AEPCOS QUARTERLY PUBLICATION LIST

JULY—SEPTEMBER 2014

Highlighted articles

Cassina M, Donà M, Di Gianantonio E, Litta P, Clementi M. First-trimester exposure to metformin and risk of birth defects: a systematic review and meta-analysis. Hum Reprod Update. 2014 Sep-Oct;20(5):656-69. doi: 10.1093/humupd/dmu022. Epub 2014 May 25. Review. PMID: 24861556.

Commentary (CM):

The use of metformin during the first trimester of pregnancy is supported by the lack of reports suggesting an increased rate of major birth defects in the offspring of women treated with this drug. However, specific studies addressing this issue have not been published. Metformin is a category-B drug according to the FDA pregnancy classification, meaning that "animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women."
The object of this meta-analysis was to review prospective and retrospective studies on women treated with metformin during the first-trimester of pregnancy to determine the frequency of major birth defects. The inclusion criteria were patients with PCOS or pre-pregnancy diabetes type 2, and first-trimester exposure to metformin. A disease-matched control group not exposed to metformin or other anti-diabetic agents was used for comparison.
In nine controlled studies of PCOS patients that met the criteria for inclusion, it was detected that the rate of major birth defects in the metformin exposed group was statistically similar when compared with the disease-matched control group. The metformin-exposed sample was composed of 351 pregnancies and the OR of major birth defects was 0.86 (95% confidence interval: 0.18–4.08). By evaluating all of the non-overlapping PCOS studies, even those without an appropriate control group, the rate of major anomalies was 0.6% in the sample of 517 women who discontinued the therapy upon conception or confirmation of pregnancy and 0.5% in the sample of 634 women who were treated with metformin during the first trimester of their pregnancy. On the other hand, there were not sufficient studies regarding type 2 diabetic women exposed to metformin during the first trimester to proceed with the meta-analysis.
However, there are several limitations: 1) the data were taken from studies not specifically designed to evaluate the rate of congenital defects; 2) the samples were small, highly selected and non-homogeneous in terms of treatment protocols for infertility, duration of treatment, obesity and glycemic control; 3) no detailed information on other medications taken during pregnancy was reported.
The authors concluded that there is currently no evidence that metformin is associated with an increased risk of major birth defects in women affected by PCOS and treated during the first trimester. In addition, they suggest that larger

ad hoc studies are warranted in order to definitely confirm the safety and efficacy of this drug in pregnancy. Nonetheless, to design a study of this type has important ethical implications; although metformin is generally regarded as a non-teratogenic drug, it would be inappropriate to expose a large number of pregnant women to use a drug only to determine their degree of teratogenicity.

Ujvari U, Hulchiy M, Calaby A, Nybacka Å, Byström B, Hirschberg AL.Lifestyle intervention up-regulates gene and protein levels of molecules involved in insulin signaling in the endometrium of overweight/obese women with polycystic ovary syndrome. Hum Reprod. 2014 Jul;29(7):1526-35.

Commentary (KH)

While there is evidence for weight loss in PCOS improving metabolic parameters, there is debate on the possible impact of weight reduction on pregnancy rates. There is some concern that obesity decreases pregnancy rates and implantation rates in IVF including in donor oocyte IVF suggesting there are specific endometrial impacts of obesity. It is also possible that menstrual dysfunction is exacerbated by obesity. Unfortunately there are few data published on the impact of weight loss on the endometrium. The impact of insulin resistance that is associated with PCOS may impact the endometrium adversely. Many studies that demonstrate ovulatory responses to treatment in PCOS do not show correspondingly high pregnancy rates despite this ovulatory response suggesting independent endometrial effect. Lifestyle modification is an important component of the clinical treatment of PCOS in the setting of obesity but its impact on the endometrium has had limited study. The authors of this paper included 20 women who were obese with a history of PCOS (mean BMI of 37 kg/m2) in a lifestyle intervention program for 3 months. This was an individualized weight reduction program involving dietary restriction and increased physical activity. Women had monthly visits with a dietician and followed a high protein diet. They were prescribed aerobic activity for 45 minutes 2-3 times per week and were given gym memberships. At the start of the program and at 3 months they were given endometrial biopsies. The investigators also studied 10 obese controls, 9 normal weight women with PCOS and 10 normal weight control women. Of the 20 women enrolled in the lifestyle intervention program, the investigators were only able to analyse the data in 17 as 2 dropped out of the program and one had insufficient endometrial sampling. Average body weight decreased by 5% and 88% had some weight reduction. Menstrual patterns improved in 65% and 35% were documented to be ovulatory. Proliferative endometrium was studied. Endometrial insulin signalling was studied in the specimens. It was noted that endometrial levels of insulin receptor substrate -1 (IRS1) and glucose transporter 4(GLUT4) mRNA were significantly lower in obese women with PCOS compared to BMI matched control women suggesting an impact of insulin resistance on the endometrium of PCOS women. After the intervention there was a significant increase in IRS1 and GLUT1, particularly in those who demonstrated improved menstrual

function. This increased level was comparable to those in the normal groups. Overall this suggests that lifestyle intervention enhances the function of IRS1 and insulin sensitivity in the endometrium of obese women with PCOS and it appears to correlate with improved menstrual function. It remains to be seen if these improvements have a role in improvement in fertility or pregnancy rates however.

LIST OF PUBLICATIONS

Congenital Adrenal Hyperplasia and Disorders of Steroidogenesis

Metwalley KA, El-Saied AR.Bone mineral status in Egyptian children with classic congenital adrenal hyperplasia. A single-center study from Upper Egypt. Indian J Endocrinol Metab. 2014 Sep;18(5):700-4. doi: 10.4103/2230-8210.139236 PMID: 25285289

Eckoldt-Wolke F.Timing of surgery for feminizing genitoplasty in patients suffering from congenital adrenal hyperplasia. Endocr Dev. 2014;27:203-9. doi: 10.1159/000363664. Epub 2014 Sep 9. PMID: 25247657

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PCOS-Adolescence

El-Sharkawy AA, Abdelmotaleb GS, Aly MK, Kabel AM.Effect of metformin on sleep disorders in adolescent girls with polycystic ovarian syndrome. J Pediatr Adolesc Gynecol. 2014 Dec;27(6):347-52. doi: 10.1016/j.jpag.2014.01.004. Epub 2014 Sep 23. PMID: 25256878

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PCOS-Dermatology

Hagag P, Steinschneider M, Weiss M.Role of the combination spironolactone-norgestimate-estrogen in Hirsute women with polycystic ovary syndrome. J Reprod Med. 2014 Sep-Oct;59(9-10):455-63. PMID: 25330687

PCOS-Endocrine Disruptors

Patisaul HB[1], Mabrey N[2], Adewale HB[2], Sullivan AW[2].Soy but not bisphenol A (BPA) induces hallmarks of polycystic ovary syndrome (PCOS) and related metabolic co-morbidities in rats. Reprod Toxicol. 2014 Sep 19;49C:209-218. doi: 10.1016/j.reprotox.2014.09.003. [Epub ahead of print] PMID: 25242113

PCOS-Animal models

Várbíró S, Sára L, Antal P, Monori-Kiss A, Tőkés AM, Monos E, Benkő R, Csibi N, Szekeres M, Tarszabo R, Novak A, Paragi P, Nádasy GL.Lower-limb veins are thicker and vascular reactivity is decreased in a rat PCOS model: concomitant vitamin D3 treatment partially prevents these changes. Am J Physiol Heart Circ Physiol. 2014 Sep 15;307(6):H848-57. doi: 10.1152/ajpheart.01024.2013. Epub 2014 Jul 11. PMID: 25015958

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Caldwell AS, Middleton LJ, Jimenez M, Desai R, McMahon AC, Allan CM, Handelsman DJ, Walters KA.Characterization of reproductive, metabolic, and

endocrine features of polycystic ovary syndrome in female hyperandrogenic mouse models. Endocrinology. 2014 Aug;155(8):3146-59. doi: 10.1210/en.2014-1196. Epub 2014 May 30. PMID: 24877633

Yan X, Yuan C, Zhao N, Cui Y, Liu J.Prenatal androgen excess enhances stimulation of the GNRH pulse in pubertal female rats. J Endocrinol. 2014 Jul;222(1):73-85. doi: 10.1530/JOE-14-0021. Epub 2014 May 14. PMID: 24829217

PCOS-General Health

Conway G, Dewailly D, Diamanti-Kandarakis E, Escobar-Morreale HF, Franks S, Gambineri A, Kelestimur F, Macut D, Micic D, Pasquali R, Pfeifer M, Pignatelli D, Pugeat M, Yildiz B; ESE PCOS Special Interest Group.European survey of diagnosis and management of the polycystic ovary syndrome: results of the ESE PCOS Special Interest Group's Questionnaire. Eur J Endocrinol. 2014 Oct;171(4):489-98. doi: 10.1530/EJE-14-0252. Epub 2014 Jul 21. PMID: 25049203

Cheema BS, Vizza L, Swaraj S.Progressive resistance training in polycystic ovary syndrome: can pumping iron improve clinical outcomes? Sports Med. 2014 Sep;44(9):1197-207. doi: 10.1007/s40279-014-0206-6. PMID: 24872311

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Barry JA, Azizia MM, Hardiman PJ.Risk of endometrial, ovarian and breast cancer in women with polycystic ovary syndrome: a systematic review and meta-analysis. Hum Reprod Update. 2014 Sep-Oct;20(5):748-58. doi: 10.1093/humupd/dmu012. Epub 2014 Mar 30. Review. PMID: 24688118

PCOS – Genetics

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