

**P-097 The impact of SARS-CoV-2 on male gonadal function. A longitudinal study**

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**Study question:** Can severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) be detected in the semen of SARS-CoV-2 positive men, and does SARS-CoV-2 infection affect male reproductive function?

**Summary answer:** No SARS-CoV-2 RNA was detected in semen. An impact of SARS-CoV-2 infection on semen quality and reproductive hormone profile awaits evaluation at 3+6 months follow-up.

**What is known already:** SARS-CoV-2 may use angiotensin-converting enzyme (ACE)2 as an entry point into the cell. As ACE2 is expressed in testicular tissue, it has been speculated that SARS-CoV-2 may affect the male reproductive system. A cohort study including 38 male COVID-19 patients showed that SARS-CoV-2 was present in the semen of six patients (15.8%) [Li et al., 2020]. Later studies including a total of 223 patients have not provided evidence of transmission of SARS-CoV-2 via semen. There are to date no available longitudinal studies on semen quality following SARS-CoV-2 infection.

**Study design, size, duration:** Longitudinal cohort study including 50 non-hospitalized men from the general population in the Capital Region of Denmark. All participants had a confirmed SARS-CoV-2 infection by reverse-transcription polymerase chain reaction (RT-PCR) on oropharyngeal swab material within the last week. The presence of SARS-CoV-2 in semen samples by RT-PCR, semen parameters and reproductive hormone profile were assessed at inclusion and at 3 + 6 months follow-up. SARS-CoV-2 antibody levels were assessed 3-5 weeks after inclusion.

**Participants/materials, setting, methods:** SARS-CoV-2-positive males (age 18-60 years) were included. Oropharyngeal and semen samples were tested by RT-PCR applying the E-Sarbeco primers and probe published by Corman et al. 2020 and adapted to TaqMan Fast Virus 1-step master mix and LightCycler 480 as previously reported by Jørgensen et al. 2020. SARS-CoV-2 antibodies were detected using the serological immunoassay from Shenzhen YHLO Biotech on the iFlash 1800. Semen quality parameters were analysed according to World Health Organisation (WHO) standards.

**Main results and the role of chance:** To date, 25 men with a mean age of 35 years have been included in the study. SARS-CoV-2 RNA could not be detected in the semen samples of any of the 25 men at the time of inclusion. Twenty-one of the 25 men (84,0%) had a same day RT-PCR-confirmed SARS-CoV-2 infection in an oropharyngeal swab. RT-PCR cycle threshold (ct) values were distributed as follows: four (19,0%) were strongly positive (ct <25), 16 (76,2%) intermediately positive (ct 25-35) and one (4,8%) weakly positive (ct 35-45). The four men without PCR-confirmed SARS-CoV-2 infection all had a positive IgG response to SARS-CoV-2 at the time of inclusion. Longitudinal semen and reproductive hormone profiles analyses will be performed. Further studies are needed to prove whether SARS-CoV-2 can be transmitted to the male reproductive tract and whether SARS-CoV-2 infection may cause alterations of spermatogenesis and endocrine function.

**Limitations, reasons for caution:** Strengths of this study are the unselected population of men examined within a week after confirmed SARS-CoV-2 infection and the follow-up of semen parameters and endocrine profile. Limitations are the limited sample size and the fact that semen quality was not known before the participants were diagnosed with COVID-19.

**Wider implications of the findings:** Knowledge of viral detection and semen persistence of SARS-CoV-2 is essential for clinical practice and public health. There is a need for evidence-based counselling on the impact of SARS-CoV-2 infection for patients undergoing assisted reproduction technology and patients who have a need for semen cryopreservation.

**Trial registration number:** H-20027362

