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Clinical Outcome Using the Q300™ Device in a Reproductive Laboratory Environment

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INTRODUCTION

Embryologists face challenges in accurately assessing sperm morphology without the use of staining techniques, which has sparked interest in emerging technologies such as artificial intelligence (AI). These innovative methods enable simultaneous evaluation of morphology parameters in live sperm, allowing for real-time, stain-free sperm selection. A previous study that compared Q300 with traditional manual staining methods demonstrated a high level of agreement and repeatability, indicating that Q300 is accurate in measuring live sperm cells. This technology supports morphology-based selection aligned with WHO2021 criteria without the need for staining, potentially revolutionizing sperm assessment.

METHODS

Q300™ is an optical system utilizing holographic imaging to evaluate both sperm morphology and motility in a non-invasive manner. The device aids embryologists in selecting WHO-morphologically compliant sperm cells. 34 couples meeting inclusion criteria were recruited for ICSI procedures. The data was compared to 42 stratified-historical control couples that met the inclusion and exclusion criteria without using the Q300 device. Laboratory and clinical data collected were compared to parallel results from couples who met the inclusion and exclusion criteria without using the Q300 device, along with the Key Performance Indicators (KPI) for ART laboratories based on the Vienna Consensus. Endpoints: fertilization, day-2 and day-3 embryo development, blastocyst and good-blastocyst development rates, and cumulative pregnancy rates.

RESULTS

The analysis revealed no significant differences in the age of the patients, sperm parameters, and the number of oocytes. However, a significant difference was observed in the rate of day-3 embryo development (91.7% for the Q300 group compared to 84.3% for the non-Q300 group, P=0.05). The blastocyst development rate was higher in the Q300 group (54.3%, compared to 43.2% in the non-Q300 group, P=0.056). The cumulative pregnancy rate per retrieval was also significantly higher in the Q300 group (65%, compared to 34.1% in the non-Q300 group, P<0.05). No significant differences were found in terms of fertilization, day-2 development or good-quality blastocysts rates.

650 sperm imaging procedures were performed using the Q300 device to select 266 morphologically suitable cells for ICSI. The utilization of the product resulted in approximately a 40% yield of cells, based on morphological compliance" with WHO2021 criteria. This observation offers insights into the characteristics of cells routinely chosen for injection into oocytes.

Parameter	Q300™ Group	Control Group	P Value
Enrolled couples	34	42	
Female average age	34	33	
Number of oocytes	266	355	
Average number of oocytes per couple	7.82	8.45	p = 0.62
Sperm volume [mL]	3.3 (0.2-6.5)	3.04 (0.5-6.5)	p = 0.53
Sperm concentration [million cells / mL]	32.2 (1.8-180)	25.45 (1.1-150)	p = 0.42
Sperm motility [%]	57.5 (5-100)	44.8 (5-89)	p = 0.16
Total number of sperm injected	266	355	
Total number of fully-compliant (a.k.a "green") sperms injected	61		
Number of borderline compliant (a.k.a "yellow") sperm cells injected	205		
% injected cells vs. Q300™ evaluated cells	266/650 (40.9%)		

A comparison of clinical data between patients using Q300™ and patients in the control group.

Parameter	Q300™ Group	Control Group	P Value	Vienna Consensus
Number of injected oocytes	266	355		
Total fertilization rate (total number of fertilizations per group divided by total number of oocytes injected per group)	77.8% (208/266)	81.6% (290/355)	p=0.65	≥65%
Day 2 embryo development rate	95.5% (173/181)	91.3% (265/290)	p=0.29	
Day 3 embryo development rate	91.7% (166/181)	84.3% (232/275)	p=0.05	
Blastocyst development rate	54.3% (56/103)	43.2% (48/111)	p=0.056	>40%
Good blastocyst development rate	36.9% (38/103)	31.5% (35/111)	p=0.16	>30%
Total usable embryos rate per couple (out of the number of fertilized oocytes)	59.1% (123/208)	54.8% (159/290)	p=0.2	
Cumulative pregnancy rate per retrieval	65% (20/31)	34.1% (14/41)	p<0.05	
Miscarriage rate (out of total pregnancies)	20% (4/20)	14% (2/14)	p=0.67	

Comparison of Q300™ results to control group results and KPIs for ART laboratories based on the Vienna Consensus

CONCLUSION

This study aims to evaluate the practical usability and early clinical impact of the Q300™ device also provide the quantitative assumptions for a statistically-powered RCT in IVF laboratories. Preliminary data indicates positive results on the embryo and blastocyst development and highly favorable impact on pregnancy rates. Further research is necessary to determine the most suitable patients for its use.

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