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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

Youden's index increased at decreasing sperm concentration, with its maximum in the case of sperm concentration <1 M/ml (39.7). Likewise, as for CFTR polymorphisms the model performance was comparable (AUC: 51.9% vs. 52.2% vs. 51.5% vs. 51.8% vs. 51.9% vs. 51.3% vs. 49.9%). The Youden's index for CFTR polymorphisms was maximum in the case of sperm concentration <10 M/ml (4.3).

Conclusions: Current EAU guidelines for CFTR mutations testing (<1.5 ml) depicts an overall good performance in identifying both CFTR deletion and polymorphisms. However, given the greater prevalence of a reduced sperm concentration compared to a reduced semen volume in the everyday clinical practice, this newly-suggested cut-off appears to be more widely applicable while maintaining the same performance values.

SC24 Clomiphene citrate and FSH treatment in men with elevated sperm DNA fragmentation index: Findings from a cross-sectional study

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Introduction: Sperm DNA fragmentation index (SDF) has been associated with impaired spermatogenesis and infertility, with negative consequences on biological events such as fertilization and embryonic development. Clomiphene citrate (CC) and FSH treatment (either highly purified FSH (uhFSH) and recombinant human FSH (rhFSH)) have been used to empirically improved sperm quality, but their effect on SDF is relatively poorly studied. We cross-sectionally analyzed the effect of CC and FSH treatment on SDF in men presenting for primary couple's infertility.

Materials and methods: Data from 433 men treated with either CC (n=370, 85.5%) or FSH (n=63, 14.5%) for pathologic SDF were analyzed. Semen analysis, SDF (according to SCSA) and serum hormones were measured in every patient; health-significant comorbidities were scored with the Charlson Comorbidity Index (CCI). Pre vs. post treatment semen analysis and SDF were evaluated with paired t-test. Logistic regression analysis was used to test potential predictors of SDF improvement after treatment.

Results: Overall, median (IQR) age, FSH and SDF were 37.5 (24, 64) years, 4.8 (2.8, 5.0) mUI/mL and 43.5% (33.2, 61.4), respectively. At first post-treatment (any) assessment, an improvement in terms of SDF, sperm concentration, percentage of progressive motility and of normal morphology was observed in 36 (60%), 167 (52.5%), 152 (54.9%), and 154 (57%) men, respectively. SDF rate was significantly reduced after treatment (any) (44.9 vs. 52.5%; mean post vs. pre change -7.6; p=0.001). Conversely, sperm concentration (12.3 vs. 15.0 × 10⁶/mL) and progressive motility (18.6 vs. 19.1%) were slightly but not significantly improved after treatment (any). Normal morphology (10.8 vs. 6.5%) was significantly reduced after treatment (any) (p<0.001), particularly after CC treatment (10.9 vs. 6.9%, p<0.001). Both CC (p=0.001) and FSH (p=0.04) therapy significantly improved SDF levels, with a higher improvement after CC compared to FSH treatment (-12.5 vs. -2.5; p=0.01). ROC curves revealed that baseline SDF>35% could predict SDF improvement after treatment, with 97% sensitivity and 71% specificity. At multivariable logistic regression analysis, only a baseline SDF>35% was associated with SDF improvement after treatment, after accounting for age, BMI, serum FSH and smoking status.

Conclusions: Both CC or FSH treatment improved SDF in primary infertile men. Patients who benefit most are those with higher baseline SDF, with SDF>35% as a possible clinical cut-off.

SC25 Challenging the guidelines: Proposal of a new sperm concentration cut-off for Y chromosome microdeletions testing in primary infertile men

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Introduction: The 2019 EAU guidelines for male infertility suggest performing Y-chromosome microdeletion test if the sperm concentration is <5 M/ml. Recently, a systematic review showed that most microdeletions occur in men with sperm concentrations of ≤1 M/ml sperm. We evaluated the sensibility, specificity and predictive accuracy (PA) of the EAU guidelines sperm concentration cut-off in comparison with other sperm concentration values in identifying Y-chromosome microdeletions in a homogenous cohort of white-European men presenting for primary couple's infertility.

Materials and methods: Complete data from the last 823 primary infertile men were analyzed. Semen parameters were assessed based on 2010 WHO reference criteria. EAU guidelines for Y-chromosome microdeletion testing (sperm concentration <5 M/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 vs. azoospermia) was tested. Youden's index calculation was used to identify the best cut-off for sperm concentration. AUC curve was used to graphically display the correlation between sensibility and false positive rate (FPR) at different cut offs.

Results: Of 823, 524 (69.7%) patients had sperm count <5 M/mL; of them, 19 (3.5%) actually displayed a Y-chromosome microdeletion. Overall predictive accuracy, sensibility, specificity, FPR and AUC of EAU guidelines were 37.4%, 100%, 36%, 64% and 68%, respectively. 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 vs. azoospermia), model performance increased (PA: 41.9% vs. 45.6% vs. 49.4% vs. 56.2% vs. 66.1%; AUC: 70.1% vs. 72.2.6% vs. 71.5% vs. 72.5% vs. 77.5%). The Youden's index increased at decreasing sperm concentration, with its maximum in case of azoospermia (55.02).

Conclusions: Current EAU guidelines for Y-chromosome microdeletion testing (<5 M/ml) misclassify patients in two thirds of cases. The accuracy of testing increases steadily at decreasing level of sperm concentration with maximum predictive performance in the case of azoospermia. Therefore, in non-azoospermic infertile men, 1 M/ml should be used.

SC26 infertile men have higher PSA values than aged-matched fertile controls: Potential implications for personalized prevention strategies

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Introduction: Infertile men are at greater risk of oncologic and non-oncologic chronic disease than the fertile of comparable age. Thereof, male factor infertility (MFI) may be considered an identifiable early sentinel marker for the development of prostate cancer (PCa). We investigated serum PSA levels in a cohort of men presenting for MFI associated with primary couple's infertility compared to a cohort of aged-matched fertile controls, according to the EAU recommendation that a first PSA assessment should be obtained at 40–45 years of age.

Materials and methods: Data from 956 (90%) infertile men and 102 (9.6%) fertile controls were analysed. Comorbidities were scored with