Title: DIAGNOSTIC VALUE OF THE COMET ASSAY IN PATIENTS UNDERGOING ICSI

Objective: Sperm DNA integrity is essential for the transmission of genetic information. Any
form of sperm chromatin abnormalities or DNA damage may result in male infertility. Comet assay could measure single and double strand breaks in spermatozoa. DNA fragmentation is classified as mild, moderate and severe according to the tail moment. Our objective was to determine the best cutoff value of severe DNA damage in male partners of couples undergoing ICSI to distinguish between pregnant and non pregnant group.

**Design:** Prospective clinical study

**Materials and Methods:** 48 semen samples from infertile partners of couples undergoing ICSI for male-factor were tested. Sperm DNA damage was analyzed by Comet test (single cell gel electrophoresis). Tail moment was measured as the relation of the DNA tail length to the DNA tail content. Scoring was done using Comet IV software (www.perceptive.co.uk).

**Results:** Spermatozoa showing tail moment >40 were considered to have severe DNA damage. The median value (25th and 75th percentile) of the percentage of sperm showing severe DNA damage in the non-pregnant group was significantly higher 29 (12, 35) compared with the pregnant group 10 (5.5, 18) (P = 0.01). The pregnancy rate was 56% (16 of 31) at a cutoff value of <28% DNA damage, and the pregnancy rate dropped to 0 (0 of 17) at cutoff value ≥ 28%,(P = 0.03). At this cutoff (>28%) the assay showed 100% sensitivity with 53.1% specificity.

**Conclusions:** DNA damage measured by comet assay is a reliable test for predicting pregnancy outcome in couples undergoing ICSI. A cutoff value >28% in the severely DNA damaged population is predictive of poor ICSI outcome.

**Support:** None

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