

Place of Rapid SP-10 Immunochromatographic Tests in Predicting Hidden Acrosomal Deficiencies and Indirectly Fertilization Failures in Normozoospermic Men

Yasemin Çekmez

Assoc Prof, Department of Obstetric and Gynecology, Private Clinic

Abstract

While conventional microscopic semen analysis focuses on cell counting during male infertility evaluation, the functional fertilization capacity of sperm can sometimes be overlooked. The detection of the SP-10 (Sperm Protein 10/ACRVI) intra-acrosomal protein, used in rapid home sperm tests, measures the functional protein load of the acrosome rather than the cellular quantity. This study aims to retrospectively examine cases who took a rapid home SP-10 test resulting in negative yet had normal sperm counts in standard sperm analysis, thereby revealing the diagnostic superiority and clinical advantage of the test in predicting hidden acrosomal deficiencies and low fertilization potential.

Keywords: SP-10 protein, ACRV1, Acrosome ratio, Normozoospermia, Unexplained infertility, Immunochromatographic test, Fertilization failure

Introduction

Male-factor infertility is responsible for approximately 40-50 percent of reproductive failures. In clinical practice, microscopic semen analysis forms the basis of male fertility evaluation. According to World Health Organization guidelines, a sperm concentration above $15 \times 10^6/\text{mL}$ is defined as normozoospermia. However, despite conventional parameters appearing completely normal in a portion of normozoospermic men, unexpected fertilization failures can occur during intrauterine insemination or in vitro fertilization processes.

Rapid home sperm tests, which have become widespread, are particularly preferred by men who lack the time to provide a sample at the hospital, cannot find an appointment, or carry privacy concerns. The result evaluation of the test relies on the immunochromatographic detection of the SP-10 antigen located in the acrosomal matrix of the sperm head. These tests generate a positive band if the amount of SP-10 protein in the sample reaches a level corresponding to the $15 \times 10^6/\text{mL}$ threshold value.

The critical biological point here is that SP-10 tests do not directly count cell bodies, but rather measure the cellular acrosome protein load. If a man's sperm count is normal but his acrosome structure is deficient, the released SP-10 protein remains below the threshold value, resulting in a negative test. This negativity serves as an early biological warning mechanism that directly exposes functional and structural acrosome disorders overlooked by conventional spermograms.

The aim of this study is to evaluate the functional diagnostic advantage and clinical utility value provided by the test by retrospectively reviewing the data of patients whose home-administered rapid SP-10 test results were negative but who were found to be normozoospermic in the laboratory.

Materials and Methods

Study Design and Patient Population

This study is a retrospective clinical evaluation research conducted through the medical records of patients admitted to our clinic. Data from 20 male patients who applied to our clinic with a suspicion of low sperm count after performing a commercially available rapid SP-10 immunochromatographic home sperm test with a negative result were included in the study. (Alltest Hangzhou, China)

Laboratory Evaluations and Acrosome Analysis

Data of semen samples obtained from various IVF centers within Istanbul after 2-5 days of sexual abstinence were scanned. Sperm concentration and motility parameters determined according to the World Health Organization guideline, along with Kruger strict morphology records on smears prepared using the Papanicolaou staining method, were extracted.

The acrosome structure on the sperm head was examined in detail; cases where the acrosome did not cover 40-70 percent of the sperm head and remained below 15 percent were recorded as low acrosome ratio / acrosomal hypoplasia.

Statistical Analysis

The obtained data were analyzed using SPSS v26.0 software. Continuous variables were presented as mean $\pm$ standard deviation. Student's t-test and Mann-Whitney U test were used in comparing SP-10 negative normozoospermic cases with the control normozoospermic group. A $p < 0.05$ value was considered statistically significant.

Findings

When examining the laboratory semen analysis data of 20 patients who applied to our center with concerns of oligozoospermia and whose home-administered rapid SP-10 tests were negative:

- Oligozoospermia ($<15 \times 10^6/\text{mL}$) was confirmed in the laboratory in 18 patients, consistent with the test result. These patients were classified as the control group.
- In 2 patients (10 percent), laboratory analysis showed that sperm concentration was entirely within normal limits ($22.5 \times 10^6/\text{mL}$ and $31.0 \times 10^6/\text{mL}$, mean $26.8 \pm 6.0 \times 10^6/\text{mL}$), but the acrosome ratio was low. These patients were classified as the study group.

Table 1: Comparison of groups

Parameter	Control Group (n = 18)	Study Group (n = 2)	p Value
Sperm Concentration ($10^6/\text{mL}$)	11.4 ± 2.1	26.8 ± 6.0	<0.001 (Significant)

Parameter	Control Group (n = 18)	Study Group (n = 2)	p Value
Acrosome Ratio (percent)	52.1 ± 6.8	10.5 ± 2.1	<0.001 (Significant)
Kruger Strict Morphology (percent)	6.2 ± 1.8	1.5 ± 0.7	<0.001 (Significant)

Discussion

The most striking clinical finding of this study is showing that a negative result given by the rapid SP-10 test in normozoospermic men is not a test error, but rather diagnoses a hidden acrosome deficiency that routine spermograms fail to detect.

SP-10 protein is an essential acrosomal matrix component for sperm to bind to the egg membrane and perform the acrosome reaction to ensure fertilization. Even if the sperm count is normal, in individuals with a low acrosome ratio, the level of SP-10 protein released on a cellular basis remains below the detection limit of the test, causing the test to yield a negative band.

Clinical Advantages and Contribution to ART/IVF Processes

- **Biological Explanation in Unexplained Infertility:** In couples diagnosed with unexplained infertility because their standard spermogram came back normal, a negative rapid SP-10 test directly sheds light on the underlying acrosomal protein deficiency and fertilization disorder.
- **Prevention of Incorrect Treatment Options:** Conventional intrauterine inseminations or standard IVF applications performed with these sperms having insufficient acrosomal protein may result in failure. Pre-detection of this condition via the rapid SP-10 test ensures the patient is directed toward microinjection and, if necessary, artificial oocyte activation processes without losing time.
- **Complementary Functional Screening Beyond Standard Counting:** Rapid SP-10 tests strengthen clinical evaluation not merely as a cell counting tool, but as a valuable secondary screening test measuring the biochemical and functional fertilization capacity of sperm.

Limitations of the study: The low number of cases is a limitation of this study. However, given that home-type sperm tests are very new in our country and their usage is just starting to become widespread, the importance of this small-scale clinical study is substantial. It is clear that broader series of studies will contribute to the selection of treatment methods chosen to achieve pregnancy.

Conclusion

Rapid SP-10 immunochromatographic tests offer the advantage of detecting hidden functional deficiencies linked to low acrosome ratios in normozoospermic individuals, moving beyond simply performing a numerical evaluation. A negative rapid SP-10 test in a normozoospermic patient serves as a critical early warning biomarker for clinicians regarding acrosome disorders and potential fertilization failures. This test is an auxiliary diagnostic tool of high clinical value complementing standard microscopic analysis in modern reproductive medicine.

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