New surgical technique for managing placenta accreta spectrum and pilot study of the "CMNT PAS" study

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INTRODUCTION: The gold standard for treating the placenta accreta spectrum (PAS) is a cesarean hysterectomy, which harms fertility. Another conservative surgical approach allows the uterus to be preserved: one-step conservative surgery. We will compare these two approaches through the "CMNT PAS" study. Before this main study, we conducted a pilot study to determine the required sample size.

STUDY DESIGN: This pilot study, conducted over 31 months, included patients who underwent surgery for suspected PAS based on imaging findings. Participants were divided into the conservative surgery group (CSG: 6 patients) and the Caesarean Hysterectomy Group (control group [CG]: 6 patients). For the CSG, our team adapted the approach described in previous research by Palacios-Jaraquemada.

RESULTS: The primary objective of our study is to ascertain the appropriate sample size for our main investigation on the conservative surgical management of PAS. Concerning the primary outcome, the estimated amount of blood loss was lower in CSG compared to CG, although this difference was not statistically significant (1298.04±556 mL vs 891.051±348 mL, *P*=.159). The mean decrease in hemoglobin (Δ Hb) was 2.8±1.3251 g/dL in the CG group compared to 1.933±1.0614 g/dL in the CSG group (*P*=.240). The mean number of transfused red blood cell units was 3±3.2249 in the CG group and 1.5±1.64317 in the CSG group (*P*=.334).

CONCLUSION: The estimated blood loss between the two groups is not statistically significant. The required sample size is 22 patients.

Key words: conservative surgery, hysterectomy, massive hemorrhage, placenta accreta

Introduction

In recent years, the rate of cesarean sections has risen significantly. Consequently, there has been an increased incidence of the previously rare pathology, placenta accreta, characterized by a defect in decidualization, leading to the absence of a functional decidua.[1] Placenta accreta spectrum (PAS) encompasses three types of abnormal placental attachment, classified based on the depth of invasion into the uterine wall: placenta accreta, where the placenta attaches directly to the myometrium without intervening decidua; placenta increta, characterized by invasion into the myometrium; and placenta percreta, where the placenta penetrates through the uterine serosa and may involve adjacent organs.[2] This pathology is life-threatening, with maternal mortality rates around 7%.[1]

Recent research suggests that problems within the PAS remain undetected before delivery, with as many as two-thirds of cases being discovered after childbirth because of retained placenta.[2] Prenatal diagnosis largely depends on subjective interpretation of sonographic findings, with reported signs varying widely in sensitivity and specificity; we defined these findings for diagnosing PAS as an irregular placental-myometrial interface, loss of the clear zone, and the presence of lacunae.[2]

Cesarean hysterectomy is the gold standard delivery method for women with PAS. However, conservative management approaches, such as leaving the placenta in situ to allow natural resorption, aim to preserve fertility.[1] The use of this approach has been mainly promoted in France to reduce maternal morbidity in cases of placenta percreta.[3] In a 2018 French study, they found that the rates of perioperative and postoperative complications are higher than in the initial reports concerning this conservative treatment and that 86% of delayed hysterectomies were performed in cases of percreta, even though it is supposed to be the best indication for this treatment.[4] In 2004, a new conservative surgical technique, called "one-step conservative surgery," was published.[5,6] A technique that we adopted with some modifications. This technique allows the uterus to be preserved and avoids the complications of leaving the placenta in situ.

This pilot study compared the conservative surgical technique for PAS, developed from a method described in 2004 to cesarean hysterectomy, primarily focusing on estimated blood loss (EBL), to address the lack of data needed for determining the appropriate sample size.[7]

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Why was this study conducted?

This pilot study aims to determine the required sample size for the main "CMNT PAS" study, using estimated blood loss as the primary outcome measure. The lack of comparable studies in the existing literature necessitates this approach.

What are the principal findings?

The required sample size for the "CMNT PAS" study is 22 patients per group.

What contribution does this review make to our existing knowledge?

This is the first prospective study comparing cesarean hysterectomy, the gold standard, with conservative surgical treatment in managing the placenta accreta spectrum.

Methods

This pilot study was part of the broader "CMNT PAS: Centre de Maternité et Néonatologie de Tunis, Placenta Accreta Spectrum" research project. The pilot phase commenced on January 4, 2020, and concluded on August 17, 2022. It was conducted within Department C of the Tunis Maternity and Neonatology Center. The main CMNT PAS study was completed on January 30, 2024, and officially closed on February 2, 2024, after all required data were collected (Figure 1). Importantly, patients from the pilot study were not included in the main study.

The CMNT PAS study is conducted in a level 3 maternity ward with an anesthesia-intensive care team accustomed to massive transfusions[3] (Figures 2 and 3).

Patient recruitment was conducted continuously during the study period from January 4, 2020, to January 30, 2024.

In this pilot trial, a prospective, comparative interventional cohort study was conducted at a single center. The local ethics committee of the Tunis Maternity and Neonatology Center, Tunis, Tunisia, approved our clinical trial under 03102020. It is registered on ClinicalTrials.gov under the identifier NCT06253832, following the WHO 24-item Trial Registration Data Set, version 1.3.1.

The authors affirm that they have no financial assistance or conflicts of interest.

All cases in the study were operated on by a single surgeon who already has expertise in the management of PAS.[8]

Brecher's formula for estimating blood loss calculates the amount of blood lost based on changes in hematocrit levels before and after surgery.[9] In the presence of a clinical context suggestive of PAS, such as a scarred uterus and low-lying placenta, ultrasound, with or without magnetic resonance imaging (MRI), can confirm the diagnosis—especially in cases of placenta percreta—or raise further suspicion. MRI was regularly conducted alongside ultrasonography for planned cesarean deliveries. Nevertheless, ultrasound alone was deemed enough when there was a lack of timely transfer or when patients were in active labor.

A radiologist performed and interpreted the ultrasound scans using criteria such as an irregular placental-myometrial interface, clear zone loss, and placental lacunae.

All patients undergoing elective or emergency cesarean section for suspected PAS on imaging were included in the study after providing written informed consent. Exclusion criteria consisted of successful manual removal of the placenta without significant bleeding and the absence of histologic confirmation of PAS postoperatively. The PAS poses a significant threat to life due to the risk of massive hemorrhage. Consequently, we selected EBL as the primary endpoint of this pilot study. Patients who underwent the Gold standard treatment, cesarean hysterectomy, are included in the control group (CG). The conservative surgery group (CSG) includes patients treated with the new technique based on one-step conservative surgery. Surgical constraints and surgeon assessment determined group assignment. For example, if there is not enough uterine tissue to perform uterine reconstruction or if there is severe hemorrhage, the surgeon will proceed with a hysterectomy.

A sample size of 6 patients per group was chosen arbitrarily, as the primary objective of this pilot study was to gather data for calculating the sample size for a subsequent, more extensive study.

Statistical analysis of the data was conducted anonymously using SPSS version 29.0.2.0. The analytical data were displayed as means (standard deviation) or medians (interquartile range) and analyzed using either Student's *t*

FIGURE 1
Stages of the "CMNT PAS" study.

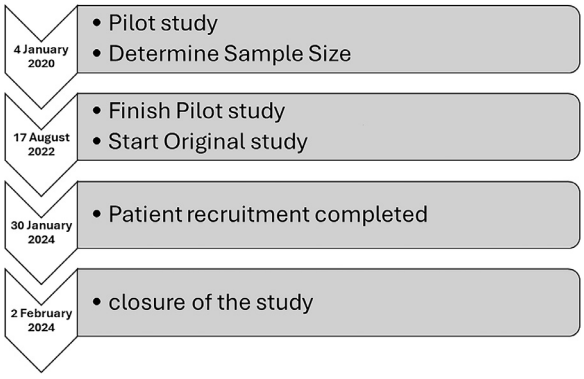

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FIGURE 2
The significance of bleeding in managing PAS is highlighted by the substantial use of surgical drapes and compresses. (A) Cesarean hysterectomy. (B) Conservative surgery for PAS.

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test or Mann–Whitney *U* test, depending on the data distribution. The sample size estimation was carried out using GPower 3.1.9.2 software.[10] The formula used to calculate the required sample size for the subsequent study was based on established statistical methodologies.[11,12]

Modified one-step conservative surgery for PAS

As international guidelines recommend, the term for delivery is 36 weeks gestation and does not exceed 37 weeks.[13] To mitigate the risk of hyaline membrane disease in neonates, dexamethasone was administered in two doses, either 24 hours apart or, when indicated, 12 hours apart. This protocol was chosen considering the reported occurrence of hyaline membrane disease beyond 36 weeks of gestation.[14]

We have included cases of placenta accreta, increta, and percreta.

After appropriate conditioning and monitoring, and under spinal anesthesia, a double-J ureteral stent was placed before performing the cesarean section in cases of placenta percreta.[15]

Upon confirmation of PAS during surgery, the operation is briefly stopped to provide general anesthesia. Implementing this method enables us to circumvent superfluous general anesthesia in the event of a false positive for PAS.

A midline sub-umbilical laparotomy was performed. Adhesiolysis was initiated. The vesicouterine peritoneum was dissected with careful attention to the ligation of newly formed vessels, allowing for the lowering of the bladder.

Placental boundaries are delineated via extrauterine palpation, followed by a transverse hysterotomy performed just above the upper margin of the placenta, as demonstrated in Supplementary Video S1.

Therefore, we have shifted from the often-used fundal hysterotomy[16] in cases with PAS, as this method leads to two uterine incisions (Figure 4), which may complicate the repair process. Instead, we have implemented a single-incision modality that enables the simultaneous removal of the fetus and repair of the uterus (Video S1). As an alternative to ligating the hypogastric or uterine arteries,[17] we opt to use a tourniquet.[8]

We incise the pathological part of the uterine wall facing the placental bed where there are invasion disorders until we reach the healthy tissues (Figure 5). Excision can be done up to a maximum of 2cm above the cervix to allow reconstruction.

We combine the upper and lower uterine segments to perform the initial

FIGURE 3
Macroscopic appearance. (A) Hysterectomy specimen for PAS. (B and C) Placenta increta. (D and H) Placenta accreta. (E–G) Placenta percreta.

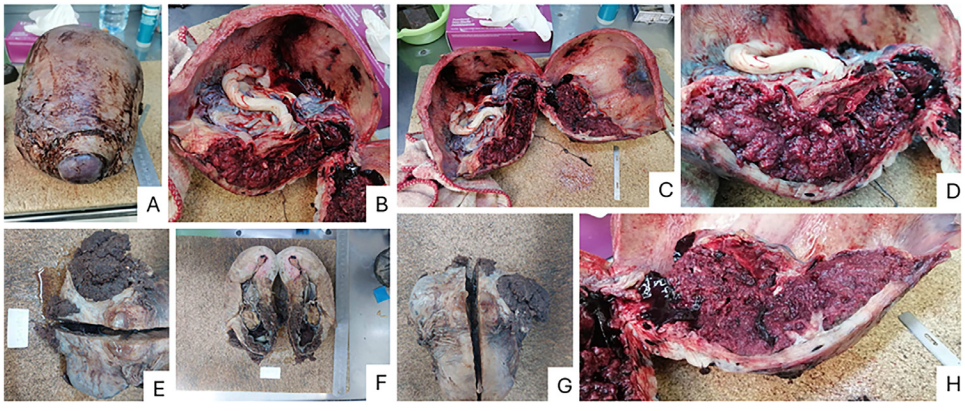

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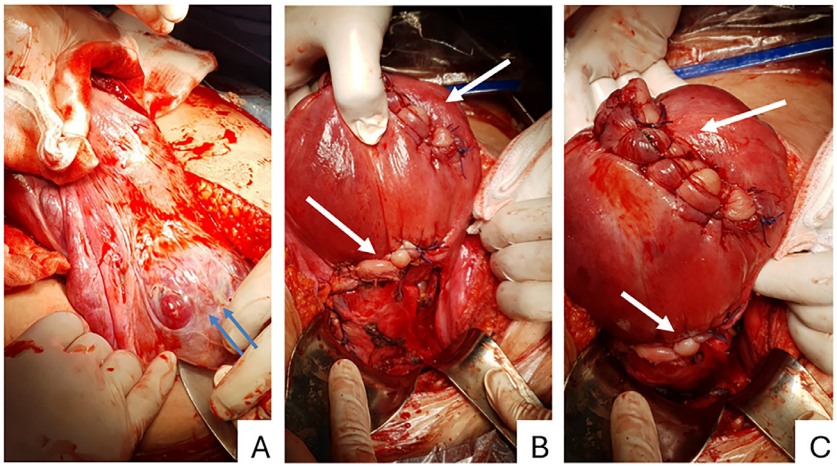
FIGURE 4
Two uterine incisions made after a single-step conservative surgery using fundal hysterotomy. (A) Perioperative aspect of placenta percreta (two blue arrows). (B and C) Results after uterine reconstruction and hysterotomy suturing (white arrows).



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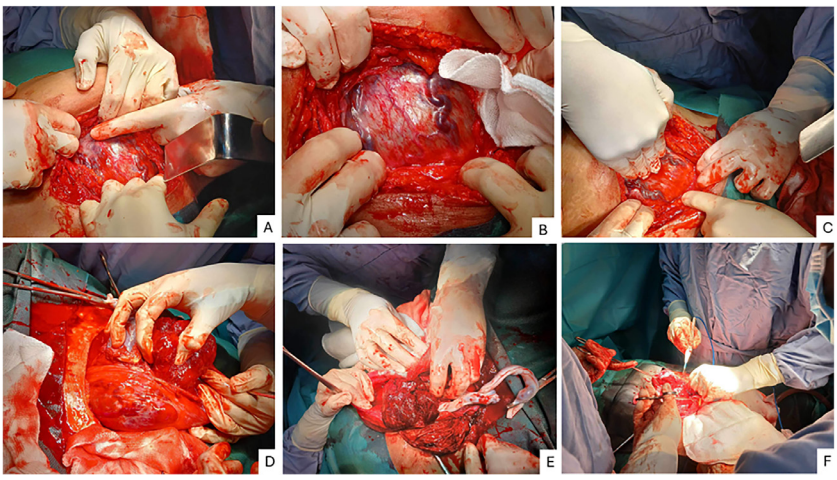
overlock suture. A second layer of sutures with separate stitches reinforces this. If the loss of uterine substance does not exceed 50% of the uterine circumference, reconstruction remains feasible. The tourniquet is removed once the uterine repair is complete. The modified B-Lynch suture technique is systematically performed to ensure adequate hemostasis. After peritoneal washing with saline to verify hemostasis, a Redon drain is placed in the Douglas pouch.[18] Following the surgery, the double J ureteral stent is removed.

Cesarean hysterectomy

We initiate the procedure with spinal anesthesia, and after confirming the diagnosis, we advance to general anesthesia. After a median laparotomy incision, the hysterotomy is performed above the upper edge of the placenta. Following fetal extraction, gentle traction on the clamped umbilical cord is applied to confirm the absence of placental detachment. The placenta is left in situ, and a hysterorrhaphy is performed. As previously described, the bladder is carefully lowered. A tourniquet is applied, which will be removed after the hysterectomy (Video S2).

FIGURE 5
Modified one-step conservative surgery for placenta percreta. (A and B) Identification of Neovascularization. (C) Bladder identification. (D and E) Identification of the myometrial invasion area. (F) Incision of the bed of pathological placental insertion.



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Results

The two pilot study groups were comparable in age, obstetric history (parity and gestity), weight, height, and baseline hemoglobin levels, with no statistically significant differences observed between the groups (Table 1).

The EBL in the CSG was lower than that in the CG, although this difference was not statistically significant (1298.04±556 mL vs 891.05±348 mL, *P*=.159). The required sample size for our forthcoming study is 22 patients, aiming to achieve a power of 80% and an alpha risk of 5%, to detect a minimum reduction of 407 mL in the primary outcome measure, precisely EBL.

The mean decrease in hemoglobin (Δ Hb) was 2.8±1.3251 g/dL in the CG group compared to 1.933±1.0614 g/dL in the CSG group (*P*=.240). The mean number of transfused red blood cell units was 3±3.2249 in the CG group and 1.5±1.64317 in the CSG group (*P*=.334) (Table 2).

In neither group were any maternal deaths reported during the early or late postoperative period.

Only one patient had diagnostic hysteroscopy and laparoscopy at this stage of the trial for fertility purposes. The uterine cavity was free of synechiae but exhibited micropolyp formation and hemorrhagic spots, suggesting chronic endometritis, confirmed by endometrial biopsy using a Novak curette and immunohistochemical analysis of CD138 expression. The right ostium was visualized, while the left ostium was obscured. Laparoscopy with a methylene blue test revealed the presence of omental adhesions on the anterior abdominal wall, particularly at the level of the midline scar, along with proximal obstruction of

TABLE 1
Baseline characteristics

	CG[b] (*n*=6)	CSG[a] (*n*=6)	*P*[Ω]
Age mean (SD)	33.67±3.077	37.17±2.927	.071
Parity mean (SD)	2.83±0.983	4±0.894	.057
Gestity mean (SD)	3.5±1.049	4.83±1.472	.101
Size mean (SD), cm	161±2.366	159.33±1.506	.176
Weight mean (SD), kg	84±4.195	86±4.648	.452
Baseline Hb[c] mean (SD), g/dL	12.8±1.0658	11.483±1.849	.162

[a] Conservative surgery group.; [b] Control group.; [c] Hemoglobin, Ω Student's *t* test for independent samples.
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both fallopian tubes. No organ lesions were reported in the bladder, digestive tract, or ureters; however, one patient in the CSG developed disseminated intravascular coagulation (DIC).

Discussion

Three distinct methodologies have been established for managing the PAS:

1. **American radical approach:** Cesarean hysterectomy is the predominant treatment in the United States. Although effective, it poses significant challenges, particularly in preserving the reproductive capacity of young women.[1,19]
2. **Conservative method:** Primarily used in France, this approach leaves the placenta in situ to minimize surgical intervention. While potentially preserving fertility, it is associated with risks such as hemorrhage, infection, DIC, and a high likelihood of secondary hysterectomy (approximately 22%).[20,21] Additionally, recurrent placenta accreta is at risk in subsequent pregnancies.[22]
3. **One-step conservative surgery:** Initially introduced by Palacios-Jaraquemada in 2004, this novel technique offers the advantage of blood sparing while addressing reproductive concerns. Despite its potential benefits, its adoption remains limited due to perceptions of complexity and a steep learning curve. However, efforts to simplify this procedure, such as stepwise approaches, have demonstrated its feasibility for broader clinical application.[23] Variations such as the Triple P, modified one-step conservative surgery (MOSCUS) techniques reflect ongoing refinements to enhance, blood-sparing techniques safety and efficacy.[24–29]

Our study's focus on a modified one-step conservative method addresses the gap in the literature regarding a simplified surgical alternative for PAS management. This approach seeks to mitigate the complications of radical and conservative methods while maintaining reproductive potential.

Importance of a novel conservative method

The necessity for innovative conservative techniques arises from the limitations of current practices. Radical approaches, while effective at controlling hemorrhage, carry the irreversible consequence of infertility. On the other hand, traditional conservative methods frequently necessitate secondary interventions due to retained placental tissue or infection. By offering a structured, stepwise technique, the MOSCUS aims to reduce surgical complexity and complications while preserving fertility.

In our study, the **EBL** in the CG aligns with values reported in the literature for cesarean hysterectomy. However, it remains significantly higher than EBL observed with MOSCUS and other conservative methods, underscoring the potential benefits of these approaches in reducing intraoperative hemorrhage. For example, the PACCRETA study highlighted reduced blood loss and transfusion requirements with the conservative method, albeit with increased risks of embolization and postpartum complications.[30] These findings emphasize the need for balanced approaches like MOSCUS that minimize both blood loss and long-term complications.

TABLE 2
Comparison of outcomes between groups

	Control group (CG)	Conservative surgery group (CSG)	*P* value
Mean decrease in hemoglobin (Δ Hb) (g/dL)	2.8±1.3251	1.933±1.0614	.240
Mean number of transfused RBC units	3±3.2249	1.5±1.64317	.334
Mean duration of surgery (min)	190±60.663	125±65.34524	.104

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Role of imaging in PAS management

Accurate diagnosis and planning are pivotal in PAS management. Ultrasound serves as the primary imaging tool for identifying at-risk patients, while MRI offers detailed assessments of placental invasion. Recent studies demonstrate the utility of MRI in predicting significant complications, with a proposed threshold of 2.5 cm for myometrial invasion offering a sensitivity of 96%.[31] In our series, MRI played a central role in preoperative planning, providing critical insights into the extent of invasion and anticipated blood loss.[32]

Limitations and future directions

The absence of randomization is a recognized limitation of our study. However, given the severity of PAS and the variability of intraoperative findings, randomization was deemed impractical. Intraoperative decisions often hinge on the severity of myometrial invasion and the extent of hemorrhage, which may necessitate cesarean hysterectomy in some cases.

Population-based observational cohort studies may offer a pragmatic alternative for evaluating PAS management strategies.[30,33,34] Additionally, evidence from classic studies and randomized trials raises questions about the efficacy of traditional interventions, such as bilateral ligation of the internal iliac arteries, due to limited and transient reductions in blood flow.[35,36] These findings further support the need for tailored surgical approaches like MOSCUS that balance efficacy, safety, and fertility preservation.

Conclusion

Our objective in this study is to ascertain the appropriate sample size.

To achieve an EBL reduction of at least 407 mL, we need a sample size of 22 patients.

Patient consent statement

The patients provided written informed consent to participate in the study and to have their images published.

Author contributions

Frikha Hatem, Abir Karoui and Rachid Hentati: Investigation. Hammami Rami and Eya Azouz: Software. Abouda Saber Hassine and Mehdi Khila: Formal analysis. Ben Marzouk Sofiene: Conceptualization. Sana Minjli: Writing—original draft. Aloui Haithem: Methodology. Hayen Maghrebi: Supervision. Chanoufi Mohamed Badis: Validation. ■

Declaration of competing interest

The authors declare no conflicts of interest and received no financial support for this work.

CRediT authorship contribution statement

Hassine Saber Abouda: Formal analysis. **Haithem Aloui:** Methodology. **Eya Azouz:** Software. **Sofiene Ben Marzouk:** Conceptualization. **Hatem Frikha:** Investigation. **Rami Hammami:** Software. **Sana Minjli:** Writing − original draft. **Rachid Hentati:** Investigation. **Mehdi Khila:** Formal analysis. **Badis Mohamed Chanoufi:** Validation. **Abir Karoui:** Investigation. **Maghrebi Hayen:** Supervision. ■

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.xagr.2024.100430.

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