

Original Research Article

ROLE AND OUTCOME OF INTRAUTERINE INSEMINATION (IUI) IN INFERTILE COUPLES IN A TERTIARY CARE HOSPITAL

Sangati Bhargavi¹, Pradeep S², Monika Bhaskar K³, Punugunta Keerthy Priya⁴, Kommineni Sri Pooja¹, Charishma Krothapalli¹

¹Post Graduate, Department of Obstetrics and Gynaecology, PES Institute of Medical Sciences and Research, Kuppam, Andhra Pradesh, India

²Professor and Head, Department of Obstetrics and Gynaecology, PES Institute of Medical Sciences and Research, Kuppam, Andhra Pradesh, India

³Assistant Professor, Department of Obstetrics and Gynaecology, PES Institute of Medical Sciences and Research, Kuppam, Andhra Pradesh, India

⁴Senior Resident, Department of Obstetrics and Gynaecology, PES Institute of Medical Sciences and Research, Kuppam, Andhra Pradesh, India

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Corresponding Author:

Dr. Sangati Bhargavi,
Post Graduate, Department of
Obstetrics and Gynaecology, PES
Institute of Medical Sciences and
Research, Kuppam, Andhra Pradesh,
India.
Email: sangatibhargavi68@gmail.com

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ABSTRACT

Background: Infertility affects a substantial proportion of couples worldwide, and intrauterine insemination (IUI) is a widely used, low-cost, minimally invasive first-line assisted reproductive technique, but predictors of its success remain variably reported. The objective is to assess the outcome of IUI in infertile couples and correlate outcome with various clinical and procedural parameters.

Materials and Methods: Prospective observational study of 61 couples undergoing 142 therapeutic homologous IUI cycles at PESIMSR, Kuppam, over 18 months. Clinical pregnancy (β -hCG positivity) was the primary outcome, correlated with age, duration and type of infertility, ovulation induction protocol, endometrial thickness, follicle number/size, and post-wash sperm parameters, including logistic regression analysis.

Results: Clinical pregnancy was achieved in 7.04% of cycles (10/142) and 16.39% of couples (10/61). Pregnancy-positive cycles showed a non-significantly higher mean endometrial thickness (9.73 vs 9.00mm; $p=0.255$) and preovulatory follicle number (2.80 vs 2.49; $p=0.267$), and non-significantly lower female/male age, than pregnancy-negative cycles. Type of IUI (single vs double) was not associated with outcome ($p=1.000$). On logistic regression, the number of preovulatory follicles was independently and positively associated with clinical pregnancy ($\beta=0.402$, $p=0.001$), while the number of IUI cycles was independently and negatively associated with pregnancy ($\beta=-0.353$, $p=0.020$); no other variable reached significance.

Conclusion: IUI remains an effective, affordable first-line option for appropriately selected infertile couples. Ovarian response (preovulatory follicle number) and cumulative treatment cycles are the strongest independent predictors of success, supporting careful patient selection and counselling to optimise the cost-effectiveness of IUI therapy.

Keywords: Intrauterine insemination; infertility; clinical pregnancy rate; preovulatory follicles; assisted reproduction.

INTRODUCTION

The wish for a child is a deeply felt need shaped not only by individual instinct but also by personality, sociocultural processes, economic factors, and

interpersonal dynamics between partners; failure to achieve this is associated with substantial physical and psychological stress. Infertility is a global health concern with important psychological, economic, demographic and medical implications. The World

Health Organization defines infertility as a disease of the reproductive system characterised by failure to achieve a clinical pregnancy after 12 months or more of regular unprotected intercourse,¹ and it can also be defined as failure to conceive after 12 months of regular intercourse in women under 35 years, or after 6 months in women 35 years and older.² Infertility may be primary (a couple who have never conceived) or secondary (failure to conceive following a previous pregnancy).

In couples attempting conception, approximately 50% of women conceive within 3 months, 75% by 6 months, and more than 85% within 1 year; the term 'subfertility' describes couples who are not sterile but exhibit decreased reproductive efficiency.³ One in every four couples in developing countries is affected by infertility, and the WHO estimates that 60–80 million couples worldwide are currently affected, of whom 15–20 million are in India alone.⁴ The WHO estimates the overall prevalence of primary infertility in India to be 3.9–16.8%.⁵ The probability of achieving a live birth without treatment decreases with increasing age and duration of subfertility, falling by about 5% for each additional year of female age and 15–25% for each additional year of subfertility; most spontaneous pregnancies occur within the first 3 years, after which the prognosis without treatment is relatively poor.⁶

Management of infertility is a complex process influenced by the duration of infertility, the couple's age (especially female), the diagnosed cause, and the level of distress experienced. A complete infertility work-up is a prerequisite before a treatment plan can be developed. Among assisted reproductive techniques, intrauterine insemination (IUI) is considered a first-line therapeutic procedure because it is simple, safe, minimally invasive, cost-effective, well-tolerated, and associated with low dropout rates and an absence of serious complications.⁷ IUI involves depositing washed and capacitated sperm into the uterine cavity, and remains one of the most widely used techniques for mild male factor infertility, unexplained infertility, PCOS as an adjunct to ovulation induction, mild endometriosis, and tubo-peritoneal factors in a young patient with at least one functional and patent fallopian tube.⁸

The rationale for IUI is to bypass factors such as vaginal acidity and cervical mucus hostility and to deliver a concentrated bolus of motile, morphologically normal sperm close to the oocyte. Ovulation induction combined with IUI remains a mainstay of infertility therapy, though reported pregnancy rates per cycle vary considerably depending on age, cause and duration of infertility, use of ovarian stimulation, sperm preparation technique, and number of cycles performed. IUI carries minimal side effects, most commonly mild infection, pain, or vasovagal response, with serious complications such as ovarian hyperstimulation syndrome largely confined to cycles using

controlled ovarian stimulation. This study was undertaken to evaluate the success rate of IUI in terms of clinical pregnancy in infertile couples and to establish its role in the management of infertility.

Aims and Objectives:

1. To assess the outcome of intrauterine insemination (IUI).
2. To correlate the outcome of IUI with various parameters associated with infertility.

MATERIALS AND METHODS

Study design and setting: Observational prospective study conducted at PES Institute of Medical Sciences and Research (PESIMSR), Kuppam, Andhra Pradesh, over 18 months.

Study population and sampling: Couples with infertility undergoing therapeutic homologous IUI at a tertiary care centre were enrolled by purposive sampling. Inclusion criteria were couples with unexplained infertility, anovulation, mild oligospermia (10–15 million sperm/mL), minimal or mild endometriosis, or sexual dysfunction. Exclusion criteria were bilateral tubal blockage, moderate-to-severe endometriosis, or severe male factor infertility with post-wash sperm count <1 million/mL.

Outcome measures: Primary outcomes were pregnancy rate per couple and per cycle; secondary outcomes were live birth rate and ongoing pregnancy rate per couple and per cycle.

Procedure: After institutional ethics committee approval and informed consent, data were collected via a pre-designed proforma covering duration of marriage, number of ovulation induction cycles, endometrial thickness, total sperm count and motility, type of infertility, ovulation induction drug used, side of the ovulatory follicle, and cycle outcome.

Statistical analysis: Data were entered in Microsoft Excel and analysed using SPSS version 23.0. Categorical variables were expressed as frequencies and percentages and continuous variables as mean $\pm$ standard deviation, with appropriate descriptive graphs; logistic regression was used to identify independent predictors of clinical pregnancy.

RESULTS

Sixty-one couples underwent a total of 142 IUI cycles; the majority underwent two cycles (28/61), followed by three cycles (16/61), one cycle (10/61), and four cycles (7/61). The mean age of female partners was 29.16 ± 4.17 years and of male partners 34.85 ± 4.98 years, and the mean duration of infertility was 5.99 ± 2.93 years. Primary infertility (39/61, 64%) was more common than secondary infertility (22/61, 36%). Unexplained infertility was the most common indication (24/61), followed by anovulation (17/61), mild male factor infertility (12/61), and minimal/mild endometriosis or sexual

dysfunction (4/61 each). Letrozole was used for ovulation induction in the majority of cycles

(120/142) and gonadotropins in the remainder (22/142).

Table 1: Baseline characteristics of study couples (n=61)

Parameter	Value
Mean female age $\pm$ SD (years)	29.16 $\pm$ 4.17
Mean male age $\pm$ SD (years)	34.85 $\pm$ 4.98
Mean duration of infertility $\pm$ SD (years)	5.99 $\pm$ 2.93
Primary infertility, n (%)	39 (64%)
Secondary infertility, n (%)	22 (36%)
Total IUI cycles performed	142
IUI cycles per couple: 1 / 2 / 3 / 4	10 / 28 / 16 / 7

Clinical pregnancy, confirmed by urine or serum β -hCG positivity, was achieved in 7.04% of cycles and 16.39% of couples.

Table 2: Clinical pregnancy outcome per cycle and per couple

Outcome level	Category	n	%
Per cycle (n=142)	Negative	132	92.96
Per cycle (n=142)	Positive	10	7.04
Per couple (n=61)	Not pregnant	51	83.61
Per couple (n=61)	Pregnant	10	16.39

No statistically significant association was observed between type of IUI (single vs double) and clinical pregnancy outcome (95/102 vs 37/40 negative;

p=1.000). Comparison of clinical and procedural parameters between pregnancy-positive and pregnancy-negative cycles is shown in [Table 3].

Table 3: Comparison of parameters between pregnancy-positive and pregnancy-negative cycles

Parameter	Pregnancy positive (mean $\pm$ SD)	Pregnancy negative (mean $\pm$ SD)	p value
Female age (years)	28.20 $\pm$ 3.58	29.67 $\pm$ 4.08	0.243
Male age (years)	33.30 $\pm$ 2.91	34.76 $\pm$ 4.95	0.174
Duration of infertility (years)	6.05 $\pm$ 3.81	5.79 $\pm$ 2.79	0.837
Endometrial thickness (mm)	9.73 $\pm$ 1.88	9.00 $\pm$ 1.47	0.255
Number of preovulatory follicles	2.80 $\pm$ 0.79	2.49 $\pm$ 0.98	0.267
Size of follicles (mm)	18.91 $\pm$ 1.34	19.35 $\pm$ 1.49	0.341
Sperm count (million/mL)	34.78 $\pm$ 10.33	41.63 $\pm$ 16.08	0.077
Sperm motility (%)	49.00 $\pm$ 11.62	49.92 $\pm$ 14.72	0.817
Number of IUI cycles	1.60 $\pm$ 0.70	1.85 $\pm$ 0.89	0.311

None of the evaluated female characteristics or post-wash sperm parameters showed a statistically significant association with clinical pregnancy outcome on univariate comparison. Logistic

regression analysis was performed to identify independent predictors of clinical pregnancy [Table 4].

Table 4: Logistic regression analysis of factors associated with clinical pregnancy

Variable	β (coefficient)	SE	Wald z	p value
Female age (years)	-0.123	0.098	-1.256	0.209
Male age (years)	-0.065	0.079	-0.821	0.412
Duration of infertility (years)	0.029	0.119	0.245	0.806
Endometrial thickness (mm)	0.368	0.237	1.551	0.121
Number of preovulatory follicles	0.402	0.355	1.134	0.001
Size of follicles (mm)	-0.192	0.240	-0.798	0.425
Sperm motility (%)	-0.015	0.024	-0.613	0.540
Sperm concentration (million/mL)	-0.033	0.024	-1.401	0.161
Number of IUI cycles	-0.353	0.482	-0.734	0.020

On logistic regression, only the number of preovulatory follicles (β =0.402, p=0.001) and the number of IUI cycles (β =-0.353, p=0.020) showed statistically significant independent associations with clinical pregnancy outcome — the former positive and the latter negative — while female age, male age, duration of infertility, endometrial thickness, follicle size, sperm motility, and sperm concentration did not reach significance.

DISCUSSION

The mean age of female partners in this study was 29.16 $\pm$ 4.17 years and of male partners 34.85 $\pm$ 4.98 years. Sharma and Dabhadkar, in a study of 167 participants, reported a comparable mean age of 30.58 $\pm$ 4.43 years,^[9] consistent with the present findings. Koli et al. reported lower mean ages among pregnancy-positive participants (26.4 $\pm$ 5.35

years for women, 33.6 ± 4.9 years for men), with no statistical significance,^[10] while Surur reported higher mean ages of 32.04 ± 4.61 years for women and 37.36 ± 6.71 years for male partners.^[11] The present study similarly showed a decline in pregnancy incidence with increasing age, consistent with prior evidence that age significantly affects pregnancy rates with assisted reproductive technologies such as IUI, reflecting the association between advancing age, declining ovarian reserve, and reduced oocyte quality.^[12]

The majority of couples in this study underwent more than one IUI cycle, most commonly two. Koli et al. reported a lower mean number of cycles in pregnancy-positive cases (2.00 ± 1.05) than in negative cases (3.8 ± 1.92),^[10] while Surur reported that most couples (87.63%) completed only a single cycle.^[11] The mean duration of infertility in the present study (5.99 ± 2.93 years) was comparable to that reported by Surur (5.23 ± 3.24 years),^[11] while Koli et al. reported a somewhat longer duration in both pregnancy-positive (6.7 ± 2.79 years) and pregnancy-negative (7.5 ± 4.15 years) groups.¹⁰ Primary infertility was more common than secondary infertility in the present cohort, consistent with both Koli et al.,^[10] and Surur,^[11] and unexplained infertility was the leading indication for IUI, again in agreement with these studies. Letrozole was the predominant ovulation induction agent used, in contrast to Koli et al., who reported clomiphene citrate as the most common agent.^[10] The majority of cycles in the present study were single IUI, consistent with both comparator studies,^[10,11] and no significant difference in outcome was observed between single and double IUI ($p=1.000$).

The mean endometrial thickness at the time of IUI in this study was 9.05 ± 1.50 mm, comparable to the findings of Surur (≥ 9 mm)¹¹ but higher than the values reported by Koli et al. in both pregnancy-positive (8.5 ± 1.43 mm) and pregnancy-negative (8.7 ± 2.83 mm) cycles.¹⁰ Most cycles demonstrated two to three preovulatory follicles, consistent with Surur's findings,^[11] while Koli et al. reported a higher mean follicle number in pregnancy-positive cycles (3.4 ± 2.67) than in negative cycles (2.0 ± 1.16).¹⁰ The mean largest follicle size (19.32 ± 1.48 mm) and post-wash sperm parameters (concentration 41.15 ± 15.82 million/mL; motility $49.86 \pm 14.49\%$) in this study were broadly comparable to those reported by Koli et al. and Surur.^[10,11]

In the present study, clinical pregnancy was confirmed in 7.04% of cycles and 16.39% of couples. Koli et al., analysing 264 cycles, reported a lower per-cycle pregnancy rate of 3.8% but a comparable per-couple rate of 17.25%,¹⁰ while Surur reported a per-cycle rate of 9.0% and a per-couple rate of 10.31%.^[11] Reported fecundity rates with IUI in the literature range from 7% to 29%, and Houmard et al. linked higher maternal age and fewer ovulatory disorders to lower clinical pregnancy

rates.^[13] A UK national retrospective audit of 30,669 IUI cycles (2012–2016) reported pregnancy success ranging from 11.6% to 12.1%,^[14] Demir et al. reported clinical pregnancy rates of 15.8% per cycle and 18.8% per couple,^[15] and Wadhwa et al., auditing 800 IUI cycles at a tertiary centre, reported a per-cycle rate of 14.1% and a per-couple rate of 17.3%.^[16] These variations across studies likely reflect differences in underlying causes of infertility, treatment protocols, and the younger age at which women in this population sought treatment.

Pregnancy-positive cycles in this study demonstrated a non-significantly higher mean endometrial thickness and preovulatory follicle number, and non-significantly lower female and male age, than pregnancy-negative cycles; none of the evaluated female characteristics or post-wash sperm parameters reached statistical significance. Sharma and Dabhadkar similarly reported no significant difference in clinical pregnancy rates by infertility type, though found a significant association between endometrial thickness and pregnancy rate ($p=0.001$) and higher pregnancy rates in women aged 30–45 years (21.3%) than in those under 30 (18.2%).^[9] In contrast, Koli et al. found that duration of infertility, type of infertility, endometrial thickness, follicle size and number, sperm count, sperm motility, and single versus double IUI did not significantly affect outcome.^[10] On logistic regression, the number of preovulatory follicles was independently and positively associated with clinical pregnancy ($\beta=0.402$, $p=0.001$), while the number of IUI cycles was independently and negatively associated with pregnancy ($\beta=-0.353$, $p=0.020$); no other variable reached significance. This is consistent with Koli et al., who similarly found a significant correlation between follicle number, cycle number, and pregnancy occurrence on regression analysis.^[10]

Limitations:

The main limitations of this study were its prospective observational design and a sample size that may not have been sufficiently large to detect differences in some of the analysed parameters. Larger randomised controlled trials with bigger sample sizes are needed to further clarify the factors associated with the success rate of IUI.

CONCLUSION

In this study, the pregnancy rate per couple was 16.39% and the overall pregnancy rate per cycle was 7.04%. Owing to its affordability and effectiveness when accompanied by appropriate patient selection, IUI remains a first-line option among the available treatments for infertile couples. The number of preovulatory follicles and the number of treatment cycles were identified as significant independent predictors of IUI outcome; pregnancy-positive cycles showed a higher mean endometrial thickness and follicle number, and somewhat lower female

and male age, than pregnancy-negative cycles. Effective ovarian stimulation combined with careful patient selection may improve therapeutic outcomes, supporting more informed counselling of infertile couples and improved cost-effectiveness of IUI therapy.

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