3

Srikrishna S[1], Robinson D[1], Cardozo L[1], Cartwright R[1]
1. Kings College Hospital

DEFINING SURGICAL CURE: DO SURGICAL GOALS MEET PATIENT EXPECTATIONS?

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 incidence of surgery is 11% with a third requiring further operations. There are no standardised outcome measures and the relative clinical importance of objective and subjective tools remains to be determined. The definition of cure is problematic particularly with regards to surgical outcome. (1) Whilst QoL assessment is integral in outcome assessment, recently studies have focused more on achievement of patient selected outcomes. (2)

The aim of this study was to examine "cure" following pelvic floor dysfunction surgery using objective outcome measures such as Pelvic Organ Prolapse Quantification (POP-Q) and urodynamic assessment and subjective measures such as achievement of patient goals, patient satisfaction and Quality of Life assessment.

Study design, materials and methods

This was a prospective longitudinal observational study conducted at a tertiary referral centre. Women were recruited from the waiting list for pelvic reconstructive or continence surgery. Pre-operative objective assessment included clinical examination (POP-Q) and videocystourethrography (VCU). Women were asked to complete 3 validated Quality of Life questionnaires to document the impact of their urinary, prolapse or sexual dysfunction on their lives using the Kings Health Questionnaire (KHQ), Prolapse Quality of Life Questionnaire (PQoL) and Golombok Rust Inventory of Sexual Satisfaction (GRISS). Patients listed up to 5 personal goals they hoped to achieve following surgery and documented degree of goal fulfilment at the at 6 weeks, 3 months, 6 months and 1 year post operative review using a Visual Analogue Scale (VAS). Women were also re examined and completed a Patient Global Impression of Improvement (PGI-I) at each review. Post operative VCU was also performed at the 6 month review.

SPSS (V 14 Chicago Illinois) was used for statistical analysis. The paired t- test (POP-Q), Wilcoxon Signed Rank (QoL scores), and independent sample t test (PGI-I) were used. Correlation was performed using Pearsons coefficient.

Results

In total, 61 women were followed up over 1 year; 43 had pelvic reconstructive surgery, 13 had continence surgery and 5 had a combined procedure. Mean patient goal achievement was 75% at 1 year. PGI-I scores showed an improvement from the 6 week review (1.58) and this was maintained at the 1 year review (1.45). (Table 1) Objective assessment showed statistically significant improvement in POP-Q scores ($p<0.05$) and 88.8% cure rate of urodynamic stress incontinence on post operative VCU. The QoL questionnaires showed a significant improvement from pre operative scores at the 1 year review ($p<0.05$). (Table 3). However, there was only a weak correlation between the improvement in the objective POP-Q scores with the improvement in PGI-I at the one year review (Pearsons correlation co efficient 0.361; $p=0.015$). PGI-I was significantly better in those women who were objectively dry on repeat urodynamics. (Mean PGI-I 3.6 vs. 1.3; $p=0.033$)

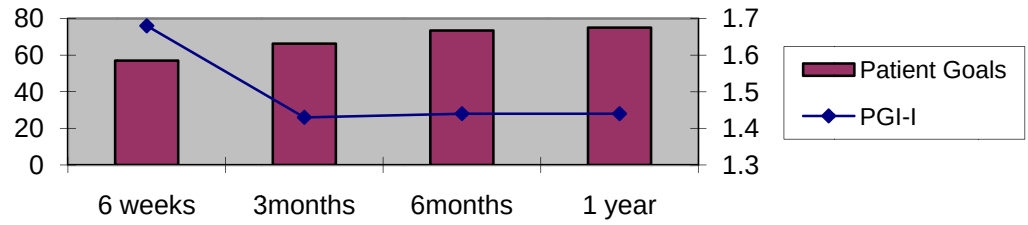

Table 1: Mean patient goal achievement (%) and PGI-I

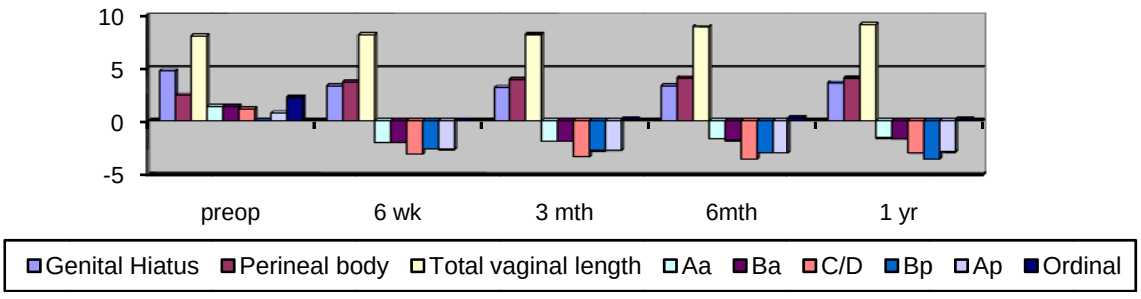

Table 2: POP-Q scores

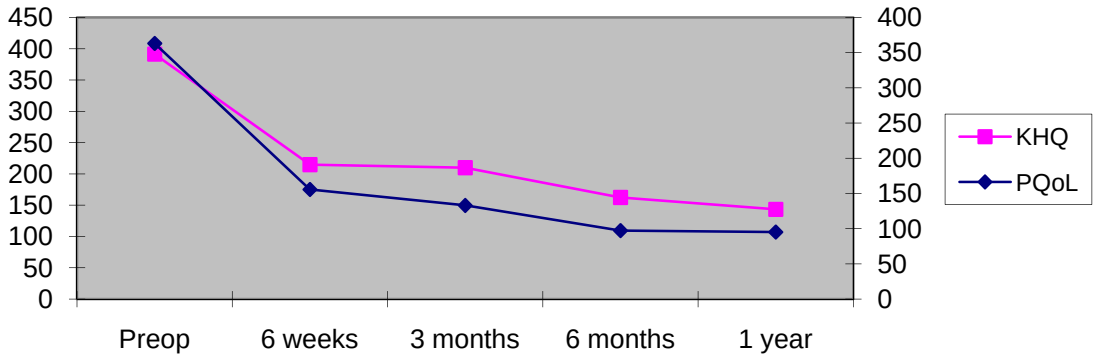

Table 3: QoL scores

Interpretation of results

There is no current consensus of opinion regarding definition of cure and use of outcome measures. Objective outcome measures tend to be used more often in the research setting whilst subjective measures are used more commonly in clinical practice. (3) This study has shown a concomitant improvement in both objective and subjective physician based outcome measures as well as patient orientated goals. However, the improvements in objective assessment are not necessarily reflected in the patient's perception of improvement in their condition.

Concluding message

Various different measures of success have been used to evaluate outcome of surgical treatment in this study. As they do not necessarily measure the same thing it is appropriate to utilise several different outcome assessment tools. Pelvic floor dysfunction is multi-dimensional and therefore assessment needs to incorporate subjective and objective measures. Ultimately "cure" may be best assessed using patient centred goals and expectations.

References

1. BJOG 2002.109(10):1081-8
2. Am J Obstet Gynecol 2004.191(1):201-5
3. Int Urogynecol J Pelvic Floor Dysfunct 2007.18(3):273-9

FUNDING: NONE
CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.
HUMAN SUBJECTS: This study was approved by the KINGS COLLEGE HOSPITAL ETHICS COMMITTEE and followed the Declaration of Helsinki Informed consent was obtained from the patients.