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# Clinical analysis of the preoperative condition and operative prognosis of post-cesarean section scar diverticulum: a case series

<https://doi.org/10.1515/jpm-2020-0008>

Received January 7, 2020; accepted July 8, 2020; published online August 10, 2020

## Abstract

**Objectives:** Post-cesarean section scar diverticulum (PCSD) is a long-term sequela of cesarean section (CS). The aim of this study was to evaluate the clinical utility of PCSD scoring criteria, and also retrospectively investigate the efficacy and fertility of two different surgical methods in 304 patients with PCSD.

**Methods:** A total of 304 PCSD patients who underwent hysteroscopy or combined hysteroscopy and laparoscopy (referred to as laparoscopy) in our hospital from 2016 to 2018 were retrospectively analyzed. Preoperative condition was analyzed by the PCSD scoring criteria and its influencing factors were explored. The efficacy, its influencing factors and pregnancy success rate of the two different surgical methods on PCSD was also analyzed after 6- and 12-months follow-up.

**Results:** PCSD was more severe (high score) in patients who experienced caesarean section with one of the following conditions: age >30 years old, without medical indications or retroflexed uterus. The postoperative efficacy of patients subjected to hysteroscopy or laparoscopy was 81.25 and 89.47% (after 6 months), and 79.53 and 87.50% (after 12 months), respectively. Hysteroscopic surgery was better for PCSD patients who had fewer CS and thicker residual muscle layer and worse for PCSD patients with a longer distance of incision defect to the end of the cervix. Postoperative fertilization showed that pregnancy success rate of patients subjected to hysteroscopy or laparoscopy was 56.2 and 50%, respectively.

**Conclusions:** The PCSD scoring is an effective method for assessing the severity of PCSD, and hysteroscopy and

laparoscopy are effective modalities for PCSD. Hysteroscopy is also an option for patients with fertility needs.

**Keywords:** combined hysteroscopic and laparoscopic; factors influencing treatment efficacy; hysteroscopy; PCSD scoring.

## Introduction

Post-cesarean section scar diverticulum (PCSD) is a long-term complication after cesarean section (CS). Because the incision after CS healed poorly, a diverticulum connecting to the uterine cavity is formed with the scar tissue at the lower end of the diverticulum, blocking the outflow of menstrual blood. Thus, the menstrual blood accumulates in the diverticulum and is delivered after menstruation, gradually leading to clinical manifestations of abnormal uterine bleeding (AUB), dysmenorrhea, secondary infertility and so on [1]. In recent decades, the number of CS has been rising globally [2–5]. According to the latest data, the CS rate in China has risen to 54.5% in 2011 [6]. With the full liberalization of the national second-child policy, the vast majority of women with scared uterus still choose CS when they are pregnant again, thereby significantly increasing the number of CS and the incidence of PCSD. Therefore, the diagnosis and treatment of PCSD have gradually received extensive attention.

At present, there is no unified standard for the classification and grading of PCSD [7]. In 2013, Tower proposed a relatively comprehensive PCSD scoring standard [8], which includes five indexes namely the Residual myometrial thickness (RMT) of PCSD, Percentage of myometrium remaining, Patient's menstrual condition, Number of CS, and number of scars. After classifying and assigning scores of each index, the sum score of the indexes was used for grading PCSD. In this study, we, for the first time, applied the PCSD scoring criteria to assess the severity of patients' PCSD and explore the risk factors that influence the score with the aim to validate the clinical relevance of the PCSD scoring system.

The current two major surgical treatments of PCSD, hysteroscopy and combined hysteroscopic and laparoscopic, have been extensively compared for their advantages,

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disadvantages and efficacy [9, 10]. However, which surgical modality is better for what kind of PCSD patients is still under debate. In this study, we collected patients' information as well as their follow-up data at six months and one year to investigate the efficacy of hysteroscopy and combined hysteroscopy and laparoscopy (referred to as laparoscopy) treatment of PCSD patients and the factors influencing their efficacy. At the same time, we also followed up the reproductive outcomes of patients with fertility requirements after PCSD to investigate the impact of two type of surgical on fertility.

The present study aimed to assess the clinical utility of PCSD scoring criteria, as well as retrospectively investigated the efficacy and fertility of hysteroscopy and combined hysteroscopy and laparoscopy treatment of PCSD patients and the factors influencing their efficacy.

## Materials and methods

### Research subjects

The study was conducted at the Department of Obstetrics and Gynecology, The Third Xiangya Hospital of Central South University, Changsha, China. The study protocol was approved by the Ethical Committee at the Third Xiangya Hospital of Central South University. We carry out a retrospective analysis of data relating to 304 patients with symptomatic post-cesarean section diverticulum who underwent either combined hysteroscopic and laparoscopic or hysteroscopic between January 2016 and June 2018. Patients were included if they (1) had symptomatic of AUB including Prolonged post-menstrual bleeding, Metrorrhagia or bleeding intermenstrual after CS or relapse after drug treatment failure or withdrawal, (2) the

presence of a monographically and hysteroscopic documented diverticulum, and (3) the exclusion criteria included Patients had possible pathological conditions for abnormal vaginal bleeding such as submucosal uterine fibroids, endometrial polyps, endometritis, and gynecological tumors.

### General information and disease history

Patients' general information and disease history were collected including preoperational age, the age of CS, the interval between two CS, the timing of CS, the cause of CS, the number of CS, menstruation before and after CS, whether the diverticulum has a flap function, whether there is blood in the diverticulum, and the biopsy results of diverticulum intima.

### B-ultrasound data collection

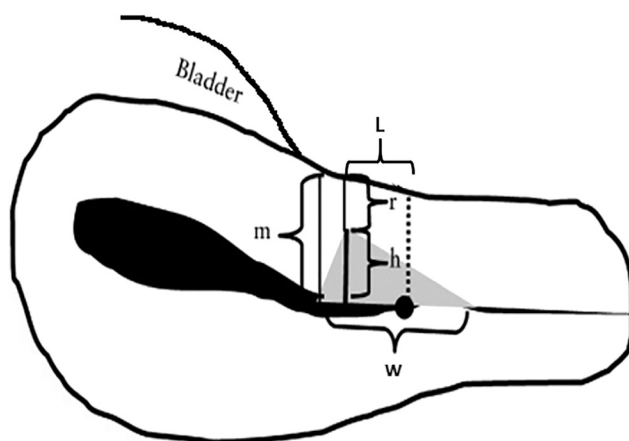
Data were collected by the same chief physician of the Department of B-ultrasound according to the measurement method proposed by Osseir [11] for patients with PCSD under Three-dimensional (3D) color doppler ultrasound (Figure 1), including the position, length, width and height line of uterine, the Residual myometrial thickness (r), the full-thickness adjacent to defect (m), the incision defect width (w) and height (h), as well as the distance of the diverticulum to the cervix internal oral (l).

### PCSD scoring and grading

PCSD was analyzed based on the PCSD scoring criteria shown in Table 1 and graded based on the scores (Table 1).

### Surgical treatments

All patients underwent the surgical in their follicular phase. Hysteroscope were conducted under general anesthesia, and patients were placed in dorsal lithotomy position. Hysteroscopy was performed with a continuous perfusion hysteroscope using 5% mannitol at distention pressure of 80–100 mmHg and unipolar annular electrodes to cut the scar tissues. The incisional diverticulum was observed using a hysteroscope with a diameter of 4.5 mm. After dilation, an 8 mm resectoscope was used to remove the scar



**Figure 1:** A schematic diagram of B ultrasonic measurement. The thickness of the remaining myometrium (r); The thickness of the myometrium close to and fundal to the defect (m); The width of the defect (w); The height of the defect (h); The distance of the diverticulum to the cervix internal oral (L).

**Table 1:** The PCSD scoring.

	3 points	2 points	1 point	0 point
Thickness of remaining myometrium (mm)	TVUS $\leq$ 2.2		TVUS > 2.5	
Myometrium remaining (%)	<20	20–50	>50	
No. of distinct scars			>1	1
No. cesarean section deliveries			>1	1
Menstrual pattern			Abnormal	Normal

TVUS, transvaginal ultrasound.

tissue and trim the lower edge tissue to promote blood flow. Spherical electrode electrocoagulation was performed to coagulate endometrial tissue, and the operation was ended when no obvious bleeding from the wound was observed.

Combined laparoscopy and hysteroscopy surgery was performed under general anesthesia. Patients were placed at the Trendelenburg (head-down) position. The position and size of PCSD were determined by placing a hysteroscope into the uterine cavity. After clearly positioning, the muscular wall of the diverticulum was excised with an ultrasonic scalpel and the uterine muscle wall and serous layer were intermittently sutured. Hysteroscopy was performed again to examine the uterine cavity and confirm whether the shape and structure of the uterine cavity returned to normal. Cefoxitin prophylaxis was used for 2–3 days after operation to prevent infection.

### Follow up and postoperative efficacy

Postoperative efficacy was assessed by menstrual improvement. At six months and one year after operation, patients were followed up to evaluate their menstrual improvement according to the method proposed by Li et al. [12]. The cure of PCSD was defined as menstrual period <8 d; Improvement of PCSD was defined as that menstrual period is still >8 d, but shortened by >2 d compared with before treatment; Invalid treatment was defined as no change or <2 d shortening of a menstrual period. Based on the above evaluation criteria, patients were divided into menstrual improvement group (cured group + improvement group) and invalid group. The treatment efficacy was calculated using the following formula:

$$\text{Efficacy (\%)} = \frac{\text{total number of cured and improved patient}}{\text{total number of patients}} \times 100\%$$

### Statistical analysis

Statistical analysis was performed using SPSS 19.0 (SPSS for Windows, SPSS Inc., Chicago, IL, USA). Measured data were expressed as mean  $\pm$  standard deviation and analyzed using the *t*-test. Count data were expressed as the percentage and analyzed using the  $\chi^2$  at test level  $\alpha=0.05$ . The factors affecting PCSD score and treatment efficacy were statistically analyzed.  $p<0.05$  was considered as statistically significant. Factors with OR > 1 were considered as risk factors and factors with OR < 1 as protective factors at the test level  $\alpha=0.05$ . Factors that may affect the choice of operative methods were used discriminant analysis.

## Results

### Patients' general information

In terms of the number of CS patients underwent, there were 158 (52.1%), 137 (45.2%), and 8 (2.6%) patients had once, twice and three times CS respectively. In terms of CS indication, there were 89 (37.6%) patients had CS without medical indications (CS upon maternal request), 117

(49.4%) due to maternal factors, 28 (11.7%) due to fetal factors, 3 (1.3%) and for other reasons. In terms of time of CS, there were 184 (81.4%) patients underwent selective CS, 34 (15.0%) had CS during the latent phase of labor, 3.1% (7/304) during the active phase of labor, and 0.4% (1/304) at the second stage of labor.

In terms of intraoperative conditions, 290 (95.7%) patient's diverticulum had valve function to block the outflow of blood and 14 patients not; 296 (97.7%) patients had visible residual hematometra in the diverticulum, and seven had no visible residual hematometra (Table 2).

**Table 2:** Patients' general information.

Preoperative indicators	
Age (mean $\pm$ SD, years)	32.96 $\pm$ 4.13
Clinical manifestations	
Prolonged menstruation, n (%)	285 (93.7%)
Intermenstrual bleeding, n (%)	19 (6%)
Dysmenorrhea, n (%)	14 (4.6%)
Chronic pelvic pain, n (%)	10 (3.2%)
Number of CS	
1, n (%)	158 (52.1%)
2, n (%)	137 (45.2%)
3, n (%)	8 (2.6%)
Age of previous CS when symptoms appear (mean $\pm$ SD, years)	26.53 $\pm$ 4.41
The interval from the previous CS when symptoms appear (mean $\pm$ SD, years)	5.50 $\pm$ 2.81
Average time of when symptoms appear after CS (mean $\pm$ SD, years)	1.22 $\pm$ 2.09
The cause of the previous CS	
Without medical indications factors, n (%)	89 (37.6%)
Maternal factors, n (%)	117 (49.4%)
Fetal factors, n (%)	28 (11.7%)
Other factors, n (%)	3 (1.3%)
The cause of the previous cesarean section when symptoms appear	
Elective, n (%)	184 (81.4%)
Latent phase of labor n (%)	34 (15.0%)
Active phase of labor, n (%)	7 (3.1%)
Second stage of labor, n (%)	1 (0.4%)
Intraoperative situation	
Whether the diverticulum had valve function to block the outflow of blood	
No, n (%)	14 (4.3%)
Yes, n (%)	290 (95.7%)
The presence of bleeding at the incision	
No, n (%)	7 (2.3%)
Yes, n (%)	296 (97.7%)
Pathological examination results	
Endometrium during the secretory period n (%)	14 (5.1%)
Endometrium during the proliferative period, n (%)	261 (94.9%)

## Vaginal B-ultrasound parameters

The incision scar defect due to cesarean section was  $17.89 \pm 30.99$  mm wide and  $7.57 \pm 8.46$  mm high. The RMT at the incision was  $4.84 \pm 2.68$  mm, the percentage of myometrium remaining was  $39.83 \pm 13.04\%$ , and the distance of the diverticulum to the cervix internal oral  $5.59 \pm 2.16$  mm (Table 3). All data were shown as mean  $\pm$  SD.

## PCSD scoring and its influencing factors

Forty-nine (18%) patients had mild PCSD with score of 2–3 and belonged to grade I, 211 (78%) patients had moderate PCSD with score of 4–6 and belonged to grade II, and 11 (4%) had severe PCSD with score of 7–8 and belonged to grade III (Table 4).

Ordered logistic regression analysis of the factors affecting PCSD score of patients showed that age  $>30$  years old (OR=6.46), CS without medical indications (OR=13.30), and the retroflexed uterus (OR=5.13) were a risk factor for high PCSD score of all patients (Table 5).

## Postoperative follow-up and influencing factors of efficacy

In this study, 275 patients were treated with hysteroscopy and 29 patients were with combined laparoscopy and hysteroscopy. Among them, 227 patients were effectively

**Table 5:** Factors influencing PCSD scores.

	B	SE	Wald	p-Value	OR	OR 95% CI
Cesarean section age						
>30	1.865	1.065	3.065	0.080	6.46	(0.80, 52.03)
Cause of caesarean section						
No indication	2.558	1.551	2.720	0.099	13.30	(0.62, 269.89)
Uterus position						
Retroverted	1.636	0.636	6.619	0.010	5.13	(1.48, 17.87)

followed up at 6 and 12 months after the operation. In the hysteroscopic group, treatment efficacy rate was 81.25 and 79.53% respectively after 6 and 12 months follow-up. In the combined laparoscopy and hysteroscopy group, treatment efficacy rate was 89.47 and 87.50%, respectively after 6 and 12 months follow-up. There were no significant differences between the two groups ( $p > 0.05$ , Table 6).

Results of logistic regression analysis showed that after 12 month follow-up, number of CS ( $n=1$ ) and RMT were protective factors (OR = 0.14 and OR = 0.515, respectively). By contrast, the distance of the diverticulum to the cervix internal ora was a risk factor (OR = 1.805, Table 7).

## Discriminant analysis of hysteroscopy and laparoscopy

The discriminant analysis was performed to analyze the possible factors affecting the choice of the two surgical methods, in which “Whether the diverticulum has a flap function ( $X_1$ )” and “percentage of myometrium remaining ( $X_2$ )” were included as independent variables in the

**Table 3:** Three-dimensional (3D) color Doppler ultrasound.

B-ultrasound indicator	
The thickness of the remaining myometrium in the incision (mean $\pm$ SD, mm)	$4.84 \pm 2.68$
Percentage of myometrium remaining (%)	$39.83 \pm 13.04$
The distance of the diverticulum to the cervix internal oral (mean $\pm$ SD, mm)	$5.59 \pm 2.16$
W (mean $\pm$ SD, mm)	$17.89 \pm 30.99$
h (mean $\pm$ SD, mm)	$7.57 \pm 8.47$
The length of uterus (mean $\pm$ SD, mm)	$47.66 \pm 10.12$
The width of uterus (mean $\pm$ SD, mm)	$36.44 \pm 9.61$
The height of uterus (mean $\pm$ SD, mm)	$46.17 \pm 7.95$

**Table 4:** PCSD scoring and grading.

PCSD scoring and grading	Number of patients
Grade I (2–3 scores)	49 (18%)
Grade II (4–6 scores)	211 (78%)
Grade III (7–8 scores)	11 (4%)

**Table 6:** Postoperative follow-up.

	Effective	Non-effective	Efficacy (%)	p-Value
Efficacy at 6 months after operation				
Hysteroscopy	169	39	81.25	p>0.05
Combined hystero- scopic and laparoscopic	17	2	89.47	
Efficacy at 12 months after operation				
Hysteroscopy	101	26	79.53	p>0.05
Combined hystero- scopic and laparoscopic	14	2	87.50	

equation. The obtained discriminant equation was  $\ln(P) = -0.769 + 2.015X_1 - 0.038X_2$ . Including the information of the 304 patients into the discriminant, equation showed that the choice made based on the equation was in accordance with the actual surgical methods adopted for 229 patients, showing a correct rate of 88.76% (Table 8).

## Fertility status follow-up

A total of 79 patients including 73 patients in the hysteroscopy group and six patients in the combined laparoscopy and hysteroscopy group had fertility needs. Among the former, 41 patients were successfully pregnant after 12 months follow-up. Of them, three had unhealthy pregnancies, including one incision pregnancy, one missed abortion, and one spontaneous abortion. Thus, the pregnancy rate was 56.2%. Among the latter, three patients had successful pregnancies, showing a pregnancy success rate of 50%. There was no significant difference in pregnancy success rate between the two surgical methods ( $p > 0.05$ ) (Table 9).

## Discussion

To improve the live birth rate, resulting in a continuous increase in the number of CS in China. Therefore, as a long-term CS complication, the incidence of PCSD also increases. The harm that PCSD brings to women has also received increasing public attention [13, 14].

The mechanism behind the development of PCSD is still unclear, however, it is believed that acquired diverticulum is mainly caused by poor wound healing after

**Table 9:** Fertility status follow-up.

Operation	Pregnancy status	Delivery	Success rate	p-Value
Hysteroscopy	28	13	56.2% (41/73)	>0.05
Combined hysteroscopy and laparoscopy	0	3	50% (3/6)	

cesarean section, with an incidence of 4–9% [15]. Recently, researchers found that the occurrence of PCSD related to multiple factors, which may include the degree of cervical dilatation and the contractile effort of the uterine musculature, leading to thinning at the uterine incision site [16]. It is also possible that some individual conditions may influence the quality of the wound healing process [17, 18].

In this study, we, for the first time, applied the criteria for PCSD scoring to patients and analysis the effect of these factors related to the cause of PCSD on PCSD scoring. The age of CS >30 years old is a risk factor for high score. The reason may be related to that patient's best reproductive age are 27–30 years old, but the specific mechanism needs to be further studied. Cesarean section (CS) without medical indications is a high-risk factor for high score. The reason may be that most non-medical indicators of CS are performed without the contracting, the low uterine segment (LUS) is not fully formed. Thus, it is easy to have a high position incision. Due to the structure differences in cervix and uterus muscle tissues, the upper end of the incision is short and thick, while the lower end is long and thin. Therefore, the chance to have larger diverticulum increases. The retroflexed uterus is also a high-risk factor. Due to the flexion structure of the uterus, the lower part of

**Table 7:** Factors influencing the treatment efficacy of PCSD.

	B	SE	Wald	p-Value	OR	OR 95% CI
Number of cesarean section (n=1)	-4.272	2.055	4.323	0.038	0.14	(0.000, 0.783)
The thickness of the remaining myometrium	-0.664	0.316	4.406	0.036	0.515	(0.277, 0.957)
The distance of the diverticulum to the cervix internal oral	0.591	0.252	5.493	0.019	1.805	(1.102, 2.958)

**Table 8:** Discriminant analysis of hysteroscopy and laparoscopic hysteroscopy.

	B	SE	Wald	p-Value	OR	OR at 95% CI
Whether the diverticulum had valve function to block the outflow of blood (X <sub>1</sub> )						
No valve function	2.015	0.988	4.156	0.041	7.500	(1.081, 52.048)
Percentage of myometrium remaining (X <sub>2</sub> )	-0.038	0.019	3.861	0.049	0.962	(0.926, 0.999)
Constant	-0.769					



the anterior uterine wall is excessively stretched, causing muscle wall ischemia and poor menstrual blood discharge and subsequent intrauterine pressure increase, which ultimately affect the healing of the incision, making it easier to form a larger diverticulum. Wang and Yebovi [7, 19] have shown that the average PCSD depth of the retroflexed uterus was significantly greater than that of the anterior. Our results show that the PCSD score criteria can be more appropriate to explain the condition of PCSD, and are in line with the actual clinical conditions. Therefore, this study provides medical evidence to promote the clinical use of PCSD criteria.

Among the factors affecting the hysteroscopic efficacy, the number of CS ( $n=1$ ) is a protective factor: the efficacy of hysteroscopy was better for PCSD patients with fewer cesarean sections. Wang et al. [19] showed that an increase number of CS is a risk factor for the formation of the large diverticulum, which in turn affects the efficacy of hysteroscopy. The reason may be patients receiving multiple CS had thin and poor elastic uterine scar. When separating the myometrium during the operation, both sides are easy to be torn, leading to increased bleeding. Therefore, the more times CS, the higher the risk for poor healing [20].

The RMT represents the distance from the incision to the serosal layer of the uterus [8]. In related studies, the RMT is an important index to measure the size of the diverticulum [21, 22]. In our study, PCSD patients with thicker RMT had better efficacy. This is likely due to two reasons. First, PCSD with thicker RMT had a smaller volume of diverticulum. The RMT  $>3$  mm can be used as a good indicator of scar healing after the CS, the volume of the diverticulum will be smaller [23], so that the efficacy is better. Second, PCSD with thicker RMT is safer to use hysteroscopy. Some scholars have found that when using a bipolar electrode, the RMT should  $>2$  mm, while when using a unipolar electrode, the RMT should  $>5$  mm. Therefore, the RMT less than the above value is a factor causing uterine perforation and bladder damage. Hysteroscopic surgery is effective and safe only when the remaining myometrium of PCSD patients is maintained at a certain thickness. However, the specific RMT needs to be studied in prospective studies.

The distance of the diverticulum to the cervix internal oral in this study represents the location of PCSD in the LUS. It was found that this distance is a risk factor for hysteroscopic treatment. The greater the distance is the upper the diverticulum, the worse efficacy. The reason is that when the site of the CS is selected too high, different myometrium recovery at the upper and lower segments of the uterine incision will result in greater difference in the thickness of the upper and lower myometrium of the

incision, affecting the healing of the uterine incision [1, 2] and leading to the formation of a large diverticulum. Therefore, the upper the PCSD is located, the worse the efficacy of the hysteroscopic treatment.

Our study used the discriminant equation to analyze the factors influencing the choice of the two surgical. This equation suggests that a gynecologist may need to consider the choice of surgical approach from the percentage of remaining myometrium and whether the diverticulum has function as a flap or not. Discriminant analysis including the percentage of remaining myometrium further validated the importance of the RMT for hysteroscopic treatment of PCSD. The second important point of hysteroscopic treatment of PCSD is to remove the flap function of the diverticulum. Including the criterion of the flap function of the diverticulum as an independent variable in the discriminant equation indicated to a certain extent that the discriminant equation has certain clinical guidance. The use of discriminant analysis for selection of surgical approach is an innovation of the study. The main purpose of the study is to remind clinicians to rationally use clinical data to analyze the patient's condition so as to realize personalized treatment. The discriminant equation obtained by performing discriminant analysis with a larger sample size in the two groups will be more clinically meaningful.

Currently, there is controversy over the choice of surgical treatment for PCSD patients who have fertility needs. Some scholars believed that hysteroscopic could not only not increase the RMT, but also weaken the resistance of the remaining myometrium [24, 25]. Therefore, hysteroscopic is not recommended for patients with fertility needs [13]. But Tsuji et al. [10] showed that due to fluid retention in PCSD, hysteroscopic resection and application of cauterization of inflammatory substances on PCSD surface will relieve internal pressure, promoting myometrial regeneration at PCSD, effectively increasing the thickness of the remaining myometrium and improving the lower uterine segment structure, all of which could be used to treat PCSD patients with fertility needs if their RMT is  $\geq 2.5$  mm. In hysteroscopic group, pregnancy rate was 56.2% (41/73). With the extension of the follow-up, the pregnancy rate may increase. Our data directly showed that PCSD patients who have fertility needs could be treated successfully with hysteroscopy.

Given the current high cesarean section rate, the incidence of PCSD is increasing. Our study with large sample size indicates that hysteroscopic or combined hysteroscopic and laparoscopic for PCSD patients is safe and effective. In addition, the age of CS, retroflexed uterus, and no-medical indications CS are factors influencing PCSD

score, and the RMT, the number of CS, and the distance of the diverticulum to the cervix internal oral are the factors influencing the efficacy of hysteroscopic treatment of PCSD. Among these factors, the RMT and the number of CS affect both PCSD score and efficacy of hysteroscopic treatment of PCSD, revealing that PCSD score has great clinical significance. The data used in this study also showed that hysteroscopy is also suitable for PCSD patients with fertility needs. A discriminant equation was proposed to guide the choice of surgical methods in clinics for PCSD patients.

In order to reduce the incidence of PCSD, it is more important to take precautions for the increasing trend of CS. Therefore, the concept of reasonable mode of delivery needs to be advocated. Meanwhile, in the clinical practice, diagnosis, treatment strategies and individualized treatment plans should be standardized. The study also has disadvantages. First, it is a retrospective study. Second, although the sample size of this study is relatively large in the research on PCSD, there is bias. If we can further adopt a prospective study with a larger sample size from multiple centers, the results will be more instructive.

**Acknowledgments:** Our clinical research would not have been possible without the help of all the doctors who helped to collect the original data, along with permission from the participants for ongoing research. The authors would like to express the deepest appreciation to participants who participated in this study by providing their valuable information.

**Research funding:** None declared.

**Author contributions:** All authors have accepted responsibility for the entire content of this manuscript and approved its submission.

**Competing interests:** Authors state no conflict of interest.

**Informed consent:** Informed consent was obtained from all individuals included in this study.

**Ethical approval:** The study protocol was approved by the Ethical Committee at the Third Xiangya Hospital of Central South University.

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