VALIDATION OF SPERM CHROMATIN DISPERSION (SCD) TEST USING A MAIL-IN, AT-HOME SEMEN COLLECTION KIT.

Felipe Navarrete, [2] Anthony Anderson, [1] Kristina Burgess,[1] Paul Simon, [1] Ramy Abou Ghayda[1,3]

[1]Give Legacy Inc., Boston, MA, USA; [2]Embryo director, San Antonio, TX, USA ; [3]University Hospitals, Case Western Reserve University, Cleveland, Ohio.

Introduction

DNA fragmentation index has been recognized as an essential data point and prognostic factor, providing insight and added value in the diagnosis, treatments, and outcomes of male infertility [1]. In recent years, home testing for male fertility has gained momentum [2]. The covid-19 pandemic has accelerated the use of direct-to-consumer offerings of at-home, mail-in kits for semen parameters, and DNA fragmentation. However, mail-in semen collection kits involve incubation in transport media and overnight shipping. DNA fragmentation can be confounded by multiple extrinsic factors such as storage temperatures, transportation media, handling conditions, time after ejaculation, and oxidative stress, among others [3].

Objective

The objective of this study was to validate the sperm chromatin dispersion test using at-home, mail-in sperm collection kits. To do so, we evaluated and assessed the effect of transportation media and shipping on sperm DNA integrity using a Halosperm® G2 kit in normozoospermic human sperm samples.

Materials & Methods

- 50 healthy normozoospermic human semen samples were included in the study group.
- These samples were split into two equal groups. The first group was directly analyzed for sperm DNA fragmentation using a Halosperm® G2 kit in the lab.
- The second group samples were incubated for 24 hours in transportation media (TM), then these incubated semen samples were packaged and Shipping was simulated.
- The samples were then returned to the lab, where they were subsequently analyzed for sperm DNA fragmentation using a Halosperm® G2 kit.
- Control group of 10 healthy normozoospermic subjects analyzed for sperm DNA fragmentation using a Halosperm® G2 kit.
- To control for inter-observer variability, 10 aliquots were shipped to an independent, third-party CLIA-certified laboratory and processed using the same Halosperm® G2 kit technique.

RESULTS

The Sperm DNA fragmentation index was not statistically significantly different between the non-incubated freshly analyzed sperm samples (20 %, SD +/-9%) and the 24-hour incubated samples with shipping conditions (24% SD +/- 13) (p-value: 0.0549).

During the external validation study, when the internal and external lab technicians scored the same samples, the sperm DNA fragmentation percentage (SDFs) were not statistically significantly different (p-value: 0.1213) correlated (r = 0.85, p = 0.0016).

CONCLUSIONS

This study revealed that the sperm DNA fragmentation index of normozoospermic human sperm sample is not statically significant impacted by a 24-hour transport media incubation and subsequent exposure to shipments conditions.

IMPACT STATEMENT

- Our study showed that the accuracy and validity of DNA fragmentation detection using the Halosperm® G2 kit of TM-incubated and shipped human sperm samples was comparable to those of fresh samples analyzed at the lab in normozoospermic human sperm samples.
- Therefore, at-home mail-in kits may provide a viable testing option for DNA fragmentation index.
- Similar future studies will be imperative to perform in order to address and help mitigate the barriers to access to affordable and readily available fertility care.

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