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EVALUATION OF EXPERIENCE WITH MINIARC AND AJUST SYSTEM MINI-SLING ANTI-INCONTINENCE PROCEDURES

Hypothesis / aims of study

The aim of this study was to evaluate the efficacy of the MiniArc and AJUST system mini-sling anti-incontinence procedures for female stress urinary incontinence, minimum - 24 months after operation. The hypothesis was that the cure effect of the MiniArc and AJUST system is similar.

Study design, materials and methods

This clinical study included 66 women with previously untreated stress urinary incontinence, and 63 patients completed the study. These women were randomly divided by the envelope method into two groups; the first group of patients underwent operations using the MiniArc (n=33) technique, while the second group were treated with the AJUST (n=33) technique. The efficacy of AJUST and MiniArc procedure (n=31/32) was evaluated on an average of 28/29 months (minimum - 24 months; mean number of days was 843/873) after the procedures. We briefly present the subjective and objective outcomes of these procedures from the 5 hospitals which participated in the study. Subjective assessment of the cure rate and the leakage of urine was based on the five-point Likert scale and on the International Consultation on Incontinence Questionnaire - Short form (ICIQ-UI SF). Improvement in urinary incontinence by ICIQ-UI SF was defined as a drop in the score of more than 50%. The evaluation of the five-point Likert scale was: 5-cured, very satisfied; 4-improved, satisfied; 3-no change to preoperative status; 2-worsened, not satisfied; 1-significantly worsened, not satisfied. Before the operation the women received a prophylactic antibiotic treatment, an iv dose of Unasyn (1.5g). Objective assessment of leakage of urine was assessed by the cough test. All subjects gave written consent to participate in the study.

Data were processed and statistical analysis performed by Number Cruncher Statistical System (NCSS). Changes in time and differences between groups were assessed using t-tests, Wilcoxon tests or Fischer exact test; the level of significance was set to 0.05.

Results

The patients' mean age before the operation was 59 (SD 8.4) years in the AJUST group and 60.2 (SD 8.12) years in the MiniArc group. Mean body mass index (BMI) was 29.1 (SD 5.03)/28.6 (SD 4.86) in the AJUST/MiniArc group, and mean parity was 2.06 (SD 0.57)/2.25 (SD 0.62). We did not find statistically significant differences between these two groups.

Objective assessment by cough test showed that 29/31(93.5%)/26/32(81.3%) of patients had negative results for this test 28/29 months after AJUST/MiniArc operation. The difference between groups is not statistically significant.

Subjective assessment by the ICIQ-UI SF questionnaire showed that 29/31 (93.5%)/ 31/32 (96.9%) of patients were dry or improved 28/29 months after the AJUST/MiniArc operation. The difference between groups is not statistically significant. ICIQ-UI SF questionnaire showed that 21/31(67.7%)/20/32(62.5%) of our patients were completely dry 28/29 months after AJUST/MiniArc operation. The difference between groups is not statistically significant. The ICIQ-UI SF mean score before the AJUST/MiniArc operation was 15.26 (SD 3.43)/15.56 (3.35); and 28/29 months after the operation it was 2.94 (SD 5.45)/2.53 (SD 4.33). The difference between groups is not statistically significant. In answer to the question "Overall, how much does leaking urine interfere with your everyday life?" the mean score 28/29 months after the operation was 1.55 (SD 3.08)/ 1.25 (SD 2.57). The difference between groups is not statistically significant. The mean Likert score 28/29 months after AJUST/MiniArc operation was 4.42 (SD 1.20)/4.46(SD 1.07). The difference between groups is not statistically significant.

Interpretation of results

Our initial experience with AJUST and MiniArc procedures are positive. From the results 28/29 months after operation we can conclude that the cure effect of AJUST and MiniArc is similar.

Concluding message

The hypothesis that the cure rates of AJUST and MiniArc procedure is similar was confirmed by cough test, Likert score or by the score of the ICIQ-UI SF questionnaire. The differences in the cure effect of AJUST and MiniArc procedure 28/29 months after operation was not statistically significant.

Disclosures

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Clinical Trial: Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Ethical committee of General University Hospital, Prague, Czech Republic **Helsinki:** Yes **Informed Consent:** Yes