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Pelvic Artery Embolization for Delivery Hemorrhage, assessment of Risk Factors for Severe Maternal Morbidity: A retrospective study

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Faculté des sciences
médicales et paramédicales
Aix-Marseille Université

**Embolisation des artères pelviennes pour hémorragie de la délivrance :
évaluation des facteurs de risque de morbidité maternelle sévère**

T H E S E

Présentée et publiquement soutenue devant

**LA FACULTÉ DES SCIENCES MEDICALES ET PARAMEDICALES
DE MARSEILLE**

Le 5 Octobre 2021

Par Madame Ornella MALTESE

Née le 21 septembre 1991 à Marseille 05eme (13)

Pour obtenir le grade de Docteur en Médecine

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Pelvic Artery Embolization for Delivery Hemorrhage, assessment of Risk Factors for Severe Maternal Morbidity: A retrospective study.

Introduction

Postpartum hemorrhage (PPH), defined as estimated blood loss > 500 ml after delivery, is a common condition that occurs in France after 5% of deliveries¹⁻³ and the United States has seen a marked increase in its incidence rate since the 1990s⁴⁻⁵. Although it remained for many decades the leading cause of maternal mortality⁶, PPH has become, in France, in 2021, the third leading cause of maternal mortality, behind cardiovascular etiologies and suicides⁷⁻⁸. Due to the development of precise therapeutic protocols and interventional radiology techniques, its mortality rate has been divided by two in 15 years⁷. Pelvic artery embolization (PAE), introduced in 1979, is a technique, which has the major advantage of preserving fertility and avoiding surgery. PAE has proven its effectiveness in refractory postpartum hemorrhage with success rates close to 90%⁹⁻¹³. In case of failure, a second embolization or a hemostasis hysterectomy (HH) may be discussed. Although PAE is widely practiced in the world, its technique is not standardized^{9,14-15}. Few studies have investigated failure risk factors. The five largest studies on the subject have identified primiparity, massive transfusion of RBCUs, Disseminated Intravascular Coagulation (DIC), placenta accreta, and arterial anatomical variations¹⁶⁻¹⁹. Minor complications occur in up to 23% of cases^{13,20} and include inguinal pain, hematoma at the puncture site, post-embolization syndromes, and pelvic infections. The major complications are rarer (between 2% and 9%) but are severe and include ischemic lesions such as uterine, bladder and skin necrosis, ischemia of the lower limbs or sciatic nerve, and arterial dissections^{9,13,20}. No study has investigated the causes of these major complications with a high level of evidence. Repeated embolization, malplacentation¹¹ and use of alcohol particles (Polyvinyl Acetate)¹⁴ may be risk factors. Although there is no consensus definition, severe maternal morbidity (SMM) has been steadily increasing worldwide over the past twenty years²¹. The most common definition refers to the Centers for Disease Control's (CDC)²² organ dysfunction criteria: renal failure, cardiac arrest, sepsis, shock, DIC, myocardial infarction, transfusion, mechanical ventilation, pulmonary edema, and eclampsia. SMM has been poorly studied²³⁻²⁶ and to our knowledge, no study has investigated SMM in the context of refractory PPH requiring PAE.

The objective of our study is to evaluate the risk factors for SMM of obstetric-indicated PAE.

Material and methods

Experimental design

An observational retrospective study was conducted in the two obstetrics departments of Marseille University Hospital between 2013 and 2021.

Inclusion criteria

All women who underwent PAE after delivery were included in these two centers during this period. We formed two groups: PPH group corresponding to patients who received PAE for PPH refractory to first-line treatments, avec prophylactic group to patients with placenta accreta, treated by systematic PAE, for prophylactic purpose, immediately in postpartum. PPH has been defined, according to its French consensus definition, as estimated blood loss > 500 ml after delivery avec severe PPH > 1000 ml after delivery. Primary PPH was defined as PPH occurring within the first 24 hours after delivery, while secondary PPH was defined as bleeding occurring later than this period. Patients who presented vaginal thrombus or intraperitoneal hemorrhage were excluded.

Description of the procedures undertaken

Management of PPH refers to the CNGOF¹ recommendations and was the subject of a Mediterranean Network protocol. It starts with obstetric measures (uterine massage, artificial delivery-uterine revision, examination of the birth canal, administration of oxytocin) undertaken in association with resuscitation measures. These include scoped monitoring, installation of a second venous access with volume expansion by crystalloids, control of hypothermia, oxygen therapy, optimal transfusion protocol (RBCUs + FFP + fibrinogen +/- platelets), with hourly monitoring of hemoglobin level and hemostasis, administration of tranexamic acid and antibiotic prophylaxis in case of endo-uterine procedure. Blood loss is monitored using a graduated collection bag. In case of failure within 30 minutes or in case of severe bleeding, treatment with Sulprostone

is given. Despite these therapies, if bleeding persists after 60 minutes from the start of management, PPH is said to be refractory to first-line treatments, and management depends on patient's hemodynamic status and mode of delivery. If patient is hemodynamically unstable or if hemorrhage occurs during C-section, conservative surgical treatment by arterial ligation or uterine plication is recommended. In case of hemodynamic stability, joint management by obstetricians and interventional radiologists is performed to realize PAE. In the meantime, the obstetrician is free to use intrauterine tamponade (Bakri Balloon). Patients requiring PAE were transferred, under close monitoring, to the interventional radiology department, where arteriography was performed through a unilateral common femoral approach using a 5-F valve introducer. This guides the procedure and highlights arterial anatomical variants. Next, catheterization of uterine artery is performed in most case using a 5-F cobra catheter, or internal iliac artery or other suspected arteries. If more distal catheterization was required, a microcatheter could be used. Most of the time, this procedure was reproduced contralaterally using the same femoral approach. Finally, an arteriography was performed at the end of the procedure to ensure proper vascular occlusion. Post-procedure, patients were hospitalized in intensive care units (ICU) in case of hemodynamic or biological failure, or in the obstetrical unit in case of good tolerance. In all cases, if bleeding persisted despite second-line treatments, a HH was performed without delay. In case of refractory PPH occurring in maternity unit in the region that did not have the technical platform, an inter-hospital transfer could be carried out in an emergency. The departments concerned are Hautes and Basses-Alpes, Bouches-du-Rhône, Corsica, and the Brignoles hospital in the Var. On the other hand, placenta accreta presented a specific management. Indeed, in case of suspicion of placenta accreta, a C-section was scheduled at term, or performed urgently before if necessary. At the time of delivery, if placental disorders are confirmed, the attitude of the service was to propose conservative treatment in the first instance using in situ placenta technique²⁷⁻²⁸. The placenta was left in place, either totally or partially, depending on the existence of the cleavage plane and the invasion of adjacent organs. C-section was immediately followed by systematic embolization even in case of physiological bleeding. The same interventional radiology team was on call at both hospitals. The products available at the AP-HM were: gelatin particles (Curaspon®, Gelfoam®, coils and microcoils, Polyvinyl Acetate (PVA) microspheres (Embozene®), liquid embolization implants (Onyx®), and N-butyl Cyanoacrylate (NBCA) liquid glue.

Endpoints

Epidemiological and obstetrical data, elements of therapeutic management and clinical evolution were collected, retrospectively, from the patient's medical records. Drug management was considered optimal if it complied with CNGOF recommendations defined above (ureterotonics, tranexamic acid and antibiotic prophylaxis). Effectiveness of the procedure was defined by the cessation of bleeding after embolization with the need for no additional invasive intervention.

The primary outcome was SMM, defined as a composite outcome:

- **Failure of the PAE procedure**, requiring a subsequent invasive procedure (second embolization or radical surgical treatment) and/or
- **Major resuscitative complications**: admission to ICU and/or transfusion ≥ 5 RBCUs and/or hemorrhagic shock and/or DIC and/or
- **Ischemic complications**

Choice of resuscitation criteria refers to the SMM definition found by Delphi method study conducted in the department. The threshold of 5 RBCUs was chosen arbitrarily, targeting an intermediate threshold compared with the data in the literature. Indeed, the CDC²² used transfusion of at least 1 RBCU as a morbidity criterion, and Lee et al¹⁶ had shown that transfusion of more than 10 RBCUs was a risk factor for PAE failure. Hemorrhagic shock and DIC were defined according to their consensus definitions. Hemorrhagic shock was defined as arterial hypotension, i.e., systolic blood pressure less than 90 mmHg, or a drop of more than 30% or 40 mmHg from usual blood pressure, in a suggestive clinical setting. The diagnosis of biological DIC was retained in case of increased D-dimer with one major or two minor criteria (SFAR₂₉ minor and major criteria given in the FigA.1).

The secondary endpoints were: occurrence of other major complications, minor complications and benign infectious complications. Post embolization syndrome was defined by an inflammatory fever without infectious criteria.

Statistical methods

The qualitative variables were presented in percentages; the quantitative variables were presented in mean with standard deviation or upper and lower limits.

The analysis of risk factors was performed by adjustment using a penalized multiple logistic regression model, with univariate study (Chi² and Fisher test), then collinearity analysis, and finally multivariate analysis. The thresholds used were $p < 0.20$ for the univariate and $p < 0.05$ for the multivariate.

Ethic

This study figured in the register of processing activities of the AP-HM, in accordance with the General Data Protection Regulation (GDPR) (reference: DSN_2019-10-28_7814) and received approval from the ethics committee (reference: 2021-06-03-05).

Results

Between 01/2013 and 06/2021, 2158 patients were treated for PPH in Marseille University Hospitals (Timone N=1231 and Nord N=927), 128 patients were managed for placenta accreta (Timone N = 80 and Nord N=48) and 190 patients required a PAE following their delivery.

Descriptive analysis concerned all our patients (N=190). Epidemiological and obstetrical characteristics are shown in Table 1. We excluded from the main analysis the 36 patients included in prophylactic group. Therefore, the main analysis (Table 2) focused on risk factors for SMM in 154 patients who received therapeutic PAE for treatment of refractory PPH (PPH group).

Descriptive Analyses:

Minority of patients have a history of PPH (13.6%) or PAE (5.7%). Many of them had a uni-scarred (23.1%) or bi-scarred (21%) uterus. For the current pregnancy, 11.5% of patients were followed for preeclampsia, 14.2% for placenta previa and 8.9% of patients had a multiple

pregnancy. Most of patients delivered at term (84.7%), by C-section (65.3% versus 34.7% vaginal delivery). 5.3% of the children were macrosomic. Of the 91 patients (47.9%) who went into labor, 25.2% had induction of the labor, mostly by prostaglandin (60%). Delivery was directed in 85.8% of cases. The main etiologies were uterine atony (57.4%) and placental disorders (30%). In 62.6% of cases, PPH was severe. The mean volume of blood loss was 1078.25 ml [500-4000]. PPH was secondary in 10.5% of cases with a mean time of 17.79 [5-45] days.

Elements of treatment are reported in Table B.1 (appendix). 40 patients (21.1%) received an emergency inter-hospital transfer. Less than one third of the patients received Bakri balloon. When it was carried out, it stopped the bleeding in only 11.5% of cases. 69.5% of patients were transfused with RBCUs. 4.7% of the patients underwent surgical arterial ligation during C-section, and 4.2% underwent emergency laparotomy for exploration or packing.

Data on radiological techniques are given in Table B.2 (appendix). Catheterization was bilateral in almost all cases (98.4%). In 32.6% of cases, the use of a microcatheter was necessary. Uterine arteries were mostly targeted (87.9%). Gelatin particles alone were used in 89.5% of cases. Another product was used alone in 2.6% of cases. Radiologists used two embolization products in 7.4 % of cases: gelatin particles were combined with PVA particles in 6 patients, with coils in 4 patients, with liquid embolization implants in 2 patients, or with NBCA in 1 patient. PVA was mainly used in patients with placenta accreta (4/6) and coils in those with a pseudo-aneurysm or uterine artery injury (2/4 and 2/4). 3 of the 14 patients who received a double embolization product had undergone a second embolization because of failure of the first.

Risk factors for severe maternal morbidity (SMM)

Main analysis concerns the PPH group (N=154). The results of univariate and multivariate analyses are given in Table 2. In univariate analysis, patients who developed SMM had significantly lower parities than the others ($p = 0.08$). They had developed more severe PPH, with greater volumes of blood loss ($p = 0.001$ and $p=0.01$ respectively) and had more often undergone inter-hospital transfer ($p = 0.016$). Bakri Balloon, laparoscopic exploration and surgical arterial ligation were more often associated with SMM ($p=0.027$, $p=0.005$, $p=0.05$).

After collinearity analysis, the variables subjected to multivariate analysis were parity, previous C-section, inter-hospital transfer, mode of delivery, severity of PPH, efficacy of uterine tamponade, exploratory laparotomy, surgical arterial ligation, and type of embolization product used. In multivariate analysis, significant results were found for the use of another embolization product than gelatin (OR 4.36 [1.01-18.84] p=0.048) and the severity of PPH (OR 2.81 [1.21-6.55] p=0.002).

Univariate analysis was performed in the prophylactic group (N=36). The results were not significant.

The distribution of the different variables composing our primary endpoint, and the rate of hysterectomy in total sample, and in subgroups are shown in Table 3.

Effectiveness of PAE

Main characteristics of patients with PAE failure are noted in Table B.3 (appendix). Success rate of PAE in the PPH group (N=154) was 94.2%. 4 patients had immediate failure with persistent bleeding and 5 had recurrent bleeding at distance. The success of a second embolization was 66.7%. For the second embolization, gelatin alone was used in all patients except the 2 patients with pseudoaneurysm in whom microcoils were used. The uterine conservation rate in this subgroup was 96.1%. The etiology mainly associated with therapeutic failures was placental disorders (55.5%) followed by pseudoaneurysm (22.2%).

In the prophylactic group (N=36), prophylactic PAE for placenta accreta prevented bleeding in 83.4% of cases. All bleeds (6/36) were delayed secondary PPH hemorrhage, with a mean delay of 18.6 [1-50] days. Success of a second embolization was 40%. Rate of uterine conservation in this subgroup was 83.3%.

Resuscitative complications

Among our population (N=190), 16.3% of the patients were admitted to the ICU, either for management of hemorrhagic shock (12.1%), or for management of pain or pregnancy complications such as Hellp Syndrom. There were 13 patients (6.8%) who were complicated by DIC. 1 patient died from complications of hemorrhagic shock with DIC and multivisceral failure.

Ischemic complications

Main characteristics of patients who experienced an ischemic complication are shown in Table B.4 (appendix). 9 patients (4.7%) had an ischemic complication, of which 4 required invasive surgical treatment. 6 patients presented uterine necrosis, one of them with bladder necrosis and vesico-uterine fistula, and 2 of them required hysterectomy or hysterectomy + partial cystectomy. Two patients presented skin necrosis on the buttock, one of which required surgical trimming. 1 patient presented with ischemic colitis, requiring an extended digestive resection. This complication was rather attributed to the low flow linked to the hemorrhagic shock in this patient. Of the 9 patients, the main etiology found was uterine atony (55.5%). The other patients (44.4%) had placenta accreta, without immediate bleeding for 3 out of 4 patients. 2 patients presented severe PPH. All but one had a successful PAE. All patients had been embolized with gelatin particles alone. None had anterior embolization history.

Evaluation of secondary endpoints

Incidences of other complications in our total cohort (N=190) are given in Table B.5 (Appendix). Post-embolization syndrome was frequent (10%) and with spontaneously favorable evolution. 19 patients (1%) developed sepsis from pyelonephritis or endometritis and 1 patient presented with stercoral peritonitis from digestive injury. 3 of these patients developed septic shock. 4 PAE were complicated by uterine artery dissection, with resolute spontaneous evolution. 4 patients presented venous thrombosis, mainly of the gonadal veins. The evolution was satisfactory under curative anticoagulation.

Discussion

Principal Findings: We have shown that PAE is an effective technique in the management of refractory PPH (success rate: 94.1%) with a low major complication rate (3.9%). In this context, SMM is estimated at 37.6% and risk factors could be PPH severity and use of another product than gelatin.

Result in the context: Introduction of PAE has revolutionized the management of PPH refractory medical treatment. Its main interest, in addition to avoiding laparotomy, is the preservation of fertility. A review of the literature³⁰ did not find any significant difference between conservative surgical and radio-interventional treatments. The use of EAP is restricted in some countries by the lack of data on its morbidity. In France, and in many countries, the use of conservative surgical or radio-interventional treatments is often left to the discretion of the surgeon³¹. The choice of this strategy according to the etiology is mentioned by RANZCOG³², which does not retain indication for uterine ruptures, placenta accreta, or uncontrolled massive hemorrhage, and the WHO³³, which indicates PAE mainly for uterine atony. In terms of timing, ACOG³⁴ RCOG³⁵ and SOGC³⁶ indicate PAE for persistent, nonexcessive bleeding in a hemodynamically stable patient. The SOGC³⁶ states that PAE should be performed before surgical treatment. In all cases, the experts emphasize that surgical treatment should be considered in case of delayed access to embolization³³⁻³⁶. However, the German guidelines³⁷, recommend conservative surgical treatment as a first-line option. According to CNGOF¹, PAE is preferentially indicated in cases of resistant uterine atony, particularly after vaginal delivery, or complex cervico-vaginal tear not accessible to surgery. If PPH occurs during C-section, only surgical treatment should be performed.

To date, no study has evaluated the SMM of PAE. There is no consensus definition of SMM. In France, the first stage of the EPIMOMS²¹, led to the adoption of a broad consensus

definition (FigA.2). An unpublished study conducted in the department used a Delphi process to define SMM by the presence of at least one of the following CDC criteria²²: DIC, hypovolemic shock, transfusion, or admission to ICU. We therefore relied on these studies to define resuscitative complications. To evaluate the risk factors of SMM, we chose a composite criterion, intended to study SMM in its entirety. The three criteria are robust and co-dependent. Indeed, it is known that uncontrolled bleeding leads to hemorrhagic shock and DIC, which affect both vital prognosis and chances of therapeutic success¹⁷⁻¹⁹. The death of one patient in our series is notably attributed to these complications. In addition, therapeutic failure leads to a delay in management, and occurs major complications¹⁷. In our cohort, 9 of the 15 patients who failed developed hemorrhagic shock.

Implications: Our study showed that severity of PPH was a risk factor for SMM in refractory PPH treated by embolization. This result is not surprising given that resuscitative complications are closely linked to blood loss severity, and that severe bleeding is associated with EAP failure¹⁶⁻¹⁷. Our result is also consistent with scientific recommendations^{1,35,37}, according to PAE should not be performed in case of severe bleeding with hemodynamic instability and in case of distance from the technical platform. Moreover, the univariate analysis suggested that inter-hospital transfer was a risk factor for SMM ($p < 0.016$). However, due to lack of power, these results could not be confirmed by multivariate analysis with a p-value at the limit of significance ($p = 0.074$).

We found that using another embolization product than gelatin or using two embolization products were significantly associated with the occurrence of SMM. No clinical trials have compared PAE techniques. Gelatin particles are the most commonly used products worldwide¹⁴. These are the only resorbable embolization products^{14,15,38}. This property explains vessel repermeabilization at 4-6 weeks and suggests less ischemic injury. It works by

activating the coagulation cascade. Therefore, it would be less effective in cases of DIC, or in cases of active and significant hemorrhage, such as in ruptured pseudoaneurysms or vascular injury³⁸. In these indications, NBCA would be more pertinent because its action involves rapid polymerization on blood contact independently of the coagulation cascade. Metal coils are also indicated in pseudo aneurysms¹⁵. The property of gelatin particles requires manual preparation with water dissolution, which has a direct impact on the final size of the particles. Small particles could migrate into collateral vessels and be responsible for ischemia³⁸. This risk is also known for PVA particles < 500mm³⁸. Our results could be explained by the fact that patients with active hemorrhage due to uterine artery injury or pseudoaneurysm were treated, for the reasons stated above, with another product than gelatin, and that 3 patients who presented failure of first embolization were re-embolized with a combination of two particles (gelatin+coils or PVA). It should be noted that all PVA particles used were > 700 mm and contrary to expected, all patients with ischemia had been embolized with gelatin particles.

Moreover, contrary to that suggested^{10,11,18}, our study showed no association between SMM, etiology, and mode of delivery.

Compared with studies in the literature, our cohort has a significant rate of placental disorders. Uterine devascularization strategies after conservative treatment may be effective to prevent severe bleeding but remain poorly studied³⁹⁻⁴⁰. In this specific indication, PAE may be more effective than surgical ligation⁴¹. Although not recommended by IS-AIP²⁸ because of the lack of sufficient data and possible morbidity associated, prophylactic embolization of placenta accreta was routinely performed in our units. In the largest series⁴² studying the conservative approach in 167 patients, prophylactic PAE was performed in only 37.1% of patients. Uterine preservation rate was 78.4%. It was 83.4% in our series with systematic PAE, which could suggest a beneficial effect of PAE in these patients. In our series, the rate

of SMM in patients with placenta accreta (prophylactic + therapeutic) was not significantly different than patients with refractory PPH related to another etiology (33.3% versus 36.8% respectively). The main risk factor for placenta accreta morbidity appears to be the occurrence of immediate PPH although these conclusions remain to be proven in a dedicated study.

Strengths and Limitations: Our study is the first to assess risk factors for SMM in patients receiving PAE for obstetric indication. It is also the first to study the technical aspects. Its strength is its large sample size, greater than the majority of studies^{9-14,16-19}. The main limitations of our study are its retrospective design and its unicentric character. Selection bias is probably limited by inclusion of other hospitals patients.

Conclusion:

Thus, our results allow us to conclude that PAE presents a real benefit in the management of refractory PPH. PAE should be performed early, before the occurrence of resuscitative complications. The risks of ischemic complications are low and should not limit its use. The choice and use of products must be considered, guided by the clinical context.

Tables

Table 1: Epidemiological and obstetrical characteristics

Caractéristiques	Moyenne +/- ET / Nombre (%) N =190
Maternal and obstetrical characteristics	
Maternal age (years)	32.05 +/- 5.6
Parity :	
P0, P1	105 (55.3 %)
≥ P2	85 (44.7%)
Previous cesarean section	84 (44.2%)
Term (SA)	36.4 +/- 5.3
Mode of delivery	
Cesarean section	124 (65,3%)
Etiology	
Uterine atony	109 (57.4%)
Placental disorder	57 (30%)
Uterine arterial injury	9 (4.7%)
Acquired/iatrogenic hemostasis anomaly	11 (5.7%)
Thrombocytopenia	5 (2.6%)
Anticoagulant treatment	3 (1.6%)
HELLP Syndrome	3 (1.6%)
Genital tract injury	5 (2.6%)
Pseudo aneurysm of the uterine artery	5 (3.9%)
Arteriovenous malformation	4 (2.1%)

Table 2: Assessment of risk factors for SMM in patients with refractory PPH N=154.
Results of univariate and multivariate analysis (Fisher and Chi² tests)

Characteristics	SMM occurrence N=58	SMM absence N=96	p-value univariate	p-value multivariate	Odds Ratio [IC95%]
Obstetrical data					
Parity	1.2 (+/- 1.4)	1.6 (+/- 1.5)	0.08	0.92	1.01 (0.74-1.38)
Number of previous cesarean sections	0.4 +/- 0.9	0.6 +/- 1.0	0.13	0.51	1,16 (0,73-1,85)
Cesarean sections	29 (50%)	59 (61.5%)	0.16	0,18	1,79 (0,75-4,25)
Severe PPH	36 (62.1%)	26 (27.1%)	0.001	0.01	2.81 (1.21-6.55)
Volume (l)	1.6 +/- 0.7	1.2 +/- 0.6	0.01		
Secondary PPH	10 (10.4%)	10 (17.2%)	0.22		
Etiology					
Uterine atony versus other	37 (63.8%)	72 (75%)	0.45		
Malplacentaion versus other	9 (15.5%)	12 (12.5%)	0.59		
Therapeutic management					
Inter-hospital transfer	21 (36.2%)	18 (18.8%)	0.016	0.07	2.24 (0.92-5.43)
Non-compliance with drug protocol	13 (13.5%)	9 (15.5%)	0.73		
Bakri Balloon	23 (39.7%)	24 (25%)	0.027	*	*
Exploration by laparotomy	6 (10.3%)	1 (1%)	0.005	0.07	8.89 (0.78-101.29)
Surgical artery ligation	6 (10.3%)	2 (2.1%)	0.05	0,33	2,54 (0,37-17,18)
Diagnostic-embolisation time (minutes)	225 (45-840)	165 (60-360)	0.26		
Interventional radiology technique					
Bilateral catheterization	56 (96.6%)	95 (99%)	0.05	*	*
Uterine artery(s) alone	47 (81%)	85 (88.5%)	0.45		
5F catheter	37 (63.8%)	66 (68.8%)	0.59		
Embolization product other than gelatin or 2 products used	11 (18.9%)	3 (0.03%)	0.001	0,048	4,36 (1,01-18,84)

*These variables were removed from the multivariate after collinearity analysis.

Table 3: Distribution of the different variables of the primary endpoint in the subgroups studied and in the total population

Criteria	Refractory PPH N = 154	Preventive PAE for accreta N = 36	Total N = 190
Severe Maternal Morbidity (SMM)	58 (37.6%)	10 (27.8%)	68 (35.8%)
Failure	9 (5.8%)	6 (16.6%)	15 (7.9%)
Immediate failure	4 (2.6%)	0 (0%)	4 (2.1%)
Distant recurrent bleeding	5 (3.3%)	6 (16.6%)	11 (5.3%)
Second embolization	6 (3.9%)	4 (5.5%)	10 (5.2%)
Hemostasis hysterectomy	5 (3.3%)	4 (11.1%)	9 (4.7%)
Resuscitative complications:			
Intensive care unit admission	28 (18.2%)	3 (8.3%)	31 (16.3%)
Transfusion ≥5 RBCUs	37 (24%)	0 (0%)	37 (19.5%)
Hemorrhagic shock	22 (14.3%)	1 (2.8%)	23 (12.1%)
DIC	13 (8.4%)	0 (0%)	13 (6.8%)
Ischemic complications	6 (3.9%)	3 (8.3%)	9 (4.7%)
Hysterectomy	6 (3.9%)	6 (16.6%)	11 (5.3%)
Hemostasis hysterectomy	5 (3.3%)	4 (11.1%)	8 (4.2%)
Hysterectomy for other indication	1 (0.6%)	2 (5.5%)	3 (1.1%)
Death	1 (0.6%)	0 (0%)	1 (0.05%)

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Appendix:

Fig A1: Definition of major and minor DIC criteria (SFAR²⁹)

D-Dimer > 500 µg/L + 1 major criteria or 2 minor criteria

Parameter (unit)	Major	Minor
Platelet count (G/L)	≤ 50	50 < - ≤ 100
Prothrombin level (%)	< 50	50 ≤ - < 65
Fibrinogen concentration (g/L)	--	≤ 1

Fig A.2: Definition of Severe Maternal Morbidity (EPIMOMS²¹):

One criterion is sufficient to enter the definition:

- 9 severe conditions: severe obstetric hemorrhage, eclampsia, HELLP syndrome, retroplacental hematoma, preeclampsia, pulmonary embolism, constituted stroke, transient ischemic attack, acute severe psychiatric disorder
- 6 organ dysfunctions: cardiovascular, respiratory, renal, neurological, hepatic, hematological
- 2 management elements: surgical procedures outside of delivery, admission to intensive care unit
- Maternal death.

Table B.1 : Therapeutic management

Place of delivery and embolization center	N = 190
Inter-hospital transfer	40 (21.1%)
Embolization center	
Nord	99 (52.1%)
Timone	91 (47.9%)
Diagnosis-embolization time	196,8 [30-960]
Therapeutic management	
Optimal drug management	132 (85,7%)
Bakri Balloon	52 (28,8%)
Effectiveness of Bakri Balloon	6 (11,5%)
Exploration by laparotomy	8 (4.2%)
Vascular ligation per cesarean	9 (4.7%)
Complex vaginal suture	4 (2.1%)

Table B.2: Technical data

Technical data for PAE	N = 190
Type of catheter	
Cathéter	128 (67,4%)
Microcathéter	62 (32,6%)
Catheterization	
Unilateral	3 (1,6%)
Bilateral	187 (98,4%)
Embolized artery	
Uterine artery	167 (87,9%)
Uterine artery + internal iliac artery	14 (7,4%)
Uterine artery + other	6 (3,2%)
Vaginal or pudendal artery	2 (1,1%)
Internal iliac artery	1 (0,5%)
Embolization product	
Gelatin	170 (89,5%)
Liquid embolization implant	3 (1,6%)
NBCA	1 (0,5%)
Coils	1 (0,5%)
Gelatin + other product	14 (7,4%)
Missing Data	1 (0.5%)

Table B.3: Patients with PAE failure: characteristics and outcomes

N°	Year	Age, GP	Number of previous C-sections	Number of previous PPH	Delivery route and indication	Etiology	Severity	Embolization product used	Failure	Second procedure	Outcome	Complication
1	2013	26 yrs G1P0	0	0	Scheduled C-section > 37 GW Twin pregnancy	Atony	No	Gelatin	Immediate	Second PAE	Failure →HH	0
2	2018	25 yrs G3P2	2	0	Scheduled C-section > 37 GW for bi- scared uterus	Pseudo Aneurysm	Yes	Gelatin + microcoils	Recurrence at 30 days	Second PAE	Successful	Hemorrhagic shock
3	2017	35 yrs G2P1	0	0	Emergency C-section > 37 GW	Pseudo Aneurysm	No	Gelatin + microcoils	Recurrence at 15 days	Second PAE	Successful	Hemorrhagic shock
4	2016	36 yrs G2P1	1	0	Emergency C-section at 31 GW for bleeding on placenta previa	Placental Disorders	Yes	Gelatin	Recurrence at 17 days	Second PAE	Successful	Hemorrhagic shock Venous thrombosis Pelvic peritoneal abscess
5	2020	28 yrs G1P0	0	0	Emergency C-section > 37 GW	Uterine artery injury	Yes	NBCA	Immediate	HH	Successful	Hemorrhagic shock, DIC, death
6	2020	36 yrs G2P1	1	0	Scheduled C-section >37 GW for suspected placenta accreta Thrombocytopenia 100G/L	Placental Disorders	Yes	Gelatin	Immediate	HH	Successful	Hemorrhagic shock, DIC
7	2021	31 yrs G4P2	3	0	Emergency C-section at 29 GW for bleeding on placenta percreta	Placental Disorders	Yes	Gelatin	Recurrence at 21 days	Second PAE	Successful	Hemorrhagic shock
8	2021	32 yrs G4P1	1	0	Scheduled C-section > 37 GW for suspected placenta accreta	Placental Disorders	Yes	Gelatin	Recurrence at 31 days	HH	Failure → Second PAE, multiples packing	Hemorrhagic shock, DIC
9	2021	27 yrs G7P3	3	0	Emergency C-section at 39 GW for bleeding on placenta accreta	Placental Disorders	Yes	Coils	Immediate	HH	Successful	Hemorrhagic shock, DIC
10	2021	33 yrs G9P5	4	0	Scheduled C-section > 37 GW for suspected placenta accreta	Placental Disorders	No	Gelatin+PVA	Recurrence at 16 days	Second PAE	Successful	Post Embolization syndrome
11	2015	37 yrs G4P3	1	1	Emergency C-section at 24 GW for bleeding on placenta accreta	Placental Disorders	No	Gelatin	Recurrence at 11 days	Second PAE	Failure →HH	Hemorrhagic shock,
13	2015	29 yrs G8P7	5	0	Scheduled C-section > 37 GW for penta-scared uterus	Placental Disorders	No	Gelatin	Recurrence at 1 day	HH	Successful	0
13	2016	32 yrs G4P3	1	0	Emergency C-section at 32 GW for bleeding on placenta accreta	Placental Disorders	No	Onyx	Recurrence at 50 days	Second PAE	Failure →HH	0
14	2014	31 yrs G8P0	0	0	Emergency C-section at 26 GW for bleeding on placenta accreta	Placental Disorders	No	Gelatin	Recurrence at 21 days	Second PAE	Failure →HH	0
15	2018	30 yrs G9P4	3	0	Scheduled C-section >37 GW for suspected placenta accreta	Placental Disorders	No	Gelatin	Recurrence at 23 days	Second PAE	Successful	Uterus necrosis requiring hysterectomy

Patients 1 to 9 were embolized for refractory PPH (PPH group). Patients 10 to 15 underwent prophylactic PAE for placenta accreta (Prophylactic group)

Yrs = years, GW = Gestation Week.

Table B.4: Patients with ischemic complications: characteristics and outcomes

N°	Year	Age, GP	Number of previous C-sections	Number of previous PPH	Delivery route and indication	Etiology	Severity	Embolization product used	Type of ischemia	Time	Outcome
14	2018	37 yrs G1P0	0	0	Emergency C-section at 42 GW	Atony	No	Gelatin	Uterus necrosis	4 days	Spontaneous resolution
15	2015	37 yrs G5P3	3	0	Emergency C-section at 36 GW	Atony	No	Gelatin	Uterus necrosis	6 days	Spontaneous resolution
16	2013	38 yrs G7P4	1	0	Emergency C-section at 26 GW	Atony	Yes	Gelatin	Uterus necrosis	30 days	Spontaneous resolution
17	2018	31 yrs G5P2	0	0	Scheduled C-section >37 GW	Atony	No	Gelatin	Uterus necrosis	15 days	Spontaneous resolution
18	2015	34 yrs G3P2	0	0	Emergency C-section at 40 GW	Atony	Yes	Gelatin	Ischemic colitis	3 days	Colectomy
19	2019	24 yrs G4P3	3	0	Emergency C-section at 34 GW	Placental disorders	/	Gelatin	Uterus and bladder necrosis	180 days	Hysterectomy + partial cystectomy
20	2015	34 yrs G3P2	1	0	Scheduled C-section >37 GW	Placental disorders	/	Gelatin	Necrosis of the buttock	5 days	Spontaneous resolution
21	2014	30 yrs G7P5	2	0	Emergency C-section at 36 GW	Placental disorders	/	Gelatin	Uterus necrosis with septic shock	8 days	Hysterectomy
22	2018	30 yrs G9P4	3	0	Scheduled C-section > 37 GW	Placental disorders	/	Gelatin	Necrosis of the buttock with septic shock	12 days	Hysterectomy Surgical trimming

Patients 14 to 19 were embolized for refractory PPH (PPH group). Patients 20 to 22 underwent prophylactic PAE for placenta accrete (Prophylactic group).

Yrs = years, GW = Gestation Week.

Table B.5 : Other complications

General complications	N=190
Lowest hemoglobin level	8,10 [3,6 – 14,2]
Other complications :	
- Endometritis	9 (4.7%)
- Pyelonephritis	10 (5.3%)
- Pulmonary embolism	1 (0.5%)
Minor complications	
Post-embolization syndrome	19 (10%)
Pelvic pain	9 (4,7%)
Pelvic-peritoneal collection	5 (2,6%)
Inguinal hematoma	4 (2,1%)
Major complications	
Inguinal hematoma	4 (2,1%)
Venous thrombosis	4 (2,1%)
Arterial thrombosis	0

Serment d'Hippocrate

« Au moment d'être admis(e) à exercer la médecine, je promets et je jure d'être fidèle aux lois de l'honneur et de la probité.

Mon premier souci sera de rétablir, de préserver ou de promouvoir la santé dans tous ses éléments, physiques et mentaux, individuels et sociaux.

Je respecterai toutes les personnes, leur autonomie et leur volonté, sans aucune discrimination selon leur état ou leurs convictions. J'interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité ou leur dignité. Même sous la contrainte, je ne ferai pas usage de mes connaissances contre les lois de l'humanité.

J'informerai les patients des décisions envisagées, de leurs raisons et de leurs conséquences.

Je ne tromperai jamais leur confiance et n'exploiterai pas le pouvoir hérité des circonstances pour forcer les consciences.

Je donnerai mes soins à l'indigent et à quiconque me les demandera. Je ne me laisserai pas influencer par la soif du gain ou la recherche de la gloire.

Admis(e) dans l'intimité des personnes, je tairai les secrets qui me seront confiés. Reçu(e) à l'intérieur des maisons, je respecterai les secrets des foyers et ma conduite ne servira pas à corrompre les mœurs.

Je ferai tout pour soulager les souffrances. Je ne prolongerai pas abusivement les agonies. Je ne provoquerai jamais la mort délibérément.

Je préserverai l'indépendance nécessaire à l'accomplissement de ma mission. Je n'entreprendrai rien qui dépasse mes compétences. Je les entretiendrai et les perfectionnerai pour assurer au mieux les services qui me seront demandés.

J'apporterai mon aide à mes confrères ainsi qu'à leurs familles dans l'adversité.

Que les hommes et mes confrères m'accordent leur estime si je suis fidèle à mes promesses ; que je sois déshonoré(e) et méprisé(e) si j'y manque. »