

Full length article

## Maternal and neonatal outcomes following a proactive peripartum multidisciplinary management protocol for placenta creta spectrum as compared to the urgent delivery<sup>☆</sup>



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### ABSTRACT

**Background:** Adherent and invasive placenta, termed Placenta Creta Spectrum (PCS), is associated with increased maternal morbidity and mortality. Incidence and risk factors for Placenta Creta are on the rise and call to optimize the obstetric care for this condition.

**Objectives:** We sought to compare maternal and neonatal outcomes between a ProActive Peripartum Multidisciplinary Approach (PAMA) as compared to the urgent management of the Placenta Creta Spectrum patients.

**Study design:** We conducted a single-center prospective observational study between 2005–2016. PCS patients registered with the implementation of a PAMA protocol 2014–2016 epoch (E2) were compared with the pre-PAMA 2005–2013 epoch (E1), managed by urgent team recruitment. The PAMA protocol is grounded on a continuum of care; A. Antenatal: PCS risk assessment based on clinical history and imaging, surgical, anesthesia, urological consults and designation of a dedicated team to be present at planned surgery; B. Delivery: planned at 34–35 weeks, massive transfusion protocol activation, insertion of ureteral catheters, vertical uterine incision, placement of vessel loops on the iliac vessels, avoidance of active placenta delivery, followed by the decision of hysterectomy or uterine repair; C. Post-operative care: intensive care admission. We evaluated maternal and neonatal outcomes.

**Results:** During the study period 158,438 deliveries were registered in our institution; we identified a total of 72 PCS cases (0.05%): 50 (69.4%) in E1 and 22 (30.6%) in E2. Patient characteristics were comparable among epochs. Significantly, patients in E2 vs. E1 had fewer events of massive blood transfusion 36.0% vs. 13.6%,  $p=0.05$ ; were transfused less RBC units: median 4 vs. 1.5,  $p=0.012$ , had no transfusion-related respiratory complications and hemorrhage control re-laparotomies. Hysterectomy and hollow visceral injury rates were comparable (72% vs. 63.7%, 26% vs. 22%; respectively). The hysterectomy pathology assessment was available for the majority of the cases in both epochs; percreta diagnosis rate significantly increased in E2. The neonatal outcome was similar among the epochs.

**Conclusions:** Institution of a PAMA protocol for PCS resulted in eliminating the urgent deliveries and in reducing the associated significant hemorrhagic related maternal morbidity, with no increase in the rate of hysterectomy or adverse neonatal outcome.

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## Introduction

Placenta Creta Spectrum (PCS) disorder is a contemporary term to describe both the adherent and invasive placenta and defined as abnormal adherence to or invasion of the villous tissue into the deeper vascular areas of the myometrium [1,2]. This abnormal type of placentation results in an incomplete or absent plane of cleavage from the uterine wall, which translates clinically as massive hemorrhage at the removal of the placenta at delivery [3,4]. Since major risk factors for PCS such as advanced maternal age, parity and repeat cesarean section rates are on the rise [5], contemporary obstetrics departments are facing the challenge and aim to optimize the care of an increasing number of patients with PCS.

While strategies to reduce the rate of pregnancies complicated by PCS would be welcomed, in the current obstetrical setting, strategies must be devised to effectively and safely manage cases of PCS. To this end, we herein present data from a single tertiary medical center with pregnancies complicated by PCS. In this study, we compare both maternal and neonatal outcomes and the complication rates in the epochs before and after the implementation of a Pro-Active Peripartum Multidisciplinary Approach (PAMA).

## Study design, patients and methods

### Obstetric facility and protocol description

Shaare Zedek Medical Center is a tertiary, teaching medical center. The labor and delivery department consists of 15 delivery rooms with two operating rooms. Approximately 16,000 deliveries are attended annually with a center cesarean delivery rate of 11% (reported national cesarean rate of 19%). All patients' care is covered by the National Health Insurance plan. We identified all cases of pre- or perioperatively diagnosed with PCS in the period between 1 January 2005 and 31 December 2016; the data were identified using the computerized hospital database. Independent

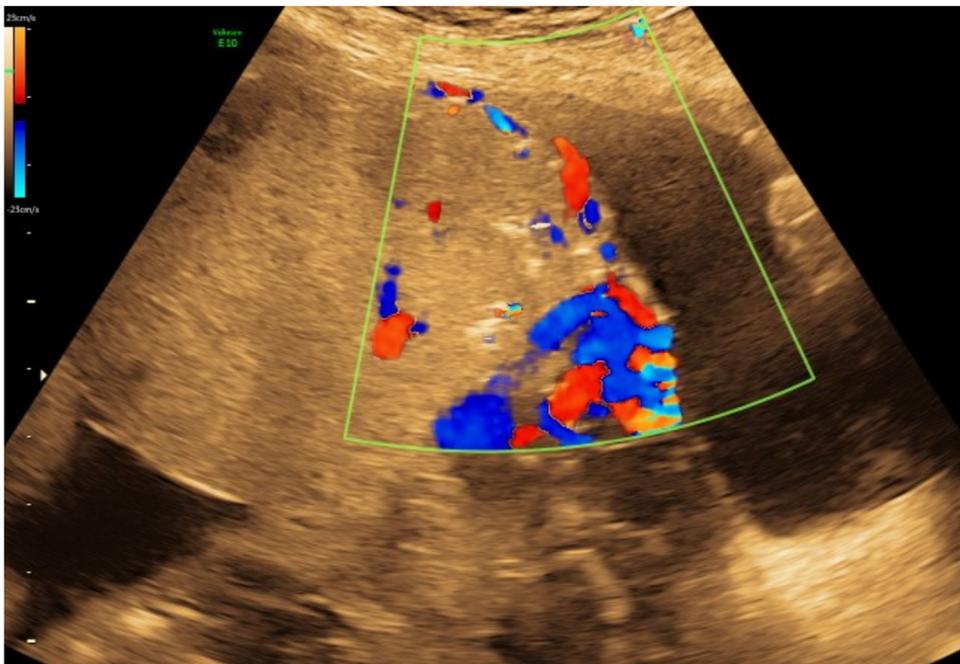
confirmation of the data and additional medical information was retrieved from the individual operative notes, obstetrical, anesthesiology and intensive care unit medical records by two authors (JS and DG). The report on non-concordant information was discussed and decided by all authors.

This study analyzed and compared two separate epochs within the study period: cases registered with the implementation of PAMA protocol 2014–2016 epoch(E2) and pre-PAMA 2005–2013 epoch(E1), treated by *ad hoc* urgent team recruitment. Statistical analysis was carried out in this prospective observational study for both epochs: E1 (2005–2013) and E2 (2014–2016).

The PAMA protocol was planned and devised by our division and includes in-hospital pre-delivery assessment and planning, peri-delivery systematic surgical approach, and post-delivery follow-up. The following is an outline of our PAMA protocol:

### Pre-delivery stage

Morbidly adherent placenta (MAP) outpatient risk assessment is carried out on all suspected cases based on clinical history and sonographic imaging around midtrimester routine or fetal anatomy scan in the community clinics. Patients suspected of the MAP are referred and assessed in-hospital starting at 28–29 weeks gestation with a follow-up Ultrasound and MRI when confirmation of MAP is inconclusive. Sonographic assessment of risk is carried out using recognized MAP landmarks such as blood lacunae around the lower segment (Fig. 1), obliteration of the Nitabuch layer, and frank invasion of bladder, parametria or other adjacent organs [6,7]. Patients defined at risk of PCS undergo antenatal surgical, obstetric anesthesia, urological consultations that include cystoscopy and neonatology evaluations. The surgical team is composed of a board-certified obstetrician, a gynecology- oncology trained surgeon and the obstetrician on service. The ICU and the blood bank are informed of the upcoming surgery. A cell server device and the technical support is present at surgery. During the



**Fig. 1.** Antenatal Sonographic diagnosis of MAP – Bridging vessels from placental mass to uterine-bladder interface.

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study period, the core gynecological oncology surgeons remained in service (M.S, F.H, and B.Z).

#### Peri-operatively and surgical protocol

For patients included in the PAMA protocol, there is a rigorously followed surgical approach outlined herein (Figs. 2,3). A multidisciplinary team is present at planned surgery which is scheduled electively between 33–35 weeks or any time the patient presents with uterine contractions or antenatal bleeding that require delivery. The surgery protocol is followed independently of the time of surgery. Our surgery protocol includes:

- Massive transfusion protocol activation
- Cystoscopic insertion of ureteral catheters
- Visual assessment of abnormal vascular pattern on the uterine wall and bladder (Fig. 2)
- Vertical or fundal/posterior wall uterine incision (dependent on the antenatal imaging location of the placenta relative to uterine cavity) (Fig. 3)
- Delivery of the neonate
- Prophylactic placement of vessel loops on the iliac vessels
- Avoidance of active placenta delivery
- Observation for spontaneous placenta detachment for 5–10 min during an inspection of the adjacent organs and vessels
- The decision of hysterectomy with the placenta in situ and closure of the uterine incision or uterine repair in cases where the placenta detached spontaneously and placental bed bleeding under control (sutures or uterotonics)

Pre-cesarean prophylactic balloon placement in the internal iliac artery to prevent postpartum hemorrhage is not part of the PAMA protocol and employed solely for the management of postpartum bleeding in hemodynamically stable patients. Visualization of the placenta by intraoperative ultrasound on the uterus after its exposure is not performed.

#### Post-operatively

ICU transfer is decided according to the estimated blood loss, blood transfusion requirements, and hemodynamic stability.

Otherwise, the patients are followed for the first 24 h post-surgery in the post-anesthesia care unit (PACU).

Following the introduction of PAMA, we hypothesized that the novel systematic multidisciplinary approach would yield benefits to the patients presenting with PCS by reducing peri-operative morbidity without compromising fetal wellbeing. To evaluate this hypothesis, we compared several maternal and neonatal characteristics and outcomes between both epochs, namely E1 & E2. Maternal characteristics: maternal age, age > 35 years, parity, Gestational Diabetes Mellitus, a hypertensive disorder in pregnancy, prior miscarriage, previous Cesarean Section delivery.

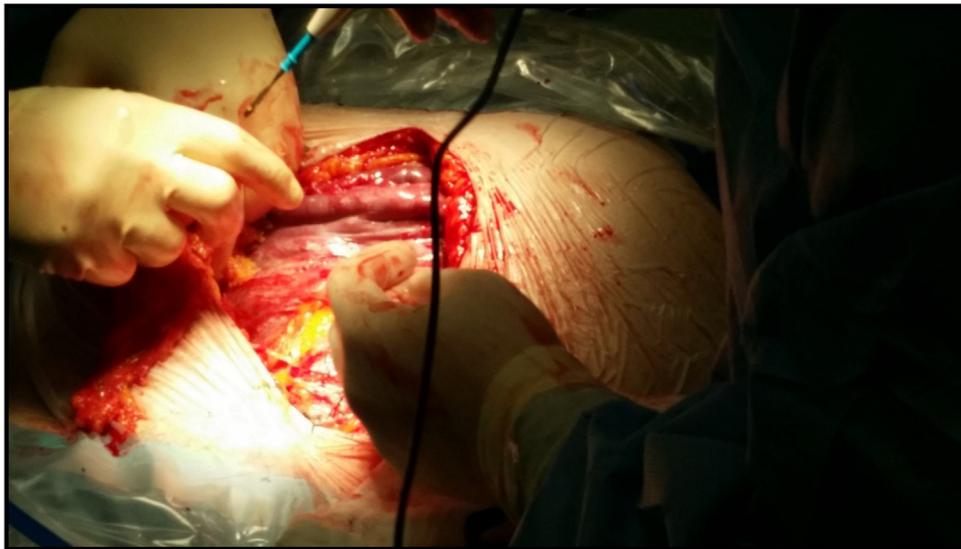
Maternal outcomes: hemoglobin drop > 3gr% between admission and the lowest level recorded, transfusion of blood products: Packed RBC units, Fresh frozen Plasma units, cryoprecipitate units, massive transfusion (>4 Packed RBC units transfused), puerperal fever, bleeding control re-laparotomy, hollow viscus injury, maternal hospitalization length > 7 days, respiratory complications (ARDS/TRALI).

Neonatal outcomes: gestational age at birth, birth weight, 5' APGAR < 7, mean number of neonatal hospitalization days, neonatal hospitalization > 7 days, NICU hospitalization > 72 h.

The statistical methods: Continuous variables were presented as mean  $\pm$  SD and median and interquartile range, categorical variables were displayed as proportions (%). Comparisons: Relations between categorical variables were evaluated by chi-square and Fisher's exact tests. The effect of categorical variables on continuous measurements was tested by unpaired student *t*-test and by Mann-Whitney test. The choice of a parametric or nonparametric test depended on the distribution of a continuous variable. The p-values were 2-sided when p-values < 0.05 were considered statistically significant. All analyses were carried out by IBM SPSS Statistics V22.0.

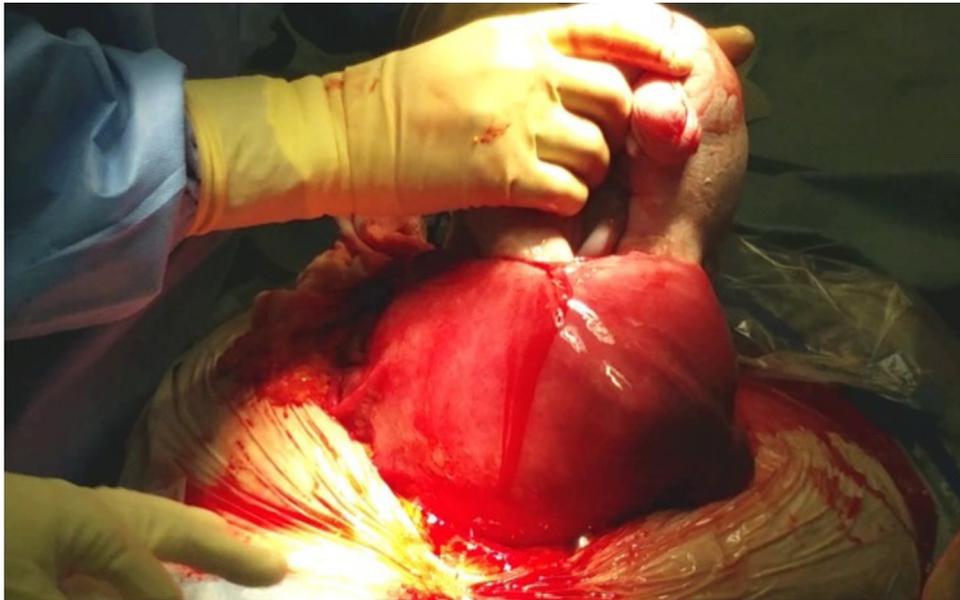
#### Results

During the study period, 158,438 deliveries were registered. A total of 72 pregnancies complicated by PCS (0.05%) were identified and included: 50 (69.4%) in E1 and 22 (30.6%) in E2. Patient characteristics were similar in both epochs; mean maternal age, the proportion of elderly gravidas (defined as patients over > 35



**Fig. 2.** Skin midline incision, visual assessment of placental vasculature.

For patients included in the PAMA protocol, there is a rigorously followed surgical approach including skin midline incision followed by a visual assessment of abnormal vascular pattern on the uterine wall and bladder guiding the surgical approach for the uterine incision.



**Fig. 3.** Posterior vertical uterine incision and delivery of the neonate.

The type and location of uterine incision depend on the antenatal imaging location of the placenta relative to the uterine cavity and visual assessment of the placenta during surgery.

years), ethnicity, parity, and educational status were similar in both groups (Table 1).

The maternal associated co-morbidity rates for the women in the two epochs were comparable; gestational diabetes mellitus rates (6% and 13.6%,  $p=0.259$ , respectively), hypertensive disorders complicating pregnancy (12% and 4.5%,  $p=0.305$ , respectively). The majority of patients in both groups were multiparous, experienced previous multiple miscarriages (58% and 72%  $p=0.178$ , respectively), had at least one previous C-section before a pregnancy complicated by PCS (96% and 90.9%,  $p=0.357$  respectively) (Table 1).

Inherent of the definition all E1 patients were delivered on an urgent basis. Notably, all PAMA patients in E2 reached planned surgery.

The maternal outcomes as compared between E1 and E2 were significantly different. Patients in E2 received less blood product transfusions; median 4 (1–8) vs. 1.5 (0–4) packed red blood cell units per patient  $p=0.012$  respectively and experienced fewer events of massive blood transfusions 36.0% vs. 13.6%,  $p=0.05$ .

We identified 6 (12%) bleeding control explorative re-laparotomies in E1 and none (0%) in E2 ( $p=0.102$ ). While 6 cases of ARDS/TRALI (12%), were recorded in E1, none occurred in E2 ( $p=0.102$ ).

Among epochs, hollow viscus injury and hysterectomy rates were not significantly different (26% vs. 22%; 72% vs. 63.7%,  $p=0.508$ , 0.329, respectively) (Table 2).

The neonatal outcome evaluated was similar after comparison for the two study epochs. The mean gestational age at delivery:

$34.96 \pm 2.9$  vs.  $34.14 \pm 3.62$  weeks, as well as the birth weight  $2460 \pm 682.9$  vs.  $2317 \pm 798.9$  g,  $p=0.442$ , respectively. The neonates had similar rates of 5' APGAR < 7 and spent similar periods in the NICU, 27.3 vs. 27.8,  $p=0.608$  (Table 3).

Overall, we obtained pathology assessment for 51 cases (70.8%); 38 (74.5%) were derived from hysterectomy specimens and the rest from the placental uterine bed and uterine wall defects repaired at surgery. A significantly higher rate of placenta percreta diagnosis in E2 in comparison to E1 was observed (15.1% vs. 50%,  $p=0.008$ , respectively) (Table 4).

## Discussion

Placenta Creta Spectrum (PCS) is a cluster of conditions whose nomenclature and classification are still evolving [2,1]. Recent studies focused on elucidating the pathophysiology at the basis of this conditions that represents a challenge of antenatal diagnosis and delivery management [3]. Despite advances in diagnosis, including ultrasonographic prenatal diagnosis and risk scoring [6,8,9], the delivery is still associated with a significant risk of maternal morbidity [4].

It appears that is the incidence of PCS is rising in parallel to the incidence of the risk factors for this condition; maternal age and repeat cesarean sections, with recent estimates approximating 1 per 333 – 1 per 533 deliveries [10,11].

The requirement for the feasibility of a standardized multidisciplinary team approach to the management of PCS became

**Table 1**  
Population characteristics in the two study epochs.

	E1 (2005–2013)	E2 (2014–2016)	P value
N (%)	50 (69.4)	22 (30.6)	
Maternal age (years), mean $\pm$ SD	35.2 $\pm$ 4	34.7 $\pm$ 4	0.651
Age >35 years, n (%)	23 (46)	10 (45.5)	0.966
Parity, n $\pm$ SD	4.94 $\pm$ 2.69	6.46 $\pm$ 3.49	0.075
Gestational Diabetes Mellitus, n (%)	3 (6.0)	3 (13.6)	0.259
Hypertensive Disorder in Pregnancy, n (%)	6 (12.0)	1 (4.5)	0.305
Prior Miscarriage, n (%)	29 (58.0)	16 (72.7)	0.178
Women with previous Cesarean Section, n (%)	48 (96.0)	20 (90.9)	0.357

**Table 2**

Maternal outcome in the two study epochs.

	E1 (2005–2013), n = 50	E2 (2014–2016), n = 22	P value
Massive transfusion (>4 PRBC units), n (%)	18 (36.0)	3 (13.6)	0.047
Packed RBC units, median (interquartile range)	4 (1.5–8.0)	1.5 (0–4.0)	0.012
Fresh Frozen Plasma units, mean $\pm$ SD	3.96 $\pm$ 5.7	1.7 $\pm$ 2.3	0.24
Cryoprecipitate units, mean $\pm$ SD	5.98 $\pm$ 14.0	2.77 $\pm$ 5.82	0.41
Hemoglobin drop >3gr, n (%)	32 (68.1)	15 (68.2)	0.610
Puerperal fever, n (%)	2 (4.0)	2 (9.1)	0.357
Respiratory complications (ARDS/ TRALI)*, n (%)	6 (12.0)	0 (0.0)	0.102
Bleeding control re-laparotomy, n (%)	6 (12.0)	0 (0.0)	0.102
Hollow viscus injury, n (%)	13 (26.0)	5 (22.7)	0.508
Maternal Length of hospitalization > 7 days, n (%)	20 (40.0)	10 (45.5)	0.429

\* ARDS – Acute respiratory distress syndrome, TRALI – Transfusion-related acute lung injury.

**Table 3**

Neonatal outcome in the two study epochs.

	E1 (2005–2013), n = 50	E2 (2014–2016), n = 22	P value
Gestational age at delivery (weeks), mean $\pm$ SD	34.96 $\pm$ 2.9	34.14 $\pm$ 3.62	0.261
LBW* neonates, n (%)	15 (45.5)	12 (66.7)	0.123
VLBW* neonates, n (%)	2 (6.1)	3 (16.7)	0.230
NICU > 72 hours, n (%)	21 (42.0)	15 (68.2)	0.036
APGAR < 7 at 5 minutes, n (%)	9 (27.3)	5 (27.8)	0.608
Mean hospital stay, days (median, interquartile range)	10.2 (6.1 – 16.1)	10.16 (5.9 – 32.9)	0.559
Women with a hospitalization length > 7 days, n (%)	16 (48.5)	9 (50.0)	0.575

\* LBW – Low Birth Weight. VLBW – Very Low Birth Weight.

**Table 4**

Pathology assessment of the Placenta Creta Spectrum patients.

Pathology	E1 (2005–2013), n = 33	E2 (2014–2016), n = 18	P value
Accreta, n (%)	9 (27.3)	4 (22.2)	0.75
Increta, n (%)	19 (57.6)	5 (27.8)	0.042
Percreta, n (%)	5 (15.1)	9 (50.0)	0.008

evident, both in the community hospital setting as well as the tertiary medical center setting and is reflected in the different studies published until now [12–16].

In the present study, we present data comparing the maternal and neonatal outcomes before and after the strict implementation of a Proactive Peripartum Multidisciplinary Management Protocol (PAMA) for PCS, provided a steady patient population, health insurance coverage and no turnover of the core surgeons, for more than a decade.

Our data indicate that the implementation of a structured PAMA protocol leads to improved maternal outcomes, primarily related to obstetric hemorrhage, blood products transfusion of any magnitude and its complications. Notably, also the bleeding control re-laparotomies and the ARDS/TRALI complication were lower in the PAMA period (E2). We postulate that this difference in morbidity further contributed to the maternal length of hospitalization, which was significantly shorter in E2.

The adjacent viscus injury and the rate of cesarean hysterectomy did not differ among the periods. Albeit the implementation of the cystoscopy and ureteral catheters insertion before surgery, we found no decrease in the ureteral injury. However, this may be explained by the blunt dissection to visualize the ureters (ureter exploration) while approaching the uterine bleeding vessels control, even in the absence of the ureter catheters. Although in the presence of skilled surgeons, ureteral catheters insertion had no impact on injuries, it may have contributed to the surgeon's confidence to manage uterine vessel derived hemorrhage, surgery time and consequently less hemorrhagic complications. Two-thirds of the patients underwent a cesarean hysterectomy

in both epochs; the E2 hysterectomy rate was lower albeit a higher rate of percreta diagnosis on the pathology examination. However, we reached no statistical significance, and the study was limited to evaluate the PCS cesarean delivery – hysterectomy risk covariates. Larger statistically powered studies are to be reported to evaluate the hysterectomy risk at PCS cesarean delivery. In the present study, the observed difference could be a result of the time required to gather an *ad hoc* surgical team while unexpected bleeding event during cesarean and placenta removal in E1, thus the surgeons' tendency to perform a hysterectomy for rapid bleeding control.

The present study is remarkable for the availability of the pathological assessment in the two epochs. The pathology reports of both epochs showed that significantly more diagnoses of percreta placentas were received in E2, for a similar rate of hysterectomies. This may reflect either the evolution of a different and more severe PCS disorder or a change in the pathological assessment.

The planned cesarean delivery for PAMA at 33–35 weeks gestation proved to be safe for the mother and the neonate while eliminating the urgent delivery; other studies which implemented a decision to deliver at a more advanced gestational age of 34–35 weeks, based on neonatal consideration, reported emergency deliveries for PCS. This group also suggested scheduling delivery before the standard 34- to 35-week timeframe to eliminate the maternal morbidities associated with urgent delivery [17,18].

We herein show that neonates in E2 fared no worse than those in E1. As our data indicate, while neonates had a higher risk for NICU admission in E2, inherent to the designed gestational age at delivery, all other measures of adverse immediate neonatal outcomes were similar between both epochs, including the rate of low APGAR scores and the mean overall length of hospitalization. While the gestational age at delivery was similar among the two study epochs, the higher admission rate and the longer NICU stay in the PAMA study may be due to more neonates being born closer to 33 weeks of gestation as well as the different neonatology protocols used.

Our study bears inherent limitations: 1. The PAMA protocol is based on a high rate of antenatal diagnosis of PCS, raised index of suspicion and community awareness. 2. A limited number of patients, that limited the ability to perform multivariate analysis; however, the number of women included in the study was proportional to the deliveries of the center and within the range of the published incidence of PCS; 3. A homogenous population that may lower the external validity of the study, although the reported results were similar to other populations; 4. Highly trained personnel availability based on a national health plan insurance program, which may not be available in other health systems; 5. The decision to perform primary hysterectomy versus placental bed bleeding control is left to the surgeon's discretion and not part of the PAMA protocol; 6. We had no information of antenatal steroid administration for fetal lung maturation, and thus their impact on the neonatal outcome could not be assessed; 7. The burden of the health cost of the urgent versus PAMA approach was beyond the scope of this study and may differ geographically.

Our study has significant strengths: 1. It is one of the largest single-center cohorts published to date reviewing maternal and neonatal outcomes of pregnancies complicated by PCS; 2. The validated electronic medical database, software program, and coding; 3. The PAMA protocol was strictly implemented using a stable core of the surgeons; 4. The pathology assessment of the PCS for a majority of the patients in both study epochs.

Notwithstanding, we conclude that the implementation of the suggested PAMA protocol results in lower bleeding and transfusion-related maternal morbidity without a detrimental neonatal outcome. We are confident that multicenter studies on the implementation of PAMA or a PAMA similar approach will provide further maternal benefits such as uterine preservation, as well as insights into the pathophysiology of PCS.

#### Conflict of interest and financial disclosure statements

The Authors report no conflict of interest.

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#### Details of ethics approval

The study was approved by the Institutional Review Board for clinical studies of Shaare Zedek Medical Center, Affiliated with the Hebrew University Hadassah School of Medicine, Jerusalem, Israel on Nov. 16th, 2017. Approval ID: 0287-17-SZMC. All Figures are original and were taken by the author (JM) and are included in this paper after receiving informed consent from the patient.

#### Author's contribution

JS: Research performance and author of the manuscript  
 JM: Author of the manuscript, critical review of the manuscript and correspondent author  
 SA: Surgical core team and critical review of the manuscript  
 FH: Surgical core team and critical review of the manuscript  
 BZ: Surgical core team and critical review of the manuscript  
 MS: Surgical core team and critical review of the manuscript  
 AI: Obstetric anesthesia and member of the surgical core team  
 OS: Urology service and member of the surgical core team

DG: Research performance assistance

RF: Data retrieval, database linkage, and statistical analysis

AT: A critical review of the manuscript

AS: A critical review of the manuscript and member of the surgical core team

SGG: Research concept, statistical analysis, manuscript review, and critical appraisal, team coordinator and member of the surgical core team

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