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### Title

Bleeding patterns do not differ between nulliparous and parous women using a levonorgestrel 52 mg intrauterine system

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using an INVOcell device is a more cost-effective treatment for lesbian couples compared to standard dIUI (donor intrauterine insemination) cycles.

**DESIGN:** Cost-Effectiveness Analysis (CEA)

**MATERIALS AND METHODS:** We performed a cost-effective analysis to determine out-of-pocket costs for lesbian couples in fertility treatment. The mean costs for a vial of donor sperm, shipping, and one-time miscellaneous fees (e.g. 6 months of onsite storage, access to donor profiles) were calculated from pricing information available online from three sperm banks: Xytex, California Cryo Bank, and Seattle Sperm Bank. Note that prices for ART donor sperm vials are less expensive and only one vial of sperm is needed for an IVC cycle; therefore, storage fees were removed from the miscellaneous fees category. A current clinic cost sheet for self-pay patients was utilized to determine the cost of a dIUI cycle and an INVO cycle. Clinic fees for IUI included an average of 1.5 monitoring visits (i.e. follicle scans, blood work), medication, sperm preparation, and the insemination. Fees for an INVO cycle included 2 monitoring visits, oocyte retrieval, insemination, sperm preparation, INVOcell device and embryo transfer. Similarly, fees for subsequent FET (frozen embryo transfer) from an INVO cycle and subsequent dIUI cycles were determined.

**RESULTS:** Results of CEA is listed in the table below.

**CONCLUSIONS:** An IVC cycle requires more upfront money than standard treatment. However, after 3 dIUI cycles, an IVC cycle appears to be a more cost effective option. Two points for consideration is if the IVC cycle is successful, there is a possibility for a subsequent FET cycle. If the IVC cycle is unsuccessful (i.e. fertilization failure, nothing to transfer) patients can move quickly to a more aggressive therapy. More research is needed in the efficacy of IVC treatments when using donor sperm. However, pregnancy rates for dIUI compared to published IVC cycle rates should strongly be considered. Clinicians should evaluate cost-effectiveness along with pregnancy success when treating lesbian couples.

*Reference:*

1. <http://www.Xytex.com><http://www.cryobank.com><http://www.seattlespermbank.com>

**P-435** Wednesday, October 10, 2018 6:30 AM

#### **ANALYSIS OF CONCORDANCE IN BLASTULATION BETWEEN PARTNERS OF SAME-SEX MALE COUPLES USING SIBLING OOCYTES FROM A SIGLE OVUM DONOR.**



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**OBJECTIVE:** Oocyte donation is increasingly utilized for treatment of numerous infertility conditions and is the only option (together with surrogacy) available for same-sex male couples or single men seeking parenthood. Prior studies have analyzed the outcomes of shared oocytes donations, mainly focusing on factors relevant to egg donors or female recipients. To our knowledge, there are no studies to date examining embryo development of sibling oocytes from a single donor, fertilized by sperm from both partners of a same-sex male couple.

**DESIGN:** Retrospective cohort study

**MATERIALS AND METHODS:** To assess differences in fertilization and embryo development rates, IVF cycles where the donor's oocytes were shared equally by each partner of the same-sex male couple were analyzed (n = 139) between January 2015 and December 2017 at a single IVF center. The following parameters were compared by paired T testing between partners: age, sperm quality, fertilization, cleavage, and blastulation rates. Relative differences were calculated to determine any discordant results between partners. Concordant and discordant groups were compared by ANOVA.

**RESULTS:** In total, 278 men in same-sex relationships ranging from 25 to 60 years of age were included in this study. The only discordance between partners of couples was the blastulation rates with a relative percentile difference of  $36.4\% \pm 19$ . Based on this cut-off of discordant blastocyst development of sibling oocytes, couples were classified as concordant (Group 1, n = 77) or discordant (Group 2, n = 62). Men from Group 1 and Group 2 were similar in terms of age ( $36.8 \pm 5.7$  vs.  $36.3 \pm 5.6$ ) and semen quality (mean concentration  $74.6$  million/ml  $\pm 53.7$  vs.  $75.6$  million/ml  $\pm 53.8$  and motility  $51\% \pm 15.8$  vs.  $52\% \pm 15.9$ ). While groups were similar in embryo cleavage of day 3 ( $97.3\% \pm 0.9$  vs.  $94.9 \pm 14.7$ , P = 0.1); significant

difference in blastulation rates were observed ( $50.2\% \pm 20.5$  vs.  $43.2\% \pm 26.6\%$ , P = 0.01).

**CONCLUSIONS:** As sibling oocytes were donated by a single donor and randomly split, egg quality should not be different between each partner. Therefore, discordant results of blastocyst development between some partners should only be explained by the contribution of each partner's sperm to development. Paternal contribution to embryo development could be underestimated without proper embryo assessment following genome activation on day 3 of embryo development.

## **CONTRACEPTION**

**P-436** Wednesday, October 10, 2018 6:30 AM

#### **SERUM AMH ASSESSMENT IN FEMALES OF REPRODUCTIVE AGE BOTH ON AND OFF ORAL CONTRACEPTION: IMPLICATIONS FOR CESSATION.**



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**OBJECTIVE:** Serum anti-Müllerian hormone (AMH) is considered an accurate marker of ovarian reserve and is heavily utilised in the world of assisted reproductive technologies (ART). Given its important role in reproduction, AMH values are highly relevant and are seen to vary extensively, with the single greatest influencer being age. Oral contraceptives (OC) are considered as confounders to the true AMH value but the full extent of this effect is largely unknown. Do general population and ART recipient's serum AMH levels differ and to what extent do OC influence serum measurements. Over what time period are values likely to return to normal following OC cessation.

**DESIGN:** Over a 3-year period, serum AMH levels were measured in an age-matched general population cohort of 4,322 women and 1,280 ART recipients. A separate non-ART cohort (n=1,837) were identified with either current use of COCP (n=155) versus those who have never taken OC (n=337).

**MATERIALS AND METHODS:** All serum AMH measurements were conducted on the Roche Cobas automated platform. Procurement times, storage conditions and time to analysis were carefully controlled for all cohorts.

**RESULTS:** A normogram was created to demonstrate the age-related decline in serum AMH levels. Age-matched ART participants and general population means were identical ( $17.0$  vs  $17.1$ , P=0.77). The effect of OC was assessed and showed an average 5% depressive effect on serum AMH levels relative to those who have never taken OCP (P<0.001) despite being an average 3 years younger ( $31.9$  vs  $34.9$ , p<0.001).

**CONCLUSIONS:** Data from this large-scale study indicates serum assessment of mean AMH levels in general population and ART cohorts are identical but vary depending on OC use. OC use depresses serum AMH levels by 5%, relative to age matched individuals with no history of OC use. AMH levels in those individuals who stop taking OC typically return to "normal" within 3 to 6 months of cessation.

*Supported by:* This project was entirely funded by Sims IVF and Virtus Health. There are no conflicts of interest.

**P-437** Wednesday, October 10, 2018 6:30 AM

#### **BLEEDING PATTERNS DO NOT DIFFER BETWEEN NULLIPAROUS AND PAROUS WOMEN USING A LEVONORGESTREL 52 MG INTRAUTERINE SYSTEM.**



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**OBJECTIVE:** Compare bleeding patterns and amenorrhea rates over 2 years in nulliparous and parous women using a levonorgestrel 52 mg intrauterine system (IUS).

**DESIGN:** Prospective multicenter clinical trial

**MATERIALS AND METHODS:** Eligible nulliparous and parous women 16-45 years old received a levonorgestrel 52 mg IUS in the ACCESS IUS trial evaluating efficacy and safety of Liletta® for up to 10 years after insertion. Participants completed daily diaries for the first 2 years with bleeding information, including subjective evaluation of flow. Bleeding events included no bleeding or spotting (amenorrhea), bleeding, spotting, and bleeding or spotting (B/S). We compared bleeding patterns per 28-day cycle in nulliparous and parous women over 13 cycles (1 year) and at cycle 26 (2 years). Fisher's exact testing was performed to compare outcomes between groups.

**RESULTS:** The median B/S days in nulliparous (n=976) and parous (n=715) women were 15 and 13, respectively, in cycle 1. Median B/S days decreased steadily in both groups to 3 or fewer days per cycle by cycle 10 and 2 or fewer days per cycle by cycle 21. The median bleeding days per cycle were 5 for each group in cycle 1 and declined in nulliparous and parous women to a median of 0 by the 4<sup>th</sup> and 5<sup>th</sup> cycle, respectively. The median spotting days per cycle were 2 or less by cycle 6 in both groups. Amenorrhea rates increased over two years and were similar (See Table). Over 26 cycles, 13 (1.3%) nulliparous and 26 (3.4%) parous women discontinued for bleeding complaints (p=0.003).

**CONCLUSIONS:** Amenorrhea rates and B/S days are comparable between nulliparous and parous women using a levonorgestrel 52 mg IUS. Bleeding and spotting days decrease over time. More than half of all users experience no bleeding by the 5<sup>th</sup> cycle. Discontinuation for bleeding complaints over 2 years is low overall, but parous women are more likely to discontinue for bleeding complaints than nulliparous women.

Amenorrhea Rates by Parity with Levonorgestrel 52 mg IUS Use

Cycle	Amenorrhea				P-value
	Nulliparous		Parous		
	N	n(%)	N	n(%)	
1	976	5 (0.5%)	715	5 (0.7%)	0.75
2	962	68 (7.1%)	693	54 (7.8%)	0.63
6	917	246 (26.8%)	644	164 (25.5%)	0.56
13	841	305 (36.3%)	554	181 (32.7%)	0.19
19	753	290 (38.5%)	498	188 (37.8%)	0.81
26	674	309 (45.8%)	445	190 (42.7%)	0.33

Supported by: Medicines360

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**POSTPARTUM FAMILY PLANNING METRICS: ANALYSIS FROM MARYLAND ALL PAYERS' CLAIMS DATABASE.**

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**OBJECTIVE:** This study assesses family planning quality metrics in the post-partum period and up to 6 months after birth, among women enrolled in private health insurance in the state of Maryland.

**DESIGN:** We performed a retrospective cohort study analyzing claims based on a statewide database operated by the Maryland Department of Health.

**MATERIALS AND METHODS:** We identified 47,684 women who gave birth between January 2013 and October 2014 and who had at least two months of pharmacy coverage after delivery. We describe levels of use of most and moderately effective contraception (MMEC) (including steriliza-

tion, long acting reversible contraception (LARC) and short acting hormonal methods) and LARC use within 3 days, 60 days and 6 months post-partum. We conducted multivariate analyses to assess odds of MMEC and LARC use at each time point. We also conducted survival analysis to estimate time to MMEC and LARC initiation after delivery.

**RESULTS:** At 3 days postpartum 10% of women had received MMEC, the percentage rising to 23% at 60 days and 40% at six months postpartum. LARC use was non-existent at 3 days and remained low at 60 days (1.7%). By 6 months postpartum, 5.6% of women were using LARCs, comprising 14% of the method mix of MMECs. MMEC uptake progressed more rapidly among mothers aged 15-19 years, reaching 27% at 60 days and 51% at 6 months compared to 20% and 35% among women over the age of 35. Likewise, MMEC uptake also increased more rapidly from 26% to 45% during this time period among those living in the poorest neighborhoods versus 22% to 36% among those living in the most affluent areas

**CONCLUSIONS:** In 2013-14, postpartum uptake of contraception in the 3 days following delivery was low in Maryland. Use of MMEC, including LARC, increased in the 6 months after delivery, reaching 40% overall but demonstrating higher uptake among teenagers than women over 35 years of age.

Supported by: This study was funded by Bayer US, LLC

P-439 Wednesday, October 10, 2018 6:30 AM

**HIGHLY EFFECTIVE CONTRACEPTIVE USE IN THE POSTPARTUM PERIOD AMONG WOMEN WITH DIABETES.** J. R. Morris. Emory University, Atlanta, GA.



**OBJECTIVE:** The number of reproductive age women affected by diabetes is increasing. Almost half of pregnancies in the United States are unintended with a higher rate among women with chronic disease. Use of contraception, particularly highly effective methods (sterilization or long acting reversible contraception [LARC], including intrauterine devices and implants), decreases risk for unintended pregnancy and LARC's allow for pregnancy planning when disease control is optimal. Although women with diabetes are overall less likely to use postpartum contraception, one study found they were more likely to undergo postpartum sterilization and less likely to receive LARC's than women without diabetes among women in California. This study sought to determine the prevalence of highly effective contraceptive use and factors associated with using sterilization versus LARCs among postpartum women with diabetes and without diabetes.

**DESIGN:** This study used population-based, state-specific data from the Pregnancy Risk Assessment Monitoring System (PRAMS). This analysis included data from women with live births during 2012 to 2015 in all states with >60% response rate (2012-2014) or >55% response rate (2015).

**MATERIALS AND METHODS:** Women were asked if they had diabetes before or during their most recent pregnancy, if they were currently using contraception, and method(s) of use. Percents and Chi-square p-values were calculated for sterilization and LARCs among women with diabetes compared to women without diabetes. Multivariate logistic regression was used to assess factors associated with female sterilization, compared to LARCs, among women with diabetes.

**RESULTS:** After exclusions, there were 94,981 women included in analyses, of which 10,606 (11%) had chronic or gestational diabetes. Women with diabetes were more likely to use female sterilization than women without diabetes and less likely to use LARCs than women without diabetes (p<0.0001). Among women with diabetes, older age, less education, higher parity, unsure recent pregnancy intention, and cesarean delivery were associated with being more likely to use sterilization than LARCs. After adjustment, women with diabetes were more likely to endorse sterilization versus LARCs as compared to women without diabetes (adjusted OR 1.34, 95% CI 1.22, 1.48).

**CONCLUSIONS:** This study found women who reported diabetes were more likely to use female sterilization and less likely to use LARCs for postpartum contraception compared to women without diabetes. Certain characteristics such as less education and unclear pregnancy intention were associated with sterilization among women with diabetes. It is important women with diabetes receive counseling about and access to all methods. While highly effective postpartum contraception is ideal for women with medical conditions affecting pregnancy, further studies are needed to assess