A randomized clinical trial comparing the cervico-isthmic compression suture versus lower anterior wall uterine resection in cases of the morbidly adherent anteriorly situated placenta

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Abstract

Objective: To evaluate the effectiveness and safety outcome of cervico-isthmic compression suture compared to lower anterior wall uterine resection in preserving fertility and minimizing blood loss in cases of anterior situated morbidly adherent placenta.

Methods: the study was conducted at Mansoura University Hospitals, Mansoura, Egypt during October 2020 to November 2022. A total number of 74 patients with morbidly adherent placenta fulfilled the inclusion criteria and were enrolled and divided into two equal groups. GA, cervico-isthmic compression suture group and GB, lower uterine wall resection group. The main primary outcome measures were intraoperative complications, need for blood or its elements transfusion and emergent hysterectomy, while the secondary outcome measures involved the occurrence of postpartum hemorrhage (PPH) and need for ICU admission as well as neonatal outcome.

Results: the baseline characteristics showed no significance differences between both groups in maternal age, gravidity, parity, fetal gestational age, body mass index, number of previous vaginal or caesarean deliveries, number of previous abortions, ectopic pregnancies, preterm labor or history of gynecological operations as well as preoperative hemoglobin levels, (p>0.05). Despite the number is equal in both groups but there is a significant difference as regard the grade of accretion as grade I is found in 9 cases of GA vs 2 only in GB, whilst grade II was diagnosed in 28 cases in GA vs 35 cases in GB, (p<0.05). the mean estimated operative time showed no difference between both groups (p >0.05) but the mean estimated intraoperative blood loss and the need for packed RBCs transfusion appeared statistically significant between

both groups being lower in GA compared to GB (p 0.001). Sixteen cases of GA were in need of internal iliac artery ligation (IIAL) vs 22 cases in GB, but this did not give any significance. The occurrence of postpartum hemorrhage, endometritis, need for emergent hysterectomy or ICU admission appeared similar in both groups. On the other hand, there is recorded statistical significance as regard bladder injury and mean hospital stay time being lower in GA than GB (p <0.05). The neonatal outcome demonstrated similar results in both groups with no evident of any neonatal complication or need for NICU admission.

Conclusion: The use of cervico-isthmic compression suture appeared more effective and safer than lower uterine wall resection in cases of anteriorly located placenta accreta particularly in terms of intraoperative blood loss, blood transfusion, intraoperative bladder injuries and the postoperative hospital stay.

Keywords: PAS, lower uterine resection, cervical compression sutures.

Introduction

Placenta accreta spectrum [PAS] is an abnormal trophoblastic invasion of part or all of the placenta into the myometrium [1]. It is classified into 3 main subtypes, according to the invasion depth: grade I is abnormally adherent placenta (Creta) when the villi adhere directly to the myometrium without a decidual interface, grade II is an abnormal invasion of placenta (increta) when the villi invade into the myometrium while grade III is abnormal invasion of placenta (percreta) when invasion reaches the peritoneum (3a), surrounding pelvic tissues, vessels, and organs (3b) [2]. PAS prevalence over the last four decades has been continuously increasing and most likely owing to a change in predisposing factors with a notably increased rate of cesarean deliveries [CD] [3-6]. Moreover, when the number of CDs increased the more liability for placenta

accreta grades as Marshal et al 2011 [7] proved that the risk increased from 0.3% in females with one preceding CD to 6.74% for females with at least five CDs. Other significant predisposing factors comprise placenta previa even with no prior CD, advanced maternal age, multiparity, assisted reproduction techniques, submucosal leiomyomas or myomectomy, preceding uterine surgeries including curettage or manual placental excision, localized A Sherman syndrome, smoking, and hypertension [8-11].

Despite there is no characteristic clinical data used for the diagnosis of PAS, but this serous obstetric complication should be suspected when one or more of the previous risks are present till assuring the diagnosis by two-D or three-D ultrasound in addition to color Doppler imaging [12-14]. Though magnetic resonance imaging (MRI) also has an important function in the context of PAS diagnosis, with high sensitivity and specificity [15], but US has demonstrated superiority over MRI in this aspect therefore used as a first screening tool [16]. As stated earlier by many researches, the optimal management of such cases should include a standardized procedure with a multidisciplinary care team in a highly specialized tertiary care institutes including a skillful obstetrician and maternal–fetal medicine subspecialists, neonatologist, pelvic surgeon, urologist, interventional radiologist, obstetric anesthesiologist and critical care experts [11, 17].

The main aim of the surgeons during operative management is to minimize operative blood loss, preserve the pelvic organs and to lessen fetal and neonatal complications in addition to intensive hemodynamic supervision in the early postsurgical period in an intensive care unit (ICU). For these benefits, many maneuvers were studied namely, balloon occlusion catheters [11, 18], uterine artery embolization or IIAL [19, 20] all appear to give similar results. Conservative treatment of placenta accreta "leaving the placenta in situ approach" with or without embolization

or vessel ligation was also tried by some studies [21, 22]. In addition, uterine-sparing techniques can be performed via cervico-isthmic compression sutures or tamponade technique [23, 24]. Local uterine resection followed by immediate repair and reconstruction with pelvic devascularization was selected as a line of treatment by Smith D et al., 2016 [25]. Immediate supra-vaginal hysterectomy or planned delayed hysterectomy may be used as a definitive surgical management when extensive invasion of the surrounding structures is proved [26, 27].

Reported maternal complication are many with PAS and may be increased with operative treatment, namely injury to local organs, PPH, internal hemorrhage, amniotic fluid embolism, massive blood transfusion, coagulopathy, electrolyte disturbances, infections, postsurgical thromboembolism, multiple organ failure, hysterectomy or even maternal mortality [28, 29]. Placenta accreta itself appears not directly harmful to the baby or can cause neonatal death but prematurity complications remain threatening for the neonates especially in low resource settings [28, 29]. The aim of the present study was to properly investigate the efficacy and safety of cervico-isthmic compression sutures compared to local myometrial resection in the management of PAS with morbidly adherent anteriorly situated placenta.

Patients and Methods

This was a prospective, randomized controlled parallel-group study conducted within the period from October 2020 to November 2022 in Obstetrics and Gynecology department and high-risk pregnancy unit in Mansoura University Hospitals, Mansoura, Egypt. The study design was approved by the Mansoura Faculty of Medicine Institutional Research Board (Code No. MS.20.09.1246) and as a result has been conducted according to the ethical standards of Declaration of Helsinki. During the study period, we selected 91 pregnant females and diagnosed to have placenta accrete grade 1 or 2. All the possible participants were interviewed, received sufficient information about the protocol of the study, and then counseled to be enrolled. The potential participants were then assessed for meeting the inclusion and exclusion criteria.

The main inclusion criterion were those pregnant patients below 40 years, diagnosed as PAS with anterior situated placenta and graded by FIGO as grades, 1 and 2 [2] and welling to preserve fertility. Patient classified as FIGO grade 3, those above the age of 40 years, had having medical disorders as cardiovascular diseases, uncontrolled DM, renal dysfunction, hepatic diseases or those who declined to contribute to the study were excluded. An informed consent was taken from every included patient with the right to withdraw from the study without giving any reason. By this, 74 cases were allocated into either one of the two equal groups using the closed envelope method. Group A: 37 patients underwent Cervico-isthmic compression sutures and Group B: 37 patients underwent anterior wall uterine resection. All patients were subjected to complete history taking, complete general, obstetric but no local examination. Gestational age was calculated depending on the due date of the first day of the last normal menstrual period and transabdominal sonography. Basic laboratory investigations, including CBC, bleeding profile, INR, liver function tests, and kidney function tests were taken from all contributors.

Transabdominal ultrasound using the LOGIQ F6 (GE Healthcare) machine was used for the diagnosis of placenta accreta by the same senior sonographer during the 2nd or 3rd trimester. Absence of normal hypoechoic retroplacental zone, multiple vascular lacunae giving irregular vascular spaces within the placenta, placental tissue bridging, uterine-placental margin, myometrial-bladder interface and retroplacental myometrial

thickness of less than 1 mm [30]. Color Doppler studies were also done for all cases for confirmation of diagnosis and precision of the degree of invasion where lacunar flow patterns and sonolucent vascular lakes with turbulent flow were searched [31]. Transabdominal sonography was also used for fetal data collection primarily fetal number, viability, assessment of amniotic fluid, gestational age, estimation of fetal weight, and presentation.

Preoperatively all patients shaved their pubic hair, took a shower with an antiseptic soap, antibiotic prophylaxis, and a urinary catheter was inserted. All operations were done by the same surgical team and senior obstetrician under spinal anesthesia. After skin sterilization, Pfannenstiel incision was done followed by cutting the subcutaneous fat and rectus sheath and blunt entry into the peritoneum until reaching the uterus. Uterine artery was ligated bilaterally at multiple levels in all involved cases to minimize intraoperative and probably postoperative blood loss followed by a lower segment uterine incision and retroplacental approach for fetal extraction.

In group A, and after delivery of the fetus and placental removal, cervico-isthmic compression sutures was done. First, the bladder was reflected downward to avoid ureteric and bladder injury. A silastic drain was introduced into the internal and across the external os, to drain the uterine cavity and to keep the cervical canal open. Then the surgeon introduced his hand across the uterine incision into the lower uterine segment (LUS) till it touched the cervix. A long Allis forceps passed across the uterine incision and was utilized to grasp the anterior cervical lip pulling the cervix upwards into the uterine cavity. Then the anterior cervical lip was sutured to the posterior surface of the anterior wall of the LUS using continuous locked absorbable stitches (Vicryl no. 2). This aided in compressing the bleeding areas of the placental bed and supported the very thin

LUS detected in those patients. The uterus was repaired completely with continuous unlocked suture in two layers using Vicryl 1 suture. The peritoneum was left unsutured while the muscle layer was opposed with Vicryl 0. The rectus sheath was sutured by Vicreyl 1, and the skin was closed with subcutical suture by Proline double zero.

In group B, the same steps were followed till placental delivery then both corners of the uterine incision and the superior and inferior lips were clamped by using four Mayo clamps with blunt dissection of the bladder downwards and uterus peritoneal reflection was performed. The partial anterior wall of the myometrium in which the placenta was deeply adherent was resected together with the invading placenta remnants. It was essential to confirm that enough myometrium above the peritoneal reflection was available for an optimal closure. After that, the remaining placenta tissues were removed as much as possible in piecemeal manner from the uterine incision edge. Clamps and multiple hemostatic sutures were applied quickly on hemorrhagic points on removing the remaining placenta according to the need and the obstetrician's insight. Then, the superior and inferior lips of the uterine incision were sutured to reconstruct a residual uterus and close the abdomen as before. In some cases when bleeding continued, other maneuvers to control bleeding and save patients, including IIAL and compression sutures up to hysterectomy were tried conferring to the consultants' and surgical team opinion.

Measurement of blood loss started following skin incision in every patient. Two trained nurses, one for each group, were responsible for blood and amniotic fluid collection in 2 different suction sets and weighing the surgical towels or gauzes before and after the surgery and depended on the corresponding conversion based on the ratio of 1.05g in weight to one ml in volume. In addition, PPH during the initial 24 hours postoperative was evaluated by

weighing soaked napkins. Presurgical and postoperative data including hemoglobin and hematocrit values 120 minutes before and 24 hours following the operation, the need for whole blood transfusion or packed RBCs, the amount of intra and postoperative blood loss, associated injury to local pelvic organs, ICU admission, hospital stay time, maternal mortality together with neonatal outcome such as; Apgar score, admission to neonatal ICU (NICU), and neonatal mortality were evaluated in the two groups.

Statistical analysis and data interpretation

The sample size was calculated using G*Power version 3.1.9.4 for Windows. Based on intensive literature review, the standard deviation of the mean operative time in the cases underwent uterine wall local resection and reconstruction in the study conducted by Zhao et al. (2018) was found to be 24.5 minutes. At 95% level of significance and power of 80%, the sample size calculated was 37 cases in each group to determine the difference of 1.5 points. Data were gathered, tabulated and analysed by IBM computer using the SPSS (SPSS version 22.0. Armonk, NY: IBM Corp.). Chi- square test was utilized to compare the association between categorical variables between groups and Fisher exact test was used where necessary. Student t-test was utilized to compare means of quantitative variables in parametric data. The differences between two groups were measured by utilizing paired t-test and P value <0.05 was set significant.

Results

A total of 91 patients with morbidly adherent placenta were enrolled in the study, of them 17 were excluded due to failure for fulfilling the inclusion criteria [11] or refutilized to participate [6] (figure 1). The remaining were equally divided into two groups; GA [cervico-isthmic compression suture] and GB "lower uterine wall compression suture". Baseline characteristics are shown in Table (1); there were no significance differences between both groups in maternal age, gravidity, parity, fetal gestational age, body mass index, number of previous vaginal or caesarean deliveries, number of previous abortions, ectopic pregnancies, preterm labor or history of gynecological operations and preoperative hemoglobin levels, p>0.05. despite the number is equal in both groups but there is a significant difference as regard the grade of accretion as grade I is found in 9 cases of GA vs 2 in GB, whilst grade II was diagnosed in 28 cases in GA vs 35 cases in GB, p<0.05, table (1).

Despite the mean estimated operative time showed no difference between both groups (108.00 ± 16.90 vs 109.43 ± 16.5 , p >0.05) but the mean estimated intraoperative blood loss and the need for packed RBCs transfusion appeared statistically significant between both groups being lower in GA compared to GB (1612 ± 800.85 vs 2633 ±1153.92 and 2 ± 3.2 vs 4 ± 2.8 respectively, p value 0.001) table (2). Also, in table (2), there was no manifested differences in both groups as regard the intraoperative need for IIAL [16 vs 22 cases], occurrence of postpartum hemorrhage (one case in every group, occurrence of endometritis [no cases in GA vs 1 case in GB). No cases of both groups were subjected to hysterectomy or ICU admission, table (2). On the other hand, a statistical significance regard bladder injury (8.1% in GA vs 16.2 % in GB, p value 0.02) and mean hospital stay time in days (4 ± 2.2 vs 6 ± 5.3 respectively, p value 0.021), table (2). Neonatal outcome showed no statistical differences in both groups as regard APGAR score at 1 and 5 minutes or need for neonatal intensive care unit admission (p>0.05), table (2).

Discussion

The primary findings of the study confirmed that cervico-isthmic compression suture appeared better in the mean of intraoperative blood loss, bladder injury and postoperative

hospital stay time when compared to lower anterior uterine wall resection in patients with PAS as fertility sparing surgery.

It has been reported that reduction of blood loss at CD in high risk group, as those having placenta accrete, significantly reduced postoperative maternal morbidity and risks associated with blood transfusions [8, 31]. Conservative management of PAS could be applied to preserve fertility in young women or those with low parity, but the obstetricians should always remember that maternal and neonatal comorbidities and suspected increased mortalities might not appear except during or after treatment. Therefore, many methods were tried including cervico-isthmic compression suture, triple p procedure, uterine artery embolization, local excision of the placental site with involved myometrium and uterine compression sutures (32, 33). None of these studies used comparative maneuvers, so the authors of the current study tried to compare the safety outcome and efficacy of cervico-isthmic compression suture to the anterior wall uterine resection in preserving fertility and minimizing blood loss in such cases.

The technique of cervical inversion and compression was successful in stopping hemorrhage, with a success rate of 90%, and less operative and postoperative blood loss as proved in a study done earlier by Madny et al. 2019 [35]. Despite this comes in accordance with the findings of this study but the previous research [35] demonstrated two cases of interactable bleeding saved by emergent hysterectomy, the measure which is not resorted to for saving any of our cases in both groups.

Some authors demonstrated that patients with PAS treated by local uterine wall resection might be in need of adjoining maneuver as prophylactic abdominal aorta balloon occlusion, uterine or internal iliac tourniquet followed by reconstruction to preserve the uterus [36]. This also supports the current results and proves the superiority of cervico-

isthmic compression suture over lower uterine resection as 16 cases only were in need of accompanied IIAL in the first group compared to 22 cases in the later one. In this respect, some stated that the therapeutic effect of IIAL is negligible compared to uterine artery ligation approaches for bleeding management in PAS [37], the point which is not proved by the current study.

In the existing work, no significant difference was reported as regard the mean operative time between both groups of the study but on the other side some international studies confirmed less operative time [36, 38] and others established more time was needed [39] for a comparable maneuver.

As an intraoperative complication, urinary bladder injury occurred less in GA compared to GB and this comes in agreement with findings published before by some authors used lower uterine resection in management of PAS [35, 36].

The intense need for packed RBCs intraoperative infusion in our study appeared less in GA compared to GB and this comes in accordance to results ascertained by Cırpan et al. 2019 [38]. No cases in the current study groups, as mentioned before, had been underwent hysterectomy and this was the same findings reported by recent researches who used uterine preservative surgeries for managing PAS [40]. Postoperatively, the mean hospital stay time in days was shorter in cervico-isthmic compression group compared to lower uterine resection group and this comes supporting results published before [36, 38] and specified longer time when using lower uterine wall resection as fertility preserving surgery in cases of PAS.

In the current study, there was no significant difference in the neonatal outcomes in both groups regarding the maneuver used and this agrees with scientific fact proved recently by Li Q et al., 2023 [41] which state that the pathophysiology of PAS didn't participate in adverse neonatal outcomes and the increase

in incidence of neonatal respiratory or other adverse events will be related to lower gestational age at labor. The mean age in both groups more or less similar and all fetuses were close to maturity [36.19 ± 3.61 vs 35.84 ± 4.11 and $P > 0.05$].

The authors can specify that the primary limitations of this study are lack of double-blind technique and being a single center study instead of multicenter one that will be more informative and the limited number compared to the long study time also.

Conclusion

Cervico-isthmic compression suture and anterior wall uterine resection are apparently safe conservative managements for PAS. However, anterior wall uterine resection is accompanied by more intraoperative blood loss, more hospital stays and more liability for bladder injuries.

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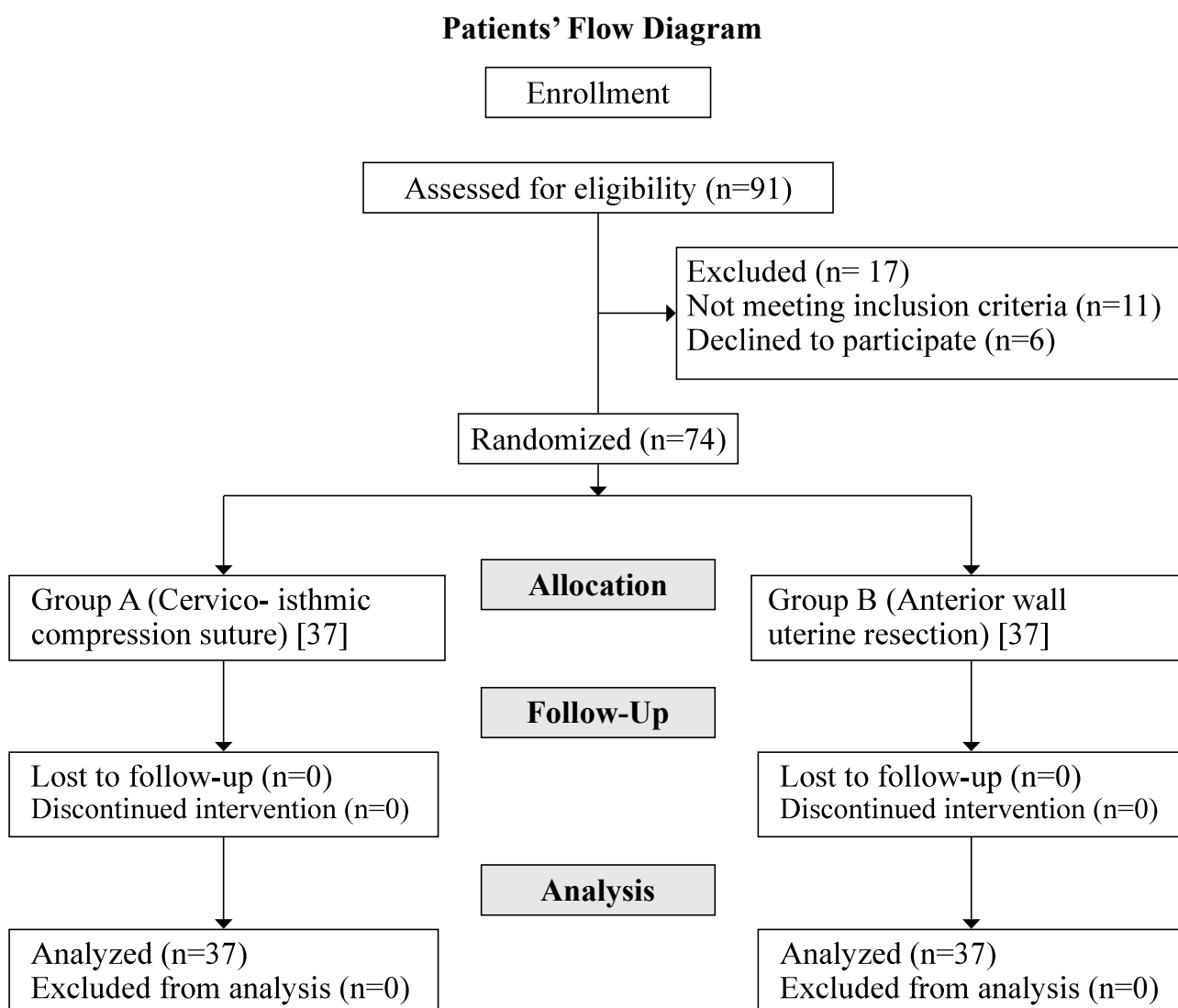
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Figure 1. Study flow diagram

Patients' Flow Diagram

Enrollment

Assessed for eligibility (n=91)

Excluded (n= 17)
Not meeting inclusion criteria (n=11)
Declined to participate (n=6)

Randomized (n=74)

Allocation

Group A (Cervico- isthmic compression suture) [37]

Group B (Anterior wall uterine resection) [37]

Follow-Up

Lost to follow-up (n=0)
Discontinued intervention (n=0)

Lost to follow-up (n=0)
Discontinued intervention (n=0)

Analysis

Analyzed (n=37)
Excluded from analysis (n=0)

Analyzed (n=37)
Excluded from analysis (n=0)

Table (1): Sociodemographic, clinical, and baseline characteristics of the two study groups.

Variable	Group A (n= 37)	Group B (n= 37)	P values
Age (Years) ± SD	31.19 ± 5.24	31.22 ± 4.72	0.981
BMI (Kg/m^2) ± SD	32.91 ± 3.76	32.05 ± 4.62	0.387
Gestational age (Weeks) ± SD	36.19 ± 3.61	35.84 ± 4.11	0.679
Gravidity ± SD	4 ± 2.7	5 ± 2.1	0.130
Parity ± SD	3 ± 1.6	3 ± 1.7	0.803
Previous CD	3 ± 1.2	2 ± 1.4	0.951
Number of previous Abortion	0 (0-3)	0 (0-10)	0.096
Number of previous preterm	0 (0-2)	0 (0-1)	0.184
Previous ectopic pregnancy	0 (0%)	1 (2.7%)	0.314
Preoperative hemoglobin (gm/dl)	10.89 ± 0.88	10.90 ± 0.73	0.943
History of gynecological procedures NO Dilatation and curettage MVA Dilatation and curettage plus MVA	32 (86.5%) 3 (8.1%) 3 (5.4%) 0 (0%)	27 (73%) 5 (13.5%) 3 (8.1%) 2 (5.4%)	0.373
Grading of placenta accreta Grade I Grade II	 9 (24.3%) 28 (75.7%)	 2 (5.4%) 35 (94.6%)	 P= 0.022*

The data is presented as number (%), mean ± (SD), and the p-value is set statistically significant if below 0.05.

Abbreviations: BMI; body mass index, VD; vaginal delivery, CD, cesarean delivery, MVA; manual vacuum aspiration.

Table (2): Operative data and postoperative complications in the two study groups.

Variable	Group A (n= 37)	Group B (n= 37)	P value
Operative time (minutes)	108.00 ± 16.90	109.43 ± 16.5	0.714
Estimated intraoperative blood loss (ml)	1612 ± 800.85	2633 ± 1153.92	0.001
Units of transferred packed RBC units	2 ± 3.2	4 ± 2.8	0.001
Postoperative hemoglobin (gm/dl)	10.94 ± 1.07	10.35 ± 1.03	0.019
Internal iliac artery ligation	16 (43.2%)	22 (59.5%)	0.163
Hysterectomy	0 (0%)	0 (0%)	
APGAR Score	8.92 ± 0.68	8.95 ± 0.78	0.874
Intraoperative and postoperative complications Bladder injury Hospital Stay (Days) Maternal ICU admission Hemorrhage Endometritis NICU admission	 3 (8.1%) 4 ± 2.2 0 (0%) 1 (2.7%) 0 (0%) 0 (0%)	 6 (16.2%) 6 ± 5.3 0 (0%) 1 (2.7%) 1 (2.7%) 0 (0%)	 0.02 0.021 ----

The data is presented as number (%), mean ± (SD), and the p-value is set statistically significant if below 0.05.

Abbreviations: RBC; red blood corpuscles, APGAR, appearance; pulse; grimace; activity; respiration, ICU; intensive care unit, NICU; neonatal intensive care unit.