191

Hartshorn T[1], Tarnay C[1], Cecilia W[1], Doris B[1], Parvataneni R[1]
1. *University of California Los Angeles Department of Obstetrics and Gynecology*

RISK PREFERENCES OF WOMEN PLANNING SURGICAL MANAGEMENT OF PELVIC ORGAN PROLAPSE

Hypothesis / aims of study:
Pelvic organ prolapse (POP) is a common disorder affecting women, which causes a significant reduction in quality of life. A recent survey study indicated 23.7% of women in the U.S are affected by POP [1]. Unfortunately traditional vaginal repairs have historically shown a high rate of recurrence, and that recurrence is significant enough to require repeat surgical correction in up to 29% of women [2]. An effort to reduce recurrence rates have led to the introduction of graft augmented repairs. Biologic grafts have been demonstrated to be safe, but have not added durability over traditional repair while synthetic grafts demonstrate improved durability of repair but complications rates remain high [3]. The decision to utilize graft materials has long been primarily a physician driven decision, as we have little information that help guide patient preference on acceptance of risk of recurrence versus risk of graft related complication. The aims of our study are to: 1) determine the risks that patients are willing to accept to achieve lasting surgical correction of POP; and 2) identify predictors of patient preferences. In order to investigate this, we designed a novel disease-specific questionnaire utilizing preference-based instruments. We anticipate this study will enable physicians to better understand patient values with regards to acceptable surgical outcomes and to more effectively educate patients about treatment options.

Study design, materials and methods
The study design is a cross-sectional survey. Women with pelvic organ prolapse considering surgical treatment were included. Women younger than 18 years old, cognitively impaired, pregnant, with gynecologic malignancy, or with previous mesh augmented repair were excluded. Participants completed a two-part written questionnaire in a face-to-face interview. Part one of the questionnaire was the Pelvic Floor Distress Inventory, which is a previously validated tool used to objectively assess the impact of POP has on the patient's quality of life. Part two of the questionnaire incorporated three established health utility methods. 1) **Visual analog scale (VAS)**: The VAS measures patient's response on a linear scale measured in millimeters (from 0-100) that inversely corresponds to the impact they think a particular outcome might have on their life. It is measured in millimeters with increasing length correlating with decreased impact on quality of life. 2)**Time Trade-Off (TTO)**: This utility determines how much time a patient might be willing to sacrifice (from their remaining life expectancy) in return for a particular outcome. 3) **Standard gamble (SG)**: determines the risk of death that one would be willing to accept to improve the state of health. All three measurement tools were used to derive health utility scores of patient preferences in POP surgery.

Results
Thirty-nine women meeting the inclusion criteria completed the questionnaire. The mean age of the participants was 57.9 years. *Vaginal bulge* and *leakage of urine* were reported in 87% and 64% of patients respectively. 48% of women reported prior abdominal surgery, 15% had prior prolapse surgery and 18% had previously used a pessary. Nearly 95% of the participants were found to be at least "*somewhat*" bothered by a bulge in the vagina, and over half of these women reported a significant impact on their quality of life. Perceived level of health was derived from the VAS scored from 0 to 100mm with 0 indicating feeling "like I'm going to die" and 1.0 indicating feeling "like I'm in perfect health". Average VAS score reported when asked to indicate the baseline impact of prolapse symptoms on level of health was 0.49 (SD=0.26). If the prolapse symptoms resolved permanently with surgery, the average VAS score was 0.88 (SD=0.18); whereas if the prolapse recurred, the average score was 0.39 (SD=0.25). Introducing a scenario of prolapse recurrence, and a second surgery, VAS scores for different outcomes were the following: Prolapse resolution 0.77 (SD=0.26); prolapse recurrence 0.28 (SD=.27); complications such as pain, bleeding or dyspareunia 0.31 (SD=0.25).. However, if a second surgery was done to correct the complications, perceived health by VAS was 0.73 (SD=0.30). The TTO-utility anchor scenario revealed that women would be willing to give up 72 weeks from a set 10 years of life (14% of remaining life expectancy) for spontaneous resolution of prolapse symptoms. Single surgery prolapse resolution 14.1 weeks (SD=31.9), Single surgery prolapse recurrence 23.5 weeks (SD=48.8), single surgery with complications 30.6 weeks (SD=57.4), second surgery prolapse resolution 16.3 weeks (SD=26.7). Participants indicated that they would be willing to sacrifice an average of 31 weeks (6%) for successful prolapse surgery even if faced with complications requiring a second surgery. Conversely, women were only willing to sacrifice about half that time (16 weeks 3.1%) if they required a second surgery for recurrent prolapse even without experiencing complications.

Interpretation of results
This study fills in a gap in research by eliciting health utility scores for prolapse treatment outcomes for the first time. The data derived from this study indicate that patients with POP place high value on long-term correction of their prolapse symptoms. VAS scores were directly related to outcome. Using a high score of prolapse resolution after a single surgery as the benchmark, recurrent prolapse successfully managed with a second surgery closely approximated a single surgery alone. If initial outcome was complicated by pain/bleeding/dyspareunia a second surgery to resolve the problems scores were lower but not statistically significant. TTO utilities indicate patients again value resolution of prolapse. Scaled to spontaneous resolution of prolapse, patients would give up 10% more of life expectancy avoid graft related complications compared to the prospect of prolapse recurrence.

Women considering surgical management of pelvic organ prolapse place greater value on long-term correction of their prolapse and are willing to accept a certain level of risk in return for such an outcome.

Concluding message

The results of this study show that patients associate a high value with achieving long-term correction of prolapse. These findings underscore the importance of the notion of patient risk acceptance in the implementation of prolapse surgical techniques. Health utility values should be used in the evaluations of emerging prolapse treatments.

References

1. Nygaard, Ingrid, et al. Prevalence of Symptomatic Pelvic Floor Disorders in US Women. JAMA 2008;300(11):1311-1316
2. Olsen, Ambre L., MD, et al. Epidemiology of Surgically Managed Pelvic Organ Prolapse and Urinary Incontinence. Obstet Gynecol 1997;89(4):501-506.
3. Nguyen, John N., MD, and Raoul J. Burchette, MA, MS. Outcome After Anterior Vaginal Prolapse Repair: A Randomized Controlled Trial. Obstet Gynecol April 2008;111(4):891-898

Specify source of funding or grant	**None**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**University of California Institutional Review Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**