




FACTORS INFLUENCING INTRAUTERINE INSEMINATION OUTCOMES IN BRUNEI FEMALES

BRUNEİ KADINLARINDA İNTRAUTERİN İNSEMINASYON SONUÇLARINI ETKİLEYEN FAKTÖRLER

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ABSTRACT

Objective: To determine the effects of female age, body mass index (BMI), hormonal profile, infertility duration and causes on pregnancy outcomes in females undergoing intrauterine insemination (IUI).

Material and Method: This retrospective study included 199 infertile females who underwent IUI from 2015 to 2019 at Raja-Isteri-Pengiran-Anak-Saleha Hospital, Brunei Darussalam. Age, BMI, hormonal profile, duration of infertility, and causes of infertility associated with pregnancy outcome during treatment were studied. Urine pregnancy test confirmed the pregnancy post-IUI. The statistical analysis tests for categorical variables were the Chi-Square test and Fisher's exact test. One-way ANOVA was used to assess numerical variables. P-values <0.05 were deemed statistically significant.

Result: The mean age of the pregnant females was 32.8±4.9 years, the mean BMI was 24.7 kg/m² and 12.5% of the participants had normal weight, 5.5% were overweight, and 9% were obese. Overall, 18 females (9%) achieved successful outcomes. Despite the lack of a significant relationship between BMI and pregnancy outcome, 83% of females with positive outcomes were obese. Furthermore, 72.2% of the females who were infertile for <6 years had conceived. A decreasing trend of hormones was noticed with an increasing BMI (p<0.05). Overall hormonal values did not significantly determine IUI outcome (p>0.05).

Conclusion: Successful outcomes after IUI were observed in females with unexplained or female-caused infertility. Male infertility did not influence the positive pregnancy outcome. Females with an age range of 30-39 years, duration of infertility less than six years, and BMI index of >25 kg/m² were able to conceive.

Keywords: Female infertility, clinical characteristics, intrauterine insemination, pregnancy outcome

ÖZET

Amaç: Bu çalışmanın amacı, intrauterin inseminasyon (IUI) uygulanan kadınlarda yaş, vücut kitle indeksi (BMI), hormonal profil, kısırlık süresi ve nedenlerinin gebelik sonuçları üzerine etkisinin araştırılmasıdır.

Gereç ve Yöntem: Bu retrospektif çalışmaya, 2015-2019 yılları arasında Brunei Sultanlığı Raja-Isteri-Pengiran-Anak-Saleha Hastanesi'nde IUI uygulanan 199 infertil kadın dahil edildi. Yaş, BMI, hormonal profil, kısırlık süresi ve nedenleri ile tedavinin hamilelik sonucu ile ilişkisi incelendi. IUI sonrası gebelik, idrar gebelik testi ile doğrulandı. Kategorik değişkenler için istatistiksel analiz testleri Ki-Kare testi ve Fisher testi kullanıldı. Sayısal değişkenler için tek yönlü ANOVA testi uygulandı. P-değerleri <0,05 ise istatistiksel olarak anlamlı kabul edildi.

Bulgular: Yaş ortalaması 32,8±4,9 ve ortalama BMI 24,7 kg/m² olan çalışma grubunda gebe kalanlar arasında %12,5'i normal, %5,5'i fazla kilolu ve %9'u obez idi. Tüm grupta 18 kadında (%9) başarılı sonuçlar elde edildi. BMI ile gebelik sonucu arasında anlamlı bir ilişki olmamasına rağmen, pozitif sonucu olan kadınların %83'ü obezdi. Ayrıca, altı yıldan düşük infertilite süresi olan kadınların %72,2'sinin gebe kaldığı görüldü. BMI arttıkça hormonal değerlerde azalma eğiliminin olduğu gözlemlendi (p<0,05). Hormonal değerlerin tümünün IUI sonucunun belirlenmesinde anlamlı olmadığı sonucuna varıldı (p>0,05).

Sonuç: İnfertilite nedeni açıklanamayan veya kadın kaynaklı olgularda IUI sonrası başarılı sonuçların alındığı gözlemlendi. Erkek infertilite faktörünün gebelik sonucunu etkilemediği gösterildi. Yaşları 30-39 aralığında, kısırlık süresi altı yıldan az ve BMI indeksi >25 kg/m² olan kadınlarda gebelik elde edilebilmiştir.

Anahtar Kelimeler: Kadın infertilitesi, klinik özellikler, intrauterin inseminasyon, gebelik sonucu

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INTRODUCTION

Infertility is the inability of couples of childbearing age to conceive after 12 months of regular, unguarded sexual interaction (1). This condition affects between 8% and 12% of couples within that age (2). The risk has been further increased by the addition of external factors, such as lifestyle and the environment. Male factors of infertility alone account for 20%–30% of cases; however, it can rise to 40% in cases of mixed infertility (3). For this reason, assisted reproductive techniques (ART) are available for treating infertility when appropriate.

Intrauterine insemination (IUI) is a relatively low-cost, effective, and least invasive assisted reproductive procedure that is often offered as a first-line treatment (4). However, it is only recommended for unexplained infertility, male sex, unilateral tubal obstruction, cervical or ovulatory dysfunction, and mild or minimal endometriosis. Several IUI studies have reported a high global pregnancy rate of a 30% chance of successful pregnancy achieved via IUI, but this rate may vary depending on the population studied (5).

Numerous previous studies have shown that maternal age, body mass index (BMI), serum hormonal levels, and the causes of infertility are factors that influence the outcome of IUI treatment (4). The duration of infertility is another factor that affects the success rate, although there is no set limit. Additional treatments, such as controlled ovarian hyperstimulation (COH), can substantially improve the success rate (6). The only noted risk factor for ovulation induction medication is ovulation hyperstimulation syndrome (OHSS), in addition to multiple pregnancies (7). Because fertility treatment involves the emotions and time of patients considering the therapy, it is crucial to weigh the benefits of IUI above every potential drawback, including the likelihood of success and its impact on the patient's mental health (8).

We hypothesised that increased female age and body mass index, prolonged duration of infertility, and a deranged hormonal profile negatively impact the success rate of IUI. Therefore, the objective of our study was to examine the effects of female age, body mass index, hormonal profile, infertility duration, and causes on pregnancy outcomes of females undergoing IUI.

MATERIAL AND METHODS

Study design and study population

This cohort retrospective study was conducted in the Raja Isteri Pengiran Anak Saleha (RIPAS) Hospital, Brunei Darussalam; after the approval obtained from Joint Research Ethics committee of the PAPRSB Institute of Health Science (IHSREC), Universiti Brunei Darussalam, and the Ministry of Health (MHREC) (Date: 09.12.2021,

No:UBD/PAPRSBIHSREC/2021/83). Data on women undergoing IUI treatment from 2015 to 2019 were retrieved from the clinical database of the Brunei Health Information Management System (BruHIMS). Forty patients per year were randomly selected and de-identified into individual codes, resulting in 199 female patients.

Infertile female patients who were diagnosed with unexplained infertility, endometriosis (stage I – II), mild male factor infertility, or semen allergy and underwent IUI were included in the study.

Patients with (1) missing data, (2) increased female age (over 50 years), (3) diagnosed with bilateral tubal obstruction, (4) severe endometriosis, (5) chronic infections, or (6) receiving anti-tuberculous treatment for the last three months were excluded from the study. Additionally, severe male factor infertility (with a post-wash sperm count of <1 million/mL) was excluded from the study.

Patients were grouped into three groups according to age: 20-29 years old, 30-39 years old, and 40-49 years old. BMI data were categorized into three groups with different BMI ranges according to the South Asian Criteria for BMI: normal (18.5-22.9 kg/m²), overweight (23.0-24.9 kg/m²), and obese (≥25.0 kg/m²) (9).

Based on available records and with details of the duration of infertility, females were categorised into two groups; with a cut-off of six years and also into four groups based on the infertility causes namely: unknown causes, male factor, female factor, and both. Furthermore, hormonal levels were also sorted into low, normal, or high. The reference normal serum hormone ranges were: follicular stimulating hormone (FSH): 3.5-12.5 IU/L, luteinizing hormone (LH): 2.4-12.6 IU/L, and progesterone (p): 5.02-75.9 nmol/L. Oestradiol (E2) was not included because it was not routinely measured, and sufficient data were not available for analysis.

Intrauterine insemination protocol

Ovulation induction: All females were prepared for IUI by administering ovulation induction medications; either clomifene citrate (CC) (Y.S.P Industries (M) Sdn Bhd, Malaysia) 50–150 mg or Gonal F (GF) (Merck Serono S.p. A, Italy) 75–150 mg, or a combination of both. This regimen was started on the second day of the menstrual cycle for five days for CC and 10 days for GF. Ultrasound evaluation and relevancy blood tests were performed to monitor follicular maturation as recommended by the physician. Human chorionic gonadotrophin (HCG) (N.V. Organon, The Netherlands; Jubilant HolisterStier LLC, USA) (5000 or 10000 IU) was administered 36 hours before IUI to aid the release of mature eggs during ovulation.

Sperm sample processing: To increase the total motile sperm yield, abstinence period of 3 days (72 hours) were

applied to all male partners. The semen sample was then subjected to several processes such as sperm separation, washing, and centrifugation.

Insemination: The insemination procedure was generally performed on the day of ovulation, either naturally or by HCG induction (10).

Confirmation of pregnancy: A urinary pregnancy test was performed by the females to assess the success of the IUI procedure.

Statistical analysis

The data were organised in Microsoft Excel, and Rstudio version 1.3.1093 was used for statistical analysis. Fisher's exact test was used when >20% of the expected cell counts were <5 and categorical variables were analysed using the Chi-Square test. Quantitative data were compared by One-way ANOVA, where $p < 0.05$ reflected significance.

RESULTS

The infertile females had a mean age of 32.8 ± 4.9 years, with 62% between the ages of 30 and 39 years. Of the 199 female patients, 68.3% ($n=136$) had infertility for six years or less. Unexplained infertility was the leading cause of infertility (49.8%), followed by female causes (41.2%) and male factors (8%) (Table 1).

Female age and BMI were not significantly different between IUI-failed and successful patients (Table 2). Nine percent ($n=18$) of females had successful outcomes after the insemination. The results showed a non-significant relationship between the success rate of IUI and age and BMI ($p=0.93$ and $p=0.78$, respectively). However, out of the 18 successful outcomes, 83% were obese women.

Stratification based on BMI showed that 17 patients who had a successful IUI outcome were below the age of 40 years and only one patient above that age conceived successfully, although both differences were not statistically significant.

Out of the total females, 8% ($n=16$) were normal, 9% ($n=18$) were overweight, and 82.5% were obese ($n=165$), where 12.5% of the normal (2 out of 16), 5.5% of the overweight (1 out of 18), and 9% of the obese (15 out of 165) had successful IUI outcomes.

From 18 successful conceptions after IUI, 72.2% had a duration of infertility of six years, whereas the remaining 27.7% were infertile for more than six years.

A trend of decrease in progesterone, FSH, and LH levels and an increase in BMI ($p < 0.05$) was observed (Table 3). The overall hormonal levels did not significantly determine the outcome of IUI ($p > 0.05$); hormone levels were low in patients who experienced IUI failure.

Table 1: Demographics of infertile female patients undergoing intrauterine insemination

Variables	n	(%)	Mean (SD)
Age (years)			32.8 (4.9)
20-29	54	27.1	27.0 (1.8)
30-39	124	62.3	33.8 (2.7)
40-49	21	10.6	41.8 (2.2)
Ethnicity			
Malay	186	93.5	
Chinese	6	3.0	
Philippine	2	1.0	
Indian	5	2.5	
BMI (kg/m²)			24.7 (1.9)
Normal (18.5-22.9)	16	8.0	20.5 (1.4)
Overweight (23.0-24.9)	18	9.0	24.2 (0.5)
Obese (≥ 25.0)	165	83.0	29.2 (3.8)
Duration of infertility (years)			
≤ 6	136	68.3	3.4 (1.7)
> 6	63	31.7	9.5 (2.8)
Causes of infertility			
Unknown	99	49.8	
Male factor	16	8.0	
Female factor	82	41.2	
Both	2	1.0	

SD: standard deviation, n: sample size, BMI: body mass index

DISCUSSION

The current study showed that females who had the maximum conception after IUI were between the ages of 30 and 39 years. Increasing age is a negative predictor of successful IUI (11, 12). Deterioration in ovarian reserve with increased risk of aneuploidy in oocytes is evident with advanced age. Studies have shown that women aged 40 years have a higher IUI success rate (3, 13, 14). Likewise, Ashrafi et al. did not observe any relationship between age 40 years and IUI outcomes (15). Nevertheless, our study exhibits a higher success rate of IUI in patients aged 40 years, supporting the trend in prior studies (3).

Obesity is a crucial factor, particularly with more than 50% Bruneian population being over the normal BMI range and females making up 29.5% (9). High BMI is known to be a potential risk factor for infertility because it induces anovulation, increases endometrial thickness, causes menstrual dysfunction, reduces the quality of oocytes, impairs the fertilisation capacity and alters endometrial receptivity. A common complication of obesity is anovu-

Table 2: Distribution of variables stratified according to IUI outcome

Variables	n	IUI failure		IUI success		P value
		n	Mean (SD)	n	Mean (SD)	
Age (years)						
20-29	54	49	27.0 (1.7)	5	27.2 (2.5)	0.93 ^a
30-39	124	112	33.8 (2.7)	12	33.0 (2.9)	
40-49	21	20	41.9 (2.2)	1	40.0 (-)	
BMI (kg/m²)						
Normal (18.5–22.9)	16	14	20.6 (1.5)	2	20.0 (0.8)	0.78 ^a
Overweight (23.0–24.9)	18	17	24.3 (0.5)	1	23.4 (-)	
Obese (≥25.0)	165	150	29.2 (4.7)	15	29.4 (5.8)	
Duration of infertility (years)						
≤ 6	136	123	3.7 (1.5)	13	3.6 (1.9)	0.73 ^b
> 6	63	58	9.3 (2.7)	5	7.3 (0.6)	
Causes of infertility						
Unknown	99	90		9		0.57 ^a
Male factor	16	16		0		
Female factor	82	73		9		
Both	2	2		0		

^a: Fisher's exact test, ^b: One-way ANOVA test, BMI: body mass index, IUI: intrauterine insemination

lation, which can be overcome by administering ovulation-induction drugs to females receiving treatment (3, 16). On the other hand, increased endometrial lining observed in high-BMI patients is thought to improve the pregnancy success rate, cancelling the negative impact of obesity on uterine receptivity (10). Our study results revealed a higher proportion of obese (15 patients out of 18) females with a positive pregnancy outcome.

In our study, females with greater BMI had a higher success rate following IUI, which although negates our hypothesis, the improved success can be explained by the correction of ovulation and improvement in the hormonal profile in obese females by medicines used for ovulation induction. Researchers have documented positive IUI outcomes in obese females treated with gonadotropins, human menopausal gonadotropin and treatment with letrozole (17-20).

As reported by Wang et al., BMI is an essential factor influencing the regulation of the hypothalamic-pituitary-ovarian (HPO) axis (20). Increased free fatty acids in the serum inhibit the synthesis of gonadotrophin (Gn), resulting in the fall in serum levels of reproductive hormones like E2, LH, and P, disrupting the menstrual cycle regulation and thereby leading to anovulation. Several studies reported different results regarding BMI, and the findings were inconsistent (21). In theory, BMI may be a strong predictor of IUI outcome, as weight control is an important factor before the start of the proce-

dure. Yavuz et al. also reported the negative influence of obesity on IUI outcomes, explaining the reduced oocyte quality, poor uterine environment, and impaired insulin sensitivity secondary to increased BMI (22). High BMI alters hormonal levels, which in turn affect the quality of the uterine endometrium (3). However, BMI was reported to be a less reliable predictor of pregnancy outcomes in obese patients. Results from our study showed that BMI influenced the outcome of the IUI procedure because 83% of the successful outcomes were females with obesity. This finding is inconsistent with the results of Whynott et al., who reported that the IUI success rate was the same compared with patients with high BMI (22).

Other factors to be discussed in this study, such as basal hormone levels, duration and infertility diagnosis, follicular count, and endometrial thickness, showed inconclusive results. Most of the females who approached the infertility clinic had a duration of infertility of 6 years. Noujua-Huttunen et al. proved in their study that the chances of successful IUI outcomes diminish with long-standing infertility (13). Tomlinson et al. observed that the success rate of IUI was higher in couples with infertility of less than four years (23). Yavuz et al. recently reported that the success rate is higher with shorter subfertility periods, indicating that the duration of infertility becomes essential when selecting IUI as a suitable treatment mode (21).

Table 3: Relationship between BMI and hormonal values in female patients with the outcome of IUI (n=199)

Hormone	BMI (kg/m ²)						Outcome					
	Normal (18.5-22.9)		Overweight (23.0-24.9)		Obese (≥25.0)		p-value ^a	IUI failure		IUI success		p-value ^a
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)		n	%	n	%	
Progesterone												
Low	2	21.7 (1.4)	9	24.1 (0.6)	96	29.3 (5.2)		97	90.7	10	9.3	
Normal	14	20.3 (1.4)	7	24.6 (0.2)	62	29.1 (4.1)	<0.05	76	8	7	8.4	0.92
High	0		2	23.6 (0.1)	7	29.2 (5.6)		8	88.9	1	11.1	
Follicle stimulating hormone												
Low	0		8	24.2 (0.6)	96	29.0 (4.9)		97	93.3	7	6.7	
Normal	16	20.5 (1.4)	10	24.3 (0.5)	64	29.4 (4.7)	<0.05	79	87.8	11	12.2	0.34
High	0		0		5	30.6 (4.3)		5	100.0	0	0.0	
Luteinizing hormone												
Low	0		7	24.1 (0.6)	85	28.4 (4.6)		83	90.2	9	9.8	
Normal	15	20.5 (1.5)	9	24.3 (0.5)	61	29.7 (5.0)	<0.05	78	91.8	7	8.2	0.94
High	1	20.7	2	24.7 (0.3)	19	31.2 (4.5)		20	90.9	2	9.1	

^a: Fisher's exact test, IUI: intrauterine insemination. The mean values are for hormone levels.

Regarding the cause of infertility, almost 50% of females with unexplained infertility underwent IUI and accounted for half of the females (n=9) who achieved successful pregnancy. Successful conception can be attributed to stimulation of the ovaries by medicines and correction of some other factors like inadequate coital frequency (24). Similar results were proposed by Noujua-Huttunen et al. (13). This contrasts with our findings, which showed no significant difference in the percentage of success rate between unexplained infertile females and female factor infertile females. The results prompt that IUI should be deliberated as the first line of approach before opting for IVF in women with unexplained infertility.

The study was limited due to the inaccessibility of data before 2012, retrospective nature, and small sample. The data do not represent all females undergoing IUI in Brunei Darussalam, as IUI treatment is also performed in other hospitals in Brunei. Therefore, the generalizability of the results was not possible. The patient records did not mention the endometrial thickness, which is another limitation of our study. Furthermore, we analysed the results

based on age and BMI independently; the data was not stratified and analyzed according to age.

CONCLUSION

IUI treatment played a significant role in treating infertile couples with ovulatory disorders or unexplained infertility. The success of IUI was largely affected by the female age (30–39 years), and the duration of infertility six years. Although conception occurred mostly in women with BMI > 25 kg/m², weight management strategies, effective counselling and personalised treatment may be advised to optimise fertility health in all infertile couples. Females with an age range of duration of infertility and a BMI index of >25 kg/m² were able to conceive.

Ethics Committee Approval: Approval was obtained from Joint Research Ethics committee of PAPRSB Institute of Health Science (IHSREC), Universiti Brunei Darussalam and Ministry of Health (MHREC) (Date: 09.12.2021, No:UBD/PAPRSBIHSREC/2021/83).

Informed Consent: Due to the retrospective design of the study, informed consent was not taken.

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