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CLINICAL ARTICLE

Obstetrics

Incidence and ultrasonographic characteristics of cesarean scar niches after uterine closure by double-layer barbed suture: A prospective comparative study

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Abstract

Objective: To compare the ultrasonographic features of uterine scars and clinical symptoms after cesarean delivery (CD) using barbed and conventional smooth sutures.

Methods: This case–control study enrolled women who underwent primary CD at 37 weeks of pregnancy or later. The uterus was closed using either double-layer unidirectional barbed suture or conventional double-layer smooth suture. Ultrasound scans of the uterine scar and evaluations of menstrual patterns were performed at 6, 12, and 24 months after surgery.

Results: In all, 102 patients underwent uterine closure with barbed suture, while 135 patients underwent smooth suture. At 6 months, patients in the barbed group had a lower incidence of uterine niches (20.2% vs 32.6%) that were also shallower in depth ($P < 0.001$). Lower incidence of niches was also observed in the barbed group at 12 and 24 months ($P = 0.043$ and 0.048, respectively). At these two follow-up times, the smooth group had a higher number of patients reporting postmenstrual spotting ($P < 0.05$) and more postmenstrual spotting days per month ($P < 0.050$).

Conclusion: The use of double-layer barbed suture during CD was associated with a lower incidence of scar niches and a more favorable menstrual pattern compared with the use of smooth suture.

KEYWORDS
barbed suture, cesarean scar defects, dysmenorrhea, fishbone suture, monofilament suture, postmenstrual spotting, uterine niches

1 | INTRODUCTION

Cesarean delivery (CD) is the most performed surgical procedure worldwide, and its rate is rising globally.[1] There has been growing awareness of short- and long-term morbidity following this procedure, due to the high number of CDs over the last two decades.[2] Most postoperative sequelae, such as placenta accreta spectrum (PAS) disorders and uterine rupture, have been also related to the uterine suturing technique.[3]

In 25%–50% of cases, uterine niches (also called "uterine scar defects"), defined as a disruption of the myometrium in the uterine scar, can be observed at ultrasound 6–12 months after a CD.[4]

Uterine niches have been associated with prolonged menstrual bleeding, postmenstrual spotting, and an increased risk for obstetric complications in subsequent pregnancies, including uterine rupture and PAS disorders.[5]

Transvaginal sonography (TVS), with or without saline or gel contrast, magnetic resonance imaging, or hysteroscopy can examine uterine niches. Transvaginal ultrasound should be considered the first-line tool as it is widely available and not expensive.[6] The use of gel or saline contrast sonography (sonohysterography) or three-dimensional dimensional (3D) reconstructions can improve the characterization of uterine niches. In 2019, an international group of experts reached a consensus through a modified Delphi procedure to guide a detailed TVS evaluation of uterine niches.[7]

Growing evidence suggests that the surgical technique used to close the uterine wall during CD may influence scar healing.[8] Although many comparison studies have been carried out (i.e., single-layer closure vs double-layer suture, locked vs unlocked suture, or continuous vs interrupted suture), a definitive conclusion about the optimal closing technique to prevent subsequent uterine scar defects and following placental abnormalities cannot be drawn.[8]

A barbed suture is a monofilament suture with barbs that allow self-anchoring while maintaining tissue approximation without the need for surgical knots.[9] In the last 10 years, barbed sutures have been proposed to close the hysterotomy during CD. A systematic review with meta-analysis showed that the use of a barbed suture during CD may lead to significant advantages in terms of reduced surgical time and need for additional hemostatic sutures, without increasing morbidity or estimated intraoperative blood loss compared with conventional smooth (monofilament/multifilament) suture.[10] Because a barbed suture provides constant tension on tissue, which improves bleeding control,[9] its use may lead to improved uterine wall healing following CD, therefore also reducing the formation of uterine scar defects (considered a surrogate endpoint for future uterine rupture and abnormal placentation).[4,5] However, the impact of barbed sutures on uterine wall healing after a CD has not been analyzed.

The present study aims to compare the ultrasonographic characteristics of the uterine scar and the clinical symptoms following CD performed with barbed and conventional smooth sutures.

2 | MATERIAL AND METHODS

This was a single-center case–control study that enrolled women with singleton pregnancies who underwent primary CD at 37 weeks or later of pregnancy. This study was performed by the Unit of Gynecology and Obstetrics, IRCCS Ospedale Policlinico San Martino (Genoa, Italy), in collaboration with Piazza della Vittoria 14 Srl (Genoa, Italy). The study was conducted between March 2019 (first women enrolment) and July 2022 (last follow-up visit).

The primary outcome was to compare the postoperative ultrasonographic characteristics of the uterine wall scar in the short and long term following uterine closure during CD, using double-layer barbed or smooth sutures. The secondary outcomes were to compare short- and long-term patient symptoms (menstrual pattern and dysmenorrhea) and to analyze intra- and postoperative complications associated with the use of these two sutures.

The exclusion criteria for this study were active labor (with regular uterine contractions and cervical dilatation >4 cm) at the time of CD, CD performed before 37 weeks of pregnancy, concomitant surgical procedures during the CD (i.e., tubal sterilization), a previous abdominal surgery (with the exception of appendectomy) including a CD or other laparotomic/laparoscopic uterine surgical procedure (i.e., myomectomy), a previous diagnosis of Müllerian uterine anomalies, and evidence of PAS disorders or placenta previa.

During the CD, a low transverse hysterotomy was closed using either a double-layer unidirectional barbed suture or a conventional double-layer smooth suture. The use of a barbed suture was offered to all the patients who consented to take part in this study. Women were informed about previous evidence regarding the use of barbed sutures in uterine surgery[11] and during CD.[10] Patients who agreed to receive the treatment were included in the barbed group and those preferring to use the conventional suture were allocated to the smooth (control) group. Sonographers and statisticians who participated in this study were blinded to the suturing technique.

Baseline characteristics (i.e., maternal age, body mass index [BMI, calculated as weight in kilograms divided by the square of height in meters], previous vaginal birth, gestational age at CD, and indication for CD) were collected after the study inclusion. Intraoperative characteristics (i.e., uterine closure and total operative times, the need for additional sutures, and blood loss) related to the CD were collected before patients' discharge.

Participants were invited to undergo ultrasound examinations at 6, 12, and 24 months after the surgical procedures. At each follow-up visit, participants were asked about their menstrual patterns and the presence of dysmenorrhea. Postmenstrual bleeding was defined as when patients experienced bleeding for 1 day or longer in the form of spotting at least 2 days following the end of menstruation. During the follow-up visits, data about postoperative complications were collected.

2.1 | Surgical procedures

The CDs were performed by three surgeons (F.A., M.G.C., S.F.) with extensive experience in gynecological and obstetric surgical procedures (each performing over 500 procedures/year).

All patients received prophylactic intraoperative antibiotics (cefazolin 2 g or clindamycin 900 mg in case of penicillin allergy). All patients underwent a standard transverse hysterotomy on the lower uterine segment, with a correct approximation of the cutting edges. The hysterotomy was closed either by a double-layer unidirectional barbed suture (V-LocTM 180, 0, needle: 48 mm, ½ circle; Covidien) or a conventional double-layer smooth suture (Monosyn® gluconate monofilament, 1-0, needle: 48 mm, ½ circle; Braun). In the case of the double-layer unidirectional barbed suture, the uterine wall

was closed with the previously described "fishbone" technique[12] (Figure 1).

This approach involves closing the hysterotomy with two barbed suture layers, each starting from opposite ends of the transverse uterine incision. On both sides, a full-thickness suture pass is made just beyond the end of the incision, then the needle is inserted into the loop to anchor it. The first layer includes a minimal decidua (<5 mm) and about two-thirds of the inner myometrium, spaced 1 cm apart, until reaching the opposite end of the surgical incision. The second layer involves spacing the sutures 1 cm apart and including the parts of the uterine wall not involved in the first layer (the external third of the myometrium and the serosa). Each pass of the needle resembles a "figure-of-eight," with its main axis perpendicular to the hysterotomy. It starts from the serosa about 5 mm from the cranial edge of the incision, passes through the myometrium, emerges above the incision, re-enters the myometrium on the caudal side, and ends by passing through the serosa. The first layer aims for hemostasis and to bring the incision edges together, while the second layer ensures introflexion of the suture. After completing the two layers, both sutures are cut close to the uterine wall. In the case of the smooth suture, the first layer of the hysterotomy was closed with a continuous unlocked suture, excluding the endometrial layer, while the second layer was closed with a continuous unlocked suture. If necessary, a hemostatic suture using a polyglactin 910 suture (Coated VICRYL®, 1-0, needle: 48 mm, ½ circle; Ethicon) was performed in both groups, either as a single pass or as a "figure-of-eight" with a knot tie.

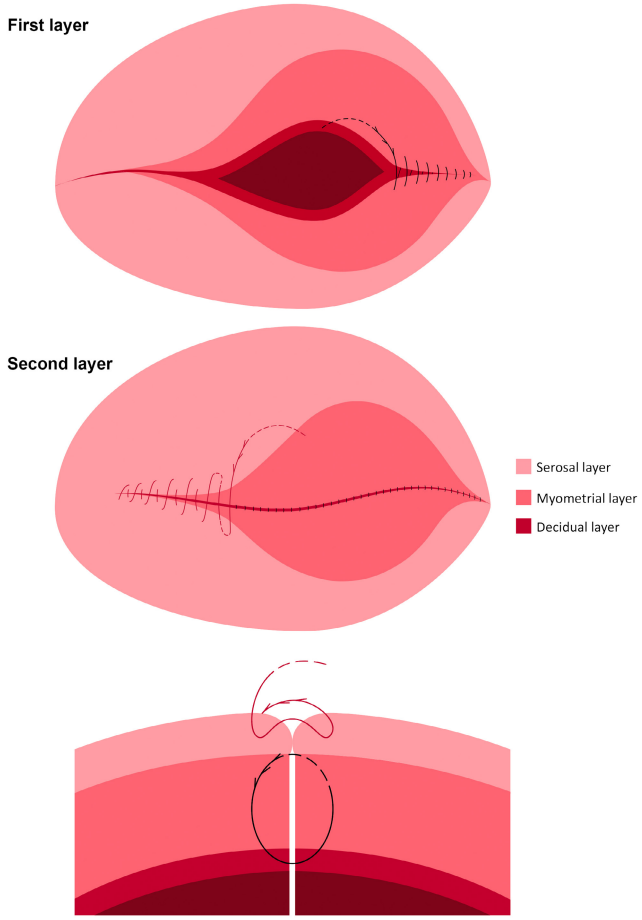

FIGURE 1 Double-layer barbed suture according to the "fishbone" technique.

Uterine breach closure time was defined as the time required to perform the double-layer suture, also including that needed to do any additional hemostatic sutures. Total operation time was defined as the time from skin incision to skin closure. Total blood loss was estimated at the end of the procedure by weighing the dry laparotomy pads (standard weight 23 g each) used by the surgeons at the incision site, with the increase defined as the amount of bleeding during closure. Postoperative complications were recorded at the follow-up visits and classified according to the Clavien–Dindo classification.

2.2 | Ultrasonographic evaluation

Two gynecologists with experience in gynecological imaging (F.B. and G.E.; with more than 1500 scans/year) performed the ultrasonographic evaluations using Voluson E6 and E10 machines (GE Medical Systems) that were equipped with transvaginal probe.

As previously reported,[13] during the ultrasonographic exams, the sector angle was adjusted to obtain an optimal uterine resolution. After visualizing the entire uterus, the focal depth was set at the level of the uterine CD scar. If there was relevant shadowing due to scar tissue in the anterior uterine wall, the transvaginal probe was positioned in the posterior fornix to evaluate if there was improvement in the field of interest. The entire uterus was scanned in the sagittal plane from right to left and in the transverse plane from the cervix to the fundus to obtain an optimal view and to exclude any uterine abnormalities before focusing on the analysis of the cesarean scar. The CD scar is almost always visible and appears as a hypoechoic indentation in the myometrium where the surgical incision was performed.[14] A uterine niche is defined as an indentation at the site of the CD scar with a depth of at least 2 mm, according to the modified Delphi criteria.[13]

The presence of niche branches (a branch is defined as a thinner part of the main niche that is directed towards the serosa and has a smaller width than that of the main niche visible in the sagittal or transverse plane) was identified. Three types of niches were distinguished: (1) simple niche (no branches), (2) simple niche with one branch, and (3) complex niche (more than one branch).

The length, depth, and width of each niche were evaluated by excluding the endometrium from each measurement. The size was measured in a straight line parallel to the uterine cavity/cervical canal, its depth was calculated as the vertical distance from the base of the defect to the myometrium at the apex of the niche, and its width was measured in the transverse plane at its largest point, which could be at the base or apex of the defect. The niche volume was estimated using virtual organ computer-aided analysis (VOCAL; GE Medical Systems) by obtaining a sequence of 20 sections of each niche around a fixed axis after each 9° rotation from the previous

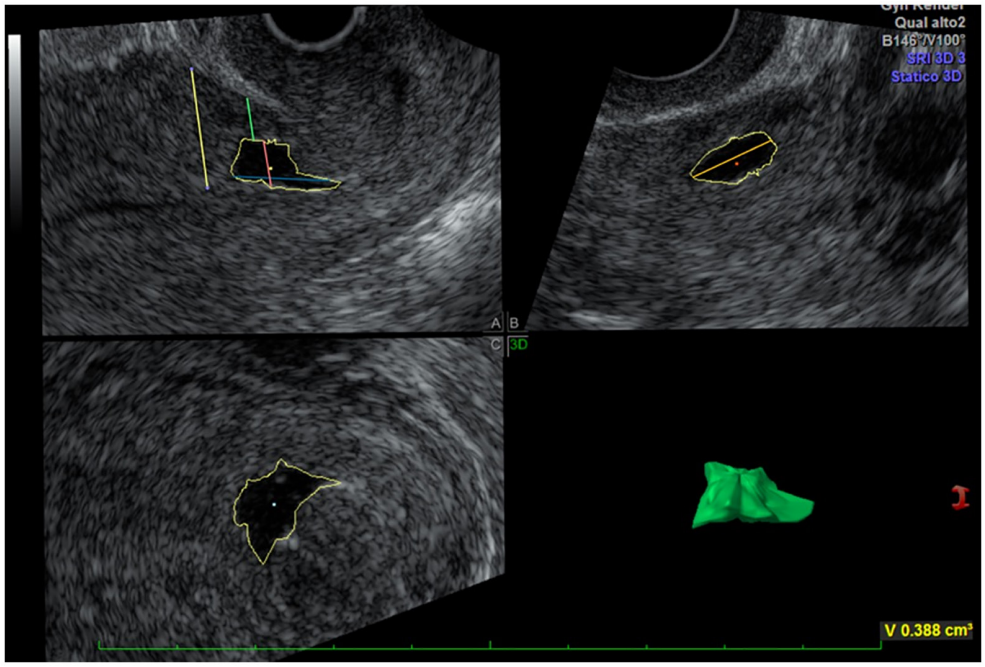

FIGURE 2 Evaluation of a large niche using three-dimensional (3D) ultrasound and virtual organ computer-aided (VOCAL) analysis to estimate its main dimensions and volume. Length of niche (represented by blue line): 12.1 mm; depth of niche (represented by red line): 5.8 mm; width of niche (represented by orange line): 11.0 mm; residual myometrial thickness (represented by green line): 5.3 mm; and adjacent myometrial thickness (represented by yellow line): 11 mm. The volume of the niche calculated by VOCAL analysis is 388 mm^3.

section. The contour of the object of interest was drawn manually using the ultrasound machine's rollerball cursor (Figure 2), as done in our previous study[15] and reported by other authors in this setting.[16]

Residual myometrial thickness (RMT) was evaluated in the sagittal plane by measuring where the myometrium was thinnest, from the top of the main niche to the serosa, perpendicular to the border with the serosa. Adjacent myometrial thickness was measured at the border of the niche base perpendicular to the cervical canal, where the myometrium was thickest. The distance between the niche and the vesicovaginal fold was evaluated from the top of the main niche where RMT was the smallest, and the distance between the niche and the external cervical meatus was measured parallel to the cervical canal.

2.3 | Ethical approval

Ethical approval from our local ethics committee was obtained through the institutional review board (prot. BARB-CSCAR; ethical approval CER Liguria 1159/2020). Participants in the study provided written informed consent. This study followed the STROBE checklist for case–control studies (Appendix S1).[17] The trial has been registered on ClinicalTrials.gov under the identifier NCT04825821.

2.4 | Statistical analysis

Data are presented as mean ± standard deviation (SD), median (range), or percentage (%), as appropriate. Dichotomous data were compared using the χ^2 test with continuity correction. Group comparisons were made using a *t*-test, assuming equal variances within each group. For data that did not meet the assumptions of the parametric test, the Mann–Whitney *U*-test was used. Logistic regression analysis was performed to predict a dependent variable by analyzing the relationship between one or more independent variables and was quantified as odds ratio (OR) and its 95% confidence interval (CI). A *P*-value of less than 0.05 was considered significant.

The statistical analysis was done using SPSS version 24.0 (IBM Corp., Armonk, NY, USA).

The sample size calculation was based on a recent meta-analysis by Di Spiezio Sardo et al.,[8] which reported a 46% risk of developing a uterine niche after a double-layer suture during CD. A sample size of 150 patients (77 per group) provides 80% power to detect a 50% relative reduction in the primary outcome from a baseline risk of 46%, with a two-sided type 1 error of 5%.

3 | RESULTS

3.1 | Demographic characteristics

In all, 247 patients were eligible for enrollment in this study: 102 women underwent CD with barbed sutures, and 135 women with smooth sutures (Figure 3). Both groups had a similar mean (±SD) age (36.3 ± 4.1 vs 36.6 ± 4.5; $P = 0.327$) and gestation age at CD (39.6 ± 1.0 vs 39.5 ± 1.2; $P = 0.184$). Table 1 lists the other demographic characteristics of the study population.

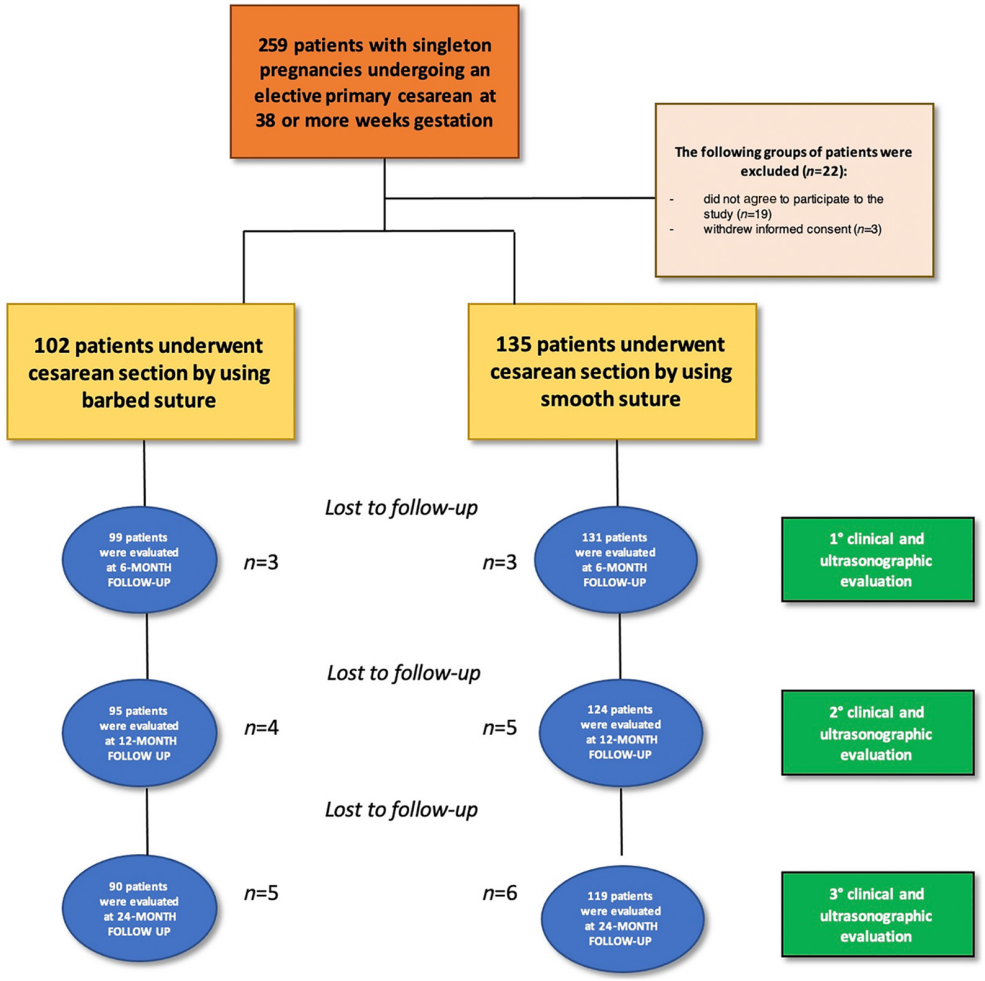

FIGURE 3 Flow chart of the study.

In terms of surgical outcomes, the total operation time was similar in the barbed and smooth groups (41.5 ± 6.1 vs 40.1 ± 5.7 min, $P = 0.070$); however, there was a higher number of patients in the smooth group who required an additional hemostatic suture (30.4% vs 49.6%; $P < 0.001$). There were no differences in postoperative complications between the two study groups. Table 2 provides a summary of other surgical outcomes for the study population.

3.2 | Ultrasonographic findings

At the 6-month follow-up, there was a lower incidence of niches in the barbed suture group (20.2%, $n = 20/99$) than in the smooth suture group (32.6%, $n = 43/132$; $P = 0.037$). However, the incidence of simple niches with one branch and complex niches was not significantly different between the two suture groups (2.0% vs 2.3%, $P = 0.896$; 3.0% vs 4.5%, $P = 0.556$). In the barbed group, the niches had a significantly lower mean depth (2.6 ± 0.8 vs 3.7 ± 1.0 mm, $P < 0.001$), but a similar mean length (3.5 ± 3.3 vs 3.6 ± 3.2 mm^3, $P = 0.822$) and width (3.6 ± 1.0 vs 3.9 ± 3.7 mm^3, $P = 0.745$). Additionally, patients with niches in the smooth group had a significantly higher mean RMT (4.7 ± 1.2 vs 3.4 ± 1.2 mm, $P < 0.001$). At the 12-month follow-up, there was a significantly lower incidence of niches in the barbed suture group (14.9%, $n = 14/94$ vs 26.2%, $n = 33/126$; $P = 0.043$), which was also confirmed at the 24-month follow-up (14.4%, $n = 13/90$ vs 25.6%, $n = 31/121$; $P = 0.048$). At both follow-up times, the mean RMT and niche depth remained higher in the smooth suture group ($P < 0.05$; see Table 3). At the 24-month follow-up, the niches in the barbed group also had a significantly lower length (2.6 ± 0.8 vs 3.7 ± 1.0 mm; $P < 0.001$). Figure 4 shows the volume of niches at the three different follow-up visits.

In a longitudinal evaluation, 6/94 (6.4%) patients in the barbed group and 9/126 (7.9%) patients in the smooth group resolved their niches between the 6- and 12-month follow-up visits, with no significant intergroup difference ($P = 0.806$). The respective results between the 12- and 24-month follow-up visits were 1/90 (1.1%) in the barbed group and 1/121 (1.7%) in the smooth group ($P = 0.842$).

3.3 | Clinical symptoms

In the analysis of clinical symptoms, potential confounders such as concomitant gynecological disease (i.e., evidence of endometriosis

and uterine fibroids) and other demographic characteristics potentially affecting the pattern of the menstrual cycle (Table 1) at baseline were taken into consideration and controlled for.

Clinical symptoms related to the menstrual cycle were evaluated in 67.1% (n = 155/231), 91.8% (n = 202/220), and 96.2% (n = 203/211) of patients who were not amenorrheic at 6-, 12-, and 24-month follow-up visits, respectively. The difference in the use of contraceptive hormonal options (estroprogestins and progestins) was not statistically significant between the barbed and the smooth suture groups at 6-month follow-up (27.2% vs 28.9%; $P = 0.745$), 12-month follow-up (38.3% vs 41.3%; $P = 0.399$), and 24-month follow-up (42.2% vs 39.7%; $P = 0.900$).

At the 6-month follow-up, 6 (9.2%) patients in the barbed group and 10 (11.1%) patients in the smooth group experienced postmenstrual spotting, with no significant intergroup difference ($P = 0.704$). Furthermore, the mean VAS symptoms for dysmenorrhea were similar between the two groups (2.8 ± 1.1 vs 3.3 ± 1.6; $P = 0.362$). However, at the 12-month follow-up, a higher number of patients reported postmenstrual spotting (23.7%, n = 27/114 vs 12.5%, n = 11/88; $P = 0.044$) and a higher number of postmenstrual spotting days/month (2.2 ± 1.0 vs 1.5 ± 0.9; $P = 0.032$) in the smooth suture group.

Patients with an ultrasonographic visualization of a uterine niche with RMT < 3 mm in both the barbed (OR 4.32, 95% CI 4.12–4.63) and smooth (OR 4.67, 95% CI 4.24–4.89) suture groups had a higher number of bleeding days/month ($P < 0.001$ and $P < 0.001$, respectively). Additionally, patients in the barbed suture group with dysmenorrhea reported a lower mean intensity on the VAS scale (3.0 ± 0.9 vs 4.0 ± 1.3; $P = 0.009$). These findings were confirmed at the 24-month follow-up. Table 4 reports the clinical symptoms investigated in the study population.

TABLE 1 Demographic characteristics of the study population.

Demographic characteristics	Barbed suture (n = 102)	Smooth suture (n = 135)	P-value
Age (years) (mean ± SD)	36.3 ± 4.1	36.6 ± 4.5	0.327
Ethnicity (n [%])			0.411
Caucasian	92 (90.2%)	120 (88.9%)	
Asian	1 (0.9%)	2 (1.5%)	
African	2 (2.0%)	3 (2.2%)	
Hispanic	7 (6.9%)	10 (7.4%)	
Body mass index (mean ± SD)	26.9 ± 2.8	26.2 ± 3.0	0.438
Smoking (n [%])	5 (4.9%)	6 (4.4%)	0.251
Previous vaginal delivery (n [%]) (median [range])	0 (0–2)	0 (0–2)	0.476
Dysmenorrhea before pregnancy (n [%])	15 (14.7%)	14 (10.4%)	0.313
Postmenstrual bleeding before pregnancy (n [%])	8 (5.9%)	9 (8.8%)	0.392
Gestational age at CD (weeks) (mean ± SD)	39.6 ± 1.0	39.5 ± 1.2	0.184
Indication for CD (n [%])			
Fetal macrosomia	22 (21.6%)	27 (20.0%)	0.421
Twin pregnancy	6 (5.9%)	8 (5.9%)	
Intrauterine growth restriction	21 (20.6%)	30 (22.2%)	
Breech and malpresentation	41 (40.2%)	54 (40.0%)	
Other	12 (11.8%)	16 (11.9%)	

Abbreviation: CD, cesarean delivery.

4 | DISCUSSION

This is the first study to compare the impact of double-layer barbed sutures and conventional double-layer smooth sutures on uterine scar defects and clinical symptoms following CDs. Our results showed that at 6, 12, and 24 months after the surgeries, there was a lower rate of uterine niche visualization at ultrasound with barbed

TABLE 2 Intraoperative characteristics of the study population.

	Barbed suture (n = 102)	Smooth suture (n = 135)	P-value
Uterine closure time (min) (mean ± SD)	6.1 ± 1.8	5.9 ± 1.7	0.492
Total operation time (min) (mean ± SD)	41.5 ± 6.1	40.1 ± 5.7	0.070
Additional hemostatic suture (n [%])	31 (30.4%)	67 (49.6%)	0.003
Estimated blood loss during uterine closure (mL) (mean ± SD)	239.7 ± 45.3	257.0 ± 87.2	0.069
Estimated total blood loss (mL) (mean ± SD)	381.6 ± 147.2	389.6 ± 171.7	0.707
Postoperative hemoglobin[a] (mg/dL) (mean ± SD)	11.2 ± 1.3	11.3 ± 1.4	0.800
Need for transfusion (n [%])	4 (3.9%)	7 (5.2%)	0.647
Hospital stay (days) (median [range])	3 (2–9)	3 (2–11)	0.347
Complication C–D I–II (n [%])	5 (4.9%)	7 (5.2%)	0.922
Complication C–D III–IV (n [%])	4 (3.9%)	4 (3.0%)	0.686

Abbreviation: C–D, Clavien–Dindo.

[a]Evaluated 2 days following the surgical procedure.

TABLE 3 Ultrasonographic characteristics at follow-up visits.

	Barbed suture (*n* = 99)	Smooth suture (*n* = 132)	*P*-value	Barbed suture (*n* = 94)	Smooth suture (*n* = 126)	*P*-value	Barbed suture (*n* = 90)	Smooth suture (*n* = 121)	*P*-value
	6 Months			12 Months			24 Months		
Uterine niche (*n* [%])	20 (20.2%)	43 (32.6%)	0.037	14 (14.9%)	33 (26.2%)	0.043	13 (14.4%)	31 (25.6%)	0.048
Length[a] (mm) (mean ± SD)	3.5 ± 3.3	3.6 ± 3.2	0.822	3.0 ± 2.6	3.7 ± 2.7	0.322	2.7 ± 2.3	3.7 ± 2.7	0.127
Depth[a] (mm) (mean ± SD)	2.6 ± 0.8	3.7 ± 1.0	<0.001	2.3 ± 0.6	3.9 ± 1.0	<0.001	2.3 ± 0.6	3.7 ± 1.1	<0.001
Width[a] (mm) (mean ± SD)	3.6 ± 1.0	3.9 ± 3.7	0.745	3.3 ± 1.0	4.0 ± 1.9	0.227	3.2 ± 0.8	4.0 ± 2.0	0.144
Volume[a] (mm) (mean ± SD)	24.7 ± 57.8	28.2 ± 55.9	0.819	9.0 ± 10.5	31.4 ± 55.2	0.135	6.3 ± 3.6	26.1 ± 44.2	0.116
RMT[a] (mm) (mean ± SD)	4.7 ± 1.2	3.4 ± 1.2	<0.001	4.5 ± 1.1	3.2 ± 1.2	0.002	4.8 ± 0.8	3.4 ± 1.3	0.001
AMT[a] (mm) (mean ± SD)	7.3 ± 0.8	7.1 ± 0.9	0.222	7.1 ± 0.6	7.1 ± 0.7	0.850	7.1 ± 0.5	7.1 ± 0.7	0.911
Distance from VVF[a] (mm) (mean ± SD)	3.6 ± 0.9	3.4 ± 0.7	0.118	3.6 ± 1.0	3.3 ± 0.6	0.247	3.6 ± 1.1	3.5 ± 0.7	0.695
Distance from ECM[a] (mm) (mean ± SD)	3.7 ± 0.5	3.5 ± 0.7	0.236	3.6 ± 0.5	3.5 ± 0.6	0.614	3.6 ± 0.5	3.5 ± 0.6	0.622

Abbreviations: AMT, adjacent myometrial thickness; ECM, external cervical meautus; RMT, residual myometrial thickness; VVF, vesicovaginal fold.

[a]Evaluated in patients showing uterine niches.

sutures (−12.4%, −11.3%, and − 11.2%, $P<0.05$); furthermore, patients in the barbed suture group had better niche characteristics, with higher RMT and lower niche depth observed at all three follow-up times, and a shorter length at 24 months post-surgery (Table 3).

The use of barbed sutures was first proposed in laparoscopic gynecological surgery by Greenberg et al.[18] More than 10 years ago, our research group performed a randomized controlled study evaluating the use of barbed sutures for closing the uterine wall during laparoscopic myomectomy.[11] Their use significantly reduced the time for uterine wall repair, overall operating time, and intraoperative blood loss compared with conventional smooth sutures[11,19]; at the same time, it also addressed the technical challenge of tying laparoscopic intracorporeal surgical knots. Since 2016, our group has employed barbed sutures for a specific double-layer uterine closure during CD (referred to as the "fishbone suture"; which was previously described[12]; Figure 1).

Several factors appear to contribute to the development of uterine niches, such as a low incision that involves cervical tissue, which has mucus-producing glands that can interfere with wound healing, concurrent surgical interventions that increase the formation of adhesions, and, importantly, a suboptimal suturing technique. In terms of surgical factors, the location of the hysterotomy on the lower uterine segment, the type of suture and the specific technique used to close the uterine wall, and the number of previous CDs may all play a significant role.[20] Additionally, uterine scar healing is also influenced by patient-related factors such as a genetic predisposition or comorbidities such as coagulation disorders and diabetes.[20]

Uterine niches have been linked to gynecological symptoms such as abnormal or postmenstrual spotting and chronic pelvic pain, as well as potential obstetric complications such as scar pregnancy and uterine rupture.[5] Another concern is the risk of abnormal placentation at the inner side of the CD scar. The most widely accepted theory about the cause of PAS diseases is that a defect in the endometrial–myometrial interface may prevent normal decidualization in the uterine scar area, leading to abnormal deep anchoring villi and trophoblast infiltration in subsequent pregnancies.[21] Given these considerations, it is important to develop strategies to reduce the incidence of uterine niches following CD.

In a recent meta-analysis by Di Spiezio Sardo et al.,[8] the incidence of uterine niches, as well as uterine dehiscence and rupture in subsequent pregnancies, was found to be similar for single- and double-layer closures of the uterine incision. In our study, the incidence of niches in the smooth suture group 6 months postoperatively was lower than that reported in the aforementioned meta-analysis (32.6% vs 43.0%).[8] However, that review included patients undergoing double-layer suture with both monofilament and multifilament sutures, without specifying whether the decidual layer was excluded. In this regard, the use of multifilament suture and inclusion of the decidual layer has been linked to a higher rate of uterine niches.[22] Additionally, the studies included in this review had heterogeneous definitions of niches and different postoperative ultrasonographic evaluation timing. By contrast, in the control (smooth) group, all surgical procedures were performed by three

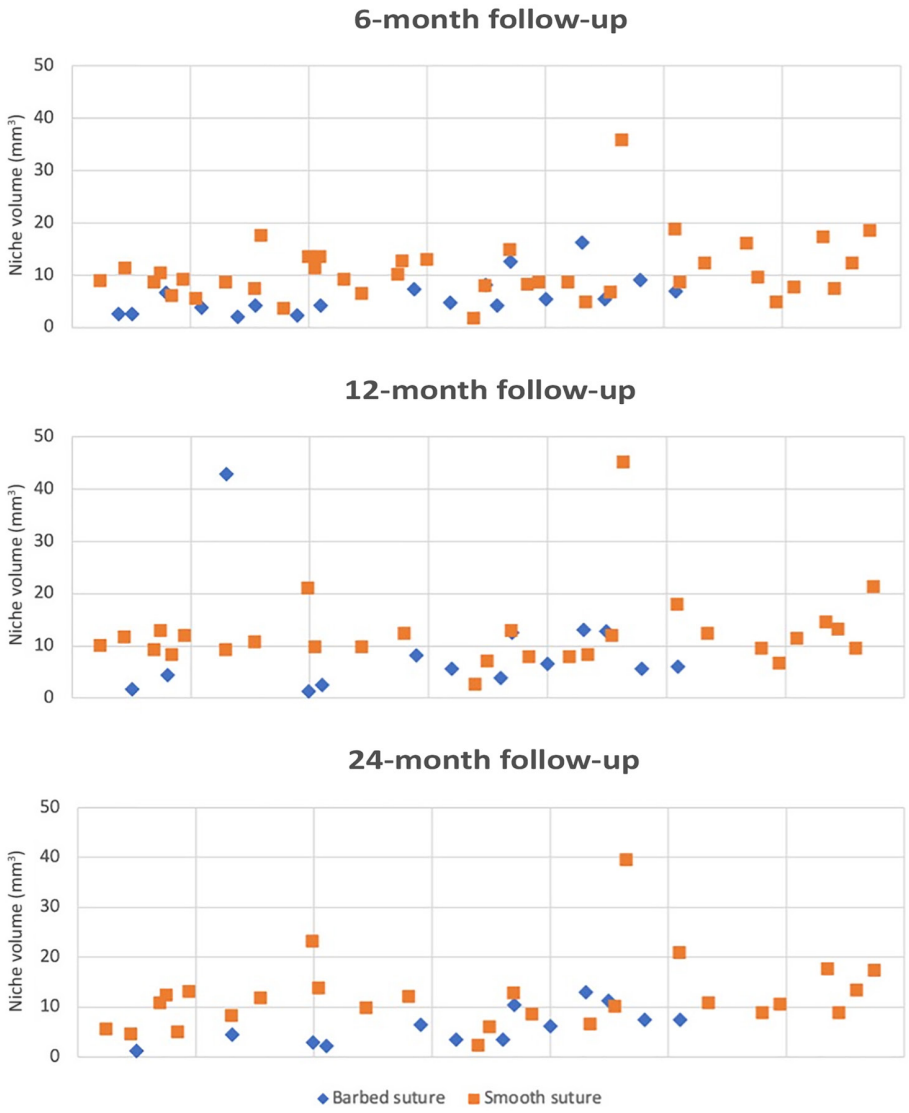

FIGURE 4 Scatter plot depicting the volume of niches at various study follow-up visits. The following number of niches with a volume greater than 50 mm^3 were excluded from the graphical representation: four for the smooth suture and two for the barbed suture at the 6-month follow-up; four for the smooth suture at the 12-month follow-up and four for the smooth suture at the 24-month follow-up.

skilled operators using a standardized double-layer uterine wall closure, excluding the decidual layer and using a monofilament suture. This may explain the lower incidence of niches compared with the meta-analysis.[8]

Residual myometrial thickness is another indirect measure of uterine scar healing and a surrogate outcome to predict adverse obstetrics outcomes, particularly uterine rupture, related to the uterine scar,[4] which has been reported as higher in the case of double-layer uterine sutures.[5] A cut-off of RMT less than 3 mm is used to identify large niches, which have a higher risk of uterine dehiscence and cause more frequent gynecological symptoms. RMT also influences the surgical approach for treating niches; the hysteroscopic approach is considered for niches with RMT greater than 3 mm, while a laparoscopic or vaginal approach is more suitable for those with RMT less than 3 mm.[23] Our study showed higher RMT in the barbed suture group at 6, 12, and 24 months of follow-up (mean +1.3, +1.3, +1.4 mm, respectively; $P < 0.05$), which persisted until the end of the study. In addition, ultrasound visualization of a uterine niche with RMT less than 3 mm predicted a higher number of bleeding days per month in both the barbed and smooth suture groups ($P < 0.001$).

A previous systematic review and meta-analysis showed a lower need for additional hemostatic sutures in patients undergoing CD with barbed sutures compared with smooth sutures, with similar total operative time, need for blood transfusions, and length of postoperative stay.[24] These results were confirmed in our study (Table 2). However, this trial was not powered to detect slight differences in postoperative complications, so the results did not show a clear advantage of one technique over the other.

Most studies comparing uterine closure techniques during CD do not focus on investigating gynecological symptoms. A double-blind, randomized, multicenter trial reported that double-layer uterine closure after the first CD is not superior to single-layer closure in terms of postmenstrual spotting and dysmenorrhea.[25] Until now, no long-term studies have evaluated gynecological

TABLE 4 Clinical symptoms at follow-up visits.

	Barbed suture ($n=65$[a])	Smooth suture ($n=90$[a])	*P*-value	Barbed suture ($n=88$[a])	Smooth suture ($n=114$[a])	*P*-value	Barbed suture ($n=87$[a])	Smooth suture ($n=116$[a])	*P*-value
	6 Months			12 Months			24 Months		
Dysmenorrhea (*n* [%])	11 (16.9%)	20 (22.2%)	0.362	16 (18.2%)	22 (19.3%)	0.840	18 (20.7%)	23 (19.8%)	0.880
Dysmenorrhea, (VAS scale 0–10) (mean ± SD)	2.8 ± 1.1	3.3 ± 1.6	0.327	3.0 ± 0.9	4.0 ± 1.3	0.009	3.1 ± 1.0	4.0 ± 1.3	0.0433
Postmenstrual spotting (*n* [%])	6 (9.2%)	10 (11.1%)	0.704	11 (12.5%)	27 (23.7%)	0.044	10 (11.5%)	28 (24.1%)	0.022
Postmenstrual spotting (days/month)[b] (mean ± SD)	1.0 ± 0.0	1.3 ± 0.5	0.226	1.5 ± 0.9	2.2 ± 1.0	0.032	1.4 ± 0.7	2.3 ± 1.3	0.052
Total bleeding (days/month) (mean ± SD)	4.4 ± 1.0	4.2 ± 1.0	0.096	4.5 ± 1.2	5.0 ± 1.6	0.049	4.8 ± 1.2	5.3 ± 1.9	0.030

Abbreviation: VAS, Visual Analogic Scale.

[a]Excluding patients with amenorrhea.

[b]Evaluated in patients experiencing postmenstrual spotting.

complaints after the use of barbed sutures. Our results showed higher rates of postmenstrual spotting (+11.2% and +12.6%; $P<0.05$) and more postmenstrual spotting days per month (mean +0.7 and +0.9 days per month; $P<0.05$) in patients who underwent CD with smooth suture (Table 4). The favorable bleeding pattern and less intense dysmenorrhea observed in the barbed suture group may be due to a lower incidence of deep niches and better uterine wall healing.[14]

In this study, a 6-month ultrasound examination after CD had a high rate of amenorrhoeic patients (32.9%, $n = 76/231$), reducing the potential influence of unfavorable bleeding patterns on the willingness of women to participate (a potential selection bias). An early ultrasonographic assessment also minimizes the confounding effect of endometrial thickness variations during the menstrual cycle, as amenorrhea limits these variations. Another strength of this study is the homogeneity of the study population, consisting of participants who underwent primary elective CD (not in active labor). Additionally, the long follow-up period of 24 months provides an advantage in observing the presence of uterine niches at various points in the healing process after CD, which is typically completed within 4–9 months.[20] Lastly, the detection and characterization of uterine niches were performed in accordance with the latest Delphi consensus on the topic.[7]

A limitation of this study is its single-center, unblinded design without randomization, as women were assigned to different suture types based on their preferences. However, the sonographers and statisticians who performed the analysis were blinded to the closure technique, and the three surgeons who performed the CDs in both groups had similar experience in gynecological and obstetrical procedures (performing more than 500 procedures per year). As patients underwent primary elective CD and were not in active labor (>4 cm of cervical dilatation), these findings may not be applicable to patients in advanced labor who have a very thin lower uterine segment. Additionally, the study compared two different suture materials with different tensile strengths; however, it is possible that other factors, such as the specific use of "fishbone" technique or of a longer tensile strength suture, may have contributed to the differences observed in the results. All these factors raise questions about the external validity of the findings. Another final limitation of this study is that, as previously mentioned and reported in the literature,[12] the evaluation of uterine niches provides an indirect measure of uterine healing and is only a surrogate outcome for predicting uterine rupture or other adverse outcomes related to the uterine scar. This surrogate endpoint was adopted because uterine rupture and PAS disease are rarer complications.[3] Thus, a study including these endpoints would require a large sample size and would need to be based on a very long-term follow-up.

5 | CONCLUSION

The results of this study suggest that use of a double-layer barbed suture during CD is associated with a lower incidence of scar niche

formation and reduced niche size in patients who develop them. Additionally, the barbed suture group observed a more favorable postoperative bleeding pattern. These findings provide valuable insights into the potential benefits of using barbed sutures in CD for improving uterine healing and reducing postoperative menstrual irregularities.

AUTHOR CONTRIBUTIONS

Study conceptualization and design: Franco Alessandri, Maria Grazia Centurioni, Fabio Barra, Claudio Gustavino, and Simone Ferrero. *Data acquisition and analysis*: Umberto Perrone, Giulio Evangelisti, Claudia Urso, Marco Paratore, Elisabetta Guida, Elisabetta Guida, and Fabio Barra. *Data interpretation of data*: Franco Alessandri, Fabio Barra, Simone Ferrero and Maria Grazia Centurioni. *Writing—original draft*: Fabio Barra, Umberto Perrone, Giulio Evangelisti, Claudia Urso, Marco Paratore, Elisabetta Guida and Alice Nappini. *Writing—review and editing*: Franco Alessandri, Maria Grazia Centurioni, Fabio Barra, and Simone Ferrero. All the authors approved the final version of the manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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