EVALUATION AND EFFECTIVENESS OF FIRST-LINE TREATMENTS FOR POLYCYSTIC OVARY SYNDROME (PCOS) ANOVULATORY INFERTILITY: A REAL WORLD EVIDENCE STUDY

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OBJECTIVES

Polycystic ovary syndrome (PCOS) is the most common endocrinopathy affecting reproductive aged women, with a prevalence of between 8% and 13%.[1] PCOS has significant reproductive, metabolic and psychological features and accounts for 90-95% of women attending infertility clinics with anovulation. In July 2018, international evidence-based guidelines were published in effort to streamline the assessment and management of care. However, the international committee found the overall evidence to be low to moderate quality, requiring significant research expansion.[2] This study utilizes real word data to compare recent treatment guidelines for PCOS anovulatory infertility, assessing which treatments are most likely to result in successful pregnancy outcomes following diagnosis of PCOS.

METHODS

Female patients aged 18-45 with at least two PCOS documented visits (ICD-10 E28.2) during January 1, 2014 – January 1, 2017 were identified in TriNetX Research utilizing a longitudinal dataset of linked primary care data, medical and pharmacy claims of 190M patients. Patients had at least 1 year of medical history prior to and after first diagnosis of PCOS. Treatment Pathways analytic calculated percentage of first-line patients on specified treatments. Cohorts of patients treated with the highest yielding single or combination therapies, but no other treatment exposure were then used to assess risk of pregnancy (ICD-10 Z33 or CPT O00-O9A) within 12 months from first exposure to each treatment by measures of association and survival analysis conducted via Kaplan-Meier estimator.
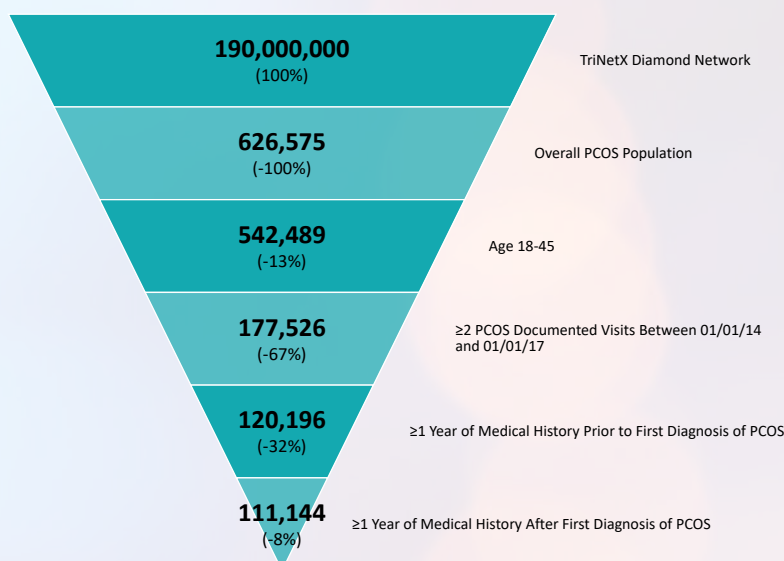

Figure 1. Inclusion/exclusion criteria analysis

RESULTS

The study included 111,144 PCOS patients (median age 32.4y). See Figure 1. Top first-line treatments identified were metformin (67.9%), dietary counseling and surveillance (13.8%), clomiphene + gonadotropins (5.4%), letrozole (4.1%), laparoscopic ovarian surgery (3.7%), gonadotropins (1.9%), and in vitro fertilization (0.9%). See Figure 2. Pregnancy outcomes were highest for IVF-treated patients (risk 69.90%; survival probability 24.92%) followed by gonadotropins (46.07%; 44.77%), clomiphene + gonadotropins (39.82%; 57.10%), letrozole (39.70%; 54.31%), dietary counseling and surveillance (10.80%; 87.57%), laparoscopic ovarian surgery (10.65%; 87.32%), and metformin (8.95%; 9.57%). See Table 1, Figures 3 and 4.
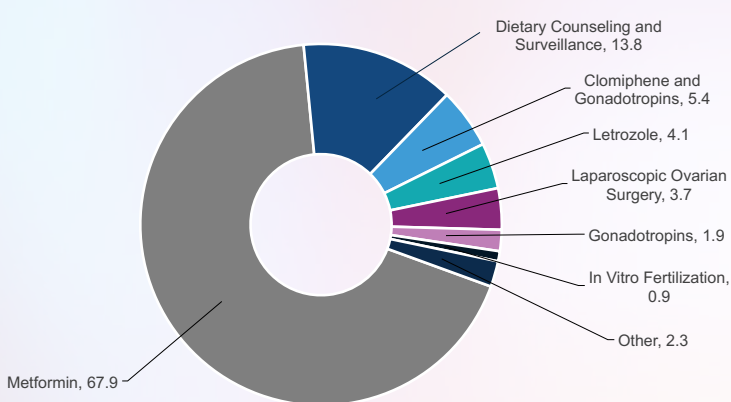

Figure 2. Percentage of PCOS patients on specified first-line treatments

	Patients in Cohort	Patients with Outcomes	Risk	Survival Probability at End of Time Window
In Vitro Fertilization	392	274	69.90%	24.92%
Gonadotropins	369	170	46.07%	44.77%
Clomiphene and Gonadotropins	771	307	39.82%	57.10%
Letrozole	393	156	39.70%	54.31%
Dietary Counseling and Surveillance	4,900	529	10.80%	87.57%
Laparoscopic Ovarian Surgery	1,268	135	10.65%	87.32%
Metformin	30,750	2,751	8.95%	90.57%

Table 1. Pregnancy risk and survival probability of top first-line PCOS treatments
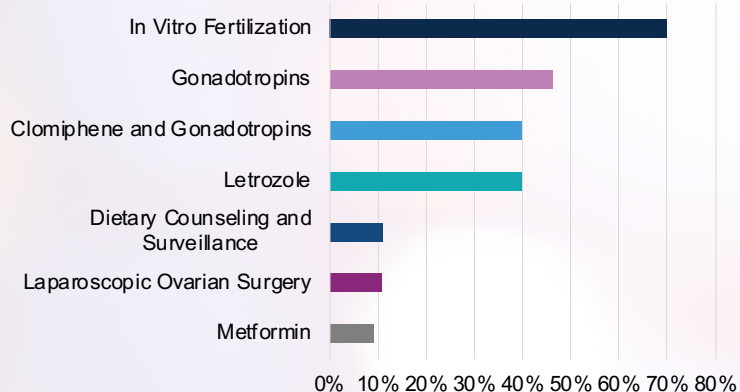

Figure 3. Risk of pregnancy within 12 months from first PCOS treatment exposure by measures of association
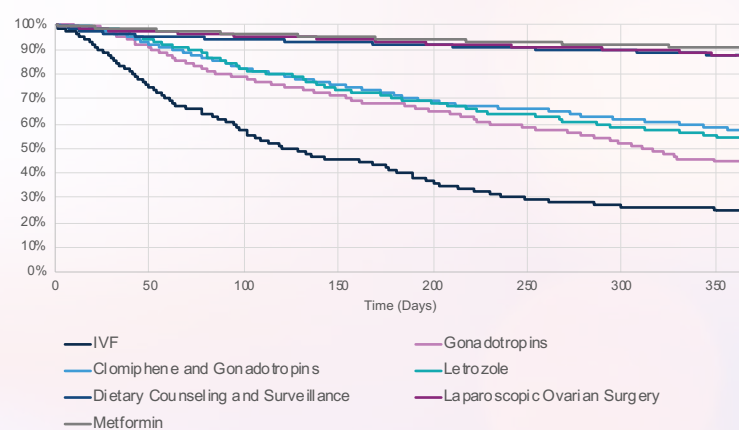

Figure 4. Pregnancy risk and survival probability of top first-line PCOS treatments

CONCLUSIONS

This study provides real world data (RWD) based insights on the prevalence of first-line treatments utilized by females with PCOS and the rate of pregnancy within first year of each treatment. Further research is warranted to investigate pregnancy outcomes in second- and third-line treated patients as well as in more therapy combinations.

1. Teede H.J., Misso M.L., Costello M.F., Dokras A., Laven J., Moran L., Piltonen T., (...), International PCOS Network (2018) Fertility and Sterility, 110 (3) , pp. 364-379.

2. Teede H, Deeks A, Moran L. Polycystic ovary syndrome: a complex condition with psychological, reproductive and metabolic manifestations that impacts on health across the lifespan. BMC Medicine 2010;8:41.