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Complications Associated With Optical-Access Laparoscopic Trocars

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OBJECTIVE: To investigate the number and type of serious complications associated with optical-access trocars reported by sources other than the medical literature.

METHODS: Optical-access trocars, first introduced in 1994, were designed to decrease the risk of injury to intra-abdominal structures by allowing the surgeon to visualize abdominal wall layers during placement. To date, very few complications with their use have been reported in the medical literature. MEDLINE, the Food and Drug Administration's Medical Device Reporting, and the Manufacturer and User Facility Device Experience databases were searched for reports of complications occurring during the use of optical-access trocars for laparoscopic access.

RESULTS: Only two serious complications resulting from the use of optical-access trocars (vena cava injuries) have been reported in the medical literature. However, 79 serious complications using these techniques have been cited in the Medical Device Reporting and Manufacturer and User Facility Device Experience databases since 1994. These include 37 major vascular injuries involving aorta, vena cava, or iliac vessels, 18 bowel perforations, 20 cases of significant bleeding from other sites, three liver lacerations, and one stomach perforation. Four of these complications resulted in patient deaths.

CONCLUSION: Optical-access trocars may be associated with significant injuries despite having the ability to visualize tissue layers during insertion. (Obstet Gynecol 2002; 99:553–5. © 2002 by the American College of Obstetricians and Gynecologists.)

Despite continued evolution of both laparoscopic instruments and techniques, injury to intra-abdominal structures continues to be a common, yet potentially avoidable complication of laparoscopy. Many of these injuries are related to the blind placement of the Veress needle or sharp primary trocar into the abdomen when performing a technique referred to as "closed" laparoscopy. Although "open" laparoscopy (where the peritoneal cavity is opened before placing a blunt trocar into the abdomen) has been successful in avoiding major vessel injury, bowel injuries with this technique have not been eliminated.[1,2] In response, trocars were developed for laparoscopy, termed "optical-access trocars." These trocars were designed to decrease the risk of injury to intra-abdominal structures by allowing the surgeon to visualize abdominal wall layers during placement, and only two serious complications have been reported in the medical literature with their use.[3–5] Two "optical-access" trocar systems are available: one uses a blade that strikes the fascia and peritoneum under laparoscopic visualization (Visiport, United States Surgical, Norwalk, CT); the other system has a conical clear tip that is rotated under laparoscopic vision as it penetrates the fascia and peritoneum (Optiview, Ethicon Endo-Surgery, Cincinnati, OH).

A complication at one of our hospitals associated with an optical-access trocar demonstrated to us that the use of optical-access trocars did not always avoid injury to intra-abdominal organs. An optical-access trocar was placed in preparation for laparoscopic cholecystectomy in a 24-year-old pregnant woman at 23 weeks' gestation. During the initial port placement, the optical-access trocar penetrated the uterine fundus into the amniotic cavity. Within 1 week of this complication, the woman experienced preterm labor and underwent a vaginal delivery. Her fetus died within 1 hour of birth because of complications associated with extreme prematurity.

Because few complications while using optical-access trocars have been reported in the medical literature, we searched for alternative sources for such reports. The Food and Drug Administration (FDA) operates databases designed for the reporting of adverse outcomes associated with medical devices, called Medical Device Reporting (MDR) and Manufacturer and User Facility Device Experience (MAUDE). The following is a report

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of the complications derived from these two databases since the introduction of optical-access trocars in 1994.

MATERIALS AND METHODS

We reviewed the medical literature published before and after FDA approval of optical-access trocars in 1994. We searched MEDLINE from 1994 to December 2000 using PubMed (http://www.nlm.nih.gov). The following key words and subject terms were searched: "optical-access trocars," "Visiport," "Optiview," and "trocar injury." All languages and publication types were included. Bibliographies of pertinent articles and reviews were searched for additional references. Relevant textbooks and foreign-language articles were also reviewed.

When few reported complications were found using the search techniques described above, we searched MDR and MAUDE databases. These voluntary reporting systems maintained by the FDA for tracking adverse medical events can be accessed through the FDA websites http://www.fda.gov/cdrh/mdrfile.html (MDR) and http://www.fda.gov/cdrh/maude.html (MAUDE). An on-line search was performed to obtain information by using the search words "Visiport" and "Optiview."

RESULTS

The MEDLINE search from 1966 to December 2000 revealed two small series describing the use of the Optiview trocar with a total of five minor complications in 106 cases.[3,4] In addition, we found one report of two cases of vena cava injury using the Visiport trocar in preparation for laparoscopic cholecystectomy.[5]

A review of the MDR and MAUDE databases revealed 79 additional cases involving complications associated with the use of optical-access trocars that have occurred since 1994. Of these 79 cases, 57 were reported through the MDR database and 22 were reported through MAUDE. These complications occurred when laparoscopy was performed for both general surgical and gynecologic procedures (Table 1).

Major vascular injury, defined as injury to aorta, vena cava, or the iliac vessels, was the most frequently reported major injury, occurring in 37 cases (Table 2). Six of these major vessel injuries involved simultaneous injury to bowel, and two resulted in patient deaths. Twenty cases involved injury of other vessels, and two of these resulted in death. A total of 24 cases of bowel injury occurred, including the six cases of combined major vessel/bowel injuries. The Optiview trocar was used in 26 cases, and the Visiport trocar in 53 cases.

Table 1. Surgical Procedures Associated With Optical-Access Trocars

Surgical procedures	Optiview injuries	Visiport injuries
Cholecystectomy	11	28
Nissen fundoplication	3	4
Herniorrhaphy	2	3
Diagnostic laparoscopy	1	3
Tubal ligation	1	1
Laparoscopically assisted vaginal hysterectomy	1	1
Colon resection	1	1
Appendectomy	0	2
Adhesiolysis	2	0
Salpingectomy	1	0
Ectopic pregnancy	0	1
Bilateral salpingo-oophorectomy	0	1
Lymph node dissection	0	1
Unspecified	3	7
Total	26	53

DISCUSSION

The results of this study indicate that the use of optical-access trocar systems for laparoscopy is associated with a risk of injury to intra-abdominal vessels and organs despite the rarity of reports of such injuries in the medical literature. Rather than only two major complications over the last 7 years as suggested by a review of MEDLINE, at least 82 serious complications (including the case briefly presented in this paper) have occurred in the United States during this time period according to the data available in the MDR and MAUDE databases.

Table 2. Injury Site Associated With Optical-Access Trocars

Injury site	Optiview	Visiport	Total
Major vessel injuries			
Iliac vessel	3	11	14
Vena cava	1	9	10
Aorta	2	5	7
Major vessel/bowel	0	6*	6
Other vessel injuries			
Mesentery	2	6	8
Portal vein	0	1†	1
Epigastric vessel	0	1	1
Presacral vessels	0	1	1
Retroperitoneal bleeding	0	2	2
Not specified	4†	3	7
Laceration or perforation of other organs			
Bowel alone	12	6	18
Liver/stomach/pancreas	2	1	3
Stomach	0	1	1
Total	26	53	79

* Associated with two patient deaths.
† Associated with one patient death.

Unfortunately, data from these databases lack sufficient details to clearly establish a causal relationship between these injuries and use of these trocars. In addition, the relative or absolute degree of risk of these instruments is impossible to determine for two reasons. The first reason is that the number of cases performed with either of the two optical-access techniques during this time period is unknown. However, the reported rate of major vessel and bowel injury reported using a standard closed technique is approximately three in 100,000 cases and 26 in 100,000, respectively.[6] In light of the 37 major vessel injuries and 24 bowel injuries contained in the present report, a total of approximately 1,200,000 ($37 \times 100{,}000 \div 3$) such procedures would have had to have been performed with this technique during the reporting period for the risk to be equivalent to the standard closed technique for major vessel injury, and 92,000 ($24 \times 100{,}000 \div 26$) procedures respectively for bowel injury. The second reason the relative or absolute degree of risk cannot be established is that there is no way to determine if the complications have been underreported because reporting in this system is voluntary.

This type of data does not allow for an accurate comparison of injury rates between standard trocars and optical-access trocars, as the complications are reported voluntarily and the actual numerators and denominators remain unknown. Although the degree of risk or serious complication remains uncertain, it is clear that the use of optical-access trocars does not avoid serious injury to intra-abdominal structures. The actual safety of these techniques will have to be determined by large studies of their use in practice with an accurate record of the associated complications.

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Estradiol Absorption From Vaginal Tablets in Postmenopausal Women

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OBJECTIVE: To evaluate absorption of estradiol (E2) and compare two low doses of 17 β-E2 (25 μg and 10 μg) in postmenopausal women with atrophic vaginitis.

METHODS: In a double-masked, randomized, parallel-group study, 58 postmenopausal women were treated with 25 μg or 10 μg of 17 β-E2 for 12 weeks. We report data for 42 eligible subjects who had serum E2 concentrations below 20 pg/mL at baseline and complete data available at the baseline visit (30 minutes before tablet insertion) and weeks 2 and 12. Serum E2 and FSH concentrations were measured at specified intervals. The area under the curve, maximal concentration, and time to maximal concentration were measured for serum E2 concentrations. Maturation values of vaginal epithelial cells were assessed as indicators of change in vaginal epithelium condition in response to treatment.

RESULTS: After 12 weeks of treatment, the area under the curve, maximal and average over 24-hour E2 concentration were higher in the 25-μg (563 pg · hour/mL, 49 and 23 pg/mL) than in the 10-μg (264 pg · hour/mL, 22 and 11 pg/mL) group. Seventy-four percent in the 25-μg and 96% in the 10-μg groups had low systemic absorption of E2, that is, area under the curve (0–24 hour) less than 500 pg/mL. All but three women who received 25 μg had mean FSH levels below 35 mIU/mL.

CONCLUSION: Treatment with 25 or 10 μg of 17 β-E2 vaginal tablets resulted in low absorption of estrogen without systemic effects often associated with hormone replacement therapy. After 12 weeks of therapy for atrophic vaginitis, absorption patterns remained consistent, and women did not have accumulations of circulating E2. (Obstet Gynecol 2002;99:556–62. © 2002 by the American College of Obstetricians and Gynecologists.)

Over half of postmenopausal women will have urogenital discomfort associated with estrogen deficiency.[1,2] A previous study[2] found that although many women use oral hormone replacement therapy (HRT), urogenital symptoms persist. Many women can get additional benefits from local therapy.

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Vaginal administration of low-dose estradiol (E2) tablets offers safe and convenient local relief of vaginal symptoms.[1,3,4] Vaginal estrogen is often more effective for relieving urogenital symptoms than conventional systemic estrogen therapy because hepatic metabolism is avoided and vaginal tissues have increased response to locally applied estrogen. Those characteristics make it possible to use significantly lower doses of estrogen with local therapy compared with oral therapy.

Studies have shown that vaginal estrogen preparations can result in rapid and efficient absorption of E2 into systemic circulation.[5,6] However, low-dose preparations that contain 10 and 25 μg of E2 effectively relieve symptoms of atrophic vaginitis without unwanted systemic side effects.[3,6] A low-dose (25 μg) 17 β-E2 vaginal tablet (Vagifem, Novo Nordisk, Baegsvard, Denmark) has been developed to treat estrogen-deficient atrophic vaginitis. Those tablets contain a film-coated hydrophilic cellulose matrix that adheres well to the vaginal epithelium and hydrates slowly to provide a controlled release of E2. They are designed to provide estrogenization of the vaginal epithelium while preventing significant increases in serum estrogen concentrations.

In this study, the vaginal absorption of E2 was evaluated, and two low doses of 17 β-E2 (25 μg and 10 μg) were compared in postmenopausal women with atrophic vaginitis.

MATERIALS AND METHODS

This single-center, randomized, double-masked, parallel-group study was conducted in Atlanta, GA. The study was approved by the appropriate institutional review board, and written informed consent was obtained from each subject. The study was conducted in compliance with the Declaration of Helsinki of 1975, revised in 1983.

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