**Participants/materials, setting, methods:** During the study period all normozoospermic patients with high DNA fragmentation index (>25%) were included in the study, while oligospermic, asthenozoospermic samples, patients with poor ovarian reserve and advanced maternal age were excluded from the study. All A grade embryos were vitrified and transferred in frozen embryo replacement cycle. Both groups were compared on the basis of fertilisation rate, day 3 grade A embryo development rate, clinical pregnancy rate and miscarriage rate.

**Main results and the role of chance:** Cycle characteristics (female age, length of stimulation, gonadotrophin dose, number of occytes and number of transferred embryos) were similar in both groups. Between the 2 groups, There was a significant increase observed in day 3 grade A embryo development rate (60% vs. 38%, p-0.003), clinical pregnancy rate (62% vs. 41%, p-0.004) while a significant decrease in miscarriage rate (12% vs. 25%, p-0.028). On the other hand there was no statistical difference observed in fertilisation rate (82% vs. 78%, p-0.48).

**Limitations, reasons for caution:** Larger randomised control studies are needed to strengthen these results.

Wider implications of the findings: We have demonstrated that sperm sorted by microfluidic is not only correlated with better DNA integrity but also with the reproductive outcome. Using it in routine practice can help in reducing the extraneous effect of sperm processing techniques and achieving higher pregnancy rate and sustaining it.

Trial registration number: MCDH/2017/35

## P-025 Cap-Score<sup>™</sup> accurately predicts the probability of generating pregnancy across maternal age stratifications

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**Study question:** Do predicted probabilities of generating pregnancy based on the Cap-Score male fertility assay differ from observed outcomes even when stratified by maternal age?

**Summary answer:** In women eligible for intrauterine insemination (IUI), Cap-Score remains predictive across maternal age stratifications, with predicted and observed clinical pregnancy outcomes matching closely.

What is known already: Sperm must capacitate to fertilize. Cap-Score, which quantifies capacitation status to functionally assess male fertility, was prospectively shown to predict pregnancy. Based on clinical pregnancy outcomes from IUI patients at five fertility clinics and across a wide age range, the relationship between Cap-Score and the probability of generating pregnancy (PGP) was previously defined. However, maternal age is linked with reduced fertility. The ability of Cap-Score to predict PGP across stratified maternal ages is unknown and tested here. IUI was chosen as an experimental model since the number and timing of inseminations relative to ovulation could be documented and controlled.

**Study design, size, duration:** Data were collected (11/2016-09/2018) from 175 couples who generated a pregnancy within, or completed, 3 rounds of IUI, and 18 couples who became pregnant through natural conception (NC). Relationships between maternal age and PGP were tested using analysis of variance (ANOVA). Differences between predicted and observed pregnancy rates, and age and outcome, were examined using Chi-Square analysis. The potential relationship between Cap-Score and delivery or miscarriage was also evaluated on a preliminary basis (t-test).

**Participants/materials, setting, methods:** Semen was collected as part of a standard fertility evaluation at 5 different centers. Samples having fewer than 10x10<sup>6</sup> motile sperm were excluded. Fixed specimens were shipped overnight to Androvia, where the Cap-Score assay was performed. Only female fertility

that would preclude attempts at IUI led to exclusion, resulting in a representative test population of patients pursuing IUI across age ranges.

Main results and the role of chance: Observations were separated into the following age groups:  $\leq 29$ , 30-34, 35-39, and  $\geq 40$ . There was no relationship between outcome and age group (p=0.5). The average PGP derived from the Cap-Scores (predicted, PRED) and the observed pregnancies (OP) in each group were, respectively:  $\leq 29$  (35% PRED, 26% OP, n=27); 30-34 (36% PRED, 38% OP, n=87); 35-39 (34% PRED, 38% OP, n=53); and  $\geq 40$  (39% PRED, 50% OP, n=8). There were no differences between observed and predicted pregnancy rates in any maternal age group (p=0.431, 0.626, 0.472, and 0.317, respectively). Cap-Scores and resultant PGPs reflect male fertility and did not differ across maternal age stratifications (ANOVA p=0.677).

Preliminary data from one center from 20 couples pregnant by IUI (65% live births; 35% miscarried) and 18 by NC (61% live births; 39% miscarried) were also evaluated to determine if live births were similar between high and low Cap-Scores. There was no difference in Cap-Score between miscarriages and live births in either the IUI (p=0.226) or NC groups (p=0.982). The role of chance is increased when evaluating data from a single center versus multicentric studies, and when evaluating smaller versus larger datasets.

**Limitations, reasons for caution:** Caution is needed when evaluating smaller datasets and those from a single center. Women over 40 had the smallest sample size and thus the greatest risk of stochastic impact. Preliminary data suggest no relationship between Cap-Score and miscarriage. More data from multiple clinics are needed to address this issue definitively.

Wider implications of the findings: Female age and fertility are indisputably linked; however, if eligible for IUI, then PGP based on Cap-Score accurately predicted outcomes even when stratified by maternal age. This likely reflects that PGPs were originally quantified based on actual clinical pregnancy outcomes collected across a representative age range.

Trial registration number: not applicable

## P-026 Longitudinal analysis of patients who eventually achieved live birth after micro dissection testicular sperm extraction (micro TESE) and ICSI at a single fertility center

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**Study question:** How many attempts including embryo transfers(ET) are required to give birth to a first child in micro TESE-ICSI couples, and a there more congenital anomalies?

**Summary answer:** The maximum and median number of oocyte retrieval and ET cycles were 9 and 1, 10 and 2.5, respectively, and congenital defect rate was 4.0%.

What is known already: Micro TESE-ICSI provides a high therapeutic effect for non-obstructive azoospermic (NOA) couples, however the condition of retrieved testicular sperm often affects treatment efficacy. Because the background of NOA patients is various and, in many cases abnormal and/or immotile sperm are utilized, many couples who were subjected to micro TESE-ICSI feel that children from testicular sperm may have a higher birth defect rate than ejaculatory sperm.

**Study design, size, duration:** This retrospective study was conducted with infertile couples who underwent micro TESE, including unexplained NOA, Klinefelter's syndrome, after orchidopexy, azoospermia factor (AZF) c microdeletions, cryptozoospermia, severe oligozoospermia with successful acquisition of sperm by micro TESE, consequently obtained at least one liveborn between September 2013 to December 2017. Patients were followed longitudinally during consecutive ICSI and embryo transfer cycles with testicular sperm.

**Participants/materials, setting, methods:** The maternal age at the time of micro TESE-ICSI was  $32.8\pm3.1$  years and their average AMH levels was  $4.9\pm3.8$  ng/ml. We assessed the maximum and median numbers for micro TESE, total oocytes used for ICSI, transplanted embryos, oocyte retrieval cycles, embryo transfer (ET) cycles, respectively. Time spent for ICSI per oocyte, total time required to find sperm were also evaluated. Finally, we examined sex, average birth weight, and congenital anomaly rate in 177 newborns.