

RANDOMIZED TRIAL OF AN ENHANCED VISUAL CONSULTATION AND STANDARD CONSULTATION FOR PROLAPSE: IMPACT ON PATIENT SATISFACTION, KNOWLEDGE AND TREATMENT DECISIONS.

Hypothesis / aims of study

To evaluate the effect of an enhanced visual consultation using an interactive prolapse program on patient satisfaction, knowledge, and decisional conflict.

Study design, materials and methods

Women presenting with pelvic organ prolapse (POP) to specialty urogynecology clinic, who agreed to participate, after receiving informed consent, were randomized to standard consultation (SC) or enhanced visual consultation (EC). Randomization occurred using a randomized number generated, and the consultation physician opened the assigned opaque envelope in the patient room. Patient, providers and staff were blinded to the assignment, until the envelope was opened. In addition to receiving the same scripted consultation as the SC group, the EC group received the Boston Scientific Interactive POP-Q Program. Participants completed a pre-visit Visual Analog Scale (VAS) questionnaire to assess baseline satisfaction with prolapse knowledge and the validated Prolapse and Incontinence Knowledge Questionnaire (PIKQ) to assess baseline prolapse knowledge. After consultation was provided by the physician, patients answered a post-visit VAS questionnaire, post-visit PIKQ, and the validated Decisional Conflict Scale (DCS-10) questionnaire. Assuming a 15% difference to detect between the two groups in the VAS questionnaire with the assumed standard deviation of 21%, 30 per group (total 60) is required to achieve a power of 80% with an alpha of 0.05 using a two sample t-test. Statistical analysis was carried out with SAS 9.4, SAS Inc., Cary, NC.

Table 1. Demographics

	Standard (n=30)	Enhanced (n=34)	p value
Age, years	53.6 +/- 10.4	55.7 +/- 10.8	0.59
Education, years	9.0 +/- 4.0	7.2 +/- 4.0	0.08
Language of Preference			
Spanish (n)	29 (96.7)	34 (100)	0.46
English	1 (3.3)	0 (0)	
Time of prolapse consult (min)	5.8 +/- 2.0	7.9 +/- 2.4	0.000

Table 2. Results

	Standard (n=30)	Enhanced (n=34)	p value
Change in VAS	50.0	47.1	0.606
Change in PIKQ	-1.3	2.0	0.175
DCS-10	6.3	15.3	0.011

Results

Of the 136 patients who were assessed for eligibility, 64 were enrolled and randomized to either standard or enhanced consultation. Only participants who completed pre- and post-visit questionnaires were analysed. The majority of participants were Spanish speaking with a mean age of 54.7 years (+/- 10.6) and a mean of 8 years (+/- 4.1) of education. The change in patient satisfaction with knowledge of prolapse was not significantly different between the EC and the SC groups (47.1 vs 50, p=0.606). The change in PIKQ scores was not significantly different between the EC and the SC groups (2.0 vs -1.3, p=0.175). The EC group had more decisional conflict compared to the SC group (15.3 vs 6.3, p < 0.05). The prolapse consultation time in the EC group was significantly higher than in the SC group (7.9 min vs 5.8 min, p<0.01). The treatment choice significantly differed between the groups (p<0.05). The EC group had more than 4 times greater odds of choosing surgery as opposed to kegel & pessary compared to the SC group (OR = 4.11, p=0.0185).

Interpretation of results

An enhanced consultation for POP, using an interactive electronic platform did not significantly improve patient satisfaction regarding their level of knowledge with POP. In addition, there was no difference of patient knowledge scores between the two groups. However, patients in the EC group had greater decisional conflict and also, were more likely to choose surgical as opposed to conservative management. This study may show that additional information and visual representation of a patient's condition may not ease decisional conflict, but may impact patient decision-making. Of note, our patient population was predominately low-income, and minimal educational background. These socioeconomic factors may play a role in the patient's interpretation of information given at the initial consultation visit.

Concluding message

The use of an interactive prolapse program did impact the treatment of choice for women with POP in our underserved patient sample. However, it did not affect prolapse knowledge or satisfaction with prolapse knowledge, and it was associated with greater decisional conflict.

1. Patient with a "enhanced visual" consultation had more decisional conflict that those randomized to "standard" consultation.
2. In addition, those experiencing "enhanced visual" consultation chose surgery at 4 times the rate of the SC group.

Disclosures

Funding: NA **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** La Biomedical Institute Helsinki: Yes **Informed Consent:** Yes