The automated SPERMALITE® Sperm Quality Analyser – Visual (SQA-V) versus conventional microscopic semen analysis

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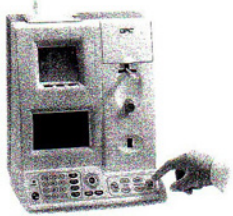
Introduction

Semen analysis is an important laboratory investigation when assessing male fertility. Performing the analysis is time consuming and requires extensive training, however it can still be subjective with varying results between trained scientists. The SPERMALITE® Sperm Quality Analyser – Visual (SQA-V) is an analytical medical device that performs a complete qualitative and quantitative evaluation of semen parameters by combining electro-optics, computer algorithms and video microscopy. A complete analysis including morphology can be performed within a few minutes.

The instrument works by inserting a specially designed SQA-V capillary, filled with semen, into the electro-optic chamber. Very precise light beams are transmitted through the sample to photo detectors that translate information based on light interruption and absorption into electrical signals. These signals are detected, digitised and sent to an internal computer that analyses the data and applies specially formulated algorithms to generate test results based on derived WHO criteria.

Aim

The aim of our evaluation was to assess the reliability, accuracy, reproducibility and efficiency of the SQA-V compared with conventional manual microscopic techniques for analysing fresh human semen samples.



The SPERMALITE® SQA-V

Method

Routine semen specimens submitted for analysis to our main laboratory in Clayton were used for this evaluation. Highly viscous and non liquefied samples were eliminated from our study because they require further preparation or treatment for analysis by the SQA-V. Low volume samples (<1.5mL) were also eliminated due to insufficient specimen.

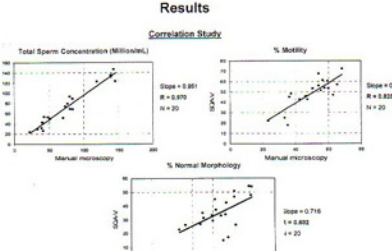
A direct comparison between manual microscopy and the SQA-V was performed on 20 semen samples analysed at room temperature within 2 hours of collection. Each sample was assessed microscopically by two scientists in a double blind study to decrease the possibility of human error. The average of these results were used for the comparison. The samples were concurrently analysed twice using the SQA-V.

The parameters assessed were motility, total sperm concentration and morphology using WHO guidelines (4th Ed 1999)[1]. The manual microscopic method included assessing motility by grading 200 spermatozoa according to the WHO protocol. Percentage motility was calculated by adding the grades rapid progressive, slow/sluggish and non progressive motility together. Total sperm concentration was performed using Kova counting chambers with a 1:20 dilution. Morphology of 200 spermatozoa was assessed from a fixed Diff-Quick stained slide and recorded as percentage normal morphology based on WHO criteria.

A reproducibility study was also performed on 7 semen samples. Each sample was analysed five times on the SQA-V. The manual microscopic method included performed the full microscopic analysis five times on each sample.

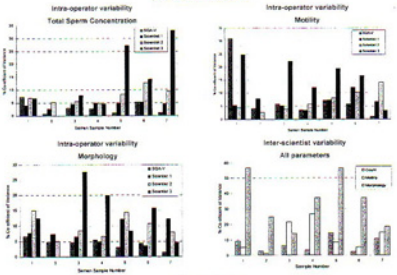
Results

Correlation Study



Reproducibility study

(SQA-V: 3 scientists, 5 repeats)



Discussion

The direct comparison study has shown very good preliminary results. Total sperm concentration shows an excellent correlation between the SQA-V and manual microscopy (R=0.970). Motility also shows a good correlation (R=0.825), its slightly lower value most likely due to the variability of the scientists. Normal morphology shows a lower correlation (R=0.602) and again is most likely due to the variability and subjectivity of the scientists. This is demonstrated by the External Quality Assurance Scheme for Reproductive Medicine program which shows a wide variation in morphology results between laboratories across Australia. Clinical interpretation of sperm morphology is often difficult and is not yet standardised.[2]

The SQA-V proved that it is reproducible in all parameters with the coefficient of variation less than 7.3% for all except one outlier. The reproducibility study shows that some scientists are reproducible within themselves (%CV<2.6) while others have a wide variability in their results (%CV<33.03). The person to person variability is dependent on the parameter assesses. There was less inter-scientist variability for total sperm concentration (%CV up to 14.46), however there was a very large variation for morphology (%CV up to 58.58). For the initial correlation study the scientists involved varied, therefore the likely cause for the lower correlation of the motility and particularly the morphology is the lack of reproducibility of the conventional microscopic method.

The preliminary results of this evaluation shows that the SPERMALITE® SQA-V appears to be a rapid, reliable, efficient and acceptably accurate alternative to the conventional manual microscopic assessment for human semen analysis, based on derived WHO criteria. A greater number of samples need to be tested to confirm this.

References

1. World Health Organisation. WHO laboratory manual for the examination of human semen and sperm-cervical interaction. Fourth edition. Cambridge University Press, 1999.
2. Tarn Yablonsky. Male Fertility Testing. Laboratory Medicine. 1996;27:378-383.

Acknowledgments

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