



OPTIMIZING PREGANANCY AND LIVE BIRTH RATE WITH OPT-IVF DECISION SUPPORT TOOL: A RETROSPECTIVE COHORT STUDY

Dr. Urmila Diwekar,¹ M.Tech., Ph.D., Dr. Sanjay Joag,¹ M.D., Ph.D., Dr. Nayana Patel,² M.D., Dr. Niket Patel,² M.D., Dr. Molina Patel,² M.D., and Ms. Dopal Parmar,² M.Sc.

1. Opt-IVF LLC, Crystal Lake, IL, USA; 2. Akanksha Hospital and Research Center, India

PURPOSE & OBJECTIVES

Background: Success rates and costs of Assisted Reproductive Technology (ART) heavily depend on the superovulation phase. Previous studies suggest that using Opt-IVF for hormone dosing improves outcomes, including increased high-quality embryo counts, lower hormone dosages, fewer ultrasound tests, and higher pregnancy rates. This retrospective cohort study assesses the efficacy, safety, and clinical benefits of incorporating Opt-IVF in routine practice, outside of a controlled trial setting.

Objective: The study investigates whether implementing Opt-IVF, a clinical decision support tool for hormone dosing during superovulation, improves clinical pregnancy rates and live birth outcomes in routine IVF practice.

WHAT IS KNOWN ALREADY: ART success rates and cost depend heavily on the superovulation stage of the cycle. Theoretical results, two earlier single-center trials, and two multi-center trial showed that Opt-IVF improves success rates and reduces costs and potential side effects associated with medication and testing. This is a cohort study of use Opt-IVF in a clinical hospital for 12 months.

MATERIAL & METHODS

Design: This retrospective cohort study evaluated patients undergoing an IVF cycle utilizing Opt-IVF at a single center over 12 months.

Duration: The study spanned 24 months.

Subjects: A total of 204 women aged 25-45 underwent superovulation using hormone dosages recommended by Opt-IVF (intervention group). The control group comprised 207 women who underwent superovulation without Opt-IVF guidance. Table 1 and 2 below provide the age and patient type distributions.

Intervention: The intervention used a clinical decision support tool, Opt-IVF, to guide Gonadotropin dosing and trigger dates for a personalized controlled ovarian stimulation cycle. The tool uses the distribution of follicle sizes on days 1 and 5, assessed by ultrasound, and hormone dosages given on days 1 to 4.

Main Outcomes: The main outcomes included the cumulative Gonadotropin dosage, the number of oocytes retrieved, the number of M2 oocytes, the total number of embryos formed, the number of good-quality blastocysts obtained during the cycle, clinical pregnancy rates, and birth rates after the first implantation.

Patient Type	Opt-IVF Group n = 204	Control group n = 207
Poor Responders	33 (16%)	29 (14%)
PCOS Patients	75 (37%)	71 (34%)
Normal Responders	96 (47%)	107 (52%)
Total	204	207

Age	Opt-IVF Group n = 204	Control group n = 207
Age <35	140 (69%)	142 (69%)
Age 35-39	47 (23%)	59 (28%)
Age 40-45	17 (8%)	6 (3%)

SUMMARY

- The success of IVF depends upon successful superovulation, defined by the number and uniformly high quality of eggs retrieved in a cycle
- The daily dosage of hormones required for this stage, is normally customized for each patient based on almost daily ultrasound and blood test. Although there are general guidelines for dosage, the dose is not optimized for each patient, and complications, such as overstimulation, can occur
- Cost of testing and drugs make superovulation stage very expensive
- To overcome these shortcomings, a mathematical procedure and decision support are developed, which can provide a personalized and optimized dosage for each patient.
- We use a hybrid approach for modeling superovulation phenomena, which couples first principle models based on the physics of the problem and data-driven approaches.
- This is a unique approach to modeling biomedical systems.
- This is a one-year cohort study that includes all protocols and all types of patients. The results are similar to the four clinical trials done previously
- The results show that this approach reduces drug dosage by 20-30%, reduces the need for ultrasound testing by 50-75%, and improves outcomes - with significantly higher numbers of good blastocysts and significantly higher pregnancy rates and live birth rates (per cycle till the fist embryo is implemented).
 - for normal responders, the clinical pregnancy rate increased from 33% for controls to 44% and the live birth rate increased from 30% to 41% for Opt-IVF patients
 - for poor responders, the clinical pregnancy rate increased from 15% to 41%, and the live birth rate increased from 14% to 27%.
 - for older patients (>39 years), the clinical pregnancy rates increased from 0 to 38%, and the live birth rate increased to 25%.

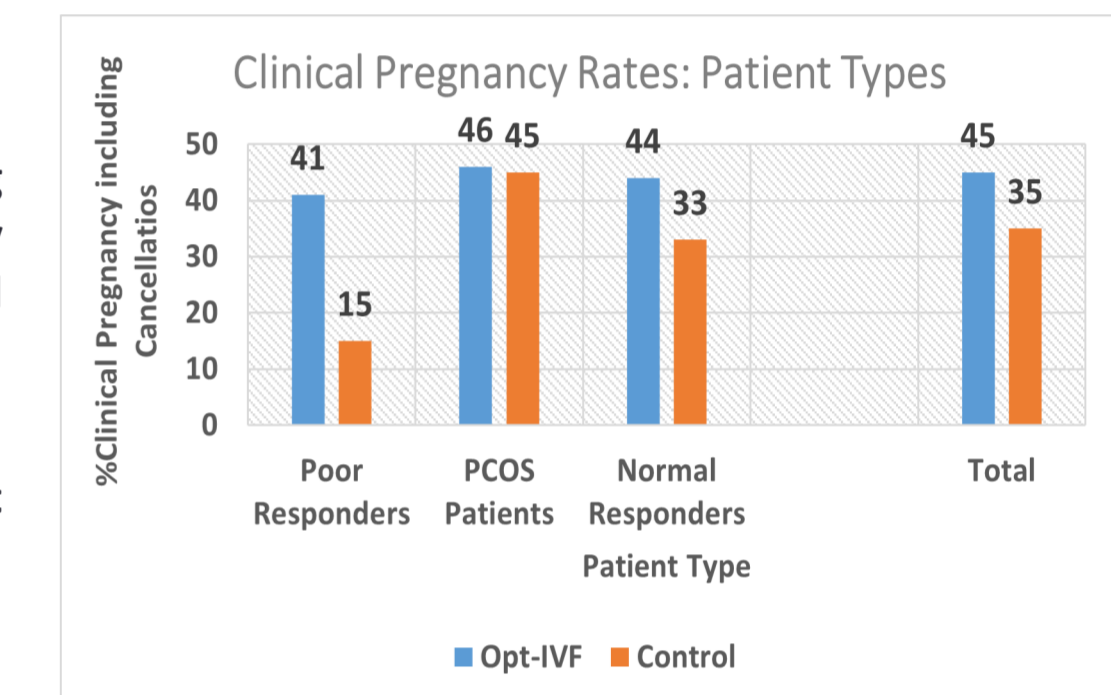
RESULTS

- Hormone Dosage:** The Opt-IVF group had significantly (20-30%) lower cumulative gonadotropin dosages compared to controls
- Embryo Count:** The Opt-IVF group had 20% more total embryos ($p < 0.001$) and 50% more high-quality embryos ($p < 0.0001$) than the control group. Primarily using day 3 embryos for implantation

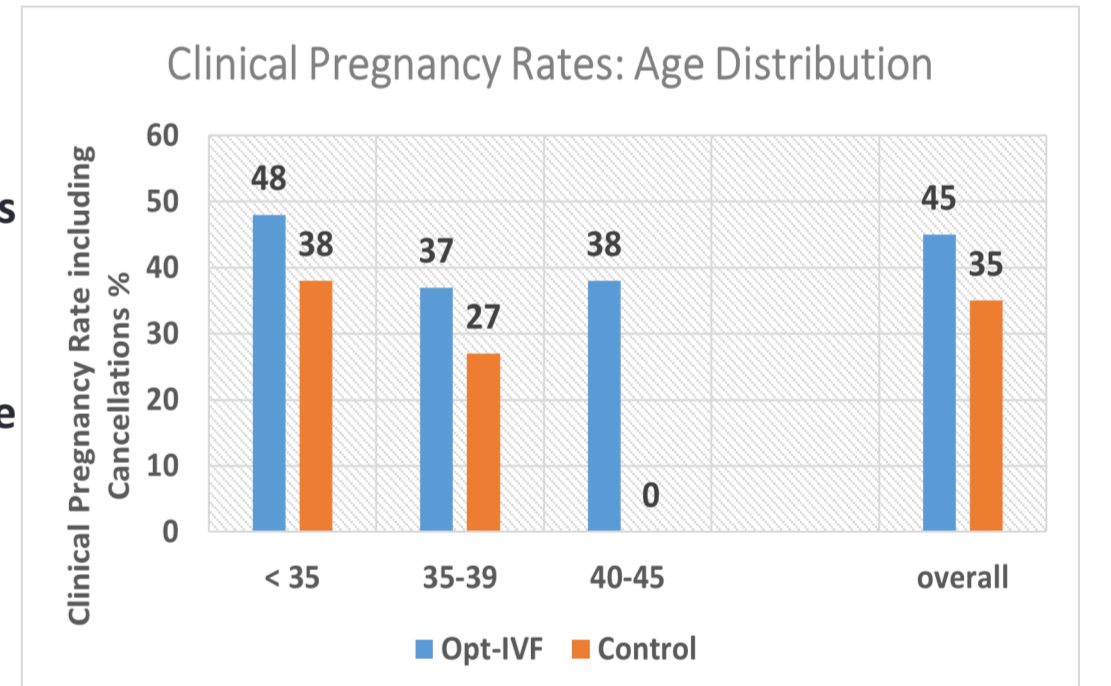
No. of Grade A Embryos and Blastocysts

Patients/Results	Opt-IVF	Control	t-test
Poor responders	1.4	0.8	$p < 0.05$
PCOS patients	4.1	3.1	$P < 0.01$
Normal responders	2.8	1.8	$p < 0.001$
Total	3.0	2.1	$p < 0.001$

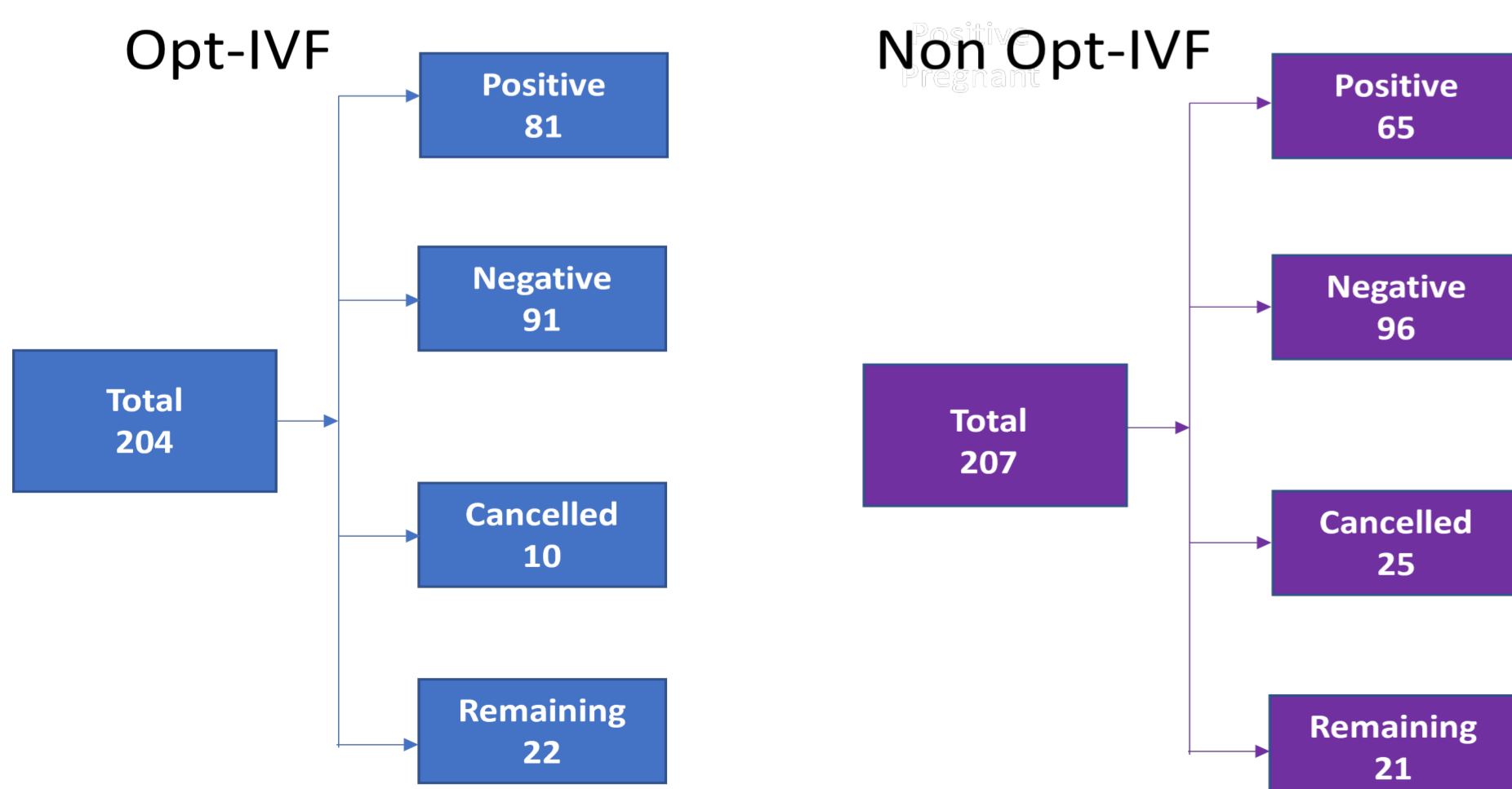
- Clinical Pregnancy Rates:** Including cancelled cycles, the clinical pregnancy rate increased from 35% in the control group to 45% in the Opt-IVF group.
- For poor responders the improvement is more pronounced.



- Clinical Pregnancy Rates:** for all ages improved significantly.
- The results for older patients is more pronounced.



RESULTS

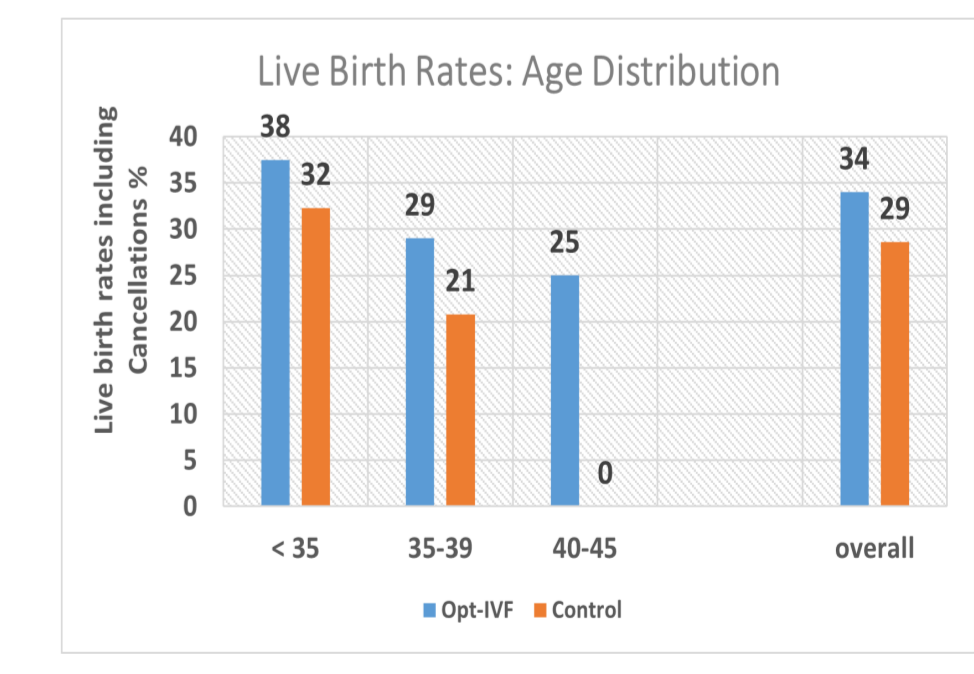
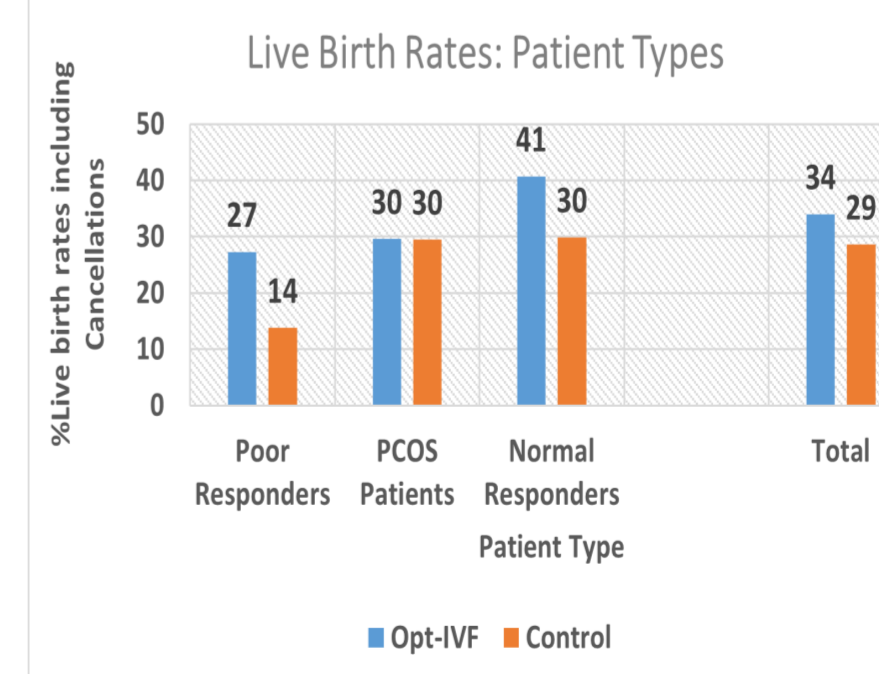


CONCLUSIONS

Using Opt-IVF for hormone dosing during superovulation significantly reduced hormone dosages and testing. This approach led to increased embryo numbers and improved pregnancy and live birth outcomes compared to traditional methods. Notably, older patients and poor responders showed marked improvements, highlighting the potential of Opt-IVF to enhance ART success in clinical practice.

REFERENCES

- Diwekar U, Patel N, Patel N, Patel M, Bhadarka H, Ghoghari P, et al., 2022. A Non-Randomized Clinical Trial of a Decision Support Tool to Optimize controlled ovarian stimulation Cycles in Individual Patients. J Fertil In vitro IVF World w Reprod Med Genet Stem Cell Biol. 10:261.
- Diwekar U, Patel N, Patel N, et al. IVF Stimulation - personalized, optimized, and simplified using an advanced decision-support tool: A randomized trial. Journal of IVF-Worldwide. 2023;1(1-3):1-12.
- Diwekar U., S. Gupta, A. Gahlan, S. Hota, K. Murdia, N. Murdia, V. Chandra, N. Bhoi, and S. Joag, A New Decision-Support Tool in a Multi-Center Randomized Trial for Personalized, Optimized, and Simplified Fertility Treatment in non-PCOS Patients, Reproduction and Fertility, 5(3), e240013, 2024a.
- Diwekar U., S. Joag, N. Patel, N. Patel, M. Patel, H. Bhadarka, P. Ghoghari, S. Dhaduk, and D. Parmar, 2024b, Enhanced Clinical Pregnancy Rates Utilizing a Clinical Decision Support Tool: A Retrospective Cohort Study, Indian Obstetrics and Gynaecology Journal, 40(2), 25



Live Birth Rates: Cycle live birth rates increased from 29% in the control group to 34% in the Opt-IVF group.

Results are more pronounced for poor responders and older patients.

CONTACT INFORMATION

Dr. Urmila Diwekar, Opt-IVF LLC, USA

E-mail: urmila@vri-custom.org, urmila@uic.edu

Tel: +1(630)886-3047