

Uterus Preservation Versus Caesarean Hysterectomy in Management of Placenta Accreta Spectrum: A Multicentre International Study

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Abstract

Objective: To compare peripartum outcomes of uterus preserving procedures to caesarean hysterectomy in women with placenta accreta spectrum (PAS), and to identify risk factors associated with adverse maternal outcomes. **Design:** Retrospective study (ClinicalTrials.gov identifier: NCT04384510) **Setting:** 11 tertiary centres from 9 countries **Population or Sample:** women with of PAS who were managed in participating centres between January 1st, 2010 and December 31st, 2019. Women who had confirmed diagnosis with PAS with adequate documentation and follow-up, were considered eligible. **Main Outcome Measures:** Primary outcome was massive PAS-associated perioperative blood loss (intraoperative blood loss [?] 2500 ml, bleeding associated massive transfusion protocol, or complicated by disseminated intravascular coagulopathy). **Results:** Out of 797 women, 727 were eligible for the study. Five hundred ninety-two (81.43%) women were managed by uterus preserving procedures versus 135 (18.56%) who underwent caesarean hysterectomy. After adjustment for significant or close-to-significance variables, type of management was not associated with higher risk of massive blood loss (aOR 1.71, 95% CI 0.78 - 3.81). Other factors that were significantly associated with higher risk of massive PAS-associated blood loss included body mass index, preoperative haemoglobin, centrally located placenta, diffuse placental invasion, parametrial invasion, and intrauterine foetal death. **Conclusions:** In the presence of sufficient experience, uterus preserving procedures may not be associated with higher risk of massive blood loss compared to caesarean hysterectomy. **Funding:** none

Introduction

Placenta accreta spectrum (PAS) refers to a spectrum of pathological placental adherence disorders, in which trophoblastic growth invades the deeper tissue of the uterine wall to various degrees (1). PAS has drawn considerable attention in the current century since the incidence of PAS has increased significantly in response to the rising trend of caesarean deliveries (CD) (2). The incidence of PAS rose from 1 in 4,000 deliveries in the 70s of the last century to 1 in 533 to 1 in 730 deliveries in the last decade (3). PAS is associated with significant maternal morbidity including massive obstetric haemorrhage, coagulopathy, ICU admission, mechanical ventilation, infection, and prolonged hospitalization. Maternal mortality reaches 30% in some reports (4).

Caesarean hysterectomy is, by far, the most widely accepted management of PAS since it promotes controlled surgical circumstances and precludes massive bleeding from placental disruption. Caesarean hysterectomy is endorsed by the American College of Obstetricians and Gynecologists (ACOG) and the Royal College of Obstetricians and Gynaecologists (RCOG) as a primary approach in women with PAS (5, 6). Nevertheless, the practice of uterine preservation, which comprise several procedures that aim at stopping uterine bleeding without removing the uterus, is widely adopted worldwide (7). This practice is driven by high motivation of many women to preserve their future fertility, which has led to increasing experience of performing these procedures (8). However, evidence on efficacy and safety of most uterus preserving procedures are limited due to paucity of consistent studies and limited sample size. These factors have resulted in a wide gap between evidence-based recommendations and current practice regarding PAS management in many countries of the world.

Placenta accreta spectrum international database (PAS-ID) is a large international multi-center study of women with confirmed diagnosis of PAS. The objective of this study is to compare perioperative massive blood loss between women who underwent uterus preserving procedures and caesarean hysterectomy. In addition, the study aims at identifying antenatal and intrapartum risk factors associated with massive bleeding in women with PAS.

Methods

Study population

The “Placenta Accreta Spectrum International Database (PAS-ID)” is a multicentre international database of women diagnosed with PAS that was initiated on January 21st, 2020 by Middle-East Obstetrics and Gynaecology Graduate Education (MOGGE) Foundation (*ClinicalTrials.gov identifier: NCT04384510*). A consortium of 11 PAS referral centres, which conduct both caesarean hysterectomy and uterus preservation, contributed to the study. These centres locate in 9 countries (*Portugal, Russia, Turkey, Taiwan, Indonesia,*

China, Pakistan, Egypt, and Cameroon), which present 3 different continents. Data of PAS patients were retrospectively collected between January 1st, 2010 and December 31st, 2019. Inclusion criteria included clinical and histopathological diagnosis of PAS, management, and delivery by the respective center, including at least 6 weeks of postpartum follow-up. Women with deficient documentation, inadequate antenatal or postpartum follow-up, or no documented authorization to use clinical data for research purposes, were excluded from the study. Variability of PAS management protocols were limited among centres and over time within the same center. In general, diagnosis of PAS was made by greyscale transabdominal and transvaginal ultrasound with Doppler assessment during mid-trimester foetal anatomy scan, which might be repeated if necessary. Magnetic resonance imaging was confined to cases where extent of invasion beyond the uterus is suspicious. Women with PAS Patients were counselled on management options. Deliveries was planned between 35 and 37 weeks of gestation unless earlier delivery was indicated for emergency situations or due to another obstetric indication. Either preoperative or intraoperative ultrasound was performed to localize the placenta. Intraoperatively, adequate exposure of the lower uterine segment was made prior to delivery, the uterus was incised away from placental site. Once the foetus was delivered, uterine bleeding and placental invasion were assessed to determine surgical approach. Common uterus preserving procedures included swing of placental bed, vascular ligation, and compression sutures, most commonly B-Lynch and Nausicaa sutures (9). Uterine wall resection was considered when area of invasion was localized, and re-approximation of uterine edges was achievable. Blood transfusion was determined by clinical assessment until laboratory test results were available. Interventional radiology was not available in most centres and was offered to a few patients if it was supported by a multidisciplinary team decision. Postoperative admission to intensive care unit (ICU) versus high dependency unit was decided by the surgeon and the anaesthetist based on maternal hemodynamic stability, laboratory tests, and the presence of other risk factors.

Data abstraction

Data of eligible patients were reviewed and abstracted using a standardized spreadsheet that comprise patient baseline information (*e.g. age, parity, body mass index “BMI”, ethnicity, smoking status*), obstetric and gynaecologic data (*e.g. obstetric complications, previous CS, prior gynaecologic surgeries*), medical history, antepartum and intrapartum disease characteristics (*e.g. PAS type, complete versus focal uterine wall invasion, bladder invasion, parametrial invasion, placental location*), diagnosis (*antepartum versus intrapartum diagnosis, imaging modality, and gestational age at diagnosis*), antepartum haemoglobin level, intraoperative details (*e.g. hysterectomy versus uterine preservation, uterus preserving procedures used either surgical or IR-related, success of uterine preservation, use of preoperative or intraoperative sonographic assessment, type of uterine incision and its relation to the placenta, intraoperative blood loss, transfused blood products, surgical complications*), maternal outcomes (*success of uterine preservation, length of hospital stay, admission to intensive care unit [ICU], postoperative complications*), and neonatal outcomes. Data collection was completed on June 15th, 2020.

Study Outcomes

Primary outcome of the study was massive PAS-associated blood loss. This indicates intraoperative blood loss equal to or greater than 2500 ml, blood loss necessitating massive blood transfusion (defined as transfusion of at least 10 units of packed red blood cells [RBCs] within 24 hours) or disseminated intravascular coagulopathy (DIC) secondary to intraoperative blood loss. Statistical analysis Continuous variables were described in means and standard deviations/medians and interquartile ranges (IQR), and categorical variables were summarized in numbers and percentages. Shapiro-wilk test was used to test normality of distribution; parametric variables were compared using student’s t test while non-parametric variables were tested using Mann-Whitney U test. Logistic regression was used to test association between the primary independent variable (uterus preservation vs. caesarean hysterectomy), with adjustment for potential confounders, and outcomes (massive PAS-associated blood loss and admission to ICU). Each independent variable was first tested using univariable logistic regression and results were expressed in unadjusted odds ratio (OR) and 95% confidence interval (CI). Variables which yielded p-values of less than 0.2 in univariable logistic regression were included in the final multivariable logistic regression model. Results were presented as adjusted

ORs (aORs) and 95% CIs. Statistical analysis was conducted using STATA 16 software (StataCorp, College Station, TX).

Results

Out of 797 women who were reviewed during data collection, 727 women were eligible for the study. Five hundred ninety-two (81.43%) women were managed by uterus preserving procedures, while 135 (18.56%) underwent caesarean hysterectomy. Their mean ages were 32.99 ± 4.94 and 33.83 ± 4.73 years, respectively. Of women managed by uterus preserving procedures, PAS type was accreta in 293 (49.49%) and 10 (7.41%) in women who had caesarean hysterectomy. Placenta percreta was present 86 (63.70%) of women who had caesarean hysterectomy. In women managed by caesarean hysterectomy, placental site was most commonly central, covering the internal os in 78 (57.78%) women, while it was equally localized anterior low, posterior low, or central in women who had uterus preservation. Among women who were treated with uterus preserving procedures, compression sutures were applied to 195 (32.94%) patients, placental bed swing was done in 115 (19.43%) patients, vascular ligation was performed in 89 (15.03%), and local uterine wall resection was achieved in 33 (5.57%) patients. Uterus preservation was unsuccessful in 20.1% of cases. Massive blood loss was reported in 129 (17.74%) of women. Patient characteristics, PAS features and management approaches are summarized in Table 1.

Incidence of intraoperative complications were significantly higher among women managed by caesarean hysterectomy. Specifically, unintentional cystotomy occurred in 33 (24.44%) women in the “caesarean hysterectomy” group compared to 41 (6.93%) in the “uterus preservation” group ($p < 0.0001$). Otherwise, bowel and ureteric injuries were comparable in both groups. PAS-associated massive blood loss was more common in “caesarean hysterectomy” group compared to “uterus preservation” group (43 [31.9%] vs. 86 [14.5%], respectively; $p < 0.0001$). There was no significant difference in the incidence of maternal admission to ICU between the 2 groups. Table 2 shows a summary of clinical outcomes of treatment groups.

On univariate analysis, uterus preservation was associated with lower risk of PAS-associated massive blood loss (unadjusted OR 0.36, 95% CI 0.24 - 0.56). After adjustment for significant or close-to-significance variables, management approach was not associated with higher risk of massive blood loss (aOR 1.71, 95% CI 0.78 - 3.81). Massive blood loss was significantly associated with BMI (aOR 1.09, 95% CI 1.02 - 1.15), gestational age at diagnosis (aOR 1.08, 95% CI 1.02 - 1.14), preoperative haemoglobin (aOR 0.77, 95% CI 0.65 - 0.92), interventional radiology (aOR 5.62, 95% CI 2.38 - 13.29), centrally located placenta (aOR 2.28, 95% CI 1.25 - 4.18), diffuse versus localized invasion (aOR 3.15, 95% CI 1.61 - 6.16), incision away from the placenta (aOR 0.26, 95% CI 0.13 - 0.51), bladder invasion (aOR 3.08, 95% CI 1.95 - 8.61), parametrial invasion (aOR 5.37, 95% CI 1.21 - 23.79), and intrauterine foetal death (aOR 10.25, 95% CI 1.51 - 69.34) (Table 3).

Discussion

Main Findings

In the current study, data from a multicentre study was used to compare uterus preserving procedure to caesarean hysterectomy in women with PAS. After adjusting for potential confounders, uterus preserving procedures did not seem to increase risk of perioperative massive blood loss. Our results also showed that increased BMI, more advanced gestational age at diagnosis of PAS, use of interventional radiology, centrally located placenta over the internal os, diffuse placental invasion, parametrial and bladder invasion, and intrauterine foetal death were risk factors for massive blood loss. On the other side, higher preoperative haemoglobin, and uterine incision away from the placenta were both protective against significant bleeding. Incidence of complications between the two approaches were comparable with higher incidence in unintentional cystotomy in women undergoing caesarean hysterectomy.

Strengths and limitations

The study is supported by a large PAS cohort, that is representative of international practice. The study conveyed results of the most used conservative approaches. The study precluded the confounding effect of

most clinically relevant determinants of outcomes. However, the study was limited by the inherent disadvantages of retrospective studies. Retrospective approach was selected due to recruitment difficulties associated with uncommon disorders. The study did not include all uterus preserving procedures, such as “leaving the placenta in situ”, which may be less commonly adopted. The study did not include antenatal sonographic features, which were not feasible to assess and include in retrospect while outcomes were already known.

Interpretation

Uterus preserving procedures are considered by many obstetricians worldwide in women with PAS who are highly motivated to preserve their fertility. However, evidence on safety of these procedures is lacking and therefore, their use has not been endorsed by guidelines. An exception is “leaving the placenta in situ”, which is considered by RCOG and FIGO (the International Federation of Gynaecology and Obstetrics) (6, 10). Unfortunately, this approach is not commonly incorporated in practice due to concerns on complexity of postpartum care and possibility of serious complications (11). Uterus preserving procedures lack evidence-based support because data are derived from small studies, which usually present new or modified techniques rather than validation of a previous technique (12, 13). In addition, many of these studies do not define criteria of eligible women for uterus preserving procedures versus caesarean hysterectomy. Instead, they describe a successful technique that was performed on a selected group of patients. Paucity of cases of PAS is another barrier to validation of these studies. Therefore, available data are unlikely to draw a robust conclusion on these procedures. PAS-ID was created to permit studying of a large cohort of women with PAS, that were managed by centres that offer both caesarean hysterectomy and uterus preserving procedures. The study was conducted internationally to convey spectrum of the most widely accepted management options, which were noticeably consistent.

Although current results seem to support uterus preserving procedures as a safe alternative to caesarean hysterectomy in women interested in future fertility, this conclusion should be cautiously interpreted. The study was conducted in PAS referral centres, with long experience in uterus preserving procedures. Since these procedures are not recognized or no longer supported in many countries, experience is limited to some foreign obstetricians and similar results cannot be granted. Accordingly, uterus preserving procedures should only be considered in experienced centres. However, incorporation of uterus preservation training, as a part of a PAS training program, may be encouraged to rebuild and enhance this experience particularly in nationally recognized PAS centres. Interpretation of our results should also encompass patient selection. There were no strict criteria to define which women were considered for uterus preserving procedures in our cohort other than patient preference, and the decision was mainly made intraoperatively. Therefore, our results may be caused by appropriate obstetricians’ judgement in patient selection, which should be recapitulated into criteria to facilitate reproducibility of outcomes. Accordingly, we defined factors which would alter risk of massive blood loss to improve selection process. While relation of these factors to blood loss, such as parametrial invasion, are apparently justifiable, clinical judgement of these factors is necessary. For example, interventional radiology is probably associated with, rather than causative of, massive blood loss since selected women may be those at higher risk of significant intraoperative bleeding. Moreover, a previous study on women who were managed with uterus preserving procedures was conducted using the same database, to create a scoring system that predict success of these procedures. The MOGGE CON-PAS score comprises specific parameters that can be used to calculate probability of success of uterine preservation and can be used to improve selection process (14).

Conclusion

uterus preservation procedures may be comparable to caesarean hysterectomy in probability of perioperative massive blood loss if robust experience in performing these procedures is available. Awareness of antenatal and intraoperative risk factors is crucial for proper patient selection. However, prospective studies may be recommended to validate these conclusions.

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Contribution to Authorship:

SAS: principal investigator, study concept, study design, data analysis, manuscript writing
IH: Regional principal investigator, study design and data collection, manuscript reviewing
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PVP: Regional principal investigator, study design and data collection, manuscript reviewing
SI: Regional principal investigator, study design and data collection, manuscript reviewing
JNT: Regional principal investigator, study design and data collection, manuscript reviewing
ASA: Regional principal investigator, study design and data collection, manuscript reviewing
MAS: Data cleaning, statistical analysis, manuscript writing, manuscript reviewing
AAR: Data cleaning, statistical analysis, manuscript writing, manuscript reviewing
EGS: Data cleaning, statistical analysis, manuscript writing, manuscript reviewing
GME: Data cleaning, statistical analysis, manuscript writing, manuscript reviewing
EMH: Data cleaning, statistical analysis, manuscript writing, manuscript reviewing
SSA: Data cleaning, statistical analysis, manuscript writing, manuscript reviewing
ASD: Study design, manuscript writing, manuscript reviewing
AME: Study coordinator, data collection, manuscript reviewing
AOY: Data collection, review of collected data and quality assessment, manuscript reviewing
SS: Data collection, review of collected data and quality assessment, manuscript reviewing
IMI: Study coordinator, data collection, manuscript reviewing
JK: Data collection, review of collected data and quality assessment, manuscript reviewing
KYH: Data collection, review of collected data and quality assessment, manuscript reviewing
EY: Study coordinator, data collection, manuscript reviewing
YL: Study coordinator, data collection, manuscript reviewing
HA: Data collection, review of collected data and quality assessment, manuscript reviewing
TA: Data collection, review of collected data and quality assessment, manuscript reviewing
AA: Data collection, review of collected data and quality assessment, manuscript reviewing
ÇA: Study coordinator, data collection, manuscript reviewing
YK: Data collection, review of collected data and quality assessment, manuscript reviewing
AK: Data collection, review of collected data and quality assessment, manuscript reviewing

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NA: Study coordinator, data collection, manuscript reviewing

AV: Study coordinator, data collection, manuscript reviewing

AM: Data collection, review of collected data and quality assessment, manuscript reviewing

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DS: Data collection, review of collected data and quality assessment, manuscript reviewing

AYP: Data collection, review of collected data and quality assessment, manuscript reviewing

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Details of Ethics Approval:

Before the study was conducted, all participating centers obtained institutional review board (IRB) approval. Primary IRB approval was issued in Aswan University by Aswan faculty of medicine ethics committee (*date: 11/2/2020; reference number: Aswu/439/2/20*). The study was approved by the Inonu University scientific research and ethical committee on 3/3/2020 (*reference number: 2020/476*), by Ege University IRB on 14/4/2020 (*reference number: 20-4.1 T/3*), by Fatima memorial hospital/college of medicine and dentistry on 5/12/2020 (*reference number: FMH-03-2020-IRB747-M*), by Van Yuzuncu yil University ethical board on 09/06/2020 (*reference number: 55163642-100-E.36909*), by Kazan State University local ethical committee on 30/6/2020 (*reference number: 1765*), by Centro Hospitalar São João ethics committee on 21/5/2020 (*reference number: 76/2020*), National Taiwan University College of Medicine ethical committee on 30/3/2020 (*reference number: 202003007RINC*), Faculty of Medicine of University of Yaoundé I ethical committee on 25/2/2020 (*reference numbers: 1019/CIERSH/DM/2020*). Both Peking University Shenzhen Hospital and Universitas Padjadjaran Bandung were waived for the minimal risk per their local hospital policies.

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