

Date:	6/1/16
Title	Uterosacral Ligament Suspension: A Radiographic Study of Anatomy and Suture Location
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Hatton #:	15-092

IRB Review Type:

☐Exempt☐Expedited☒Full Board**Purpose of Study:** Please describe:

Uterosacral ligament suspension is a commonly performed procedure to support the vaginal apex at the time of pelvic reconstructive surgery for pelvic organ prolapse (POP). Despite being a well established durable option for patients, there is little research describing ligament suspension suture location in the living model. The available literature is limited to cadaveric studies, which suggest suture placement is in close proximity to vital structures such as the ureter, blood vessels, rectum and nerves.

Hypothesis or Research Question

We, therefore, seek to describe suture location in relation to the surrounding anatomy in post-operative patients following high uterosacral ligament suspension. Our secondary aim is to determine safe zones for suture placement.

Background

High uterosacral ligament suspension is a common procedure performed for the treatment of pelvic organ prolapse. It is typically performed at the time of vaginal hysterectomy or other vaginal reconstructive procedures. The technique involves affixing the vaginal apex to the bilateral uterosacral ligaments using either permanent or delayed-absorbable sutures.

Although considered a safe and minimally invasive procedure, complications from suture placement have been well documented and can cause significant morbidity for the patient. Ureteral occlusion has been reported to be as high as 4.5-11% [1, 3, 4]. Other risks include injury to major blood vessels and nerve entrapment.

Cadaver studies have evaluated suture location relative to the ureter, rectal lumen and sacral nerves. In one study using 15 cadavers, sutures were noted at a mean distance of 14 mm from Pauls

the ureter with a range of 0-33 mm [2]. Additionally, sutures were a mean distance of 10 mm from the rectal lumen [2]. Vascular perforation by sutures has been documented as high as 4.1% in another model [2]. Nevertheless, cadaveric studies have inherent limitations due to nature of tissue fixation and lack of dynamic function of nerves, vessels and the ureter.

Postoperative pain, numbness and weakness from nerve injuries during uterosacral ligament suspension may occur in up to 1.6- 6.8% of patients [5,6,7]. Nerve entrapment by sutures has been demonstrated in several cadaveric studies as well [8,9]. However, current imaging techniques prohibit characterization of the pelvic nerves accurately. Clinical information regarding nerve function pre and post operatively will inform regarding anatomic placement of these sutures.

A more thorough understanding of the postoperative location of the sutures placed during uterosacral ligament suspension will be valuable to pelvic surgeons. Characterization of the surrounding anatomy in a living model will enhance surgical technique. This in turn may allow us to delineate safer suture locations and decrease the incidence of morbid complications for patients.

Research Plan

- **Study Design**
 - Prospective cohort
- **Setting for the study**
 - Cincinnati Urogynecology Associates and Good Samaritan and Bethesda North Hospitals
- **Participants**
 - *Describe*
 - Seventeen women (aged 18-85) under the care of Cincinnati Urogynecology Associates who have chosen vaginal hysterectomy with uterosacral ligament suspension (USLS) as their treatment choice for pelvic organ prolapse (POP) will be approached for enrollment.
 - At the time of surgery, a titanium vascular clip (size small) will be applied to the base of each delayed absorbable suture placed at the vaginal apex on the internal vaginal side to help in identification by imaging.
 - All patients will undergo intraoperative cystoscopy with documentation of ureteral patency as per standard surgical technique.
 - All patients will undergo a postoperative CBC and BMP on postoperative day #1 as per standard protocol for the division.
 - On POD#1, patients will undergo CT scan of the pelvis. The CT scan will involve administration of IV contrast for imaging of the ureters and vascular structures.
 - The clip will fall off when the sutures dissolve at 12 week postoperatively.
 - All patients will be asked to complete a lower extremity neurological questionnaire preoperatively and postoperatively

- All patients will undergo a preoperative and postoperative lower extremity neurological physical exam by one of the study investigators
- *Inclusion criteria*
 - Women, aged 18-85 with POP who have elected USLS for treatment
- *Exclusion criteria*
 - Contraindication to computed tomography (CT), or intravenous (IV) contrast
 - Those with claustrophobia
 - Previous POP surgery
 - Previous pelvic surgery to the fallopian tubes, ovaries, or rectum
 - Previous pelvic radiation
 - Known pelvic inflammatory disease or endometriosis
 - Those with preexisting ureteral or vascular pathology or sacral anatomic abnormality
 - Those with connective tissue disorders
 - Those with preexisting neuropathy, chronic lower extremity pain disorders, or neurological disorders
 - Those with renal anomalies such as pelvic kidney, duplication of the collecting system, prior nephrectomy
 - Those with allergy to titanium
 - Removal of the uterosacral sutures due to ureteral obstruction intraoperatively
- This is a one-group pilot study, therefore a sample size calculation was not performed; all participants will undergo the same radiographic procedures
 - A sample size of 15 women was felt to be representative, we will enroll 17 to allow for possible exclusions.
- **Data Collection**
 - Basic demographics, surgical procedure data and laboratory results will be collected (Appendix A)
 - We will collect data on the exact location of the uterosacral sutures including its relationship to the vasculature, ureters and rectum using computed tomography. Exact imaging protocols have been standardized by the radiology department at TriHealth. (Appendix B)
 - Both sutures on each side will be measured at the midsection of the clip relative to structures
 - Distances (in mm) between the sutures and surrounding structures such as the bilateral ureters and rectum will all be measured.
 - The PI and the radiologist sub-investigator will review all images for measurements. These will be taken using standard radiologic techniques.
 - We will collect data on the preoperative and postoperative neurological physical exam findings (Appendix C)

- We will collect data from the preoperative and postoperative neurological questionnaire (Appendix D, E)
- We will collect data 6 weeks postoperatively regarding any complications during the postoperative period
- **Intervention or experimental aspect of the study**
 - This is a descriptive pilot study; no intervention
- **Statistical Analysis**
 - Descriptive statistics will be calculated for demographics and all measurements. Mean (SD) values will be used for data meeting the assumptions for normality; median (IQR) values will be used for data not meeting the assumptions for parametric procedures.

Ethical Considerations

- **Informed consent**
 - Following study recruitment in the offices of Cincinnati Urogynecology Associates, the informed consent process will be administered by the research nurse or one of the study investigators. Informed consent statements will be kept in a locked file drawer in the office of the principal investigator, which will be locked when unoccupied. They will be kept for three years following study closure, and then shredded.

- **Privacy information**

Patients will be identified by a unique study ID. Patient names will be used solely for the purpose of recruitment for the study. Data sheets will be identified with the study ID number. This information will not be kept with the data, nor will any participant's name be associated with the data. The study records will be stored -for 2 years after completion of the study, and then deleted/purged. Paper data sheets will be kept for 10 years after study completion, and then shredded.

Cost/Budget

CT pelvis w/ contrast (74% discount)	\$215.80 x 17	\$3668.60
IV Contrast	\$100.00 x 17	\$1700.00
Folders		\$15.29
Total:		\$5383.89

Estimated Period of time to complete study:

- **When will study begin?** Following IRB approval (November 2015)
- **What is the estimated duration of the study?**
 - **Pre data collection:** 2 weeks
 - **Data collection:** 6 months (completed by April 2016)
 - **Data analysis:** 1 month (completed by May 2016)

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- **When and how will results be disseminated?** We will submit these findings for presentation at one of our specialty's scientific meetings.

References

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6. Flynn, M., et al. (2006). "Sensory nerve injury after uterosacral ligament suspension." American Journal of Obstetrics and Gynecology **195**(6).e1869-1872.
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9. Wieslander, C. et al. (2007). "Uterosacral ligament suspension sutures: Anatomic relationships in unembalmed female cadavers." American Journal of Obstetrics and Gynecology **197**(6). 672.e1-672.e6