

LOST IN TRANSLATION? COMPARISON OF OBJECTIVE OUTCOMES AND PATIENT GOALS IN PELVIC FLOOR DYSFUNCTION SURGERY

Hypothesis / aims of study

Pelvic organ prolapse and incontinence are common and distressing conditions, known to have a significant impact on Quality of Life (QoL). The lifetime risk of surgery is 11% with a third requiring further surgery. Whilst QoL assessment is integral in outcome assessment, recent studies have focused on achievement of patient selected outcomes. The term EGGS has been coined to improve physician understanding of these outcomes. (E- expectations, G-goal setting, G-goal achievement, S-satisfaction) (1) Patient satisfaction has been directly related to the fulfilment of patient orientated goals. (2) In addition, clinicians and patients may not agree on the definition of a "successful" surgery (3) The aim of this study was to compare objective outcome measures with patient centred outcomes in women undergoing continence and pelvic reconstructive surgery. The secondary aim of this study was to compare patient overall satisfaction with achievement of these goals and with that of the operating surgeon.

Study design, materials and methods

This was a prospective longitudinal observational study. Women complaining of urogenital symptoms, on the waiting list for pelvic reconstructive or continence surgery were recruited from a tertiary referral centre. Women were pre-operatively assessed objectively by clinical examination, (POP-Q scoring system) and videocystourethrography (VCU). They completed a visual analogue score (VAS) of satisfaction with their pre-operative treatment and listed up to 5 personal goals following surgery. Operating surgeons also listed up to 5 goals which they hoped to achieve. Women were reviewed at 6 weeks, 3 months, 6 months and 1 year post operatively and examined using the POP-Q system. Each completed a VAS documenting the degree of goal fulfilment. They also completed the Patient Global Impression of Improvement (PGII) at each visit. In addition, the operating surgeon scored the extent to which their surgical goals had been met. Patient goals were categorised as being related primarily to symptom relief, return to physical activity, social activities, sexual function and body image. Surgical goals were categorised as being related to anatomical correction, functional improvement, avoidance of new bladder/bowel symptoms, long term cure and improvement of Quality of Life. SPSS version 14 (Chicago Illinois) was used for statistical analysis, with paired t- test for POP-Q measurement and Wilcoxon Signed Rank for PGII scores.

Results

109 women (Mean age 64.2 years, Range 42-85 years) were followed up over 1 year. 77 patients underwent surgery for pelvic organ prolapse (POP), 19 underwent continence surgery and 10 underwent a combined surgery for POP and incontinence. Based on the VAS, patients reported a lower mean satisfaction with their GP (75%) than with hospital care (86%).

Objective assessment using POP-Q showed a statistically significant improvement at 6 weeks which was maintained at the 1 year review. ($p < 0.05$) (Figure 1) Objective cure of USI on post operative VCU at 6 months follow up was 86.2%.

Women reported a total of 407 goals and surgeons a total of 478 goals. Surgeons reported a high achievement rate in anatomical restoration and functional improvement. The mean goal achievement per patient was 89% and that for the surgeon was 93% at 1 year. There was significantly higher goal achievement in the surgical goals than patient goals. (Table 2) The PGII scores showed a significant improvement from the 6 week (1.63) to the 1 year follow up (1.36) even in those women who felt that one or more of their goals had not been met.

Interpretation of results

Surgeons expressed consistently similar goals and achieved significantly higher goal fulfilment than patients. It was unclear whether this was a reflection of stating more "realistic" goals or a reflection of surgical bias. Patient goal achievement for prolapse surgery compared better with subjective and objective measures of success than continence surgery. Most patients with prolapse achieved the majority of their goals by 12 weeks. Women who underwent continence surgery showed high goal achievement for symptom

relief but lower achievement in goals related to body image, confidence, restoration of sexual function and psychosocial goals. Most women stated a significant improvement in PGII. However there was not always a correlation between objective and subjective "success". Some patients continued to express dissatisfaction with their surgical outcome if specific goals were not met even though they admitted to an overall improvement post operatively.

Figure 1: POP-Q scores

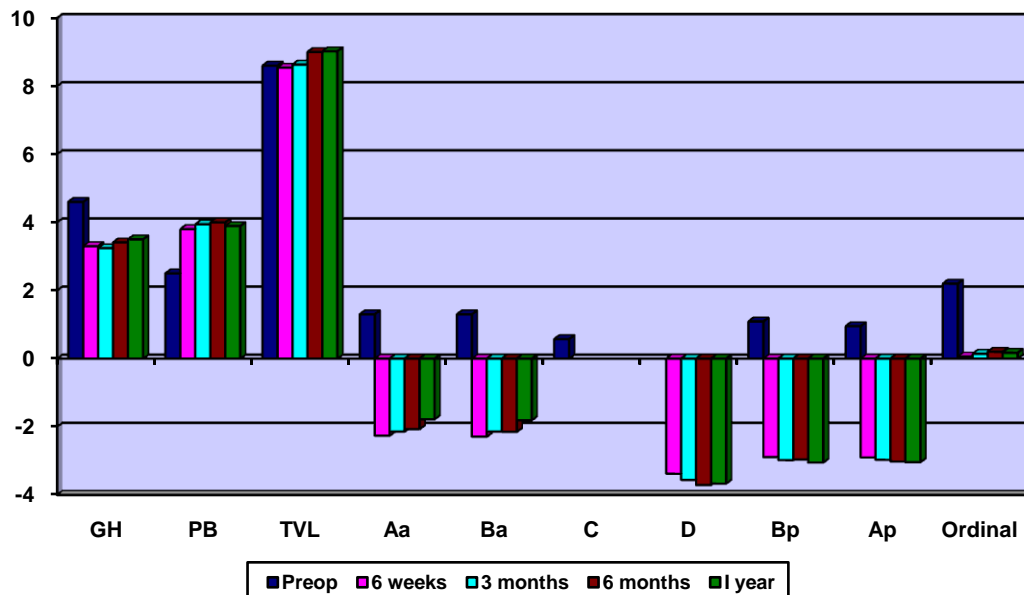


Table 1: Patient goal achievement in prolapse and incontinence at 1 year

Prolapse goals	Achieved	Incontinence goals	Achieved
Physical activity (39)	99.5%	Not need pads(19)	94.1%
Social activity (21)	96.3%	Not leak (13)	91.5%
Rid of bulge (54)	92.1%	Physical activity (36)	86.4%
Rid of discomfort (35)	91.1%	Not smell (10)	83.1%
Body image (7)	86.8%	Social activity (29)	76.8%
Faecal problems (19)	85.2%	Sleep at night (7)	74.1%
Sexual function (31)	67.9%	Sexual function(14)	69.5%

Table 2: Surgeon's goal achievement in prolapse and incontinence at 1 year

Surgeon Goal	Achieved
Functional improvement in prolapse (84)	95.1%
Anatomical restoration (65)	94.6%
Functional improvement in incontinence(30)	93.4%
Improve QoL (64)	90.5%
Long term cure (9)	90.3%
Avoid new LUTS/ bowel symptoms (124)	88.7%
Improve sexual function (26)	82.7%

Concluding message

This study confirms that patient centred goals for continence and pelvic reconstructive surgery are subjective and personal, often based on lifestyle factors. Achievement of these goals for each woman seems to be the primary reason for undergoing surgery. An objective cure does not predict subjective measures such as patient satisfaction or achievement of goals and patients may be dissatisfied despite apparent high "cure rates". In contrast, surgeons goals are more consistently similar, largely based on objective outcome measures and more significantly achieved. The development of reliable and valid methods for assessment of patient centred outcomes would enable better evaluation of effectiveness of treatment.

References

1. Int Urogynecol J (2005)16;171-173.
2. Am J Obstet Gynaecol (2004) 191; 201-205.
3. BMJ (1997)315; 1493.

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	Kings College Hospital Ethics Committee
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes