Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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19 symptoms or if they had been in contact with someone suspected or confirmed to be positive for the virus. Only patients determined to be at low risk for COVID-19 were allowed to enter the clinic for fertility treatment. Both patients and staff were required, upon arrival at the clinic, to wear a mask, complete a symptom-based questionnaire, record body temperature, and keep a safe social distance of more than 6 feet at all times. Any individual recording a fever over 100.4°F and/or two or more symptoms was instructed to stay/return home for self-quarantine. Specimen collection for viral screening involved an anterior nose sampling method and storage in a FDA approved viral transport medium. Viral RNA was isolated using the MagMAX™ Viral/Pathogen II (MVP II) Nucleic Acid Isolation Kit (Thermo Fisher Scientific). Molecular testing for active SARS-CoV-2 viral RNA infection was performed using the FDA emergency use authorized TaqPath™ RT-PCR COVID-19 test (Thermo Fisher Scientific) for every patient within 3-5 days prior to oocyte retrieval or an attempt to achieve a pregnancy, and for all staff bi-weekly. Positive cases were reported to each respective local State Health Department.

RESULTS: Of the 2,074 patients tested for COVID-19 between May and July 2020 across nine fertility clinics in the US, only 3 (0.15%) were found to be positive for SARS-CoV-2 viral RNA infection. In all cases the patients were asymptomatic and passed the triage protocol. PCR testing of staff bi-weekly identified 6 positive cases. All but one indicated having one or two mild symptoms. There were no recorded community transmissions among either patients to staff or between staff members.

CONCLUSIONS: A comprehensive risk mitigation strategy that includes a combined triage protocol, safe social distancing and molecular testing for active SARS-CoV-2 viral RNA infection in both patients and staff enables early detection and isolation of infected asymptomatic or pre-symptomatic individuals, thereby creating a safe environment for patient care and staff welfare during the global COVID-19 pandemic.

SUPPORT: None

TABLE 1

| Test | G1 (n=10) | G2 (n=30) | P value |
|------|-----------|-----------|---------|
| TEX101 (ng/ml) | 13.5 (7.5-22.3) | 9.8 (2.8-18.2) | 0.014 |
| FSH (mIU/ml) | 5.1 (3.5-9.2) | 15.9 (3.5-31.2) | 0.001 |
| LH (mIU/ml) | 4.2 (2.4-6.5) | 6.3 (2.7-27) | 0.01 |
| Total testosterone (nmol/L) | 5.1 (2.2-13) | 4.5 (1.9-10.8) | 0.818 |

Data are expressed as median (range). Area under curve using ROC was 0.76 and a cut-off value of ≥ 9.9 ng/ml showed sensitivity of 90% and specificity of 57% in pre-operative TEX-101 prediction of recovery of sperms.

CONCLUSIONS: Pre-operative seminal TEX-101 can be used as a predictor for recovery of sperms in the ejaculate after varicocelectomy in men with NOA and palpable varicocele. NCT04397887.

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SEMINAL TEX-101 MAY PREDICT RESTORATION OF SPERMATOGENESIS AFTER VARICOCELECTOMY IN AZOOSPERMIC MEN WITH PALPABLE VARICOCELE. Ahmed Mohamed El Guindi, M.D,1 Mina Saad, MSc,1 Zeinab Nour, M.D,2 Hamed Abdallah Hamed, M.D,3 Mohamed Wael Ragab, M.D1 Cairo University, Cairo, Egypt; 4Cairo University, Cairo, Egypt.

OBJECTIVE: Around 40% of men with non-obstructive azoospermia (NOA) and palpable varicocele may benefit from varicocelectomy with appearance of sperms in ejaculate. Testicular histopathology predicts the outcome of varicocelectomy and men with hypospermatogenesis or late maturation arrest have better prognosis compared to men with early maturation arrest or Sertoli cell only (SCO) syndrome.

Testis expressed protein (TEX-101) is a seminal plasma protein that shed from testicular germ cells and it has been found to be significantly lower in men with SCO in compare with other NOA subtypes.

We aimed to assess the predictive role of seminal TEX-101 in recovery of sperms in ejaculate after varicocelectomy.

DESIGN: Prospective cohort.

MATERIALS AND METHODS: Forty male patients with NOA and palpable bilateral varicocele were subjected to seminal TEX-101 by ELISA (Wuhan Fine Biotech Co., Ltd. China), serum gonadotropins and total testosterone evaluation, followed by sub-inguinal microsurgical varicocelectomy. Two seminal analyses were performed in 3- and 6-months follow-up periods to assess appearance of sperms in ejaculate.

Pre-operative seminal TEX-101 was used to compare pre-operative seminal TEX-101, FSH, LH and testosterone between the group of men with observed sperms in ejaculate during follow-up (group 1) and men with persistent azoosperma (group 2). Receiver operating curve (ROC) test was used to calculate a cut-off value and diagnostic indices (sensitivity and specificity) of pre-operative seminal TEX101.

RESULTS: After varicocelectomy, spermatozoa were found in the ejaculate of 10/40 (25%) through the follow-up 17 patients at the 3-months follow-up and additional 3 patients at 6-months follow-up. In these ten patients (G1), no significant differences were observed in pre-operative testicular volume or serum testosterone levels in compare with patients with persistent azoosperma during follow-up period (G2).

Pre-operative seminal TEX-101 was significantly higher in G1 in compare with G2 (p=0.014), while serum FSH and LH were significantly higher in G2 (p=0.001, p=0.01 respectively), as shown in table (1).

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EFFECT OF HORMONAL CONTRACEPTION ON ILLNESS SEVERITY IN WOMEN WITH POSITIVE SARS-CoV2 TESTS. Vaidhehi Mujumdar, MD,1 Ariel T. Levy, MD,2 Rachel Madding, BA,3 Vincenzo Berghella, MD,1 Johanna Quist-Nelson, MD,4 William D. Schlaff, MD,1 Brent C. Monseur, MD, ScM3 Thomas Jefferson University Hospital, Philadelphia, PA; 5Weill Cornell Medical Center, New York Presbyterian Hospital, New York, NY; 6Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia, PA; 7University of North Carolina, Chapel Hill, Chapel Hill, NC; 8Stanford Hospitals and Clinics, Sunnyvale, CA.

OBJECTIVE: To evaluate if hormonal contraception affects illness severity in SARS-CoV-2 positive women.

DESIGN: Retrospective cohort study.

MATERIALS AND METHODS: Chart review of reproductive age (12-49 yo) women who tested positive for SARS-CoV2 at a tertiary medical center from March 28-April 27, 2020. Exclusion criterion was pregnancy. Women using hormonal contraception were compared to patients not using hormonal contraception. Patients were not contacted to confirm contraception. The rate of hospitalization for SARS-CoV2 was low for users and non-users of hormonal contraception (2.3% vs. 3.8%, respectively; p=0.001).table 1).

Preliminary evidence that use of hormonal contraception does not have a significant effect on the illness severity in SARS-CoV2 as measured by hospitalization.

The rate of hospitalization for SARS-CoV2 was low for users and non-users of hormonal contraception (2.3% vs. 3.8%, respectively). TABLE 1.

| Test | G1 (n=10) | G2 (n=30) | p value |
|------|-----------|-----------|---------|
| IUD (n=9; 19.6%), injectable progesterin (n=2; 4.35%), oral progesterin (n=3; 6.52%), oral contraceptive (n=24; 52.1%), transdermal patch (n=4; 8.70%), vaginal ring (n=4; 8.70%) and 86 did not use hormonal contraception. The rate of hospitalization for SARS-CoV2 was low for users and non-users of hormonal contraception (2.3% vs. 3.8%, respectively) and was not statistically different between groups. There was no difference between the rate of symptoms and clinical signs of infection between groups.

CONCLUSIONS: Sex hormones may play a significant role in regulating immune response and can impact disease state. We provide preliminary evidence that use of hormonal contraception does not have a significant effect on the illness severity in SARS-CoV2 as measured by hospitalization.
TABLE 1. Primary and secondary outcomes

|                  | Hormonal contraception (n= 44)a | Not on hormonal contraception (n=79)a | Adjusted OR (95% CI) |
|------------------|---------------------------------|-------------------------------------|----------------------|
| **Primary Outcome** |                                  |                                     |                      |
| Hospital admission | 1 (2.3)                          | 3 (3.8)                             | 0.99 (0.68-1.44)     |
| **Clinical Signs** |                                  |                                     |                      |
| Composite score of illness severityb | 1 (2.3) | 2 (2.5) | 0.98 (0.67-1.43) |
| Heart rate > 100 beats/min | 4 (9.1) | 3 (3.8) | 0.99 (0.68-1.45) |
| Respiratory rate > 22 breaths/min | 1 (2.3) | 1 (1.3) | 0.97 (0.67-1.42) |
| Urine output < 0.5 mL/kg/hr | 1 (2.3) | 1 (1.3) | 0.97 (0.66-1.42) |
| Lactate > 3 mmol/L | 0 | 0 | c |
| Temperature > 100.4 ⁰F | 6 (13.6) | 8 (10.1) | 0.98 (0.67-1.42) |
| WBC > 12,000 or < 4,000 / mm³ | 0 | 0 | c |
| Intubation | 0 | 0 | c |

Data are shown as n/N (%) unless otherwise specified. a n=2 & n=7 patients excluded in the hormonal vs. not hormonal groups, respectively, due to no data on hospital admission. b Components of the composite: hypoxia (O2 < 94%), > than 50% lung involvement on imaging, respiratory failure, respiratory shock, multiorgan dysfunction, death. c Unable to perform logistic regression due to cells with 0 counts.

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TOLL-LIKE RECEPTOR-2 AND TISSUE INHIBITOR OF MATRIX METALLOPROTEINASE-2 GENETIC VARIANTS AS PREDICTORS OF TOBACCO-MEDIATED FEMALE INFERTILITY AMONGST MYCOBACTERIUM TUBERCULI-POSITIVE ASIAN INDIAN COHORT. Saumya Pandey, M.Sc., Ph.D. Indira IVF Hospital, Udaipur, India.

OBJECTIVE: Tobacco-consumption is a significant predictor of metabolic-perturbations in female reproductive physiology, including endometriosis/stillbirths/miscarriages/infertility worldwide. Targeting Toll-like receptor-2 and Tissue Inhibitor of Matrix Metalloproteinase-2 genetic polymorphisms in demystifying the underlying genetic/cellular/molecular basis of tobacco-mediated female infertility amongst Asian Indian cohort is an immunotherapeutically attractive strategy for cost-effective infertility management. This study aimed to evaluate the role of TLR-2(-196 to -174del) and TIMP-2 (-418G>C) [rs8179090] gene-polymorphisms in susceptibility to tobacco-mediated infertility amongst Asian Indian women.

DESIGN: Prospective case-control (1:1) hospital-based study.

MATERIALS AND METHODS: 100 Asian Indian Mycobacterium tuberculosis-positive infertility patients (>35 years) and 100 unrelated/age-matched/M. tb.-negative/married (parity: 2-4 children) female controls of similar ethnicity were enrolled (sample-size calculation using Quanto); M. tb.-positivity was assessed using Gene-Expert/TB-Gold PCR-testing. Endometrial thickness was determined using Color-Doppler imaging. Genomic DNA extraction from peripheral blood samples collected from study subjects (N=200) was carried out using salting-out method. TLR-2/TIMP-2 genotyping was performed using polymerase chain reaction-based restriction fragment length polymorphism. Self-reported tobacco-usage was ascertained using bilingual Questionnaire in English/Hindi dialects. Statistical data-analysis was performed using multivariate logistic regression analysis with Bonferroni’s corrections for multiple comparisons in stratified subgroups (SPSS ver.16.0).

RESULTS: The findings demonstrated no significant association between TLR-2 (-196 to -174del) and TIMP-2 (-418G>C) gene-polymorphisms and risk of developing M. tb.-mediated infertility in the study population; stratified-analysis using case-only study-approach revealed no effect of TLR-2/TIMP-2 polymorphisms on M. tb.-positive infertile patients (N=100) with thin endometrium (<6.0 mm); recombinant Granulocyte-Colony-Stimulating-Factor infusion (300 mcg) significantly increased endometrium thickness (p<0.05). TLR-2 and TIMP-2 genetic variants modulated the risk in infertile patients who smoked/chewed tobacco (55% tobacco-users) with borderline association (p=0.046); TLR-2 ins/del genotype showed strong association (OR=1.9 [95%CI=1.1-3.3]) with tobacco-usage in infertile women with M. tb.-positivity. Overall, the study demonstrated lack of association between TLR-2 and TIMP-2 gene-polymorphisms and infertility susceptibility in women of Asian Indian ethnicity.

CONCLUSIONS: The study highlighted the significance of TLR-2/TIMP-2 genetic variants in tobacco-mediated infertility susceptibility in Asian Indian women providing fascinating avenues for future development of TLR-2/TIMP-2 predictive biomarkers in stratifying M. tb.-positive infertile patient-populations.

SUPPORT: None

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PRETERM BIRTH SUBTYPES BY FERTILITY STATUS AND FERTILITY TREATMENT: A POPULATION-BASED COHORT STUDY. Yimin P. Wang, MSc,1 Jessica Pudwell, MSc, MPH,1 Joel G. Ray, MD, MSc,2 Yingwei Peng, PhD,3 Maria P. Velez, MD, PhD1 Queen’s University, Kingston, ON, Canada; 2St. Michael’s Hospital, Toronto, ON, Canada.

OBJECTIVE: To evaluate preterm birth (PTB) subtypes, according to both fertility status and infertility treatment (IT).

DESIGN: Retrospective cohort study using linkage of universal health databases from Ontario, Canada.

MATERIALS AND METHODS: Included were all singleton births, April 2006-March 2014. Exposure categories were defined as spontaneous conception (reference); subfertility (history of an infertility consultation billed as ICD-9 code 628 in the absence of IT); non-invasive IT (ovulation induction or intrauterine insemination); and invasive IT (IVF or ICSI). PTB outcome subtypes were classified as spontaneous or provider-initiated (iatrogenic). Modified Poisson regression generated risk ratios (RR) for the association between exposure categories and preterm birth subtypes by fertility status and infertility treatment (IT).

TABLE. Risk of preterm birth subtypes according to exposure to fertility status and fertility treatment

| Exposure category | Relative risk of preterm birth (95% CI) |
|-------------------|---------------------------------------|
|                   | Any preterm birth | Spontaneous preterm birth | Provider-initiated preterm birth |
| Spontaneous conception | 1.00 (ref) | 1.00 (ref) | 1.00 (ref) |
| Subfertility | 1.16 (1.13 to 1.20) | 1.15 (1.10 to 1.19) | 1.23 (1.16 to 1.31) |
| Non-invasive IT | 1.27 (1.17 to 1.36) | 1.19 (1.09 to 1.31) | 1.48 (1.29 to 1.69) |
| Invasive IT | 1.63 (1.52 to 1.75) | 1.40 (1.27 to 1.53) | 2.35 (2.09 to 2.64) |