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MINI-SLING PROCEDURES IN STRESS URINARY INCONTINENCE: A SYSTEMATIC REVIEW OF EFFICACY AND COMPLICATIONS.

Hypothesis / aims of study

A number of surgical treatment modalities have been developed over the past decade to treat women with stress urinary incontinence. The Burch colposuspension was replaced by the retropubic tape as the gold standard. The complications of bowel, bladder and vascular injury lead to the development of the transoburator device. This tape has however been associated with a number of complications, notably groin and hip pain. The mini-sling devices were launched to avoid these complications of the retropubic and transoburator passage. Despite the widespread use of these products, there is unfortunately limited data available on the efficacy and complications of these procedures. In this systematic review, we have chosen to review the efficacy and complications of three mini-slings including TVT Secur^R (Gynecare, Ethicon, Somerville, NJ, USA), Miniarc^R (American Medical Systems Inc., Minnetonka, MN) and Ajust^R (Bard Urological Division, Covington, GA, USA).

Study design, materials and methods

This systematic review was implemented in accordance with recommendations from the Meta-Analysis of Observational Studies in Epidemiology group (MOOSE)(1). The search strategy was both automated and manual. With the automated search the databases included: PubMed (MEDLINE), MeSH, Google Scholar, Africa Healthline, CINAHL, Cochrane, LILACS, and Science Direct. The manual search included journals and abstracts of international conferences, including oral podium presentations and oral poster presentations. These were from the IUGA and ICS annual meetings. The following were used as keywords when searching for relevant articles: 'Miniarc', 'TVT Secur', 'Ajust', 'stress urinary incontinence', 'continence surgery' and 'mid urethral sling'. Studies were included if they showed any relevance to the topic of "mini-slings". Data was extracted by two independent reviewers and entered into an excel database. This included number of participants in the study, publication type, whether the surgery performed was primary or secondary, the diagnosis including either stress or mixed urinary incontinence, type of "mini-sling" performed, follow up time, mean operative time, complications (including de novo urgency, groin and/or hip pain, vaginal erosion bladder injuries and voiding problems), objective and subjective cure and improvement rates. Data was then checked by a third reviewer. Overall success and complication rates were calculated using SPSS version 17.0. We determined pooled objective and subjective success rates for the studies reporting these outcomes. Separate analyses were carried out to determine success and complication rates for the different devices and for the small number of papers on the mini-slings published in peer-reviewed journals. We also made a crude attempt to obtain pooled efficacy data for all the studies in the review and for this we had to determine an overall cure rate for each paper. To determine the numerator, the number of women objectively cured was used if only objective cure rates were given or if both subjective and objective rates were provided. If only subjective cure rates were provided, then subjective values were used. To determine the denominator, the number of women followed up was used. If this number was not provided, the number at the start of the study was used. We also pooled complication data using a similar method.

Results

A total of 59 studies were identified as being suitable for inclusion in this review. Two were excluded as the subjects were non-human in one study and cadavers in another. Eleven published journal articles and 46 conference abstracts were therefore included, leaving a total of 5513 women available for the purpose of analysis. Thirty-seven studies involved TVT SecurTM, 12 MiniarcTM, one AjustTM, one study used either TVT SecurTM or MiniarcTM and one used either TVT SecurTM, MiniarcTM or AjustTM. Five did not specify which of the mini-slings had been used. Thirty-two studies reported the type of study that had been performed. Of these, three were randomised controlled trials, nine retrospective, and 20 prospective studies. Of note is that the mean follow up period for all of these studies was 36 weeks. Of the 45 studies that included the length of follow up, two-thirds (30 studies) reported a follow up period of more than six months. Type of incontinence was reported in 33 trials with 3095 women treated for stress urinary incontinence and 1134 women for mixed urinary incontinence. Fifteen studies reported using general anaesthesia for the operation, eight authors used spinal or epidural anaesthesia, 18 reported using local or regional anaesthesia, and eight reported using sedation. Cystoscopy was reported to have been performed in four papers and not performed in three and was not reported on in 50 papers. Twenty papers reported operative times and these ranged from 5 to 32 minutes. Authors made use of a broad range of criteria to describe the efficacy of the mini-slings. For the purposes of this systematic review, we calculated subjective, objective or overall cure rates. Subjective cure rates were reported in 19 studies. Most studies made use of questionnaires to determine subjective cure rates but visual analogue scales, a telephone interview and self-reports were also utilised. Using subjective cure criteria, 70% (841/1194) of women who underwent "mini-sling" surgery were cured. Objective cure rates were reported in 26 studies. Cough stress tests were used to determine objective cure rates in the majority of the studies but urodynamics and pad tests were also employed. The overall objective cure rate of the 26 studies was calculated as 81% (2060/2532). Only 14 studies reported those women who were not cured but had experienced an improvement in symptoms and the pooled calculation for this was 29.9% (284/949). Of the 57 studies reviewed, 15 did not provide us with objective or subjective cure values and so cure rates could not be determined for these studies. The overall cure rate for the remaining 42 studies was calculated as 80.8% (2746/3398). The overall cure rate of the 11 papers that were published in peer-reviewed journals was 75.6% (561/733). Subjective cure rates were reported in five studies and objective in seven. Using subjective and objective criteria, 71% (299/420) and 74% (363/485) of women in these peer reviewed publications respectively were cured. In these papers TVT Secur demonstrated subjective cure of 72.9% (233/323) and objective cure rates of 72.6% (252/347) whereas Miniarc was found to be associated with subjective cure of 68%(66/97) and

objective cure of 80.4%(111/138). Overall cure rates for TVT Secur were 75.6% (450/595) and for Miniarc 80.4% (111/138). There were no published papers on Ajust. When we pooled all the available data on the various devices TVT Secur demonstrated subjective cure rates of 70.6% (704/1002), objective cure rates of 80.8% (1552/1922) and overall cure rates of 79.8% (2184/2734). Subjective cure for the Miniarc was 71.3%(137/192), objective cure 85.3% (455/533) and overall cure of 86%(479/557) (Table 4) The one study on the Ajust reported 100% (30/30) cure rate. The overall cure rate of minislings in the 46 abstracts was 82% (2102 out of 2546) of which only ten used objective criteria. Voiding dysfunction was reported in 26 trials including either TVT SecurTM, MiniarcTM or Ajust^R and was calculated as 2.3% (66/2907). The mean incidence of de novo urgency was 6.6%(224/3358) in 23 trials, mean groin or hip pain 0.65% (5/770) in 11 trials reporting this complication and mean bladder injury as 0.45% (17/3750) in 28 trials and mean vaginal erosion 2.5% (71/2838) in 31 trials. When analysed individually, TVT-S was found to be associated with a 2.5% risk of a voiding problem, 6% de novo urgency, 0.4% risk of bladder injury and a 3% risk of erosion. Miniarc was found to be associated with a 1.2% risk of voiding problems, 11.3% de novo urgency, 0.75% bladder injury and 1% risk of vaginal erosion.

Interpretation of results

In this systematic review of the mini-slings overall cure rates for stress incontinence ranged from 70% to 81%, using subjective and objective outcome data. Our study found the risk bladder injury and groin and hip pain following the mini-slings to be less than 1%. This is less than the complication rates reported for the retropubic and transobturator tapes respectively.

Concluding message

In this systematic review, overall cure rates for the mini-slings appears to be lower than the reported rates reported for the retropubic and transobturator tapes. The complication rates, however, appear to be reduced when performing the mini-slings.

References

1. Stroup DF, Berlin JA, Morton SC, Olkin I, Williamson GD, Rennie D, et al . Meta-analysis of Observational studies in epidemiology: a proposal for reporting. Meta-analysis of Observational studies in epidemiology (MOOSE) group. JAMA 2000; 283: 2008-12

<i>Specify source of funding or grant</i>	none
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require ethics committee approval because</i>	It was a systematic review of published trials
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	No