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SHORT TERM OUTCOME OF A NEW SURGICAL TREATMENT FOR FEMALE STRESS INCONTINENCE WITH AJUST - ADJUSTABLE SINGLE-INCISION SLING

Hypothesis / aims of study: To evaluate the short-term surgical outcomes and complications of a new adjustable sling (AJUST, C.R. Bard, Inc., USA) for the treatment of female stress urinary incontinence (SUI).

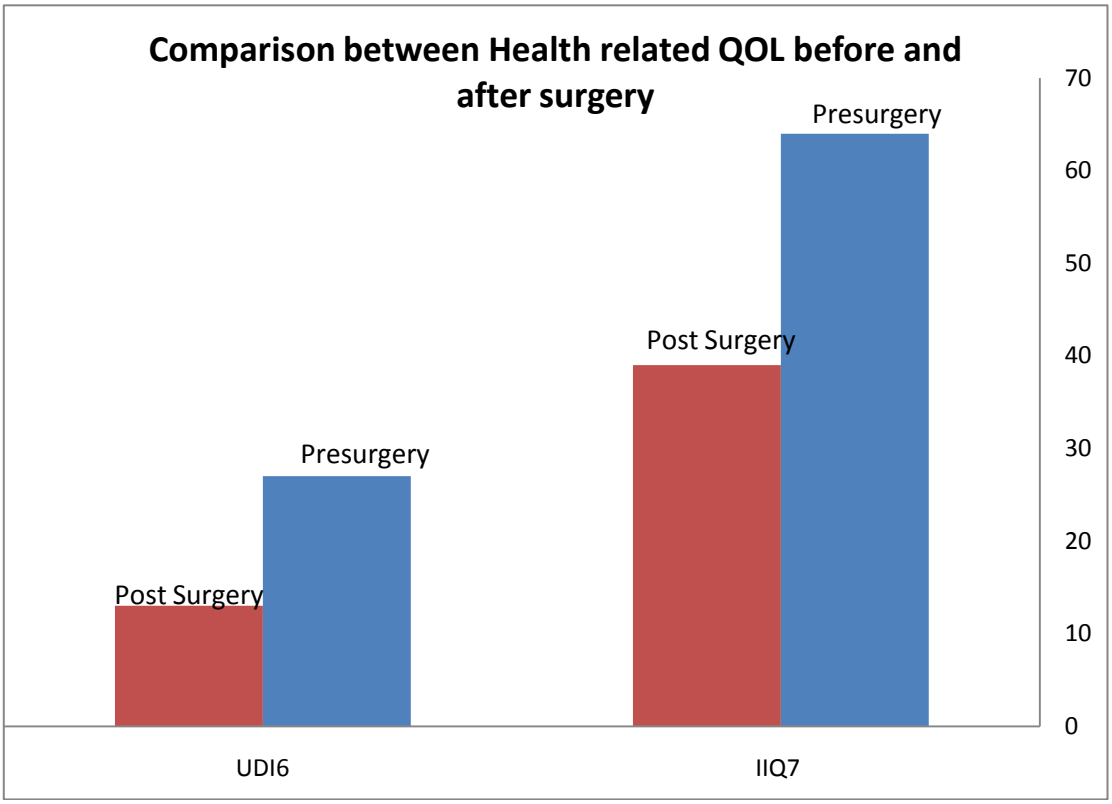
Study design, materials and methods. Following an IRB approval, a retrospective cohort analysis was made on 44 consecutive women who had an AJUST procedure, from April 2009 to January 2010. During this time period AJUST was offered to all patients with primary urodynamic stress urinary incontinence. Data regarding clinical history, physical examination for uterovaginal prolapse and urodynamic testing was retrieved from patients` charts. Exclusion criteria were mixed urinary incontinence, pelvic organ prolapse (POPQ score≥2) and patients who had prior anti- incontinence surgery. Postoperative pain was assessed by visual analogue scale. Participants returned for routine post operative visit at 8 weeks period. Objective outcomes were evaluated by stress cough test with bladder filled to 300 ml volume. Subjective outcomes of surgery were evaluated by inquiring the patients prior to and following surgery how much is she bothered by her symptoms of urinary incontinence. Patients were also asked if her urine incontinence was cured, improved or had no change following the operation. Improvement of health-related QoL (quality of life) was assessed by the incontinence impact questionnaire-short form (IIQ-7) and the urogenital distress inventory-short form (UDI-6). Data was computed and analyzed by the SPSS version 17 (Chicago, IL).

Results. Overall 43 women with a median age of 58 (36-78) years returned for follow up evaluation. The majority of patients (68%) were postmenopausal, the median BMI was 28 (20-37). The average duration of surgery was 17 minutes (12-30 minutes), with an estimated blood loss of 65 cc (20-70 cc). The median pain score (VAS) around 10 hours post-surgery was 3(0-7). Positive cough test was demonstrated in 4 (9%) patients. Subjective failure was reported in 5 (11%) patients. IIQ7 and UDI6 total scores were statistically significantly lower following surgery (64±11 vs. 39±10, $p<0.0001$ and 27±9 vs. 13±17, $p<0.0001$, respectively, figure 1). Urgency appeared de novo in 8 patients (18%). There was one case of AJUST removal due to vaginal erosion. Urine obstruction at 48 hours following procedure was observed in two patients, in one case sling division was needed due to lack of spontaneous improvement in voiding function. Wound dehiscence was recognized in one patient at postoperative day 7. At two months follow up, urinary tract infection was diagnosed in 4 patients. Overall the subjective score of bothersome from urinary incontinence decreased significantly from a level of 8.5 to 2 on a scale of `0 -no bother at all` to `10 cannot tolerate`, $p<0.0001$).

Interpretation of results. Short term follow up demonstrates that the AJUST is a relatively safe procedure with comparable results to the traditional midurethral slings procedures. Longer follow up is needed to evaluate if these findings are stable.

Concluding message. AJUST sling is a simple surgical procedure with relatively a low rate of complications. The duration of surgery is short and its success rate is about 90% at two months follow up period. Comparative studies with longer follow up periods are needed before recommending on the AJUST as the treatment of choice for stress urinary incontinence.

Figure 1.



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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Macabi Health Care Services, ethical commitee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**