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TRANS-OBTURATOR TAPE (TOT) FOR STRESS URINARY INCONTINENCE, SIXTEEN MONTHS OUTCOMES USING PRE AND POST OPERATIVE KING'S HEALTH QUESTIONNAIRE.

Hypothesis / aims of study

TOT procedure for woman with stress urinary incontinence is highly effective and minimally invasive (1). The aim of the study is to evaluate the outcome of these procedures using King's Health Questionnaire (KHQ) and to explore factors that interact with King's scoring Part 1 and Part 2 and its relationship to the patient's symptoms outcome.

Study design, materials and methods

82 patients were enrolled on this study .57 patients completed the study had urodynamic stress incontinence (USI), 38 of them underwent trans-Obturator tape procedure (Monarc R) (2). 19 patients underwent Tension Free Vaginal Tape Obturator procedure (3) between January 2004 and May 2005. Mean age was 56 (36 to 84), mean parity 2 (0 to 5) and mean BMI 28.7 (20.9 to 54.7). The preoperative evaluation included a detailed history, physical examination, urodynamic testing, pre and post-operative King's Health Questionnaire.

The difference between patients pre and post King's score part 1 and pre and post KHQ score Part 2 were measured. The patients' percentage improvements between their KHQ score Part 1 and 2 were also examined to see if the improvement was higher in one than the other.

The group percentage improvement statistics is calculated using the median as the data has a skew distribution. Wilcoxon signed ranks test was also used to examine the statistical significance of the percentage improvement of Part 1 and Part 2. Factors interacting with KHQ score Part 1 and Part 2 was also explored including age, parity, BMI, previous surgery, urodynamic diagnosis, concomitant operations and type of surgery

Results

Mean follow up for 16 months (14 to 24). Success rate was 78 (95.1%) (Cured) with only 4(4.9%) unsuccessful (not cured). There were no intra operative complications. One patient required tape release on the third postoperative day due to successive high postoperative void residual. At eight weeks follow up seven patients (12% patients reported irritative symptoms, only one was commenced on anti-cholinergic and required a cystoscopy at six months which showed no abnormality).

At sixteen months follow up the improvement of King's Health Questionnaire part1 in the group was 64.7%.The improvement in part 2 was 56.5%.41 patients out of 57 had a higher percentage improvement in KHQ score between pre and post treatment in Part 1 than in Part 2. 16 patients were the reverse (they had higher percentage improvement in Part 2 than in Part 1. None stayed the same.

Interpretation of results

Using Wilcoxon signed ranks test to examine the statistical significance of the percentage improvement of Part 1 (mean equal 55.89%, SD =l 25.7% and Part 2 (mean equal 46.38%, SD= 25.13%. A significant difference in improvement (P 0.01) was observed. This means that group percentage of movement in Part 1 of Kings Health Questionnaire is significantly greater than in Part 2.

Exploring confounding factors and close observation among the groups showed that there is a marginal percentage improvement in the older patients (under 65) over the younger patients as displayed by the summary statistics.

Using Unvariant Analysis, improvement measures were modeled by the following factors: age group, BMI, parity, type of procedure, previous surgery. The KHQ scores were very significant but none of the suspected factors could explain the observed improvement, all their p-values >0.05.

Concluding message

TOT procedure for woman with stress urinary incontinence is highly effective and minimally invasive. Kings Health Questionnaire is a valid tool to assess the procedure outcomes. In this study it was evident that the improvements are in both patient's symptoms and quality of life. However improvement in symptoms is not necessarily reflected in the quality of life. Confounding factors like age, BMI, parity, type of procedure, previous surgery did not influence patent's symptoms or quality of life but might be due to the small study sample. A larger sample might change our results.

References

1. Prog urol 2001 Dec; 11(6):1306-1313.
2. Int Urogynecol J 2004 Jul-Aug; 15(4) 227-232.
3. Eur Urol 44(6):724-730.

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?	**No**
This study did not require eithics committee approval because	**Trans Obturator Tape procedure is routinely offered to all our patients with urodynamic stress incontinence as a treatment of choice. All patients complete pre and post operative Kings Health Questionnaire. This study was an audit of our practice and it was registered with the hospital RND & AUDIT Department. We were advised that ethics committee approval was not required.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**