ORIGINAL ARTICLE

Comparative Study between Effect of Hysteroscopic Uterine Septal Resection and Effect of Expectant Management on Reproductive Outcome in Women with Septate Uterus

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Abstract

Background: ***A Septate uterus, a congenital defect characterized by a fibrous band known as a septum, can be treated surgically via hysteroscopic uterine septal resection (HUSR). Women who have a septate uterus may have better reproductive success after this operation, which entails removing the septum.***

Aim: ***To evaluate the efficacy of HUSR in relation to expectant management in achieving a successful pregnancy in women who have a septate uterus.***

Subjects and methods: ***One hundred pregnant women participated in this randomized clinical trial that ran from April 2023 through February 2025 at the obstetrics outpatient clinic of Al-Hussain Hospital, Al-Azhar University.***

Results: ***Significant differences were observed in several secondary outcomes. Clinical pregnancy achievement rates differed significantly between groups (p=0.001), though interestingly, pregnancy loss rates were identical (22% in both groups, p=0.386). Statistically, the SR group had a higher rate of successful continuation of pregnancy (36% vs. 28%, p=0.028). Most significantly, the SR group had a lower rate of preterm births (6% vs. 26%, p=0.001) than the EM group. There were no statistically significant variations in the frequencies of multiple pregnancies, ectopic pregnancies, or placental abortions across the groups. However, the marked difference in preterm birth rates (EM: 26% vs. SR: 6%, p=0.001) represents one of the most clinically significant findings of this study.***

Conclusion: ***The significant reduction in preterm birth rates following septal resection may influence clinical decision-making, particularly in patients with previous adverse pregnancy outcomes. The low complication rates associated with the surgical procedure also support its consideration as a safe treatment option.***

Keywords: HUSR; Reproductive outcome; Hysteroscopy; Septate uterus

1. Introduction

The primary goal of HUSR is to increase the chances of pregnancy and decrease the risk of miscarriage for women with a septate uterus. The procedure is believed to improve the ability of the uterus to support a pregnancy and can also reduce the risk of preterm labour and other complications during childbirth.[1]

Expectant management is an alternative treatment option for women with a septate uterus. This approach involves monitoring the patient's condition and waiting to see if pregnancy occurs naturally. Expectant management is typically used for women who have no symptoms or minimal symptoms related to their septate uterus.[2]

One of the main advantages of expectant management is that it avoids the risks associated with surgery. This approach also allows the patient to preserve her fertility, as surgery carries a risk of damaging the uterus or other reproductive organs. However, expectant management may not be the best option for all women with a septate uterus. If a woman has severe symptoms or a history of recurrent miscarriages, surgery may be recommended to improve her chances of pregnancy and childbirth.[3]

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The choice between HUSR and expectant management should be made on a case-by-case basis and after a thorough discussion with a qualified healthcare professional. Factors that should be considered include the patient's age, symptoms, and overall health.[3]

HUSR is not a guaranteed solution for a successful pregnancy. Additionally, not all women with a septate uterus will have difficulty getting pregnant, and some may even have a successful pregnancy without any treatment.[4]

The aim of this study was to compare the effect of HUSR and expectant management on reproductive outcome in women with septate uterus.

2. Patients and methods

This randomized clinical trial was conducted on 100 women at obstetrics outpatient clinic, Al-Husain Hospital, Al-Azhar University from April 2023 till February 2025. The studied patients were divided into 2 groups: Group-A (study group): 50-cases were subjected to hysteroscopic septal resection and Group-B (control group): 50-cases were subjected to expectant management without intervention.

Inclusion criteria:

Women of reproductive age (18-40 years) with a confirmed diagnosis of a septate uterus, women who were willing and able to participate in the study and sign informed consent, women who have been trying to conceive for at least 12 months and have been diagnosed with infertility or recurrent miscarriage, and women who have not undergone any previous surgical procedures for their septate uterus

Exclusion criteria:

Women with known contraindications for hysteroscopic surgery, such as active pelvic infection or bleeding disorders, women with any of the ovarian causes of infertility, women with any of the tubal causes of infertility, women with other uterine anomalies or conditions, such as bicornuate uterus or unicornuate uterus, and women who are unable or unwilling to comply with the study protocols and follow-up schedule.

Sampling Method "Randomisation":

Women who met the inclusion requirements were randomly assigned to one of the two groups using systematic random sampling. Each of the 100 opaque envelopes was assigned a unique number, and inside each one, the letter representing the assigned group was placed in accordance with the randomization table. After then, each envelope was sealed and placed in a single box. A randomization sheet was prepared using MedCalc ® version 13 for the purpose of computerization.

Sample size justification:

Results from a study conducted by Rikken et al.,[3]. The following assumptions were taken into account when using Epi Info STATCALC to determine the sample size: There is an 80% power and a 95% two-sided confidence level. 5% inaccuracy. The Epi-Info output allowed for a maximum sample size of 92 in the end. Therefore, in order to account for potential cases of dropout during follow-up, the sample size was raised to 100 participants.

Ethical considerations:

The OB/GYN department's council at Al-Azhar University declared the protocol and all associated documentation for ethical and research approval before the study began, ensuring compliance with any applicable local regulations. Prior to inclusion in the study, all patients were asked to provide their informed consent.

Participants were required to undergo a comprehensive medical history (including menstrual, obstetric, contraceptive, medical, surgical, and family history of infertility, as well as any complications experienced by the mother or the unborn child) as per the inclusion and exclusion criteria.

Surgeons were free to use whichever instruments they saw appropriate, which may have included standard mechanical scissors, bipolar vaporization electrodes, needle and/or loop electrosurgical instruments, or resectoscopes with one or both currents. Ultrasound or laparoscopic monitoring was recommended to check the extent of the myometrial excision and avoid uterine perforation throughout the procedure.5 Expectant management women did not get any special care but were encouraged to keep trying to conceive on their own or with the help of IVF if they were unable to. Patients with antiphospholipid syndrome and recurrent miscarriages were given low-dose aspirin or low-molecular-weight heparin. Women had the option to have hysteroscopic septum excision if they experienced a miscarriage during their first pregnancy following randomization or if they were unable to conceive after a year of follow-up.

We tracked women for at least a year, and we tracked the pregnancies of those who got pregnant during that time. We tracked women who experienced a miscarriage within a year until they had their second successful pregnancy, or until 12 months following randomization if that wasn't possible.

Primary outcome:

Conception leading to live delivery within 12 months after randomization. When a fetus is born alive after 24 weeks of gestation, it is considered a live birth (GA).

Secondary outcomes:

Conditions resulting in clinical pregnancy, miscarriage, continued pregnancy, or premature delivery, occurring within 12 months following randomization, as determined by conception. Pregnancy outcomes such as multiple pregnancies, ectopic pregnancies, placental abruption, uterine rupture, and delivery mode were evaluated in pregnant women. Urine perforation, fluid overload, endometritis, and other particular problems during and after hysteroscopic septum excision were included in the data set.

Statistical analysis:

Statistical Package for the Social Sciences (SPSS) software (version 20) was used for data analysis. A chi-square test was used for the comparison of qualitative variables, which were reported as percentages and frequencies. The quantitative measurements were compared using a Student's t-test and displayed as means ± standard deviation (SD). The mentioned variables were subjected to regression analysis and correlation. There was a significant result with a p-value less than 0.05.

3. Results

Table 1. Demographic data analysis.

		MEAN ± SD	RANGE	P-VALUE
AGE, YEARS	EM	27.96 ± 3.591	22-36	0.176
	SR	28.94 ± 3.594	22-36	
	Total	28.45 ± 3.608	22-36	
BMI, KG/M^2	EM	23.74 ± 2.933	18-32	.453
	SR	25.70 ± 3.382	18-32	
	Total	24.72 ± 3.300	18-32	
PARITY (GRAVIDA/PARA)	EM	0	0	0.001*
	SR	1.36 ± 1.367	0-4	
	Total	0.68 ± 1.180	0-4	
NUMBER PREVIOUS LIVE BIRTHS	EM	0	0	0.001*
	SR	0.30 ± 0.505	0-2	
	Total	0.15 ± 0.386	0-2	

SR= septal resection, EM= expectant management

The mean age of EM group was 27.96 ± 3.591 years, while in SR group was 28.94 ± 3.594 years, p= 0.176. The mean BMI in EM group was 23.74 ± 2.933 kg/m2, while in SR group was 25.70 ± 3.382 kg/m2, p= 0.453. On the other hand, there was a statistically significant difference regarding parity and number of previous live births, p= 0.001, (table 1).

Table 2. Character of SR technique.

TYPE OF ANESTHESIA	GENERAL	50 (100%)
INSTRUMENTATION USED	Resectoscopes	9 (18%)
	scissor	41 (82%)
MONITORING DURING PROCEDURE	Laparoscopic	15 (30%)
	ultrasound	35 (70%)

Regarding the type of anesthesia, whole patients in SR Technique received general anesthesia. The instrumentation used was resectoscopes in 9-patients (18%) and scissors in 41-patients (82%). The monitoring during procedure was done via laparoscope in 15-patients (30%) vs ultrasound in 35-patients (70%), (table 2).

Table 3. Complications of SR technique.

UTERINE PERFORATION	NO	49 (98%)
	Yes	1 (2%)
FLUID OVERLOAD	No	50 (100%)
ENDOMETRITIS	No	48(96%)
	Yes	2(4%)

Regarding the complications of SR technique, one case developed uterine perforation while 2 cases developed endometritis, (table 3).

Table 4. Comparison between both groups regarding GA.

	MEAN ± SD	RANGE	P-VALUE
EM	34.96 ± 3.483	28-40	0.058
SR	36.50 ± 1.944	30-39	
TOTAL	35.78 ± 2.852	28-40	

There was no statistically significant difference between EM and SR regarding GA at birth, p=0.058, (table 4; figure 1).

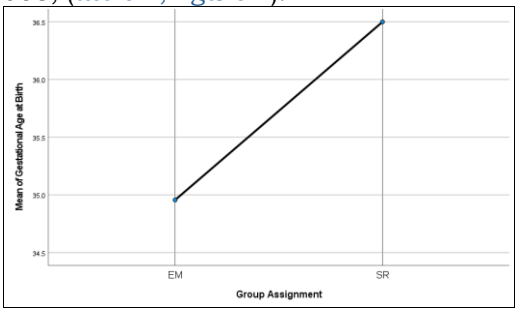

Figure 1. Comparison between both groups regarding GA.

Table 5. Comparison between both groups regarding secondary outcomes

		GROUP ASSIGNMENT		TOTAL	P-VALUE
		EM, (N=50)	SR, (N=50)		
CLINICAL PREGNANCY	No	18(36%)	25(50%)	43(43%)	0.001*
	yes	29(58%)	23(46%)	52(52%)	
ACHIEVED	Missing	3	2	5	
PREGNANCY LOSS	No	35(70%)	37(74%)	72(72%)	0.386
	yes	11(22%)	11(22%)	22(22%)	
	Missing	4	2	6	
ONGOING PREGNANCY	No	33(66%)	17(34%)	50(50%)	0.028*
	yes	14(28%)	18(36%)	32(32%)	
	Missing	3	15	18	
PRETERM BIRTH	No	35(70%)	45(90%)	80(80%)	0.001*
	yes	13(26%)	3(6%)	16(16%)	
	Missing	2	2	4	

*: p-value is significant.

There were statistically significant differences regarding clinical pregnancy achievement, ongoing pregnancy and preterm birth, p= 0.001, 0.028 and 0.001, (table 5; figure 2).

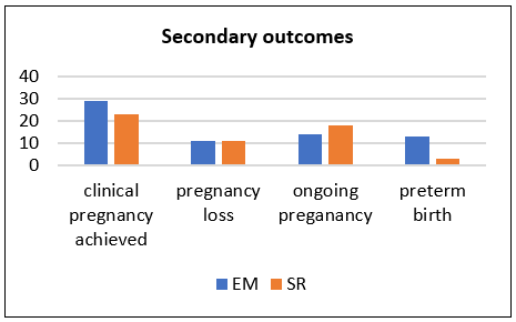

Figure 2. Comparison between both groups regarding secondary outcomes.

4. Discussion

A uterine abnormality known as the septate uterus occurs during birth. In women of childbearing age, it is quite rare, with a prevalence of between 0.2 to 2.3%. There is an elevated risk of infertility, miscarriage, and premature delivery for women who have a septate uterus. To restore normal uterine anatomy and improve reproductive results, hysteroscopic septum excision is currently the standard treatment.[6]

Surgical repair of a septate uterus did not seem to increase the likelihood of conception, avoid pregnancy loss, or delay delivery, according to a recent large cohort study involving 257 women. Seven women, or 4.6% of the total, experienced problems during surgery.[7]

Our study groups were well-matched in terms of basic demographic characteristics, with no significant differences in age (EM: 27.96 ± 3.591 years vs. SR: 28.94 ± 3.594 years, p= 0.176) or BMI (EM: 23.74 ± 2.933 kg/m² vs. SR: 25.70 ± 3.382 kg/m², p= 0.453). This homogeneity in baseline characteristics strengthens the validity of our comparative outcomes.

According to the data presented by[3], in a comparison of expectant care and hysteroscopic septum excision for women with a septate uterus, all groups began with similar baseline characteristics. The average age in both groups was determined to be 31 years.

Also,[6] He sought to discover how hysteroscopic septum incision affected the success rate of in vitro fertilization (IVF) in women who were infertile but had a complete septate uterus and had never experienced a miscarriage before. They found that both the expectant treatment group (31.7 ± 3.8 years old) and the hysteroscopic septum incision group had an average age of 32.3 ± 3.2 years old. Both groups were similar in age and body mass index (P> 0.05).

The current study found a notable disparity in parity and prior live births between the groups (p 0.001). The SR group had a higher parity rate (1.36 ± 1.367) than the EM group (0). This difference might reflect the real-world clinical scenario where patients with previous pregnancies may be more likely to opt for surgical intervention based on their reproductive history. This also agrees with3 who found that parity >1 was present in 5% in SR group vs 2% in EM group.

In the current study, in the SR group, the majority of procedures (82%) were performed using scissors rather than resectoscopes (18%), with ultrasound monitoring (70%) being preferred over laparoscopic monitoring (30%).

This preference aligns with findings by (91), who reported superior outcomes with ultrasound-guided procedures in the objective evaluation of the success of the hysteroscopic surgery for the uterine septum.

In this study, the complication rate was notably low, with only one case (2%) of uterine perforation and two cases (4%) of endometritis.

In agreement,[3] found that septum resection was associated with one treatment consequence, a uterine perforation.

In this study, the primary outcome of conception leading to live birth showed comparable results between the groups (EM: 46% vs. SR: 52%, p 0.656).

This finding is particularly interesting as it differs from some previous studies, such as 8. The postoperative live birth rate was 66% in patients who underwent hysteroscopic septum excision for recurrent miscarriage and a septate uterus. The live birth rate was significantly higher in these patients.

In our study, the gestational age at birth showed a trend toward better outcomes in the SR group (36.50 ± 1.944 weeks) compared to the EM group (34.96 ± 3.483 weeks).

In the current study, significant differences were observed in several secondary outcomes. Clinical pregnancy achievement rates differed significantly between groups (p= 0.001), though interestingly, pregnancy loss rates were identical (22% in both groups, p= 0.386). The ongoing pregnancy rate showed better outcomes in the SR group (36% vs. 28%, p 0.028). Perhaps most notably, there was a significant reduction in preterm birth rates in the SR group (6%) compared to the EM group (26%, p 0.001).

This finding aligns with research by[8], who also found reduced preterm birth and miscarriage rates following septal resection.

This disagrees with[3] who also found no changes in the rates of continuing pregnancies, premature births, or miscarriages.

This goes against the grain of prior research that has shown promise for hysteroscopic septum removal in reducing miscarriage rates and providing possible advantages, especially for women with a septate uterus who suffer from

repeated miscarriages.[9]

On the other hand,[6] found a slightly greater rate of miscarriage in the surgical group (30.8% vs. 22.2%), but it was not statistically significant compared to the expectant group. The small sample size and other variables that affect the likelihood of miscarriage after a donation could explain this surprising finding. It is also not known how the endometrium may react to surgical incisions compared to how the uterine cavity morphology can be improved by removing the septum. Neither the surgical group nor the expectant management group differed significantly in terms of clinical pregnancy rate or continued pregnancy rate.

However, the marked difference in preterm birth rates (EM: 26% vs. SR: 6%, p= 0.001) represents one of the most clinically significant findings of this study.

This outcome supports the findings of[10] who reported similar reductions in preterm birth rates following surgical intervention.

Study strengths and limitations:

The thorough follow-up, matched baseline features, and prospective design of this study are its strongest points. Nevertheless, there are a few caveats to consider, such as the small sample size and the possibility of selection bias in group assignment. The study's potential lack of generalizability could be due to its single-centre design.

4. Conclusion

The significant reduction in preterm birth rates following septal resection may influence clinical decision-making, particularly in patients with previous adverse pregnancy outcomes. The low complication rates associated with the surgical procedure also support its consideration as a safe treatment option.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

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Conflicts of interest

There are no conflicts of interest.

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