Original article

QOL audits of TVT surgery applied to small patient numbers are a worthwhile addition to clinical practice

OMAR GAILANI[(1)], PAUL DUGGAN[(2,3)]

[(1)] Registrar in Obstetrics and Gynaecology, Lyell McEwin Hospital-Australia
[(2)] Department of Obstetrics & Gynaecology,University of Adelaide-Australia
[(3)] Gynaecology Unit Royal Adelaide Hospital Adelaide

Abstract: This paper considers whether a validated quality of life (QoL) questionnaire would be a useful clinical audit tool for practitioners or units who operate for stress urinary incontinence, have a relatively small case-load and who may be interested in using these data for credentialing or reaccreditation. We prospectively evaluated changes in QoL domains using the King's Health Questionnaire (KHQ) in a series of 14 women undergoing a TVT procedure. All women had urodynamically proven stress incontinence and completed the KHQ preoperatively and again between 12-61 (mean 32.8) months after surgery. The women were also asked to complete non-validated analog scale responses to two questions regarding satisfaction with the procedure and the extent of residual incontinence and to indicate whether they would recommend their procedure to a friend. Five of the nine KHQ domains showed clinically and statistically significant improvements in QoL and three domains showed clinically significant improvements which did not reach statistical significance. Six (43%) women were completely dry following their procedure and these were the only women who were completely satisfied. Nine women would definitely recommend the procedure to a friend. Prospective collection of KHQ data provides an estimate of the degree of improvement resulting from treatment and provides a basis for benchmarking of the performance of an individual or group. However, current QoL questionnaires are deficient when it comes to the evaluation of common complications of surgery such as urinary retention.

Key words: Quality of life; Kings health questionnaire; Tension free vaginal tape

INTRODUCTION

Urinary incontinence has a significantly adverse affect on quality of life (QoL).[1] When surgery for stress urinary incontinence is contemplated, currently, the TVT procedure appears to be the operation of first choice. Large, multicentre studies have demonstrated significant improvement in QoL indices following a TVT procedure.[2, 3, 4] Because of the substantially smaller caseload of individual practitioners there is uncertainty regarding the sensitivity of QoL questionnaires to detect changes in small series. It has not been established if an individual surgeon would be able to demonstrate clinically or statistically significant improvements in QoL parameters. Medical practitioners are increasingly required to produce evidence of satisfactory performance for credentialing and re-accreditation, with demands coming from employers, hospitals and professional colleges. Thus, it is useful to establish if prospective QoL audit has a place for small units and individual practitioners who perform continence procedures.

In this paper we explore the use of the Kings Health Questionnaire (KHQ) - a validated QoL questionnaire[5] - in the prospective evaluation of a small series of women presenting with urinary incontinence and undergoing a TVT procedure. We determine whether the KHQ could be a useful addition to routine clinical assessment and follow up when continence surgery is planned.

METHODS

Fourteen women presenting for management of urinary incontinence to the Lyell McEwin Health Service in Adelaide Australia completed the Kings Health Questionnaire (KHQ),[5] as a baseline evaluation at the time of their preoperative urodynamic study and again by postal follow up between 12-61 (mean 32.8) months after their TVT procedure. Preoperatively, nine women reported urge and stress incontinence and five women reported pure stress incontinence. Thirteen women had urodynamically proven stress incontinence and one woman urodynamically proven stress incontinence and idiopathic detrusor overactivity. The women's ages ranged from 37.6 – 82.3 (mean 56.8) years at the time of their procedure and parity ranged from 0-4 (mean 2.3). Two women had previous procedures for incontinence, three had previous prolapse surgery and eight had a previous hysterectomy.

The version of the KHQ that we employed is available in the reference cited[5] and comprises 21 questions ordered in to 9 domains (table 1). The raw scores for each question, which are in the range of 0-5, are recalculated to a score of 0-100 for each domain where 0 indicates no problem and 100 indicates a very severe problem. A change in a domain score of plus or minus 5% is thought to represent the minimal clinically significant change.[6] The most recent version of the KHQ is currently available to download from the website of the National Institute for Clinical Excellence (www.nice.org.uk/nicemedia/pdf/word/cg40implmentation advicekhq.doc).

The surgical procedures were predominantly undertaken by trainees under the supervision of a consultant gynaecologist. Four women had a vaginal repair and one woman vaginal hysterectomy and repair in addition to the TVT procedure. The remaining nine women had a TVT procedure only. Clinical records were used to determine demographic details and complications of the procedure.

Three additional non-validated questions were sent with a covering letter accompanying the follow up KHQ. Two questions were "Please choose a number between 1 and 10 to rate your overall satisfaction with your treatment, where 1 = completely unsatisfied and 10 = completely satisfied", and "Please choose a number between 1 and 10 to rate any residual wetness following your treatment where 1 = wet all the time and 10 = completely dry". Women were also asked whether they would recommend this treatment to a friend with the same condition. Possible answers were "Yes", "No" or "Don't know". These additional data were collected to undertake correlation analysis against the KHQ domains to help us to establish if a simplified questionnaire would suffice for routine clinical audit.

The results for the KHQ domains, which were not normally distributed, were analysed using the Wilcoxon Signed Rank test using SPSS for Windows 15. A power calculation for the Wilcoxon Signed Rank Test is not available in this software package. Descriptive statistics and the Spearman rho correlation test were run in SPSS 15.

Table 1. – A description of the domains of the Kings Health Questionnaire (Kelleher 1997).

Domain	Number and type of questions	Likert scale
General Health Perception	One question addressing general health not directly related to urinary incontinence	1-5 (very good – very poor)
Incontinence Impact	One question addressing effect of incontinence on quality of life	1-4 (Not at all-A lot)
Role Limitations	Two questions addressing effect of incontinence on ability to perform normal tasks of daily living	1-4 (Not at all-A lot)
Physical Limitations	Two questions addressing effect of incontinence on ability to perform physical exercise and travel	1-4 (Not at all-A lot)
Social Limitations	Two questions addressing effect of incontinence on ability to perform social activities	1-4 (Not at all-A lot)
Personal Relationships	Three questions addressing effect of incontinence on relationships and sex life	0-4 (Not applicable-A lot)
Emotions	Three questions addressing effect of incontinence on emotions and feelings	1-4 (Not at all-Very much)
Sleep/Energy	Two questions addressing effect of incontinence on sleep and energy	1-4 (Never-All the time)
Severity Measures	Five questions dealing with strategies used to manage incontinence, worry and embarrassment	1-4 (Never-All the time)

A repeat analysis of the dataset was undertaken using the statistical functions (paired t-test and correlation) available in Excel, which assume data are normally distributed. This was done because most practitioners do not have ready access to stand alone statistical software and to determine whether the conclusions would be significantly altered by assuming normality of distribution and running the readily available standard parametric tests.

Ethics approval for this study was given by the North Western Adelaide Health Service ethics committee.

RESULTS

Five of the nine KHQ domains showed clinically and statistically significant improvements in QoL (table 2) after the TVT procedures. Three domains showed clinically significant improvements which did not reach statistical significance. In one domain (General Health) there was no change. These conclusions were not materially altered by re-running the analysis using the parametric statistical functions available in Excel.

Overall, the magnitude of change in QoL was large and in the direction of improvement. The median improvement in score was 50 points or more for five domains and between 16-45 points for three others. The domain General Health showed a deterioration of 12 points in its median value (p=0.79).

The postoperative satisfaction and dryness scores each ranged from 1-10 with 10 women recording scores above 5 for both variables. Only six (43%) women were completely dry following their procedure and these were the only women who were completely satisfied with their procedure. Satisfaction and dryness scores were very strongly correlated (Spearman's rho 0.98, p <0.001). The correlations between postoperative KHQ data and satisfaction scores are shown in table 2.

Table 2. – Preoperative (before) and postoperative (after) Kings Health Questionnaire (KHQ) data in 14 women undergoing a TVT procedure for urodynamic stress incontinence (p values in column 6 calculated with the Wilcoxon signed rank test). Column 7 shows the Spearman's rho correlation coefficients between the KHQ domains and analog satisfaction scores as reported postoperatively only (* p<0.05, ** p<0.01, *** <.001).

Domain	Median before	Median after	Interquartil range before	Interquartile range after	p-value	Correlation with satisfaction score
General health	25	37	25-50	0-50	0.79	-0.64*
Incontinence impact	67	16	67-100	0-67	0.01	-0.87***
Role limitations	58	0	29-83	0-54	0.02	-0.69**
Physical limitations	67	0	33-83	0-54	0.01	-0.68**
Social limitations	16	0	8-44	0-25	0.24	-0.62*
Personal relations	50	0	0-87	0-75	0.13	-0.87**
Emotions	56	11	30-81	0-70	0.07	-0.86***
Sleep/energy	50	33	33-83	17-54	0.02	-0.75**
Severity measures	67	17	38-93	0-62	0.02	-0.92***

Complications in this series included one case of bladder perforation (no sequelae), one case of de novo bladder instability, one case of urinary retention requiring postoperative catheterisation for less than 48 hours, one case of urinary retention requiring postoperative catheterisation for less than one week, and two cases of urinary retention requiring catheterisation of up the three weeks, giving an overall rate of urinary retention of 28%.

DISCUSSION

Our data demonstrate that it is possible to show clinically and statistically significant improvements in KHQ QoL domains following TVT procedures in only a small series of unselected cases. The first domain called "General Health" is not expected to be improved by a continence procedure but the remaining eight domains may be expected to show improvement postoperatively, depending on the effectiveness of the procedure and the sensitivity of the instrument. Although possibly due to small numbers in this series three of the KHQ domains did not show a statistically significant improvement, we have shown that the KHQ is sensitive enough to be used by those who wish to audit surgical outcomes in a small case series. The KHQ is simple to administer preoperatively and by mail for post-operative follow up. The main disadvantage of the KHQ and other QoL questionnaires is that data entry and manipulation are required to record the responses to the questionnaire and to recalculate the answers to each question to a percentage score for each domain. This is relatively simple and can be done in Excel, which is inexpensive and widely available.

An alternative to the individual practitioner approach would be for colleges such as the RANZCOG or organisations such as AAVIS to support their members by providing data entry and analytical facilities ideally through a secure web site. The problem of patient confidentially could easily be resolved by only permitting data entry by de-identified ID number, which would require the practitioner to keep a record of the ID key to permit patient identification through his or her practice.

The question remains whether the KHQ or other QoL questionnaires are worth the effort compared with the simple, non-validated questions regarding satisfaction, dryness and recommendation to a friend. On this occasion, we have shown very strong negative correlations between a simple "1-10" satisfaction score and many of the postoperative KHQ domains. However, we did not find these strong correlations in another series from our unit which evaluated QoL in women treated non-surgically for mixed incontinence[7] and others have concluded that simple analog scores are insufficient.[8]

Thus, there would be little prospect of having data accepted for publication if only non-validated methods were employed. There is also a real problem in determining a suitable "cut point" for the arbitrary values[1-10] defined in our non-validated questions if we want to explore more than just the extreme, inarguable case of a "10" or perfect result, which in this series was reported by only 43% of women. This 43% "completely dry" rate is consistent with published data on the TVT procedure.[9,10] Conversely, pre- and post-operative KHQ data permit an estimate of the degree of improvement resulting from treatment using an instrument that has been validated against objective criteria such as pad tests and urodynamic studies. It also forms a good basis for benchmarking one's performance against the performance of colleagues undertaking the same procedures, both in terms of baseline severity (case selection) and improvement following surgery.

In our opinion a very important deficiency of the version of the KHQ that we used and other QoL questionnaires is that they do not directly measure the commonest and arguably most problematic complication of continence surgery, which is urinary retention and associated problems including recurrent urinary tract infection (UTI) and symptoms of obstructive voiding. The latest version of the KHQ, which was not available when we set up our data base, contains a question related to symptoms of recurrent urinary tract infection (UTI). In our small series the rate of postoperative urinary retention was 28%, albeit that in all cases the retention had resolved within three weeks. There were no cases of recurrent UTI. For a meaningful audit, these and related data (e.g. requirement for tape division or excision; new and persisting obstructive voiding symptoms) must be reported.

In conclusion, we recommend the KHQ to practitioners wishing to engage in prospective audit of continence procedures provided the language of the questionnaire is appropriate to their population and provided additional data are collected particularly in relation to postoperative voiding difficulties.

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