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Original Research Article

Analysis of successful outcome in patients undergoing homologous intrauterine insemination

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ABSTRACT

Background: Intrauterine insemination (IUI) is a cost-effective, non-invasive and its success depends on the various factors. The factors associated with the success of IUI and its literature is least available in the Indian context. Objectives were to analyze the outcome of patients undergoing homologous IUI in terms of pregnancy rates (clinical pregnancy) and its predictors for the outcomes.

Methods: This is a prospective observational study among 200 couples with infertility undergoing therapeutic homologous IUI in a tertiary care centre. Among the study participants, undergoing IUI, after obtaining the informed written consent, the data related to the outcomes and associated factors were collected through a pre structured Questionnaire.

Results: Among the study participants who undergone the procedure, 40 (20%) become positive for pregnancy. Of the 40 positive, 30 (15%) delivered normal babies and 7 (14%) went for spontaneous abortions and 1 (0.5%) went for D and C. Type of infertility, drug for induction of ovulation, age in years, years of marriage, day of ovulation, no. of ovulation induction and were not statistically significant with the outcomes. Endometrial thickness, greatest dimension of follicular size, increased total sperm count, percentage of motility, post wash count and post wash motility were significantly associated with the positive outcomes.

Conclusions: Since the success rate of the IUI is comparable to the other studies reported, and the procedure is relatively cheaper, the same can be recommended as the simple and cost effective first line management of certain specific indications of the infertility.

Keywords: IUI, Infertility, Successful outcome in IUI

INTRODUCTION

Intrauterine insemination (IUI) is a procedure of artificial insemination for treating infertility, wherein sperms are washed and concentrated and placed in the uterus during the time of released of eggs from ovary. The conception happens overcoming natural barriers to sperm ascent in the female reproductive tract.¹ IUI is the most cost-effective first line treatment and procedure of choice for moderate subfertility due to male factors.² Intrauterine insemination (IUI) is a cost-effective, non-invasive first-line therapy for particular patients with functionally normal fallopian

tubes, and infertility owing to a cervical factor, anovulation, moderate male factors, unexplained factors, immunological factors, and ejaculatory disorders with clinical pregnancy rates per cycle ranging from 10 to 20%.³

The concept of IUI was initially proposed by Cohen in 1962. Since then, IUI has progressed through the innovations such as preparation of sperm, monitoring of timing of pre-ovulation and induction of ovulation through drugs and with human chorionic gonadotrophin (hCG).^{4,5}

There are a number of variables which influence the success of IUI such as patient characteristics, type of ovarian stimulation and number of inseminations per cycle.² Studies have reported a pregnancy rate varying between 4% to 40%. The reasons in the differences were due to various factors such as differences in characteristics of the study subjects, difference in ovarian stimulation protocols and insemination techniques.⁶⁻¹²

The factors associated with the success of IUI and its literature is least available in the Indian Context especially in Tamil Nadu. To analyze the outcome of patients undergoing homologous IUI in terms of pregnancy rates (clinical pregnancy) and its predictors for the outcomes.

Aim

Aim of the study was to analyse the outcome of patients undergoing homologous IUI in terms of pregnancy rates (clinical pregnancy) and its predictors for the outcomes.

Objectives

Primary objective

Primary objectives were to analyses the outcome of patients undergoing homologous IUI in terms of pregnancy rates (clinical pregnancy).

Secondary objective

Secondary objectives were to identify the predicators of pregnancy rates among women undergoing homologous IUI (in terms of preovulatory follicles (>17 mm), motile spermatozoa count, type and duration of infertility, female age, insemination timing and cycle number).

METHODS

Study subjects

Study population consists of couples with infertility undergoing therapeutic homologous IUI in a tertiary care centre.

Study design

Prospective observational study design used as a study design for this study.

Study setting

Institute of obstetrics and gynaecology/iso government Kasturba Gandhi hospital for women and children, madras medical college, Chennai.

Sampling procedure

Convenient sampling used for the study.

Inclusion criteria

Couples with anovulation, mild oligospermia (10-15 million sperms /ml), unexplained infertility, minimal and mild endometriosis, sexual dysfunction

Exclusion criteria

Bilateral tubal blockage, moderate to severe endometriosis, severe male factor infertility with post wash sperm counts of <1 million /ml.

Study period

The study conducted for 2 years (October 2018 to September 2020).

Sample size

According to Jayakrishnan et al study, considering the prevalence of the overall pregnancy rate as 15.2% with a precision of 5% and 95% confidence interval, the sample size is calculated by:¹³

$$N=Z^21 - \alpha/2 \times p \times (1-p)/d^2$$

 $Z^{2}1-\alpha/2$ -Two tailed probability for 95% confidence interval=1.96, p (%)-prevalence of the overall pregnancy rate=0.152, d (%)-precision or allowable error for the overall pregnancy rate=0.05,

N=1.96²×0.152×(1-0.152)/0.05²=198.06

Thus, the total sample size required for the study is 198.

The sample size was rounded off to a total of 200.

Study procedure

Among the study participants, undergoing IUI, after obtaining the informed written consent, the following details collected through pre-structured questionnaire. The data collected were years of married life, no. of ovulation induction, endometrial thickness, total sperm count (millions/cu.mm) and percentage of motile sperms, post wash count (millions/cu.mm) and percentage of motility. Type of infertility, drugs used for induction of ovulation, side of the ovulatory follicle and outcome of the procedure.

Ethical consideration

Institutional ethical committee approval was obtained before the start of the study. Informed written consent was obtained from each participant.

Statistical methods

Descriptive statistics and inferential statistics are used. For test of significance, chi-square test is used. Fisher's exact test is used when more than 20% of the cell values have expected cell value less than 5. P values less than 0.05 were considered statistically significant. Data was entered in MS excel sheet and analyzed using SPSS software version 16.

RESULTS

Age distribution among the study population

Majority of the study population, 106 (53.0%) were belonging to the 26-30 age category, followed by the 20-25 age category (44, 22.0%). The categories of the age are represented in the following Figure.

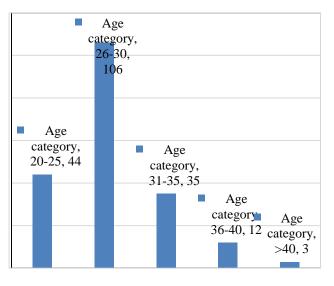


Figure 1: Age category.

Years of marriage among the study population

The following histogram represents the years of married life among the study participants.

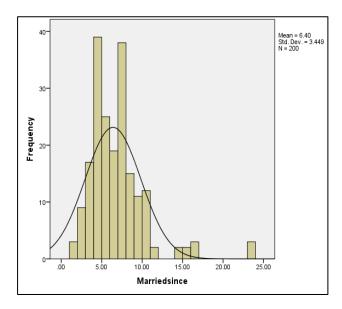


Figure 2: Years of married life.

Type of infertility

Among the study participants, 180 (90%) were suffering from primary infertility and remaining 20 (10.0%) were suffering from secondary infertility. The type of infertility is represented in the following Figure.

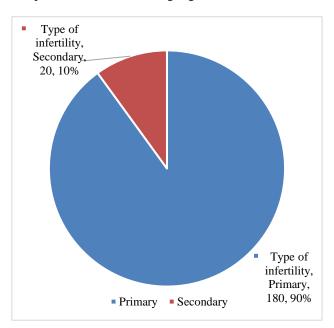


Figure 3: Type of infertility.

Drugs used for induction of ovulation

For induction of ovulation, majority of the study population (108, 54%) were on tablet letrozole with dose of 2.5 mg and 5 mg among 30 (15.0%) and 98 (49.0%) respectively. The remaining 72 (36%) were on clomiphene citrate with a dose of 50 mg and 100 mg among 30 (15.0%) and 42 (21.0%) respectively. The drugs used for induction of ovulation is represented in the following Figure.

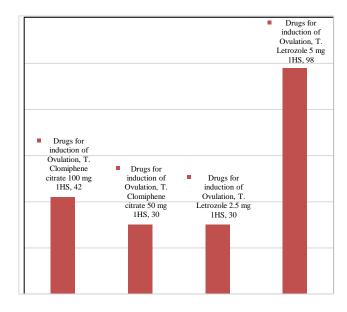


Figure 4: Drugs used for induction of ovulation.

Day of ovulation induction

The median and mode of day of ovulation induction is 14. The minimum and maximum values of day of ovulation induction are 10 and 20 respectively.

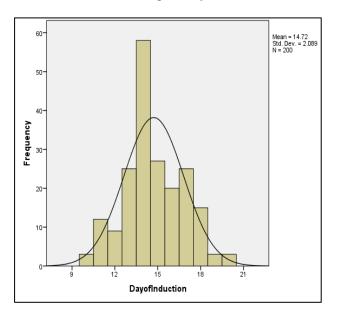


Figure 5: Day of ovulation induction.

Greatest dimension of follicular diameter

The minimum and maximum values of greatest dimension in mm are 18 and 32 respectively.

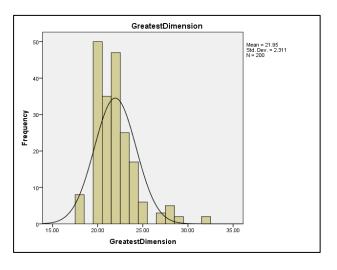


Figure 6: Greatest dimension in mm.

Outcome of the procedure

Among the study participants who undergone the procedure, 40 (20.0%) become positive for pregnancy. Of the 40 positive, 30 (15%) delivered normal babies and 7 (14%) went for spontaneous abortions and 1 (0.5%) went for D and C. The outcome of the procedure is represented in the following Figure.

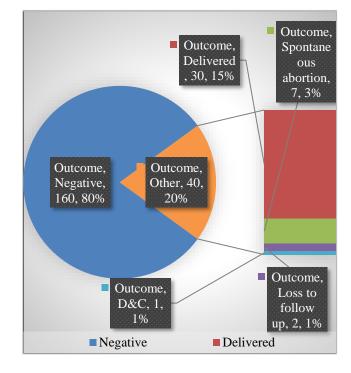


Figure 7: Outcome.

Association of numerical variables with the outcomes

When outcomes of the procedure were associated with the numerical variables of the study, age in years, day of induction, years of marriage and no. of ovulation induction were not statistically significant with the outcomes. Greatest dimension in mm, endometrial thickness, increased total sperm count, percentage of motility, post wash count and post wash motility were significantly associated with the positive outcomes. The mean, SD and p value (t test) of the numerical variables among the outcomes are represented in the following Figures.

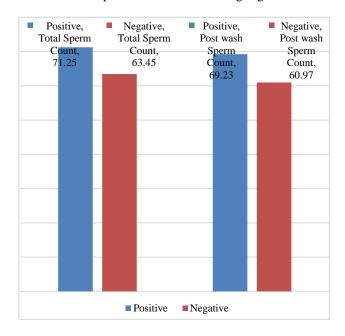


Figure 8: Total sperm count vs outcome.

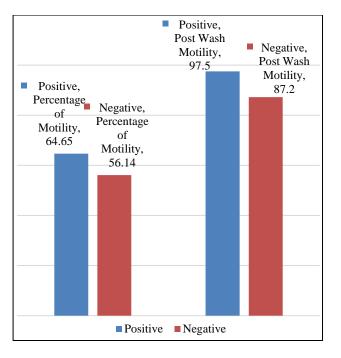


Figure 9: Percentage of motility vs outcome.

DISCUSSION

The main objective of the study is to analyze the outcome of patients undergoing homologous IUI in terms of pregnancy rates (clinical pregnancy) and its predictors for the outcomes. Fertility reduces with increasing maternal age, as early as 32, and especially a marked reduction after the mid-30's (37-39) In this study, the study population has lower age compared to other studies, the reasons behind this pattern may be due to early age of marriage and early initiation of treatment for infertility among the study population. Jayakrishnan et al in their study observed age of female has a minimum of 20 maximum of 47, mean of 29.7 and standard deviation of 4.9.¹³

The median and mode of age of the study participants are 28 and 24 respectively. The minimum and maximum values of age among the study participants are 23 and 42 respectively. Majority of the study population, 106 (53%) were belonging to the 26-30 age category, followed by the 20-25 age category (44, 22.0%).

Various studies have showed a positive relationship between the quality of married life and sexual satisfaction with infertility.^{14,15} In this study, we studied the total years of married life and not the quality of married life. The median and mode of years of marriage 6 and 7 respectively. The minimum and maximum of years of marriage 1.5 and 23 respectively.

Ahmed et al did a retrospective study to study the factors influencing the success rates of IUI. They observed a success rate of IUI as 21.58%. They observed that age and duration of infertility were significant predicting factors of successful pregnancy outcomes.¹⁶

Cantineau et al studied the ovarian stimulation usefulness with (anti-oestrogens, gonadotrophins with and without GnRH agonists/antagonists) for IUI among women with subfertility. They concluded that the vigorous indication is lacking but based on the existing results gonadotrophins might be the most effective drugs when IUI is combined with ovarian hyper stimulation.¹⁷

Ovulation induction increases IUI success rates especially in women with increased age. Panda et al from Bhubaneswar observed from 300 infertile couples, a clinical pregnancy rate of first cycle IUI attempts was 17.3%.¹⁸

In this study, the minimum and maximum values of number of ovulation induction are 1 and 12 respectively. Among the study population, majority have the ovulatory follicle in the right side (123, 61.5%).

In this study, among the study participants who undergone the procedure, 40 (20.0%) become positive for pregnancy. Of the 40 positive, 30 (15%) delivered normal babies and 7 (14%) went for spontaneous abortions and 1 (0.5%) went for D and C. Among the participants with primary infertility, 20.6% become positive and among the participants with Secondary infertility, 15% become positive. The increased proportion of positive outcome among the participants with primary infertility is not statistically significant.

Jayakrishnan et al in their study observed that the overall pregnancy rate per cycle with COH/ IUI in their study was 15.2%.¹³

CONCLUSION

Among the study participants who undergone the procedure, 40 (20.0%) become positive for pregnancy. Of the 40 positive, 30 (15%) delivered normal babies and 7 (14%) went for spontaneous abortions and 1 (0.5%) went for D and C.

The increased proportion observed with the positive outcome among the participants with primary infertility is not statistically significant. Among the study population, who received clomiphene citrate and letrozole for drug for induction of ovulation nearly one fifth of them become positive outcome and is not statistically significant.

When outcomes of the procedure were associated with the numerical variables of the study, age in years, day of induction, years of marriage and no. of ovulation induction were not statistically significant with the outcomes. Greatest dimension in mm, endometrial thickness, increased total sperm count, percentage of motility, post wash count and post wash motility were significantly associated with the positive outcomes.

Since the success rate of the IUI is comparable to the other studies reported, and the procedure is relatively cheaper,

the same can be recommended as the simple and cost effective first line management of certain specific indications of the infertility.

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