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ABSTRACT
Aim: In the present study a conservative management protocol to treat postpartum hemorrhage (PPH) in high risk patients with the diagnosis of placenta previa major is reported.

Materials and methods: Retrospective analysis of 55 patients with placenta previa major who underwent cesarean section, treated with the following protocol: preliminary prophylactic transfemoral/transhomeral catheterization, cesarean section, use of multiple square endouterine hemostatic sutures, application of an intrauterine Bakri balloon combined with B-Lynch suture and devascolarizing ligature/selective embolization of the uterine arteries followed by hysterectomy in case of failure.

Results: In four cases we used selective embolization of the uterine arteries (7.2 %). In three cases, we performed hysterectomy (5.4 %). Fourteen patients (25.4%) underwent blood transfusion. Four patients (7.3%) were admitted to the general intensive care unit for one day.

Conclusions: We evaluate the effectiveness of the use of this protocol which could represent the leading treatment option of PPH in these high risk patients.

Key words: Postpartum hemorrhage, conservative protocol, uterine sandwich technique.

INTRODUCTION
Postpartum hemorrhage (PPH) is the leading cause of maternal death worldwide. In addition to death, serious morbidity may follow(1).

PPH is commonly defined as an estimated blood loss of more than 500 ml after vaginal delivery or more than 1000 ml after cesarean section; however assessment of blood loss is often inaccurate(2). The severity of the bleeding can be rapidly evaluated using the ACOG scheme, which provides 4 degrees of progressive severity (Table I).

Table I. ACOG scheme to evaluate the severity of the bleeding.

<table>
<thead>
<tr>
<th>CLASS</th>
<th>Compensated</th>
<th>Blood loss between 500-1000 ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLASS II</td>
<td>Slight</td>
<td>Blood loss between 1000-1500 ml</td>
</tr>
<tr>
<td>CLASS III</td>
<td>Moderate</td>
<td>Blood loss between 1500-2000 ml</td>
</tr>
<tr>
<td>CLASS IV</td>
<td>Severe</td>
<td>Blood loss between 2000-3000 ml</td>
</tr>
</tbody>
</table>

RIASSUNTO
Obiettivo dello studio: In questo studio abbiamo descritto un protocollo conservativo per il trattamento dell’emorragia post-partum in pazienti ad alto rischio emorragico, con diagnosi di placenta previa major.

Materiali e metodi: Si tratta di uno studio retrospettivo su 55 pazienti con diagnosi di placenta previa major, sottoposte a taglio cesareo e trattate con tale protocollo: preliminare cateterizzazione profilattica transfemorale/transomerale, taglio cesareo, utilizzo di suture quadre endouterine a scopo emostatico, applicazione intrauterina di Bakri balloon combinata con sutura di B-Lynch e legatura devascolarizzante/embolizzazione selettiva delle arterie uterine seguita da isterectomia in caso di fallimento di tale strategia.

Risultati: In quattro casi è stata utilizzata l’embolizzazione selettiva delle arterie uterine (7,2%). In tre casi è stata effettuata l’isterectomia (5,4%). Quattordici pazienti (25,4%) sono state sottoposte a trasfusioni di sangue. Quattro pazienti (7,3%) sono state ricoverate in unità di terapia intensiva generale per un giorno.

Conclusioni: Valutando la reale efficacia dell’utilizzo di tale protocollo, possiamo affermare che questo potrebbe rappresentare una opzione terapeutica per il trattamento dell’emorragia postpartum nelle pazienti ad alto rischio.

Parole chiave: Postpartum hemorrhage, conservative protocol, uterine sandwich technique.

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All pregnancies are at risk of PPH, but the main causes are represented by placenta previa/accreta, retention of placental cotyledons or flaps, lacerations of the soft tissues of the birth canal, uterine atony, uterine rupture and coagulopathies. Several maternal factors, play an important role as risk factors such as maternal age, multiparity, multiple pregnancy, obesity, previous episodes of PPH, protracted and/or precipitous labor, abnormal placentation, operative delivery and previous cesarean sections.

The risk of maternal death, in fact, doubles if the woman has more than 35 years; moreover the cesarean section is associated with maternal death three times more than natural childbirth.

Placenta previa is the main condition related to the risk of severe hemorrhage. According to the last RCOG guideline, placenta previa (placenta inserted wholly or in part into the lower segment of the uterus) can be classified in major previa if the placenta lies over the internal cervical os, and minor or partial praevis if the leading edge of the placenta is in the lower uterine segment but not covering the cervical os.

One of the most dreadful complications of placenta previa is its association with accretism. This pathological condition is characterized by the invasion of placental trophoblast into the endometrium beyond the Nitabuch’s layer due to a defect in the decidua basalis. If the trophoblast invades the myometrium or the serosa, placenta increta or percreta respectively are defined. The frequent association between placenta previa and accretism is related to a greater maternal morbidity and mortality.

According to the Italian Guidelines (Italian National Institute of Health – National System of Guidelines: SNLG-ISS) on cesarean section (January 2012), placenta previa represents an indication for cesarean delivery and must be performed in a tertiary level hospital to manage possible fetal-maternal emergencies, in order to reduce perinatal/maternal mortality and morbidity.

The diagnosis of placenta previa major was based on clinical findings, sonography and on Magnetic Resonance Imaging (MRI), planned at 32-34 weeks of gestation.

The main aspects of this organizational model were: extensive information and discussion with the patient and the couple of issues related to risk factors; presence of interventional radiologists in the surgery room; temporary clamping of uterine vessels before placental delivery; systematic association of B-Lynch suture and Bakri balloon application.

The diagnosis of placenta previa major was based on clinical findings, sonography and on Magnetic Resonance Imaging (MRI), planned at 32-34 weeks of gestation.

The patients were adequately hydrated during the 4 hours before intervention (1000 ml of saline solution 4 hours before the surgery and 1000 ml 1 hour before) and were wearing support stockings. Central venous catheter (CVC) positioning was applied before surgery. Cells separator, 4 blood bags (2 ready for use and 2 in standby) and portable digital angiography were available in the operating theatre. Radiolucent operating
table, medical thermal blankets and lead aprons were used for the procedure. Positioning of the graduate sterile bag was aimed to the evaluation of the blood loss during cesarean section.

The protocol for management of PPH used in our institution is shown in Figure 1 and can be briefly summarized as follows: preliminary prophylactic transfemoral/transhomer al catheterization using 5 french catheter. (This step was not applied in case of urgency and/or emergency);

Delivery of the fetus, administration of oxytocics (carbetocine) within one minute, temporary clamping of uterine arteries by ring forceps, followed by placental delivery. Multiple square endouterine hemostatic sutures (Affronti’s sutures). Their application (on the anterior or posterior uterine wall) was related to the prevalent site of bleeding. Preparation of B-Lynch compressive sutures. Application of hydrostatic balloon (Bakri balloon) and partial filling with 30-60 ml of saline solution. Hysterorrhaphy. Repositioning of uterus followed by hydrostatic balloon inflation with a maximum of 400 ml (depending on the size of the uterus) and B-Lynch ligature, finally further inflation of 100 ml of saline solution in the Bakri balloon.

When required, especially in case of previous cesarean section, surgical sealants were used.

In case all the previous maneuvers failed, devascolarizing ligature/selective embolization of the uterine arteries was performed.

When even the previous described procedures failed, hysterectomy were done.

Maternal hematologic parameters monitorin was carried out 24 hrs before cesarean section and 2 hrs after the procedure, then every 2-4 hrs for the following 24 hrs, in relation to clinical conditions/blood loss and, finally, at 48 hrs.

Blood transfusion was performed only in case the hemoglobin values dropped above 7 g/dl and/or hematocrit value was less than 21%.

Bakri balloon was removed 24 hrs from delivery, 30 minutes after rectal administration of misoprostol 400 mcg.

In three cases, it was necessary to perform hysterectomy (5.4%). In two of the three cases, due to a massive blood loss, hysterectomy was performed immediately after extraction of fetus and placental delivery.

In one case even if embolization of uterine arteries were performed, the bleeding did not stop, and therefore hysterectomy and following embolization of internal iliac arteries was done due to massive bleeding from implants of pelvic endometriosis.

Fourteen patients (25.4%) underwent intraoperative or postoperative blood transfusion. Four patients (7.3%) were admitted to the general intensive care unit for one day, due to postoperative hemodynamic instability (Table II).

<table>
<thead>
<tr>
<th>Procedures</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embolization</td>
<td>7.2</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>5.5</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>25.4</td>
</tr>
<tr>
<td>General intensive care unit</td>
<td>7.3</td>
</tr>
</tbody>
</table>

The mean surgery time was 46 minutes. All patients received oxytocics (carbetocin) and prostaglandins (misoprostol). Hematologic parameters were checked postoperatively and at 2 days (Table III). The mean estimated blood loss was 1640 cc (range: 900-4200 cc).

The mean hospital stay was 6 days. Eighteen patients (32.7%) experienced complication as fever (mean body temperature 38°C) within 48 hrs from cesarean section. Intravenous antibiotic therapy was administered to all patients.

**DISCUSSION**

The present study updates our previous experience published in 2010 in evaluating the effectiveness of a conservative management protocol in placenta previa.

The diagnosis of placenta previa was carried out by ultrasound and confirmed by MRI. Esakoff et al demonstrated that ultrasound examination is a good diagnostic tool to evaluate accretism in women with placenta previa. The importance to make a correct diagnosis is related to the significantly increased risk of patients with accretism. Otherwise Derman et al identified the most sensitive MRI signs of accretism and proposed criteria for the classification of invasive placentation with abnormal placental vascularity.

A massive obstetric hemorrhage, resulting
from the failure of normal obstetrical, surgical and/or systemic hemostasis, has been estimated, from a recent review, to be responsible for 25% of maternal deaths worldwide each year (10) and uterine atony is an indication for emergency peripartum hysterectomy in 20.6% to 43% of the cases (11). This is the reason why primary prevention of PPH begins with an assessment of identifiable risk factors.

Abnormal placentation includes a group of important conditions at risk not only of severe hemorrhage with maternal complications comprising maternal death, but also of neonatal sequel and/or death (6,12).

The aim of the management of PPH is to apply conservative intervention and use the hysterectomy as the last possible treatment option.

In our protocol (Figure 1), the first step of the conservative management is the use of uterotonic. We supported the use of carbetocin associated with misoprostol. Carbetocin is a long-acting oxytocin agonist; with respect to oxytocin, it shows higher elimination half-life (40 min vs 5 min) and higher duration of action (5 hrs vs 1.5 hrs). Moreover, in comparison to oxytocin, it is associated with reduced need for additional oxytocics and uterine massage. That is why it appears to be the drug of choice for the prevention/treatment of PPH (13,14).

Misoprostol, an E1 prostaglandin analog, has been explored as an alternative due to its ability to induce uterine contractions, low cost, stability at room temperature and ease of administration.

### Table III.

<table>
<thead>
<tr>
<th></th>
<th>Preoperative</th>
<th>Postoperative (6 hrs)</th>
<th>At 2 days</th>
<th>Δ Mean Preoperative-postoperative (range %)</th>
<th>Δ Mean Preoperative-2 days (range %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCT, %</td>
<td>33.50</td>
<td>27.89</td>
<td>28.24</td>
<td>-5.61 (-15.4 to -0.6)</td>
<td>-5.26 (-11.9 to -0.3)</td>
</tr>
<tr>
<td>HGB, g/dl</td>
<td>11.14</td>
<td>9.46</td>
<td>9.43</td>
<td>-1.68 (-12.7 to 0)</td>
<td>-1.71 (13 to -0.3)</td>
</tr>
<tr>
<td>RBC, 10^6 g/dl</td>
<td>3.88</td>
<td>3.32</td>
<td>3.42</td>
<td>-0.56 (-4.26 to 0)</td>
<td>-0.46 (-4.19 to 0.05)</td>
</tr>
<tr>
<td>PLT, 10^3 g/dl</td>
<td>208.73</td>
<td>182.27</td>
<td>212.88</td>
<td>-26.46 (-179 to 4)</td>
<td>-4.15 (-225 to 5)</td>
</tr>
</tbody>
</table>

### CONSERVATIVE MANAGEMENT PROTOCOL

1. Preliminary prophylactic transfemoral/transhomer al catheterization using 5 french catheter. This is the only step that was not applied in case of urgency and/or emergency;
2. Delivery of the fetus, administration of oxytocics (carbetocine) within one minute, temporary clamping of uterine arteries by ring forceps, followed by placental delivery;
3. Multiple square endouterine hemostatic sutures (Affronti’s sutures) (2). Their application (on the anterior or posterior uterine wall) was related to the prevalent site of bleeding;
4. Preparation of B-Lynch compressive sutures;
5. Application of hydrostatic balloon (Bakri balloon) and partial filling with 30-60 ml of saline solution;
6. Hysterorrhaphy;
7. Repositioning of uterus with a-Hydrostatic balloon inflation with a maximum of 400 ml (depending on the size of the uterus) b-B-Lynch ligature, followed by further inflation of 100 ml of saline solution in the Bakri balloon.
   When necessary, especially in case of previous cesarean section, application of surgical sealants
8. If these maneuvers failed, the next step was the devascularizing ligature/selective embolization of the uterine arteries.
9. If all the above described procedures failed, hysterectomy.

![Figure 1](image-url)

*Figure 1*

Scheme of the protocol
There is now good evidence that justifies its use for PPH\(^{15}\).

The “uterine sandwich” technique is a combination of external (B-Lynch suture) and internal (Bakri balloon) uterine compression for simultaneously applying pressure to both surfaces of the uterine wall. There is evidence that the application of this method is an effective tool to treat uterine atony and PPH, avoiding in most cases hysterectomy\(^{16,17}\). The present protocol, provides the combination of the “uterine sandwich” technique with Affronti endouterine sutures, to achieve hemostasis at the site of placental insertion in the lower uterine segment\(^{8}\). The application of the above described approach is in sequential steps and it is characterized by the wide use of technical and professional resources.

In the present series, we had a very low incidence of embolization of the uterine arteries (7.2%), internal iliac arteries (1 case), hysterectomy incidence of embolization of the uterine arteries (7.2%), internal iliac arteries (1 case), hysterectomy (5.4%), intraoperative or postoperative blood transfusion (25.4%) and admission to the general intensive care unit (7.3%). It is also to note that the potential main complication of embolization, i.e. uterine necrosis\(^{18}\), was not observed in our cases.

All pregnancies were at risk of PPH. The management was finalized mainly to preserve the patient’s life and it was influenced by other considerations such as desire to preserve fertility. It highlights the pressing need for research and for clinical audit focusing on etiological factors, preventative measures and quality of care, to guide current clinical practice\(^{19}\). A conservative management should represent the leading aim for treatment of PPH in high risk patients with placenta previa major and/or with other risk factors. The results of the present conservative protocol was encouraging and suggested that all tertiary level obstetric units should have the facilities, professionals and equipments in place to manage properly such emergency\(^{10}\).

REFERENCES

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