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Comparison of long-term clinical effect and re-pregnant outcomes between hysteroscopic resection and laparoscopic defect repair in patients with non-severe cesarean scar defect: a retrospective study

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Abstract

Objective To evaluate and compare the long-term therapeutic effect and the re-pregnant outcomes of hysteroscopic resection and laparoscopic defect repair in the treatment of non-severe cesarean scar defect (CSD).

Methods The clinical data of 154 CSD patients whose residual myometrium thickness (RMT) ≥ 3 mm that treated at Maternal and Child Health Hospital of Hubei Province from January 2019 to May 2022 were retrospectively analyzed (74 accepted hysteroscopic resection and 80 received laparoscopic defect repair). We compared the general clinical data, laboratory tests, surgical related indicators and perioperative complications of two groups of patients, followed up and recorded the menstrual days at the 3rd, 6th, and 12th months after surgery, as well as the obstetric outcomes of re-pregnant patients.

Results The surgical duration, intraoperative bleeding, postoperative vaginal bleeding days, hospital stay, and total treatment cost in hysteroscopic group were all obviously lower than those in laparoscopic group. More importantly, the incidence of postoperative complications such as fever and pelvic pain was also significantly lower in patients undergoing hysteroscopic surgery than those undergoing laparoscopic surgery. In terms of menstrual improvement, at the postoperative 3rd,6th and 12th month, the patients of hysteroscopic group had shorter menstrual days than laparoscopic group. Additionally, the postoperative re-pregnancy rate of hysteroscopic group (61.29%) was higher than that of laparoscopic group (55%). No serious obstetric complications such as placenta implantation and uterine rupture occurred in the re-pregnant patients of both groups.

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Conclusions Although both hysteroscopic resection and laparoscopic defect repair have good clinical effects on improving the symptoms of non-severe CSD patients. But in contrast, the hysteroscopic resection displays the advantages of minimal trauma, shorter surgical time, less intraoperative bleeding, shorter hospital stay, lower treatment costs, faster postoperative recovery, lower incidence of postoperative complications, and higher re-pregnancy rate. Hence, hysteroscopic resection is safe and effective, and could be the first choice for the treatment of no-severe CSD patients.

Keywords Cesarean scar defect, Abnormal uterine bleeding, Secondary infertility, Hysteroscopic surgery, Laparoscopic surgery

Background

Cesarean scar defect (CSD), one of the long-term complications of cesarean section, is the space or depression formed in the uterine incision site that communicates with the uterine cavity [1]. According to statistics, the incidence of CSD is about 24 to 84% worldwide [2, 3]. At present, the causes of CSD formation are not clear and may be related to factors such as patient age, delivery timing, surgical duration, uterine suturing method, and perioperative infection [4, 5]. The most common clinical symptom of CSD is abnormal uterine bleeding, manifested by prolonged menstruation and continuously vaginal bleeding after menstruation [6]. In addition, CSD may also lead to chronic pelvic pain, secondary infertility, uterine scar pregnancy, etc.,which will seriously affect the quality of life and endanger the life safety of patients [1, 7]. Therefore, taking proactive and effective treatment measures as early as possible to improve CSD related diseases is of great clinical significance.

Currently, treatments for CSD include medication and surgery [8]. To some extent, drug treatment can improve the symptoms of prolonged menstruation, but it cannot restore the normal anatomy of the uterine scar. Additionally, it has great side effects and the symptoms are easy to relapse after drug withdraw, so the long-term treatment efficiency of medication is not satisfactory [9, 10]. Thus, the main treatment of CSD is surgery in clinical practice. The methods of surgical treatment are varied, and currently there is no unified standard. Some studies have classified CSD as non-severe and severe type based on whether the residual myometrium thickness exceeds 3 mm. The study aims to compare the long-term effect of hysteroscopic resection and laparoscopic defect repair in the treatment of non severe CSD (RMT ≥ 3 mm), as well as their impact on the re-pregnant outcomes of patients that have the requirement of fertility, and we are committed to provide more clinical basis for the selection of treatment for CSD patients.

In fact, some previous studies have reported that both surgical methods can improve the abnormal uterine bleeding symptoms of CSD patients in the short term [11–13]. However, we found that previous patients sample was small, the long-term efficiency and complications were not clear, and the tracking of re-pregnant outcomes in patients with fertility requirements was lack. Therefore, based on the above points, our study designed a relatively more comprehensive and reasonable retrospective trial, aiming to find a more optimal surgical modality for the treatment of non-severe CSD.

Materials and methods

Patients

Retrospectively collecting clinical data of CSD patients admitted to Maternal and Child Health Hospital of Hubei Province from January 2019 to May 2022. Inclusion criteria: (1) Patients with history of one or more cesarean sections; (2)Patients diagnosed as CSD based on medical history, signs, imaging, or hysteroscopy examination; (3) Patients combined with abnormal uterine bleeding symptoms; (4)Patients with residual myometrium thickness (RMT) ≥ 3 mm; (5)Patients received treatment with hysteroscopic diverticulectomy or laparoscopic defect repair. Exclusion criteria: (1)Lactating and pregnant women; (2) Patients with other organic diseases that cause abnormal uterine bleeding; (3)RMT<3 mm; (4)Patients who received conservative drug treatment; (5)Patients with incomplete medical records and lost follow-up. This study was a retrospective research, and both the patients and their families signed the informed consent form to participate in the study. The Health Research Ethics Committee of Maternal and Child Health Hospital of Hubei Province approved the study.

Procedures

Hysteroscopic resection

Using hysteroscopy to observe the whole uterine cavity to locate the defect. Then using the annular electrodes remove the scar tissue at the upper and lower edges of the isthmocele in stages. Recheck the defect for flattening, electro-coagulate the endometrium growing in the defect, and complete the hysteroscopic resection.

Laparoscopic defect repair

Laparoscopically separating the adhesions between bladder and uterine, then downward pushing the bladder to expose the isthmocele, locating it by pointing the hysteroscopic light directly at the top of the defect to find the upper and lower edges of the scar. Subsequently,

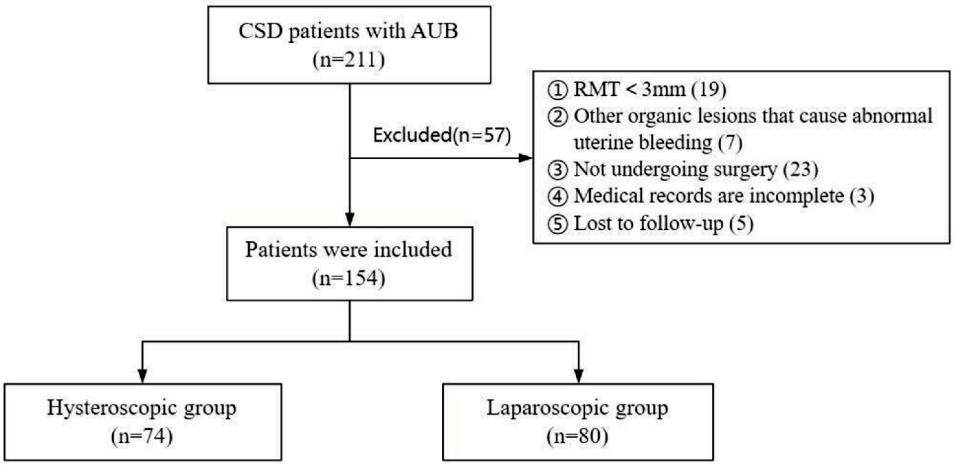

Fig. 1 The study flowchart. CSD, Cesarean Scar Defect; AUB, Abnormal Uterine Bleeding; RMT, Residual Myometrium Thickness

removing the scar tissue and its edges under laparoscopy. The fresh wound edges are exposed, and then the upper and lower edges of the incision are continuously closed with 1.0 absorbable thread, and sew it again for reinforcement, finally complete the laparoscopic defect repair surgery.

Data collection

General data, preoperative and postoperative laboratory indicators, surgery-related indicators, and the occurrence of intraoperative and postoperative complications of CSD patients were collected. Two months after surgery, vaginal ultrasound was conducted to assess the healing status of the defect and compare the changes in residual myometrium thickness (RMT) of isthmocele before and after treatment. Using outpatient and telephone follow-up, record the patient's menstrual improvement at the postoperative 3rd, 6th, and 12th month, as well as their subsequent re-pregnant outcomes.

Statistical analysis

Using SPSS 27.0 statistical software for data statistical analysis. The comparison of data that conform to normal distribution between two groups is conducted using t-test, and the data is represented by mean and standard deviation. The comparison of categorical data is conducted using χ^2 test or Fisher's exact probability method, and the data is expressed in terms of rate and component ratio (%). $P < 0.05$ is considered statistically significant.

Results

From January 2019 to May 2022, a total of 211 patients were diagnosed CSD at Maternal and Child Health Hospital of Hubei Province. According to the inclusion and exclusion criteria, 154 patients were ultimately enrolled in this study and divided into hysteroscopic surgery group (74 cases) and laparoscopic surgery group (80 cases) based on different treatment methods. The flowchart of the experiment is shown in Fig. 1.

Table 1 Clinical characteristics of the patients

Factors	H group($n=74$)	L group($n=80$)	t	*p*
Age(years)	34.51 ± 4.17	33.76 ± 4.06	1.132	0.260
BMI(kg/m2)	21.84 ± 2.27	21.95 ± 2.44	-0.308	0.759
Number of pregnancy	3.04 ± 1.23	3.35 ± 1.27	-1.530	0.128
Number of CS	1.36 ± 0.51	1.50 ± 0.50	-1.651	0.101
Number of miscarriage	1.42 ± 1.10	1.54 ± 1.26	-0.620	0.536
Time since the last CS (years)	3.89 ± 1.27	3.80 ± 1.33	0.439	0.661
Preoperative menstrual duration (days)	14.91 ± 1.32	14.88 ± 1.13	0.154	0.878
Width of diverticulum (mm)	8.28 ± 1.65	8.19 ± 1.68	0.338	0.736
Depth of diverticulum (mm)	6.11 ± 1.13	6.04 ± 1.24	0.369	0.713
Preoperative RMT (mm)	3.34 ± 0.45	3.29 ± 0.28	0.708	0.480

BMI, Body Mass Index; CS, Cesarean Sections; RMT, Residual Myometrium Thickness

General data and biochemical indicators

The general clinical data of the two groups of patients are shown in Table 1. By comparing the general characteristics such as age, BMI, number of pregnancies and miscarriages, number of cesarean sections (CS), the time since last CS and preoperative menstrual duration, as well as preoperative imaging indicators such as the width, depth, and residual myometrium thickness (RMT) of the defect, we can find that the above factors of the two groups of patients are roughly equal, and the difference is not statistically significant ($p > 0.05$). Similarly, there were no remarkable changes in laboratory test results such as

Table 2 The preoperative and postoperative biochemical parameters in the two groups

Factors	H group($n=74$)		L group($n=80$)		t		*p*	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Hgb (g/l)	119.61 ± 12.62	115.01 ± 13.66	120.81 ± 10.59	112.11 ± 11.04	-0.643	1.454	0.521	0.148
K (mmol/l)	4.01 ± 0.32	3.89 ± 0.33	4.01 ± 0.25	3.95 ± 0.38	0.062	-0.964	0.951	0.337
Na (mmol/l)	136.51 ± 15.53	136.10 ± 2.92	137.78 ± 2.36	136.55 ± 2.55	-0.727	-1.019	0.468	0.310
Cl (mmol/l)	103.12 ± 11.90	104.38 ± 3.21	103.04 ± 11.75	104.75 ± 2.74	0.042	-0.774	0.967	0.440
Ca (mmol/l)	2.27 ± 0.11	2.12 ± 0.13	2.26 ± 0.12	2.09 ± 0.12	0.776	1.664	0.439	0.098

Hgb, hemoglobin; Pre, Preoperative; Post, postoperative

Table 3 Relevant intraoperative and postoperative indicators in the two groups

Groups	Surgical duration (h)	Intraoperative bleeding (ml)	Postoperative vaginal bleeding time (d)	Hospital stay (d)	Treatment costs ($)
H group ($n=74$)	35.34 ± 10.55	8.69 ± 6.88	2.92 ± 0.75	5.81 ± 1.30	1314.25 ± 226.63
L group ($n=80$)	98.23 ± 30.44	30.61 ± 17.44	4.29 ± 0.90	7.31 ± 1.39	2247.49 ± 291.09
t	-16.856	-10.109	-10.263	-6.903	-22.035
p	<0.001	<0.001	<0.001	<0.001	<0.001

Table 4 The occurrence of perioperative complications in the two groups

Complications	H group ($n=74$)	L group ($n=80$)	F	*p*
Fever	1	5	-	-
Pelvic inflammatory disease	1	2	-	-
Massive haemorrhage	0	0	-	-
Bladder injury	0	0	-	-
Venous thrombus	0	0	-	-
Electrolyte disturbances	0	0	-	-
Others	1	4	-	-
Total ($n=14$)	3(4.05%)	11(13.75%)	4.373	0.037

Note: Others Including chest tightness, asthma, anemia, diarrhea, headache

Table 5 Changes in RMT before and after surgery in the two groups

Groups	Pre(mm)	Post(mm)	t	*p*
H group ($n=74$)	3.34 ± 0.45	3.35 ± 0.43	-0.168	0.867
L group ($n=80$)	3.29 ± 0.28	4.87 ± 0.47	-25.606	<0.001
t	0.708	-20.750	-	-
p	0.480	<0.001	-	-

RMT, Residual Myometrium Thickness; Pre, Preoperative; Post, postoperative

hemoglobin and electrolytes between the two groups (Table 2).

Surgery-related indicators and complications

All surgeries had been successfully completed without any serious complications such as peripheral organ damage or excessive bleeding. Reviewing the surgical conditions of two groups (Table 3), we found that the hysteroscopic group had significantly lower surgical duration, intraoperative bleeding, and postoperative vaginal bleeding time compared to the laparoscopic group. Correspondingly, the patients of hysteroscopic group had the shorter hospital stay and lower treatment costs. In terms of surgical complications (Table 4), one patient experienced fever, one patient had pelvic pain, and one patient had headache due to previous neck joint disease after hysteroscopic surgery. Five patients in the laparoscopic group had fever, two patients experienced pelvic pain, one patient experienced chest tightness and shortness of breath due to anxiety, two patients developed moderate anemia, and one patient had constipation. After symptomatic support treatments such as anti-infection, pain relief, oxygen therapy, correction of anemia, and assisted defecation, the symptoms of the above all patients have improved. Overall, the incidence of postoperative complications in hysteroscopic surgery group was also visibly lower than that in laparoscopic surgery group (4.05% vs. 13.75%, $p<0.05$).

Postoperative imaging test results

Comparing the preoperative and postoperative residual myometrium thickness of patients (Table 5), there was no clearly change in the hysteroscopic group. While the RMT in the laparoscopic group increased noteworthily after surgery and was obviously thicker than in the hysteroscopic group, with a statistically significant difference ($P<0.05$).

Postoperative menstrual improvement

The improvement of postoperative symptoms in patients is shown in Table 6. Follow up the menstrual changes at the 3rd, 6th, and 12th month after surgery, and the data showed that the menstrual duration of both groups of patients was significantly shortened after treatment compared to the before. While, the effect of shortening vaginal bleeding days in hysteroscopic group was evidently better than that in laparoscopic group ($p<0.05$).

Postoperative re-pregnancy

Following up and comparing the postoperative re-pregnant outcomes of the patients of two groups (Table 7),

Table 6 The postoperative menstrual improvement in the two groups

	H group ($n=74$)	L group($n=80$)	t	*P*
The 3rd month				
Menstrual duration (d)	7.11 ± 0.71	8.40 ± 1.07	-8.717	<0.001
The 6th month				
Menstrual duration (d)	6.82 ± 0.82	8.46 ± 1.01	-11.042	<0.001
The 12th month				
Menstrual duration (d)	6.57 ± 0.76	8.55 ± 0.95	-14.195	<0.001

Table 7 Pregnancy outcomes in re-pregnant patients

Postoperative pregnancy outcome	H group ($n=31$)	L group ($n=40$)	χ^2	*p*
Number of pregnancies	19(19/31)	22(22/40)	0.283	0.595
Full-term delivery	9(9/19)	13(13/22)	-	0.538[a]
Premature birth	7(7/19)	6(6/22)	-	0.737[a]
Spontaneous abortion	1(1/19)	1(1/22)	-	1.000[a]

[a] Fisher's exact probability test

we found that the re-pregnancy rate of CSD patients who treated with hysteroscopic resection (61.29%) was higher than those who accepted laparoscopic defect repair (55%). 31 patients in hysteroscopic group had the desire to conceive again, and ultimately 19 patients conceived (18 natural conception and 1 in vitro fertilization embryo transfer (IVF-ET)). 40 patients of laparoscopic group had pregnant intentions, and 22 patients successfully conceived (19 natural conception and 3 IVF-ET). Among the 19 re-pregnant patients in hysteroscopic group, there were 9 cases of full-term cesarean section, 7 cases of premature cesarean section, 3 cases of miscarriage(1 spontaneous abortion, 1 induced abortion and 1 ectopic pregnancy). In the laparoscopic group, there were 22 cases of re-pregnancies, including 13 full-term delivery (cesarean section), 6 premature birth (1 vaginal delivery, 5 cesarean section), 1 natural abortion, 1 ectopic pregnancy and one patient is currently in the mid-pregnancy state (no obvious abnormalities observed during prenatal examination). No serious pregnancy complications such as cesarean scar pregnancy, placenta previa and uterine rupture occurred in all delivered patients. There was no significant difference in re-pregnant outcomes between the two groups.

Discussion

In recent years, with the increase of cesarean section rate in the world, the incidence of cesarean scar defect remains high, and researches in this field have become increasingly important [5]. Transvaginal ultrasound (TVUS) or hysteroscopy are currently the main methods used in clinical diagnosis of CSD [3, 14]. The abnormal uterine bleeding, chronic endometritis, pelvic pain, secondary infertility, scar pregnancy and other symptoms caused by CSD have seriously affected the quality of life of childbearing age women, even endangering the life safety of pregnant women [7, 15]. Therefore, effective treatment measures for CSD are urgently needed in clinical practice.

Until now, the etiology of CSD is unclear, and there are no unified criteria for its treatment [16]. The treatment modalities currently being employed include medical therapy and surgery treatment. Drug therapy includes short-acting contraceptives, traditional Chinese medicine, the levonorgestrel intrauterine sustained-release systems etc. It is mainly suitable for the short-term treatment of patients without fertility requirements, and can effectively improve the vaginal bleeding symptoms of CSD patients. However, the recurrence rate after medication discontinuation is high,, and the treatment cycle is long, which may lead to unsatisfactory long-term efficiency if the patient's compliance is poor [10]. So, drug therapy is often recommended as an adjuvant way for CSD. Surgery has a share in CSD patients whose symptoms seriously affect their daily life or have the desire for reproduction. The purpose of surgery is to eliminate defect lesions, reduce the accumulation of substances, facilitate the discharge of blood and secretions, thereby improving symptoms, reducing postoperative complications, and ascending the life quality of CSD patients [8].

Surgical methods mainly include hysteroscopy, laparoscopy, and transvaginal repair [17, 18]. Moreover, some scholars have found that hysteroscopy-guided natural orifice repair could also be a feasible alternative for the treatment of defect [19]. The above methods have their own advantages and disadvantages, and different ways may have different therapeutic effects on the clinical manifestations and re-pregnant results of CSD patients. In clinical practice, individualized treatment plans should be formulated based on the patient's symptoms, indications, and fertility requirements. In this study, we analyzed the hysteroscopic resection and laparoscopic defect repair on the long-term improvement of menstruation and the outcomes of re-pregnancy in CSD patients, so as to provide the reference for the patients' treatment selection.

Hysteroscopic resection can directly locate the position of the CSD in the uterine, remove the scar tissue at the edge of the defect, eliminate the structure that hinders menstrual blood flow, which is conducive to the outflow of accumulated material inside the isthmocele. At the same time, the electrodes can cauterise the hyperplastic endothelial tissue and blood vessels at the bottom of the diverticulum, and reduce the formation of secretion in the diverticulum, so as to further eliminate the clinical symptoms [20, 21].

A retrospective study found that the presence of abnormal uterine bleeding in CSD may be associated with increased local angiogenesis at the scar defect [22]. Cauterising the abnormal mucosal tissue and the hyperplastic blood vessels within the isthmocele, not only can decrease the bleeding caused by the surgery itself, but also can improve the internal environment of the defect, thus achieving the therapeutic purpose. Dou et al. [23] retrospectively analyzed the clinical data of 99 patients with CSD and conducted follow-up. The results showed that hysteroscopic surgery can effectively improve the symptoms of menstrual extension caused by CSD. In addition, one research analysed 85 CSD patients who underwent hysteroscopic surgery and found a significant reduction in post-menstrual spotting bleeding symptoms and an evidential improvement in the quality of sexual activity through a questionnaire at 6 months postoperatively [24]. These all showed that hysteroscopic resection has a remarkable positive impact on the physical and psychological health on quality of life of CSD patients.

Currently, most scholars believe that this surgical method is only suitable for non-severe CSD patients with residual myometrial thickness ≥ 3 mm [25–27]. In our study, 74 non-severe CSD patients accepted hysteroscopic resection, and the symptoms of abnormal uterine bleeding had significantly improved in all the patients after the operation. In the postoperative follow-up, 19 patients with re-pregnancy did not suffer from labour complications such as placenta accreta, cesarean scar pregnancy and uterine rupture. Although there was no significant change in postoperative RMT in hysteroscopic surgery group, patients had better treatment results, higher re-pregnancy rate and lower complication rate than laparoscopic surgery group. Based on the above results, we can consider that hysteroscopic diverticulectomy for the treatment of non-severe CSD patients is safe and effective, and has no obviously adverse effects on postoperative re-pregnancy.

Laparoscopic defect repair can expand the surgical field of view, comprehensively explore the patient's pelvic and uterine conditions, and perform surgery under direct vision, which is beneficial to discovering abnormal lesions and accurately locating them. It can treat the existing uterine fibroids and pelvic adhesions together, so then improve the pelvic and uterine environment, and increase the postoperative pregnancy rate [28]. Besides, the surgical procedure of removing the isthmocele and then performing bilateral docking and suturing effectively reconstructed the anatomical structure of the defect, increased the residual myometrium thickness, and increased the safety of re-pregnancy [29, 30].

A system review showed that laparoscopic surgery can effectively improve abnormal uterine bleeding caused by CSD. Meanwhile, it can also reduce the risk of miscarriage, premature birth, and uterine rupture in re-pregnant patients for the repair of the myometrium [8]. In addition, Zou et al. [31] found that laparoscopic surgery can correct the retroverted uterus, which is beneficial for the discharge of menstrual blood and reduces intrauterine fluid accumulation. Moreover, it not only reduces the degree of uterus retroflexion, but even corrects the uterus into an anterior or flat position, which reduces the tension in the lower segment of the uterus and increases the blood perfusion at the incision site, thus facilitating the healing of the wound. 80 CSD patients in our research underwent laparoscopic defect repair, and the operation was successfully completed in all patients without serious complications occurred. The postoperative residual myometrium thickness significantly increased than before, which would greatly raise the safety of re-pregnancy. Furthermore, in the postoperative follow-up, the menstrual bleeding days was observably shorter, and the rate of re-pregnancy was equally not low.

Nevertheless, compare to the hysteroscopic operation, laparoscopic surgery is more invasive, and it has longer surgical duration, more intraoperative bleeding, and higher incidence of postoperative complications, accordingly resulting in relatively longer hospital stay and higher treatment cost for CSD patients. Besides, the result of this study also showed that the postoperative re-pregnancy rate in the laparoscopic surgery group was lower than that in the hysteroscopic surgery group. Thus, it is reasonable to think that hysteroscopic resection is safer and more economically advantageous in improving the patient's symptoms and increasing the re-pregnancy rate than laparoscopic defect repair.

It is worth noting that there are still some shortcomings in this study. As it was a retrospective study, some patients were not included in the experiment due to incomplete medical records and non-cooperation with follow-up, which may led to bias in the results. Furthermore, the sample size of re-pregnancy patients in this research was small, which may correspondingly lower the representativeness of the analysis of postoperative re-pregnancies outcomes in CSD patients. Hence, a mass of prospective studies with larger samples and long-term follow-up are still needed to investigate the clinical efficacy of different methods for treating CSD.

Conclusions

In summary, for the treatment of CSD patients, the best surgical method should be selected based on the patient's specific situation and requirements. This study shows that both hysteroscopic resection and laparoscopic defect repair have good clinical effects on improving clinical symptoms of non-severe CSD patients. However, the therapeutic effect of hysteroscopic surgery is actually

more considerable than that of laparoscopic surgery. Furthermore, from the perspectives of safety and healthy economics, hysteroscopic resection also has the advantages of minimal trauma, shorter surgical time, shorter hospital stay, lower treatment costs, faster postoperative recovery, lower incidence of postoperative complications and higher re-pregnancy rate. Therefore, we believe that hysteroscopic surgery is safe and effective for non-severe CSD patients, and has clinical recommendation value.

Abbreviations

CSD	Cesarean scar defect
RMT	Residual myometrium thickness
BMI	Body mass index
CS	Cesarean section
AUB	Abnormal uterine bleeding
ART	Assisted reproductive technology
IVF-ET	In vitro fertilization embryo transfer
TVUS	Transvaginal ultrasound

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Author contributions
All authors contributed to the study. Shiyu Cheng wrote first draft of the manuscript. Han Gao and Yanli Li proposed and designed the study. Xin Li, Tingzhu Meng and Dan Teng performed the data analysis. Mei Du and Dongqin Deng validated the analytical methods. Jing Liu, Xiyan Ouyang and Lingna Chai collected the material and data. Jie Shi and Han Gao critically revised the work. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Data availability
The original contributions presented in the study are included in the article, further inquiries can be directed to the first author.

Declarations

Ethics approval and consent to participate
This is an observational and retrospective research, and both the patients and their families signed the informed consent form to participate in the study. The study adhered to the Declaration of Helsinki. The Health Research Ethics Committee of Maternal and Child Health Hospital of Hubei Province approved the study.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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