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Protocol for a prospective multisite cohort study investigating hysterectomy versus uterine preservation for pelvic organ prolapse surgery: the HUPPS study

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ABSTRACT

Introduction Pelvic organ prolapse (POP) is the descent of pelvic organs into the vagina resulting in bulge symptoms and occurs in approximately 50% of women. Almost 20% of women will elect surgical correction of this condition by age 85. Removal of the uterus (hysterectomy) with concomitant vaginal vault suspension is a long-standing practice in POP surgery to address apical (uterine) prolapse. Yet, contemporary evidence on the merits of this approach relative to preservation of the uterus through suspension is needed to better inform surgical decision making by patients and their healthcare providers. The objective of this study is to evaluate POP-specific health outcomes and service utilisation of women electing uterine suspension compared with those electing hysterectomy and vaginal vault suspension for POP surgery up to 1-year postsurgery.

Methods and analysis This is a prospective cohort study planning to enrol 321 adult women with stage ≥2 POP from multiple sites in Alberta, Canada. Following standardised counselling from study surgeons, participants self-select either a hysterectomy based or uterine preservation surgical group. Data are being collected through participant questionnaires, medical records and administrative data linkage at four time points spanning from the presurgical consultation to 1-year postsurgery. The primary outcome is anatomic failure to correct POP, and secondary outcomes include changes in positioning of pelvic structures, retreatment, subjective report of bulge symptoms, pelvic floor distress and impact, sexual function and health service use. Data will be analysed using inverse probability weighting of propensity scores and generalised linear models.

Ethics and dissemination This study is approved by the Conjoint Health Research Ethics Board at the University of Calgary (REB19-2134). Results will be disseminated via peer-reviewed publications, presentations at national and international conferences, and educational handouts for patients.

Trial registration number NCT04890951.

Strengths and limitations of this study

- This study enables women to self-select their surgery group to promote patient autonomy in conjunction with propensity score weighting to account for systematic differences in patient characteristics across groups, striking a balance between shared decision making and methodological rigour.
- Surgical procedures in both the hysterectomy and uterine preservation groups will be restricted to those involving native tissue repair to ensure procedures being compared are analogous.
- Outcomes include a combination of clinical/anatomic measures, validated patient-reported outcome measures and healthcare use metrics providing a comprehensive view of postsurgery outcomes.
- Unmeasured confounding is possible due to the observational nature of this study.
- As with all prospective studies, there is the potential for attrition which we have accounted for in our sample size calculations.

INTRODUCTION

Pelvic organ prolapse (POP) is a disorder where one or more pelvic organs (ie, bladder, uterus, small bowel, rectum) descend from their normal position and bulge into or through the vagina.[1] Symptoms include sensations of pressure or pain in the pelvis and/or vagina, urinary incontinence, difficulties with defecation and uncomfortable intercourse.[2] Major risk factors for POP are older age, high body mass index, increasing parity and number of vaginal deliveries.[3] POP greatly affects women's well-being, and is associated with a diminished quality of life,[4] increased risk of depression and anxiety,[5 6] and negative body image.[7 8] Women with POP often report self-consciousness, isolation and avoidance of sexual intimacy due to embarrassment or shame.[7 8] Estimated prevalence of POP is 3%–6% when based on patient-reported symptoms but up to 50% when based on vaginal examination,[9 10] and 12%–19% of women will have POP surgery by age 85.[11 12] Initial surgery is not always successful, and

around 19% of women with prior POP surgery undergo reoperation.[11]

POP surgery traditionally involves removal of the uterus (hysterectomy) to access pelvic ligaments and tissues for suspension of the vagina, even in cases when the uterus is not among the prolapsed organs.[13] Data from British Columbia, Canada indicate that POP is the most common indication for vaginal (72%) and laparoscopic (43%) benign hysterectomies.[14] Inclusion of hysterectomy in POP surgery is entrenched in medical culture, such that the essential role of uterus removal in surgery success has mainly been investigated in the last decade. As understanding of the pathophysiology of POP has improved, clinicians have acknowledged that the uterus may act as a 'keystone' of support in the pelvis; removal may thus have unintended consequences for patients through destabilisation of pelvic support, and consequently, recurrence of POP years after hysterectomy.[15 16] A 2018 systematic review of 53 studies reported that POP surgery with uterine preservation is associated with less blood loss, shorter operating time and lower odds of graft complications compared with similar surgical routes with hysterectomy, without significant differences in POP outcomes in the years following surgery.[17] However, existing literature is generally limited by small sample sizes (N<200), retrospective data collection and variable lengths of follow-up. In some instances, comparisons of procedures are not necessarily analogous due to use of different ligaments as suspensory anchors in each surgical group, or comparing native tissue repairs to those augmented with permanent mesh. Additionally, most studies focus on medical definitions of POP cure, with less consideration given to patient-reported outcome measures (PROMs) such as subjective reports of POP cure or sexual function, and healthcare utilisation. Methodologically rigorous evidence that investigates both clinical and patient outcomes of uterine preservation vs hysterectomy for POP surgery is needed.

Study objectives

The objective of this study is to evaluate POP-specific health outcomes and service utilisation of women electing uterine preservation compared with those electing hysterectomy for POP surgery up to 1-year postsurgery, using a combination of clinical and patient-reported outcomes.

METHODS AND ANALYSIS

Study design and setting

We are conducting a prospective cohort study following patients from their first surgical consultation to 1-year postoperation. Participants are being recruited from two hospitals, an academic tertiary centre and an academic community hospital, in Calgary, Alberta, Canada. The five participating surgeons at both sites are urogynaecologists who have completed a fellowship in pelvic reconstructive surgery and are trained to perform both uterine-preserving surgeries and hysterectomies. Our team's approach to care is that, in the absence of pelvic pathology such as cervical or endometrial hyperplasia, all women seeking surgical correction of POP are supported to make an individualised decision between uterine preservation or hysterectomy-based procedures, with no preference implied by the surgeon. In the context of apical prolapse, there are no patient risk factors (eg, obesity, age) that we deem to necessitate one procedure over another. Standardised pamphlets developed by the International Urogynecology Association are used to guide collaborative discussion with patients, but decision making is ultimately patient driven.

In alignment with this approach, our group opted for the pragmatic design choice of a prospective cohort over a randomised controlled trial (RCT) for several reasons. First, we are aiming to generate evidence on effectiveness, taking into account a routine care setting and diverse patient population.[18] While RCTs are rightfully considered the 'gold standard' of internal validity, effect sizes observed in a controlled and ideal setting do not readily translate into a 'real-world' setting, where patient-level, provider-level and system-level factors influence intervention implementation.[19] Second, RCTs often suffer from low external validity;[20] participants in RCTs systematically differ from the general patient population,[21] and this can be attributed to strict eligibility criteria and/or intervention procedures, but also the implicit notion that participants are comfortable relinquishing their treatment autonomy to the randomisation process. The latter is particularly problematic in the context of gynaecology, where only one in three women have no preference on whether or not to keep their uterus in treating POP.[22 23] Moreover, the notion of removing women's autonomy in decisions regarding their reproductive organs too closely resembles the paternalistic backdrop of reproductive healthcare and research that our field has been working to dismantle, and this point should not be overlooked in the quest of internal validity. To this end, our group felt that a non-randomised design where women self-select their surgical group is the most pragmatic, patient-centred and ethical approach to studying this topic.

Eligibility criteria

Patients are eligible if they: (1) have diagnosed POP of stage ≥2 using the globally recognised Pelvic Organ Prolapse-Quantification System (POP-Q); (2) elect surgical management of POP; (3) demonstrate presence of apical prolapse on clinical examination deemed to require either a hysterectomy and concomitant vaginal vault suspension *or* uterine suspension to properly address their POP during surgical correction; (4) have no prior hysterectomy; (5) desire no further pregnancy; (6) can communicate in English and (7) are ≥18 years in age.

Study team members identify eligible patients prior to their surgery and invite them to participate during their initial consultation. Recruitment began in July 2020 and is ongoing at the time of publication.

Surgical intervention

Women are classified into one of two surgical groups: (1) hysteropexy (ie, uterine preservation through suspension); or, (2) hysterectomy and vaginal vault suspension (ie, uterine removal and sewing the vagina upwards). Receipt of either intervention is part of standard care. In alignment with the pragmatic nature of this study,[18] concomitant procedures are permitted and recorded, such as anterior and/or posterior colporrhaphy, incontinence procedures, salpingectomy, oophorectomy or endometrial ablation. Within each group, we subclassify the surgical route (vaginal vs laparoscopic surgery) and anatomic ligament used for upwards fixation of the uterus or posthysterectomy vagina (sacrospinous vs uterosacral ligament). These groupings allow hysterectomy versus uterine-preserving procedures to be compared in aggregate, and by surgical modality and suspensory ligament. We estimate that roughly 35% of women will select uterine preservation and 65% will select hysterectomy based on published literature and our clinic experience.[22–24] All repairs are native tissue; no mesh is being used to correct POP.

A listing of the uterine preservation and hysterectomy-based procedures used in this study is in online supplemental appendix A. Techniques used for vaginal and laparoscopic uterosacral vault suspensions after hysterectomy for apical prolapse have been previously published by our team,[25] and methods of sacrospinous suspension are analogous to prior publications with the Boston Scientific Capio device.[26 27] A surgical video of the laparoscopic uterine suspension has been developed by our team and will be available on the Canadian Society for the Advancement of Gynecologic Excellence Video Library as of September 2021 (https://cansagevideos.com).

Data collection

Table 1 depicts the process of data collection, which occurs from three sources across four time points.

Participant questionnaires

Participants are asked to complete a series of questionnaires before surgery, at 6–8 weeks postsurgery and at 1-year postsurgery. Questionnaires collect information on sociodemographic characteristics, medical and obstetrical history, and three pelvic floor symptom measures that were selected by the Canadian Society for Pelvic Medicine in 2019 as key PROMs to be used in clinical research.[28] Strategies to reduce missing data at the data collection stage include administering questionnaires by a medium of the patient's preference (ie, paper or electronic), serial follow-up contacts by email, telephone and during clinical visits, and honorariums for completing the 1-year postsurgery questionnaire.

Table 1 Data collection sources and timeline

	T1: Presurgery	T2: Perioperative	T3: 6–8 weeks follow-up	T4: 1 year follow-up
Participant Questionnaires	► Sociodemographic: age; gender; education; ethnicity ► Personal: body mass index ► Obstetrical: parity; previous complications; modes of delivery ► Occupational: job; heavy lifting ► Condition specific: pelvic floor symptoms; pain; sexual functioning; quality of life		► Condition specific (repeat from T1)	► Condition specific (repeat from T1)
Medical Charts	► POP-Q stage and scores ► Type(s) of POP ► Incontinence ► Uterine size	► Intraoperative: anaesthesia; type and route of surgery; length of surgery; blood Loss ► Postoperative: length of stay; narcotic use; procedural complications; infection (eg, abscess); spontaneous voiding	► POP-Q stage and scores	► POP-Q stage and scores ► Retreatment with physiotherapy, pessary or surgery
Administrative Data				► Emergency department visits ► Hospital readmission

POP, pelvic organ prolapse; POP-Q, Pelvic Organ Prolapse-Quantification System.

The Pelvic Floor Impact Questionnaire-7 (PFIQ-7) is a 7-item scale with 3 subscales each measuring how POP, colorectal-anal and urinary symptoms impact activities, relationships and feelings.[29] Respondents are asked how each set of symptoms affect various domains of life (eg, ability to do household chores) on scale from 0 (not at all) to 3 (quite a bit). Higher total or subscale scores indicate a greater degree of pelvic floor-related impact on daily function. Psychometric properties of the PFIQ-7 and subscales include excellent correlation to the full PFIQ and test–retest reliability, and responsiveness to change following both surgical and non-surgical treatments.[29 30]

The POP Incontinence Sexual Questionnaire Revised (PISQ-IR) is a scale measuring sexual functioning in the context of POP symptoms, containing 1 block of 22 items for sexually active respondents with 6 subscales, and a separate block of 12 items for sexually inactive respondents with 4 subscales.[31] Subscales include condition impact (both blocks), global quality (both blocks) and desire (sexually active block). Higher total or subscale scores indicate a greater impact of POP on sexual function. Psychometric properties of the PISQ-IR and subscales include good internal consistency, test–retest reliability, and criterion validity, and responsiveness to change following surgical treatment.[31]

The Pelvic Floor Distress Inventory-20 (PFDI-20) is a 20-item scale with 3 subscales each measuring presence and related distress from POP (6 items), colorectal-anal (8 items) and urinary (6 items) symptoms.[29] Respondents are asked whether they experience symptoms (eg, pressure in the lower abdomen) and, if so, how bothersome symptoms are on a scale from 1 (not at all) to 4 (quite a bit). Higher total or subscale scores indicate a greater degree of pelvic floor-related distress. Psychometric properties of the PFDI-20 and subscales include excellent correlation to the full PFDI and test–retest reliability, and responsiveness to change following both surgical and non-surgical treatments.[29 30]

Medical charts

Information from healthcare visits during the study period is extracted from participant medical charts and entered into study data collection forms. These visits include the routine presurgical consultation, time of surgery and postoperative stay, routine postoperative visit at 6–8 weeks, and a non-routine visit for study purposes at 1-year following surgery. To ensure accuracy of data entry from charts, a random subset of forms from 25% of the final sample will be verified by a second extractor.

Clinicians complete a pelvic exam for each participant at the presurgical consultation and at both follow-up visits. A cough-stress test is performed to evaluate for stress urinary incontinence and a POP-Q examination is performed to evaluate POP. The POP-Q is a clinical system for quantifying and staging pelvic support in women. It includes six points in the pelvis for measurement in centimetres above/proximal to the hymen (negative number) or below/distal to the hymen (positive number) with the plane of the hymen defined as zero, and three landmarks (eg, total vaginal length) measured in centimetres. Measurements are typically reported in integers, ranging from −10 to +10, inclusive of 0. These nine measurements are used to assign individuals to a corresponding stage, ranging from 0 (no prolapse) to 4 (severe prolapse). The POP-Q is the most frequently used measure of surgical failure in existing literature.[32]

Administrative data

Administrative data will be deterministically linked to questionnaire and chart data using a combination of personal health numbers and unique identifiers such as date of birth and postal code. Linked databases include the Discharge Abstract Database (DAD), which contains data on all inpatient hospitalisations, and the National Ambulatory Care Reporting System (NACRS), which houses data on all emergency department visits, day surgeries, and some hospital-based and community-based outpatient clinics.

Outcomes

Primary

Our primary outcome will be anatomic failure to correct apical POP at 1-year postsurgery, measured using the POP-Q tool and defined as descent of the apex (point C) equal to or beyond one half of the total vaginal length.

Secondary

POP presentation

Overall failure to correct POP will alternatively be measured as POP-Q stage ≥2 in any compartment, and as retreatment of POP with physiotherapy, pessary or repeat surgery at 1-year postsurgery. We will also compare the changes in individual POP-Q points C, Aa, Ap, Ba, Bp and Total Vaginal Length (TVL) at 1-year postsurgery. Subjective failure will be measured by patient report of bulge symptoms at 6 weeks or 1 year, using one item on the PFDI-20: 'Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?', including a sensitivity analysis exploring increasing gradation of bother (somewhat, moderately, quite a bit).[33] Clinical measures of pelvic floor function will include presence of new incontinence symptoms after surgery using a uniform cough stress test that is endorsed by the International Continence Society and previously used by our group for incontinence research.[34 35]

Perioperative details

Surgery-related outcomes will include length of surgery in minutes, estimated blood loss during surgery >500 mL, procedural complications (eg, perioperative blood transfusion, visceral injury), and presence of postoperative infection (eg, abscess, urinary tract infection). Outcomes during the postoperative stay will include opioid use in-hospital measured by morphine milliequivalent, resumption of spontaneous voiding in days and length of postoperative stay.

Proms on pelvic floor function

Patient-reported pelvic floor function will include total and subscale PFIQ-7 scores, total PISQ-IR score, total and subscale PFDI-20 scores at 6–8 weeks and at 1-year postsurgery. In addition to analysing numeric scores, minimum clinically important differences defined as the magnitude of change in score corresponding to a clinically relevant improvement/worsening for patients will be used to dichotomise scores where available.[29 36 37]

Health service use

Service utilisation outcomes will be presentation at the emergency department and hospital readmission up to 30 days postsurgery for any health complaint, and up to 1-year postsurgery for a pelvic floor-related complaint. Both DAD and NACRS databases use the International Classification of Disease, 10th Revision, Canada (ICD-10-CA) for recording diagnostic information and the Canadian Classification of Health Interventions (CCI) for recording procedural information. The list of ICD-10 and CCI codes pertinent to pelvic floor complaints will be developed through a collaboration between urogynaecologist and administrative data methodologists on our team, and examples of relevant codes include N81 (female genital prolapse) in the ICD-10-CA and 1.RM.74 (fixation of uterus and surrounding structures) in the CCI.

Sample size

Sample size was calculated following the Difference ELicitation in TriAls (DELTA^2) guidance.[38] A sample size of 257 participants should provide 80% power for detecting a 15% difference between groups for the primary outcome of anatomic failure of surgery, based on 65% of women choosing hysterectomy,[22–24] 15% failure in women with hysterectomy at 1 year (estimated using a combination of data from published trials and clinical expertise),[17] and a two-sided alpha of 0.05. A 15% threshold has been previously noted as the magnitude of difference required for pelvic floor surgeons to favour one procedure over another.[39 40] For our PROMs, this sample size will provide us with >85% power to detect a 20-point difference between presurgery and postsurgery scores for the PFDI-20 and PFIQ-7 assuming presurgery scores of mean 100 and SD 50,[41 42] and a 3-point difference for the PISQ-IR assuming presurgery scores of mean 30 and SD 6.[43 44]

From a feasibility perspective, our surgeons share 20 operating room (OR) days per month; each OR day has 1–3 cases involving uterine suspension or hysterectomy for POP, providing an average of 40 eligible patients each month. Approximately 75%–80% of patients at our study sites participate in research.[35 39 45–47] Our analysis of unpublished data suggests moderate attrition (15%) at 1-year follow-up, which we expect will increase slightly due to the COVID-19 pandemic (20%). Therefore, our target sample size is 321 participants recruited over a 12-month period with uneven group sizes of n=209 women electing hysterectomy and n=112 women electing uterine preservation. To maximise data generation in the (smaller) uterine preservation group, maintain meaningful precision of results, and reduce the likelihood that our study is underpowered, we plan to continue recruitment until a minimum of 110 women are enrolled in the uterine preservation group and 321 women in the study overall.

Analysis plan

Since women who choose uterine preservation may differ systematically from women who choose hysterectomy, we will address this source of confounding through the calculation of propensity scores defined as the probability of surgical group assignment conditional on measured baseline covariates. We will build a logistic regression model for the propensity to choose uterine preservation (over hysterectomy) using all gynaecological (ie, POP and other gynaecological concerns documented before surgery), sociodemographic, obstetrical and personal variables available at baseline. Individuals will then be inverse probability weighted using their propensity score for all ensuing analyses; this attempts to mimic the same balance of baseline characteristics achieved with participant randomisation, and eliminates individual covariate adjustment and related data sparsity.[48] Compared with traditional regression adjustment, application of propensity scores, particularly those developed using high-dimensional data, has been shown to better reduce residual confounding and produce results from observational data that more closely resemble results from RCTs.[49–51]

We will conduct intention-to-treat analysis using generalised linear models to compare each primary and secondary outcomes across study groups. Heterogeneity of surgical approach effect by surgical modality and choice of suspensory ligament will be examined for perioperative outcomes only by adding interaction terms to each model.[52] Between-group differences will be reported using point estimates and two-sided 95% CIs; results with a 95% CI that do not include the null value (ie, 1 for ratio estimates and 0 for difference estimates) will be considered statistically significant.

Missing data on POP presentation or PROMs at 1-year post surgery will be handled using two approaches. First, we will apply conservative imputation assuming no change from baseline for presurgery and postsurgery comparisons, or worst-case scenario for categorical outcomes. Second, we will examine patterns of missingness across baseline characteristics and 6-week outcome data (if available), and repeat our main analysis using either multiple imputation or adjustment for covariates related to missingness.[53]

Patient and public involvement

Patients perspectives have been integrated into the selection of outcomes and design of study questionnaires. Through previous priority-setting interviews with 10 patients, we identified two themes: difficulties making

surgical decisions given the lack of information regarding long-term outcomes of uterine preservation versus hysterectomy, and the paucity of information regarding the impact of the two approaches on sexual function (unpublished data). Accordingly, we selected a range of objective and subjective outcomes on POP cure and sexual function to address these information gaps and better support informed surgical decision making. Our questionnaires were drafted to include a combination of quantitative validated PROMs, open-ended questions and original content. We pilot-tested questionnaires among 10 women to ensure comprehensiveness of scope, clarity of wording and an acceptable time to complete. Questionnaires were then revised according to feedback from the pilot before proceeding with full-scale implementation.

Impact of COVID-19

Our study protocol was first established before the onset of the COVID-19 pandemic (in January 2020), and we made two substantive modifications prior to commencing recruitment in July 2020 to accommodate local changes to healthcare as a result of this public health emergency. First, we increased the estimate of attrition from 15% to 20% in our sample size calculation, owing to anticipated difficulties retaining participants who may be experiencing economic and personal hardships during the pandemic. Second, we originally intended to collect data from in-person clinical examinations at 6–8 weeks postoperation, and to analyse primary and secondary failure outcomes at this time (in addition to 1-year postsurgery). However, to prioritise the safety of clinic patients and staff by reducing the volume of in-person contact, women were given the option to attend their 6–8 weeks visit in person or by telephone, and our analysis of short-term failure outcomes was eliminated. 1-year follow-up visits commenced in June 2021, and are prioritised to occur in-person.

Ethical considerations

The Conjoint Health Research Ethics Board at the University of Calgary approved this study and provides ongoing monitoring of ethical compliance and adverse events (REB19-2134). We obtain informed written consent from all participants on enrolment in the study. All data are stored in a secure, encrypted online database through the Research Electronic Data Capture (REDCap) application, and are accessible by password and two-factor verification to study team members only. Due to inability to link questionnaire data to electronic medical records in real time, PROM data are not reviewed routinely as part of integrated clinical care; however, these data can be made available to assist in patient care on request from the participant or supervising physician. A protocol has been established for managing unexpected findings during non-routine clinical exams (eg, diagnosis of a medical condition related to pelvic floor or reproductive organs) or patient complaints of symptoms during study contacts, whereby a member of the research team will liaise with clinic staff to arrange appropriate follow-up care with a physician.

Impact and dissemination

Globally, there continues to be a steady rise in the ageing population,[54 55] and thus an increasing number of women will experience POP and elect for surgical correction in the coming years. There is an imminent need for high-quality evidence on a broad range of short-term and long-term outcomes of uterine preservation versus hysterectomy in POP surgery. We plan to disseminate our results to health providers, researchers and patients to inform them about the risks, benefits and prognosis of each approach. Results will be presented at research rounds and conferences and published in peer-reviewed articles, with a focus on forums and journals in women's health and gynaecology. Lay summaries and infographics of findings will be developed and shared via social media and our clinical networks. To ensure information from our study reaches women and their families, we will update both hard copy handouts distributed at the Pelvic Floor and Gynaecology Clinics in Calgary and digital handouts available through Alberta Health Services website (available to all women seeking information online).

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Contributors EAB conceived the study concept. NVS designed the study methodology with feedback from EAB and KR. EAB selected patient-reported and clinical outcomes of interest. EAB and NVS secured funding for the study. NVS drafted the initial manuscript, which was revised by EAB and KR. All authors approved the final manuscript.

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