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VAGINAL EXPOSURE IN LONG-TERM FOLLOW-UP STUDIES EVALUATING TRANS-OBTURATOR TAPES FOR THE SURGICAL TREATMENT OF FEMALE STRESS URINARY INCONTINENCE: A SYSTEMATIC REVIEW OF THE LITERATURE

Hypothesis / aims of study
Tension-free vaginal tape (TVT) has become the gold standard for the surgical treatment of female stress urinary incontinence, with high cure rates and limited complications (1). Nevertheless, the risk of organ and vessel injuries prompted researchers to explore alternative paths for the positioning of mid-urethral tapes – the obturator foramen (2,3). Trans-obturator tapes proved to be as effective as TVT and to reduce the risk of bladder perforations, but introduced a new complication, groin and thigh pain. Common to both approached, and still an unsolved issue, remain vaginal exposures. Since it has been reported that such complications may also have a late onset, aim of this report is to evaluate the rate of vaginal exposures in studies evaluating trans-obturator tapes with a long-term follow-up, their time of onset and the approaches used to solve the complication.

Study design, materials and methods
An updated search of the literature was. All studies describing mid- and long-term effectiveness and safety of MUS in women affected by stress urinary incontinence were included in this review. They were identified by searching the MEDLINE, EMBASE, National Library for Health, ClinicalTrials.gov, and Google Scholar databases (up to February, 2015). The abstracts from International Conferences were not included in this systematic review. The search terms included simple text or subject subheadings with language limited to English. They included: “stress urinary incontinence, midurethral sling, tension-free tape, transobturator tape, follow-up”. Hand search was performed on the bibliographies and citation lists of all relevant reviews and primary studies to identify articles not captured by electronic searches with restriction to the English language. No ethical approval was requested for this study, being a systematic review. Retrospective, cohort, prospective non-randomized and randomized (RCT) studies of women who underwent TO-MUS (trans-obturator mid-urathral slings, including TVT-O and TOT) as the primary procedure for stress urinary incontinence with a mean or median follow-up of at least 36 months. RCTs comparing RP-MUS to TO-MUS with a minimum follow-up of 36 months were also included in the analysis, limiting data extraction to TO-MUS. No limitations for inclusion criteria of each study were set and only studies comparing TO-MUS to another synthetic sling were included in this review. Three reviewers (GAT, CF, and AF) selected the studies independently on the basis of the inclusion criteria and clarifications were sought from the individual trial lists if required. Disagreements among reviewers on the studies to include were solved by discussion and, if necessary, using a majority of reviewer’s conclusion to make a decision. In case of studies with multiple publications, safety data were extracted by all published articles. Three researchers (GAT, CDC, and CF) extracted data for quality and results independently. Data included number of subjects evaluated at the last follow-up, mean or median follow-up, number of alteration to vaginal integrity clearly related to TO-MUS procedure (defined as vaginal erosion, exposure,
discontinuity of vaginal mucosal integrity), time of onset (or time of reporting) of vaginal exposure, and actions taken to solve vaginal exposure.
Statistical analyses were performed by one author (GAT). For non RCT studies, regression rates from individual studies were meta-analyzed using a fixed effect model. Statistical analyses were performed using CMA software (Biostat, Englewood, NJ, USA). Heterogeneity among studies was assessed analyzing I2. Differences in the proportions were performed using the $\chi 2$ test and were expressed as OR with 95% CI. Statistical significance was set for a $p < 0.05$.

Results
A total of 24 studies was included in the analysis. There were 12 RCTs, 4 non-randomized comparative studies and 8 cohort studies, with a total of 2588 patients, 1722 treated with TVT-O and 866 with TOT. The sample size ranged from 26 to 185 patients evaluated at last follow-up. The mean follow-up of the studies was 52 .6 ± 16.1 months. Heterogeneity among studies was found to be from moderate to limited. Overall, a total of 64 vaginal exposure was reported, 31 in the TVT-O group (1.8%) and 33 in the TOT group (3.8%) (p = .002; OR 2.161, 95%CI 1.279-3.653. Since most of TOT exposure were caused by the Obtape device, which has been withdrawn from the market, a separate analysis omitting this device was performed. After removing studies evaluating Obtape, the number of vaginal exposure in the TOT group decreased to 16 (2%), a value which was not significantly higher than TVT-O (p = .7; OR 0.878, 95%CI 0,461-1.688). Most of vaginal exposure cases were reported within the first year from the original procedure (34, 53.1%), with a further peak at 60 months (15, 23.4%), mainly due to 10 Obtape cases. Omitting these cases, 20 cases were reported 24 months after the original procedure. Regarding TVT-O, 24 vaginal exposure (77.4%) were reported within the first 12 months after surgery, while only 6 (22.6%) after the first year (p = .01; OR 3.429, 95%CI 1.178-10.298). In the TOT group, most of cases were observed after the first year from surgery (23, 69.7% vs. 10, 30.3%) (p = .001; OR 0.189, 95%CI 0.057-0.607). Omitting the Obtape cases, the distribution of cases remained similar, with 7 cases in the first 12 months (43.7%) and 9 thereafter (56.3%), but not significantly (p = .5; OR 0.605, 95%CI 0.117-3-040). Five studies did not report the modality of management of vaginal exposure, thus 2097 patients were evaluated from this point of view. A total of 57 re-interventions for the management of vaginal exposure were performed in the studies included, with a rate of 2.7% (95%CI 2.01-3.39), with TVT-O showing a lower intervention rate in comparison with TOT (1.7% vs. 5.1% (p < .0001; OR 0.332, 95%CI 0.189-0.581). This difference was not significantly different omitting the Obtape cases (1.7% vs. 2.7%; p = .2, OR 0.700, 95%CI 0.343-1.450). Re-intervention was necessary for all 17 cases of tape exposure observed with the Obtape device. Most studies (15) report that vaginal exposure was managed with partial excision of the exposed part of the tape, while in three studies the tape was removed. In total, there were 52 tape excisions (25 for TVT-O and 27 for TOT) and 5 tape removals (one for TVT-O and 4 for TOT). Four studies reported to have used a conservative approach with vaginal estrogenIn one study this led to healing, while in the other three re-intervention was necessary.

Interpretation of results

Overall vaginal exposure rate in studies evaluating trans-obturator tapes in the long-term was limited. TVT-O showed a significantly lower vaginal exposure rate in comparison with TOT, mainly due to studies evaluating Obtape. This difference disappeared when Obtape was excluded from the analysis., The higher rate for TOT is reflected by a higher re-operation rate for this complication, but, again, this disappears when Obtape is excluded from the analysis. Vaginal exposure are significantly more likely to be reported in the first post-operative year for TVT-O, while the time of onset for TOT does not decrease over time. Most studies dealt with vaginal exposure with the excision of the exposed portion of the tape and only 5 cases needed tape removal. Treatment with vaginal estrogens seems to be ineffective to manage vaginal exposure, but numbers reported in literature are too limited to draw any significant conclusion.

Concluding message

Vaginal exposure is still an unsolved issue for mid-urethral slings, but its incidence in the research setting of long-ter follow-up studies seems to be very limited. TVT-O seem to imply a similar risk of vaginal extrusion than TOT and an earlier onset in comparison with TOT. Re-interventions to manage this complication are minimally invasive in the majority of cases. More data are needed to evaluate this complication in non-research settings.

References

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