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Grafting with collagen fleece TachoSil® after plaque incision or excision in Peyronie's disease patients: Results from a multicenter prospective study

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Introduction: To describe the results of a multicenter prospective registry on Peyronie's disease (PD) patients undergoing plaque incision or excision and grafting with collagen fleece TachoSil®, in order to evaluate the efficacy and safety of this procedure.

Materials and methods: A prospective non-controlled multicenter study of PD patients was performed between May 2016 and March 2018. Patients with stable PD for at least 3 months, difficulties in sexual intercourse, normal erectile function with or without pharmacological treatment, curvature > 45° and/or penile shortening and/or complex deformities were included. All patients underwent plaque incision or excision and grafting (PIG/PEG). Collagen fleece TachoSil® was the graft used in all patients. Main variables assessed were penile curvature correction, penile shortening, erectile function with the 5-item version of the International Index of Erectile Function (IIEF-5) and the Erection Hardness Score (EHS), patient satisfaction with not validated questionnaires, and complications.

Results: A total of 52 patients were enrolled in the study. The mean (SD) preoperative penile curvature was 72.8 (17.0) degrees. PIG was the preferred technique (80.8%). Complete curvature correction was achieved in 92.3%, and no significant penile shortening was recorded in 80.8% of subjects. No statistically significant difference from the baseline was found in IIEF-5 and EHS at 3 months nor at 6 months. Six months after surgery, 78.5% of men were satisfied with intervention. Swelling and ecchymosis were the most common perioperative complications (23.1%). Two cases (3.8%) of wound infection were recorded. At 6 months from surgery 35.7% of patients reported mild penile hypoesthesia.

Conclusions: This is the first multicenter study on PD patients undergoing grafting with collagen fleece. TachoSil® grafting after PIG/PEG is an effective and safe procedure.

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Risk of unfavorable outcomes after penile prosthesis implantation – results from a national registry (INSIST-ED)

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Introduction: Penile prosthesis implantation (PPI) can result in unfavorable outcomes in terms of both relevant complications and postoperative low patients' satisfaction. We tested the risk of unfavorable outcomes after hydraulic PPI using data from the national multi-institutional national registry of penile prosthesis (INSIST-ED).

Materials and methods: INSIST-ED registry data including patients implanted from 2014 to 2019 were analyzed. All data have been prospectively recorded by 45 surgeons on a dedicated website (www.registro.andrologiaitaliana.it) and revised by a single datamanager. Patients' baseline characteristics and postoperative complications were recorded. All patients were re-assessed at 1-yr follow-up (FU)

using the validated questionnaire Quality of Life and Sexuality with Penile Prosthesis (QoLSPP). Unfavorable outcomes were defined as significant postoperative complications (Clavien-Dindo \geq 2) and/or QoLSPP scores below the 10th percentile. Logistic regression analysis tested the association between clinical characteristics and the risk of unfavourable outcomes after surgery.

Results: Overall, 1-yr FU data were available for 256 patients (median (IQR) age 60 years (56, 67)) after three-piece PPI. Erectile dysfunction (ED) etiology was pelvic surgery/radiotherapy, organic and Peyronie's disease in 102 (40%), 108 (42%) and 46 (18%) patients, respectively. Of all, 25 (10%) patients experienced complications after surgery. Of 25, 2 (8%) and 10 (40%) patients had Clavien-Dindo 2 and 3 complications, respectively. At 1-yr FU, median (IQR) QoLSPP total score was 65.5 (60, 71); 38 (15%) patients showed unfavourable outcomes because of significant postoperative complications and/or QoLSPP score below the 10th percentile (i.e., <47). At logistic regression analysis, age emerged to be non-linearly associated with the risk of experiencing unfavourable outcomes, with an U-shaped correlation showing lower risk for younger and older patients and higher risk for middle-aged men. ED etiology and surgical volume were not associated with PPI outcomes.

Conclusions: Unfavorable outcomes in terms of both postoperative complications and low QoL scores are not uncommon after hydraulic PPI. Physicians should be aware that middle-aged men could be at higher risk of being unsatisfied after PPI compared to both younger and older patients.

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Challenging EAU guidelines: Proposal of a new sperm concentration cut-off for CFTR Gene testing in infertile men

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Introduction: The 2019 EAU guidelines for male infertility suggest to perform CFTR gene screening during infertility work-up if semen volume is <1.5 ml. We evaluated the sensibility, specificity and predictive accuracy (PA) of the current EAU guidelines' cut-off based on semen volume in comparison with a different cut-off based on sperm concentration values in order to more reliably identifying CFTR gene alteration(s) (i.e., mutations and polymorphisms) in a homogenous cohort of white-European men presenting for couple's infertility.

Materials and methods: Complete data from 1037 infertile men were analyzed. Semen parameters were assessed based on 2010 WHO reference criteria. EAU guidelines for CFTR gene alterations testing (semen volume <1.5 ml as for WHO criteria) were firstly adopted in our cohort; thus, the predictive performance and accuracy of different sperm concentration cut-offs (5 M/ml vs. 4 M/ml vs. 3 M/ml vs. 2 M/ml vs. 1 M/ml for CFTR deletion and 15 M/ml vs. 10 M/ml vs. 5 M/ml vs. 4 M/ml vs. 3 M/ml vs. 2 M/ml vs. 1 M/ml for CFTR polymorphisms) were tested. Youden's index calculation and AUC were used to identify the best cut-off for sperm concentration.

Results: Of 1037, 151 (14.5%) patients had semen volume <1.5 ml and would have deserved CFTR testing according to EAU guidelines; of 151, 4 (0.3%) actually displayed a CFTR mutation. Conversely, of 1037, 150 (14.5%) patients displayed a CFTR polymorphism. Overall predictive accuracy (PA), sensibility, specificity, FPR and AUC of EAU guidelines were 86.8%, 50%, 86.9%, 13% and 68% for CFTR mutations and 77.6%, 22.6%, 86.9%, 13%, 54% for CFTR polymorphisms. As for CFTR mutations, 535 (51.5%) patients had sperm concentration <5 M/ml. Lowering the cut-off of 1 M/ml each step (5 M/ml vs. 4 M/ml vs. 3 M/ml vs. 2 M/ml vs. 1 M/ml), the model performance was kept, compared to EAU guidelines (AUC: 61.9% vs. 63.7% vs. 65.1% vs. 67.2% vs. 69.8%). The