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Septum Resection Did Not Improve Reproductive Outcomes in A Group of Han Chinese Women with Septate Uterus Undergoing In Vitro Fertilization/ Intracytoplasmic Sperm Injection Embryo Transfer (IVF/ICSI-ET)

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ABSTRACT

Background: The septate uterus is a common anomaly affecting about 5% of infertile patients. Septum resection is recommended to improve pregnancy outcomes. However, several recent studies challenged the necessity of surgical removal of septum based on lack of benefit, increased risk to the patients, and avoidable economic burden to the health care system.

Methods: This retrospective study aimed to evaluate the impact of septum resection on reproductive outcomes in a group of infertile patients with septate uterus. All patients underwent in vitro fertilization-embryo transfer or intracytoplasmic sperm injection-embryo transfer (IVF/ICSI-ET). Reproductive outcomes were compared between patients with septum resection and patients without septum resection.

Results: A total of 91 patients, with half of them received septum resection, were included in this analysis. For the 45 patients with septum resection, 25 pregnancy (56%) were achieved with 20 live births (44%), 7 were preterm delivery (35%). Similarly, out of the 46 patients without septum resection, 24 pregnancy (52%) were achieved with 19 live births (41%), 6 were preterm delivery (32%).

Conclusion: This study demonstrated that Han Chinese women with septate uterus did not benefit significantly from septum resection, in the context of undertaking IVF/ICSI-ET assisted pregnancy. However, although it did not reach statistical significance, a trend was noticed that primary infertile women might derive more benefit from septum resection compared to women with a history of recurrent abortion.

INTRODUCTION

The septate uterus is the most common congenital uterine anomaly, affecting 2.3-3.0% of the general population of reproductive age. The prevalence of septate uterus increases to 5.3% in women with a history of spontaneous abortion. In women with both infertility and a miscarriage history, the prevalence rate markedly increases to 15.4% Chan et al. (2011b), Ludwin and Ludwin, (2015). It has been suggested that the uterine septum could impair the embryo implantation and development, i.e., lower number of glandular and ciliated cells in the endometrial lining of the intrauterine septum and uncoordinated uterine contractility were mostly accountable for abnormal embryo development Sparac et al. (2001), Rikken et al., (2019), Fedele et al., (1996), Makino et al. (2011), Abdel Moety et al. (2016). Not surprisingly, women with a septate uterus generally have an increased risk of subfertility, pregnancy loss, preterm delivery, and fetal malpresentation Chan et al. (2011a). Consequently, hysteroscopic septum resection has been recommended as a potential means to improve reproductive outcomes for women with a septate uterus Valle and Ekpo, (2013).

There exists controversy regarding the necessity of septum resection. The American Society of Reproductive Medicine (ASRM) mildly recommended (Grade C) surgical intervention to remove the intrauterine septum (Practice Committee of the American Society for Reproductive Medicine. Electronic address and Practice Committee of the American Society for Reproductive, 2016), while the European Society of Human Reproduction and Embryology (ESHRE) guideline for recurrent pregnancy loss, as well as the Royal College of Obstetricians and Gynecologists (RCOG) guideline for recurrent miscarriage recommended not to perform the surgery RPL et al. (2018), RCOG, (2011), based on the

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facts that several studies identified no improvement in reproductive outcomes from the surgical intervention Rikken et al. (2021), Rikken et al. (2020).

Women with uterine anomaly and a wish to conceive often seek pregnancy assistance via in vitro fertilization-embryo transfer or intracytoplasmic sperm injection-embryo transfer (IVF/ICSI-ET). In this context, the necessity of septum resection is also controversial. Studies indicate that the uterine septum could impair the embryo implantation and development Sparac et al., (2001), Rikken et al. (2019). Multiple groups reported improved pregnancy rate and other secondary outcomes for women underwent septum resection Mollo et al., (2009), Tang et al. (2022), Noventa et al. (2022). In contrast, a recent review by Rikken et al. questioned the proposed benefit of septum removal after reviewing more than 250 women across multiple centers in the Netherlands, USA, and UK Rikken et al. (2019). In addition, the first randomized trial (TRUST-the randomized uterine septum trial) found no significant difference in live birth rate in patients allocated to septum resection versus expectant management. The authors concluded that, "in light of the lack of any evidence of effectiveness and the potential for harm, we recommend against septum resection as a routine procedure in clinical practice" Rikken et al. (2021). Given the lack of clear guidance, whether to remove the septum prior to receiving IVF/ICSI-ET procedure remain to be patients and their treating physician's choice.

In this study, we retrospectively identified 97 Han Chinese women with a septate uterus, with or without septum resection, and compared their reproductive outcomes following IVF/ICSI-ET. The primary outcome was pregnancy rate and live birth. The secondary outcomes consisted of pregnancy loss and preterm birth. The potential impact of septum resection on these reproductive outcomes were investigated.

MATERIALS AND METHODS

Study and Patients

This current work was a single center study including Han Chinese women with a septate uterus and a wish to conceive. Retrospectively, we identified the patients by searching keywords, such as septate uterus, uterus anomaly, and septum resection in electronic patient files and medical records, within the time frame of January 2016 to December 2020. The septate uterus was diagnosed by the treating doctor according to the classification system at that time, via hysterosalpingography (HSG), or hysteroscopy combined with laparoscopy (Hyst+Lap), or 3D ultrasound, prior to seeking pregnancy assistance in the Center for Reproductive Medicine, Shanxi Women and Children Hospital. We extracted data on baseline characteristics, interventions, and on all pregnancies that occurred via their medical records. Patients with septum resection were allocated to the treatment group, while patients without septum resection to the control group. Exclusion criteria included: patients received embryo transfer before and after septum resection; patients never received embryo transfer; pregnancy termination due to disease or labor induced due to fetus abnormity; loss of contact. The cutoff time for embryo transfer was December 31, 2021. The cutoff time for follow-up was September 30, 2022. This study was approved by the Institutional Review Board at Shanxi Women and Children Hospital and written informed consent was obtained from all participating patients.

Given the retrospective nature of this study, registration is not applicable

Reproductive outcomes

All included patients underwent at least one cycle of IVF/ICSI-ET. The egg retrieval procedure was determined by each patient and her physician, consisting of luteal phase long procedure, short procedure, agonist procedure, extra-long procedure, and natural phase. Embryo used for transfer consisted of fresh embryos and frozen embryos. Typically, four to five weeks post embryo transplantation, patients were checked via ultra sound to detect for gestational sac and primitive heartbeat. Patients fulfilling the two requirements were considered clinically pregnant. Patients were evaluated at 14 days, 30 days, and 12 weeks after embryo transfer; close to labor; and after birth. Patients were contacted by clinical visits or telephone interviews to complete follow-up.

Baseline characteristics

Hormone levels including follicle stimulating hormone (FSH), luteinizing hormone (LH), estradiol (E2) were assessed using the Automated Enzyme Immunoassay Analyzer AIA-2000ST (Tosoh Corporation, Tokyo, Japan) and the corresponding kits Fahie-Wilson et al. (2000).

Statistical analysis

We used Shapiro-Wilk test to identify the normality of continuous variables. Normally distributed variables were expressed as mean ± standard deviation. Skewed variables were reported as median and interquartile range (IQR). Continuous variables were compared using t-test and categorical data were compared using the Chi-square test or the Fisher's exact test. Logistic regression model was used to determine the influencing factors of various outcomes. The statistical tests were two sided, with $p<0.05$ considered significant. SAS version 9.4 (SAS Institute) was used to carry out the analyses.

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RESULTS

Patients' selection and characteristics

To study the impact of septum resection on IVF/ICSI-ET, we searched the electronic medical files of 18014 patients who received pregnancy assistance in our center between January 2016 and December 2020. A total of 97 patients were identified as having septate uterus, diagnose and confirmed with hysterosalpingography (HSG), hysteroscopy combined with laparoscopy (hyst+ lap), or ultrasound (Table 1).

We excluded 6 patients to ensure that embryos were transferred only after septum resection. Among the remaining 91 patients, 45 patients had the septum resected before seeking pregnancy assistance in our center, referred to as the treatment group; while 46 patients never received septum resection and referred to as the control group.

Table 1: Patients baseline characteristics.

	Treatment Group With septum resection (n=45)	Control Group No septum resection (n=46)	2/t	P value
Age n (%)			0.86	0.65
<30	12 (26.67)	10 (21.74)		
30-37	28 (62.22)	28 (60.87)		
≥37	5 (11.11)	8 (17.39)		
Baseline hormone (mean ± sd)				
FSH (mIU/ml)	8.13±2.93	8.57±3.73	0.48	0.64
LH (mIU/ml)	4.75±2.89	4.23±2.52	0.7	0.49
E2 (pg/ml)	65.92±27.85	73.88±36.26	0.91	0.37
BMI (kg/m2)	23.18±2.72	23.12±3.78	0.09	0.93
Years of infertility			0.32	0.85
<3	17 (37.78)	15 (32.61)		
03-Jun	18 (40.00)	19 (41.30)		
≥6	10 (22.22)	12 (26.09)		
Type of infertility				
Primary	21 (46.67)	23 (50.00)		
Secondary	24 (53.33)	23 (50.00)		
Previous conceptions			0.02	0.89
1	13 (54.17)	12 (52.17)		
2	11 (45.83)	11 (47.83)		
Previous live births			—	0.18
0	23 (95.83)	18 (78.26)		
1	1 (4.17)	4 (17.39)		
2	0 (0.00)	1 (4.35)		
Previous spontaneous abortions			6.58	0.04
0	7 (29.17)	15 (65.22)		
1	9 (37.50)	3 (13.04)		
≥ 2	8 (33.33)	5 (21.74)		
Diagnostic procedures used to confirm a septate uterus				
HSG	7 (15.56)	6 (13.04)	0.12	0.73
	38 (84.44)	40 (86.96)		
Hyst + Lap	38 (84.44)	35 (76.09)	1	0.32
	7 (15.56)	11 (23.91)		
Ultrasound	7 (15.56)	10 (21.74)	0.57	0.45
	38 (84.44)	36 (78.26)		

Primary infertility was defined as the inability to conceive without previous pregnancy. Secondary infertility was defined as the inability to conceive after previous pregnancies. HSG: hysterosalpingography; Hyst + Lap: hysteroscopy combined with laparoscopy.

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The two groups of patients showed no significant differences regarding age, baseline hormone levels, and BMI. The type and duration of infertility was also similar between the two groups with about half patients being primary infertile. Regarding previous pregnancy history in the secondary infertile patients, in the treatment group, 24 patients had one or two pregnancies leading to one live birth (4%); while in the control group, 23 patients had one or two pregnancies leading to five live births (22%). Across the two groups, the rate of spontaneous abortion was significantly different. Seventeen patients (71%) from the treatment group had one or more than one spontaneous abortion, while only eight patients (35%) from the control group had multiple spontaneous abortion (p=0.04).

Pregnancy outcomes

All 91 patients went through IVF/ICSI-ET within a year and the cut-off for following up was December 2021. In the treatment group, 25 patients (56%) achieved pregnancy, resulting in 20 live birth (44%). Five patients had miscarriage at the first trimester and in the 20 live births, seven were preterm delivery (35%). In a similar trend, 24 patients in the control group (52%) achieved pregnancy, resulting in19 live birth (41%). Four patients had miscarriage at the first trimester while one patient had miscarriage at the second trimester. In the 19 live births, six were preterm delivery (32%). Overall, the reproductive outcomes were similar across the treatment and control groups.

Pregnancy outcomes in patients with primary infertility

Next, we took a closer look at patients with primary infertility. Out of the 21 patients with septum resection, 14 pregnancy (67%) was achieved, higher than the control group where 9 patients out of 23 (39%) achieved pregnancy. A total of 3 miscarriage occurred during the first trimester, resulting in 11 live births with 4 preterm delivery (36%) in the treatment group. In contrast, the 9 pregnancies in the control group led to 9 live births and the preterm delivery happened to 4 patients (44%) (Table 3). Both the pregnancy rate and the live birth rate were higher in patients with septum resection, but the difference compared to the control group was not statistically significant.

Table 3: Assisted pregnancy outcome in the subgroup of patients with primary infertility.

	With septum resection (n=21)	No septum resection (n=23)	OR (95% CI)	P value
Pregnancy achieved, n (%)				
No	7（33.33）	14（60.87）		
Yes	14（66.67）	9（39.13）	0.78（0.23-2.67）	0.69
Live birth, n (%)				
No	10（47.62）	14（60.87）		
Yes	11（52.38）	9（39.13）	1.71（0.52-5.67）	0.38
Miscarriage at 1st trimester, n (%)				
No	11（78.57）	9（100.00）		
Yes	3（21.43）	0（0.00）	0.79（0.60-1.03）	0.25
Miscarriage at 2nd trimester, n (%)				
No	14（100.00）	9（100.00）		
yes	0（0.00）	0（0.00）	----	----
Preterm delivery, n (%)				
No	7（63.64）	5（55.56）		
yes	4（36.36）	4（44.44）	1.40（0.23-8.46）	0.71

Pregnancy outcomes in patients with a history of spontaneous abortion

Lastly, we focused on patients with a history of spontaneous abortion. As shown in Table 4, among 17 patients with septum resection, 8 pregnancy was achieved, 2 miscarriages occurred during the first trimester, resulting in 6 live births with 3 preterm deliveries. In contrast, out of the 8 patients without septum resection, 5 pregnancy was achieved, 2 miscarriages occurred during the first trimester, resulting in 3 live births, all being full term delivery. The preterm delivery seemed to happen more frequently in the treatment group of patients.

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Table 4: Assisted pregnancy outcome in patients with a history of spontaneous abortion.

	With septum resection (n=17)	No septum resection (n=8)	OR (95% CI)	P value
Pregnancy achieved, n (%)				0.67
No	9 (52.94)	3 (37.50)		
Yes	8 (47.06)	5 (62.50)	0.53 (0.10-2.98)	
Live birth, n (%)				1
No	11 (64.71)	5 (62.50)		
Yes	6 (35.29)	3 (37.50)	0.91 (0.16-5.20)	
Miscarriage at 1st trimester, n (%)				1
No	6 (75.00)	3 (60.00)		
Yes	2 (25.00)	2 (40.00)	0.50 (0.05-5.51)	
Miscarriage at 2nd trimester, n (%)				NA
No	8 (100.00)	8 (100.00)		
yes	0 (0.00)	0 (0)	----	
Preterm delivery, n (%)				NA
No	3 (50.00)	3 (100.00)		
yes	3 (50.00)	0 (0.00)	----	

A history of spontaneous abortion was defined as two or more, not necessarily consecutive, pregnancy losses before 24 weeks of gestational age.

DISCUSSION

Septum resection is generally recommended for women wishing to conceive, based on reported benefit including higher pregnancy rate and live birth rate, as well as decreased preterm delivery rate and spontaneous abortion rate post-surgical removal of the septum Mollo et al. (2009) Tang et al. (2022), Carrera et al. (2022), Carugno et al. (2022). Although opposite data had been published, the general opinion in the field remains that "evidence is not adequate to change clinical practices based on decades of scientific literature" Noventa et al. (2022).

To study the impact of septum resection on patients receiving IVF/ICSI-ET, we retrospectively identified 91 Han Chinese women with septate uterus seeking pregnancy assistance in our center. To enable proper comparison, we did not include patients who underwent IVF/ICSI-ET before and after septum resection. We did not include patients with other congenital uterine abnormalies either. Therefore, our study consisted of a small number of patients to address a specific question, if septum resection could improve reproductive outcome in patients receiving IVF/ICSI-ET.

Due to the limited information we could gather in electronic records, we failed to retrieve valuable information such as if the septum were partial or complete, what medical instruments were used for the surgery. Nor did we know for each case the quality of surgical care, the thickness and length of the septum. Another piece of valuable information we could not get was the time gap between septum resection and initiation of IVF/ICSI-ET procedure. These caveats withholding, we made some observations.

First, we identified 97 patients with a septate uterus who were diagnosed by their treating physicians. The prevalence of septate uterus in a pool of patients with subfertility, hence seeking pregnancy assistance in our center was 0.54% (97/18014), lower than what had been reported in the literature Qiu et al. (2022). The 91 patients included in this study naturally fell into two groups, the treatment group with septum resection (n=45) and the control group without septum resection (n=46) at roughly 1:1 ratio. This may reflect the daily practice in northern China. Given the lack of a clear guidance regarding septum resection, patients and their treating physicians made the decision whether to take the surgical procedure, leading to no strong trend towards one specific treatment.

Second, we noticed the only significant difference between the treatment and control group was the rate of previous spontaneous abortion. The treatment group had a higher rate of spontaneous abortion (71% vs. 34% in the treatment and control group respectively, p=0.04). This observation may be best explained by the fact that a history of spontaneous abortion was the main reason motivating the patients to take surgery for septum resection.

Third, our data demonstrated that septum resection did

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not improve reproductive outcome, as similar pregnancy rate, live birth rate, spontaneous abortion rate, and preterm delivery rate were observed in the treatment and control groups (Table 2). However, in the subgroup of primary infertile patients, septum resection seemed to improve the pregnancy rate (67% vs. 39%), live birth rate (52% vs. 39%), but a higher miscarriage rate at the 1st trimester (21.4% vs 0%) for the treatment group was also noted. None of these differences reached statistical significance.

Table 2: Embryo transfer and pregnancy outcomes.

	Treatment Group With septum resection (n=45)	Control Group No septum resection (n=46)	OR (95% CI)	P value
Embryo transferred n (%)				
1	2（4.44）	7（15.22）		
2	18（40.00）	18（39.13）	3.50（0.64-19.19）	0.25
≥3	25（55.56）	21（45.65）	4.17（0.78-22.25）	0.34
Pregnancy achieved, n (%)				
No	20（44.44）	22（47.83）		
Yes	25（55.56）	24（52.17）	1.15（0.50-2.61）	0.75
Live birth, n (%)				
No	25（55.56）	27（58.70）		
Yes	20（44.44）	19（41.30）	1.14（0.50-2.61）	0.76
Miscarriage at 1st trimester, n (%)				
No	20（80.00）	20（83.33）		
Yes	5（20.00）	4（16.67）	1.25（0.29-5.35）	0.76
Miscarriage at 2nd trimester, n (%)				
No	25（100.00）	23（95.83）		
yes	0（0.00）	1（4.17）	1.04（0.96-1.13）	0.49
Preterm delivery, n (%)				
No	13（65.00）	13（68.42）		
yes	7（35.00）	6（31.58）	0.86（0.23-3.25）	0.82

A pregnancy was defined as a viable intrauterine pregnancy of at least 12 weeks duration confirmed on an ultrasound scan. Preterm delivery was defined as birth before a gestational age of 37 complete weeks.

Notably, a closer assessment of patients with a history of spontaneous abortion revealed an opposite trend. Not only the treatment group had lower pregnancy rate (47% vs 63%), also the preterm delivery rate was higher (50% vs. 0%). Again, these differences did not reach statistical significance.

In summary, our observatory study of 91 Han Chinese women receiving IVF/ICSI-ET indicated that septum resection did not improve reproductive outcomes. In the subgroup of patients with primary infertility, septum resection might be associated with better pregnancy outcomes. In the subgroup of patients with a history of spontaneous abortion, septum resection should be considered with caution as no clear benefit was detected. Larger and better controlled studies are needed to determine the necessity of septum resection for patients with septate uterus undertaking IVF/ICSI-ET.

DECLARATIONS

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Data will be available upon requesting to the first author.

Declaration of interest

All the authors declare no conflict of interest.

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