Halosperm® is an easy, available, and cost-effective alternative for determining sperm DNA fragmentation

José Luis Fernández, M.D., Ph.D.,[a,b] *Lourdes Muriel, Ph.D.,*[a] *Vicente Goyanes, M.D., Ph.D.,*[a,b] *Enrique Segrelles, M.D.,*[b] *Jaime Gosálvez, Ph.D.,*[c] *María Enciso, Ph.D.,*[c] *Marie LaFromboise, B.S.,*[d] *and Christopher De Jonge, Ph.D.*[d]

[a] Sección de Genética y Unidad de Investigación, Complejo Hospitalario Universitario Juan Canalejo, and [b] ARGGORA Unidad de la Mujer, A Coruña, Spain; [c] Unidad de Genética, Facultad de Biología, Universidad Autónoma de Madrid, Madrid, Spain; and [d] Reproductive Medicine Center, University of Minnesota, Minneapolis, Minnesota

The characteristics of Halosperm® make this kit a reasonable alternative to allow basic and clinical research on sperm DNA fragmentation in any basic laboratory around the world. (Fertil Steril® 2005;84:860. ©2005 by American Society for Reproductive Medicine.)

Key Words: Sperm chromatin dispersion test, SCD, DNA fragmentation, DNA damage, Sperm Chromatin Structure assay, SCSA, sperm chromatin

The value of the Sperm Chromatin Structure Assay (SCSA®) is not in question. However, from a clinical standpoint, a relevant concern arises. That is, the exclusive SCSA threshold values for fertility have a "tip of the iceberg" effect, meaning that the main population contains damaged DNA when the DNA fragmentation index (DFI) is >30%. The scientific basis for this iceberg effect has not, to our knowledge, been validated. New independent SCSA studies raise further concern about the validity of an iceberg effect (1).

The Halosperm® kit was not created to be a replacement for the SCSA. However, like the SCSA, the Halosperm determines sperm DNA fragmentation. As Dr. Evenson (2) points out, the SCSA has been developed over the past 25 years. Therefore, we believe that it is perfectly valid to use the SCSA as the model for comparison with the Halosperm. However, validation with SCSA was not strictly necessary because Halosperm is the only technique validated in the same sperm cell using the potent DNA breakage detection-fluorescence in situ hybridization (DBD-FISH) procedure. Regardless, the good correlation of Halosperm with SCSA was also evidenced by Chohan et al. (3). Intrinsically, correlation does not mean the same values, and there are very few samples to test the divergence with high SCSA DFI values.

Received May 5, 2005; revised and accepted May 9, 2005.
The authors have no financial interest in Halosperm®.
Supported by grants from the Xunta de Galicia (PGIDIT 04BTF916023PR), the European Community (FIGH-CT-2002-00217, TELOSENS), and INDAS Laboratories.
Reprint requests: José Luis Fernández, M.D., Ph.D., Sección de Genética y Unidad de Investigación, Complejo Hospitalario Universitario Juan Canalejo, As Xubias, 84, 15006-A Coruña, Spain (FAX: 34-981-287122; E-mail: jlfernandez@canalejo.org).

The variability of Halosperm scoring presented was derived from beginner's data, that is, from observers with no prior training. Similar data have not been reported for other techniques. Our actual coefficient of variation is 5.3%, which mirror that reported by Schlegel and Paduch (4).

Terminal deoxynucleotidyl transferase nick end labeling (TUNEL) testing relies on the access of an enzyme to a fixed material, recognition of a specific DNA break type (there may be other types), and labeling. All these steps are intrinsically variable, so reproducibility is not good, and unclear labeling is frequent.

Halosperm may not be the definitive technique, if indeed one exists, but its ease of use and interpretation facilitates its potential incorporation into any basic research and clinical laboratory in the world. This is in contrast to the more complex SCSA. With greater access to a simple, reliable, and sensitive sperm DNA fragmentation technique, perhaps conclusions about the clinical validity of such assays will be made more swiftly.

REFERENCES

1. Gandini L, Lombardo F, Paoli D, Caruso F, Eleuteri P, Leter G, et al. Full-term pregnancies achieved with ICSI despite high levels of sperm chromatin damage. Hum Reprod 2004;19:1409–17.
2. Evenson DP, Wixon R. Comparison of the Halosperm® test kit with the Sperm Chromatin Structure Assay (SCSA®) infertility test in relation to patient diagnosis and prognosis. Fertil Steril 2005;84:846–9.
3. Chohan KR, Griffin JT, Lafromboise M, De Jonge CJ, Carrell DT. Comparison of chromatin assays for DNA fragmentation evaluation in human sperm. J Androl (in press).
4. Schlegel PN, Paduch DA. Yet another test of sperm chromatin structure. Fertil Steril 2005;84:854–9.

0015-0282/05/$30.00
doi:10.1016/j.fertnstert.2005.05.013