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Outcomes after intrauterine insemination are independent of provider type

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Abstract

OBJECTIVE—We sought to determine whether the success of intrauterine insemination (IUI) varies based on the type of health care provider performing the procedure.

STUDY DESIGN—This was a retrospective cohort study set at an infertility clinic at an academic institution. The patients who comprised this study were 1575 women who underwent 3475 IUI cycles from late 2003 through early 2012. Cycles were stratified into 3 groups according to the type of provider who performed the procedure: attending physician, fellow physician, or registered nurse (RN). The primary outcome was live birth. Additional outcomes of interest included positive pregnancy test and clinical pregnancy. Repeated measures log binomial regression was used to estimate the risk ratios (RR) and 95% confidence intervals (CI) for the outcomes and to evaluate the effect of potential confounders. All tests were 2-sided, and *P* values < .05 were considered statistically significant.

RESULTS—Of the 3475 IUI cycles, 2030 (58.4%) were gonadotropin stimulated, 929 (26.7%) were clomiphene citrate stimulated, and 516 (14.9%) were natural. The incidences of clinical pregnancy and live birth among all cycles were 11.8% and 8.8%, respectively. After adjusting for female age, male partner age, and cycle type, the incidence of live birth was similar for RNs compared with attending physicians (RR, 0.80; 95% CI, 0.58–1.1) and fellow physicians compared with attending physicians (RR, 0.84; 95% CI, 0.58–1.2). Similar results were seen for positive pregnancy test and clinical pregnancy.

CONCLUSION—There was no significant difference in live birth following IUI cycles in which the procedure was performed by a fellow physician or RN compared with an attending physician.

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Keywords

infertility; intrauterine insemination; pregnancy rate; provider type

Intrauterine insemination (IUI) is an early step in the treatment of many infertile couples, often before more complex assisted reproductive technologies, such as in vitro fertilization (IVF), are employed.¹⁻³ It can be used to treat both male and female infertility due to numerous causes, including ovulatory, cervical, immunologic, ejaculatory, and unexplained infertility, as well as male subfertility. During the procedure, washed sperm are placed directly into a patient's uterus, ideally resulting in fertilization, pregnancy, and ultimately a live birth. IUI is often used concurrently with ovarian stimulation protocols to increase the likelihood of success.³⁻⁶

The success of an IUI cycle is multifactorial. A single IUI cycle with controlled ovarian hyperstimulation is estimated to result in pregnancy 10-20% of the time.^{1,6-9} Predictors of IUI success include female age, preovulatory follicle count, and endometrial thickness, as well as male factors such as the total motile sperm count and sperm morphology.¹⁰⁻²⁰

Previous studies have examined the impact of provider type on IVF outcomes and physician experience on IUI outcomes.^{21,22} One parameter that has not been well studied is the training level of the medical professional performing IUI procedures. Attending and fellow physicians have traditionally performed the majority of these procedures, with nurse practitioners and registered nurses (RNs) performing an increasing number of IUI procedures in recent years as the use of IVF has grown.^{23,24}

At our institution, we have a standardized certification and credentialing process wherein new providers (RNs and fellow physicians) are trained to perform IUI. A teaching coach who has demonstrated proficiency assesses each provider learning the procedure. The coach assesses the performance of the learner based on 19 criteria, providing feedback when indicated. The learner can be evaluated by direct observation, verbalization of knowledge, documentation review, and/or customer feedback. Examples of performance criteria include properly identifying the patient, signing consent, gathering necessary equipment, inserting the speculum, inserting the catheter through the os, and proper documentation. The learner must complete 3 successful IUIs under the supervision of an attending physician, and only when all criteria are performed satisfactorily is the learner said to have achieved competence and earned credentials. Notably, the steps that include insertion of the speculum and threading the catheter through the os allow for physician assistance when difficulties arise, such as patient intolerance or stenotic cervix. The Supplementary Material (Appendix) contains a full list of evaluable performance criteria used to demonstrate proficiency.

It has been our experience that some patients insist on having an attending physician perform the procedure because they assume they will have better outcomes. In addition, some third-party payers may reimburse only if a physician performs the procedure, deterring clinics from having midlevel providers execute the technique. This study seeks to evaluate the association between provider type and IUI success.

Materials and Methods

The Partners Healthcare Institutional Review Board at the Massachusetts General Hospital reviewed and approved this study. IUI cycles at our institution from late December 2003 through early January 2012 that met the following criteria were eligible for inclusion: patients who underwent the IUI cycles underwent their first cycle within the study's time frame at our institution, cycles were either natural or superovulation cycles using either clomiphene citrate or gonadotropins, total motile sperm count >1 million after washing at pretreatment evaluation, and known type of provider performing the procedure. For each woman, we included all IUI cycles that met the above criteria, up to cycle 6 or until a live birth was achieved. After a live birth was achieved, all future cycles for that woman were excluded.

Patients who underwent natural cycles did not receive clomiphene citrate or gonadotropins. Typically, patients undergoing superovulation received clomiphene citrate 50-100 mg orally on cycle days 3-7 or 5-9 or recombinant gonadotropin beginning on cycle day 3, followed by ovulation induction with 250 µg of recombinant human chorionic gonadotropin (hCG) (Ovidrel; Serono Laboratories, Norwell, MA) subcutaneously when the lead follicle reached at least 16 mm in diameter. Washed sperm meeting the above specifications was inseminated 35-36 hours after hCG injection. All patients were monitored with either ultrasound or both serum estradiol and ultrasound.

Cycles were stratified into 3 groups according to the type of provider who performed the procedure: attending physician, fellow physician (fellow) or RN. Regardless of the type of provider ultimately performing the procedure, the attending physician on call reviewed ultrasound findings and estradiol levels and made all medical decisions relating to the cycle, including dose of medication prescribed, time to follow-up, and when the procedure was to occur. Clinical decisions were made by physicians without knowledge of the type of provider who would ultimately perform the insemination, as patient appointments were made independently of these decisions. A patient was scheduled for her procedure as indicated by her cycle, and the provider was dictated by a pre-determined schedule based on availability. Schedules were created 6 months in advance and distributed equally among providers of the same type. The schedules included coverage schemes for vacations as well as weekend coverage, and were created prior to any patients being booked for visits. On any given day, 1 provider (an RN, fellow physician, or attending physician) was scheduled to perform the inseminations. Rarely, changes in the daily schedules for IUI coverage occurred based on the volume of patients for that particular day and availability of staff. Infertility diagnosis was designated using Society for Assisted Reproductive Technologies categories. Note that at our institution, we define diminished ovarian reserve as serum follicle-stimulating hormone >10 (IU/L).

The primary outcome of interest was live birth; secondary outcomes included positive pregnancy test, defined as a positive serum beta-hCG and clinical pregnancy, defined as a normal intrauterine gestational sac seen on ultrasound at 6 weeks' gestation. Descriptive data are reported as mean ($\pm$ SD), median (interquartile range), or proportion, depending on data type and distribution. We used generalized estimating equations to perform repeated

measures log binomial regression to account for the lack of independence among cycles from the same women while estimating the risk ratio (RR) and 95% confidence intervals (CIs) for the outcomes of interest. We did not identify any potential confounders that we believed would influence both the provider type and the primary outcome. However, we included in the model several variables thought to potentially influence IUI outcomes, such as the woman's age, partner's age, and cycle type, to account for possible differences among groups.^{4,5,14} A sensitivity analysis was performed to account for missing outcome data, and post hoc power and sample size calculations were done. All statistical analyses were performed using software (SAS 9.3; SAS Institute Inc, Cary, NC). All tests were 2-sided, and P values $<.05$ were considered statistically significant.

RESULTS

A total of 1575 women had a first IUI cycle that met eligibility criteria initiated at Massachusetts General Hospital during the study period. These women underwent 3475 IUI cycles before achieving a live birth, discontinuing care, or completing 6 cycles. The median number of cycles per woman was 2.0 (interquartile range, 1.0–3.0). During the 8 years that cycles were evaluated in this study, 8 fellows and 14 RNs have been trained. In addition, 8 attending physicians are on staff.

Of the 3475 cycles, 395 (11.4%) were performed by an attending physician, 734 (21.1%) were performed by a fellow, and 2346 (67.5%) were performed by an RN. During the study period, the proportion of cycles performed by fellows increased from 14.4% at the start of the fellowship in 2005 to approximately 25% in later years as the fellowship expanded and the volume of IUI procedures increased. A similar pattern was observed for cycles performed by RNs, which increased from approximately 50–70% over the study period. Table 1 shows baseline characteristics for first cycles performed by RNs and fellows compared with attending physicians. The average age of women undergoing IUI was significantly higher among first cycles performed by a fellow compared with those performed by an attending ($P = .007$). There were no significant differences in partner age, body mass index (kg/m^2), infertility diagnosis, cycle day 3 follicle-stimulating hormone (IU/L), number of follicles >12 mm, or total motile sperm count among the groups. An idiopathic diagnosis was the cause of infertility for one third of the cohort. Male factor infertility, diminished ovarian reserve, and combined factors were the next most frequent diagnoses.

There were opposing trends in the proportion of clomiphene citrate and natural IUI cycles as cycle number increased (Table 2). The use of clomiphene citrate decreased with increasing cycle number through cycle 4, at which point use plateaued. The proportion of natural IUI cycles steadily increased, from 12.1% in the first cycle to 30.7% in the sixth cycle. The median number of follicles >12 mm for the first 4 cycles was 2, and for cycles 4 and 5 was 1. Other parameters, including median number of follicles >12 mm, IUI preparation/sperm (millions), total gonadotropin dose, and peak estradiol remained relatively stable across cycles.

Among all cycles, 14.0% resulted in a positive pregnancy test, 11.8% resulted in a clinical pregnancy, and 8.8% resulted in a live birth. The success of the IUI cycle did not differ based on the type of provider performing the procedure. After adjusting for the woman's age, partner's age, and cycle type, there was no difference in the probability of live birth for procedures performed by an RN compared with an attending physician (RR, 0.80; 95% CI, 0.58–1.1) or for those performed by a fellow compared with an attending physician (RR, 0.84; 95% CI, 0.58–1.2). Similar results were observed for positive pregnancy test and clinical pregnancy (Table 3).

Importantly, there are missing outcome data on a number of cycles in which there was a positive pregnancy test, including 2 attending cycles, 11 RN cycles, and 6 fellow cycles. There also are missing live birth outcome data on 8 RN cycles and 1 fellow cycle among those noted to have resulted in a clinical pregnancy. A sensitivity analysis was done to account for the missing outcome data, as we assumed those cycles with missing data ended in a pregnancy loss for the primary analysis. If we assume all cycles with missing data resulted in a positive outcome, the incidences would be 13.2%, 11.4%, and 12.4% for clinical pregnancy and 11.1%, 8.6%, and 8.9% for live birth among attending physicians, fellow physicians, and RNs, respectively. These incidences yielded RRs that essentially were unchanged.

The post hoc power calculation indicated this study had only 40% power to detect a difference of the magnitude observed for live birth when comparing cycles performed by RNs versus attending physicians. A post hoc sample size calculation showed that we would need 1154 attending physician cycles and 6924 RN cycles to have at least 80% power to detect a difference of the observed magnitude.

COMMENT

The nature of a modern fertility practice often dictates that physicians cover multiple aspects of the practice on any given day. Typical demands on physicians include working in the operating room, performing procedures in radiology, seeing patients in their clinics, performing office-based procedures, or doing oocyte retrievals and embryo transfers. The appropriate use of midlevel health care providers, such as RNs, physician assistants, and nurse practitioners, is crucial to the success of the practice. One procedure that has the potential to be successfully managed by these providers is IUI. Many patients believe that their chance of pregnancy and live birth will be higher when the attending physician physically executes the technique. However, their insistence on a preferred provider type may be misguided, as was found in this study.

This study demonstrates that following appropriate training and credentialing, the success of the IUI is independent of the type of provider performing the procedure. The incidence of live birth among the 3 groups was comparable and consistent with success rates nationwide. Perhaps a more significant contributor to the success of the IUI is the amount of training the provider has invested into the procedure itself, as suggested by previous studies that found higher pregnancy rates following embryo transfer and IUI with more experienced physician

providers.^{21,22} Further investigation of success rates stratified by number of procedures performed would help answer that question.

Most women in this study underwent 3 IUI cycles, and may have been influenced by insurance mandates. During earlier years of this study, most insurance companies required 2-3 IUI cycles prior to proceeding with IVF, with exceptions for tubal and male factor diagnoses. More recently, these requirements have become less restrictive. We found that the proportion of clomiphene citrate cycles decreased with increasing cycle number, likely because patients who failed early clomiphene citrate cycles later utilized gonadotropin stimulation, or were referred to IVF. In contrast, the proportion of natural IUI cycles increased with cycle number, with many later cycles using donor sperm. Other natural cycles were composed of patients who had either failed IVF or were poor IVF candidates, but were not ready to proceed with oocyte donation and were offered up to 6 natural cycles.

We recognize that the adjusted RRs for live birth, while not significant, could suggest that IUI outcomes are not as good when the procedure is performed by an RN or a fellow compared with an attending physician. There may be a difference in the underlying cause of infertility among the women treated in each group that we are not capturing in this data set, or this could be a chance finding in this cohort with a relatively small number of cycles performed by attending physicians. If the differences in live birth were due to the type of provider who performed the insemination, we would expect similar differences in the probability of clinical pregnancy based on provider type. Absent differences in the underlying cause of infertility among women in each group, it seems unlikely that each provider type would have similar success with regard to clinical pregnancy, but that RNs and fellows would have poorer live birth outcomes. We would expect that characteristics related to IUI technique would be reflected in more proximal outcomes, such as a positive pregnancy test and clinical pregnancy. Given this study had only 40% power to detect a difference of the observed magnitude, it would be interesting to explore these questions further in future studies, additionally incorporating provider experience with provider type.

The strengths of this study include the large number of evaluated cycles, a standardized credentialing tool for IUI performance, and the large number of clinicians who have been credentialed and perform the IUIs, which may enhance its generalizability to fertility centers and physician offices that perform IUIs. It should be noted that the nature of our training institution and strict credentialing standards might have influenced the lack of significant differences in outcome among different provider types. We believe that the results of this study provide support for the effectiveness of a standardized process for evaluating competence in the IUI procedure, and should be transferable to most clinics. Additionally, these findings may encourage other practices to consider strict training of midlevel providers to ensure consistency and to increase the confidence of patients to the practice.

We also recognize the inherent limitations associated with the retrospective design of this study. It is possible that our findings could be explained by selection bias that resulted in women with a higher probability of a successful IUI being more likely to have their procedure performed by an attending physician. However, given the scheduling process, we believe that the potential for selection bias was minimal. An additional limitation is that a

very small number of patients (<1%) specifically requested that an attending physician perform their procedure instead of a fellow or RN. Similarly, if an RN or fellow was unable to complete the IUI due to cervical issues or patient intolerance, an attending physician was called to complete the procedure. These cycles were coded as attending physician cycles. If these cycles were less likely to result in a successful outcome, the results would be biased towards the null; however, these situations occur very infrequently (<1-2 times/mo) and would have a minimal effect, if any.

Midlevel providers are invaluable resources to reproductive endocrinology clinics, and allowing them to perform IUIs can help busy clinics run more smoothly. Patients and third-party payers should be reassured by the findings of this study, which show that properly trained RNs and fellows generate IUI clinical pregnancy and live birth outcomes that are not significantly different from those of attending physicians.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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TABLE 1
Patient characteristics at start of cycle 1

Characteristic	Full cohort, n = 1575	Attending physician, n = 184	Registered nurse, n = 1100	<i>P</i> value ^a	Fellow physician, n = 291	<i>P</i> value ^a
Woman's age, y	35.2 ± 4.4	34.8 ± 4.3	35.1 ± 4.5	.42	35.9 ± 4.1	.007
<35 y	700 (44.4)	86 (46.7)	510 (46.4)	.24	104 (35.7)	.05
35 to <38 y	370 (23.5)	50 (27.2)	241 (21.9)		79 (27.2)	
38 to <40 y	217 (13.8)	23 (12.5)	145 (13.2)		49 (16.8)	
40 y	288 (18.3)	25 (13.6)	204 (18.5)		59 (20.3)	
Partner's age, y	36.9 ± 5.8	36.8 ± 5.5	36.7 ± 5.8	.83	37.9 ± 6.1	.06
Body mass index, kg/m ²	23.0 (21.0–26.2)	23.0 (21.0–26.0)	23.1 (21.2–26.4)	.21	23.1 (21.1–26.1)	.36
Cycle day 3 FSH, IU/L	7.2 (5.9–8.9)	7.6 (6.0–9.3)	7.1 (5.9–8.8)	.15	7.1 (5.8–8.9)	.14
No. of follicles >12 mm	2.0 (1.0–2.0)	2.0 (1.0–3.0)	2.0 (1.0–2.0)	.24	2.0 (1.0–2.0)	.18
Total motile sperm count, million	27.5 (11.0–56.2)	25.7 (11.7–61.0)	27.7 (10.9–55.6)	.75	26.0 (10.9–57.6)	.93
Diagnosis				.73		.75
Idiopathic	520 (33.0)	55 (29.9)	370 (33.6)		95 (32.7)	
Anovulatory/PCOS	204 (13.0)	25 (13.6)	141 (12.8)		38 (13.1)	
Male factor	221 (14.0)	30 (16.3)	145 (13.2)		46 (15.8)	
Diminished ovarian reserve	205 (13.0)	24 (13.0)	138 (12.5)		43 (14.8)	
Tubal factor	50 (3.2)	9 (4.9)	35 (3.2)		6 (2.1)	
Combined factors	233 (14.8)	26 (14.1)	168 (15.3)		39 (13.4)	
Other ^b	142 (9.0)	15 (8.2)	103 (9.4)		24 (8.2)	

Data are presented as mean ± SD, median (interquartile range), or n (%).

FSH, follicle-stimulating hormone; *PCOS*, polycystic ovary syndrome.

^a Compares registered nurse to attending physician or fellow physician to attending physician;

^b Includes endometriosis, uterine factor, diethylstilbestrol exposure, single mother, same-sex relationship, other, and missing.

TABLE 2

Cycle characteristics

Characteristic	Cycle 1, n = 1575	Cycle 2, n = 918	Cycle 3, n = 535	Cycle 4, n = 239	Cycle 5, n = 133	Cycle 6, n = 75
Cycle type						
Gonadotropin	924 (58.7)	527 (57.4)	307 (57.4)	155 (64.9)	78 (58.7)	39 (52.0)
Clomiphene citrate	462 (29.3)	259 (28.2)	136 (25.4)	37 (15.5)	22 (16.5)	13 (17.3)
Natural	189 (12.0)	132 (14.4)	92 (17.2)	47 (19.7)	33 (24.8)	23 (30.7)
Cycle day 3 FSH, IU/L	7.2 (5.9–8.9)	7.2 (6.0–8.8)	7.2 (6.0–8.8)	7.3 (6.0–9.0)	7.4 (6.1–8.9)	7.5 (6.2–8.8)
Peak estradiol, pg/mL ^a						
Day before hCG	309.5 (207.0–471.0), n = 450	317.0 (214.0–476.0), n = 254	306.5 (228.0–498.0), n = 152	299.5 (190.5–440.0), n = 68	254.5 (190.0–380.0), n = 30	311.0 (270.0–465.0), n = 18
Day of hCG	478.0 (309.0–676.0), n = 415	464.0 (298.0–642.0), n = 209	437.0 (306.0–618.0), n = 126	466.0 (308.0–734.0), n = 58	395.0 (294.0–658.0), n = 33	414.0 (256.0–683.0), n = 15
Total gonadotropins, IU ^a	600.0 (450.0–875.0)	675.0 (450.0–950.0)	675.0 (475.0–1125.0)	600.0 (450.0–1200.0)	600.0 (400.0–1125.0)	675.0 (450.0–1050.0)
No. of follicles >12 mm	2.0 (1.0–2.0)	2.0 (1.0–2.0)	2.0 (1.0–2.0)	2.0 (1.0–2.0)	1.0 (1.0–2.0)	1.0 (1.0–2.0)
IUI prep/sperm parameters, million	27.5 (11.0–56.2)	25.0 (10.2–52.1)	24.5 (10.8–48.5)	19.6 (9.2–47.0)	17.5 (9.8–43.2)	23.5 (12.0–45.4)

Data are presented as median (interquartile range) or n (%).

FSH, follicle-stimulating hormone; hCG, human chorionic gonadotropin; IUI, intrauterine insemination.

^aCalculated for gonadotropin cycles only.

TABLE 3
Incidence of and risk ratio for cycle outcomes based on provider type

Outcome	Incidence, n (%)	Crude RR (95% CI)	Adjusted RR ^a (95% CI)
Positive pregnancy test			
Registered nurse	330 (14.1)	1.0 (0.77–1.3)	1.0 (0.76–1.3)
Fellow physician	101 (13.8)	0.98 (0.71–1.3)	1.0 (0.75–1.4)
Attending physician	55 (13.9)	Reference	Reference
Clinical pregnancy ^b			
Registered nurse	281 (12.0)	0.95 (0.71–1.3)	0.95 (0.71–1.3)
Fellow physician	78 (10.6)	0.83 (0.60–1.2)	0.90 (0.64–1.3)
Attending physician	50 (12.7)	Reference	Reference
Live birth ^c			
Registered nurse	200 (8.5)	0.77 (0.56–1.0)	0.80 (0.58–1.1)
Fellow physician	62 (8.4)	0.76 (0.52–1.1)	0.84 (0.58–1.2)
Attending physician	44 (11.1)	Reference	Reference

CI, confidence interval; RR, risk ratio.

^a Adjusted for woman's age, partner's age, and cycle type;

^b Missing outcome data on 2 attending physician cycles, 11 nurse cycles, and 6 fellow cycles among those cycles known to have positive beta-human chorionic gonadotropin (positive pregnancy test);

^c Missing outcome data on 8 nurse cycles and 1 fellow cycles among those cycles known to have resulted in intrauterine gestation (clinical pregnancy).