

P-104: A multicenter, prospective sibling oocyte study revealed that HyperSperm improves the number and quality of embryos in patients undergoing in vitro fertilization

M. Gomez-Elias¹, C. Bisioli², M. Horton², L. Kopcow², M. Papayannis², E. de Martino², G. Luque³, C. Baro Graf⁴, M. Attie⁵, M. Lavolpe⁵, C. Carizza⁶, V. Torres Monserrat⁶, E. Navall⁶, M. Buffone¹

¹Fecundis Lab, Research & Development, Barcelona, Spain. ²Pregna Medicina Reproductiva, Laboratorio de Reproducción Asistida y Embriología, Buenos Aires, Argentina. ³Instituto de Biología y Medicina Experimental IBYME-CONICET, Laboratorio de Biología Celular y Molecular de la Reproducción, Buenos Aires, Argentina. ⁴Instituto de Biología Molecular y Celular de Rosario, Laboratorio de Cascadas de Señalización Celular, Rosario, Argentina. ⁵In vitro Buenos Aires, Laboratorio de Reproducción Asistida y Embriología, Buenos Aires, Argentina. ⁶Fertya, Laboratorio de Reproducción Asistida y Embriología, Rosario, Argentina.



STUDY QUESTION

Does sperm preparation with HyperSperm, a novel sperm capacitation technology, improve blastocyst rate in conventional in vitro fertilization (IVF)?



SUMMARY ANSWER

HyperSperm, a novel sperm capacitation technology, increased blastocyst rates compared with standard sperm preparation, without affecting fertilization rates, in a prospective sibling oocyte IVF study.



WHAT IS KNOWN ALREADY

Sperm capacitation is critical for successful fertilization and early embryo development.

HyperSperm is a novel sperm preparation approach aimed at enhancing sperm function while preserving viability and acrosomal integrity.

Using animal models and IVF cycles with donor oocytes, HyperSperm has shown to improve embryo development and blastocyst yield. In addition, analyses performed on semen samples from infertile patients demonstrated enhanced sperm functional parameters without detrimental effects on DNA integrity or cell viability.

However, its clinical utility in IVF cycles using autologous oocytes had not yet been established.



STUDY DESIGN, SIZE, DURATION

Prospective, multicenter, sibling oocyte study

August 2023 - December 2025

3 clinics   

41 couples undergoing conventional IVF

Inclusion criteria: women aged 20-42 years with an ovarian reserve of 6-30 antral follicles and men aged 20-55 years, with the following sperm parameters: sperm concentration $\geq 10 \times 10^6/\text{mL}$, total motility $\geq 20\%$, normal morphology (Kruger criteria) $\geq 3\%$.



PARTICIPANTS/MATERIALS, SETTINGS, METHODS

For each patient, cumulus-oocyte complexes (COCs) and semen samples were split into two groups. Sibling COCs were inseminated with sperm prepared using either standard protocols (Control) or HyperSperm (Treatment).

- **Primary outcome:** blastocyst rate
- **Secondary outcomes:** fertilization rate and embryo quality
- **Other outcomes:** euploidy rates (PGT-A); pregnancy outcomes

Differences between groups evaluated by Wilcoxon signed rank test, significance set at $p < 0.05$

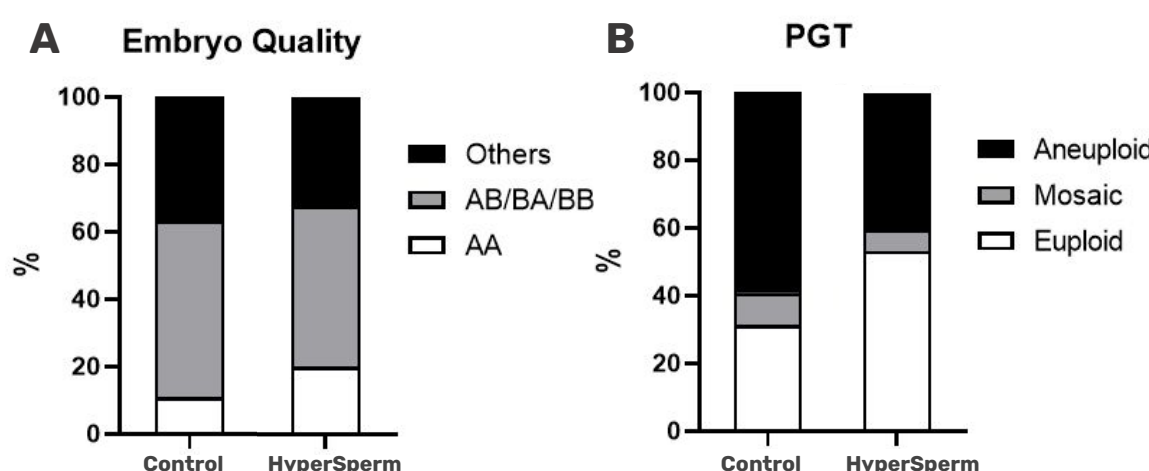


MAIN RESULTS AND THE ROLE OF CHANCE

Table 1: Participants' age and semen parameters

Female age, years	36.4 $\pm$ 3.6 (27-42)
Male age, years	38.2 $\pm$ 4.6 (30-55)
Sperm concentration, 10^6 per mL	99.3 $\pm$ 40.6 (15-225)
Semen volume, mL	2.8 $\pm$ 1.4 (1.0-6.6)
Total motility, %	63.1 $\pm$ 13.5 (22-88)

N=41 couples. Values expressed as mean $\pm$ SD (min-max)



Total	92	100
AA	11	20

Figure 1. (A) **Blastocyst quality** by Gardner ICM/trophectoderm score. Blastocysts were expansion grade ≥ 3 . AA: highest quality; AB/BA/BB: intermediate; Others: remaining grades. (B) **PGT-A results:** euploid, mosaic, and aneuploid embryos (%).

Table 2: IVF outcomes

	Control	HyperSperm	p-value
Number of COCs per arm	297	301	-
Rate of maturity (MII/COCs)	90.2% (268/297)	82.7% (249/301)	n.s.
Fertilization rate (2PN embryos/MI)	71.6% (192/268)	72.3% (180/249)	n.s.
Blastocyst rate (blastocyst/2PN embryos)	47.9% (92/192)	55.6% (100/180)	0.0038
Usable blastocyst rate (usable blastocysts/2PN embryos)	40.1% (77/192)	48.9% (88/180)	0.0104

Values are presented as % (n/N).

COCs, cumulus-oocyte complexes. 2PN, 2-pronuclear embryos. n.s. $p > 0.05$

To date, 34 ETs of HyperSperm-derived embryos resulted in:

- ★ 11 biochemical pregnancies,
 - ★ 9 confirmed clinical pregnancies,
 - ★ 4 live births, with no abnormalities reported.
- Exploratory descriptive outcomes; follow-up ongoing.



LIMITATIONS, REASONS FOR CAUTION

The study was not powered to detect differences in euploidy or pregnancy outcomes, and PGT-A was performed only in a subset of embryos.



WIDER IMPLICATIONS OF THE FINDINGS

These findings support HyperSperm as a novel sperm preparation strategy that can enhance blastocyst yield in conventional IVF cycles, potentially improving embryo availability for transfer.

Larger studies are warranted to evaluate effects on chromosomal competence and clinical outcomes.