

PRELIMINARY OUTCOMES OF PATIENTS TREATED WITH CONTASURE-NEEDLELESS® AFTER THE NEW TAILORED PROTOCOL ACCORDING TO DEGREE OF SEVERITY IN PATIENTS AFFECTED BY STRESS URINARY INCONTINENCE.

Hypothesis / aims of study

In patients affected by stress urinary incontinence (SUI), the choice between one or other surgical technique is currently in study [1]. In the recent years, the mini-slings have been really performed due to its ease and safety. However, high variability in terms of objective cure rates and patient satisfaction are published in the literature.

Our objective was to evaluate the outcomes of the mini-sling Contasure-Needleless® (C-NDL) after the implementation of a new protocol tailored for the severity of symptoms in patients affected by SUI.

Study design, materials and methods

According to our results published in 2016 when C-NDL® was compared to transobturator techniques [2], we observed that patients affected by severe SUI had worse outcomes in negative stress test and satisfaction. Consequently, we design a new protocol to select the surgical technique according to the degree of SUI severity: mild or moderate incontinence is treated with the C-NDL® technique and severe or very severe incontinence with other techniques.

In this study, all patients treated with C-NDL® since 2010 have been evaluated retrospectively and compared in two groups: group A) treated from 2010 to 2014 prior to the new protocol and group B) treated from 2014 to 2016.

With a minimum follow-up of 6 months, the objective and subjective cure rates were analyzed by the stress test and the Sandvik severity test (SSI) respectively. In addition, epidemiological data and the degree of satisfaction were recorded. Cure was defined by a negative stress test and/or SSI = 0, clinical improvement defined by preoperative SSI < than postoperative, and technique failure by postoperative SSI ≥ than preoperative SSI.

Results

A total of 118 patients were analyzed: 89 in A group and 29 in B group.

The median of presurgical SSI was 6 (1-12) vs 4 (1-6) for group A and B respectively. Epidemiological and baseline data are summarized in Table 1.

The postsurgical stress test was negative in 80.9% vs 86.2% for group A and B respectively (p=0.516). The SSI was 0 in 66.2% vs 88.5% respectively (p=0.03) and the patients were very satisfied with the surgical technique in 25.3 vs 58.6 (p=0.001) for groups A and B respectively (table 2).

Interpretation of results

At 6 months follow-up, our results showed higher rates of objective and subjective cure when the C-NDL® was performed tailored to a mild and moderate degree of SUI. The long term follow-up of these patients will confirm our preliminar data and will be helpful to select the proper surgical technique for patients affected of SUI.

Concluding message

According to our results, the mini-slings techniques might be more adequate to treat patients affected by mild to moderate SUI whereas transobturator or retropubic techniques might be reserved for patients with high severity.

Table 1. Epidemiological and presurgical data

	Group A (n=89)	Group B (n=29)	p value
Follow-up (mean, month)	30 ± 12.4	12.7 ± 6.1	<0.001
Age (mean, years)	57.6 ± 11.6	57.5 ± 10.4	0.743
BMI (mean)	28.7 ± 4.97	26.6 ± 3.8	0.09
Menopausal (%)	69.7	69	0.94
Smoker (%)	15.7	6.9	0.228
Previous conservative treatment (%)	50.6	59.3	0.267
Parity (median)	2 ± (0-6)	2 ± (0-5)	0.671
Pre-surgical Sanvik Severity Index (median)	6 (1-12)	4 (1-6)	0.029
Quality of life (ICI-Q) (median)	7 (2-10)	7 (5-10)	0.542

Table 1. Epidemiological and presurgical data

	Group A (n=89)	Group B (n=29)	p value
Symptoms of urge incontinence (%)	55.1	37.9	0.109

Data are presented as mean $\pm$ SD, median with range or n (%) and were analyzed using Student's test, Mann–Whitney U-test, chi-square test or Fisher's exact test as appropriate. Group A) Contasure-Needleless® performed from 2010 to 2014 prior to the new protocol. Group B) Contasure-Needleless® performed from 2014 to 2016. ICI-Q International Consultation on Incontinence Questionnaire.

Table 2. Objective and subjective cure rates

	Group A (n=89)	Group B (n=29)	p value
Negative stress test (%)	72/89 (80.9)	25/29 (86.2)	0.516
Post-surgical Sanvik Severity Index (%)			
0	47/71 (66.2)	23/26 (88.5)	0.03
Improvement	17/71 (23.9)	1/26 (3.8)	0.024
Failure	7/71 (9.9)	2/26 (7.7)	0.745
Satisfaction (%)			
Very satisfied	22/87 (25.3)	17/29 (58.6)	0.001
Satisfied	51/87 (58.6)	11/29 (37.9)	0.07
Dissatisfied	14/87 (16.1)	1/29 (3.4)	0.085

Data are presented as mean $\pm$ SD, median with range or n (%) and were analyzed using Student's test, Mann–Whitney U-test, chi-square test or Fisher's exact test as appropriate. Group A) Contasure-Needleless® performed from 2010 to 2014 prior to the new protocol. Group B) Contasure-Needleless® performed from 2014 to 2016.

References

1. Huang W, Wang T, Zong H, Zhang Y (2015). Efficacy and Safety of Tension-Free Vaginal Tape-Secur Mini-Sling Versus Standard Midurethral Slings for Female Stress Urinary Incontinence: A Systematic Review and Meta-Analysis. *Int Neurourol J.* Dec;19(4):246-58
2. Fernandez-Gonzalez S, Martinez Franco E, Lin Miao X, Amat Tardiu L (2016). Contasure-needleless® compared with Monarc® for the treatment of stress urinary incontinence. *Int Urogynecol J.* Dec 26.

Disclosures

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