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Safety of Culdotomy as a Surgical Approach: Implications for Natural Orifice Transluminal Endoscopic Surgery

Mary Catherine Tolcher, MD, Eleftheria Kalogera, MD, Matthew R. Hopkins, MD, Amy L. Weaver, MS, Juliane Bingener, MD, Sean C. Dowdy, MD

ABSTRACT

Objective: To evaluate the efficacy and safety of culdotomy as a surgical approach to access the peritoneal cavity and discuss its implications for natural orifice transluminal endoscopic surgery (NOTES).

Methods: A retrospective chart review of women undergoing culdotomy for tubal sterilization (N=219) between January 1995 and December 2005 was performed. The Accordion Grading System was used for the severity of complications.

Results: No intraoperative complications were noted. Postoperative complications occurred in 7 patients (3.2%): 6 infections (grade 2) and 1 case of hemorrhage (grade 3). Conversion to laparoscopy was necessary in 10 patients (2.2%) due to anatomical constraints or pelvic adhesions; however, culdotomy with entry into the abdominal cavity was nevertheless successful in all 10 cases. The difference in the proportion with a history of pelvic surgery between the conversion and nonconversion groups was not statistically significant ($P = .068$). Patients with BMI ≥30 had a higher conversion rate compared to patients with BMI <30 (11.4% versus 1.5%, $P = .011$). Tubal sterilization via culdotomy was successfully performed in all 11 women with no prior vaginal deliveries.

Conclusion: Culdotomy appears to be a safe surgical approach to access the peritoneal cavity and is associated with a low complication rate. These data support the feasibility and safety of utilizing the cul-de-sac as an access portal for natural orifice transluminal endoscopic surgery.

Key Words: Culdotomy, Transvaginal approach/route/surgery, Natural orifice transluminal endoscopic surgery (NOTES), transluminal surgery.

INTRODUCTION

The continual drive to minimize surgical morbidity brought to fruition laparoscopic surgery followed by additional minimally invasive approaches including single-incision laparoscopic surgery (SILS) and robotics. These advances marked a revolutionary leap in the practice of surgery and have emerged as the standard of care for procedures including cholecystectomy, appendectomy, oophorectomy, and hysterectomy in select patients over the last 2 decades. An overwhelming body of evidence in the literature indicates that minimally invasive surgery not only offers superior cosmetic results but, most importantly, also reduces surgical trauma and blood loss, neuroendocrine stress and inflammatory response, postoperative pain, and recovery time.[1,2] Culdotomy meets the criteria for a minimally invasive surgical approach with the potential to provide all the aforementioned benefits.

Culdotomy consists of a transverse incision in the posterior vaginal fornix into the cul-de-sac which establishes direct access to the pelvis; culdotomy is also the first step for vaginal hysterectomy. As reported by Hofmeister, Pelleton[3] is credited as the first to have reported drainage of a tubo-ovarian abscess by colpotomy in 1835. In 1896, Kelly[4] reported 10 cases of ectopic pregnancies managed surgically through the vaginal route and thus was the first to suggest the use of culdotomy as a route for specimen retrieval. Culdoscopy, in which an endoscope is inserted into the abdominal cavity through a puncture in the posterior vaginal fornix for visual examination of the female viscera, was first reported by Dimitri Oscarovich Ott,[5] a gynecologist from St. Petersburg in 1901 followed by Decker and Cherry[6] in 1944. Since then, culdotomy has traditionally been used as a means of investigating the pelvis for the diagnosis and treatment of various gyneco-

Department of Obstetrics and Gynecology, Mayo Clinic, Rochester, MN, USA (Drs. Tolcher, Kalogera, Hopkins, Dowdy).

Division of Biomedical Statistics and Informatics, Mayo Clinic, Rochester, MN, USA (Ms. Weaver).

Department of Surgery, Mayo Clinic, Rochester, MN, USA (Dr. Bingener).

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Address correspondence to: Sean C. Dowdy, MD, 200 first Street SW, Rochester, MN 55905, USA. Telephone: (507) 284-2511, Fax: (507) 266-9300, E-mail address: dowdy.sean@mayo.edu

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logic diseases among which tubal sterilization and ovarian cystectomy have predominated.[7–15]

Culdotomy was popular in the 1970s, but as laparoscopy became more widely accepted, culdotomy fell out of favor despite its merits. However, in recent years, interest in exploring even less invasive approaches has resulted in the reappraisal of transvaginal surgery by both gynecologic surgeons and general surgeons. The former have used this approach to perform salpingectomy, oophorectomy, myomectomy, and hysterectomy,[15–27] whereas the latter have utilized culdotomy to extract large specimens (gallbladder, appendix, colon, kidney, spleen) during laparoscopy[28–32] to minimize the transabdominal incision. A more recent development is culdolaparoscopy, a culdoscopy assisted laparoscopic technique that utilizes a 12-mm trocar in the vagina as a multifunctional port in conjunction with traditional laparoscopy,[33] first described by Tsin in 2001.[26,34]

The safety and efficacy of culdotomy became of even greater interest recently with the introduction of the emerging concept of natural orifice transluminal endoscopic surgery (NOTES).[35–46] NOTES is a surgical technique whereby an "incisionless" abdominal surgery is performed using a flexible endoscope introduced through a natural orifice (mouth, urethra, anus, vagina) then through an internal incision in the stomach, vagina, bladder, or colon to gain access to the abdominal cavity without abdominal wall incisions. This technique has the potential to obviate complications associated with abdominal incisions, such as wound infections and hernia formation, further minimize postoperative pain and the potential for adhesion formation, shorten hospital stay and recovery time, and improve overall morbidity and cosmesis over that observed with laparoscopy.[35–46] The first published report of a NOTES procedure was in 2004 when Kalloo et al.[47] presented a porcine survival model of transgastric peritoneoscopy. The first human NOTES procedure is credited to Reddy and Rao[48] who in the same year performed a transgastric appendectomy in a male patient. Since then, a growing volume of research in animals and recently in humans has supported the feasibility, efficacy, and safety of transluminal surgery. The transvaginal approach is a potential access portal for NOTES. The first report of human transvaginal cholecystectomy, carried out during a vaginal hysterectomy, was published in 2003 by Tsin et al.[33] whereas Marescaux et al.[49] reported in 2007 the first "pure" transvaginal cholecystectomy performed in a human. Given the current interest in culdotomy in the context of NOTES, the purpose of this study was to report our institution's experience on the efficacy and safety of culdotomy in a contemporary cohort of patients with special emphasis on transvaginal tubal sterilization as a model.

MATERIALS AND METHODS

A retrospective chart review was conducted following approval from the Mayo Foundation institutional review board. Both the institutional surgical index and the gynecologic surgery database were queried for all gynecologic surgical procedures involving a culdotomy, and all patients who underwent culdotomy for a variety of indications between 1995 and 2005 at Mayo Clinic Rochester were identified. Exclusion criteria were culdotomy performed for an indication other than tubal sterilization (TS) and lack of postoperative follow-up data. In accordance with the Minnesota Statute for Use of Medical Information in Research, only those individuals who had previously provided informed consent for the use of their medical records were included.

Medical records including operative notes, inpatient and outpatient clinic notes, as well as correspondence from outside health facilities on postoperative follow-up were retrospectively reviewed. Postoperative adverse events occurring up to 45 days following surgery were considered as postoperative complications. The contracted Accordion Severity Grading System[50] was adopted as a method to report the severity of these complications.

All procedures were performed by gynecologic surgeons, and the technique used to carry out the culdotomy has been previously described in detail in the literature.[19,23,24,27,30] Briefly, patients are prepped and draped while in the dorsal lithotomy position. The posterior lip of the cervix is grasped with a tenaculum and retracted caudally and anteriorly to expose the posterior fornix. Countertraction is applied to the posterior vagina, and an incision is made with Metzenbaum scissors at an angle parallel to the floor. This allows direct access to the cul-de-sac between the uterus and rectum. It is important that the incision not be made too close to the cervix to avoid cutting into the cervix/uterus rather than the peritoneal cavity. Deaver retractors are then used to visualize pelvic structures like the ovaries and fallopian tubes. In this series, tubal sterilizations performed were achieved by salpingectomy, as follows. The fallopian tubes were identified, grasped with an Alice clamp, and followed to the fimbriated end. The entire fallopian tube was then clamped, cut, and suture ligated with delayed absorbable suture. After confirmation of hemostasis, the culdotomy incision was closed in a running locked fashion with delayed absorbable suture. It is important to incorporate both the vaginal mucosa and

peritoneal edge in the closure to prevent occult bleeding along the incision line.

Descriptive statistics (mean, SD, median, and range) were used to summarize patient and procedural characteristics. A 95% confidence interval (CI) using a normal approximation was constructed for the overall conversion and complication rate, respectively. Patient characteristics were compared between groups using Fisher's exact test for dichotomous variables and the 2-sample *t* test or Wilcoxon rank sum test. A level of $P < .05$ was accepted as statistically significant. Statistical analyses were performed using the SAS software package (version 9.2; SAS Institute, Inc.; Cary, NC).

RESULTS

Between January 1, 1995 and December 31, 2005, a total of 224 women underwent culdotomy at our institution. Of the 224 patients, 220 underwent culdotomy for tubal sterilization (TS), 2 for salpingo-oophorectomy, 1 for drainage of tuboovarian abscess, and 1 for drainage of pelvic hematoma. For the purposes of this study, the latter 4 patients in whom culdotomy was performed for an indication other than TS were excluded. Of the 220 patients who underwent culdotomy for TS, postoperative follow-up was not available for 1 patient who was further excluded from the study.

The cohort was divided into 2 groups: one group consisted of 122 women (55.7%) undergoing vaginal TS as a single procedure (TS^-) and the other group of 97 women (44.3%) undergoing TS combined with other concurrently performed surgical interventions that may have impacted the intraoperative course and postoperative outcome (TS^+). Patient characteristics within each group are summarized in **Table 1**. The type of procedures performed at the time of TS are shown in **Table 2**.

Culdotomy was successful in 209 of the 219 patients. Thus, the overall conversion rate was 4.6% (95% CI 1.8% to 7.3%). Abandonment of the transvaginal approach was equally distributed between 2 causes: unsuitable anatomy and restricted adnexal mobility (**Table 3**); culdotomy itself was successful in all patients.

The conversion rate in patients who underwent procedures in addition to TS (TS^+) was higher than in patients with TS only (TS^-), but this difference was not statistically significant (7.2% vs. 2.5%, respectively; $P = .11$). Within the TS^+ group, patients who required conversion to laparoscopy were significantly older (mean age 42.0 vs. 35.2 years, $P = .007$) and had higher BMI (median 31.7 vs. 24.2, $P = .012$) than patients who were not converted to laparoscopy. Patients with BMI ≥30 had a significantly higher conversion rate compared to patients with BMI <30 (20% vs. 3.2%, $P = .046$) in the TS^+ group. There was

Table 1.
Patient Characteristics of Tubal Sterilization (TS) Only Group (TS^-) and TS Plus Additional Procedures Group (TS^+)

Patient Characteristics	TS only Group (TS^-) (n=122)	TS plus Additional Procedures Group (TS^+) (n=97)
Characteristic	N*	N*
Age (years)		
Mean (SD[a])	35.1 (5.4)	35.7 (6.4)
Median (range)	36 (19–47)	35 (22–50)
BMI[b]	(n=101)	(n=78)
Mean (SD)	28 (7.9)	25.8 (6.7)
Median (range)	25.9 (17.2–62)	24.6 (16.4–55.9)
BMI Categories		
Nonobese (<30)	72 (71.3)	63 (80.8)
Obese (≥30)	29 (28.7)	15 (19.2)
Gravidity	(n=81)	(n=74)
Mean (SD)	3.1 (1.3)	3.6 (1.6)
Median (range)	3 (1–7)	3 (0–9)
Parity	(n=122)	(n=95)
Mean (SD)	2.4 (1.0)	2.7 (1.4)
Median (range)	2 (1–7)	2 (0–12)
Vaginal delivery	(n=119)	(n=93)
Mean (SD)	2.3 (1.1)	2.5 (1.6)
Median (range)	2 (0–7)	2 (0–12)
Vaginal Delivery (dichotomous)		
0	4 (3.4)	7 (7.5)
≥1	115 (96.6)	86 (92.5)
Cesarean Delivery	(n=119)	(n=93)
0	106 (89.1)	76 (81.7)
1	10 (8.4)	8 (8.6)
≥2	3 (2.5)	9 (9.7)
Previous Pelvic Surgery		
0	106 (86.9)	76 (78.4)
≥1	16 (13.1)	21 (21.6)

* Values are expressed as number (%) unless otherwise indicated.

[a] SD, Standard Deviation.

[b] BMI, Body Mass Index (kg/m^2).

Table 2.
Type of Procedures Performed in Addition to Tubal Sterilization (TS) at the Time of Culdotomy (TS^+ Group)

Procedure Performed	N (% of 97)
Dilation and curettage	71 (73.2)
Hysteroscopy	20 (20.6)
Endometrial ablation	18 (18.6)
Cervical conization	8 (8.2)
Posterior colpoperineorrhaphy	5 (5.2)
Ovarian biopsy	3 (3.1)
Anal sphincter repair	2 (2.1)
Rectovaginal fistula repair	2 (2.1)
Myomectomy	2 (2.1)
Introitoplasty	1 (1.0)
Rectoperineal fistula repair	1 (1.0)
Vulvar laser	1 (1.0)
Breast surgery	1 (1.0)

Table 3.
Abandonment of Transvaginal Approach

Reason	N
I. Unsuitable anatomy	(n=5)
1. Marked uterine anteflexion	1
2. Large uterine size (11-week intrauterine pregnancy)	1
3. Adnexal structures exceedingly high in the pelvis	3
a. Idiosyncratic anatomical variation	2
b. Ovarian cyst displacing the adnexa out of the cul-de-sac	1
II. Restricted adnexal mobility–Pelvic adhesions	(n=5)
1. History of pelvic surgery	4
a. Single prior cesarean delivery	2
b. Ectopic pregnancy–right salpingo-oophorectomy	1
c. Unknown type of surgery	1
2. No history of pelvic or abdominal surgery	1
Total	10

no statistically significant difference in the median gravidity or parity ($P = .34$ and $P = .79$, respectively). A similar analysis was not performed among the patients with TS only (TS^-), because with only 3 patients requiring conversion statistical power was limited.

Table 4.
Postoperative Complications

Complication	N
I. Accordion Grade 2[a]	(n=6)
1. Vaginal cuff cellulitis	1
2. Bacterial vaginosis	2
3. Yeast vaginitis	1
4. Lower urinary tract infection	2
II. Accordion Grade 3	(n=1)
Vaginal bleeding (retained products of conception)	1
Total	7

[a] Treated with oral antibiotics or over-the-counter medication as indicated; none required hospital readmission.

The operation time of TS via culdotomy, based exclusively on data from the TS only group ranged from 13 min to 98 min (median, 33.5) and the estimated blood loss (EBL) from minimal to 250mL (median, 50). No intraoperative complications were noted. There were 7 postoperative complications (6 grade 2; 1 grade 3) encountered in 7 patients (3.2%, 95% CI 0.9% to 5.5%), occurring from 11 days up to 5 weeks postoperatively **(Table 4)**. The grade 3 complication occurred in a patient who underwent a concurrent pregnancy termination. She required repeat suction curettage for retained products of conception. This complication was thus unrelated to the culdotomy itself.

The complication rate was no different between the TS only (TS^-) and TS plus additional procedures (TS^+) groups (3.3% and 3.1%, respectively; $P = 1.00$). Considering the entire cohort collectively, the complication rate was significantly higher in patients without prior vaginal delivery compared to patients with prior vaginal delivery (18.2% vs. 2.5%, $P = .045$).

DISCUSSION

The efficacy and safety of the transvaginal route has been established in the past.[7–15,51,52] As part of the ever-growing interest in reducing surgical stress and improving cosmesis, the vaginal approach has been reconsidered recently as an access portal for NOTES. Gynecologists, therefore, should remain familiar with culdotomy as a simple, low-cost, and safe procedure. In this report we provide contemporary data to support its feasibility and safety.

It has been suggested that the technical feasibility of culdotomy depends primarily on the parity, body weight, age and the absence of pelvic adhesions obliterating the cul-desac. Nulliparity has historically been considered a relative contraindication for performing culdotomy since vaginal delivery is believed to enhance vaginal elasticity.[9] Nevertheless, Massi et al.[24] investigated the feasibility of the transvaginal approach for treatment of benign adnexal masses in 54 patients and reported successful completion of transvaginal procedures in all patients, 48% of whom were nulliparous. Similarly, although in a smaller and most likely select population, all 11 patients with no vaginal births in our series underwent successful culdotomy. BMI was indeed a limiting factor for completion of procedures through culdotomy but is not a contraindication and was not associated with reduced rates of successful culdotomy in our series. We were not able to identify any associations with conversion to laparoscopy in the TS^- group because only 3 patients required conversion. In the TS^+ group, conversions were more likely with older age and BMI >30. Prior pelvic surgery was not significantly associated with conversion and should not be considered a contraindication to NOTES. Of note, all cases of abandonment of the transvaginal route were associated with the inability to visualize or manipulate, or both, the adnexal structures, not with the inability to gain pelvic access via culdotomy. Even in the 5 cases where pelvic adhesions precluded transvaginal TS, culdotomy itself was nevertheless feasible. Conversions due to limited visualization in obese or nulliparous patients would be obviated with the NOTES approach.

Theoretical complications that could be attributed to culdotomy include rectal injury, injury to the bladder and ureters, hemorrhage, vaginal cuff hematoma, vaginal scarring, and postoperative pelvic infections. These complications are rare when the transvaginal route is used, regardless of whether TS[7,8,10,18,19,53–55] or another surgical procedure is performed.[21,25,30,52] Chang et al.[19] reported no major complications including visceral organ injuries, internal bleeding, or pelvic infections in a group of 38 patients undergoing TS via culdotomy. Hoffman et al.[22] concluded that laceration of the rectum is uncommon at the time of culdotomy. Ayhan et al.[18] evaluated 302 TS cases performed via culdotomy; 228 were TS only and 74 were TS combined with other procedures. The intraoperative complication rate was 1.3% (3 of 4 complications were rectal injuries), and the postoperative complication rate was 7.9% (all were infectious or hemorrhagic in origin). Ayhan[18] reported that most postoperative complications were associated with other procedures performed concurrently with TS or with preexisting comorbidities. The above results are similar to our findings of no intraoperative complications (including rectal injuries) and a postoperative complication rate of 3.2%. All but one postoperative complication was infectious, and all were readily treated primarily with oral antibiotics on an outpatient basis. In agreement with our results, most investigators have concluded that combined procedures at the time of TS are safe to perform.[12,56–59] A minority have concluded otherwise.[60,61]

Our results may have important implications for NOTES. With the increasing amount of rigorous research conducted on the feasibility, safety, and efficacy of NOTES, perhaps the most pressing concern is to identify the ideal port of entry to the abdominal cavity and to secure a safe viscerotomy closure. As there are currently no reliable viscerotomy closure devices, the transgastric and transcolonic routes remain troublesome, because of the potential for leakage from the access site with subsequent potentially catastrophic intraabdominal infection. In contrast, the culdotomy incision is easily closed under direct visualization with little concern for postoperative infection. Because the transvaginal route is associated with a low complication rate, most of the small series published on human NOTES procedures have adopted it as the preferred port of access.[35,37,40,42,44–46,49,62] This investigation provides additional safety data for culdotomy.

Despite its simplicity, proper surgical training and technique is required to accurately and safely perform culdotomy to enter the peritoneal cavity without injury to neighboring structures. In our study, all procedures were performed by fellowship trained gynecologic oncologists, and no intraoperative complications were noted. A 6-wk period of coital abstinence was recommended to allow the incision to heal properly.

To date, the effects of culdotomy alone on sexual function have not been studied in great detail.[63,64] In our study, we followed patients only for 45 days postoperatively, during which time no complaints of sexual dysfunction or discomfort were noted. In the context of NOTES, it would be expected that culdotomy alone would result in little to no clinical effects given the anatomic relation of the vaginal wall incision site and the position of the pelvic nerve plexus. This is further supported by the fact that culdotomy is a necessary step in performing vaginal hysterectomy, a procedure that has been performed for over 100 y.

CONCLUSION

Our contemporary data support the safety and efficacy of culdotomy as a surgical approach to access the pelvis and peritoneal cavity. Although it inarguably requires skillful surgical technique to overcome the obstacle of a restricted operative field, it is a feasible and safe procedure to perform with a low complication rate. Finally, our data lend support to the use of the transvaginal approach as an access portal for NOTES, which appears to be the most convenient and safe transluminal route.

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