INSEMINATED VOLUME 0.2 ML VS. 0.5 ML IN DONOR INTRAUTERINE INSEMINATION (dIUI) CYCLES: A RANDOMIZED CONTROLLED TRIAL

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What is known already

dIUI has an important role in the treatment of severe male infertility, and is often used in same-sex female couples and single parents. The use of conical bottom test tubes could contribute substantially to the loss of inseminated spermatozoa because it precludes the total recovery of the sample. Additionally, the insemination catheter could uphold this reduction causing sperm adhesion on the inner walls of the insemination catheter, decreasing even more the total inseminated (www.clinicaltrials.gov, trial number NCT03006523).

Objective

- The goal of this study is to prospectively determine the most appropriate insemination volume in dIUI cycles. It is expected that by utilizing a dIUI approach that increases sperm volume in the fallopian tubes (0.5mL rather than 0.2mL) at the time of ovulation will lead to higher live birth rates.

Study design, size, and duration

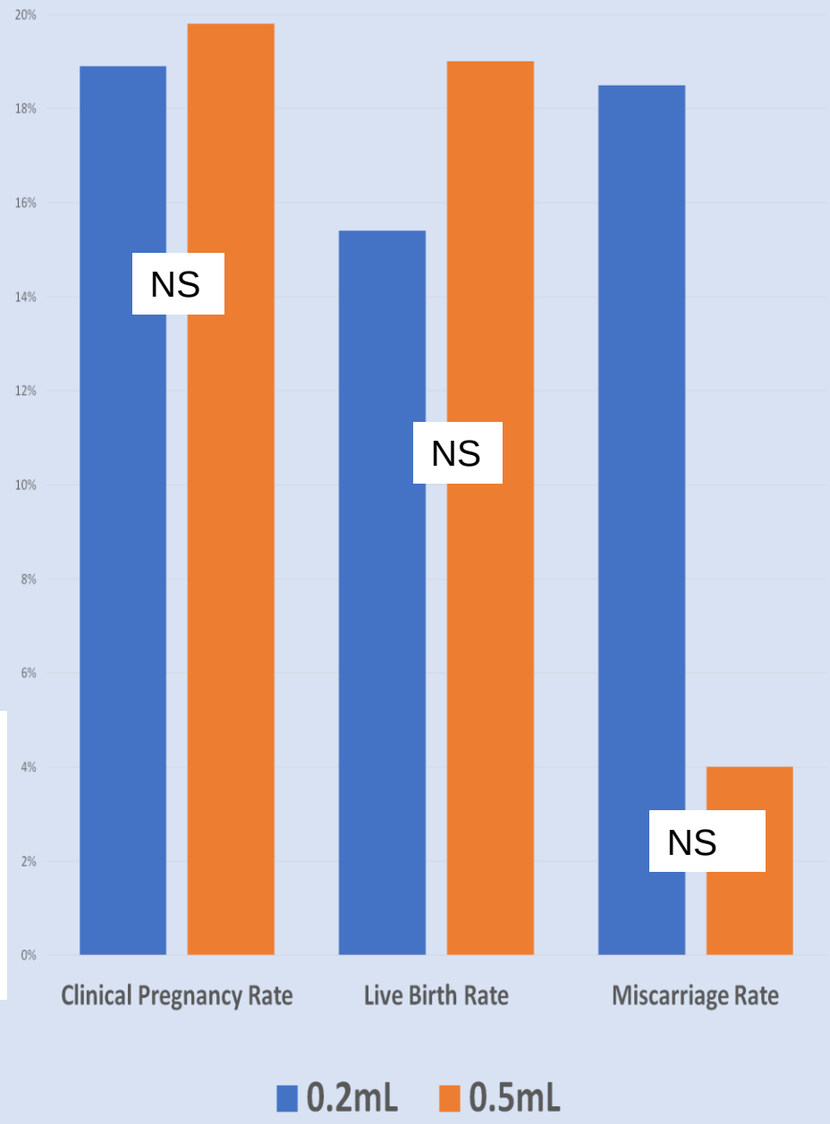
- A parallel-group, patient-blinded, randomized controlled trial was performed, including patients undergoing dIUI under ovulation induction or natural cycle. The trial was established to compare two inseminated volumes, 0.2ml (control group) and 0.5mL (study group) between March 2013 and April 2016.
- dIUI cycles (n= 293) were randomized, of which 24 were excluded (protocol deviation) and 269 received the allocated intervention. Study was designed with 90% power to detect a 5% difference in LBR with a reference of 20% and a two-tailed 5% significance level. The required sample size was 72 per group.

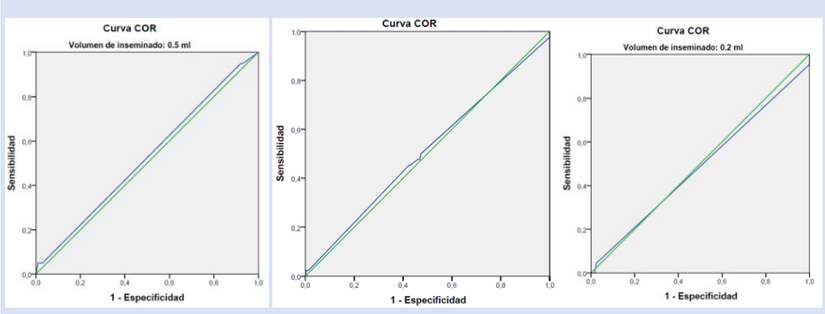
Participants/materials, setting, methods

- There were 143 cycles (control group) and 126 cycles (study group).
- A multivariate logistic regression model was constructed to adjust for potential predictor variables regardless of association within a univariate model.
- The likelihood of pregnancy is presented as an OR with SE and 95% CI.
- A receiving operating characteristic (ROC) curve was developed to determine whether live birth was associated with the inseminated volume and the TMS inseminated both as a total and by allocated group (0.2mL and 0.5mL).
- Furthermore, cycles that resulted in a live birth were compared to those that did not, both as a total and by allocated group (0.2mL and 0.5mL) assessed by the Mann-Whitney test in order to identify potential variables associated with a positive outcome in a specific subset of patients.

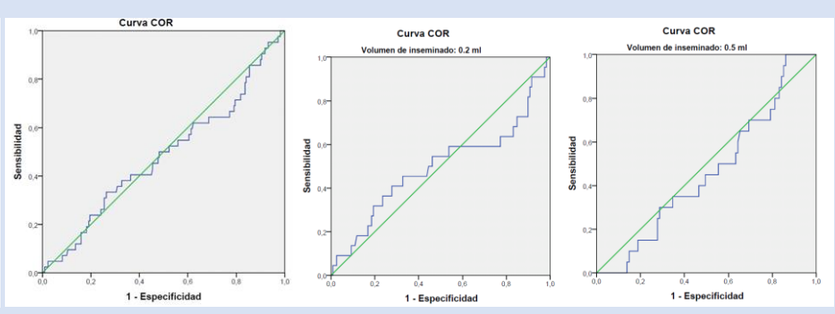
Main results and the role of chance

- Groups (control vs. study group, respectively) were similar in age (35.8±3.9 vs. 35.4±4.0), AMH (2.2±1.8 vs. 2.0±1.5), AFC (13.2±6.4 vs. 13.6±6.0), BMI (23.5±3.9 vs. 23.7±4.1), follicles>17mm (1.1±0.5 vs. 1.1±0.5), total GND dose (553.1±366.3 vs. 494.6±237.1), and TMS count (8.22±7.1 vs. 7.7±5.7).
- After adjusting for variables mentioned before in a logistic regression model, the inseminated volume was not shown to be associated with LB (OR 1.1 (95% CI 0.6 – 1.9).
- At comparison of all patients who achieved a LB vs. those that did not, no demographic differences were observed in the included variables, both as a total (LB vs. no LB) or by subgroup (LB vs. no LB in the 0.2mL group, and LB vs. no LB in the 0.5mL group).
- Lastly, an ROC curve did not demonstrated correlation of the TMS inseminated with the probability of obtaining a LB.





Receiver Operating Characteristic Curves for Live Birth vs. Inseminated Volume
A. All cycles
B. 0.2 mL
C. 0.5 mL



Receiver Operating Characteristic Curves for Live Birth vs. Total Motile Sperm (millions)
A. All cycles
B. 0.2 mL
C. 0.5 mL

Conclusions:

→ This trial did not demonstrate a benefit in inseminating with a higher volume, as results show no significant relationship between post-wash inseminated semen volume (0.2 or 0.5mL) and live birth rate. Concern of handling during processing can be alleviated, as an increase in volume does not show considerable benefit to outcome. Standard practice can be applied and patients can be informed that their clinical care is optimized with current dIUI standards.

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