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ONE-YEAR COMPARISON OF AN SINGLE INCISION MINI SLING AND CONVENTIONAL MIDURETHRAL SLINGS. A RANDOMIZED CONTROLLED STUDY

Hypothesis / aims of study

Midurethral slings have been introduced several decades ago and have a high cure rate regarding urinary stress incontinence (1). Several attempts have been made to minimize the surgical approach and thereby pain perception but still ensuring an optimal cure rate. However, so far the usefulness of single incision slings is controversial and seems to be associated with lower cure rates. Recently, an adjustable sling has been introduced and has shown promising results in relation to subjective and objective cure rates (2). Preliminary observation at our clinic demonstrated a high subjective cure rates of 89% at 6 months follow-up combined with a very low pain perception measured by VAS scores postoperative with an initial painscore of 2.5 just following surgery and at day three a Vas score of 0.9.

The aim of present study was to evaluate the subjective cure rate, complications and pain perception of a adjustable singleincision sling (Ajust®) compared to traditional midurethral sling procedures at one–year follow-up in a multicenter approach including standard midurethral sling procedures as preferred by the individual center.

Study design, materials and methods

The study was performed as a prospective multicenter randomized trial (RCT) comparing Ajust® (C.R Bard Inc) with TVT (Ethicon Inc, Somerville, NJ, USA), TVT-O inside-out (Ethicon Inc, Somerville, NJ, USA) or TOT (Monarc AMS, MN, USA) as preferred by the six local centers in Denmark, Norway and Sweden. Prior to inclusion, all women gave their informed consent. All women were randomized in blocks corresponding to each center by a computer generated list in a ratio of 1:1 to either Ajust® or the standard midurethral sling used by the specific department.

All women included had stress urinary incontinence (SUI) conformed by a standardized provocative stress test. Patients were excluded if they had predominant urge incontinence, pelvic organ prolapse (POP-Q > stage 2), previous incontinence surgery, previous pelvic irradiation, and neurological conditions such as multiple sclerosis, current treatment with corticoids and a history of genital or abdominal cancer or a pelvic mass.

The ICIQ-SF-UI and PGI-I were used to evaluate the influence of surgery on incontinence, quality of life and the patients perception of improvement.

Results

In total, 305 women fulfilled inclusion criteria (155 received Ajust® compared to 150 patients, who received conventional midurethral slings (TVT; n=83, TVT-O; n= 13 and TOT; n=54). Of these, 14 women did not participate at 1- year follow-up in the Ajust® group compared to 11 in the cenventional sling group.

Baseline characteristics showed no difference between the two group including age (44.9+6.9 vs 46..1+7.1). The number of postmenopausal women was 20% and 25%, respectively and 23% and 20% had mixed urinary incontinence in the two groups.

Duration of surgery appears from Table 1. No major complications appeared during surgery for any slings. In one women, the Ajust® sling could not be adjusted and one women experience pain following a TVT procedure. In general, all women stay less than 24 hours in hospital (99% Ajust vs 100% for conventional slings).

Pain perception (VAS score) at discharge from the hospital was equal in the groups (Ajust® 3.3±2.6 vs TVT: 4.7±2.7; TVT-O: 5.2±2.7; TOT 3.6±2.7).

Interpretation of results

Our RCT shows that Ajust® is equal to standard midurethral slings regarding surgical time and postoperative complications. Furthermore, there is no difference between the groups regarding stay in-hospital. These findings confirm previous observations, indicating that Ajust® is safe and easy to use in women with SUI.

Furthermore, no difference was observed between the groups at 1- year follow-up regarding subjective cure rate. Although our observation is restricted by a short follow-up of one year, our results confirm the notification of durability of Ajust® in short term outcomes. Further long-term follow is apparently needed in order to validate the efficacy of Ajust®.

Concluding message

In conclusion, Ajust® is feasible and associated with a low complication rate and a subjective success rate of 86% at 1 year follow-up. However, still long-term follow-up is needed, especially in respect to verification of the durability of Ajust® in relation to standard mid-urethral sling.

Table 1. Duration of surgery

	Ajust (n=150)	TVT (n=83)	TVT-O (n=13)	TOT (n=52)
Duration of surgery (min),				
- mean ± SD	16.6 ±6.9	24.4 ±11.9	18.5 ±8.9	13.2 ±4.0
- median	15.0	21.0	15.0	13.0
- range	5-48	7-105	10-40	8-33

Subjective cure rates appears from Table 2. In general no difference was observed between the groups at one-year follow-up

Table 2. Subjective cure at 12 months follow-up

	Ajust	Conventional slings		
		TVT	TVT-O	TOT
	(n=141)	(n=83)	(n=13)	(n=52)
Incontinence episodes per day %				
- Zero episodes	86.0	85.2	83.3	88.9
- One episodes	7.0	11.1	16.7	-
- >Two episode	7.0	3.7	-	11,2
PGI-I, %				
- Significantly improved	72.7	80.8	84.6	85.7
- Much improved	19.7	11.0	7.7	9.5
- Some improvement	5.3	6.8	-	2.4
- Unchanged	2.3	-	7.7	-
- Slightly worse	-	-	-	-
- Worse	-	-	-	-
Much worse	-	1.4	-	2.4

PGI-I: Patient Global Impression of Improvement

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Disclosures

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