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SELF-REPORTED PATIENT PREPAREDNESS IS ASSOCIATED WITH SUI SURGERY SATISFACTION

Hypothesis / aims of study

Patient reported outcomes have gained increasing attention since traditional measures of objective cure & patient satisfaction frequently differ. Patient preparedness for stress urinary incontinence (SUI) surgery is associated with improvements in post-operative satisfaction, symptoms & quality of life (QoL). This planned secondary analysis examined the association of patient preparedness with surgical outcomes, treatment satisfaction and quality of life.

Study design, materials and methods

The NIH-sponsored ValUE trial design and eligibility criteria have been published. Briefly, women (>21 y/o) with a history of predominant stress urinary incontinence (SUI) > 3 months and no prior incontinence surgery were randomized to undergo either standardized office evaluation with urodynamics (UDS group) or office evaluation without UDS (Office Evaluation Only group) before proceeding to planned surgical treatments at 11 US clinical sites. The primary outcome of the ValUE study was measured at 12 months and included: Urogenital Distress Inventory (UDI) and the Patient Global Index – Improvement (PGI-I). Secondary outcome measures included: Incontinence Severity Index (ISI), Patient Global Impression of Severity (PGI-S), Medical, Epidemiologic, and Social Aspects of Aging Project (MESA), and Incontinence Impact Questionnaire (IIQ-7). Patient satisfaction with treatment outcome was measured with a 5-point Likert scale (very dissatisfied to very satisfied) that queried subjects to rate the treatment's effect on overall incontinence, urge incontinence, stress incontinence, and frequency. Subjects' perception of preparedness for surgery was assessed prior to randomization using a previously published 11-question Patient Preparation Questionnaire (PPQ). The PPQ was analyzed as a continuous variable using all the questions. Possible scores range from 0-100, with higher values indicating greater perceived preparedness. The PPQ was also analyzed as a dichotomous variable using question 11, overall preparedness, with women who responded "strongly agree" classified as "prepared" and all other responses considered "unprepared".

Descriptive statistics were used to assess the level of pre-operative patient preparedness according to each preparedness question and by the overall dichotomous preparedness question (percentage in each category). Spearman correlation coefficients (r_2) were calculated to assess the magnitude of the relationship between the dichotomous overall preparedness question and incontinence severity, satisfaction, and changes in PGI-S and IIQ scores from baseline. Pearson correlation coefficients (r) were calculated to assess the magnitude of the relationship between the continuous summary preparedness measure and UDI, ISI, MESA stress, IIQ, PGI-S, satisfaction, changes in PGI-S and IIQ scores from baseline. Chi-squared tests were used to assess relationships between response to PPQ question 11 and categorical variables (e.g. pre-operative urodynamic testing, primary outcome). A 5% two-sided significance level was used for all statistical testing. All statistical analysis was performed using SAS version 9.2.

Results

The PPQ was completed by all but one participant (n=629/630, 99.8%); most [623/630 (98.7%)] completed all 11 questions. Correlation coefficients between the individual questions of the PPQ varied from 0.22 – 0.91 with a Cronbach alpha value of 0.899, indicating a high level of internal consistency. The mean (\pm SD) PPQ score was 82.7 (\pm 14.9).

Most women (507/623, 81.4%) responded that they "somewhat agreed" or "strongly agreed" with all PPQ questions, indicating that they had high levels of pre-operative preparedness. However, 116/623 (18.6%) women responded that they "disagreed" or "strongly disagreed" with at least one of the 11 PPQ questions; these women were classified as not prepared. Selected clinical and demographic characteristics were not significantly different in women who reported they were prepared compared to those who reported being unprepared. Among the measures of baseline urinary incontinence symptoms we examined, only total UDI score was associated with patient preparedness ($r_2 = 0.13$, $p = 0.001$).

Table 1. Correlation between response to PPQ question 11 and measures of severity of urinary incontinence at baseline

Baseline Measure	N	Spearman correlation coefficient, r_2	p-value
Total UDI score	629	0.13	0.001
ISI scale	623	0.07	0.10
MESA stress score	629	0.03	0.44
Total IIQ score	629	0.06	0.11
PGI-S	626	0.15	<0.001

Table 2. Association between total PPQ score & measures of incontinence severity at baseline

Baseline Measure	N	Pearson correlation coefficient, r	p-value
Total UDI score	630	0.10	0.01
ISI scale	624	0.06	0.13
MESA stress score	630	-0.01	0.81

Total IIQ score	630	0.05	0.23
PGI-S*	627	0.06	0.13

*Spearman correlation coefficient, r_2 , used here since PGI-S is not a continuous variable.

About 4 of 5 (81%) women reported that they “agreed” or “strongly agreed” that they felt prepared for their surgery and understood the purposes, risks, benefits, complications, and alternatives for the planned surgery. A question regarding feeling prepared to cope with a catheter at home after the surgery elicited the highest proportion of women reporting they felt unprepared (7% “strongly disagreed,” 7% “disagreed,” and 13% “somewhat disagreed”).

The mean total PPQ was not significantly greater in women who achieved surgical treatment success compared to those who did not (83.6 ± 13.7 and 79.7 ± 18.7 , respectively, $p=0.03$). When the secondary outcome of global improvement was used (“very much” better or “much” better on the PGI-I at 12 months), the proportion of prepared subjects who improved and did not improve did not differ significantly ($p=0.77$). However, preparedness was associated with larger changes in patient-reported severity on the PGI-S from baseline to 12 months after treatment in both the single preparedness question ($p = 0.008$) and in the continuous preparedness score ($r_2 = -0.09$, $p = 0.046$). In addition, patients who reported higher levels of preparedness were more satisfied at 12 months ($r_2 = 0.09$, $p = 0.03$). Changes in the IIQ score were not significantly correlated with preparedness obtained from the single preparedness question ($r_2 = -0.05$, $p = 0.28$) or the total PPQ score ($r_2 = -0.05$, $p = 0.23$).

Interpretation of results

About 4 of 5 women enrolled in ValUE study reported they were prepared for surgery. However, about one in four (27%) did not feel prepared to cope with a catheter at home after surgery. Urinary incontinence severity as measured by the UDI and PGI-S was correlated with preparedness level at baseline. Although preparedness was not significantly associated with treatment success after MUS surgery, preparedness scores were correlated with satisfaction at 12 months and also with greater improvement in PGI-S scores from baseline to 12 months.

Concluding message

Nearly 1 in 5 (18.6%) women enrolled in a randomized surgical trial reported they were unprepared for SUI surgery. Patients who reported higher levels of preparedness were more satisfied with their surgery at 12 months. Efforts to increase patient preparedness are warranted.

Disclosures

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