The Tensile Strength of Uterosacral Ligament Sutures: A Comparison of Vaginal and Laparoscopic Techniques

Patrick J. Culligan, MD, John R. Miklos, MD, Miles Murphy, MD, Roger Goldberg, MD, MPH, Carol Graham, MD, Robert D. Moore, DO, Meg Hainer, MD, and Michael H. Heit, MD, MSPH

OBJECTIVE: To compare the tensile strength of two approaches for uterosacral ligament suturing using a cadaver model.

METHODS: In 12 unembalmed cadavers, four polytetrafluoroethylene sutures were placed through the uterosacral ligaments. In each cadaver, two sutures were placed laparoscopically, and two more were placed vaginally. A single, experienced surgeon placed all laparoscopic sutures (n = 23), and another experienced surgeon placed all vaginal sutures (n = 22). A blinded team of investigators measured the distance from each suture to the ipsilateral ischial spine; determined whether any sutures incorporated ureters, viscera, or large vessels; and then passed the sutures through an apical vaginal incision. Using a hand-held tensiometer, progressive tensile load was then applied to these sutures along the axis of the vagina until they either broke or were completely dislodged from the ligaments.

RESULTS: The average peak tension required to break or dislodge the sutures was 26.2 ± 8.8 psi (laparoscopic) and 22.5 ± 7.4 psi (vaginal) (P = .14, 95% confidence interval [CI] −1.2, 8.6). The average force required for suture breakage (n = 28) was 28 ± 7 psi, and the average force applied when ligament failure occurred (n = 17) was 18.5 ± 6 psi (P < .001, 95% CI −13.8, −5.2). The average distance from a laparoscopic or vaginal suture to the ipsilateral ischial spine was 19.1 ± 7 mm and 17.4 ± 6 mm, respectively (P = .46, 95% CI −3.0, 6.4). None of the sutures from either technique were found to incorporate a visceral structure, ureter, or great vessel.

CONCLUSION: These suturing techniques appear to be equal in tensile strength. (Obstet Gynecol 2003;101:500–3. © 2003 by The American College of Obstetricians and Gynecologists.)

From the Department of Obstetrics, Gynecology and Woman's Health, University of Louisville Health Sciences Center, Louisville, Kentucky; Atlanta Center for Laparoscopic Urogynecology, Atlanta, Georgia; and Evanston Continence Center, Northwestern University Medical School, Evanston, Illinois.

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Recently, use of the uterosacral ligaments as the apical attachment points during reconstructive pelvic surgery has gained widespread acceptance. The intermediate portion[1] of the uterosacral ligament has been identified as the optimal fixation point for safety and strength. The long-term clinical effectiveness of the vaginal approach for suturing these ligaments using standard, nondisposable needle holders has been established.[2–4] No such evidence supports the use of other approaches or surgical devices when using these ligaments in reconstructive pelvic surgery.

Because the ergonomics, lighting, and surgical points of view of laparoscopic, vaginal, and open abdominal surgery are quite different, one cannot assume that these approaches to suturing the uterosacral ligaments are equivalent. Therefore, new techniques or devices for suturing the uterosacral ligaments should be subjected to feasibility studies before being used clinically. Cadaveric studies represent one way to compare new surgical approaches with the established vaginal[2–4] techniques.

Our primary objective for this study was to compare the tensile strength of laparoscopically and vaginally placed uterosacral ligament sutures in a cadaveric model. Our secondary objective was to qualitatively compare the two techniques for suture position along the ligaments and whether they incorporated other vital structures. We also sought to establish a cadaveric model that could be used for future studies involving uterosacral ligament suturing devices or techniques.

MATERIALS AND METHODS

Twelve unembalmed female cadavers were used for this project. These cadavers were obtained through the University of Texas Southwestern Medical School Willed Body Program. Through that program, all cadavers are screened for human immunodeficiency virus and hepatitis B virus before they are deemed acceptable for use in research. No other inclusion or exclusion criteria were

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applied. They had all been frozen shortly after death and were shipped to our study site to be thawed 72 hours before our investigation. The only demographic information available for these cadavers was their age at the time of death. To maximize the clinical relevance of our results, we simulated actual operating room conditions and techniques as closely as possible. This entire study was performed on a single day, and the ergonomics and lighting did not differ between cadavers.

We did not seek formal approval for this study protocol because the University of Louisville Human Studies Committee does not require approval for cadaveric studies. However, the study was funded (ie, approved) by a competitive intramural grant through the University of Louisville Intramural Research Incentive Grant Committee.

In each cadaver, four 2.0 polytetrafluoroethylene sutures (GoreTex, W.L. Gore and Associates Inc., Flagstaff, AZ) were placed through the uterosacral ligaments in a "figure-of-eight" fashion. Two of these sutures were placed laparoscopically, and two were placed vaginally. We attempted to place all laparoscopic and vaginal sutures in the intermediate section (ie, 1–2 cm posterior to the ischial spine) of the uterosacral ligament perpendicular to the fibers of the ligament, as recommended by Buller.[1]

Block randomization (using blocks of four) was performed to determine whether the laparoscopic and vaginal sutures were to be placed on the left or right side for each cadaver and to determine whether the proximal or distal sutures were the first to be tested in each cadaver. Therefore, both the side of suturing and the order of pullout were randomly assigned.

Two laparoscopic sutures were placed first, on one side in each cadaver. The laparoscopic sutures had to be placed first, because doing otherwise would have compromised the pneumoperitoneum. A single surgeon (JM) placed all of these sutures using a nondisposable, 5-mm needle driver (Y-Handle Snap-A-Part, Elmed Co., Addison, IL). Three laparoscopic ports (DuraGold, Applied Medical Co., Rancho Santa Margarita, CA) were used: one 12-mm epigastric port (2 cm caudad to the umbilicus) and two 5-mm ports (one suprapubic and one right paramedian). A 10-mm, 0° laparoscope was placed through the epigastric port. Steep Trendelenburg position was used, and the bowel was retracted away from the sidewall. The uterosacral ligaments were held on stretch with a vaginal probe, and they were traced backward to their most proximal point of origin. Two figure-of-eight sutures were placed through the designated ligament in the intermediate[1] portion. No knots were tied in these sutures. The two free ends of each suture were left lying along the ipsilateral pelvic sidewall.

For the vaginal suturing, all cadavers remained in the dorsal lithotomy and Trendelenburg position. The peritoneal cavity was entered through a transverse incision at the vaginal apex, and a surgical towel was inserted to retract the bowel out of the pelvis. The posterior edge of the vagina was grasped with two 12-in Allis clamps, and the uterosacral ligaments were visualized. The sutures that had been placed laparoscopically were visualized but not touched by the vaginal surgeon. On the opposite side, the ischial spine and uterosacral ligament was palpated. Two retractors (Briesky-Navratil, Marina Medical, Hollywood, FL) were positioned at 3 or 9 o'clock (to protect the structures of the pelvic wall) and at 5 or 7 o'clock (to protect the rectum). A curved needle holder (14-in Nolan CVD tip, Marina Medical, Hollywood, FL) was used to place two sutures through the uterosacral ligament in figure-of-eight fashion. As was the case with the laparoscopic sutures, an attempt was made to place all vaginal sutures in the intermediate[1] portion of the ligament.

A separate, blinded team of investigators then performed laparotomies on all of the cadavers. This team was blinded as to which sutures had been placed laparoscopically or vaginally. The distance from each suture to the ipsilateral ischial spine was measured in mm. The sutures were then passed through the vaginal incision and fastened to a hand-held digital tensiometer (DFG51, Omega Engineering Inc., Stanford, CT). Progressive tensile load was applied to the sutures individually along the axis of the vagina until they broke or were dislodged from the ligament. Before and after suture pullout, this team also determined whether any of the sutures had compromised the ureters, viscera, or any large vessels.

A power calculation was performed, based on an assumption that the vaginally placed sutures would have a mean tensile strength of 24 psi and a standard deviation of 3 psi. There is no published data regarding the "acute" tensile strength of uterosacral ligament sutures, so these estimates were made based on our previous, unpublished experience measuring tensile strength of various pelvic ligaments in female cadavers. We first decided that a 20% difference in tensile strength between the two techniques would be clinically significant. We then determined that in order to have 99% power of detecting a 20% difference between the suturing techniques with an α of 0.05, we needed 20 data points in each arm of the study. We did not power the study to detect a significant difference between suturing techniques for position along the ligament relative to the ischial spine. For the purposes of statistical analysis, we considered each uterosacral suture "pull-out" as an independent event. As such, there were four potential tensile strength data points per cadaver.

The data was assessed for normality to determine whether mean or median values were compared. The separate variance *t* test was used to compare the mean tensile strength of sutures placed vaginally or laparoscopically. Mean distances from the sutures to the ischial spines were compared using the separate variance *t* test as well. Separate analyses were performed to determine whether either surgical technique resulted in a "favorable" side for tensile strength and to determine whether presence of a uterus made a difference in tensile strength. Statistical analysis was performed with SPSS for Windows 10.0 (SPSS Inc., Chicago, IL).

RESULTS

The average age of the cadavers at the time of death was 72 ± 9.8 years. A total of 48 sutures were placed in the twelve cadavers, as planned. During tensile strength testing, one set of laparoscopic sutures and two sets of vaginal sutures dislodged together when the first suture was pulled. That left 22 vaginal and 23 laparoscopic data points available for analysis. A uterus was present in 6 of the 12 cadavers.

The average distance from a laparoscopic or vaginal suture to the ipsilateral ischial spine was 19.1 ± 7 mm and 17.4 ± 6 mm, respectively ($P = .46$, 95% confidence interval [CI] −3.0, 6.4). However, according to a post hoc power calculation, our chance of making a type II error in this assessment was 86% (power to detect a difference: .14). None of the sutures from either technique were found to incorporate a visceral structure, ureter, or great vessel.

When all laparoscopic and vaginal tensile strength values were considered together, the average force required for suture breakage was significantly higher than the force required for ligament failure. The presence or absence of a uterus made no difference. The mean value for suture breakage ($n = 28$) was 28 ± 7 psi, and the mean force applied when ligament failure occurred ($n = 17$) was 18.5 ± 6 psi ($P < .001$, 95% CI −13.8, −5.2). The mean tensile strength of all sutures placed in cadavers with and without uteri were 24 ± 8 psi and 24 ± 9 psi, respectively ($P = .83$, 95% CI −5.6, 4.5).

We found no significant difference between the tensile strength of vaginal or laparoscopic sutures, and both techniques resulted in similar tensile strength between the left and right sides. The average peak tension required to break or dislodge the laparoscopic and vaginal sutures was 26.2 ± 8.8 psi and 22.5 ± 7.4 psi, respectively ($P = .14$, 95% CI −1.2, 8.6). The mean tensile strength of laparoscopic sutures placed on the left side and right side were 25 ± 9 psi and 27 ± 9 psi, respectively ($P = .46$, 95% CI −10.5, 5.0). The mean tensile strength of vaginal sutures placed on the left side and right side were 23 ± 9 psi and 22 ± 6 psi, respectively ($P = .9$, 95% CI −6.5, 7.4).

DISCUSSION

Our objectives for this study were to compare the tensile strength and placement of two popular uterosacral suturing techniques. By doing so, we created a scientific model that could be used for studying feasibility of other devices and techniques designed for suturing the uterosacral ligaments.

We recognized the limitations of this study design, and we attempted to account for all of the confounding factors. Our inability to fully standardize the surgical approaches was both a strength and weakness of our study design. The surgeons used identical sutures and nondisposable needle holders, and they each attempted to place sutures through the intermediate[1] portion of the ligament. However, no further standardization was possible. In an effort to maximize the clinical relevance of our results, both surgeons simply tried to duplicate the techniques used in their clinical practices. Because we could not account for surgical skill as a confounding factor in our statistical analysis, we used only one experienced surgeon for each technique. Both surgeons are fellowship-trained urogynecologists and have refined their techniques during more than 200 uterosacral vaginal vault suspensions. Thus, we attempted to minimize the effect of differing surgical ability by having only very experienced surgeons place the sutures. That decision may limit the external validity of our results, which is a limitation that exists with any surgical study.

The cadavers varied in size, age, and medical history, and there was a possibility of varied technique during the tensile strength testing. We used unembalmed cadavers, because the integrity of their tissue planes is similar to living tissue. We attempted to deal with the confounding factors within the cadavers by randomizing both the side used for each technique and the order of suture pullout. We limited the bias associated with tensile strength testing by blinding the investigators as to the suturing techniques, and we attempted to reduce the variance of tensile strength testing by standardizing the pullout technique.

Our study design hinges on the assumption that the tensile strength of the sutures should correlate with their clinical utility in reconstructive surgery. We assumed that a 20% difference in tensile strength between the two techniques would be clinically relevant. Although the clinical relevance of this outcome measure is unknown, we do know that the vaginal approach to uterosacral ligament suturing is clinically effective.[2–4] Because the

threshold of tensile strength necessary to achieve this clinical success is unknown, we assumed that any new uterosacral ligament suturing device or technique (in this case the laparoscopic technique) should be similar in tensile strength to the vaginal technique.

Our decision to consider each suture pull-out test an "independent" event could be questioned. Within a given cadaver, the strength and integrity of the right and left uterosacral ligaments are largely independent of each other. Although tissue quality within a given cadaver is relatively uniform, the right and left uterosacral ligaments could have other differences (breakage points, stretching, etc) related to a patient's medical history. Therefore, pulling sutures from one ligament should not affect the results found on the opposite side. We recognized that within a given uterosacral ligament, the tensile strength testing of one suture would certainly influence the results for the other suture. In other words, we expected the tensile strength of the first suture in any ligament to be greater than that of the second suture. However, we chose to consider the two sutures within a given ligament as independent, because we randomized the order of suture pull-out. Thus we designed our randomization scheme (ie, randomizing both the side of placement and order of pullout for each technique) as a way of dealing with the fact that determinations of tensile strength within a single cadaver (ie, subject) may not, statistically speaking, be considered "independent events."

These limitations not withstanding, we demonstrated similar tensile strength between uterosacral ligament sutures placed vaginally and laparoscopically by experienced surgeons using nondisposable needle holders. This study design could be used to evaluate the feasibility of other devices and techniques for suturing the uterosacral ligaments.

As the proportion of elderly women in the United States rises, the demand for urogynecologic surgery will increase dramatically as well.[5] This demand is likely to inspire the development of products designed to make prolapse surgery faster and easier. Ideally, the feasibility of such surgical devices would be scrutinized in cadaveric and/or animal models prior to their clinical use. However, the United States Food and Drug Administration has no such requirements for new devices, as long as they have "substantial equivalence" to existing technology.[6] In other words, United States Food and Drug Administration approval for a surgical device does not necessarily imply that the device will perform as expected. By insisting to see feasibility data prior to using new surgical devices for reconstructive pelvic surgery, clinicians could be more confident about the clinical outcomes associated with these devices.

REFERENCES

1. Buller JL, Thompson JR, Cundiff GW, Sullivan LK, Schon Ybarra MA, Bent AE. Uterosacral ligament: Description of anatomic relationships to optimize surgical safety. Obstet Gynecol 2001;97:873–9.
2. Shull BL, Bachofen C, Coates KW, Kuehl TJ. A transvaginal approach to repair of apical and other associated sites of pelvic organ prolapse. Am J Obstet Gynecol 2000;183:1365–74.
3. Barber MD, Visco AG, Weidner AC, Amundsen CL, Bump RC. Bilateral uterosacral ligament vaginal vault suspension with site-specific endopelvic fascia defect repair for treatment of pelvic organ prolapse. Am J Obstet Gynecol 2000;183:1403–11.
4. Karram M, Goldwasser S, Kleeman S, Steele A, Vassallo B, Walsh P. High uterosacral vaginal vault suspension with fascial reconstruction for vaginal repair of enterocele and vaginal vault prolpasè. Am J Obstet Gynecol 2001;185:1339–43.
5. Luber KM, Boero S, Choe J. The demographics of pelvic floor disorders: Current observations and future projections. Am J Obstet Gynecol 2001;184:1496–503.
6. U.S. Department of Health and Human Services. Determination of intended use for 510(k) devices. Document #897, January 30, 1998. Rockville, Maryland: U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health, 1998.

Address reprint requests to: Patrick J. Culligan, MD, University of Louisville Health Sciences Center, Department of Obstetrics, Gynecology and Woman's Health, 315 East Broadway M-18, Louisville, KY 40202; E-mail: pculligan@louisville.edu.

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