SAFETY AND LONG TERM EFFICACY OF TRANSOBTURATOR MIDURETHRAL SLING PROCEDURE USING THE MONARC® KIT

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Introduction

During the last decade, the Monarc® surgical kit has been the procedure of choice for the treatment of female SUI in our medical center. After the interruption of the Monarc® kit production, following closure of Astora Women's health in 2016, and following public concerns about the safety of midurethral sling for the treatment of stress urinary incontinence (SUI), we evaluated safety and long-term efficacy of trans-obturator tape (TOT) procedures using the Monarc® surgical kit.

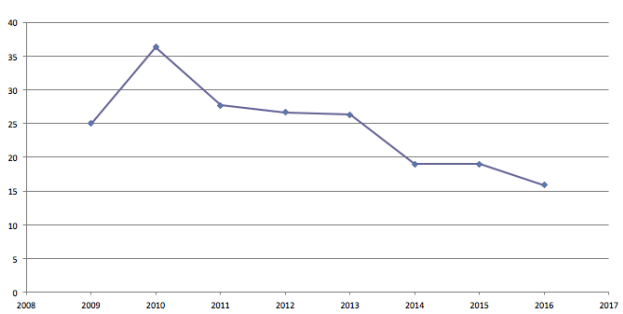
Methods

In this retrospective cohort study, patients who underwent a Monarc® procedure during the years 2009-2017, either alone or in combination with additional pelvic floor or gynecologic procedures, were summoned for a follow up visit. Pre- and peri-operative data were collected from clinical files. During follow-up visits, urogynecologic history was taken using a structured symptom questionnaire, patients were evaluated by speculum and pelvic exam, a cough stress test with a full bladder was carried out and self-administered, validated QoL questionnaires (PFDI-20, PISQ-12) were filled by patients who could read and understand Hebrew.

Table 1- Concomitant pelvic floor procedures

Procedure	Number of patients	%
Vaginal hysterectomy	82	41.2
Anterior colporrhaphy	83	41.7
Posterior colporrhaphy	63	31.7
Ant. colporrhaphy with mesh	39	19.6
Post. colporrhaphy with mesh	17	8.5
Sacrocolpopexy	19	9.5
Sacrospinous fixation	36	18.1
Le Fort Colpocleisis	9	4.5

Figure 1 - Average Operative Time (mins)



Results

Three-hundred and one women underwent a TOT procedure using Monarc® during the study period. One-hundred and ninety-nine patients (66.1%) returned for follow-up at least one year following surgery. Mean follow-up was 32.8 (12-88) months. Mean age was 60.1 years (32-90), mean BMI=27.7 (15.6-40.8). Sixty-four (32.2%) patients had pre-operative MUI. Mean LPP was 94 cm H2O. All procedures were carried out by one of five experienced pelvic floor surgeons. Fifty-eight patients underwent Monarc® only, in 12 patients Monarc® was done in combination with abdominal hysterectomy for benign indications and in the remaining patients the TOT was combined with additional pelvic floor procedures (Table 1). In the Monarc®-only patients, mean operative time was 23.6 minutes and average estimated blood loss was 30 cc. In TOT-only procedures, we observed a gradual decrease of operative time along the years (Figure 1). The only intra-operative complications were unrelated to TOT: anaphylactic reaction to Cefazolin in one patient and bleeding from the infundibulo-pelvic ligament which required laparoscopy in one patient during vaginal salpingo-oophorectomy. As for early post-operative complications, 2 patients complained of mild to moderate groin pain which resolved completely after few weeks, one patient had urosepsis, 2 patients after TOT combined with colporrhaphy had transient urinary retention which resolved within 1 week. One patient developed pulmonary edema and one patient a post-operative myocardial infarction. Both patients were treated accordingly and had a full recovery. Subjective cure rate for SUI, defined as a negative reply to questions 3 and 4 in the UDI-6 questionnaire, was 89.1% in all patients. Objective cure rate, defined as no leakage upon cough-stress test with a full bladder, was 95.4%. In the fifty-nine patients (29.6%) with urodynamic SUI combined with DO, the subjective cure rate was 93.2%. Two patients with TOT failure were re-operated and were dry after a retropubic TVT. Post-operative QoL questionnaires showed improvement in UDI-6 (pre-operative score: 10.8, post-operative score: 4.3. p= <0.001) and PISQ-12 scores (pre-operative score 30.8, post-operative score: 34.8. p=0.001). As for late complications related to the TOT procedure, two patients developed vaginal tape erosion (<5 mm): in one patient the erosion was asymptomatic and thus did not require treatment while surgical removal of the eroded mesh was required in the second patient. The de-novo urgency rate was 9.5%. No cases of long-term voiding dysfunction, sexual dysfunction or dyspareunia related to the Monarc® tape were observed.

Conclusions

According to our experience, the TOT procedure using the Monarc® kit has not been associated with significant complications and has shown long-term efficacy for the treatment of SUI. We believe the small, helicoidal shape of the tunneler allows ideal positioning of the tape at the midurethral level while avoiding danger of injury to pelvic organs and neuromuscular bundles.

References

Lo TS, Jaili S, Tan YL, Wu PY. Five-year follow-up study of Monarc transobturator tape for surgical treatment of primary stress urinary incontinence. Int Urogynecol J. 2016 Nov;27(11):1653-1659.