

## CLINICAL ARTICLE

## Obstetrics

# A randomized controlled study comparing two uterine sparing techniques in conservative management of placenta accreta spectrum

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## Abstract

**Objectives:** To compare the efficacy and safety of two uterine sparing techniques in conservative management of placenta accreta spectrum (PAS).

**Methods:** This multicenter randomized controlled study was conducted from January 1, 2017 to December 31, 2020 at two university hospitals. Patients were randomly allocated into two groups; Group 1 was managed by Assar's technique and Group 2 was managed by Shehata's technique. Operative time, blood loss, operative complications (organ or vessel injury), and postoperative complications (early and late) were reported. Success of the technique, units of blood transfusion, and intensive care unit admissions were recorded.

**Results:** Demographic data in both groups were not significantly different. The mean gestational age at the delivery time was 36 weeks in both groups. Operative time was 120 (100–140) minutes and 75 (60–100) minutes in Assar's and Shehata's techniques, respectively ( $P < 0.001$ ). Blood loss was higher in Shehata's technique than in Assar's ( $P < 0.001$ ). Intensive care unit admissions were minimal in both groups. Operative complications were comparable in both groups. The success of Assar's and Shehata's techniques in uterine preservation was 85% and 95%, respectively.

**Conclusion:** Both techniques were safe and successful in uterine sparing. Therefore, we recommend these techniques for conservative management of PAS.

**Clinical trial registration:** The trial was registered on UMIN-CTR and had the unique ID: UMIN000025315 on the following link: [https://center6.umin.ac.jp/cgi-open-bin/ctr\\_e/ctr\\_view.cgi?recptno=R000029120](https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000029120).

## KEYWORDS

Assar technique, conservative treatment, internal iliac artery, morbid adherent placenta, placenta accreta spectrum, placenta previa, Shehata technique

## 1 | INTRODUCTION

Placenta accreta spectrum (PAS) is a spectrum of life-threatening disorders in obstetrics due to their association with massive hemorrhage, severe maternal morbidity, and even mortality. Although several studies have extensively investigated surgical approaches to conserve the uterus, cesarean hysterectomy remains the only radical curative treatment of PAS despite its association with loss of fertility and social and psychological consequences.<sup>1,2</sup>

The incidence of PAS is gradually increasing in parallel with the substantial rise in cesarean deliveries. In the 1980s, the incidence was reported to be 1 per 2500 deliveries, and currently, the American College of Obstetricians and Gynecologists reports a rate of 1 per 533 deliveries.<sup>3</sup> In a national case-control study by Fitzpatrick et al.<sup>4</sup> in the UK, the incidence was reported to be only 1.7 per 10000 pregnancies by the end of 2012.

The classical conservative management of leaving the placenta in situ with or without methotrexate adjuvant therapy was associated with significantly morbid sequelae. This procedure was associated with primary hemorrhage, severe infections, the possibility of reoperation, and delayed hysterectomy up to 9 months after delivery in 58% of cases.<sup>5,6</sup>

Uterine sparing techniques are becoming more popular, and many emerging techniques have been evaluated for safety and efficacy. Conservative procedures were recently explained by FIGO (the International Federation of Gynecology & Obstetrics) in 2018 guidelines. FIGO linked uterine preservation to localized, visualized invasion operated on by experts in teams.<sup>7</sup> Uterine sparing techniques include local resection of the placenta bed,<sup>8,9</sup> different compression sutures,<sup>10-12</sup> pelvic devascularization,<sup>13,14</sup> radiologic intervention methods,<sup>15,16</sup> combined techniques in the form of the one-step procedure,<sup>17</sup> triple-P procedure,<sup>18</sup> and Shehata's simple procedures.<sup>19</sup>

FIGO also recommended managing PAS cases in well-equipped tertiary centers with available blood banks and intensive care units (ICUs) operated by well-trained teams.<sup>7</sup>

Shehata's technique comprises three main steps; bilateral uterine artery ligation at two levels before placental separation, quadruple sutures of the lower uterine segment, and triple-way catheter insertion.<sup>19</sup> Assar's technique comprises uterine and internal iliac artery ligation before placental separation, excision of the placenta and lower uterine segment, and then re-apposition of the cervix to the upper flap.

In this study, we aimed to (1) compare both uterine sparing techniques regarding surgical outcomes and efficacy in uterine preservation in women with PAS, (2) assess if these techniques could replace hysterectomy in the management of PAS, and (3) assess the safety and feasibility of both techniques to be applied in management of PAS.

## 2 | MATERIALS AND METHODS

We used a multicenter, double-armed, single-blinded, non-inferiority randomized clinical trial. It was conducted at Tanta and Benha universities from January 1, 2017 to December 31, 2020.

Informed consent was taken from patients before inclusion in the study. Data privacy was preserved and maintained throughout the study duration by numbers and codes instead of patients' names. This study was approved before recruitment by the Ethical Committee of the Faculty of Medicine, Tanta University, and was given the following code: 31188/11/16. Moreover, this trial was registered on UMIN-CTR and had the unique ID of UMIN00025315. The trial is available at the following link: <https://upload.umin.ac.jp/cgi-bin/ctre/ctrsetcoreg.cgi?Recptno=R000029120>.

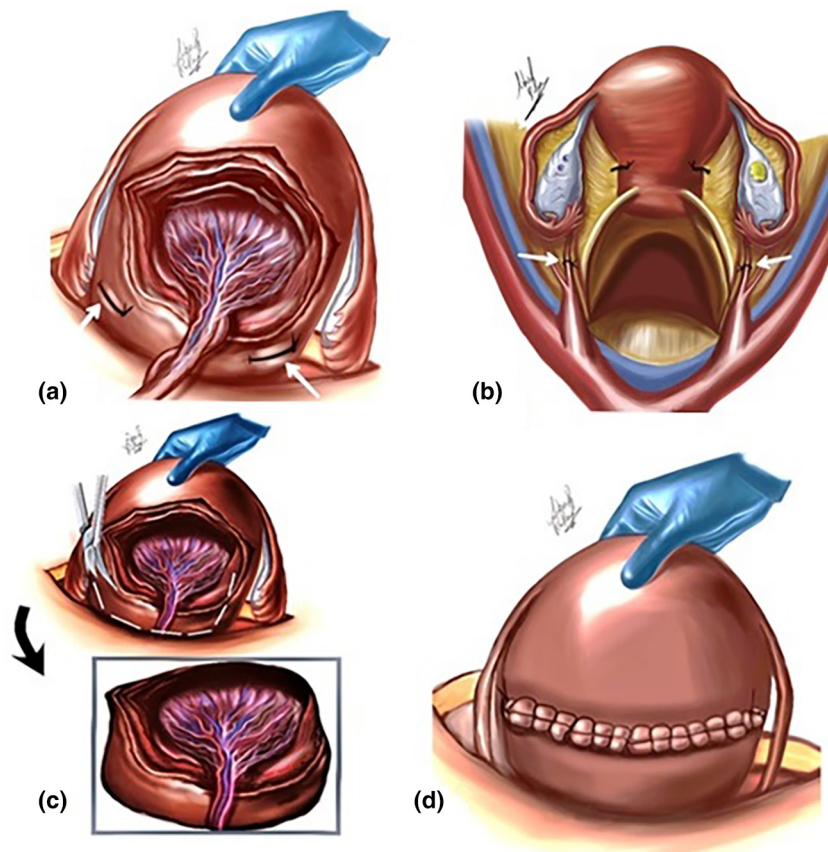
Eligible patients were recruited if they fulfilled the following inclusion criteria: (1) antenatal diagnosis of PAS by ultrasound or magnetic resonance imaging (MRI) when ultrasound diagnosis was uncertain, (2) intraoperative diagnosis of placenta accreta being partially or totally attached to the uterine wall (no cleavage plane between part or whole of the placenta and uterus), (3) patients who wanted to preserve their fertility, and (4) patients refusing hysterectomy. Exclusion criteria were (1) patients who had completed their family and accepted hysterectomy, (2) patients with three or more previous cesarean sections, or (3) hemodynamically unstable patients.

This study was designed on dependent cases and controls with one control per case. The primary outcome used in the sample size calculation was the technique's success in preserving the uterus. Previous studies indicated that the failure rate among controls was 20%, whereas the true failure rate for study participants was 5%.<sup>14,19</sup> The null hypothesis ( $H_0$ ) assumed no difference between both techniques regarding successful uterine conservation. From previous data, we needed to study 75 cases in each group to be able to reject the null hypothesis. The type I error of the null hypothesis was 0.05 with a power of 0.8. An uncorrected static  $\chi^2$  test was used to evaluate this null hypothesis. To increase the power of this study, we increased the sample size to 100 patients in each group.

Randomization was performed by a computerized program, and the allocation was written in capital letters A or S, denoting the group allocations. The letters were put in closed envelopes, and patients who opened the envelopes were not changed from their allocation. The allocation letter A denoted Group 1, which underwent Assar's technique, while the allocation letter S denoted the allocation Group 2, which was managed with Shehata's technique. Allocation was an alternating type with a 1:1 ratio.

All patients were operated on under general anesthesia, Pfannenstiel incision, proper urinary bladder dissection, and high uterine incision above placental edge. After delivery of the baby, the uterus was exteriorized without any attempt to separate the placenta, and one of the study procedures was conducted according to allocation.

Group 1 (Assar's technique): The urinary bladder is dissected after inflating the bladder with 200ml methylene blue-colored saline with more dissection of the urinary bladder. Devascularization is performed through bilateral uterine artery ligation and bilateral internal iliac artery ligation at the isthmus level. The whole placenta and lower uterine segment (myometrial-placental excision) are excised, followed by cervico-isthmic apposition (suturing cervix to



**FIGURE 1** Assar's technique: (a) bilateral uterine artery ligation at isthmus level before placental separation (arrows); (b) bilateral internal iliac ligation (arrows); (c) excision of placenta and lower uterine segment in one mass; and (d) closure of uterus at end of procedure

upper flap) and assurance of hemostasis. Intraperitoneal drains are inserted, and the abdomen is closed in layers. Ligation of vessels and closure of uterine incision is performed using Vicryl 1. This technique is illustrated in [Figure 1](#).

**Group 2 (Shehata's technique):** The urinary bladder is dissected after the exteriorization of the uterus. Devascularization is conducted before placental extraction through bilateral uterine artery ligation at two levels; the first level at the isthmus before placental separation, and the second level 3 cm above the uterine incision after placental removal. Placental separation, either manual or using scissors, is performed. Hemostasis of the bleeding placenta bed is commenced through two quadruple hemostatic sutures in the lower segment and placenta bed. Insertion of a triple-way Foley catheter through the cervix and inflating it to 50ml with saline compresses the lower segment and drain bleeding. The uterine incision is closed with Vicryl 1.<sup>19</sup> Intraperitoneal drains are inserted, and the abdomen is closed in layers. This technique is illustrated in [Figure 2](#).

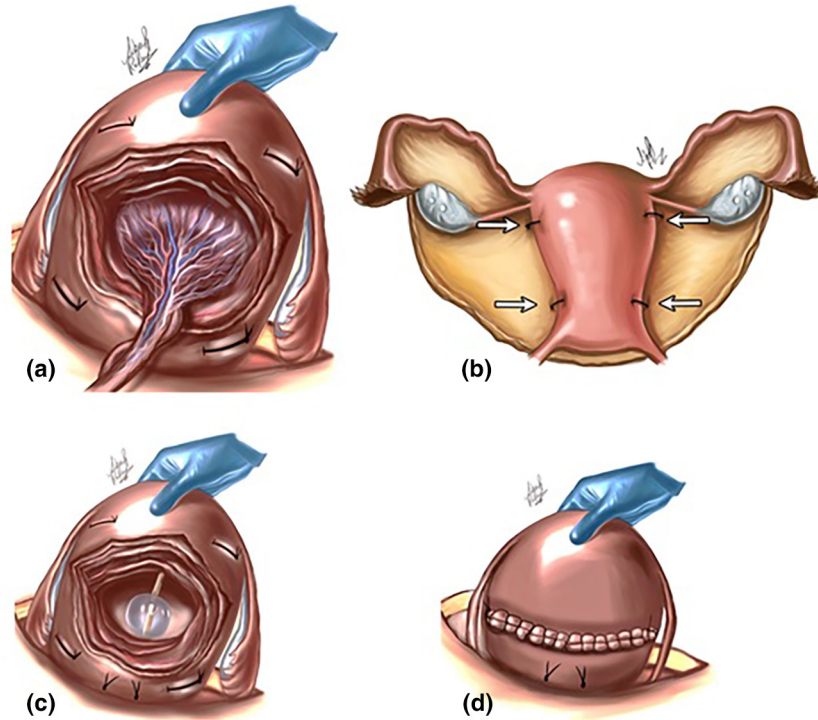
Measured parameters included operative time, blood loss, operative complications, the success of the technique in sparing the uterus from hysterectomy, and postoperative complications. The primary outcome was the success of the procedure in preserving the uterus. The procedure's success was defined by one technique's ability to preserve the uterus (no hysterectomy required). Secondary

outcomes included operative time, blood loss, and the need for other interventions.

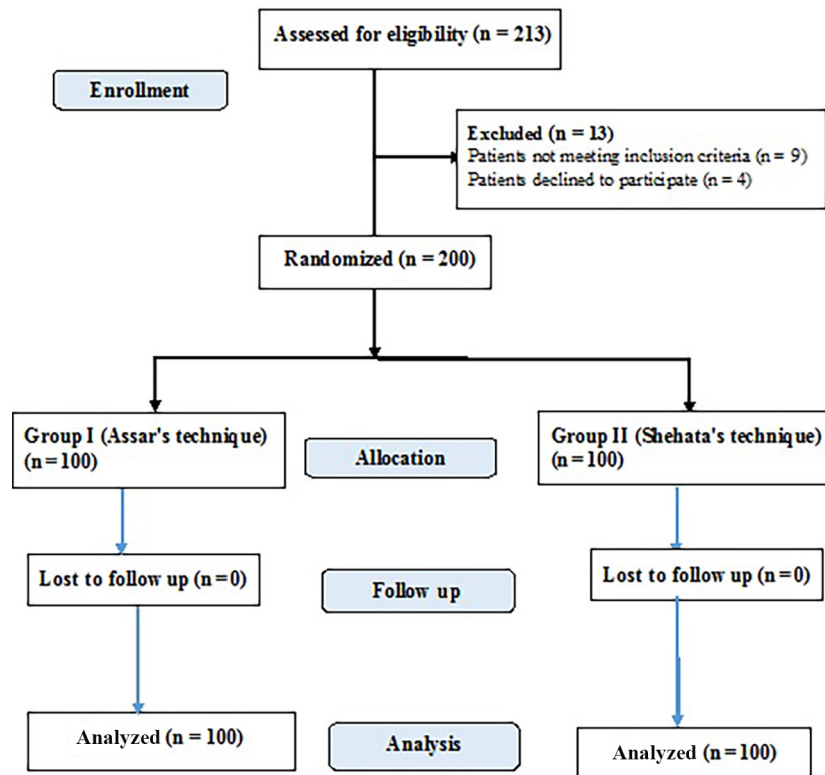
STATA 16.1 (Stata Corp, College Station, TX, USA) was used to analyze the data. A Shapiro–Wilk normality test was used to test the distribution of the continuous data. Normally distributed variables were presented as mean and standard deviation and compared with the Student *t* test. Non-normal data were expressed as median (interquartile range [IQR]) and compared using Mann–Whitney *U* test. The change in hemoglobin preoperatively and postoperatively were compared using paired *t* test. Categorical data were compared with  $\chi^2$  or Fisher exact test if the expected frequency was less than five. The confidence interval of the success rate was calculated using the Wald method. A *P* value of 0.05 or less was considered statistically significant.

### 3 | RESULTS

Initial enrollment included 213 cases of abnormal placentation from both universities within the study period. Thirteen patients were excluded: nine did not meet the inclusion criteria and four declined to participate. The CONSORT flow of cases throughout the study is shown in [Figure 3](#).



**FIGURE 2** Shehata's technique: (a) bilateral uterine artery ligation at level of isthmus level and 3 cm above uterine incision before placental separation; (b) back of uterus showing ligatures of uterine artery (arrows); (c) quadruple sutures and Foley catheter balloon inserted; and (d) closure of uterus at end of procedure



**FIGURE 3** CONSORT flow chart of cases through the study

We included 200 patients in our study and grouped them into two groups. The median age in Group 1 was 30 years (IQR 29–33 years) and in Group 2 it was 32 years (IQR 27–34 years) ( $P = 0.091$ ). There were no statistically significant differences between groups regarding gravidity, parity, and the number of previous cesarean sections. All patients were diagnosed by gray-scale ultrasonography, and MRI was used to confirm the diagnosis in 19 (19%) patients, in addition to the ultrasound in Group 2 ( $P < 0.001$ ). Preoperative hemoglobin was insignificantly lower in Group 2 ( $P = 0.059$ ) (Table 1).

Operative and postoperative data showed that the procedure was significantly shorter in Group 2, 75 (60–100) versus 120 (100–140) minutes in Group 1 ( $P < 0.001$ ). The mean blood loss was significantly higher in Group 2 (900 ml) compared with 670 ml in Group 1 ( $P < 0.001$ ). There was no significant difference in blood transfusion units in both groups, although the postoperative hemoglobin was significantly lower in Group 2. There was a significant decrease in

hemoglobin postoperatively in both groups compared with the preoperative level ( $P < 0.001$ ) (Figure 4).

There was no difference in the duration of hospital stay between the two groups. Vascular surgery was required for five patients in Group 1 (internal iliac vein injury) and three cases in Group 2 that required internal iliac artery ligation ( $P = 0.721$ ). Fifteen patients had an adjuvant hysterectomy in Group 1, while five patients required hysterectomy in Group 2. B-lynch suture was performed in two cases in Group 1 and one case in Group 2. Ten patients had paralytic ileus in Group 1, and 14 patients had a postoperative fever in Group 2. Operative and postoperative data are compared in Table 2. The reoperation rate was lower in Group 1 than in Group 2, but with no significant difference. The procedure success was significantly higher in Group 2 than in Group 1 (odds ratio [OR] 0.95, 95% confidence interval [CI] 0.91–0.99) and (OR 0.85, 95% CI 0.78–0.92), respectively.

**TABLE 1** Comparison of the baseline data between groups<sup>a</sup>

	Group 1 Assar's technique (n = 100)	Group 2 Shehata's technique (n = 100)	P value
Age, year	30 (29–33)	32 (27–34)	0.091 <sup>b</sup>
Gravidity			0.289 <sup>c</sup>
2	21 (21%)	28 (28%)	
3	36 (36%)	39 (39%)	
4	35 (35%)	30 (30%)	
5	8 (8%)	3 (3%)	
Parity			0.082 <sup>c</sup>
1	23 (23%)	35 (35%)	
2	41 (41%)	41 (41%)	
3	28 (28%)	22 (22%)	
4	8 (8%)	2 (2%)	
Previous CS			0.245 <sup>c</sup>
1	30 (30%)	39 (39%)	
2	52 (52%)	42 (42%)	
3	18 (18%)	17 (17%)	
4	0	2 (2%)	
Place of previous CS			0.147 <sup>d</sup>
University hospital	21 (21%)	19 (19%)	
General hospital	29 (29%)	42 (42%)	
Private hospital	50 (50%)	39 (39%)	
MRI-based diagnosis of PAS	0	19 (19%)	<0.001 <sup>d</sup>
Gestational age, wk	36 (35–36)	36 (35–37)	0.097 <sup>b</sup>
Preoperative hemoglobin, mg/dL	10.48 ± 0.54	10.34 ± 0.50	0.059 <sup>e</sup>

Abbreviations: CS, cesarean section; MRI, magnetic resonance imaging; PAS, placenta accreta spectrum.

<sup>a</sup>Continuous data are presented as mean and standard deviation if normally distributed and median (interquartile range) if non-normally distributed. Categorical data are presented as number (percentage).

<sup>b</sup>Mann-Whitney *U* test.

<sup>c</sup>Fisher exact test.

<sup>d</sup> $\chi^2$  test.

<sup>e</sup>Student *t* test.

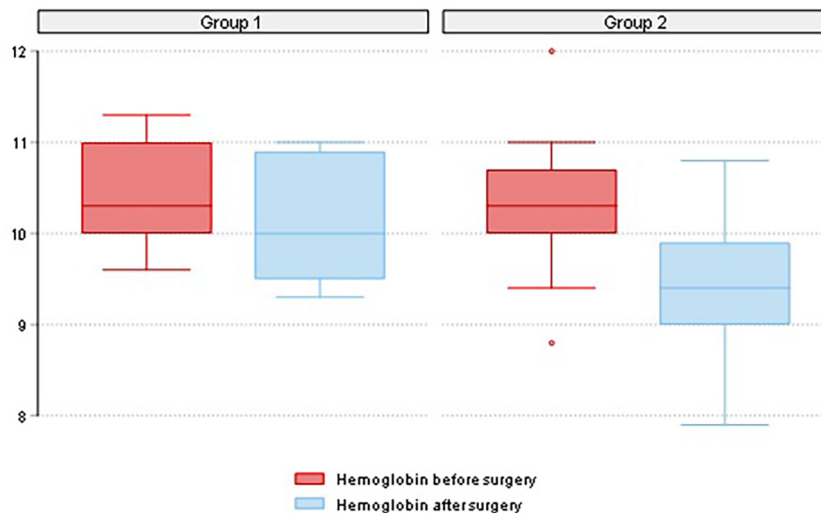


FIGURE 4 Preoperative and postoperative hemoglobin in both groups

	Group 1 Assar's technique (n = 100)	Group 2 Shehata's technique (n = 100)	P value
Duration of surgery, min	120 (100–140)	75 (60–100)	<0.001 <sup>b</sup>
Blood loss, ml	670 (580–755)	900 (800–1100)	<0.001 <sup>b</sup>
Units of blood transfused	2 (1–3)	2 (2–3)	0.224 <sup>b</sup>
Postoperative hemoglobin, mg/dl	10.16 ± 0.57	9.41 ± 0.60	<0.001 <sup>c</sup>
Need for intensive care unit	5 (5%)	1 (1%)	0.122 <sup>d</sup>
Operative complications			
Bladder injury	14 (14%)	15 (15%)	0.841 <sup>e</sup>
Internal iliac vein injury	5 (5%)	0	0.059 <sup>d</sup>
Ureteric injury	0	0	–
Adjuvant procedures			
Hysterectomy	15 (15%)	5 (5%)	0.018 <sup>e</sup>
Vascular surgery	5 (5%)	3 (3%)	0.721 <sup>d</sup>
B-Lynch compression suture	2 (2%)	1 (1%)	>0.99 <sup>d</sup>
Hospital stay, day	2 (2–3)	2 (2–3)	0.383 <sup>b</sup>
Postoperative complications			
Postpartum hemorrhage	2 (2%)	2 (2%)	1.00 <sup>e</sup>
Wound infection	13 (13%)	7 (7%)	0.157 <sup>e</sup>
Paralytic ileus	10 (10%)	0	0.001 <sup>e</sup>
Fever	0	14 (14%)	<0.001 <sup>e</sup>
Reoperation	3 (3%)	5 (5%)	0.721 <sup>d</sup>
Procedure success rate	85 (85%)	95 (95%)	0.032 <sup>c</sup>

TABLE 2 Comparison of operative and postoperative data between groups<sup>a</sup>

<sup>a</sup>Continuous data are presented as mean and standard deviation if normally distributed and median (interquartile range) if non-normally distributed. Categorical data are presented as number (percentage).

<sup>b</sup>Mann-Whitney U test.

<sup>c</sup>Student t test.

<sup>d</sup>Fisher exact test.

<sup>e</sup>χ<sup>2</sup> test.

## 4 | DISCUSSION

Placenta accreta spectrum incidence is increasing with the increasing cesarean section rates. Although the definitive treatment of PAS is cesarean hysterectomy, many studies are now investigating ways to spare the uterus, preserve future fertility, and protect against severe psychiatric problems following cesarean hysterectomy. The main aim of conservative techniques was to minimize the rate of peripartum hysterectomy and subsequent morbidity and psychological disorders. No single technique proved superior to another in conservative management of PAS, and most studies are case series or descriptive studies with no large randomized studies in this issue.<sup>20,21</sup>

The current study compared two uterine sparing techniques in conservative management of PAS. Both techniques were applied in tertiary care hospitals, in placenta accreta surgical teams, and with the availability of blood products and ICU beds. The basal demographic data of enrolled patients were not significantly different in both groups. At Benha University, the diagnosis was dependent only on ultrasound, whereas at Tanta University, MRI was used in 19% of cases with uncertain diagnoses by ultrasound.

In the current study, the success rates of both Assar's and Shehata's techniques were 85% (OR 0.95, 95% CI 0.91–0.99) and 95% (OR 0.85, 95% CI 0.78–0.92), respectively. These rates are higher than in Sentilhes et al.,<sup>22</sup> who reported 78% (95% CI 71%–84%) as an overall success rate of uterine preservation due to increased incidence of PAS cases and obtaining more experience in conservative management techniques. Shabana et al.<sup>14</sup> reported a similar success rate; they reported technique failure in 8.5% of cases.

Regarding operative time, Assar's technique had a longer operative time than Shehata's technique ( $P < 0.001$ ) owing to the added vascular ligation of both internal iliac arteries. Most studies had a long operative time compared with our study. Warshak et al.<sup>23</sup> reported  $194 \pm 1.6$  min, and Walker et al. reported 107 min (68–334 min).<sup>24</sup> In contrast, Shabana et al.<sup>14</sup> reported a shorter operative time of 85 minutes (70–140 min).<sup>14</sup>

In the current study, Assar's technique had less blood loss than Shehata's technique ( $P < 0.001$ ) owing to vascular ligation of both uterine and internal iliac arteries. Consequently, postoperative hemoglobin was higher in Assar's than in Shehata's technique. Takahashi et al.<sup>1</sup> reported that blood loss was greater than 2500 ml in their technique.

The need for ICU admission was 5% in Assar's technique and 1% in Shehata's technique. Regarding ICU admissions, Warshak et al.<sup>23</sup> reported 72%, Eller et al.<sup>25</sup> reported 30%, and Walker et al.<sup>24</sup> reported 15%.

Regarding operative complications, there was a similar incidence of bladder injury in both techniques: 14% in Assar's and 15% in Shehata's ( $P = 0.841$ ). Bladder injury during PAS surgery is a common complication reported in many studies with different incidences. Warshak et al.<sup>23</sup> reported 23% bladder injury,<sup>23</sup> Eller et al. reported 37%,<sup>25</sup> Walker et al.<sup>24</sup> reported 30%,<sup>24</sup> and Shabana et al.<sup>14</sup> reported 5.6%.<sup>14</sup>

The additional procedures required in both techniques were minimal, with no significant difference in both groups. Vascular

surgery was required because of extensive vascular engorgement and challenging anatomy. In the current study, vascular surgeons were included to manage five cases of internal iliac vein injury in Assar's technique and three cases in Shehata's technique, which had broad ligament hematoma and excessive bleeding from the perivesical plexus. A B-Lynch suture was required to manage atony in three cases; two in Assar's technique and one in Shehata's technique, as shown in Table 2. Takahashi et al.<sup>1</sup> reported additional procedures in their study where 24% required a hysterectomy, 4% required transcatheter arterial embolization, 17% required an intrauterine balloon, 6% required compression sutures, and 4% required both intrauterine balloon and compression sutures.

In the current study, the reported postoperative complications were wound infection, fever and paralytic ileus. Sentilhes et al.<sup>22</sup> reported severe maternal morbidity and complications in 6% of cases.

The reoperation rate in our study was 3% in Assar's technique and 5% in Shehata's technique. Indications for reoperation were postpartum hemorrhage (2%) for each group, and those patients were managed by hysterectomy, or pelvic hematoma (1%). The hematoma patients were managed by evacuation of collected blood and control of minute bleeding vessels. In Group 2 only reoperation was the result of disrupted infected wounds (2%), and those were managed by debridement of necrotic tissues and secondary sutures. Eller et al.<sup>25</sup> reported an 8% reoperation rate in their study.

To our knowledge, this is the first randomized study comparing two conservative approaches to managing PAS. The strengths of the study are its randomized nature, blinding, and non-inferiority design. The results of both techniques add to the evidence with two new techniques with high efficacy and safety. The weak points are the small sample size and short follow-up period.

In conclusion, both techniques were effective in the conservative management of PAS. Shehata's technique had a higher success rate but with more blood loss than Assar's technique. Both techniques were safe, with few reported complications and decreased ICU admissions. We recommend the wide application of both techniques in the conservative management of PAS.

### AUTHOR CONTRIBUTIONS

AShD contributed to protocol and study design, trial registration, operating Shehata's technique, scientific writing, revision and submission. ASaD contributed to data collection, statistical analysis, scientific writing, and revision. ShASh contributed to concept acquisition, statistical analysis, scientific writing, and revision. TMA and ASS contributed to performing Assar's technique, scientific writing, and revision.

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## CONFLICT OF INTEREST

No conflicts of interests exist.

## DATA AVAILABILITY STATEMENT

Data are available upon valuable request.

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