

# Experience of assisted reproductive technology at King Abdulaziz University Hospital

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## Summary

**Aim:** To present the authors' experience with assisted reproductive technology (ART) at King Abdulaziz University Hospital in Jeddah, Saudi Arabia. **Materials and Methods:** Retrospective analysis of data collected from the charts of 264 women who were undergoing their first cycle of ART between September 2013 and March 2014. All the women were treated with gonadotropin-releasing hormone (GnRH) antagonist protocol. For all patients, the documented data included age, infertility type, cause, and hormone profile. Number of follicles > 10 mm, endometrial thickness, number of oocytes retrieved, number of fertilized ova, and number of embryos produced, as well as the number transferred, day of transfer, cancellation rate, and treatment administered for luteal phase support (oral and vaginal progesterone) treatment type, and outcome were recorded. The data was analyzed using the Statistical Package for the Social Sciences. **Results:** The authors included women aged 21 to 39 years (mean  $\pm$  standard deviation,  $32.28 \pm 5.51$ ). Patients suffered from primary infertility in 69.7% of the cases; approximately 30% of the women had secondary infertility. Eighty of the 264 patients (30.3%) conceived; however, only 56 women (21.2%) had a live birth. The overall cancellation rate in the patients was 12.1%. The following reasons were documented for cases of failure: no oocytes, 16 (6.1%); no sperm, eight (3.0%); and no embryo, eight (3.0%). **Conclusion:** The success rate of ART at the present institution falls within the range reported in the medical literature. However, further studies should be conducted to investigate the course and outcome of ART in patients who undergo treatment in this institution.

**Key words:** Assisted reproductive technology; Infertility; Intracytoplasmic sperm injection; In vitro fertilization.

## Introduction

An estimated 10% to 15% of couples suffer from infertility, which is reported to affect men and women in approximately equal proportions [1]. However, infertility is increasingly being overcome through advancements in fertility treatment, especially assisted reproductive technology (ART), which has evolved over the last 30 years into a suite of mainstream medical interventions that have ensued in the birth of over 4.3 million babies worldwide [2].

According to the American Society for Reproductive Medicine, ART is defined as treatments and procedures that involve the use of human oocytes and sperm, or embryos, with the aim of achieving a pregnancy [3]. Based on this definition, ART includes *in vitro* fertilization (IVF) procedure with or without intracytoplasmic sperm injection (ICSI), while techniques such as intrauterine insemination and induction of ovulation using drugs are excluded [3].

In Australia, the number of ART treatment cycles and live births rose steadily until the late 2000s. According to recent estimates, 3.6% of all women who delivered in Australia in 2009 received some form of ART treatment [4]. In the United States, 176,275 ART treatment cycles were performed at 456 reporting clinics in 2012, resulting in 51,294 live births [5].

The Centers for Disease Control and Prevention reported that although ART is still relatively rare when compared to the potential demand, its use has doubled in the past ten years in the United States [5]. A similar increase in the use of ART is reported in developing countries. In India, for example, about 125 ART clinics were functional in the capital city in 2013 [6]. In the Middle East, however, the growth of ART has been hampered by cultural and religious factors [7, 8]. ART only became popular in an ultraconservative country such as Saudi Arabia after the passing of an Islamic decree in 1980 and a statement by the Islamic Fikh Council in 1984 [9, 10]. Subsequently, about 23 ART centers were established in Saudi Arabia between 1986 and 2007 [11].

In Saudi Arabia, there are limited data on the outcome of IVF. Previous studies [12-14] reported the outcome of ART in obese women and the pregnancy rates achieved with the timing of embryo transfer. Unfortunately, both studies conducted in one IVF center of Reproductive Medicine, Department of Obstetrics & Gynecology, King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia. In this study, the authors present their experience with ART at King Abdulaziz University (IVF center) in Jeddah, Saudi Arabia.

## Materials and Methods

A retrospective analysis of 264 consecutive patients who were undergoing their first cycle of ART at the In Vitro Fertilization Center of King Abdulaziz University Hospital, Jeddah between September 2013 and March 2014. The Biomedical Ethics Committee of King Abdulaziz University approved the study. Patients were included provided they fulfilled the following criteria:

- they had a diagnosis of infertility, defined as the failure to achieve a clinical pregnancy after  $\geq 12$  months of regular unprotected intercourse, [15]
- they were undergoing their first cycle of ART,
- they were aged 18-40 years,
- they had an indication for IVF,
- received the same antagonist protocol.

Exclusion criteria included all women who were undergoing a repeat ART cycle or those who received a different protocol excluded from the study.

### Protocol

Controlled ovarian hyperstimulation achieved by using the gonadotropin-releasing hormone antagonist (GnRH) protocol. Subcutaneous gonadotropin 150-300 IU administered on the third day of the women's cycle based on their age and weight. On day 6, subcutaneous cetrorelix 0.25 IU administered and cycle progression was monitored by folliculometry and measurement of serum estradiol ( $E_2$ ). In the pre-ovulatory phase, when the follicles attained a size of 18 to 22 mm, final oocyte maturation and release was effected by subcutaneous administration of 5,000 to 10,000 IU of human chorionic gonadotropin (hCG).

Under transvaginal ultrasound guidance, oocytes were retrieved 34 to 36 hours post-hCG administration. Fertilization achieved by IVF or ICSI as clinically indicated. Embryo culture performed using a sequential micro-drop system, and embryos transferred into cleavage media on days 1–3. Patients had embryo transfer when they met the criteria for transfer. Progesterone 400 mg pessaries twice daily or oral hydrogesterone ten mg twice daily administered for luteal phase support. A beta-hCG test performed two weeks following embryo transfer. A transvaginal ultrasound performed after four weeks to determine the number of gestational sacs.

In this study, pregnancy was defined as a positive serum beta-hCG test and the presence of a gestational sac detectable by ultrasound or an ectopic pregnancy. Miscarriage was defined as pregnancy loss following ultrasound confirmation of an intrauterine gestational sac. A live birth was defined as pregnancy resulting in a viable infant. Twins counted as one live birth event.

### Data collection

For all patients included in this study, the authors documented the age, infertility type and cause, hormone profile, number of follicles, number of embryos, number of embryos transferred, day of transfer, treatment type (IVF or ICSI), and outcome.

Other data recorded included the levels of follicle-stimulating hormone (FSH) and luteinizing hormone (LH). Total dose of gonadotropins administered, day of treatment, number of follicles larger than ten mm, endometrial thickness, number of oocytes retrieved, number of embryos produced, as well as the number transferred, day of transfer, number of fertilized ova, cancellation rate, and treatment administered for luteal phase support (oral and vaginal progesterone) were also recorded.

The etiology of infertility was categorized as follows: anovulation, endometriosis, tubal pathology, male factors, and others. Primary infertility was defined as a condition where a woman had never conceived, while secondary infertility was defined as pre-

Table 1. — Age distribution of the patients.

Age in years	Frequency	Percentage
21-25	40	15.2%
26-35	121	45.8%
36-40	103	39.0%
Total	264	100.0%

Table 2. — Type and cause of infertility and the procedure performed.

Type	Frequency	Percentage
Primary	184	69.7
Secondary	80	30.3

Indication		
Female factor	108	40.9
Male factor	60	22.7
Both	96	36.4

Causes		
Ovarian factor	64	24.2
Tubal factors	28	10.6
Endometriosis	16	6.1
Male factor	148	56.1
Other factors	8	3.0

Procedure		
IVF	76	28.8
ICSI	188	71.2

ICSI, intracytoplasmic sperm injection; IVF, *in vitro* fertilization.

vious conception irrespective of whether the pregnancy resulted in a live birth. All the women used their own oocytes during the procedure.

### Statistical analysis

The data analyzed using the Statistical Package for the Social Sciences Descriptive statistics computed for all study variables. Results expressed as frequency (percentage), mean  $\pm$  standard deviation (SD), and interquartile range. Odds ratio, and 95% confidences interval with statistically significant when  $p < 0.05$ .

## Results

The authors included 264 patients aged 21 to 39 years (mean  $\pm$  SD,  $32.28 \pm 5.51$ ). Women aged 26-35 years comprised the largest proportion of the sample (Table 1). In over half of the cases, the patients had primary infertility; close to 30% of the women had secondary infertility (Table 2). The etiology of infertility ranged from one factor in one partner to several factors in one or both partners: female factors, 40.9 %, male factors, 22.7%, and both male and female, 36.4% (Table 2). Male factors contributed to over half of the cases of infertility. In women, ovarian factors contributed to most of the cases of infertility, documented in approximately 24.2% of the cases. Most patients had ICSI.

Table 3. — *Follicle-stimulating hormone and luteinizing hormone levels and gonadotropin dose as well as days of treatment.*

Variable	Minimum	Maximum	Mean	SD
FSH (mIU/mL)	3.0	15.0	7.3	2.33
LH (mIU/mL)	6.0	17.0	11.1	2.37
Gonadotropin dose (IU)	150.0	300.0	271.6	50.26
Days	8.0	14.0	10.2	0.92
Total units	1500.0	4200.0	2770.5	600.13

FSH, follicle-stimulating hormone; LH, luteinizing hormone; SD, standard deviation.

Table 4. — *Number of follicles, oocytes, embryos and embryos transferred, and other characteristics of assisted reproductive technology treatment.*

Variable	Minimum	Maximum	Mean	SD
No. of follicles	1	17	7.10	2.463
No. of oocytes	0	11	3.66	2.646
No. of embryos	0	8	2.68	1.920
Embryos transferred	1	4	2.47	1.030
Day of transfer	2	4	2.23	0.461
Cryopreservation	0	4	0.33	0.878
Endometrial thickness	64	120	105.77	10.854

No., number; SD, standard deviation.

Table 5. — *Outcome of assisted reproductive technology.*

Variable	Frequency	Percentage
Negative pregnancy test	184	69.7
Positive pregnancy test	80	30.3
	264	100
Biochemical pregnancy	4	1.5
Spontaneous Abortion	16	6.1
Ectopic pregnancy	4	1.5
Normal delivery	56	21.2

The mean FSH and LH levels in the sample were  $7.9 \pm 2.3$  mIU/mL and  $11.1 \pm 2.4$  mIU/mL, respectively (Table 3). The total dose of GnRH received by the patients was 2,770.5 IU (mean,  $271.6 \pm 50.26$  IU), administered during an average of 10.2 days. Table 4 shows the number of follicles, oocytes, and embryos, as well as the number of embryos transferred, the day of transfer, and the patients' average endometrial thickness. Of the 264 patients treated, 80 conceived (30.3%); however, only 56 women had a live birth, giving a pregnancy rate of 21.2% (Table 5). In cases where fertilization was achieved, the luteal phase was maintained with progesterone pessaries in 188 women (71.2%); oral progesterone was utilized in all other cases. The overall cancellation rate in the present patients was 12.1%. The following reasons were documented for cases of failure: no oocytes, 16 (6.1%); no sperm, eight (3.0%); and no embryo, eight (3.0%).

Table 6. — *Factors affecting pregnancy rate in IVF patients (odds ratio and 95% confidence interval).*

	Outcome			Odds ratio (95% confidence interval)
	Pregnant	Non-pregnant	Total	
Age (years)				
< 35	62	99	161	2.957 (1.624–5.386) $p = 0.001$
> 35	18	85	103	
Total	80	184	264	
Procedure				
IVF	16	60	76	0.517 (0.276 – 0.969) $p = 0.025$
ICSI	64	124	188	
Total	80	184	264	
Type				
Primary	68	116	184	3.322 (1.678 – 6.575) $p = 0.001$
Secondary	12	68	80	
Total	80	184	264	
Cause				
Female factor	44	72	116	1.901 (1.118 – 3.232) $p = 0.012$
Male factor	36	112	148	
Total	80	184	264	
# of follicles				
< 8	60	152	212	0.632 (0.336 – 1.190) $p = 0.105$
> 8	20	32	52	
Total	80	184	264	
Endometrial thickness (mm)				
< 100	44	90	134	1.277 (0.754 – 2.162) $p = 0.219$
> 100	36	94	130	
Total	80	184	264	
# of fertilized oocytes				
< 4	56	130	186	0.969 (0.546 – 1.721) $p = 0.513$
> 4	24	54	78	
Total	80	184	264	
# embryo transfers				
2 or less	48	112	160	0.964 (0.564 – 1.649) $p = 0.500$
More than 2	32	72	104	
Total	80	184	264	
Day of transfer				
Day 2	60	156	216	0.538 (0.282 – 1.028) $p = 0.045$
Day 3	20	28	48	
Total	80	184	264	
Progesterone				
Oral	13	66	79	0.347 (0.178 – 0.675) $p = 0.001$
Vaginal	67	118	185	
Total	80	184	264	

Odds ratio and 95% confidence interval were calculated for the important factors, age above and below 35, procedure IVF and ICSI, type primary and secondary. The cause of infertility whether female and male factors, number of follicles less or more than eight follicles, endometrial thickness less or more 100 mm, number of fertilized oocytes less or more than four, number of embryo transfer two or less or more, day of transfer second or third day. Finally luteal phase was supported with vaginal or oral progesterone. Table 6 shows the results of the important factors that are statistically significant.

## Discussion

Saudi Arabia is increasingly moving away from the concept of early marriage, and similar to their counterparts in the West, Saudi women are progressively deferring marriage [16]. This delay in the age of first marriage is paralleled by an increase in the age of first pregnancy, [17] which may consequently lead to a rise in the incidence of infertility related to female reproductive aging [8]. On the other hand, childless couples have to confront the deeply personal experience of infertility or miscarriage in the Saudi society, where like in most Arab cultures, family is, and has always been at the center of life [16].

This report shows that the average age of women who underwent ART at the In Vitro Fertilization Center of King Abdulaziz University Hospital was  $32.3 \pm 5.5$  years, which is similar to the mean age of patients who underwent ART in Taiwan ( $33.2 \pm 4.1$  years) and Australia ( $34.4 \pm 4.9$  years). While it is generally known that younger women achieve higher rates of pregnancy and live births [19, 20], it is plausible that the women in the current study presented after the age 30 years because they suffered from infertility for several years, and they may have attempted other possible treatments of infertility. Such treatments included seeking the help of a Sheikh, following certain diets, or reading the Qu'ran, which are methods that have been cited as popular options for Saudi couples with infertility problems [21]. In a previous study, [22] other authors suggested that women were on average 32 years of age when they underwent ART due to the fact that they suffered from infertility for 4.0 to 4.4 years and incurred an additional 2.5 to 3.0 years of treatment.

The success rate of any ART procedure is  $< 30\%$  [23]. In the current study, the pregnancy rate was 30.3%, which is slightly higher than the 19.9% reported among obese women in a study conducted in Riyadh, Saudi Arabia, also higher than the 28.6% among morbidly obese women in the same study [14]. The disparity between the present findings and those of Awartani *et al.*, [14] is unclear, as obesity negatively affects implantation, pregnancy, and live birth rates in IVF candidates [14, 24]. Moreover, the present authors cannot make relevant comparisons between their finding and that of Awartani *et al.*, [14] as they did not investigate the body mass index of the patients in this sample. It should also be pointed that the present study and that of Awartani *et al.* employed dissimilar stimulation protocols. While Awartani *et al.* used the long follicular pituitary down regulation protocol, this involved the use of a GnRH antagonist.

Although other factors are essential for a successful ART therapy, patient response to ovarian stimulation is a pivotal factor associated with successful clinical pregnancy [25]. Some authors reported that there were no significant differences between the GnRH agonist long protocol and the antagonist protocol in terms of the duration of ovarian stimulation, number of recombinant FSH ampoules adminis-

tered, number of oocytes retrieved, estradiol and progesterone serum levels, endometrial thickness, and the zygote- and blastocyst-development rate [26]. Nevertheless, the implantation and clinical pregnancy rates are significantly higher in patients who receive the antagonist protocol (10.6% and 30.3%, respectively) as compared with those of patients who receive the agonist protocol (5.3% and 15.8%, respectively) [26].

In this study, women had an average of  $7.1 \pm 2.46$  follicles. A previous study that considered the various sizes of follicles showed that the pregnancy rates were higher in women who had a higher number of follicles [27]. Other authors demonstrated that the number of small antral follicles measuring 2.1 to 4.0 mm was a significant predictor of viable pregnancy confirmed on ultrasound five weeks after embryo transfer, independent of the patients' age, number of mature oocytes retrieved, fertilization rates, number of cleaved embryos, and the grade of embryos transferred [28]. In the analyses to assess the relationship between follicle number and size and pregnancy outcome, that was not significant with odds ratio of 1.277 95% confidence interval of (0.754 – 2.162) with  $p = 0.219$

The average endometrial thickness in this study was  $105.8 \pm 10.85$  mm. One study described the relationship between endometrial thickness on the day of hCG administration and pregnancy outcome in women who underwent IVF and embryo transfer at an IVF center in Riyadh. In their study, [13], the authors found a positive correlation between endometrial thickness on the day of hCG injection and pregnancy rate, suggesting that physicians should consider aiming for a thicker endometrium during ART therapy. Previous research also suggested that pregnancy rates were highest for patients with the thickest endometrial lining [29, 30]. However; other authors suggested a deleterious effect of endometrial thickness of  $\geq 14$  mm on pregnancy rates [13].

Age is known to be a strong predictor for pregnancy in candidates of ART [31] and the present authors provided an indication when the age was less than 35 years to be an important factor for pregnancy. Due to the fact that this study was a retrospective in nature, it was difficult to retrieve complete data in some cases and this may have introduced bias in the present findings.

Taken together, the present findings demonstrate that women who undergo ART procedures at this institution have a pregnancy rate that falls within the range reported in the medical literature. However, because multiple factors affect fertilization rate in candidates of ART, further studies are warranted to study the course and outcome of ART in patients who undergo treatment at this institution.

## Conclusion

The success rate of ART at the present institution falls within the range reported in the medical literature. How-



ever, further studies should be conducted to investigate the course and outcome of ART in all patients who undergo treatment of infertility with ART at this institution.

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