Weill Cornell Medicine

Method to Predict Success of Sperm Retrieval in Men with Nonobstructive Azoospermia

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Background & Unmet Need

- The optimal management of nonobstructive azoospermia (NOA) is testicular sperm extraction (TESE) and intracytoplasmic sperm injection (ICSI)
- However, sperm are absent in the testes of many men with NOA, and preoperative parameters cannot reliably predict the presence of retrievable testicular sperm
- Surgical sperm retrieval fails in ~50% of cases
- Men with unsuccessful sperm retrieval incur risk of morbidity, psychologic stress, and financial expense
- Female partners of men with NOA who fail sperm retrieval may undergo unnecessary ovarian stimulation
- **Unmet Need:** Non-invasive method to predict patient success of retrieving viable sperm during TESE

Technology Overview

- **The Technology:** Diagnostic test to predict the success of retrieving sperm from a male with NOA during TESE by measuring expression levels of the heat shock factor Y-linked gene (HSFY) in testicular or semen samples
- **The Discovery:** Patients with NOA who fail microdissection TESE have low testicular mRNA expression of the AZFb gene HSFY
- **PoC Data:** In a study of 54 men with NOA who underwent microdissection TESE, HSFY mRNA expression levels predicted successful sperm retrieval with 67% sensitivity and 93% specificity
- Good discrimination between the groups in all histologic variants of NOA (92% sensitivity for Sertoli cell only (SCO) histology, 67% sensitivity for maturation arrest (MA) histology)
- Probabilities of sperm retrieval for HSFY-positive patients was 93%, compared to 31% for HSFY-negative patients

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Patents:
US Patent 10,822,657

Publications:
Stahl et al. *Fertil Steril.* 2011.

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Technology Applications

- Selection of male NOA patients with highest probability of successful sperm retrieval during TESE

Technology Advantages

- Requires only a small sample of testicular tissue
- High specificity and sensitivity in all histologic variants
- qRT-PCR enables rapid, straightforward HSFY mRNA detection

Supporting Data / Figures

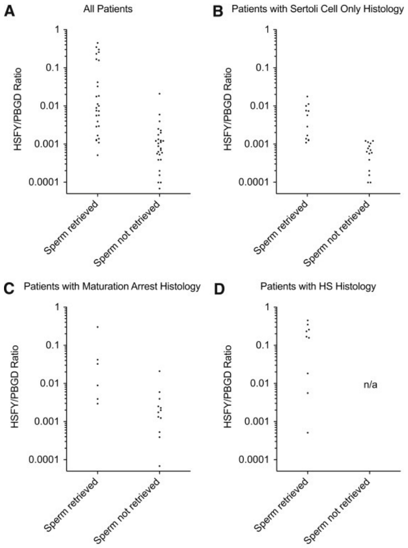

Figure 1: Scatter plots showing HSFY/PBGD expression ratios (a) for every nonobstructive azoospermia patient in the study and (b-d) for every patient within each histologic subgroup. (HS = hypospermatogenesis).

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