***Original Research Article***

**Outcome of Assisted Reproductive Technologies at A Fertility Center In Selected Hospital Of Itanagar, India**

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ABSTRACT

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| **Aim:** This study aims to evaluate the outcomes of Assisted reproductive technologies (ART) services in infertile women aged 30 years and above.**Study design:** Cross-sectional, quantitative study design.**Place and Duration of Study:** Fertility centers of two hospitals in Itanagar, Arunachal, India, between December 2018 to May 2019.**Methodology:** The outcomes of ART among 384 infertile women aged 30 years and above were evaluated. The semi-structured questionnaire was used for face-to-face interview with the participants selected by random sampling technique. The descriptive statistics were used to represent the socio-demographic characteristics and ART outcomes of the study, and the chi-square test was used to identify the factors associated with successful and unsuccessful ART outcomes. **Results:** Among the successful ART group the prevalence of primary and secondary infertility was 45.24% and 54.76% respectively; in the unsuccessful ART group the ratio was 61.5% primary and 38.50% and secondary infertility respectively. 54.68% of women had successful ART outcomes. The unsuccessful ART group was slightly older, had a slightly higher body mass index and included current smokers. Female factors were the primary cause of infertility in both groups of which endometriosis was most common followed by the tubal factory, polycystic ovarian syndrome, anovulation, uterine factor, and others. Majority of the successful ART outcome groups i.e. 96.19% had singleton outcomes, 2.38% had twins and 1.43% had triplets. 7.14% were preterm births and 11.90% had cases of low birth weight. Maternal complications among the successful ART groups were preeclampsia, gestational diabetes mellitus, hemorrhage, and hospitalization. Successful ART treatment group women were more satisfied in their life but no significant differences were found between the satisfied groups in both assisted reproductive technology treatment groups (p>0.05). **Conclusion:** ART services were beneficial to infertile women although it raised concerns about prevalence of primary infertility among women in unsuccessful ART group. Also within successful ART outcomes, complications related to pregnancy and birth outcomes was observed. |

*Keywords: In Vitro Fertilization; Fertility treatment outcomes; Infertility Management; India*

1. INTRODUCTION

Infertility refers to the lack of ability of women to conceive after one full year of regular, or normal sexual intercourse without the use of contraception. Infertility is a huge public health issue in both developed as well as developing countries. Worldwide, nearly 15% of couples of reproductive age are affected by infertility (1). Infertility is more prevalent in developing countries as compared to developed one (2).

Fertility is the vital function of adult development which can result in various problems if unmet. Infertility can be considered a social problem that affects the individual, family, and society. There are personal and familial associated problems caused by infertility. Both men and women have to deal with physical, psychological, sociocultural, emotional, ethical, and financial problems due to infertility (3). The couples or individuals are often seeded to be stressed, anxious, scared, and depressed due to infertility. The plans, self-image, self-respect, marriage life, and even the sexual life of the couples are negatively impacted (4).

Infertility has been associated with the social problem because most societies do not treat infertile women properly which leads to broken families and relationships. Further, the pre-existing issues of gender bias and discrimination also consider women as the major cause of infertility. But as per science and researches, infertility can arise either due to male or female factors of which males are likely to be 30-40% while 50% are due to female factors (5). Usually, male factor includes poor semen quality, low sperm motility, anatomical defects such as blockage in vas deferens, infections that leads to inflammation, genetic abnormalities and others (6). Regarding females, irregular ovulation, blockage in fallopian tubes, polycystic ovaries, primary and secondary amenorrhea, and others are factors associated with infertility (7).

The introduction of assisted reproductive technology (ART) has been a boon for the women and their partners experiencing the stigma attached to infertility. The huge burden of infertility can be alleviated through ART. The advancement in technology has provided assistance to address the issues of infertility. ART helps in the treatment of infertility. The process of the treatment includes surgical removal of eggs from a woman’s ovaries which are then mixed with sperm to make the embryos and placed back into the woman’s body (8). During the ART procedure donor eggs, donor sperm, or previously frozen embryos can also be used. Besides, ART may also involve a surrogate or gestational carrier. The assisted reproductive technology includes in vitro fertilization-embryo transfer (IVF-ET), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), and frozen embryo transfer (FET). These techniques are also applicable to oocyte donation and gestational. Among these techniques, IVF-ET is commonly used and it has helped many couples to conceive successfully (9).

The IVF-ET is the stepwise process where there is controlled ovarian hyper-stimulation with pituitary gonadotrophins which makes sure that there are multiple follicular developments because more than one oocyte enhances the chances of achieving a pregnancy (8, 9). After the retrieval of oocytes under sedation with subsequent fertilization by sperm in the laboratory, there is the development of embryos in culture before transfer into the uterus (8). The (GIFT) process uses the multiple eggs collected from the ovaries which are placed into the thin flexible tube (catheter) along with the sperm to be used. Both eggs and sperm are then injected into the fallopian tubes through laparoscopy. Similarly, ZIFT is the combination of both IVF and GIFT in which eggs are stimulated and collected by using IVF methods. The eggs are then mixed with sperm in the lab. Then fertilized eggs are laparoscopically returned to the fallopian tubes where they will be carried into the uterus. FET is also the type of IVF treatment where a cryopreserved embryo created in a full IVF cycle is thawed and transferred to the uterus (10).

The use of ART has been increasing slowly during the past two decades. There has been an increase intheuse of ART services by 13% to 16%. Even women aged 40 years and older have hope of giving birth to the baby using ART services. About 19% of the women who use ART services are aged 40 years and older (11).

The ART outcome can be negatively impacted due to aging because the advancing age of females can decrease the chance of live birth rates. Further, ART is expensive, time-consuming, and stressful due to which the couple needs to make decisions before starting the ART treatment (12). The objectives of this study is to determine the success rate of ART, factors influencing its success and complications associated with it. We also aim to identify and evaluate maternal and birth outcomes among successful ART participants and to compare life satisfactions between women with successful and unsuccessful ART outcomes.

2. methodology

A cross-sectional study design was used to evaluate the outcomes of assisted reproductive technology (ART) in infertile women. A quantitative study was used in this study. The study was conducted in two fertility centers of Itanagar, Arunachal Pradesh, India. These fertility centers were selected purposively and simple random sampling was used to select the study population. Women above 30 years of age were our inclusion criteria and sample size of 384 was calculated using 5% precision and 95% confidence interval.

The satisfaction with Life Scale (SWLS) was used as a measure to evaluate participants’ life satisfaction. Life satisfaction in our study was categorized through four items which ranged from 4 to 20 (ANNEX 1). The total score was divided into three categories. Scores 4 to 6 indicated satisfaction, 12 to 20 indicated dissatisfaction, and the intermediate group with scores 7 to 11 were considered as participants within one standard deviation from the mean (13-14). Women with live birth after ART was considered as a successful outcome and those with no live births after ART were considered as the unsuccessful outcome. Face-to-face interview was conducted after obtaining written consent from each participants. The 10% of the total sample size was taken as the sample for pre-testing conducted in similar group of participants.

Data analysis was carried out using IBM SPSS version 20. This study used the chi-square test to identify the factors associated with successful and unsuccessful ART outcomes. A p-value less than 0.05 was considered statistically significant.

3. results and discussion

Among 384 participants 54.68% had successful ART outcomes while remaining 45.32% had unsuccessful ART outcomes. The socioeconomic data of participants is given in Table 1. Among them, significant association was found between ART outcomes and age (*P*=0.04), body mass index (*P*=0.003) and type of family (*P*=0.02).

**Table 1. Socio-demographic characteristics**

|  |  |  |  |
| --- | --- | --- | --- |
| **Characteristics** | **Successful ART** **n=210** | **Unsuccessful ART****n=174** | **P-value** |
|  | **n (%)** | **n (%)** |  |
| **Mean age (years SD)** | 32 ± 2.3 | 34±2.8 | 0.040 |
| **BMI (kg/m2)** | 23.8±3.0 | 27.6±3.9 | 0.003 |
| **Smoking**  | 10 (4.76%) | 15 (7.14%) | 0.123 |
| **Occupation during ART** |  |  |  |
| Employed | 98 (46.67%) | 56 (32.18%) | 0.269 |
| Unemployed | 107 (50.95%) | 108 (62.06%) |
| Student or other | 15 (7.14%) | 10 (5.74%) |
| **Education level** |  |  |  |
| Primary | 87 (41.42%) | 62 (35.63%) | 0.183 |
| Secondary | 57 (27.14%) | 43 (24.71%) |
| Higher secondary | 36 (17.14%) | 45 (25.86%) |
| Bachelors | 20 (9.5%) | 17 (9.77%) |
| Masters and above | 10 (4.76%) | 7 (4.02%) |
| **Type of family** |  |  |  |
| Nuclear | 145 (69.04%) | 127 (72.98%)  | 0.020 |
| Joint | 56 (26.6%) | 42 (24.13%) |  |
| Extended | 9 (4.28%) | 5 (2.87%) |  |
| **Monthly family income** |  |  |  |
| <24999 | 25 (11.9%) | 17 (9.77%) | 0.175 |
| 25000-34999 | 76 (36.19%) | 58 (33.33%) |  |
| 35000-44999 | 84 (40%) | 50 (28.73%) |  |
| >45000 | 25 (11.9%) | 49 (28.16%) |  |

More than half 115 (54.76%) of the women with successful ART had pregnancies before ART while only 67(38.50%) of the women with unsuccessful ART had pregnancies before ART. Different characteristics of ART outcomes are presented in the Table 2.

**Table 2. Characteristics by ART outcome**

|  |  |  |
| --- | --- | --- |
| **Characteristics** | **Successful ART (n=210)** | **Unsuccessful ART (n=174)** |
|  | **n** | **%** | **N** | **%** |
| **Pregnancies before ART** | 115 | 54.76 | 67 | 38.50 |
| **Biological child before ART** | 100 | 47.61 | 35 | 20.11 |
| **Indication of ART`** |
| **Female factor** | 163 | 77.61 | 89 | 51.14 |
| Endometriosis | 68 | 32.38 | 56 | 32.18 |
| Tubal factor | 48 | 22.85 | 34 | 19.54 |
| Uterine factor | 3 | 1.428 | 4 | 2.29 |
| Anovulation | 34 | 16.19 | 21 | 12.06 |
| PCOS | 42 | 20 | 41 | 23.56 |
| Others | 15 | 7.14 | 18 | 10.34 |
| **Male factor** | 56 | 26.6 | 34 | 19.54 |
| Combined factor | 34 | 16.19 | 15 | 8.62 |
| Unexplained | 22 | 10.47 | 11 | 6.32 |
| **Duration of infertility (year ± SD)** | 2.3±2.1 |  | 3.0±2.3 |  |
| **Miscarriage or ectopic pregnancy** | 32 | 15.23 | 48 | 27.58 |
| **Types of ART**  |
| **IVF** | 158 | 75.23 | 109 | 62.64 |
| **ICSI** | 52 | 24.76 | 64 | 36.78 |

*PCOS=Polycystic ovarian Syndrome; IVF=In-vitro fertilization; ICSI=Intracytoplasmic sperm injection*

Among 210 successful ART cases 96.19% had singleton, 2.38% had twins and 1.43% had triplets. Also, there were 7.14% preterm birth and 11.9% cases of low birth weight was reported. The majority of the deliveries were carried out through cesarean section 203 (96.67%). Among pregnancy complication experienced by successful ART groups, 11.90% had pre-eclampsia which was followed by gestational diabetes mellitus (10%), post-partum hemorrhage (8.57%), and hospitalization in 5.71% cases as presented in Table 3.

**Table 3: Maternal outcome among successful ART (n=210)**

|  |  |  |
| --- | --- | --- |
| **Maternal outcome**  | **n** | **%** |
| **Multiple pregnancies** |  |  |
| Yes | 8 | 3.81 |
| No | 202 | 96.19 |
| **Mode of delivery** |  |  |
| Caesarean section | 203 | 96.67 |
| Normal | 7 | 3.33 |
| **Complications during pregnancy or childbirth** |  |  |
| Post-partum hemorrhage | 18 | 8.57 |
| Gestational Diabetes Mellitus | 21 | 10.00 |
| Pre-eclampsia | 25 | 11.90 |
| Hospitalization | 12 | 5.71 |

Women with successful ART were significantly more satisfied with their lives than the women with unsuccessful ART (mean Life Satisfaction 5.9 vs. 7.2, *P* = 0.002). Life satisfaction outcomes results are presented in Table 4. In the successful ART group, 73.81% of the women were satisfied in their life due to ART outcome whereas, despite the unsuccessful ART outcome, 51.15% of the women in unsuccessful ART groups were satisfied with their life. But there were no significant differences found between the satisfied groups and intermediately satisfied groups in both ART groups (*P*>0.05). But there was significant difference between dissatisfied participants of successful and unsuccessful ART groups (*P*=0.006).

**Table 4. Life satisfaction by ART outcome**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Successful ART (n=210)** | **Unsuccessful ART (n=174)** | **P-value** |
|
| **Life satisfaction score (4 to 20)** | **n** | **%** | **N** | **%** |  |
| Mean LS ± SD | 5.9±2.5 |   | 7.2±3.1 |   | 0.002 |
| Satisfied (4 to 6) | 155 | 73.81 | 89 | 51.15 | 0.124 |
| Intermediate (7 to 11) | 35 | 16.67 | 54 | 31.03 | 0.154 |
| Dissatisfied (12 to 20) | 20 | 9.52 | 32 | 18.39 | 0.006 |

In the current study, the prevalence of primary infertility and secondary infertility among the successful ART group was 45.24% and 54.76%respectively. Among the unsuccessful ART group, primary infertility was higher (61.5%) than secondary infertility (38.50%). A similar finding was shown, in the study by Masoumi et.al. in 015 where primary infertility was 69.5% while secondary infertility was 30.5%. Similarly, the majority of the women 54.68% had a successful ART outcome. The unsuccessful ART group was slightly older and had a slightly higher body mass index and current smoker which was similar to the study conducted by Kuivasaari-Pirinen et.al.in 2014 (15-16).

The women in unsuccessful ART groups were older as compared to successful ART groups which might have led to the unsuccessful outcomes. The study by Pierce & Mocanu (2018) also showed that an increase in the age of the female impacts the rates of embryo transfer, pregnancy, and decline in chances of live births (17). The study also demonstrated complications on maternal and birth outcomes among the successful ART groups. The study by Nagata et al (2019) also depicted that women who conceived by ART had a higher risk of maternal/perinatal complications advanced by obstetric care (18).

In this study, the majority (96.19%) had singleton outcomes, followed by 2.38% twins and 1.43% triplets. Similar results were shown in the study by Noreh et al (2009) where the majority had a singleton outcome (73%) followed by 23% twins and 4% triplets (19). There were 7.14% preterm births and 11.90% cases of low birth weight. But a similar study by Silva et.al. (2019) showed that ART pregnancies had a higher rate of multiple pregnancies and neonates had a lower birth rate and the prevalence of preterm birth was also two times higher among the ART groups (20). The difference might have existed since the later study was conducted by comparing the ART groups and spontaneous groups while the result in our study was not compared with spontaneous groups. However, similar findings were observed in the study by Wenneberg et.al. in 2016 (21).

Considering the maternal complications among the successful ART groups, our study showed that there were the complications of preeclampsia, GDM, hemorrhage, and hospitalization. Similar findings were observed in the study by Zhu et al (2016) Huang et al (2011) and where the ART groups had more chances of developing complications during their pregnancy with higher odds of developing gestational diabetes mellitus, and preeclampsia (21-22).

In this study, successful ART group women were satisfied in their life but there were no significant differences found between the satisfied groups in both ART groups. Similarly, the majority of the women from unsuccessful ART groups were dissatisfied with their life. Similar findings were revealed by Pirinen et al (2014), where women with successful ART had more satisfactory lives as compared to women who were unable to conceive (16).

4. Conclusion

In the population seeking ART services in the private sector, the incidence of primary infertility is higher than secondary infertility. Increasing the age of conception influences the causes of unexplained infertility and the female factor was commonly observed like the age of women increased while delaying the pregnancy. Among the female causes, endometriosis was the most common which was followed by the tubal factor, PCOS, anovulation, and other causes. However, ART services being a blessing to the infertile couples was successful to the majority in this study. Among those with unsuccessful ART outcomes were older, current smokers, and overweight which might have influenced the outcomes. Despite the successful ART outcomes, there are certain complications related to pregnancy, and birth outcomes that were experienced by the women in successful ART groups in our study. Even though there were a fewer proportion of twins and triplets, there was a high incidence of preterm birth and low birth weight. Similarly, mothers also had complications such as gestational diabetes mellitus, preeclampsia, hemorrhage, and hospitalizations. In addition, life satisfaction was also compared among the successful ART and unsuccessful ART groups in our study. The results depicted that majority of the unsuccessful ART groups were dissatisfied in their life which is obvious as their hope and expectations were not met by the treatment. The problem of infertility has been universal and requires a deeper understanding of the causes to solve this issue in the country such as India.

Consent

All authors declare that written informed consent was obtained from the patient for publication of this research. A copy of the written consent is available for review by editors of this journal.

Ethical approval

All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

Disclaimer (Artificial intelligence)

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1.

2.

3.

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**Annex I: Questionnaire**

Participant ID No.:

Name of the fertility center:

**Part I: Socio-demographic characteristics**

1. What is your completed age? …………..
2. What is your occupational status?
3. Employed
4. Unemployed
5. Student or other

3. What is your completed education level?

1. Primary
2. Secondary
3. Higher secondary
4. Bachelors
5. Masters and above

4. Which type of family do you belong to?

1. Nuclear
2. Joint
3. Extended

5. What is your monthly family income (Indian currency)?

1. <24999
2. 25000-34999
3. 35000-44999
4. >45000

**Part II: ART outcome**

6. Type of ART services taken:

1. IVF
2. ICSI
3. Others

7. Pregnancies before ART

1. Yes
2. No

8. Biological child before ART

1. Yes
2. No

9. Indication of ART

1. Female factor
2. Male factor (Go to Q.11)

10. Which of the female factor indicated the use of ART?

1. Endometriosis
2. Tubal factor
3. Uterine factor
4. Anovulation
5. PCOS
6. Others

11. Which of the malefactor indicated the use of ART?

1. Combined factor
2. Unexplained

12. How long was your duration of infertility?

1. One year
2. Two years
3. Three years and more

13. Did you have a miscarriage or ectopic pregnancy during ART?

1. Yes
2. No

**Part III: Maternal and birth outcomes**

14. How many children did you gave birth to?

1. 1
2. 2
3. 3 and more

15. What was the weight of your baby at birth?

1. Less than 2500 grams
2. 2500 grams
3. More than 2500 grams

16. What was your gestational age?

1. Less than 37 weeks
2. More or equal to 37 weeks

17. What was the mode of delivery of the child?

1. Cesarean section
2. Normal

18. Did you have any complications during pregnancy or childbirth?

1. Yes
2. No (Skip to Q. 20)

19. If yes, which of the following complications did you experience?

1. Post-partum hemorrhage
2. Gestational Diabetes Mellitus
3. Pre-eclampsia
4. Hospitalization
5. Others

**Part V: Life satisfaction**

20. Do you feel that your life at present is

1. Very interesting
2. Fairly interesting
3. Fairly boring
4. Very boring
5. Cannot say

21. Do you feel that your life at present is

1. Very happy
2. Fairly happy
3. Fairly sad
4. Very sad
5. Cannot say

22. Do you feel that your life at present is

1. Very easy
2. Fairly easy
3. Fairly hard
4. Very hard
5. Cannot say

23. Do you feel that at the present moment you are..

1. Very lonely
2. Fairly lonely
3. Not at all lonely
4. Cannot say