

biomarkers and explain the molecular mechanisms underlying the altered spermatogenesis. The objective of the study is to evaluate the blood plasma miR-20a-5p expression in infertile patients with non-obstructive azoospermia (NOA) compared to healthy normozoospermic men.

**Materials and methods:** From January 2018 to December 2019, 24 infertile couples were prospectively enrolled. All the patients were included into two groups: Group 1 infertile men with NOA, Group 2 healthy normozoospermic men belonging to couples with female infertility tubal factor who achieved pregnancy using IVF or ICSI. The expression of circulating miR-20a-5p was assessed by RT qPCR in plasma samples. A relative quantification strategy was adopted using the  $2^{-\Delta\Delta Cq}$  method to calculate the target miR-20a-5p expression with respect to miR-16-5p as endogenous control. Total cell-free RNA extracted from 0.5 ml plasma using the mirVana PARIS kit was submitted to RT-qPCR using TaqMan Advanced miRNA cDNA Synthesis Kit and TaqMan<sup>®</sup> Advanced miRNA Assays.

**Results:** Group 1 included 14 patients, Group 2 10 men. Mean male age was  $35.6 \pm 4.2$  years. Considering the Group 1, mean FSH value was  $19.4 \pm 7.8$  IU/l, LH  $8.5 \pm 3.4$  IU/l, TT  $12.5 \pm 3.9$  nmol/l, TSH  $2.0 \pm 1.1$  mIU/l, PRL  $10.5 \pm 3.2$  ng/ml. Mean right and left testicular volume (TV) was  $8.9 \pm 5.2$  ml and  $8.2 \pm 4.5$  ml, respectively. Group 2 showed hormonal levels and TV in the normal range. All NOA underwent testicular sperm extraction. Successful sperm retrieval (SR) with cryopreservation was found in 8/14 patients (overall SR rate: 57.1%). Mean sperm concentration was  $0.001 \pm 0.0001 \times 10^6$ /ml, motility  $0.2 \pm 0.6\%$ , biosystem straws collected  $3.2 \pm 2.0$ . Mean miR-20a-5p value was  $0.25 \pm 0.20$  and  $0.06 \pm 0.02$  in the Group 1 and Group 2, respectively. Thus, the relative expression of miR-20a-5p was significantly higher in patients affected by NOA than in healthy normozoospermic control subjects ( $p = 0.026$ ).

**Conclusions:** Blood plasma miR-20a-5p could represent a potential non-invasive diagnostic biomarker in infertile patients with non-obstructive azoospermia. A possible correlation of this marker with testicular histopathological findings could allow the clinician to correctly counsel the azoospermic patients in performing surgery for fertility purpose.

### SC11

Experience of oxygen-ozonotherapy in the management of erectile dysfunction in diabetic patients poor responder to 5-phosphodiesterase inhibitors. Preliminary results and follow-up

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**Introduction:** Erectile dysfunction (DE) has higher incidence in diabetic patients. Microvascular damages, persistent oxydant activity of free radicals (ROS), endothelial dysfunction are at the basis of frequent poor outcome of 5-phosphodiesterase (5-PDE) inhibitors for DE in this particular category of patients. Endothelial nitric oxide synthase expression increased significantly with ozone therapy in some animal models. In this study we have evaluated the effects of systemic oxygen-ozonotherapy (OOT), defined autohaemotherapy (AHMT) as possible supplementary therapy in non responders to 5PDE inhibitors.

**Materials and methods:** The rationale of OOT is in hormetic properties, i.e. paradoxical antioxidant effects obtained at low concentration of oxygen-ozone combination, aiming the reduction of all free oxydative molecules, especially nitroxic and oxygen radicals. We have selected 13 patients aged 50–70 years affected by type 2 diabetes in association with ED. All patients are diabetic in good glycemic control. All patients, non responders to 5PDE inhibitors, have been submitted to 10 weekly applications of autohaemotherapy (AHTM): from every patient we have taken venous sampling of 200 ml of blood enriched with an ozone gas mixture, administered by a specific medical device with a

concentration between 30 and 70 mcg/ml then immediately reinfused. During AHTM cycle and 2 month follow up all patients have taken daily tadalafil 5 mg. All patients have been evaluated with IIEF15 before and after 2 months follow up. All patients and their partners have been also evaluated by psychosexual counseling with weekly sitting, at the beginning for the selection, during all phases of AHTM therapy and during 2 month follow-up.

**Results:** All patients improve quality and quantity of erections with a rising response to 5PDE inhibitors during the 2 month follow up. Psychosexual couple counseling also show qualitative improvement of sexual relations. AHTM has been well tolerated to all patients. No side effect has been observed during the entire cycle of therapy and the 2 month follow up. All patients refer a personal daily improvement of glycemic control without any variation of therapy or lifestyle.

**Conclusions:** OOT could be beneficial in reducing the negative effects of diabetes on erectile dysfunction as a result of enhanced enzymatic activity in endothelial factors and reducing the effect of ROS. Preliminary results need more studies with a wider number of patients. Endothelial nitric oxide synthase expression could increase significantly with OOT with more beneficial systemic effects, with minimal contraindications and no side effects. OOT could rise the quality and quantity of erections in diabetic patients, improving the outcome in the use of 5PDE inhibitors and in glycemic control. For diabetic patients, especially for poor responders to 5PDE inhibitors a multidisciplinary approach and psychosexual counseling demonstrate good synergy to improve sexual relations and quality of life.

### SC12

Mid-Term effects of high-altitude on sexual hormonal parameters during a Himalayan expedition

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**Introduction:** The aim of this study is to assess the mid-term effects of altitude hypoxia on sexual hormonal parameters, comparing Italian trackers with native Nepalese porters who took part in a Himalayan expedition.

**Materials and methods:** Participants completed a combined circuit of 300 Km distance in 19 days with over 16000 meters of difference in altitude and average daily walk of 6 hours involving a demanding route with ascent and descent in the Himalayas, Nepal. The analyses were performed on two groups of participants: 6 Italians and 6 Nepalese. The effect of high-altitude on Hypothalamus-hypophysis-gonads axis (FSH, LH, Testosterone, Progesterone) was assessed for both groups. Samples were collected the day before the expedition beginning and the day after it was completed. The Italians had an additional sample after 10 days (follow-up sample).

Shapiro-Wilk test, Q-Q plots, Levene's test for equality of variances, Repeated Measures - ANOVA. were adopted. Significance ( $p$  value), effect size (partial  $\eta^2$ ) were reported.

**Results:** Nepalese participants had LH values higher than Italians at Pre expedition evaluation ( $4.260 \pm 2.416$  mUI/ml vs  $2.728 \pm 1.004$  mUI/ml, respectively), that was increased at Post expedition in both groups ( $4.598 \pm 1.605$  mUI/ml vs  $3.262 \pm 1.605$  mUI/ml). Among Nepalese, we found a more important reduction in FSH concentration from Pre and Post expedition ( $5.840 \pm 2.001$  mUI/ml to  $5.054 \pm 2.215$  mUI/ml) respect to Italians (from  $5.106 \pm 1.483$  mUI/ml at Pre to  $4.958 \pm 0.999$  mUI/ml at Post and down  $5.070 \pm 0.961$  at Follow up). Testosterone concentration decreased from Pre to Post expedition ( $p = 0.109$ ,  $\eta^2 p = 0.260$ ,  $\omega^2 p = 0.164$ ) also showed by post-hoc analyses, with Nepalese participants having a greater reduction (from  $4.557 \pm 0.823$  to  $3.397 \pm 1.304$  ng/ml) than Italians (from  $4.864 \pm 1.675$  to  $4.354 \pm 0.948$  ng/ml). At Follow up, Italians increased the baseline values ( $6.570 \pm 1.376$  ng/ml), as revealed by the Pre vs Post vs Follow Up

comparison ( $p = 0.038$ ,  $\eta^2p = 0.675$ ,  $\omega^2p = 0.515$ ), and significant post-hoc differences were found (Pre vs Post:  $p = 0.161$ , and Post vs Follow Up:  $p = 0.0043$ ). We found a reduction in progesterone concentration from Pre to Post expedition ( $p = 0.049$ ,  $\eta^2p = 0.364$ ,  $\omega^2p = 0.274$ ) with Italians having a greater reduction ( $p = 0.081$ ,  $\eta^2p = 0.502$ ,  $\omega^2p = 0.340$ , from  $0.550 \pm 0.339$  to  $0.302 \pm 0.093$  ng/ml) respect to Nepalese porters (from  $0.410 \pm 0.163$  to  $0.337 \pm 0.188$  ng/ml). At Follow up Italians recovered up the baseline values ( $2.867 \pm 0.354$  pg/ml), as revealed by the Pre vs Post vs Follow Up comparison ( $p = 0.011$ ,  $\eta^2p = 0.703$ ,  $\omega^2p = 0.599$ ), and significant post-hoc differences were found showed (Pre vs Post:  $p = 0.170$ , and Post vs Follow Up:  $p = 0.161$ ).

**Conclusions:** Mid-term High altitude affects the Hypothalamus-hypophysis-gonads axis. This effect seemed to be more pronounced among Italians for progesterone and among Nepalese for testosterone.

### SC13 Outcomes of inflatable penile prosthesis in patients with or without virgin primary implant: A propensity score-matched comparison

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**Introduction:** Inflatable penile prosthesis (IPP) represents a mainstay for the treatment of erectile dysfunction (ED), showing excellent results when performed in selected patients. Although IPP might provide decreased outcomes in higher-risk populations, scarce data exist on the benefits and consequences of IPP placement in this surgical setting.

To compare outcomes of IPP in patients with or without virgin primary implantation.

**Materials and methods:** Data were obtained from our prospectively maintained institutional database. Propensity score matching was carried out to reduce the effect of inherent differences between groups. Clinical and surgical data were compared. Specifically, patients' and partners' outcomes were assessed by the International Index of Erectile Function (IIEF), Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) and Quality of Life and Sexuality with Penile Prosthesis (QoLSPP) questionnaires. Complications were graded using Clavien-Dindo classification.

**Results:** Of all 66 included patients, 24 with prior surgery for erectile dysfunction and Peyronie's disease (Group 1) could be matched with penile surgery-naïve patients (Group 2) in a 1:1 ratio.

Compared with reoperative cases, surgery-naïve patients had a shorter operative time [median (IQR): 85 (67–98) min vs 64 (50–76) min;  $p = 0.01$ ] and a lower complication rate (21% vs 12%;  $p = 0.02$ ). Overall, no differences were observed concerning sexual function recovery and device utilization (both  $p > 0.2$ ). However, men in Group 2 showed a tendency for a faster return to sexual activity ( $p = 0.01$ ).

Mean (SD) scores for questionnaires demonstrated high satisfaction and IPP efficacy in Groups 1 and 2: IIEF [20.0 (6.3) vs 20.3 (5.8);  $p = 0.6$ ], patient [74.8 (23.6) vs 75.1 (21.4);  $p = 0.5$ ] and partner EDITS [72.8 (24.8) vs 73.2 (23.1);  $p = 0.7$ ].

Similarly, QoLSPP showed favourable quality of life and sexuality: functional domain [3.8 (1.1) vs 4.0 (1.3);  $p = 0.3$ ], personal [3.9 (1.1) vs 4.1 (1.0);  $p = 0.5$ ], relational [4.0 (1.2) vs 3.9 (1.1);  $p = 0.3$ ] and social [3.9 (1.2) vs 4.1 (1.2);  $p = 0.4$ ].

**Conclusions:** In experienced hands, IPP placement offers high satisfaction to both patients and partners, also in the setting of non-virgin implant.

However, given the higher morbidity, it is mandatory to adequately inform and warn those patients about possible complications after surgery.

### SC14 Teratozoospermia is a poorly informative parameter for the evaluation of the infertile male: Hints from an academic high-volume andrological center

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**Introduction:** The clinical value of sperm normal morphology is not clearly established. We aimed to evaluate the relationship between normal morphology and the male fertility potential, using total motile sperm count as a proxy measure for it.

**Materials and methods:** We collected complete demographic and clinical data from 1118 primary infertile non-azoospermic men. At least two different semen analyses were requested for every participant. Semen analyses followed 2010 WHO reference criteria and were categorized according its cut-off values. TMSC was categorized into four groups of increasing severity:  $<1$  vs. 1–5 vs. 5–10 vs.  $>10$ . The relationship between normal morphology and fertility potential was graphically depicted. The diagnostic accuracy of teratozoospermia for the detection of very poor reproductive potential (i.e.  $TMSC < 1$ ) was estimated.

**Results:** Median sperm normal morphology and TMSC values were respectively 2% (interquartile range, IQR 1–10%) and 3 (0.4–11). WHO-defined teratozoospermia overall prevalence was 62%. The percentage of men with teratozoospermia increased from the least to the most severe TMSC group (52% vs 74%,  $p < 0.001$ ). Normal sperm morphology had a non-linear relationship with reproductive potential, with a modest linear rising slope only when normal morphology was below 10%. Using a 10% cut-off instead of 4% for normal morphology resulted in higher accuracy (0.62 vs 0.42) for identifying men with very poor reproductive potential, i.e.  $TMSC < 1$ .

**Conclusions:** Normal morphology values are pathological according to WHO in the vast majority of infertile men. However, they appear to be poorly informative in terms of reproductive potential. The WHO 4% threshold is poorly informative as well when it comes to infertile men with the most impaired reproductive potential.

### SC15 Effectiveness of a new drug (Camarouf 0.006%) in treatment of delayed ejaculation

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**Introduction:** Delayed ejaculation (D.E.) is probably the less studied male sexual dysfunction but is not a such rare disorder with a prevalence of 15–30% in the higher groups. Current treatments have only an anecdotal success or important side effects, so often patient starts only a psychosexual therapy without unrealistic results.

**Materials and methods:** Camarouf is an oleoresin-based cream with capsaicin and vanilloid that has the ability to stimulate the penile nerve endings and determine an increase in the penine blood flow giving an increase in the sensation of heat. After signing a specific informed consent from June 2018 to October 2019, we recruited 54 patients with D.E.. Patients performed a preventive sexological, urological and hormonal evaluation to rule out such an etiology. Only 48 patients were eligible for the study and they were randomized into two study groups of 24 patients: A groups start with Camarouf cream and B that use a placebo oleoresin-based ones. With Topiclick® the dose was standardized at 0,25 ml/week, 15 min before sexual intercourse. After 2 months of therapy and 1 months of wash out, groups reversed treatment. IIEF 5 questionnaire, Quol questionnaire