ORIGINAL ARTICLES

Laparoscopic Retroperitoneal Hysteropexy

A Randomized Trial

Adam Ostrzenski, M.D., Ph.D.

OBJECTIVE: To assess the clinical applicability, safety and initial efficacy of a new laparoscopic retroperitoneal hysteropexy technique.

STUDY DESIGN: A relatively homogeneous group of patients (N = 62) with symptomatic uterine retroflexion was randomly allocated to laparoscopic retroperitoneal uterine suspension (n = 32, group I) and diagnostic laparoscopy (n = 30, group II). Patients from both groups were followed for at least 24 months. The following clinical parameters were compared between groups I (treated) and II (untreated): deep dyspareunia, dysmenorrhea, sense of bladder pressure with frequent urination and sense of pressure in the rectum.

RESULTS: Surgery was performed as an outpatient operation by the author. Intraoperative or postoperative complications were not observed in either group. A prospective, double-blind, controlled trial revealed that 87.5% of patients with symptomatic uterine retroflexion experienced relief from symptoms after the operation. Statistical analysis of the two groups documented that clinical symptoms improved (with P < *.0001) in a statistically significant number of cases among patients subjected to hysteropexy.*

CONCLUSION: Laparoscopic retroperitoneal uterine suspension benefitted patients and was safe. (J Reprod Med 1998;43:361–366)

[This] technique...can be executed through either the classic, laparotomy or laparoscopy approach.

Keywords: uterine diseases; surgery, laparoscopic; uterine suspension.

Introduction

A prospective, randomized, double-blind, controlled trial was designed to evaluate the initial and long-term clinical outcome of a new type of laparoscopic retroperitoneal uterine suspension for symptomatic uterine retroflexion. The control group, which had symptoms associated with uterine retroflexion, was subjected to diagnostic laparoscopy only to determine whether a problem other than uterine retroflexion caused the symptoms. The laparoscopic hysteropexy technique, as well as intraoperative and postoperative complications, were evaluated. The clinical effectiveness of the new operation was ascertained.

The pouch of Douglas sometimes opens so wide that the uterine body moves inside it. A compromised mechanism in the deep layer of the uterosac-

From the Division of Operative Gynecology, Endoscopy and Laser Surgery, Department of Gynecology and Obstetrics, Howard University College of Medicine, Washington, D.C.

Dr. Ostrzenski is Professor and Director.

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Address reprint requests to: Adam Ostrzenski, M.D., Ph.D., Division of Operative Gynecology, Endoscopy and Laser Surgery, Department of Gynecology and Obstetrics, Howard University College of Medicine.

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ral ligaments may be responsible for causing this condition. In 1921, Okabayashi[1] distinguished two layers in one anatomic unit of the uterosacral ligament: a superficial layer, composed of weak peritoneal tissue, and a stronger deep layer, made of connective tissue. Clinical consideration should be given to surgically reconstructing defects in both these layers in order to convert and maintain the uterus in an antevertion position.

Previously, operations for uterine suspension utilized extraperitoneal uterine suspensory structures, such as the round ligament and superficial layer of the uterosacral ligaments. Some pelvic surgeons include extraperitoneal reconstruction of the pouch of Douglas by utilizing either McCall's[2] or Moschowitz's technique.[3]

Methods

Upon conclusion of a pilot study incorporating 15 women,[4-6] a prospective, randomized, double-blind, controlled trial commenced in December 1991 and was completed in December 1994. The study was conducted at the Institute of Video Endoscopy and Laser Surgery of Washington, Premier Surgical Center, and at Howard University Hospital. Based upon the results of the nonrandomized pilot study, the translaparoscopic retroperitoneal uterine suspension operation completion rate was predicted to be 100%. Also predicted was an 85% absence of symptoms (deep dyspareunia, dysmenorrhea, sense of pressure in the bladder and frequent urination, and a sense of pressure in the rectum).

Complete postoperative follow-up was established in each group for 24 months at intervals of 6, 12 and 24. Patients entered the randomized trial if they met five clinical parameters: (1) no symptoms of pelvic pathology, reported and reproducible, during pelvic examination, in addition to uterine retroflexion; (2) deep dyspareunia, (3) dysmenorrhea, (4) pressure in the bladder and frequent urination, and (5) pressure in the rectum.

One hundred two women met the initial selection criteria for the study. Preoperative clinical criteria excluded patients with superficial dyspareunia and lack of at least partial relief from symptoms with a pessary when ultrasonography documented that the uterus was effectively elevated from the cul-de-sac.

Postoperative criteria excluded patients with (1) other types of laparoscopically documented pelvic pathology in addition to uterine retroflexion, (2) microscopically demonstrated endometriosis, and (3) inability to complete postsurgical follow-up for 24 months.

Sixty-two patients were randomly allocated to translaparoscopic retroperitoneal uterine suspension (group I) and to diagnostic laparoscopy (group II). Group I consisted of 32 patients, 19 white and 13 black; the patients' ages ranged from 29 to 42 years (mean, 36), and parity ranged from 0 to 5 (mean, 2). Group II consisted of 30 patients, 23 white and 7 black; their ages ranged from 27 to 43 (mean, 38) and parity from 1 to 4 (mean, 2).

Clinical Experimental Protocol

The study protocol and number of patients were approved by both departments in which the study was conducted. Informed consent was secured from each patient participating in the study, and the experimental nature of the operation was fully explained.

Preoperatively, all patients were to use a vaginal Smith-Hage pessary to predict the outcome of the operation.[7] They also underwent conservative medical treatment with oral contraceptives and nonsteroidal antiinflammatory drugs for at least six months. When both medical treatments failed, a patient qualified for the laparoscopic approach.

Patients were then randomly assigned to group I or II by telephone from a central office, depending on the last digit of the patient's hospital medical record number. Even numbers were reserved for group I and odd for group II.

The clinical parameters were collected prospectively. The patients rated and reported their pain (deep dyspareunia and dysmenorrhea) on a scale of 1–10 (from no pain to severe, disabling pain).[8,9] A sense of pressure in the bladder and frequent urination were studied by the self-monitoring frequency / volume chart.[10] A sense of pressure in the rectum was recorded as present or absent.

The symptoms associated with uterine retroflexion were rated and mapped preoperatively by the author, and the postoperative assessments were made by referring physicians. The same number of skin incisions was made in both group at the time of laparoscopy, so patients could not guess to which group they had been allocated.

In both groups, surgical time began with Veress needle insertion and concluded with complete skin approximation at the end of the procedure.

Groups I and II were also compared according to blood loss evaluations based upon preopera-

tive and postoperative hemoglobin / hematocrit levels.

Statistical Analysis

χ^2 Analysis and Fisher's exact test for 2×2 tables were used to compare dichotomous variables. A *P* value < .05 was interpreted as statistically significant.

Surgical Technique

With the patient under general anesthesia, routine preparation was made for pelvic surgery, a Foley catheter was inserted, a uterine manipulator was placed in the uterine cavity, and the rectal probe was introduced into the rectum with the patient in the modified dorsolithotomy position. Diagnostic laparoscopy of abdominopelvic area was performed in a clockwise manner (Figure 1), and any identifiable pathology was photographed and biopsied.

Laparoscopic retroperitoneal uterine suspension was initiated by identifying the ureters bilaterally, in the vicinity of the uterosacral ligament attachment to the posterior aspect of the cervix. The uterosacral ligaments were stretched by anteriorly lifting and flexing the uterus. The posterior cul-de-sac peritoneum was incised and the rectovaginal space exposed (Figure 2). The excessive cul-de-sac peritoneum was excised and sent for histopathology study. The superficial layers (peritoneal layer) of the uterosacral ligaments[1] were divided with 5-mm laparoscopic scissors. The deep layer of the uterosacral ligament[1] (the stronger part of the ligament retroperitoneally), rectal fascia and vaginouterine fascia (strong retroperitoneal pararectal and paravaginal tissue, which are part of the endopelvic fascia)[11] were identified. A no. 0 polydioxanone (PDS) laparoscopic suture was brought from the deep layer of the uterosacral ligament through the rectal fascia. This suture incorporated the opposite side of the deep layer of the uterosacral ligament, and at this point the suture was brought back through the vaginouterine fascia. This suture emerged near the initial entrance point of the deep layer of the uterosacral ligament. Three to four similar sutures were placed in this area retroperitoneally. This procedure narrowed the pouch of Douglas. At the same time, the deep layer of the uterosacral ligaments were shortened and approximated at the level of their attachment to the posterior aspect of the cervix. The sutures were tied by the initial extracorporeal sliding square knot technique and enhanced with the intracorporeal two-turn flat square knot. The superficial layers of the uterosacral ligaments were placed over the deep layer with a no. 4-0 PDS suture and tied intracorporeally with a two-turn flat square knot (Figures 3 and 4).

Figure 1 Retroflexed uterus occupying the pouch of Douglas and pushing the adnexa out of the posterior cul-de-sac.

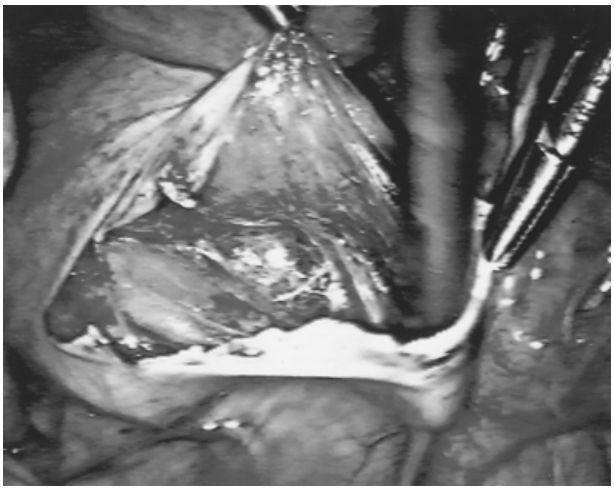

Figure 2 Opening the posterior cul-de-sac peritoneum before the excessive peritoneum is excised.

Cervical dilation was not performed so that possible temporary dysmenorrhea relief[12] could be avoided.

Results

One hundred two patients met the initial experi-

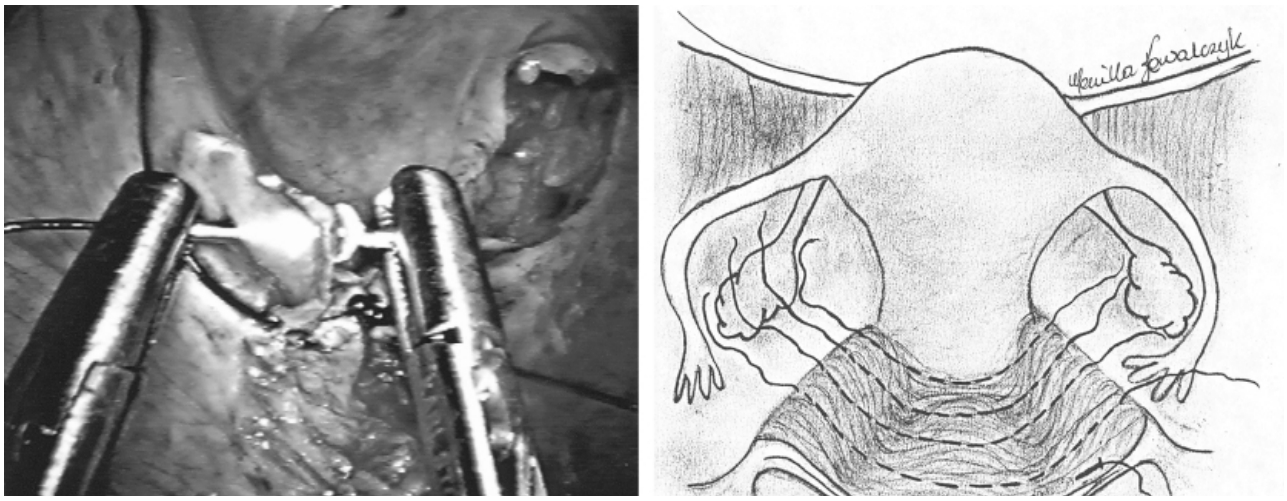

Figure 3 Reconstructing the posterior cul-de-sac.

mental protocol criteria. Sixty-two patients met all the inclusion criteria because they presented all the symptoms (uterine retroflexion, stress incontinence, no identifiable preexisting pelvic pathology, no voiding dysfunction related to detrusor instability) and were able to complete the 24 month follow-up. Nineteen patients from group I and 21 from group II were excluded from the final analysis. Fisher's exact test showed no statistically significant difference between the number of patients who completed the trial in the treated and untreated groups and showed no statistically significant difference in clinical characteristics.

In both groups there were no intraoperative complications. In the immediate postoperative period, 2 patients (6.25%) from group I and 3 patients (10.00%) from group II reported excessive nausea and vomiting; 2 patients (6.25%) from group I and 1 patient (3.33%) from group II had voiding difficulties. In the delayed postoperative interval, 1 patient from group I (1.12%) developed a left-sided, portal, 5-mm, superficial incisional infection, which was treated by superficial reopening of the incision and antibiotics.

In group I, surgical time was 37–55 minutes (average, 42); in group II, 17–29 minutes (average, 24). No statistically significant differences in blood loss existed between the groups, and the bleeding appeared to be minimal.

Following the experimental protocol analysis, which yielded a success rate of 87.5% in the laparoscopic retroperitoneal uterine suspension group, no relief of symptoms in control group II were recorded. In group I, all the patients reported (6, 12 and 24 months after the operation) complete relief from dyspareunia, from a sense of pressure in the bladder and frequent urination, and from a sense of pressure in the rectum. Four of 32 patients (12.5%) reported no relief from dysmenorrhea within two years following surgery. Statistical analysis between the control and experimental groups revealed that in experimental group I, the clinical symptoms were relieved ($P < .0001$) in a statistically significant number of cases.

Discussion

The round ligament, a predominantly peritoneal structure, is the most common extraperitoneal uterine suspensory structure utilized for uterine suspension.[13-18] Using the round ligament for uterine suspension elevates the uterus and does not place it in an antevertion position, but by elevating the uterus, the posterior cul-de-sac and rectovaginal space are exposed to fluctuating intraabdominal pressure, which may create a predisposition to enterocele formation. The pouch of Douglas sometimes opens so wide that the uterine body moves inside it, and to counteract this situation, the size of the posterior cul-de-sac should be reduced. Extraperitoneal reduction of the cul-de-sac dimensions[2,3] may not create a durable postoperative outcome. Therefore, retroperitoneal structures stronger than extraperitoneal composition appear more suitable for achieving this goal. The retroperi-

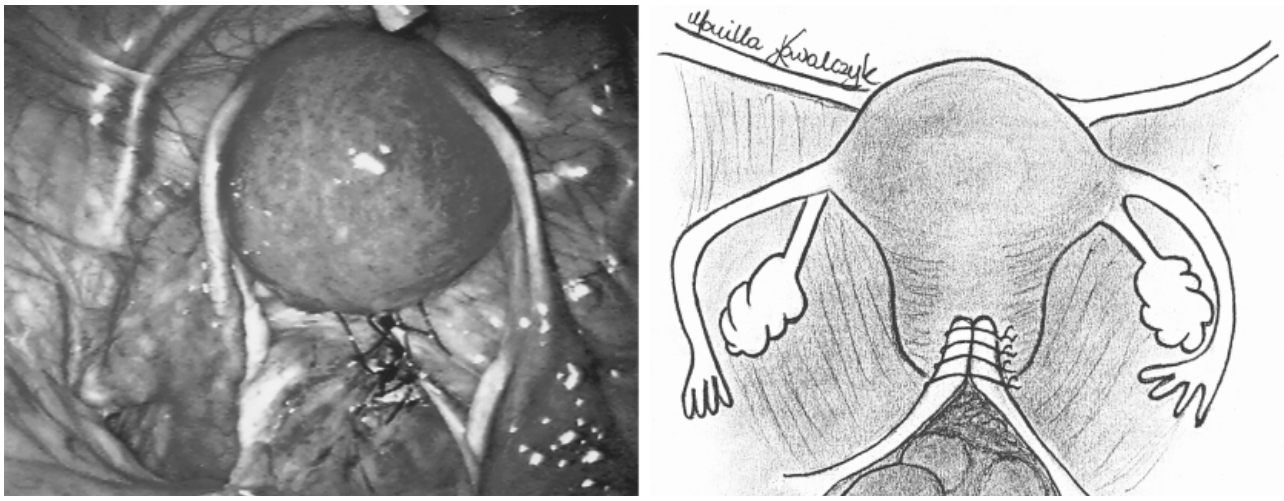

Figure 4 Translaparoscopic retroperitoneal uterine suspension (hysteropexy) completed. The suture line is depicted. The posterior cul-de-sac was narrowed, with the uterine body in the anteverted position.

toneal deep layer of the uterosacral ligaments, rectal fascia and vaginouterine fascia are strong tissues suitable for such durable reconstruction.

In 1955, Fluhmann[19] published a critical review of uterine suspension as a primary operation. Since then, the frequency of this operation drastically declined. However, the demonstrated clinical effectiveness of laparoscopic retroperitoneal hysteropexy in this trial does not support Fluhmann's position. Contrary to his conviction, a statistically significant number of patients experienced relief from symptoms in a selected group of women. Uterine suspension has fallen out of favor since Fluhmann's review of the procedure as imperfect; however, he did not question existing symptoms associated with uterine retroflexion. Fluhman did question the durability of the operation, but he offered a flawed operation as a secondary procedure.

These initial results support the consideration of this operation in those women with complex symptoms (deep dyspareunia, dysmenorrhea, pressure in the bladder and frequent urination, pressure in the rectum and no pelvic pathology in addition to uterine retroflexion). Those women with uterine retroflexion, no symptoms or an isolated symptom (particularly dysmenorrhea) do not require this operation unless proven otherwise. This trial confirmed the well-documented fact that marked uterine retroflexion produces symptoms related only to this medical entity.[20,21]

As this study revealed, in four patients out of 32 (12.5%), dysmenorrhea was refractory to this surgical treatment. Comparing this study (which demonstrated that dysmenorrhea can be ameliorated in 87.5% of cases) to a double-blind trial of laparoscopic uterosacral nerve ablation (with success of 81%[22]) makes it seems likely that plication of the uterosacral ligaments during laparoscopic retroperitoneal uterine suspension may play a role in reducing menstrual pain. However, other symptoms (such as deep dyspareunia, a sense of pressure in the bladder and frequent urination, and a sense of pressure in the rectum) are highly unlikely to be relieved by the uterine nerve ablation procedure itself.

This study appears to have been the first in the medical literature of a surgical retroperitoneal uterine suspension technique that can be executed through either the classic, laparotomy or laparoscopy approach.

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