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URODYNAMIC CHANGES AFTER TRANSOBTURATOR SUBURETHRAL TAPE: FOLLOW-UP OF MINIMUM 3 YEARS

Hypothesis / aims of study

This clinical study is a retrospective single institution study evaluating the urodynamic and quality of life changes after TOT and TVT-O procedures done by a single surgeon with a follow-up period of at least 3 years. Our hypothesis is that longer follow-up evaluation of patient who underwent TOT procedures will show similar rates of efficacy as compared to the outcome reported in the already existing literature on TVT procedures. However, we suppose that the obstructive nature of the TVT-O demonstrated on short-term studies will not get worse with time. If potential long term morbidities such as worsening of pre-existent overactive bladder symptoms (OAB) or OAB de novo or decreased bladder contractility are found after our analysis, we will try to show that these consequences can be mostly secondary to aging than the procedure itself.

Study design, materials and methods

A chart review of all patients who underwent TOT and TVT-O procedures by a single surgeon for stress urinary incontinence from January 01, 2001 to December 31, 2006 was conducted from the medical archive of a single institution. To minimize the confounding effect of other causes of de novo urge incontinence or overactive bladder symptoms, those who had concomitant prolapsed repair performed, repeated sling procedures, immediate post-op urinary retention requiring sling revision, and those with subsequent sling erosions were excluded. The sample size was determined by evaluating all of the population of interest who met the previously described inclusion criteria during the specified period. As a standard practice by the operating surgeon, all patients with stress or mixed urinary incontinence scheduled to have a sling procedure undergo pre-operative urodynamic studies. The TOT and TVT-O procedures were performed in all patients according to the method first described by Delorme using various kinds of devices including Monarc (American Medical Systems), TVT-O (Gynecare) and Aris (Mentor).[1]
Multichannel urodynamic study was also performed at a last follow-up appointment, at three years after the operation date. The urodynamic findings preoperatively and 3 years or more postoperatively that were studied are the post-void residual (in mL), the maximal flow rate (in mL/sec), the maximum urethral closure pressure (in cmH_2O) and the presence of involuntary detrusor contractions. First, a descriptive analysis of the sample will be presented by categories with frequency translated into percentages. If we find a normal curve, we will measure the average of our values. However, if the curve is not normal, we will be accounting as the median value. All the parameters with categorical values will be described by th McNemar's test and all the continuous values with paired t-tests or Wilcoxon signed-rank test dependently on the normality of the distribution.

Results

These results are partial since they picture the outcome on 33 patients (our total population being of 75 patients) The actual mean age of our sample is 60,7±8,8 years-old and the age at moment of the surgery 56,5±8,8 years old. There was a significant decrease of the maximum uroflow (Qmax 28.7 vs 23.6 mL/s, p=0,012) and of the mean uroflow (15,2 vs 10,2 mL/s, p=0,003) postoperatively. In addition, the maximum cystometric capacity significantly increased after the procedure (421,7 vs 551,3 mL, p=0,000). However, the post-void residual remained below 100mL for all the patients except for 3 (165mL, 225mL and 630 ml) of them who in the preoperative setting had residual volume of 0mL. No difference was seen in the maximum urethral closure pressure before and after the operation. Involuntary detrusor contraction found preoperatively in 5 women disappeared postoperatively (p=0,0625). Postoperative leaks were found in only 6 patients, of whom 2 presented a VLPP (Valsava Leak Point Pressure) below 90 cmH_2O, translating a residual intrinsic sphincter deficiency.

Interpretation of results

Even in a context where we see that the Qmax and the average uroflow seem to be diminished, the post-void residual clinically stayed normal. Only three patients showed a de novo urinary retention probably due to the transobturator suburethral tape. Eighty-two percent of our patients remained dry after three years and no patient developed any de novo urodynamic overactive bladder. The patterns have an obstructive nature but do not clinically have an important impact on voiding function. Nonetheless, it appears to be substantial to evaluate these patients on a more long term follow-up to be sure that they do not develop urinary retention.

Concluding message

Transobturator suburethral tapes (TOT and TVT-O) represent an appropriate option for patients suffering from stress urinary incontinence. They are not associated with any significant bladder obstruction nor long term urinary retention while having very similar cure rate as the other TVT slings. Long term follow-up seems to be important in identifying possible complications, like urinary retention. To our knowledge, this is the first study presenting a complete urodynamic assessment at three years after a TOT procedure.

References

1. Ulmsten U et al. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J 1996; 7:81-6

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**

What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Le comité d'éthique de la recherche en santé chez l'humain du CHUS et de l'Université de Sherbrooke**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**