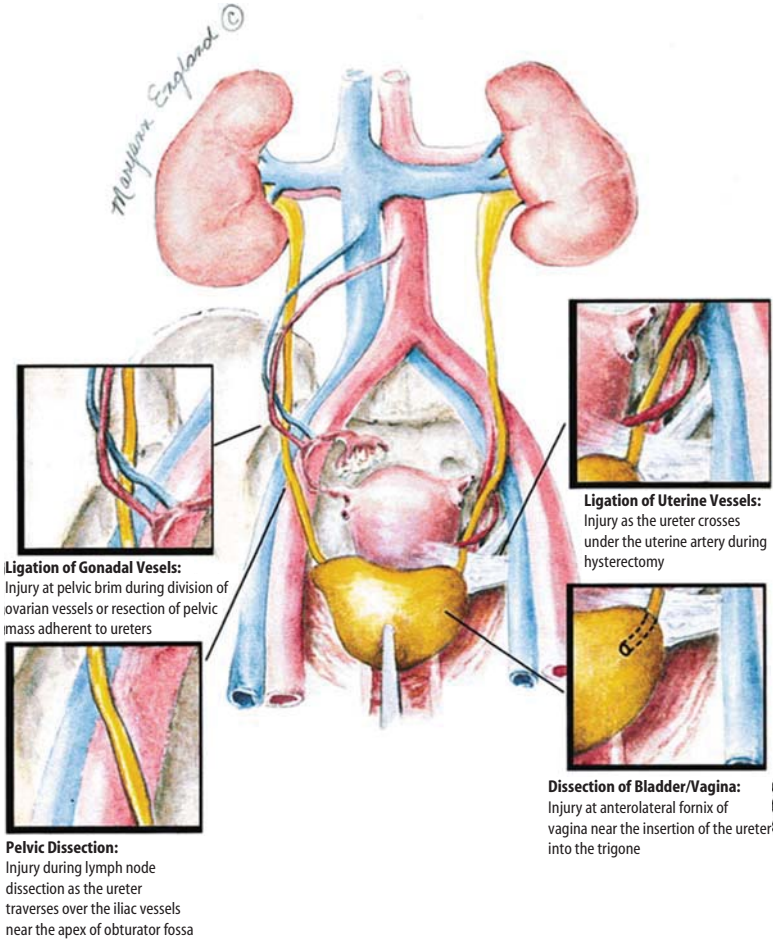

Figure 9.2. Anatomic relations of the ureters and common sites of injury [16].

the IVP and non-IVP groups. Also, a normal preoperative IVP does not negate the responsibility of the surgeon to palpate, identify, and/or dissect the ureter during gynecological operations. There are definitely cost issues with preoperative IVP. No doubt clinical examination would be a less expensive way to identify the risk factors mentioned above that were most closely associated with abnormal IVP findings.

Use of preoperative ureteric stenting is controversial and not substantiated by evidence. There is no clear-cut advantage; it is costly and not without

potential complications. A retrospective review of 3071 cases within a 24-month period found no statistically significant difference between prophylactically stented and nonstented groups with regard to ureteric injury [24]. Complications during stenting include ureteric spasm, direct ureteric injury (incidence of 1%) [25], reflux anuria, urinary tract infection, and hematuria. Lighted ureteric stents allow visualization of the ureters during advanced laparoscopic operations but are of limited value in the presence of pelvic masses or dense adhesions [26].

Adequate exposure and identification of the ureters before clamping in areas where they are most at risk are vital in prevention and, in some cases, dissection of the ureter along its course before clamping is required. In vaginal surgery, e.g., hysterectomy, downward traction of the cervix with upward countertraction beneath the bladder helps to identify and separate the uterovesical space in order to protect the ureter from injuries due to application of clamps and sutures. Paracervical and parametrial tissues near the uterus should be clamped, cut, and ligated little bits at a time.

Intraoperative Diagnosis of Urinary Tract Injury

During pelvic surgery when there is a suspicion of urinary tract injury, all attempts should be made to confirm and ascertain the extent of the injury (Figure 9.3). For the ureters, this will entail opening the posterior aspect of the broad ligament and identifying the ureter along its course. During vaginal operations it is usually more useful to carry out a cystoscopy and inspect the bladder and both ureteric orifices.

Failure to confirm or refute the suspicion of injury by the above methods should lead to use of indigo carmine or methylene blue mixed with saline intravesically to look for leakage as evidence of bladder injury. To aid diagnosis of ureteric injury, use intravenous indigo carmine (5 mL) and fill the bladder with 200–300 mL of normal saline or the denser 10% dextrose [27] via a urethral catheter, and cystoscope the bladder to visualize the blue dye coming out of the ureteric orifices at the same rate. Extravasation of the dye into tissues will suggest bladder injury. Methylene blue is cleared less readily than indigo carmine, but intravenous fast-acting diuretics may speed up this process. If despite using the above steps the diagnosis in not made, it is important to carry out a retrograde pyelography intraoperatively.

Some injuries are missed intraoperatively with significant long-term implications for patients. This has led to the suggestion that cystoscopy should be carried out routinely at the end of all major gynecological surgery. A systematic review of studies in the literature of urinary tract injury during benign gynecological surgery showed a 5-fold increase in the detection rates of injuries when cystoscopy is used routinely [6]. These higher detection rates were also evident from the findings of a recent prospective multicenter study involving 479 patients [10], with a trend to much higher detection rates when there is concurrent prolapse and incontinence surgery. Missed injuries may lead to increased morbidity; some minor injuries, though, may remain asymptomatic,

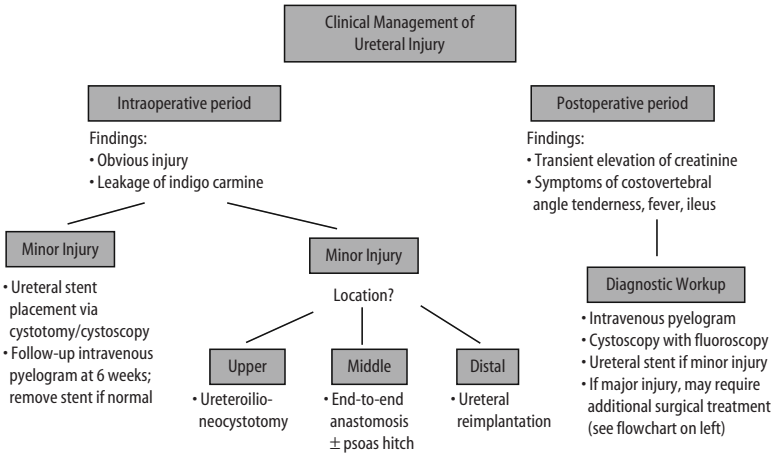

Figure 9.3. Clinical management of ureteric injury [16].

with uncertain clinical significance. Opponents to routine cystoscopy at gynecological operations highlight the uncertainty of clinical importance, the implications when injury is minor, the extra cost and inherent risks of an additional procedure, and the fact that the evidence for its routine use is not robust. Proponents cite the fact that it makes intuitive sense: The potential for significant morbidity and complications from unrecognized injuries and the better outcomes for injuries found and managed at the time of the primary surgery favor its routine use.

Postoperative Diagnosis of Urinary Tract Injury

Two thirds of ureteric injuries are diagnosed postoperatively. IVP is of paramount importance in their diagnosis postoperatively. There is a need in the postoperative period to maintain a high index of suspicion. Features to look out for are often nonspecific complaints such as loin pain and pyrexia. Others to watch for are features suggestive of a urinoma, which may be suspect when abdominal distension, swinging fever, and urinary ascites with ileus or peritonitis occur. A continuous watery vaginal discharge postoperatively is suspicious of vesicovaginal fistula. Other features are a raised white cell count and a slight rise in serum creatinine.

IVP may show hydroureter or hydronephrosis, delayed function, or extravasations. USS or CT scan may show hydronephrosis, a urinoma, or ascites. Biochemical analysis of fluid draining from either the wound, drain, or vagina will show a creatinine level higher than the serum level. Fistulogram

and double dye test to differentiate between ureterovaginal and vesicovaginal fistulae may be useful [19].

Treatment

Most gynecologists will be able to repair injuries to the bladder, and some will be able to repair some ureteric and urethral injuries, but where the injury is complex or expertise is lacking, the assistance of a urologist is a necessity.

Urethra

Prior catheterization of the urethra before dissection is essential. Repair of urethral damage is with 3/0 or 4/0 absorbable sutures, which should be interrupted, and placed horizontally. A second layer should be inserted if possible to separate the primary repair from the vaginal suture line. A martius fat pad harvested from the labia majora may be needed to reinforce the repair.

Bladder

A 2-layered repair of the bladder with delayed absorbable suture (2/0 or 3/0) should be carried out. The cystostomy is best closed with a continuous full-thickness suture, with the second layer, either continuous or interrupted, placed in an inverted manner.

If injury is close to the trigone, there is a danger of the repair kinking the intramural portion of the ureter. As a precaution, ureteric stents should be inserted before carrying out the bladder repair. Continuous bladder drainage to prevent distension (which compromises healing) is needed for 7–10 days.

Ureter

Repair of the ureter should be tension free, with care to preserve the ureters' vascular and neurological supply, and limited suturing to decrease tissue necrosis. Ureteric stenting and retroperitoneal suction drainage are important in enhancing the healing process and to prevent stenosis of the lumen.

Other techniques employed include spatulated end-to-end anastomosis with stenting, ureteroneocystostomy, ureteral reimplantation, ureteroureterostomy, and end-to-end anastomosis.

Summary

There is always a potential for injury to the urinary tract during gynecological procedures, even with supposedly simple procedures. Appreciating this fact with proper preoperative anticipation and planning, familiarity with the anatomical relations involved, careful sharp dissection, and meticulous hemostasis will help to prevent injury. When injury is suspected, all efforts should be made to diagnose the injury intraoperatively, using all investigative tests and expertise available while the patient is still under anesthesia. Proper operative documentation including any difficulties encountered should be made. Postoperatively a high index of suspicion should be maintained, and early investigation should be undertaken where suspicion of injury exists.

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10. The High-Risk Gynecology Patient: Assessment and Management

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Modern surgical, anaesthetic, and nursing care has increased the safety of gynecological surgery. Clinicians as well as patients may consider it to be routine, with very low risk. However, for a small cohort of patients the physiological insult of surgery exposes them to significant risks of morbidity and mortality; these patients are usually elderly, often with malignancy or cardiopulmonary comorbidities, and having major or emergency surgery. The leading causes of intensive treatment unit (ITU) admission in postoperative gynecology patients are hemorrhage, infection, and cardiorespiratory failure, and in these patients the 6-month mortality is 26% [1]. For those age >69 years having major open procedures, the 60-day mortality rate is up to 5% [2]. The challenge remains to accurately identify those patients who have the highest risk, to stratify their level of risk, and to modify management to ameliorate the hazards. Doing so facilitates the benefits of surgery for a group of patients for whom it may previously have been denied. In any healthcare system with limited resources, it is imperative that such resources are targeted appropriately toward those with the highest risk.

The Physiological Insult

Major surgery represents a profound physiological stress (Table 10.1). The patient's response attempts to maintain physiological homeostasis and to produce an internal environment conducive to healing and recovery.

The patient's ability to mount an adequate stress response and to tolerate the consequences of that response is vital to their outcome. In particular, the ability to increase oxygen delivery (DO_2) to supply the increased metabolic demands of the tissues is critical. Failure to do so leads to an accumulation of oxygen debt, which is manifested as myocardial ischemia, organ dysfunction, poor wound healing, and infections. Shoemaker et al. [3] demonstrated that oxygen debt after major surgery was significantly greater in those who died or who had major complications compared to survivors. Moreover, while oxygen debt develops even in those with stable hemodynamic parameters, an increase in DO_2 above normal values is associated with improved outcome [4].

Table 10.1. Summary of Physiological Stress by Organ System

Cardiovascular System
Sympathoadrenal activation
Increased global oxygen consumption (VO_2)
Myocardial oxygen supply-demand imbalance
Blood loss and fluid shifts
Effects of anesthesia
Respiratory System
Respiratory depression from anesthesia/analgesia
Diaphragmatic dysfunction
Impaired cough
Atelectasis
Renal
Hypotension and hypovolemia
Nephrotoxins
Fluid and electrolyte disturbances
Gastrointestinal Tract
Pre- and postoperative starvation
Splanchnic hypoperfusion
Bowel ileus
Hyperglycemia
Protein catabolism
Other
Activation of systemic inflammatory and coagulation cascade
Impaired thermoregulation
Immunosuppression (general anesthesia, opiates, malignancy, blood transfusion)

The splanchnic circulation is particularly vulnerable to hypoperfusion during the perioperative period, leading to bacterial translocation, endotoxemia, and stimulation of the inflammatory cytokine cascade. Low gastric mucosal pH [5] and raised levels of interleukin-6 [6] are both associated with poorer outcome.

An Approach to the Assessment of Risk

The assessment of risk is important for counseling the patient, directing anesthetic and surgical technique, and guiding the level of postoperative care. There should be a reasonable expectation that the preoperative assessment will

alter management and thereby improve outcome. The American College of Cardiology/American Heart Association (ACC/AHA) suggests that risk be appreciated in terms of the impact of the following factors:

1. Clinical markers
2. Levels of functional capacity
3. Surgery-specific risk

Clinical Markers

The basis of assessment should be the history and examination, aided by the thoughtful interpretation of simple tests. Comorbidities such as hypertension, ischemic heart disease, vascular disease, atrial fibrillation, heart failure, diabetes mellitus, smoking, chronic obstructive pulmonary disease, or obesity indicate that there is underlying physiological impairment. Nutrition status is important, as both high and low body mass indexes are associated with an increase in complications. Elucidating the presence of chest pain, dyspnea, palpitations, syncope, orthostatic intolerance, limited exercise tolerance, and clinical examination for the presence of clinical signs gives further information about the state of the disease process. Additionally, simple tests such as the resting electrocardiogram (ECG) and biochemistry may detect or refine the assessment of underlying conditions. To guide interpretation, these factors have been incorporated into a variety of specific risk-prediction models. The following are some commonly used examples.

The American Society of Anesthesiologists (ASA) classification (Table 10.2) is a subjective assessment based on clinical markers. While the negative and positive predictive value of the grading is low, increasing score does correlate with overall outcome.

Many of these tools are specifically aimed at the assessment of cardiac risk. Most have identified factors associated with adverse events in large observational studies and used this information to create a weighted scoring system. Examples are the Goldman cardiac risk index [7], later modified by Detsky [8]

Table 10.2. American Society of Anesthesiologists (ASA) Classification

ASA Grade	Patient Characteristics	Approximate Perioperative Mortality (%)
1	Healthy patient	0.05
2	Mild systemic disease that does not limit function	0.4
3	Severe systemic disease with functional limitation	4.5
4	Incapacitating systemic disease that is a constant threat to life	25
5	Moribund patient not expected to survive >24 hours without surgery	50

Note: The suffix *E* is added to the ASA grade to indicate emergency surgery.

Table 10.3. American College of Cardiology/American Heart Association Clinical Predictors of Increased Perioperative Cardiovascular Risk (MI, heart failure, death)

Major Clinical Predictors	Intermediate Clinical Predictors	Minor Clinical Predictors
Unstable coronary syndromes	Mild angina pectoris	Advanced age
Decompensated heart failure	Previous MI	Abnormal ECG
Significant arrythmias	Compensated or prior heart failure	Rhythm other than sinus
Severe valvular disease	Diabetes mellitus (especially insulin dependent)	Low functional capacity
	Renal insufficiency	History of CVA
		Uncontrolled hypertension

ECG, electrocardiogram; CVA, cerebrovascular accident.

and the Lee score [9]. More recently these scoring systems have been revised, and many of the factors have been incorporated into the comprehensive guidelines by the ACC/AHA (Table 10.3), updated in 2002 [10].

A recent review [11] examined postoperative pulmonary morbidity and found that the following clinical markers were predictive of respiratory failure after noncardiac surgery: advanced age, ASA Grade >2, functional dependence, and a history of chronic obstructive pulmonary disease or congestive heart failure, as well as high-risk procedures and serum albumin <30 g/L. The relationship with smoking and obesity was inconclusive, and simple pulmonary function tests were no better than clinical assessment.

The physiological and operative severity score for the enumeration of morbidity and mortality (POSSUM) score is used as an audit tool to provide risk-adjusted operative mortality rates and to predict 30-day morbidity and mortality. It uses 12 physiological variables (age, heart rate, blood pressure, Glasgow Coma Score (GCS), presence of cardiac signs, ECG abnormalities, any respiratory problems, and key blood results) and 6 operative factors (urgency, malignancy, peritoneal soiling, blood loss, reoperation, and severity of surgery). While originally derived from a general surgical population, POSSUM has been validated in gynecological oncology patients to predict morbidity rates, although it tended to overrate mortality risks [12].

Functional Capacity

Assessing functional capacity translates a positive history or test result into an estimate of physiological reserve, which is important to operative outcome. The inability to climb 2 flights of stairs has a positive predictive value of 90% for postoperative cardiopulmonary complications after high-risk surgery [13]. Physiological reserve is conceptualized by metabolic equivalent levels (METs). One MET is an expression of the oxygen consumption of a resting 40-year-old 70 kg man (approximately 3.5 mL/kg/min). Everyday activities are expressed

as multiples of this baseline, providing a guide to the patient's ability to increase DO_2. Risk is increased in patients who cannot reach 4 METS [14] (climbing a flight of stairs, brisk walking on the flat, playing a round of golf).

While static tests of function such as resting echocardiography do not predict adverse outcome, dynamic tests such as exercise ECG or dobutamine stress echocardiography may be better, and the ACC/AHA guidelines provide recommendations for their use.

An accurate assessment of physiological reserve is obtained by cardiopulmonary exercise (CPX) testing—a noninvasive and easily performed test that correlates well with postoperative outcome. The patient performs graduated exercise on a bicycle ergometer while O_2 consumption, CO_2 production, and the ECG are monitored. When the metabolic demands exceed the capacity of aerobic metabolism, then anaerobic metabolism begins and CO_2 production exceeds O_2 consumption—the anaerobic threshold (AT). The AT is well below the maximum aerobic capacity and is independent of motivation, and thus the test is well tolerated even in the elderly. Older et al. [15] used CPX to triage 548 patients (age >60 years or with cardiopulmonary disease) having major surgery to 3 management strategies. Those patients with an AT <11 mL/kg/min (and all those having aortic or esophageal surgery) (28%) were admitted to the ITU preoperatively for optimization with a pulmonary artery catheter (PAC) and then returned there postoperatively. Those with an AT >11 mL/kg/min but with CPX-induced myocardial ischemia (21%) were managed on the high-dependency unit (HDU), and all others (51%) were managed routinely on the ward. In-hospital cardiovascular mortality was 4.6% in the ITU group, 1.7% in the HDU group, and 0% in the ward group, demonstrating the very high predictive value of CPX testing in distinguishing those at risk from their lower-risk counterparts. This method allows the targeting of critical-care facilities to those who will benefit most and may result in cost savings by preventing unnecessary admissions.

Surgery-Specific Risk

The degree of perioperative risk is closely related to the magnitude of the physiological stress imposed by the procedure. This relates to factors such as duration of surgery, invasion of body cavities, bacterial contamination, thermal stress, blood and fluid loss, prolonged starvation, the interruption of normal medications, and the degree of postoperative pain and immobility. The ACC/AHA stratification for noncardiac surgical procedures can be modified for the field of gynecology (Table 10.4).

It can be seen that the highest perioperative risk exists in patients with severe and limiting comorbidities, patients with malignancy, and patients having major surgery. The combination of poor cardiac function and ischemic heart disease is particularly worrisome. Chronological age per se should not be used to discriminate among patients. By making a multifaceted assessment, one can stratify risk for the individual patient, and this risk must be

Table 10.4. Risk Stratification by Type of Surgery

Low Risk	Intermediate Risk	High Risk
Endoscopic procedures Minor laparoscopic procedures Day case surgery	Moderate open abdominopelvic procedures, e.g., total abdominal hysterectomy/prolapse repair	Major gyne-oncology procedures (malignancy increases risk of ITU admission by 5 times)

communicated to the patient in a way that allows meaningful interpretation. All members of the multidisciplinary team must consider the risk when planning care, ensuring that the expected benefits justify potential risks. Below we discuss some general principles of management with particular reference to recent evidence on improving surgical outcomes.

Management of the High-Risk Patient

Preoperative Management

A multidisciplinary approach should be employed in the preparation of patients, involving the surgeon, anesthetist, primary care physician, specialist physician, and others. Medical management should be optimized to treat intercurrent illness and maximize physiological reserve. As most nonsurgical morbidity is due to cardiovascular disease, the strongest evidence relates to optimizing the cardiovascular system and preventing myocardial ischemia. Here the cardiologist may play an important role. Much of this work has been done in general surgical and vascular patients but should be equally applicable in high-risk gynecological surgery. The most comprehensive guidelines have been published by the ACC/AHA [10]. In general, indications for preoperative treatment of hypertension, valvular heart disease, arrhythmias, and conduction abnormalities, and for revascularization procedures for ischemic heart disease, are the same as in the nonoperative setting. Recently, however, there has been interest in specific perioperative medical therapy to reduce rates of cardiovascular morbidity:

Myocardial Ischemia

In the perioperative period, myocardial ischemia or infarction is frequently related to an imbalance between myocardial oxygen supply and demand rather than plaque rupture and coronary thrombosis. Drugs that modulate the sympathoadrenal response reduce myocardial oxygen demand and may prevent ischemic episodes. Initial trials of β-blockers in high-risk patients showed promising results [16]; however, they have been criticized for methodological flaws, and a recent metaanalysis [17] has concluded that the evidence is

insufficiently robust to allow definite conclusions. An ongoing large, multicenter, randomized controlled trial (Peri-Operative Ischemia Evaluation [POISE]) aims to provide more definitive answers. α2-agonists (e.g., clonidine) have been shown to reduce rates of cardiac events in those with coronary artery disease [18].

Optimizing Oxygen Delivery

The observational work by Bland and Shoemaker led to the hypothesis that physiological manipulation aimed at achieving "supranormal" goals (cardiac index [CI] >4.5 L $min^{-1}m^{-2}$; DO_2 >600 mL $min^{-1}m^{-2}$; and VO_2 >170 mL $min^{-1}m^{-2}$) may improve outcome and has coined the term "goal-directed therapy" (GDT). A large number of trials have evaluated this hypothesis [19,20]. Most early studies admitted patients to the ITU preoperatively and used a PAC to guide the administration of crystalloids, packed red cells, oxygen, and inotropes or inodilators to achieve hemodynamic goals in the protocol groups—so-called preoptimization. Frequently these goals could be achieved simply with the administration of fluid. Those studies targeting supranormal goals, especially in the highest-risk patients, showed impressive reductions in hospital stay, morbidity, and mortality. One of the main limitations of this approach is that not all hospitals have the facilities to admit patients to the ITU preoperatively.

Beyond cardiovascular risk management, a recent review [21] highlights strategies to reduce morbidity in the obese woman requiring surgery. They highlight the importance of multidisciplinary care, careful case selection, and careful surgical planning to minimize the risks of hemorrhage, infection, and thromboembolism.

Intraoperative Management

Subsequent work has built on the principles of preoptimization but utilized the intraoperative period to perform the hemodynamic optimization. Gan et al. [22] randomized 100 patients having major surgery (33% gynecological procedures) to standard care with fluid administration guided by pulse rate, blood pressure, urine output, and central venous pressure or to a protocol aimed at optimizing stroke volume (and therefore CI) and aortic flow time (FTc; a variable that correlates well with left ventricular preload) as guided by an esophageal Doppler monitor. The esophageal Doppler monitor revealed subclinical hypovolemia, and thus the protocol group received more colloid than the well-matched control group and had less nausea and vomiting, a faster return of bowel function, and shorter length of hospital stay.

A study in colorectal surgical patients optimized intraoperative fluids with the esophageal Doppler monitor and confirmed shorter hospital stay, reduced intermediate and major complications, and a faster return to diet in the protocol group compared to standard management [23]. The authors noted a

reduced level of the inflammatory cytokine interleukin-6, suggesting that improving cardiac output and therefore organ perfusion may attenuate the inflammatory cascade.

Other aspects of anesthetic intraoperative care may be able to improve outcome in the high-risk patient. A recent review highlighted the benefits of epidural anesthesia and analgesia, including improvements in the balance of myocardial oxygen supply and demand, leading to a 30% reduction in cardiac morbidity; preservation of pulmonary mechanics, with 40% fewer pneumonias; shorter duration of ileus by 2 days; less blood loss; fewer thromboembolic complications; better preservation of immunity; and an overall reduction in length of hospital stay [24]. As yet no study has shown an improvement in mortality attributable to epidural analgesia.

Other aspects of care, such as maintenance of normothermia and measures to minimize allogeneic blood transfusion (a known immunosuppressant), may improve outcomes in major surgery.

Postoperative Management

All high-risk patients having major surgery should be cared for postoperatively in a critical-care environment. However, differences in the provision of such facilities make this infeasible and risks urgent cancer procedures being canceled. One solution has been the provision of an extended, overnight-stay, postanesthetic care unit with the facilities for HDU-level monitoring and nursing. As discussed, CPX testing provides a rational way of determining who will benefit most from limited resources and reduces the overall use of critical-care beds.

Where such facilities exist, GDT has been extended into the postoperative period. Pearse et al. [25] analyzed 122 high-risk patients admitted to the ITU postoperatively. After randomization, they performed GDT for a duration of 8 hours, guided by lithium indicator dilution and pulse power analysis (LiDCO plus) to measure cardiac output, aiming for a DO_2 of 600 mL $min^{-1}m^{-2}$ using fluid and the inodilator dopexamine when required. They demonstrated a reduction in complications (44% vs 68%—mainly cardiovascular and infections) and median duration of hospital stay (11 days vs 14 days), although there was no significant difference in mortality.

Major surgery may be associated with a prolonged period of starvation, with potentially deleterious consequences. A study of 122 patients having gynecological oncology surgery compared early feeding on day 1 to a conservative regime of nasogastric decompression and feeding only after first passage of flatus [26]. The protocol group had faster return to normal bowel function and a shorter hospital stay, with no increase in complications.

Other aspects of the postoperative care are beneficial, including epidural analgesia, lung expansion techniques, early mobilization, and thromboembolic prophylaxis.

Conclusion

While most gynecological surgery is performed in a population at low risk of morbidity or mortality, it is important to recognize that for a minority, the incidence of serious complications is high. Performed properly and with the aid of recently published guidelines, appropriate assessment is capable of identifying these high-risk patients. Thereafter, a targeted, multidisciplinary approach, with meticulous care before, during, and after surgery, will provide the best possible outcome for the individual patient and maximize limited resources. Clinical governance mandates that our practice adhere to the highest standards, is evidence based, and is subject to regular audit.

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11. Complications in Hysteroscopic Surgery: Prevention and Management

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> *"It takes five years to learn when to operate and twenty years to learn when not to."*
>
> —Anonymous

There is little doubt that minimal-access surgery (MAS) presents many advantages over conventional surgery: smaller scars, reduced postoperative pain, shorter hospital stay, and speedier recovery.

With any operation, there may be associated complications. These may be divided into general risks, for example, anesthesia problems, and risks specific to the way the operation is performed. MAS is no exception; hysteroscopic procedures involve introduction of instruments into the uterus, and distension with media in a fashion not used conventionally. As a result, MAS has a potentially increased risk of iatrogenic complications, particularly during the learning phase of the surgeon. This review focuses on practical and technological advances whereby complications may be decreased during hysteroscopic surgery.

The Scale of the Problem

Different procedures have different complication rates; an overview of the following data is presented in Table 11.1, which gives the complication and emergency hysterectomy rates reported for the MISTLETOE (Minimally Invasive Surgical Techniques—Laser, Endothermal, or Endoresection) Study [1].

Complications related to minimal-access procedures are relatively infrequent. However, there is little room for complacency; rare complications for an individual surgeon can still represent a major problem on an international scale.

The formation of national supervisory bodies, for example, the Royal College of Obstetricians and Gynaecologists (RCOG) Working Party [2] and the American Association of Gynecologic Laparoscopists (AAGL), has provided the impetus for structured training and accreditation.

Table 11.1. Complications Associated with Endometrial Ablation or Resection

Technique	Complication Rates (%)	Emergency Hysterectomy
Resection alone	10.9	13/1000
Rollerball alone	4.5	3/1000
Combined resection/rollerball	7.7	5/1000
Laser	5.5	2/1000

Source: Ref. 1.

General Principles of Safe Hysteroscopic Surgery

General principles of safe hysteroscopic surgery include the following:

- Appropriate case selection
- Patient preparation
- Proper equipment, including optimal exposure and knowledgeable use of electrical sources in electrosurgery
- Awareness of the learning phase

Appropriate Case Selection

Proper case selection is one of the most important factors in reducing complication rates for hysteroscopic surgery.

First, one must accept that not all cases are suitable for hysteroscopic surgery. There are uncertainties as to whether some patients are suitable for MAS, e.g., hysteroscopic surgery for large (>5 cm) type 2 submucous fibroids (Table 11.2). While there may be claims by a few specialists that it is feasible to carry out these procedures hysteroscopically, it is important to appreciate that what may be achieved by a small number of gifted surgeons may not be readily achievable by the average practicing general gynecologist.

Proper case selection is of particular importance in the "learning phase"; as a rule, start with simple cases. For example, when performing hysteroscopic resection of fibroids, start with small type 0 or type 1 submucous fibroids. Once experience and confidence have been gained, more difficult cases may be undertaken. There is good evidence that complications are more likely during hysteroscopic myomectomy and septum resections [3].

Table 11.2. Classification of Submucous Leiomyomas

Type	Location
0	Pedunculated
1	<50% intramural
2	>50% intramural

Patient Preparation

Appropriate patient preparation will make the operation easier and reduce complication rates.

Preoperative Counseling and Accurate Documentation

The most important factor in decreasing litigation is a fully informed patient, particularly if there are known risk factors, for example, adhesions, to performing surgery. Patients may have unrealistic expectations about these new procedures; a leaflet explaining the procedure is a useful adjunct to a full discussion. A plan should be made for a "worst-case scenario," for instance, the need for a laparotomy or hysterectomy in the event of a uterine perforation. When complications do occur, they should be fully documented, and remedial surgery instituted as soon as possible [4].

Endometrial Preparation in Hysteroscopic Surgery

The need for endometrial preparation prior to endometrial ablation is well recognized. However, there is no consensus on endometrial preparation for other hysteroscopic surgery, such as removal of septae or submucous fibroids. The method of preparation varies, being either mechanical (curettage), or pharmacological (gonadotropin-releasing hormone [GnRH], GnRH analogs, and danazol). The Cochrane collaboration [5] found that GnRH analogs are associated with shorter duration of surgery, greater ease of surgery, and higher rate of postoperative amenorrhea at 12 months with hysteroscopic resection or ablation. There also appears to be a beneficial effect on dysmenorrhea. The use of GnRH analogs has no effect on intraoperative complication rates, and patient satisfaction with this surgery is high, irrespective of the use of any preoperative endometrial thinning agent. The longer-term effects of any thinning agents are less certain, but where reported, the effect of endometrial thinning agents on benefits such as postoperative amenorrhea appears to reduce with time [5].

Proper Equipment

It is essential to be properly equipped before embarking on hysteroscopic surgery. The minimum requirements should include a good-quality camera system, light source, and image-recording facilities. However, it is more important that both the surgeon and the theater staff be familiar with whatever the available equipment is and how it operates.

There are general precautions to follow to avoid complications arising from the use of electrical sources in hysteroscopic surgery [6]:

1. Ensure good exposure. Activate the electric energy only when the tip of the instrument is in contact with the target tissue and in the view of the hysteroscope, using the lowest possible power setting.

2. Use bipolar instruments whenever possible; this method does not involve use of a return plate, and only a small amount of tissue is included in the circuit, which means that bipolar instruments can usually only desiccate, and capacitance cannot occur. Monopolar systems require a return plate, and the current flows through the whole body before exiting. Although monopolar instruments are more versatile, capacitance and direct coupling may occur if precautions are not taken [7].
3. Be aware of the warning signs of electricity leak, such as involuntary contraction of the patient's muscles, or "lightning" artifacts on monitors and electronic equipment. A reduction in the expected electrosurgical effect at a given power setting and energy mode may indicate that some of the electrical energy has dissipated away from the tip of the active electrode. Do not keep increasing the power output. Instead, check the application of the neutral plate and the insulation of the active electrode.

The easiest way to avoid direct coupling is to activate energy only when all of the active part of the instrument is visualized, and to ensure that part of it is not in contact with any other instrument. Direct coupling can also occur due to insulation failure, which may be a defect in the instrument's insulation invisible to the naked eye. This can be effectively confirmed only by electrical tests on the instrument, and emphasizes the need for regular inspection by testers to ensure the instrument's integrity.

While the introduction of contact-quality monitoring of the return electrode (Valleylab, Boulder, Colo) effectively eliminated alternate-site burns, the introduction of "active shielding" of the electrosurgical devices in the 1990s (Electroscope, Boulder, Colo) means that devices using this technology are extremely safe. These devices can detect direct coupling and insulation defects, and capture capacitively coupled energy. By elimination, this leaves the surgeon solely responsible for any adverse effects.

The hysteroscopic use of electrosurgery has conventionally had to use a nonionic distension medium for obvious reasons. Glycine 1.5% and sorbitol 3% are commonly used for operative hysteroscopy. Considerable amounts of these non-iso-osmotic substances can be absorbed systemically, with resultant morbidity and mortality (Table 11.3). The use of a bipolar electrosurgical

Table 11.3. AAGL Guidelines for the Management for Iatrogenic Hysteroscopic Fluid Overload

Deficit	Management
0.75 L	Plan for completion of the case, as impending excessive intravasation
1.5 L nonelectrolyte solution	Conclude case, assess electrolytes, consider diuretic administration, and initiate interventions as indicated
2.5 L electrolyte solution	Conclude case, assess electrolytes, consider diuretic administration, and initiate interventions as indicated

Source: Ref. 16.

device (Versapoint, Ethicon, Johnson & Johnson, New Brunswick, NJ), which operates in an ionic saline medium, represents a considerable feat of engineering and a valuable new instrument for hysteroscopic surgery. The instrument's small diameter means that operative procedures may be performed on conscious patients in an outpatient setting.

Awareness of the Learning Phase

It is well recognized that complication rates are higher for cases performed by surgeons during their learning phase. The following recommendations may help to reduce complication rates:

1. One should be competent and experienced in doing the procedure via laparotomy prior to embarking on an endoscopic approach.
2. There are different levels of complexity in hysteroscopic surgery [2]. One should begin with simple procedures and not undertake complex procedures until enough experience has been acquired. The complication rates of advanced hysterscopic surgery are 7 times those of simpler hysteroscopic procedures [3].
3. In some cases, hysteroscopic surgery may be safer with concurrent laparoscopic control, for example, resection of a type 2 submucous fibroid (especially if situated over the cornual region) and removal of uterine septum or dense intrauterine adhesions (Asherman's syndrome). An experienced assistant with a second camera and light source continuously monitors the amount of light transmitted across the uterine wall and keeps the bowel away from the uterus. The amount of light transmitted should be compared with that via the cornual region—and should be no more than the latter. Combined synchronous laparoscopic control should be considered in all difficult hysteroscopic cases and during the learning curve of beginners [8].
4. The RCOG has outlined special skills modules in conjunction with the British Society for Gynaecological Endoscopy. These special skills modules are designed for trainees who have completed their basic training and for established consultants to consolidate their skills. Gynecologists should contact preceptors in their region to discuss undertaking training.

Complications Specific to Hysteroscopy

As with any surgical procedure, there are potential complications due to the mode of access as well as the actual surgical procedure performed. In this section we confine ourselves to the general principles of hysteroscopic surgery with emphasis on the accepted and newer methods of avoiding complications.

Appropriate training in this new field is vital, with staged levels of procedures, progressing only after adequate experience is developed at each stage in training.

The 3 intrinsic complications to any hysteroscopic procedure are dilating the cervix, the use of distension media, and the possibility of uterine perforation.

Dilation and Perforation

Gynecologists are taught to dilate the cervix from their earliest surgical training. However, patients for operative hysteroscopy will often have received GnRH analogs. While these drugs are an important part of preoperative endometrial preparation, they can have a significant stenotic effect on the cervix. In the past, management options included traditional methods of cervical dilation such as laminaria stents (Lamicel, Cabot Medical, Langhorne, Pa) or the more commonly administered pharmacological methods, for example, prostaglandins such as Pg E2 or PgF2α. Increasingly, misoprostol (Searle PLC, Cytotec, Chicago, Il) has been used as a method to prepare the cervix prior to hysteroscopic surgery. A recent metaanalysis has demonstrated that the drug is safe, and effective in reducing cervical trauma and the need for dilation [9].

The management of perforation depends largely on the instrument being used. If a perforation occurs during uterine sounding, a conservative approach can be followed, by stopping the procedure, treatment with antibiotics, and overnight stay. After perforation with a large dilator or an operative hysteroscope, it is usually advisable to perform a laparoscopy to evaluate the extent of trauma. Occasionally it may be necessary to perform a laparotomy, particularly if a perforation by a "hot" instrument has occurred, or even a hysterectomy if bleeding is heavy. The incidence of perforation during operative procedures is experience dependent and is estimated at 1%–2% of major hysteroscopic cases [10].

Distension Media

Gas or liquid distension media are needed as a prerequisite for hysteroscopic surgery, in order to keep the uterine walls separated and obtain a clear view. It is the use of these media that creates complications specific to hysteroscopy.

The use of CO_2 was first described by Rubin in 1925. Its advantages are that it is cheap, easily available in operating theaters, nonflammable, and relatively soluble in blood. It has a similar refractive index to air and allows good-quality images to be obtained. The disadvantages of CO_2 are that it causes bubbling in the presence of excess fluid or any bleeding; this effectively limits

its use to diagnostic hysteroscopy. If intravasation occurs, deaths have been reported due to CO_2 gas embolism. Therefore, flow rates of less than 100 mL/min are fixed (a flow rate of 30–40 mL/min is usually satisfactory).

Liquid distension media include high-viscosity fluids such as dextran 70 (Hyskon), and low-viscosity fluids such as 5% dextrose, 1.5% glycine, 3% sorbitol, and 0.9% saline. Different surgeons have their preferences: In the United States many surgeons prefer Hyskon because of its immiscibility with blood and its high viscosity, which decreases the risk of extravasation. However, the high viscosity makes this medium difficult to work with and necessitates immediate washing of instruments in contact with it. Although extravasation is uncommon, a volume of only 300 mL is sufficient to cause pulmonary edema. This is because dextran 70 is very hydrophilic and in the circulation it osmotically shifts 6 times its own volume of water into the intravascular compartment. The compound also has an effect on blood coagulation, rarely causing a disseminated intravascular coagulation-type consumptive coagulopathy, and has been linked to adult respiratory distress syndrome [11].

Low-viscosity fluids are more commonly used in the United Kingdom; although they are miscible with blood, they are not associated with any coagulopathic or allergic complications. Dextrose 5% is rarely used; it has no advantage over saline and has the side effect of being hypo-osmolar. The solutions mainly used for operative hysteroscopy are 1.5% glycine and 3% sorbitol. Both of these are nonionic and therefore suitable for electrosurgery. Glycine, which was used originally by urologists, is hypo-osmolar, and excess absorption results in a dilutional hyponatemia, which can be further complicated by a subsequent hyperammonemia, which results from glycine's intrahepatic metabolism, causing the TURP syndrome. With all these compounds, vigilance is mandatory, and deaths have been reported. Sorbitol is similar to glycine, being hypo-osmolar (approx. 170 mOsm); it also has metabolic complications, causing hyperglycemia due to its breakdown. Mannitol is a relatively new medium being used [12]. Its advantage is that it is iso-osmolar (approx. 285 mOsm), and it is a natural osmotic diuretic. Little experience of any complications has been documented in the literature to date; however, mannitol will cause a volume overload if large intravasation occurs.

Until recently, operative hysteroscopic surgery was limited to requiring a nonionic medium, as electrosurgery in an ionic environment could not be performed; the current would simply disperse throughout the medium. However, Versapoint can operate in an ionic saline medium (Figures 11.1 and 11.2), which represents a considerable feat of engineering. The instrument has become a valuable device in hysteroscopic surgery; the small-diameter (5 French) means that operative procedures may also be performed on conscious patients in an outpatient setting. Our experience [14] agrees with the very positive initial reports. However, care must still be taken to avoid fluid overload, although the osmotically induced fluid shifts characteristic of other media are minimized.

It is essential that all operating theaters performing hysteroscopic surgery have a system for monitoring fluid deficits during the procedure and a protocol for the management of excessive deficits (Table 11.3) [15,16]. Prevention is better than cure, and there are many devices that attempt to calculate the

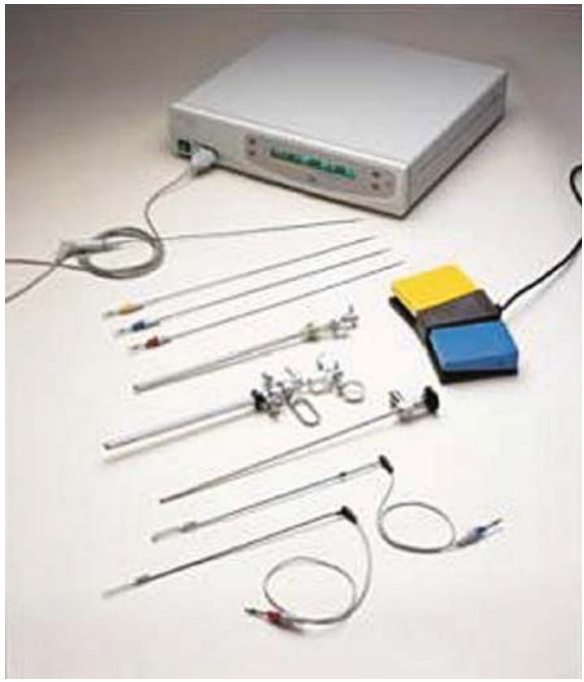

Figure 11.1. Versapoint (Ethicon, Johnson & Johnson, New Brunswick, NJ) "smart" generator, which automatically controls power output to the tissue impedance.

amount of fluid absorbed during the procedure. These range in sophistication from syringes, to calibrated fluid bags hung at a certain height over the level of the uterus (60–100 cm) with a collecting bucket or pouch in the subperineal drapes, to calibrated spring-weight gauges. If any of these simpler devices are used, the fluid balance must be checked every 5 minutes.

A biochemical method used for the assessment of absorbed fluid is the addition of a small (1%–2%) amount of ethanol to the distension media; this measures the systemic fluid absorption by analyzing the alcohol expired by the patient. There is very little literature on this area, being mostly small trials [14], and the potential complications of systemic alcohol in a postoperative patient are cause for concern.

There are a wide variety of pump systems, ranging from simple pumps, where a constant rate of flow of fluid is produced at a given pump rate, to sophisticated pressure-controlled pump systems. Our experience is with the pressure-limited rotary pump system (this avoids the catastrophic complications due to the gas-driven variety), the Hamou Endomat (Karl Storz, Tuttlingen, Germany). Our experience agrees with Hamou's findings [17]

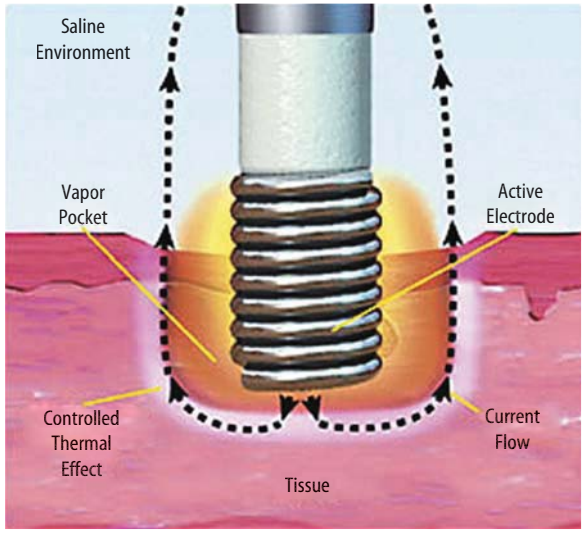

Figure 11.2. Versapoint (Ethicon, Johnson & Johnson, New Brunswick, NJ) bipolar electrosurgery in an ionic environment.

of decreased fluid absorption and decreased morbidity. At present there is no consensus on hysteroscopic monitoring; however, in France, government legislation forbids hysteroscopic surgery unless a pump system is being used.

Bleeding

The prevalence of hemorrhage depends on the form of energy used for ablation. With loop and rollerball or loop alone, the incidence of hemorrhage is 2.57% and 3.53%, respectively, whereas with laser or rollerball it is 1.17% and 0.97%, respectively [1]. The new "second-generation" endometrial ablation devices usually have no risk of causing uterine bleeding as a result of their endometrial destructive rather than resective designs.

Intrauterine bleeding occurring during the procedure should be immediately obvious and can usually be controlled by spot electrocoagulation. If coagulation fails to control the bleeding, the procedure may have to be abandoned and tamponade performed by inserting a Foley catheter and distending the balloon. The catheter should be left in situ for a few hours, after which the bleeding nearly always stops.

Occasionally these simple measures fail to control hemorrhage. This may occur if resection has been carried out too deep into the myometrium and a plexus of vessels opened. In this case hysterectomy, ligation, or ultrasound-guided embolization of the anterior branches of the internal iliac arteries may be necessary.

Less significant bleeding may be caused by tearing the cervix with the tenaculum. This can usually be managed by direct pressure (a sponge-holding forceps is useful), or occasionally a suture will be required. Lateral tears of the cervix may produce significant bleeding and may also lead to excessive absorption of the distension medium.

Adhesion Formation

Intrauterine adhesions are particularly common after myomectomies when 2 fibroids are situated on opposing uterine walls. In these cases the myomectomy is best performed in stages to prevent adhesion formation. The insertion of a copper intrauterine device and administration of estrogen minimize adhesion formation following resection, adhesiolysis, or division of a septum.

Conclusion

This chapter is an evaluation of the different methods used to decrease the risk of complications in hysteroscopic surgery. We have focused on the prevention of those complications that are related to the basic principles of hysteroscopic surgery, rather than providing a discourse on specific operative complications.

Despite the tremendous advances in this area of gynecological surgery, and the appropriate emphasis on training, accreditation, and critical appraisal of new techniques, there is a surprising lack of consensus on even the most basic techniques. Due to lack of quality research to determine the safest approaches, we have been unable to give any didactic opinions; instead, we offer a critical account of current practices, and look forward to the time when we can give more definitive answers. Minimal access surgery has now proved its superiority over conventional open surgery in a range of operations; it is now time to firmly establish the acceptable and safest methods for performing these operations, particularly in the field of endometrial ablation.

We have attempted to give as comprehensive an overview of the equipment currently available as possible. There have been exciting developments in this area, notably in improving the safety aspects of these potentially dangerous devices. Good-quality trials to confirm clinically the theoretical advantages these instruments possess are awaited.

Key Points for Clinical Practice

General

- Appropriate case selection is vital.
- Physical and psychological patient preparation are equally important.
- Confidence in surgery depends on appropriate training and the use of quality equipment with which the surgeon and theater staff are familiar.

Hysteroscopic Surgery

- Beware the difficult cervical dilation; in our experience, the degree of force required is proportional to the complication rate.
- Visualizing the endometrial cavity before and after "blind" endometrial ablation techniques is recommended.
- Select the distension media to suit the procedure and the patient; always monitor flow rates and fluid balance.
- If the uterine cavity collapses, this is uterine perforation until proven otherwise. Have a low threshold for investigating iatrogenic trauma if this occurs in operative procedures.

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12. Minimizing the Risk of Sterilization Failure: An Evidence-Based Approach

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Female sterilization is one of the commonest procedures performed worldwide. In 1999 around 50,000 female sterilizations were performed in England in the National Health Service (NHS) and charitable sectors [1]. The procedure is performed on mainly healthy women at their request, and the intention is to occlude each fallopian tube. This may be achieved through tubal surgical excision, application of a mechanical device, or electrocautery coagulation (Table 12.1). Where resources permit, the preferred and most widely established technique is laparoscopic tubal occlusion, which has, moreover, replaced the earlier technique of performing female sterilization via minilaparotomy. In the United Kingdom, the Royal College of Obstetricians and Gynaecologists (RCOG) recommends that laparoscopic sterilization be performed using either Filshie clip or ring [1]. Tubal excision and separation and related techniques (e.g., Pomeroy procedure) are preferred if sterilization is performed at cesarean delivery.

Hysteroscopic sterilization may be considered a nonincisional, nonsurgical form of permanent contraception and is a promising alternative to laparoscopic tubal occlusion. The procedure involves the insertion of a small, flexible titanium microinsert into each of the fallopian tubes through the cervix using a guidewire and a hysteroscope (Essure, Conceptus Inc., Mountain View, Calif). The procedure is usually performed under local anesthesia and/or intravenous sedation. Although hysteroscopic sterilization is licensed in the United Kingdom, the National Institute for Clinical Excellence (NICE) considers it to still be under evaluation and has stated that it should be performed only in accordance with specific NICE guidance, particularly on patient consent and coordinated follow-up [2]. This is mainly because there is insufficient evidence on long-term efficacy (single case report of failure [3] and tubal perforation [4]) and safety of hysteroscopic sterilization, with the manufacturer reporting 99.8% effectiveness at preventing pregnancy at 2-year follow-up (http://www.essure.co.uk) [5–7]. Furthermore, there are no published randomized controlled trials comparing Essure directly with commonly used female tubal occlusion methods [8].

Table 12.1. Female Surgical Sterilization Techniques

Method	Techniques	Comments
Ligating tube with partial or complete tubal excision	Pomeroy Fimbriectomy Salpingectomy	Preferred option at minilaparotomy, but laparoscopic salpingectomy is an alternative
Mechanical occlusion of the tubal lumen	Filshie clip Hulka-Clemens clip Falope ring Silastic ring	Less of the tube is damaged, increasing the chance of reversibility
Coagulation-induced tubal closure	Unipolar diathermy Bipolar diathermy	Not recommended as the first-line method in the United Kingdom by the RCOG
Hysteroscopic tubal occlusion	Expanding metal tubal micro-insert implant (Essure)	Licensed in the United Kingdom and under evaluation Guidance for usage in accordance with NICE Virtually no possibility of reversal Contraceptive precautions to continue for at least 3 months postprocedure and x-ray HSG confirmation of tubal occlusion

Rates of Sterilization Failure

Conception that occurs after sterilization is termed sterilization failure and can happen several years after the procedure. Publications have reported differences in sterilization failure rates, even with the same sterilization method. Such variation is due to differences in the characteristics of the women undergoing sterilization; operator experience; operating center workload; sterilization method chosen; and time interval to resuming sexual activity, and its frequency, poststerilization [9].

The two largest studies that have examined failed sterilization have reported the 10-year cumulative probability of pregnancy to be 18.5 per 1000 procedures (US CREST study) [10] and 8 per 1000 procedures (Canada) [11]. The reason for the lower sterilization failure rate in the Canadian study compared to the US CREST study may be predominant use of the Filshie clip and incorporation of nonteaching hospitals in the Canadian data set. However, both studies were also significant in the following aspects:

1. Utilizing the superior and preferred life-table analysis method (cumulative probability of pregnancy at serial time intervals since sterilization) for reporting sterilization failure, rather than the less accurate crude failure or Pearl index outcomes that were reported by previous studies.

2. Obtaining follow-up data for at least 5 to 15 years following the sterilization

This concept of cumulative risk of pregnancy is particularly important for those women sterilized at a young age (who will be exposed to a risk of pregnancy for a greater time period) and for those who have been sterilized by methods of low short- and long-term efficacy (because such methods, over certain time frames, will acquire a greater percentage of total failures than other more effective methods).

Both US and Canadian data-set studies [10,11] validated this concept of cumulative risk of pregnancy. In the Canadian data set, the cumulative probability of pregnancy increased from 0.3% at 1 year to 0.7% by 5 years and 0.9% by 15 years [11]. This progression is depicted in Figure 12.1. It is therefore important to quote women a 10-year risk of sterilization failure, individualized to each method and patient age, when counseling them for the sterilization procedure, bearing in mind that as long as a woman is fertile and sexually active, she may continue to be at risk for sterilization failure.The RCOG has recommended a 10-year sterilization failure rate of 2–3 per 1000 procedures be used for the Filshie clip method. However, this rate is drawn predominantly from a retrospective questionnaire study, of 5-year follow-up, with an exaggerated denominator [12]. Given this information, and considering the other reported Filshie clip studies (Table 12.2), 2–3 per 1000 risk is more likely to correspond to the first year or even annual noncumulated absolute risk of sterilization failure.

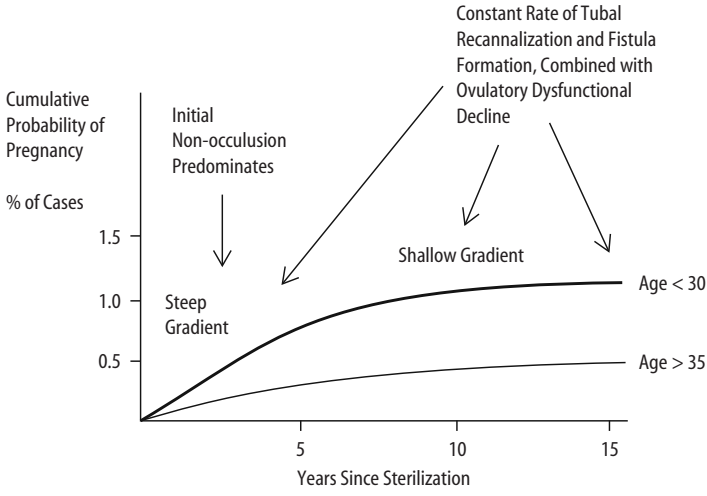

Figure 12.1. Clinicopathological mechanisms proposed in sterilization failure based on Canadian data set [11].

Table 12.2. Filshie Clip: Reported Sterilization Failure Rates

Study	Period Data Is Collected From	Sterilizations Performed	Sterilization Method	Outcome	Type of Study
Peterson, US Collaborative Review of Sterilization (CREST) [10]	1978–1986	10,685; Filshie clip was not used, as it was not licensed in the United States until 1996 [14]	Various methods Hulka spring clip (1595) Silicone rubber band (3329)	Overall, 18.5 per 1000 over 10 years Hulka, 36.5 per 1000 Silicone rubber band, 17.7 per 1000	Prospective cohort multicenter
Trussell [11]	1980–1999	311,960	Mainly laparoscopic Filshie clip	8 per 1000 (2496 failures)	Retrospective multicenter
Kovacs [12]	1994–1998	30,000 (estimate)	All Filshie	2.4 per 1000 (73 failures)*	Retrospective multicenter
Filshie [46]	1982–1992	First 202 responders from a series of 434	All Filshie	2.3 per 1000 (1 failure at 6 months)	Case series
Birdsall [37]	1988–1989	1094	Mainly laparoscopic Filshie clip	12 per 1000 at 12 months†	Case series
Sokal [45]	1984–1990	2746	Filshie clips vs rings (2 in each group became pregnant)	1.7 per 1000 for both ring and Filshie clip groups at 12 months	Randomized controlled
Dominik [44]	1984–1990	2126	Filshie clips vs Hulka clips (11 pregnancies occurred: 9 Hulka, 2 Filshie)	At 12 months: 1.1 per 1000 for Filshie clip; 6.9 per 1000 for Hulka clip At 24 months: 9.7 per 1000 for Filshie clip; 28.1 per 1000 for Hulka clip	Randomized controlled trial

* Of the 73 failures noted in the Kovacs study, 14 cases were due to operator error, 29 were properly applied clips, and 30 cases had unknown reason for failure.

† In the Birdsall study, registrars had a 1.3% failure rate and consultants had a 1.9% failure rate, and when both a consultant and registrar performed the procedure, the failure rate was 0.7%. Eighty-six percent (6/7) of failed sterilizations were due to operator error (wrong structure, initial nonocclusion).

Key Factors (Excluding Operator Error) Identified to Alter Cumulative Probability of Pregnancy

The failure rate for each sterilization method tends to stabilize over the long term (Figure 12.2) and may thus be represented as a constant lifetime risk of sterilization failure (1 in 200 is quoted for the Filshie clip [1]). However, a more precise estimate would also be based on the patient's age at sterilization and the subsequent number of fertile years during which the patient is at risk of pregnancy. The Canadian data set showed that sterilization of young women (<30 years of age) compared to older women (>35 years of age) was associated with an overall increased absolute risk of pregnancy after sterilization (1.5% vs 0.4%), and that this cumulative risk stabilized later in the younger age-group [11]. This statistic is depicted in Figure 12.1.

Multivariate regression analysis of the CREST study [10] showed that the following factors were associated with an increased risk of sterilization failure:

1. Sterilization method used (see Figure 12.2). Most effective were postpartum partial salpingectomy and laparoscopic unipolar coagulation at 7.5 pregnancies per 1000 procedures, but laparoscopic spring-clip application had the highest risk of failure at 36.5 pregnancies per 1000 procedures (Table 12.2).
2. Age at sterilization. The probability of failure for women sterilized at ages <28 years is greater than that for women sterilized at ages >34 years for all methods of sterilization except interval partial salpingectomy.
3. Race or ethnicity. Black non-Hispanic women were at significantly greater risk for sterilization failure than were white non-Hispanic women.
4. Study site. Substantial differences in procedure-specific failure rates between sites were observed, likely representing variation in operator experience, requirements to teach juniors, and volume of sterilization operations.

Notably, the US CREST study showed no statistically significant associations between risk of sterilization failure and history of pelvic inflammatory disease, history of previous abdominal or pelvic surgery, or presence of any adhesions recorded at sterilization, although these factors have been assumed empirically by practitioners to affect the risk of sterilization failure.

Sterilization Failure and Subsequent Intrauterine or Ectopic Pregnancy

Overall, for all sterilization methods, studies have shown that ectopic pregnancy may occur in 4.3%–76.0% of failed sterilizations [1]. The relative risk of intrauterine to ectopic pregnancy occurrence in failed sterilization varies

Years Since Sterilization	Cumulative Risk of Pregnancy per 1000 Sterilization Procedures					
	Bipolar	Unipolar	Silicone Band	Hulka Clip	Postpartum salpingectomy	Filshie Clip (Estimate Only)
1	2.3	0.7	5.9	18.2	0.6	2.5
2	4.6	2.3	7.6	23.8	3.9	2.5
3	6.7	2.3	8.3	29.1	4.6	2.5
4	13.1	2.3	9	30.7	5.4	2.5
5	16.5	2.3	10	31.7	6.3	2.5
6	18.3	2.3	10	31.7	6.3	2.5
7	20.7	2.3	13	31.7	6.3	2.5
8	22	2.3	16.1	31.7	6.3	2.5
9	23.3	4	16.1	34	7.5	2.5
10	24.8	7.5	17.7	36.5	7.5	2.5

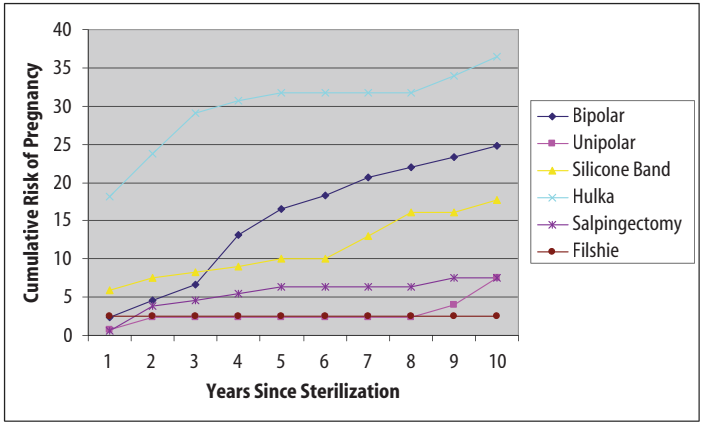

Figure 12.2. Cumulative risk of pregnancy by method extracted from US CREST study [10] and Filshie clip studies [12,14] depicted in table and graphically.

according to the sterilization method and time interval from the sterilization procedure. Women who have been sterilized have a considerably lower absolute risk of an ectopic pregnancy compared to nonsterilized fertile women (as sterilization protects against both intrauterine and ectopic pregnancies); however, should pregnancy occur, the relative risk of it being ectopic rather than intrauterine is higher in pregnant women who have been sterilized. Women should be counseled about such risks when deciding the method of sterilization.

There were 47 ectopic pregnancies in the 10,685 sterilized women in the US CREST study, which equates to a 10-year cumulative probability of ectopic pregnancy for all sterilization methods combined of 7.3 per 1000 procedures [13]. Women sterilized by bipolar tubal coagulation before the age of 30 years had a probability of ectopic pregnancy that was 27 times as high as that among women of similar age who underwent postpartum partial salpingectomy (31.9 vs 1.2 ectopic pregnancies per 1000 procedures) [13].

Classification of Causes of Sterilization Failures: The Role of Operator Error (Negligent Mechanism)

The mechanism of sterilization failure should be identified through a systematic assessment of fallopian tube histology, x-ray hysterosalpingography, and direct pelvic visual inspection. Neither of the major observational studies on sterilization failure reported on the underlying mechanism of sterilization failure [10,11]. Our systematic review identified only 81 cases in the world literature where the mechanism of sterilization failure had been confirmed by such systematic methodology [9].

Sterilization failure may be classified as arising from negligent or nonnegligent mechanisms, which may be dependent or independent of the sterilization method utilized (Table 12.3). If the mechanism of failure is due to tubal nonocclusion or wrong-structure sterilization, these are considered negligent mechanisms, whereas spontaneous tubal recanalization or fistula formation mechanisms of failure are considered nonnegligent.

Several studies have shown operator error to represent a significant (if not the major) cause of sterilization failure. One summative review showed that the overall 10-year failure rate for worldwide Filshie clip sterilizations was 0.56% in 10,000 women but fell significantly to 0.2% when cases caused by operator error were excluded [14]. A questionnaire-based study examining Filshie clip use in Australia showed that of the 73 sterilization failures from 30,000 procedures, 14 were due to operator error, 30 were due to unknown reasons, and 29 occurred in the presence of a "properly applied clip" [12]. Another study, which incorporated participants of the US CREST study, reported that all 20 sterilization failures using spring clip and silicone rubber band arose from improper application of the occlusive devices [15,16]. Of the 81 sterilization failures reported in our systematic review of published literature [9], 57 cases were due to operator error (wrong structure "sterilized" and initial tubal nonocclusion), and 24 were not due to operator error (fistula formation or recanalization). We have recently submitted an analysis of 131 cases of sterilization failure, incorporating our systematic review, where 88 were negligent and 43 were nonnegligent sterilization failures [17].

Mechanical tubal occlusive methods have lower rates of tuboperitoneal fistula formation than coagulation-based techniques [17–20]. This may be because mechanical occlusion methods destroy much less tube (approximately

Table 12.3. Classification System for Mechanism of Sterilization Failure

Dependent on the Sterilization Method

Negligent

- Initial tubal nonocclusion (poor operator technique), e.g., slippage or overclosure of Filshie clip
- Wrong structure "sterilized"
- Improperly maintained equipment (e.g., noncalibrated or nonserviced Filshie clip applicator), which contributed to initial tubal nonocclusion.

Nonnegligent

- Initial tubal nonocclusion (true method failure), reported extremely rarely and occurring despite correctly applied technique
- The ends of the fallopian tube reconnecting spontaneously (recanalization)
- Fistula developing at the occluded portion of the tube

Independent of the Sterilization Method*

Occurs when

- The woman has already conceived in the cycle prior to sterilization
- In the case of Filshie clip, the woman conceives following sterilization in the remainder of the menstrual cycle because the ovulatory ovum is proximal to the tubal sterilization point (luteal-phase pregnancy)
- In the case of hysteroscopic sterilization, the woman conceives within the 3-month interval poststerilization and/or prior to confirmation of effective sterilization by HSG or ultrasound

*Most studies on sterilization failure have excluded such pregnancies from their reported final analysis.

4 mm for clips and 2 cm for rings) than electrocoagulation methods (3–4 cm). However, the exact etiology of tubal lumen regeneration remains unclear. Other factors such as an individual's tubal "healing" response, preexisting proliferative tubal disease (e.g., endosalpingiosis), degree of tubal avascularity, and interval from operation are likely to modify tubal lumen regeneration ability [18,21–25]. Presently there is no evidence to suggest that operator fault in sterilization technique predisposes to tubal lumen regeneration, and therefore this mechanism of sterilization failure would be considered to be nonnegligent and independent of operator error.

Medicolegal Consequences

The psychological and physical morbidity following failed sterilization often leads to litigation [26]. A gynecologist has a duty to inform women of the risk of failure, to carry out the operation in accordance with accepted good medical practice, and to avoid foreseeable complications. Women who have undergone sterilization performed negligently are entitled to recover damages according to:

- Wrongful conception. In addition, an action in contract may also arise if the sterilization procedure was performed outside the NHS in the private sector.
- Negligence. A breach of duty arises when an operation is not carried out in accordance with practice accepted as proper by a reasonable body of gynecologists (Bolam test). Negligence also occurs when there is omission in appropriate preoperative counseling.
- Wrongful birth. The negligent act deprived the mother of the possibility to prevent the conception of a disabled child or to have a lawful abortion.

Women are entitled to recover general damages for pain and suffering during pregnancy and delivery, and loss of earnings during pregnancy. A recent judgment in the Australian High Court led the Australian government to amend the Civil Liberty Act to restrict the amount of damages that could be awarded in such situations [27].

In the majority of failed sterilization cases, even those in the advanced stages of litigation, the mechanism of failure remains unknown, as there is no uniform requirement for such cases to undergo systematic inquiry or to be reported to any supervisory national registry. The RCOG should consider this requirement at the time of the sterilization guideline review in 2007 [1]. Thus, a common scenario in the legal setting is to cast judgment on the likelihood of negligence or nonnegligence in cases with unknown mechanism of sterilization failure. Based on pooling the 81 cases of sterilization failure with documented interval to pregnancy and mechanism of failure, we proposed:

1. That a greater proportion of early (within 12 months from operation) than late (after 12 months from operation) sterilization failures occurred by a negligent mechanism. Thus, the time interval to sterilization failure may be predictive of negligence. Our analysis of 131 cases of sterilization failure (in press publication) showed that sterilization failure occurred significantly earlier in negligent than in nonnegligent failure mechanisms (mean failure intervals, 7.5 vs 14.2 months; hazard ratio 2.35 [95% confidence interval (CI) 1.31–4.21]) [17].
2. Initial tubal nonocclusion is more likely to lead to early sterilization failure (within 1 year), and as it is less likely to damage the tube, the resulting pregnancy is more likely to be intrauterine than ectopic. Conversely, late sterilization failure arising from tubal recanalization or fistula formation is more likely to result in an abnormal lumen, predisposing to a decreased risk of pregnancy, but should pregnancy occur, there would be an increased risk of ectopic pregnancy. This point is graphically illustrated in Figure 12.1.

Identification and Assessment of Evidence

MEDLINE (1966–2006), the Cochrane library (2006), and the RCOG were searched for relevant randomized controlled trials, systematic reviews, metaanalyses, and evidence-based guidelines relating to sterilization. The

Table 12.4. Levels of Evidence Used in This Chapter

A	Requires at least 1 randomized controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)
B	Requires the availability of well-controlled clinical studies but no randomized clinical trials on the topic of recommendations (evidence levels IIa, IIb, III)
C	Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities; indicates an absence of directly applicable clinical studies of good quality (evidence level IV)
Good practice point (GPP)	Recommended best practice based on the clinical experience of the guideline development group (equivalent to authors of this chapter)

searches were performed using the relevant medical subject heading (MeSH) terms, including "sterilization, tubal"; "sterilization"; "sterilization sexual"; "surgical instruments"; "electrocautery"; "cautery"; "liability, legal"; "jurisprudence"; "malpractice"; "medical errors"; "treatment failure"; and "risk factors". The majority of publications were retrospective observational studies, case reports, and reviews, with a paucity of prospective controlled trials or metaanalyses [1,9,28]. The definitions of the types of evidence used in this chapter are as denoted in the RCOG clinical governance advice [29]. Where possible, recommendations on strategies to minimize sterilization failure are annotated with the level of evidence that supports them (A, B, C, or GPP [good practice point]), as indicated in Table 12.4.

Minimizing the Risks of Sterilization Failure

Patient Selection (Level GPP)

There is limited evidence that preexisting gynecological pathology, in addition to increasing the technical difficulty of performing the sterilization procedure, independently predisposes to sterilization failure. Factors include preexisting tubal disease, history of abdominal or pelvic surgery, history of pelvic inflammatory disease, previous ectopic pregnancy, pregnancy or postpartum state, obesity, prior use of an intrauterine contraceptive device, previous induced abortion, congenital uterine anomalies, fibroids, endometriosis, endosalpingoblastosis and adenomyosis [10,11,19,30–34]. The myth that sterilization protects against pelvic inflammatory disease has recently been challenged [35].

Prepregnancy Testing and Timing of Procedure in Relation to Menstrual Cycle (Level C)

Both hysteroscopic and laparoscopic tubal occlusion may be performed at any time during the menstrual cycle provided that the clinician is certain that the woman has used effective contraception up until the day of the operation.

It is recommended practice that all women have a urine pregnancy test prior to sterilization. Routine preoperative same-day urine pregnancy testing should be done as this has been shown to reduce the incidence of pre- and post-procedure pregnancies, the latter group termed luteal-phase pregnancies (see Table 12.3 and section below) [36]. However, such a test may still be falsely negative in a very early pregnancy. A serum human chorionic gonadotropin (hCG) preoperatively may be considered; however, if there is any doubt, then the sterilization should be deferred until the follicular phase of a subsequent cycle.

Preprocedure Contraception and the Need to Continue Until Onset of Next Menstrual Cycle (to Reduce Risk of Luteal-phase Pregnancy) (Level GPP)

Contraception is immediately effective if the patient is using the combined pill (if commenced between day 1 and day 5 of period) and the Mirena intrauterine system. However, with laparoscopic tubal occlusion, contraception is likely to be completely effective only by the onset of the next menses. Therefore, for this method, preprocedure contraception measures should be continued until the onset of next menses to prevent luteal-phase pregnancy failure (Table 12.3). This is where sterilization has occurred just after ovulation, and the ovum is already proximal to the tubal occlusion, enabling pregnancy to occur in this luteal phase through poststerilization "unprotected" intercourse. Studies have identified the occurrence of luteal pregnancy in 0.32% to 0.6% of sterilization cases [10,36–38].

Women selecting hysteroscopic sterilization (Essure) need to continue with contraceptive precautions for at least 3 months postprocedure and may resume "unprotected" sexual intercourse only after there is confirmation of satisfactory tubal occlusion (e.g., by x-ray hysterosalpingogram).

Timing the Operation: Interval Preferred (Level B)

Wherever possible, tubal occlusion should be performed at an appropriate interval following pregnancy. Sterilization can be performed in the postpartum period (combined with cesarean section or via minilaparotomy) or

postabortion. However, this period is associated with higher rates of failure and regret by the woman [38,39], and these factors should be incorporated into the counseling and documentation prior to the procedure. In terms of postpartum sterilization, salpingectomy and Filshie clip have similar rates of failure (7.5 and 8.8 per 1000, respectively) [10,38].

Selection of Technique: Laparoscopy Preferred over Laparotomy (Level B)

Each combination of sterilization method and patient characteristics has specific advantages, disadvantages, and individualized failure rates. This information should be conveyed during the counseling process. A metaanalysis [40] and large population study [41] have shown no significant difference in failure rate or major operative morbidity between minilaparotomy and laparoscopy methods of sterilization. However, laparoscopic methods have lower minor operative morbidity and are preferred for interval sterilizations, as they offer obvious advantages in terms of shorter operative time, same-day hospital discharge, and shorter convalescence period. Ultimately, as hysteroscopic sterilization becomes more widespread and established worldwide we envisage this will eventually become the preferred sterilization method of choice in the next 2 to 5 years.

Selection of Technique: Modified Pomeroy at Cesarean Section (Level B)

A modified Pomeroy procedure rather than Filshie clip application may be preferable for postpartum sterilization performed by minilaparotomy or at the time of cesarean section, as this leads to lower failure rates [10,38,42], although both procedures are equally popular choices with surgeons [43].

Selection of Technique: Filshie Clip Sterilization Is Preferred Method (Level B)

Two small randomized controlled trials [44,45] and observational studies [12,46] have shown the Filshie clip to have the lowest failure rate for interval sterilization failure, and it has therefore been recommended by the RCOG [1] as the preferred method at laparoscopic tubal occlusion (Table 12.2). Ring methods have also been recommended by the RCOG and appear to have contraceptive efficacy equal to that of the Filshie clip. However, ring methods tend to be technically more difficult to apply to the fallopian tubes and have gradually become less popular in UK clinical practice.

Operative Technique for Filshie Clip (Levels C and GPP)

Identify Correct Isthmic Portion of Tube

Care should be taken to ensure that the Filshie clip is applied to the optimal midisthmic tubal site (1 cm to 3 cm from the uterine cornu) and that this structure not be mistaken for "sterilization" of an adjacent structure, such as the round ligament or a fold of peritoneum between the round ligament and tube [47].

Correctly Align Clip and Ensure Clip and Tube are Flattened

The Filshie clip should be applied in a manner to: completely encapsulate the tube and lumen, be fully locked with the upper jaw compressed, be completely flattened, and have its end adequately secured under the latch, (which "locks" the clip jaw, see Figure 12.3). The clip should flatten the whole tube portion within the clip without leaving any unflattened tubal "knuckles" and without transecting the tube. Finally, the clip should sit perpendicular to the long axis of the tube [47], facilitated by stretching the isthmic portion with the hinge placed on the antimesenteric aspect of the tube.

Avoid Clip Overclosure (Technique and Using Serviced Clip Applicator)

Excessive forceful clip applicator overclosure (Figure 12.3) or underclosure may lead to tubal transection and subsequent sterilization failure through luminal regeneration (i.e., tubal fistula or recanalization) or incomplete tubal occlusion [47].

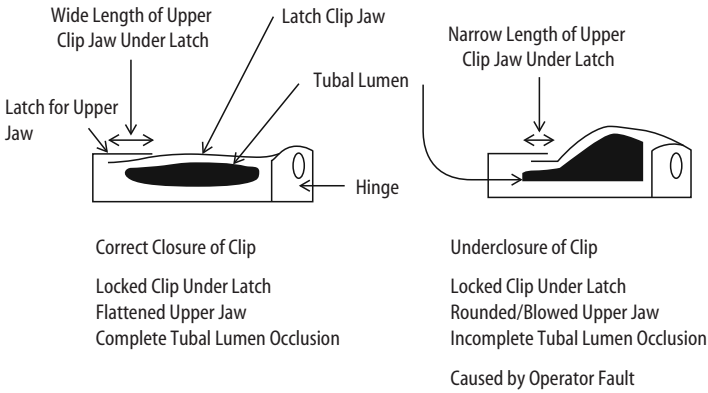

Figure 12.3. Filshie clip under-closure due to operator fault. Despite the clip appearing locked, on closer inspection the upper jaw of the clip will be noted to be incompletely compressed, rounded rather than flattened, and the end insufficiently secured under the under the latch for the upper jaw. Most causes of clip underclosure are due to operator fault.

A predisposing factor to improper closure is a "faulty" Filshie clip applicator. This is rare, however, as it is a legal requirement that device applicators be well maintained and adequately checked to ensure optimum function. In the case of the Filshie clip, both the manufacturer (Femcare, UK, www.femcare.co.uk) and the Medical Devices Agency (MDA) strongly recommend that all single Filshie clip applicators be serviced and readjusted at least once a year or after every 100 procedures. Furthermore, a closing checking gauge should be used prior to every sterilization procedure to ensure that the applicator functions correctly. There is only 1 published case of failed sterilization, which proposes Filshie clip underclosure as the most likely mechanism of sterilization failure. Therefore, this cause of failure should be considered rare [48].

Apply Only 1 Clip to Each Tube

Applying 2 mechanical clips adjacent to each other on the tube does not decrease the failure rate but may even increase it if they are applied too closely together [47,49–51].

Do Not Fail to Systematically Check Position of Clip on Tube (Take Image)

Following clip application, there should be a systematic checking procedure to ensure that the correct structure and both sides of the tube have been satisfactorily occluded, and this procedure should be documented. Although this process is not a legal requirement in the United Kingdom, we recommend:

- Taking clinical photographs or operative videos of the sterilized structures, identifying them as fallopian tubes. However, photographs may be unhelpful in confidently excluding other negligent causes of incomplete tubal occlusion, e.g., protruding knuckle of tube, inadequate locking of clip jaws, clip underclosure, or tubal transection (partial or complete).
- The presence of a second operating surgeon for counterchecking. A recent study involving 1094 sterilizations from 1988 to 1989 showed that registrars had a 1.3% failure rate, consultants had a 1.9% failure rate, and consultants and registrars performing the procedure together had a 0.7% failure rate [37]. A medical witness to confirm the sterilization procedure is a legal requirement in some countries [52].

Recognize That True Method Failure Is Extremely Rare

There is evidence that anatomical tubal patency can occur following a correctly undertaken sterilization (true method failure); this occurrence has been reported following correctly applied Filshie clips in 3 cases of Filshie clip failure (Table 12.2) [53] and is implied to have occurred in the 29 of 73 correctly applied clip sterilization failures reported by an observational study

[12]. However, persisting anatomical tubal patency does not necessarily imply sterilization failure, as tubal patency rates of 1%–2% at 3 months and 16% at 5 years have been noted following correctly applied tubal ligation, with the actual pregnancy occurrence of 1%–2% over this time period [22]. Even so, true method failure is rare and difficult to prove; nonetheless, three possible mechanisms of true method failure are suggested:

1. A partially nonoccluded segment of tubal lumen has formed within the clip. This tubal "knuckle," with a patent lumen, can exist within the completely flattened tube portion inside the clip, identifiable only at microscopy.
2. Preexisting uterotubal structural abnormalities. These abnormalities include accessory fallopian tube, uterine didelphys [54], and uterotubal fistulas.
3. Mechanical failure of the Filshie clip. Manufacturers for the Filshie clip have not reported spontaneous mechanical failure as a possibility for sterilization failure, and this concurs with an absence of such cases in the published literature. Nevertheless, there remains at least a theoretical possibility of mechanical material failure, and manufacturers such as Femcare offer an examination of the Filshie clips in failed sterilization to exclude the possibility of this failure mechanism (Dr Marcus Filshie, Chief Executive, Femcare UK, personal communication, June 2007).

Operator Experience and Training (Levels C and GPP)

Improper application of tubal occlusive devices by inexperienced surgeons is frequently reported in cases of sterilization failure [16,55,56].

The CREST study showed failure rates of 7.1 to 78.0 per 1000 for the Hulka clip and 0 to 42.5 per 1000 for the silicone ring—all dependent on the operating centers surveyed [10]. Higher failure rates were more common in centers performing fewer annual procedures. The RCOG has recommended that trainees perform at least 25 supervised laparoscopic tubal occlusions before operating without supervision [1].

Follow-up Required If Uncertainty in Tubal Occlusion (Level GPP)

Following a complicated sterilization, good clinical practice (rather than a legal requirement) dictates testing of tubal patency [16,57–60]. However, a

negative dye spill poststerilization hysterosalpingogram (HSG) does not completely preclude the possibility of pregnancy at a later stage [61].

Other Issues: Clip Migration and Dropped "Lost" Filshie Clips (Level C)

Good clinical practice dictates that proof of tubal occlusion (x-ray HSG, tubal dye insufflation, or histology of salpingectomy) should be undertaken once missing clips are identified, not only when examining failed sterilization cases, but also at laparoscopy or laparotomy for other reasons [47,62]. However, missing clips do not necessarily indicate failed application or imminent pregnancy failure, as over time there is a tendency for clips to migrate and even be expelled without resulting in clinical morbidity [12,45,63–71]. There are no reports of clip migration leading to sterilization failures [63]. It is estimated that more than 25% of women will experience a migration of 1 or more Filshie clips [63]. The tissue between the Filshie clip jaws normally undergoes avascular necrosis and fibrosis, leaving two healed stumps, which tend to separate, permitting clip displacement.

Filshie clips may be inadvertently dropped during laparoscopic sterilization. If possible, the clip should be laparoscopically removed upon completion of the sterilization procedure. However, if the clip is irretrievable, either open or closed, it should be left. Performing a laparotomy would subject the woman to greater operative morbidity risk than leaving the lost clip in the abdomen. To date, there have been no reports of any serious morbidity or mortality consequent to a lost clip. Women should be informed of the lost clip and reassured accordingly [47].

Conclusion and Further Research

Overall, the level of evidence supporting any screening or preventative measures to reduce the risk of sterilization failure remains poor. There appears to be a propensity for negligent rather than nonnegligent sterilization failures. However, this can be verified only by establishment of a national register of failed sterilizations (as recommended by the RCOG [1]) that have been subjected to systematic inquiry to establish the mechanism of failure. Like other confidential inquiries, such a registry could identify areas of substandard care that could be used as an impetus to improve research and medical training in sterilization procedures and help design effective clinical risk-prevention strategies. The introduction of an operative checklist or proforma, similar to the preoperative counseling checklist recommended by the RCOG [1] and used in another study [72], may result in reduced numbers of negligently performed sterilizations.

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13 Complications of Assisted Reproduction

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The practice of assisted reproduction has evolved significantly since the birth of Louise Brown, the world's first baby born as a result of in vitro fertilization (IVF), in 1978. Since then, more than 1 million babies have been born as a result of assisted reproduction around the world. The changes in practice are many; among them: daily blood tests and abdominal ultrasound have been replaced by infrequent transvaginal scans; laparoscopic oocyte retrieval under general anesthetic has been replaced by transvaginal ultrasound–controlled oocyte collection with sedation analgesia. In addition, advances include elective transfer of 1 to 2 embryos and introduction of new laboratory techniques such as intracystoplasmic sperm injection (ICSI), in vitro maturation (IVM), preimplantation genetic diagnosis, and new techniques in cryopreservation. While these changes have led to an increase in pregnancy rates, they have also been accompanied by well-known complications such as multiple pregnancies, ovarian hyperstimulation syndrome, and possible adverse neonatal outcome. Other complications associated with assisted reproduction may arise during different phases of treatment, from ovarian stimulation, from surgical procedures such as oocyte and sperm retrieval, and from embryo transfer, and may affect long-term outcome among the offspring. This chapter does not include complications related to laboratory practice.

Complications Associated with Ovarian Stimulation

Ovarian Hyperstimulation Syndrome

Ovarian stimulation is an integral part of assisted reproduction, and ovarian hyperstimulation syndrome (OHSS) is a known iatrogenic complication resulting predominantly from ovarian stimulation. It can be a life-threatening condition and is characterized by fluid shift from the intravascular compartment to the third space due to increased capillary permeability and

ovarian neoangiogenesis. This syndrome is invariably triggered after administration of human chorionic gonadotropins (hCG), although on rare occasion it can occur in the absence of hCG.

The true incidence of OHSS is unknown; severe forms of OHSS are reported in approximately 0.5% of stimulated cycles, moderate forms in 1%–7%, and mild OHSS in 8%–23% [1]. Although it can present early after the administration of hCG or later due to secretion of placental hCG if the patient is pregnant, the early-onset OHSS is more common. Several classifications of OHSS have been suggested over the years, and Golan classification is the most frequently used [2].

While the exact mechanism responsible for OHSS is unknown, the pathophysiological cascade of OHSS consists of neoangiogenesis and increased capillary permeability of the enlarged ovarian and other endothelial surfaces, fluid shift from the intravascular space to extravascular space, hemoconcentration, decreased renal clearance, oliguria, hyperviscosity of blood, modification in coagulation factors, and thromboembolic risks. Many mediators have been proposed to be involved in OHSS, and vascular endothelial growth factor (VEGF), a proangiogenic factor, is the most likely mediator. VEGF is present in high concentrations in the serum, follicular, and ascites fluid of patients with OHSS.

The main risk factors for the development of OHSS include young age, low body weight, polycystic ovaries, high serum estradiol concentration (>3000–4000 pg/mL), large number of oocytes retrieved, and past history of OHSS.

Patients classically present with abdominal distension and pain, nausea, vomiting, weight gain, and shortness of breath. Clinical signs include oliguria, hemoconcentration, leukocytosis, electrolyte imbalance, hypercoagulability, ascites, pleural effusion, and adult respiratory distress syndrome.

Thromboembolic event is increased in OHSS and can be explained by hemoconcentration and immobility resulting from this condition. Other factors include mechanical compression of venous blood flow in the pelvic brim and the lower limb and high estradiol level. In a study by Delvigne and Rozenberg [3], the authors reported that the most likely thrombosis event is venous in origin and the majority occur in the neck or arm veins.

Ovarian torsion is more common in the presence of OHSS. The characteristic symptoms include sudden, extreme abdominal pain accompanied by nausea. Ovarian torsion occurs in 1 of 5000 stimulated cycles [4], and early diagnosis and untwisting of the ovary at laparoscopy or laparotomy is essential and may result in survival of the ovary.

Primary prevention is the most effective way to avoid this iatrogenic condition. Ovarian stimulation should be contemplated only when alternative treatment such as lifestyle changes (diet and exercise) has failed, especially in overweight patients with polycystic ovary syndrome. Stimulation protocol should be "soft," for example, the use of low-dose step-up regimens.

A number of secondary preventative measures for OHSS include cycle cancellation by withholding hCG, and coasting, when gonadotropin administration can be decreased or stopped while continuing gonadotropin-releasing hormone agonist administration. Although coasting has been shown to be effective in compared observational studies, the only randomized controlled

trial on coasting, which compared coasting to unilateral follicular aspiration, showed no benefit [5].

Elective cryopreservation of all embryos and the use of progesterone as luteal-phase support have been advocated. Cryopreservation of all embryos has not been shown to be effective in preventing OHSS in systematic review [6], but the use of progesterone can decrease the risk of OHSS, compared to the use of hCG luteal support.

It has been suggested that administration of albumin during oocyte retrieval in high-risk patients can interrupt the development of OHSS. Systematic review by Aboulghar et al. [7] showed that it is beneficial but also associated with side effects such as viral transmission, nausea, vomiting, and febrile and allergic reactions. It is also expensive. Treatment of OHSS is mainly supportive. The condition is self-limiting, and resolution parallels with decline in hCG. While a mild degree of OHSS can be managed as outpatient, severe cases require hospital admission. Early-onset OHSS usually takes a week to resolve, whereas late-onset OHSS requires longer, approximately 10–20 days. For severe cases, the principles of management include circulatory support using intravenous fluids, maintenance of renal function, thromboprophylaxis, and drainage of third-space accumulation of fluid.

Multiple Pregnancies

The incidence of multiple pregnancies has increased substantially over the past 20 years and is attributed to the use of assisted reproductive technologies. Ovarian stimulation with the aim of inducing multiple follicular developments and the practice of multiple-embryo transfer are responsible for the increased risk of multiple pregnancies. The risk of twin pregnancy resulting from clomiphene treatment is approximately 10%; with IVF and 2 embryos replaced, the risk is 20%-30%; and with ovarian stimulation and intrauterine insemination, the risk is 10%-20%. Perinatal and maternal morbidity and mortality are increased in multiple pregnancies compared to singleton pregnancies [8]. Maternal risks include higher incidence of preeclampsia and gestational diabetes. Assisted vaginal deliveries and cesarean section rates are considerably higher in multiple pregnancies. The higher incidence of perinatal morbidity and mortality is related to prematurity and low birth weights in multiple gestations. There is an increased risk of cerebral palsy in multiple pregnancies, and the risk also becomes higher as the number of babies increases.

To reduce multiple pregnancies, a "soft" stimulation protocol should be used, and close monitoring is required during treatment. All assisted-conception units should have set criteria for cancellation or conversion to IVF. Patients must be counseled and made aware that multiple pregnancies are complications rather than "bonuses" from assisted reproduction. Elective single embryo transfer (eSET) is an effective way of reducing multiple pregnancies. Experience in Scandinavian countries showed that in selected patients with good prognosis, pregnancy rates after eSET are comparable to those seen following double embryo transfer [9,10].

Cancer Risks

Over the years, ovulation-induction agents have been linked to increased risk of ovarian or breast cancer, but direct causal relationship is hard to establish because of the limitations of the studies, including small number of subjects, short follow-up, and imprecise information on drug exposures or indication of use. Studies have also been limited by recall bias in the case of retrospective studies and the presence of confounding factors. While earlier studies by Whittemore et al. [11] and Rossing et al. [12] suggested an increased risk, more recent studies have been reassuring, and there does not appear to be any causal relationship between ovulation-inducing drugs and ovarian and breast cancer [13,14].

Based on current evidence, there is no conclusive link between ovulation induction and cancer risks. The limitations of current studies require that additional studies be performed to monitor the long-term effects of ovulation induction.

Complications Associated with Surgical Procedures

Oocyte Retrieval

The use of transvaginal ultrasound–guided oocyte retrieval instead of laparoscopic oocyte collection has made the procedure safer. Despite its low complication rates, patients still need to be counseled about the possible complications involved. There are limited data on this subject, so complications may be underestimated. Oocyte retrieval can inadvertently lead to damage to pelvic organs, bleeding from vaginal wall, or intraabdominal bleeding and infection, which may lead to serious morbidity and mortality.

The most common complication associated with oocyte retrieval is minor vaginal bleeding. Two prospective studies have been conducted; one reported an incidence of 2.8%, whereas the other reported an incidence of 8.6% [15,16]. However, Bennett et al. [16], who reported vaginal bleeding in 8.6%, did not provide information on how assessment of vaginal bleeding was made. Retrospective studies have reported the incidence of intraabdominal bleeding to be between 0.08% and 0.2% [17]. Pelvic infections leading to tubo-ovarian abscess fortunately are rare and occur in <1% of procedures [15]. The pathophysiologies of pelvic infections are possibly due to inoculation of vaginal microorganisms into the ovary, reactivation of latent pelvic inflammatory disease, or direct colonic injury [18]. Coliforms were the most commonly identified organisms in pelvic infection, and patients with a history of pelvic inflammatory disease have a higher likelihood of tubo-ovarian and pelvic abscess [19]. Prophylaxis antibiotics to date do not seem to be helpful in preventing pelvic infection.

The aspiration needle may inadvertently traumatize proximal pelvic structures. Although large prospective studies have not reported any incidence of bowel injury, there have been 2 case reports of perforated appendix but none on other parts of the bowel. It is also possible that bowel injuries occurred without being diagnosed and resolved spontaneously. Injuries to the ureter have been reported in prospective study and case reports [15]. Clinicians involved in oocyte-retrieval procedures must have a high index of suspicion; to minimize this complication, care should be taken during the procedure, and reliable transvaginal ultrasound scan should be available.

Sperm Retrieval: Nonsurgical and Surgical

For men who produce no sperm in the ejaculate, there are a variety of nonsurgical and surgical retrieval techniques to retrieve sperm from either the epididymis or the testicle itself. The method used depends on the cause of azoospermia. In patients who are anejaculatory due to spinal cord injuries or diabetes, nonsurgical methods, such as penile vibratory stimulation or electroejaculation, can be used. Although complications are rare, clinicians should look out for autonomic dysflexia, which can result in acute hypertension. In cases of high blood pressure, sublingual nifedipine 10–20 mg can be administered, and patients should be monitored closely. Other complications include local skin bruising, and there is a 1 in 1000 chance of rectal injury in the use of electroejaculation.

Surgical sperm retrieval appears to be a safe procedure, especially when performed under local anesthesia. The frequencies of complications are low. Specific complications include wound infection, hematoma, and pain. In the absence of hematoma, wound infection is rare. Significant hematoma may result from unrecognized hemorrhage of the testicular artery on the surface of the tunica albuginea. Inadvertent biopsy of epididymis can result in epididymal obstruction and significantly complicate subsequent reconstructive surgery.

Permanent testicular devascularization resulting in testicular atrophy has been reported after attempted sperm retrieval from multiple testicular sites. For repeat sperm retrieval procedures, up to 6 months may be necessary to allow complete healing and restoration of optimal spermatogenesis after testicular epididymal sperm retrieval [20].

Complications Associated with Embryo Transfer Technique

There is increasing evidence to suggest that poor embryo transfer technique is associated with higher incidence of ectopic pregnancies. Nazari et al. [21] reported an increased incidence of ectopic pregnancies with high-fundal

embryo transfer compared to mid-fundal embryo transfer, whereas Bennett et al. [22] showed higher incidence of cervical ectopic pregnancy with low transfer of embryos.

Safety of Assisted Reproduction

The ability of assisted reproduction to circumvent nature to achieve pregnancy has led to concerns about its safety. Although Hansen et al. [23] reported higher risks of birth defects in infants after IVF/ICSI compared to spontaneously conceived infants, it is yet to be established if the increase in malformations is related to assisted reproductive technology or the background history of infertility. To date, there are no studies of sufficient power to assess the efficacy and safety of assisted reproduction, and studies are hampered by lack of control, sample size, lack of agreed definition of malformations, and presence of confounding factors.

Male offspring of infertile males with chromosome abnormalities such as Y-chromosome microdeletions and autosomal aberrations are likely to inherit the same abnormality [24]. Imprinting disorders such as Beckwith-Wiedemann syndrome and Angelman syndrome have been reported to be more common in assisted reproduction, but again, studies are limited by sample size. While singleton IVF and ICSI children were more likely to need healthcare resources than children from spontaneous conception, there were no differences in cognitive development between them [25].

Due to the constraints of the available studies, no conclusion can be drawn at this stage. Clinicians must be able to provide proper counseling to couples undergoing assisted reproduction and must explain that the possibility of an increase in birth defects exists but that absolute risk of major anomalies is small [26].

Conclusion

Assisted reproduction will continue to evolve, and the risk of complications associated with surgical procedures such as oocyte collection and sperm retrieval will continue to diminish. There is a need for systematic reporting of all cases of OHSS, and to decrease the risk of OHSS, ovarian stimulation should be indicated only as a last option. If ovarian stimulation is required, a “soft” stimulation protocol should be used and should include adequate monitoring. Although different secondary preventative measures for OHSS are available, primary prevention is effective in decreasing the risk of developing this iatrogenic condition.

Urgent attention is required to minimize the risk of multiple pregnancies, given that elective single-embryo transfer is an effective method in properly selected patients. Based on the current literature, there is no conclusive link

between ovarian stimulation and cancer risks. While current studies on the safety of assisted reproduction are generally reassuring, the study by Hansen et al. [23] reporting a higher risk of birth defects is of concern. International collaboration is needed to address this uncertainty.

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