

OPTIMIZING OOCYTE YIELD UTILIZING A MACHINE LEARNING MODEL FOR DOSE AND TRIGGER DECISIONS: A MULTI-CENTER, PROSPECTIVE STUDY

AUTHORS:

Chelsea Canon¹, Lily Leibner¹, Alan B Copperman¹, Michael Fanton², David Hoffman³

1. Reproductive Medicine Associates of NY, LLP, New York, NY
2. Alife Health, Inc., San Francisco, CA
3. IVF Florida Reproductive Associates, Margate, FL

BACKGROUND:

Artificial intelligence (AI) algorithms have been developed to support clinical decision making during ovarian stimulation. Interpretable AI algorithms are being investigated to help optimize the starting dose of follicle stimulating hormone (FSH) and the timing of trigger injection by using patient's baseline characteristics, follicle growth and hormone levels. Together, these models were integrated into a Stim Assist™ platform, a clinical decision support software which provides physicians with adjunctive information for the prediction of the number of mature (MII) oocytes that may be retrieved from an ovarian stimulation cycle.

OBJECTIVE:

To evaluate clinical outcomes for patients undergoing IVF treatment where an AI platform was utilized by clinicians to help determine the optimal starting dose of FSH and timing of trigger injection.

MATERIALS AND METHODS:

This was an IRB-approved prospective, observational, post-market study of the Stim Assist™ platform. Four physicians from two assisted reproductive technology (ART) treatment centers in the United States participated in the study. The treatment arm included 291 patients undergoing IVF treatment where Stim Assist™ was utilized, and the control arm included matched historical patients from September 1, 2021 to September 1, 2022. Propensity matching was performed for each physician, comparing treatment-arm patients to their historical control-arm patients, and matched 1-to-1 based on age, baseline AMH, and baseline AFC. The primary study endpoint was to compare the average number of MII oocytes in the treatment and control arms. Average outcomes between the matched groups were compared. A t-test was used to compare the averages between the two groups were statistically significant. Additionally, a sub-analysis was performed using treatment-arm patients who were triggered in accordance with the Trigger Tool predictions.

RESULT(S):

Patient characteristics are summarized in Table 1. Average laboratory outcomes between the treatment-arm and matched control-arm are summarized in Table 2. Overall, the average number of MIIs in the treatment vs. control arm was 12.20 vs 11.24 (improvement = 0.96, p=0.16). The average number of oocytes retrieved in the treatment vs. control arm was 16.01 vs 14.54 (improvement = 1.47, p = 0.08). The average total FSH in the treatment arm was 3671.95 IUs and the average in the control arm was 3846.29 IUs (difference=-174.35 IUs, p=0.13). For patients triggered in accordance with the Trigger Tool predictions (Table 3), the overall treatment

vs. control arm MII were 15.22 ± 7.36 vs. 12.65 ± 7.5 (improvement=2.57, N=97, p=0.02). Survey results indicated that the Stim Assist™ platform was used to change or confirm the decision of starting dose or trigger timing for 89% of patients.

CONCLUSION(S):

Patients experienced a trend towards higher MII yields when clinicians utilized Stim Assist™, although these results were not statistically significant. Based on survey feedback, clinicians acknowledged the Stim Assist™ platform was used to change or confirm their decision-making strategy for starting dose or trigger timing in most patient cases. Together, this suggests that AI can safely and effectively be used in ART treatment to help optimize starting dose of FSH and trigger shot timing during ovarian stimulation.

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Table 1: Patient characteristics for treatment-arm and control-arm

Demographic	Treatment Arm	Control Arm
N	291	291
Age (years)		
All	36.10	36.07
Physician 1	36.48	36.38
Physician 2	35.54	35.45
Physician 3	35.94	35.94
Physician 4	36.91	37.18
AMH (ng/mL)		

	All	2.63	2.50
	Physician 1	3.45	3.03
	Physician 2	2.45	2.55
	Physician 3	2.01	1.99
	Physician 4	2.06	1.85
AFC (number)	All	17.20	16.47
	Physician 1	17.79	16.23
	Physician 2	17.86	17.52
	Physician 3	16.04	15.67
	Physician 4	15.88	15.69
BMI (kg/m ²)	All	24.66	25.68
	Physician 1	26.54	26.39
	Physician 2	23.47	25.22
	Physician 3	23.75	25.98
	Physician 4	24.51	24.53

Table 2: Outcomes between treatment-arm and matched control-arm

Physicians	N	Eggs Retrieved			MII Retrieved			Total FSH		
		Treatment	Control	Delta	Treatment	Control	Delta	Treatment	Control	Delta
All	291	16.01	14.54	1.47	12.20	11.24	0.96	3671.95	3846.29	-174.35
Physician 1	95	14.07	12.48	1.59	10.62	9.52	1.11	2803.08	3331.06	-527.98
Physician 2	97	17.70	16.33	1.37	13.29	12.94	0.35	3955.73	4024.74	-69.01
Physician 3	63	15.30	14.65	0.65	11.67	11.19	0.48	3977.38	4040.08	-62.70
Physician 4	36	17.78	14.92	2.86	14.28	11.28	3.00	4702.14	4401.43	300.71

Table 3: Outcomes between treatment-arm and matched control-arm for patients who were triggered in accordance with Trigger Tool predictions

Physicians	N	Eggs Retrieved			MII Retrieved			Total FSH		
		Treatment	Control	Delta	Treatment	Control	Delta	Treatment	Control	Delta
All	97	19.73	16.47	3.26	15.22	12.65	2.57	3481.37	3569.67	-88.31

Physician 1	29	18.93	15.69	3.24	14.72	11.97	2.76	2864.40	2990.98	-126.59
Physician 2	34	21.21	17.03	4.18	15.91	13.41	2.50	3738.24	3685.29	52.94
Physician 3	23	19.35	17.57	1.78	15.00	12.74	2.26	3351.09	3713.04	-361.96
Physician 4	11	18.09	14.55	3.55	14.82	11.91	2.91	4586.36	4525.00	61.36