1199

Sottner O[1], Halaska M[1], Maxova K[1], Vlacil J[1], Hurt K[1], Vojtech J[1], Kolarik D[1], Chaloupecky J[1], Zahumensky J[1], Zmrhalova B[1]

1. *Department of OB/Gyn, University Hospital Na Bulovce, First Faculty of Medicine, Charles University in Prague, Czech Republic*

INITIAL EXPERIENCE WITH THE NEW SINGLE-INCISION SLING SYSTEM MINIARC.

Hypothesis / aims of study

The aim of our study is to evaluate our initial clinical experience with the new Single-Incision Sling System MiniArc.

With the non reassuring results of the first single incision sling system TVT Secur System (TVT-S) we appreciate that there is a new mini invasive tape system to treat the female stress urinary incontinence. Mainly, the precise fixation of the tape provided by the two self-fixating tips theoretically offers the advantage to this mini invasive sling.

Study design, materials and methods

The MiniArc Single-incision Sling system developed by the American Medical Systems, Inc. treats the female stress urinary incontinence by providing additional support to the urethra with a hammock-shaped sling. It is intended for the placement of a suburethral mesh for the treatment of female stress urinary incontinence from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).The MiniArc features Type I polypropylene mesh with a midline centering mark for accurate placement. Small, integrated self-fixating tips on either end of the mesh are anchored in the obturator internus muscle through a single, small vaginal incision. The MiniArc requires only a single, 1.5 cm vaginal incision under the mid and distal urethra designed to minimize dissection as the MiniArc uses just one slim 2.3 mm needle that minimizes tissue disruption.

Two surgeons started with the MiniArc implantation after certified training for this procedure, both already competent in transobturator tapes implantation. The procedures were performed from April 2008 through March 2010; altogether we performed 45 implantations. All patients met the indication criteria for the midurethral sling and pre-operatively underwent clinical examination, pelvic ultrasound and urodynamic study. 10 females in our set had already undergone some anti-incontinence procedure before the MiniArc implantation; 1 patient had pelvic irradiation in her personal history.

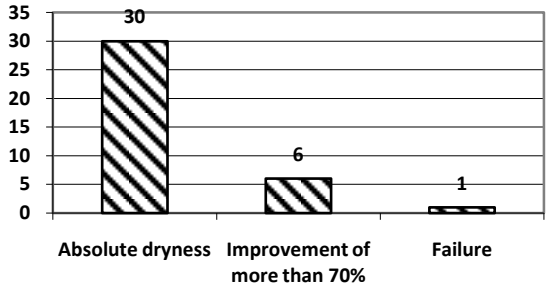
Primary outcome of the study was subjective cure; secondary outcomes were rate of intra-operative, early and late complications, postoperative healing process and post void residual urine volume (PVR). All patients were regularly checked up 6 weeks after the procedure and afterwards contacted from November 2009 through March 2010.

Results

45 procedures were performed during the two years period. We have noticed no severe intra-operative complication – no injury to bowel, urethra, urinary bladder or a major vessel. All procedures but two were performed under local anaesthesia. Two cases were under general anaesthesia because of the concomitant laparotomy – both were cases of ovarian cancer. Blood loss was not excessive in any of the cases; in 1 case we observed blood loss of 70 ml, in 2 cases it was 50 ml and in the rest 42 cases it was 30 ml or less. There was no need for permanent bladder catheter placement (except the two patients with concomitant oncogynaecologic laparotomy). All the patients passed urine spontaneously not later than two hours after the surgery. By that time post void residual volume was less than 100 ml in all females but one – in this case it was between 200 and 300 ml and it took two days to reduce to a non significant post void residual volume of less than 50 ml. With the exception of the two patients with concomitant oncogynaecologic laparotomy and one female with slightly higher post void residual urine volume we performed all MiniArc implantations in a one day surgery setting. There were no important early postoperative complications like symptomatic urinary tract infection or wound healing problems. Postoperative analgesia usage was extremely low – except the two patients with concomitant oncogynaecologic laparotomy, only three asked for one dose of an oral painkiller, the rest of 39 patients did not ask for any postoperative analgesia at all. We have not observed any important finding during the late postoperative period – we have not noticed any bladder outlet obstruction or “de novo urgency”. All overactive bladder symptoms were diagnosed and treated before the MiniArc implantation and there was no observation of significant worsening of the overactive bladder symptoms after the MiniArc implantation according to the clinical judgement of the physician. We found just one asymptomatic protrusion of the tape into the vagina requiring treatment with local estrogens and two consecutive sutures under local anaesthesia in the outpatient office. There was no case of a late postoperative pain.

Our primary outcome was subjective cure – evaluated by patients at least six weeks after the tape implantation; follow up was from 6 weeks to 23 months. We evaluated 42 females with at least 6 weeks follow up; 5 patients were lost from follow up; this means there were 37 women for evaluation. 30 (i.e. 81.1%) women declared an absolute continence under all circumstances; 6 females (i.e. 16.2%) indicated a very high level of satisfaction – improvement of more than 70%. Just in 1 case (i.e. 2.7%) there was a complete failure – no improvement; in this patient MiniArc was the fourth anti-incontinent procedure.

We did not observe any vanishing of a good postoperative outcome during the postoperative time.



Interpretation of results

The new Single-Incision Sling System MiniArc has shown a high subjective cure rate comparable to the standard retropubic or transobturator approach. If the surgeon is competent in transobturator tapes implantation the new procedure seems to have a very short learning curve, high safety and not vanishing success rate during the time.

Concluding message

From our initial experience we perceive the new Single-Incision Sling System MiniArc as very promising in the treatment of female stress urinary incontinence. The MiniArc seems to be an indeed mini invasive and safe procedure with ergonomic implantation offering a similar success rate compared to the standard retropubic or transobturator tension free vaginal tapes.

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Local Ethics Committee of the University Hospital Na Bulovce, Czech Republic**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**