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Establishing a Treatment Algorithm for Puerperal Genital Hematoma Based on the Clinical Findings

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Postpartum hemorrhage within 24 hours after delivery remains the leading cause of maternal mortality worldwide. Puerperal genital hematoma (PGHA) is a rare complication of postpartum hemorrhage, and PGHA can be life-threatening if hemostasis is not properly achieved. However, a reliable management algorithm for PGHA based on the clinical findings has not been developed. The objectives were to evaluate the management strategies for PGHA and identify the clinical findings that help select the treatment for PGHA. The medical records of women who were treated for PGHA in our department were reviewed, and data regarding the clinical findings and the treatment strategy for PGHA were analyzed. Thirty-four women who underwent treatment for PGHA were identified and divided into three groups according to the final procedure that achieved hemostasis: conservative management (CM) (n = 9), surgical management (SURG) (n = 15), and arterial embolization management (AEM) (n = 10). Regarding the clinical findings on initial evaluation, the shock index was significantly higher in the AEM group than in the CM or SURG group; and initial platelet count and fibrinogen level were significantly lower in the AEM group than in the CM group. There was no significant difference in any computed tomography (CT) finding among the three groups. In conclusion, this study clearly shows the difference in clinical findings among treatment strategies for PGHA. We suggest that the clinical findings of shock index, platelet count, and fibrinogen level together with CT findings are helpful and valuable for selecting the treatment strategy for PGHA.

Keywords: arterial embolization; clinical findings; conservative management; puerperal genital hematoma; treatment algorithm
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Introduction

Postpartum hemorrhage (PPH) within 24 hours after delivery remains the leading cause of maternal mortality worldwide (Say et al. 2014; Committee on Practice Bulletins-Obstetrics 2017). Uterine atony and trauma (including lacerations, puerperal genital hematoma [PGHA], inversion, and rupture) are estimated to cause 70% and 20% of PPH, respectively (Evensen et al. 2017). PGHA is a relatively rare complication of PPH that can be life-threatening if hemostasis is not achieved (Sheikh 1971; Mawhinney and Holman 2007). Various risk factors for PGHA have been identified (İskender et al. 2016; Rani et al. 2017) and some effective management modalities have been reported, including conservative management (CM) (Propst and Thorp 1998; Palmer and Knudtson 2008), balloon tamponade (Ghirardini et al. 2012), surgical management (SURG; suture and packing, drainage and laparotomy including ligation of the internal iliac artery) (Abbott et al. 1965; Heffner et al. 1985; Zahn et al. 1996), and arterial embolization management (AEM) (Hsu and Wan 1998; Villella et al. 2001; Baruch et al. 2015). However, the lack of scientific data to strongly support any single management approach has prevented a consensus regarding the optimal management (Zahn et al. 1996; Mawhinney and Holman 2007). AEM has received particular recognition as

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an alternative to SURG, and has been proposed as the first-line treatment for PGHA (Distefano et al. 2013; Takagi et al. 2017). However, the patients who are good candidates for this treatment have not been identified, and AEM is not always available in all institutions where deliveries occur. In addition, it is undetermined whether AEM is clearly indicated for patients with PGHA who have arterial bleeding on computed tomography (CT) but have stable vital signs and hematological findings. The most suitable modality for treatment of PGHA according to the presenting clinical symptoms or hematologic findings has not been clearly elucidated. We, therefore, consider that an optimal management algorithm should be established for PGHA that includes clinical findings such as CT, vital signs, and hematological data. In this study, the details of patients treated at the sole multidisciplinary center in Fukushima Prefecture were investigated in an attempt to identify clinical findings that would assist in the treatment selection process for PGHA.

Material and Methods

We reviewed the obstetric records of women treated for vulvovaginal hematoma at Fukushima Medical University Hospital between January 2006 and December 2017, and collected data regarding parity, antepartum complications, details of delivery, first symptom of the hematoma, vital signs (blood pressure, heart rate), shock index (SI), blood examination data at the time of initial evaluation in our hospital, CT findings, details of interventions (including anesthesia), and blood transfusion therapy. To ensure that the vital signs measured at the time of the highest SI were included in the analysis, these were measured repeatedly during the initial evaluation. Uncertain data points were clarified with reference to the records from the referring hospital. The CT and arterial embolization findings were re-evaluated by a board-certified radiologist (O.H.) and the following were recorded: hematoma size and location (supralevator ani or not), presence of extravasation, and the bleeding vessel. The women were divided into three groups according to the final management strategy by which hemostasis was achieved (CM, SURG, and AEM), and the clinical PGHA findings were analyzed for each group. Three management strategies were defined, as follows. CM, observation only, with or without gauze packing in the vaginal wall; SURG, requiring a wide incision over the hematoma or reopening the episiotomy repair, followed by removal of the blood clot and subsequent irrigation (without a drainage tube if possible); and AEM, arterial embolization of the bleeding artery via an interventional procedure. In our department, AEM is performed by an obstetrician/gynecologist and an interventional radiologist (IVR), working interchangeably as the first and second operators, sometimes with the support of additional gynecologists or IVRs (Soeda et al. 2018). In brief, unilateral access to the femoral artery was achieved in most cases by the obstetrician/gynecologist under the guidance of the IVR. The obstetrician/gynecologist or IVR first performed super-selective catheterization of the bleeding artery using the coaxial technique with a 5-Fr Mohri catheter (Terumo Clinical Supply, Gifu, Japan) and a 2.4-Fr microcatheter (Renegade Hi-Flo; Boston Scientific, Tokyo, Japan), followed by embolization with gelatin sponge pieces (Spongel; Astellas, Tokyo, Japan, or Serescue; Nippon Kayaku, Tokyo, Japan) (Soeda et al. 2018). On the basis of the significant findings of this study, we developed a potential management algorithm for PGHA.

Statistical analyses

Birthweight, maternal age, height, SI, hemoglobin, platelet count, and fibrinogen level are expressed as the means (± standard deviation). ANOVA was followed by Tukey's honestly significant difference adjustment for multiple comparisons of birthweight and maternal age, height, and hematological data. Pearson's chi-squared test followed by residual analysis was used for some patient characteristics and the CT findings. The significance level was set at $P < 0.05$. Data analyses were performed with SPSS ver. 21.0 (IBM Japan, Tokyo, Japan).

Ethical approval

The study was approved by the Institutional Review Board of Fukushima Medical University (No. 29111, approved on 20 July 2017).

Results

Table 1 lists the patient characteristics of the 34 women who underwent treatment for PGHA at our hospital between January 2006 and December 2017. Of these, 33/34 (97%) were primiparas and 6/34 (17.6%) delivered at our hospital. The remainder (28/34, 82.4%) delivered at other hospitals without facilities for evaluating blood coagulation function or without CT and IVR units, and these patients were transferred to our hospital for treatment. Preeclampsia was present in four patients (11.8%). Eleven patients (33.4%) delivered by spontaneous delivery, and 23 patients (67.6%) with use of vacuum. All patients underwent right-sided medio-lateral episiotomy.

The initial treatment as evaluated at our hospital was CM in 12, SURG in 19, and AEM in 3. Hemostasis was not achieved in three CM patients, two of whom then successfully underwent SURG, and one underwent AEM. Hemostasis could not be achieved in six SURG patients, who were then successfully treated by AEM. Thus, the final treatment method by which hemostasis was achieved was CM in 9, SURG in 15, and AEM in 10 (Fig. 1). Table 1 shows the results of analysis of the clinical parameters. The first symptom by which PGHA was diagnosed showed significant difference among the groups. In the CM group, the diagnosis of PGHA was made based mainly on the pelvic pain caused by compression and infiltration of the hematoma, and only 1/9 (11%) women complained of genital bleeding. In the AEM group, the diagnosis was based on the occurrence of genital bleeding in 10/10 (100%) and pain in 2/10 (20%) women. Table 2 lists the clinical findings for each group at the time of first treatment at our hospital or at transfer to our hospital. We included in our analyses the lowest systolic blood pressure and the highest heart rate evaluated simultaneously during the initial evaluation. The rate of women with hypotension (systolic blood pressure < 100 mmHg) was low in the CM group and significantly high in the AEM group. The median SI for all groups was 0.99 (0.47-2.5), and was significantly higher in the AEM group than in the CM or SURG groups. Platelet

Table 1. Patient characteristics according to final treatment modality.

	All (n = 34)	CM (n = 9)	SURG (n = 15)	AEM (n = 10)	
Age (y)	28.6 ± 5.36	27.1 ± 5.04	26.9 ± 4.96	32.6 ± 4.43	CM vs. AEM p = 0.032 SURG vs. AEM p = 0.004
Primipara	33/34	9/9	15/15	9/10	N.S.
Height (cm)	159.4 ± 5.1	158.4 ± 2.7	159.3 ± 5.97	160.3 ± 5.52	N.S.
Hypertensive disorder of pregnancy	4/34	0/9	2/15	2/10	N.S.
Birthweight (g)	2,987.4 ± 441.3	3,175.3 ± 404.6	2,872.4 ± 504.6	2,990.6 ± 339.2	N.S.
Delivery mode					
spontaneous	11	3	7	1	N.S.
vacuum	23	6	8	9	
Location of first treatment					
our department	6	2	2	2	N.S.
private clinic	28	7	13	8	
First symptoms					
bleeding	17	1/9*	6/15	10/10*	p < 0.05
bleeding	12	0	4	8	
pain	13	7	7	0	
bleeding + pain	5	1	2	2	
none	4	1	2	0	

CM, conservative management; SURG, surgical management; AEM, arterial embolization management; N.S., not significant.
*p < 0.05.

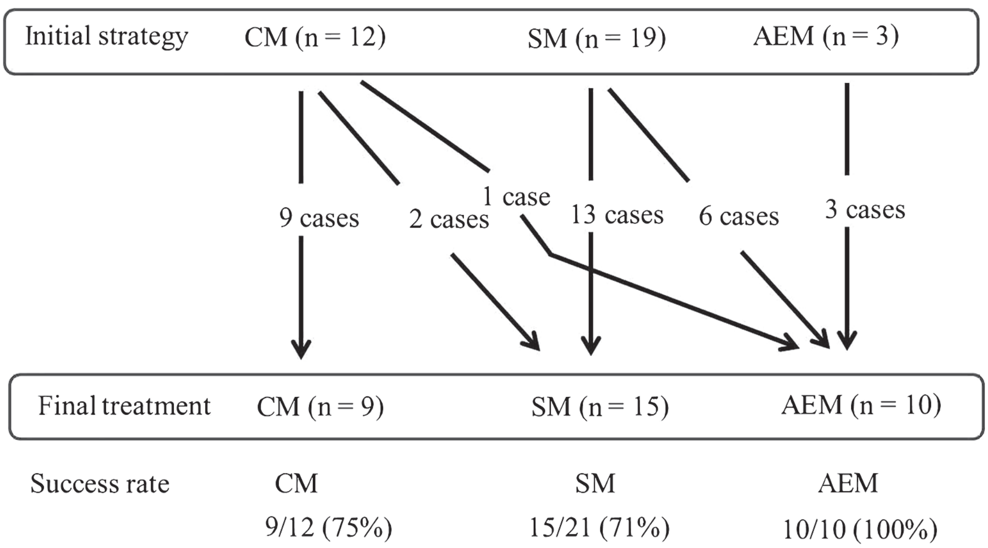

Fig. 1. Flow chart of the treatment methods.
CM, conservative management; SM, surgical management; ABM, arterial embolization management.

Table 2. Clinical findings according to final treatment modality.

	CM (n = 9)	SURG (n = 15)	AEM (n = 10)	
Shock	1/9*	2/15	5/10†	p < 0.05
Shock index	0.96 ± 0.42	0.90 ± 0.18	1.42 ± 0.51	CM vs. AEM p = 0.032 SURG vs. AEM p = 0.004
Hemoglobin	9.1 ± 1.67	8.42 ± 2.09	7.53 ± 2.44	N.S.
Platelets	19.94 ± 4.71	18.12 ± 7.84	12.22 ± 4.91	CM vs. AEM p = 0.038
Fibrinogen	345.13 ± 92.53	289.71 ± 10.89	205.8 ± 84.21	CM vs. AEM p = 0.014
Blood transfusion	3/9**	8/15	10/10††	p < 0.05

CM, conservative management; SURG, surgical management; AEM, arterial embolization management; N.S., not significant.
*, **, †, ††p < 0.05.

count and fibrinogen level on the initial evaluation were significantly lower in the AEM group than in the CM group, but showed no significant differences between the CM and SURG groups. The severity of postpartum hemorrhage (PPH) was evaluated in terms of the platelet count and fibrinogen level after dividing the women into two groups according to two cut-offs: according to the median SI of the present study (0.99) and to a previously reported SI cut-off of 0.9 (El Ayadi et al. 2016). Regarding platelet count, there was a significant difference between SI < 0.99 (n = 17, 19.5 ± 7.7/μL) and SI > 0.99 (n = 17, 14.3 ± 5.0/μL), but no significant difference between SI < 0.9 (n = 10, 17.5 ± 6.5/μL) and SI > 0.9 (n = 24, 16.6 ± 7.2/μL). In contrast, significant differences were found in fibrinogen level between SI < 0.99 (n = 16, 326.4 ± 111.3 mg/dL) and SI > 0.99 (n = 16, 228.3 ± 77.9 mg/dL), and between SI < 0.9 (n = 10, 343.0 ± 114.7 mg/dL) and SI > 0.9 (n = 24, 247.5 ± 90.8 mg/dL). In the seven patients for whom AEM was finally performed because hemostasis was not achieved by CM (n = 1) or SURG (n = 6), SI was 1.53 ± 1.38, and platelet count and fibrinogen level were 13.1 ± 5.6/μL and 212.1 ± 93.2 mg/dL, respectively.

Table 3 lists the CT findings for each treatment group. There was no significant difference in any CT finding among the three groups. In the CM group, four patients with extravasation on CT were successfully managed by CM; none of these patients had hypotension, low fibrinogen, or low platelet count. Overall, the longest axis of the hematoma was > 5 cm in 29/34 (85.3%), 11/34 (32.4%) of hematomas were located on the right side (consistent with the side of the episiotomy), 22/34 (64.7%) were located on the left side, 1/34 (2.9%) was located bilaterally; 29/34 (85.3%) were located in the supralevator ani. Hemoperitoneum occurred in 2/10 in the AEM group.

Representative CT findings of the CM and AEM groups are shown in Fig. 2. Of the 21 women treated by SURG, 12 (57.1%) were treated under intravenous analgesia, 2 were treated under intravenous anesthesia followed by general anesthesia, 2 were treated under general anesthesia, 1 was treated under spinal anesthesia, 1 was treated under epidural anesthesia, and 3 were treated with local anesthesia.

In all 10 of the women treated by AEM, local anesthesia was used prior to insertion of the catheter sheath, hemostasis was successful, and there were no post-procedural adverse events. The bleeding originated from a uterine artery in 2 women, obturator artery in 3, vesical artery in 2, inferior gluteal artery in 2, and internal pudendal artery in 1.

Discussion

PGHA can be a life-threatening complication. The reported incidence varies widely, from 1:1,500 to 1:300,

Table 3. CT findings according to final treatment modality.

	CM (n = 9)	SURG (n = 15)	AEM (n = 10)	
Early phase arterial extravasation				
+	4	10	8	
–	4	1	0	N.S.
Not performed	1	4	2	
Size of hematoma				
≥ 5 cm	9	11	9	
< 5 cm	0	2	1	N.S.
Not evaluated	0	2	0	
Location of hematoma				
Right	2	4	5	
Left	7	10	5	N.S.
Both	0	1	0	
Hemoperitoneum	0	0	2	N.S.
Supra levator ani	8	10	5	
Infra levator ani	0	2	0	N.S.
Both	0	1	5	
Not evaluated	1	3	0	

CM, conservative management; SURG, surgical management; AEM, arterial embolization management; N.S., not significant.

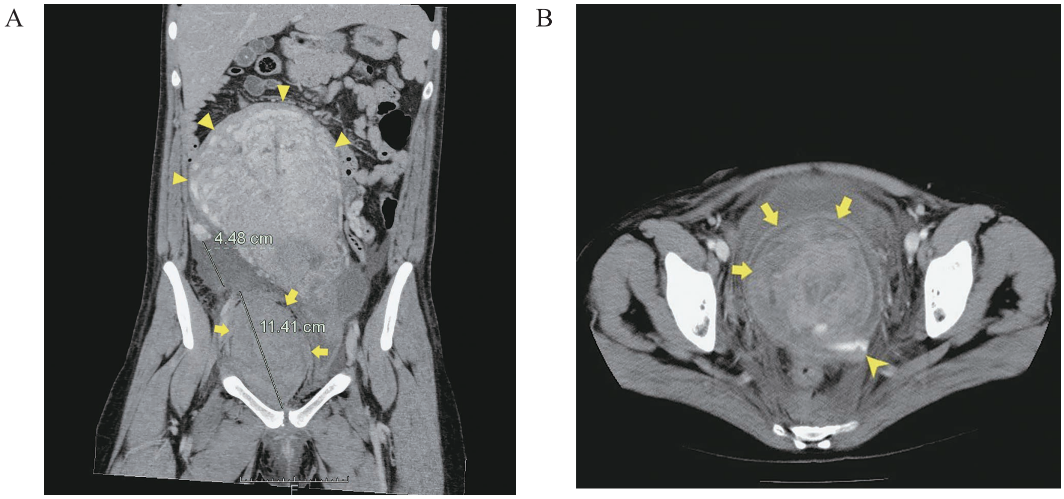

Fig. 2. Representative contrast-enhanced CT images of PGHA with and without extravasation.
A. Coronal reconstruction image shows a hematoma of long axis ~11 cm (arrows), enlarged uterus (arrowheads) and no evidence of extravasation. The PGHA was treated successfully with CM.
B. Axial image shows a hematoma of long axis ~8 cm (arrows) and extravasation from the left branch of the internal iliac artery (arrowhead). The PGHA was treated successfully with AEM.

with large hematomas complicating approximately 1:4,000 vaginal deliveries (Mawhinney and Holman 2007; İskender et al. 2016; Rani et al. 2017). PGHA is classified into three types: 1) vulval or vulvovaginal; 2) vaginal; and 3) supravaginal or subperitoneal (Mawhinney and Holman 2007). The supravaginal or subperitoneal type is clinically occult despite significant blood loss, and a high index of suspicion is required to diagnose and manage these hematomas promptly before signs of cardiovascular collapse develop (Mawhinney and Holman 2007). Effective management strategies have been reported for PGHA, including CM (Propst and Thorp 1998; Palmer and Knudstson 2008), SURG (Abbott et al. 1965; Heffner et al. 1985; Zahn et al. 1996), a balloon tamponade device (Ghirardini et al. 2012), and AEM (Hsu and Wan 1998; Villella et al. 2001; Distefano et al. 2013; Baruch et al. 2015; Takagi et al. 2017); but many of these have been described only in case reports. In deciding the treatment modality, it is necessary to identify the most reliable clinical findings; however, no prospective clinical trials or retrospective studies have been conducted in this regard. Thus, the management of PGHA is controversial and is not yet standardized, and the chosen management strategy depends on the experience of each doctor and the equipment available at each institution. Valuable indicators of the severity of PPH, such as the SI and hematological findings, have not been evaluated for their usefulness in selecting the treatment for PGHA. An informative treatment algorithm for PGHA has been previously described (Distefano et al. 2013); however, it raises several questions. Is evidence of arterial bleeding on contrast-enhanced CT enough to reject CM? Which clinical findings would be valuable, informative, and definitive for choosing the treatment method? Therefore, the present study attempted to identify the clinical findings that would assist in selection of the treatment method for PGHA.

In the present study, the intention was to establish an algorithm for the management of PGHA in a tertiary, multidisciplinary center that can provide comprehensive emergency obstetrical care with CT, a surgical theater and anesthesiologists, an interventional radiology unit and IVRs familiar with pelvic vascular therapy, and a hematology department that can arrange the necessary blood transfusion products. Thus, the most important time for selecting the treatment modality is the time of initial evaluation. Accordingly, the present focus on the clinical and laboratory findings obtained at the initial evaluation in our hospital is useful for anticipating the likely need for blood products. The present results clearly showed a significantly higher SI in patients who needed AEM compared with those treated with the other two modalities. Blood loss is frequently underestimated by visual estimation; and vital signs, systolic blood pressure, and heart rate are insufficient for evaluating hemodynamic stability because of the compensatory physiological response (Sohn et al. 2013; El Ayadi et al. 2016; Lee et al. 2019). SI is defined as the ratio of heart rate to systolic blood pressure, and has been reported as a useful better and earlier predictive marker of hemodynamic compromise compared with conventional vital signs (Sohn et al. 2013; El Ayadi et al. 2016; Lee et al. 2019). Lee et al. (2019) stated that the initial SI was independently associated with the requirement for massive blood transfusion in emergency department patients with primary PPH. El Ayadi et al. (2016) reported that in the management of PPH, an SI $\geq$ 0.9 indicates the need for referral, $\geq$ 1.4 indicates an urgent need for intervention in tertiary facilities, and $\geq$ 1.7 indicates a high chance of adverse outcomes in lower-level facilities in low resource settings. In the present study, the mean SI across all groups was ≥ 0.9 and that of the AEM group was ≥ 1.4, which suggests the importance of SI ≥ 1.4 as an informative finding, similar to the previously reported results. We recommend that in women with PGHA who are transferred to the emergency department, SI should be evaluated initially and monitored continuously thereafter. A high or rising SI value indicates continued bleeding, and immediate treatment such as AEM should be considered.

Blood tests are also important for evaluating the severity of PPH. In particular, hemoglobin, platelet count, and fibrinogen level are reported as important factors for evaluating the severity of PPH, and transfusion of red blood cells, fibrinogen, and fresh frozen plasma can be administered without waiting for the results of blood tests (Sentilhes et al. 2016). In the present study, platelet count and fibrinogen level at the initial evaluation were significantly lower in the AEM group than in the CM group. As the platelet count results are available quickly (in approximately ten minutes), these and the fibrinogen levels can be evaluated along with the SI and a transfusion can then be arranged if necessary, with little delay. In the present study, patients with a high SI (≥ 0.9 or ≥ 0.99) were found to have lower platelet counts and lower fibrinogen levels. This is an important result that suggests that the severity of the SI could be used as an indication to order platelets and fibrinogen, and could also be a helpful finding for selecting the treatment method for PGHA.

PGHA can be diagnosed on the basis of visual inspection, internal examination, transvaginal ultrasound, CT, or magnetic resonance imaging (Lev-Toaff et al. 1991; Guerriero et al. 2004; Kawamura et al. 2014). Contrast-enhanced CT is reliable and valuable for evaluating arterial extravasation (Kawamura et al. 2014), but is not available at all institutions. As mentioned above, the results of the present study are applicable for management of PGHA particularly in high-level institutions, where arterial bleeding can be diagnosed on arterial-phase contrast-enhanced CT. The combined CT and hematological findings are useful for selecting the most appropriate hemostatic therapy. Alternatively, ultrasound is useful for evaluating change in hematoma size over time (Mawhinney and Holman 2007; Youssef et al. 2019), but cannot determine the source of the bleeding. Repeated evaluation by ultrasound is feasible and acceptable because it is less invasive than CT and there is no radiation exposure.

CM is safe and desirable if hemostasis is likely; however, continued pain or infection is possible if the blood clot is not evacuated. A previous study reported that CM is likely to be successful if arterial extravasation is not seen on contrast-enhanced CT (Kawamura et al. 2014). However, no study has reported whether CM could be appropriate if arterial extravasation were seen. In the present study, 4/9 (44%) women in the CM group had arterial extravasation on contrast-enhanced CT, but none of these had hypotension (systolic blood pressure < 100 mmHg), elevated SI, or any abnormal finding related to platelet count or fibrinogen level; moreover, no hematoma enlargement was seen on repeated transvaginal ultrasound. These results indicate that PGHA with arterial extravasation, no abnormal SI, and no coagulopathy can be treated by CM and careful observation of hematoma size by transvaginal ultrasound, checking of vital signs, and hematological tests. However, in 1/12 (8.3%) women in whom CM was started, CT showed no extravasation but hemostasis could not be achieved. It is very important to understand that a lack of extravasation on CT does not guarantee the success of CM.

SURG techniques such as evacuation and suturing with or without drainage are also performed for PGHA. The effectiveness of these procedures has been reported and is well recognized (Abbott et al. 1965; Zahn et al. 1996), but in this situation the vaginal wall is friable and can be difficult to suture, and in many instances (Abbott et al. 1965; Committee on Practice Bulletins-Obstetrics 2017) the bleeding vessels cannot be identified (Heffner et al. 1985). Evacuation of the hematoma can help relieve pain and avoid infection, but the necessity of evacuation to prevent infection in the situation of controllable pain has not been well evaluated. A possible problem associated with SURG is that opening the wound can cause re-bleeding after release of compression by the hematoma (Abbott et al. 1965).

AEM has been reported as a reliable therapeutic option for PPH, especially for cases of PGHA in which hemostasis cannot be achieved by CM or SURG (Hsu and Wan 1998; Pelage et al. 1998; Villella et al. 2001; Banovac et al. 2007; Baruch et al. 2015; Soyer et al. 2015; Koganemaru et al. 2016; Committee on Practice Bulletins-Obstetrics 2017; Lee et al. 2018). Moreover, the efficacy of AEM as the initial treatment for PGHA has recently been reported (Distefano et al. 2013; Takagi et al. 2017). Although these studies emphasized the high reliability of AEM regarding identification of the bleeding vessels and the high hemostasis success rate (Hsu and Wan 1998; Villella et al. 2001; Distefano et al. 2013; Baruch et al. 2015; Takagi et al. 2017), most of these articles are case reports that did not record the specific critical indications for AEM as the initial treatment for PGHA. In the present study, AEM was effective and also the most reliable treatment method. Because AEM is not available at all institutions, clear indications and scientific data that support the selection of AEM as the first-line treatment are needed. In the present study, clinical findings such as SI, platelet count, and fibrinogen level were significantly worse in the AEM group than in the other treatment groups. In particular, SI, platelet count, and fibrinogen level were abnormal in the patients who were treated by AEM because of initial treatment failure (CM, n = 1; SURG, n = 6), and all showed extravasation on enhanced CT (n = 5). Thus, in combination with arterial extravasation detected on contrast-enhanced CT, these findings may be helpful in the decision to select AEM as the first-line treatment for PGHA. Lee et al. (2019) reported that SI has significant ability to predict adverse outcomes of

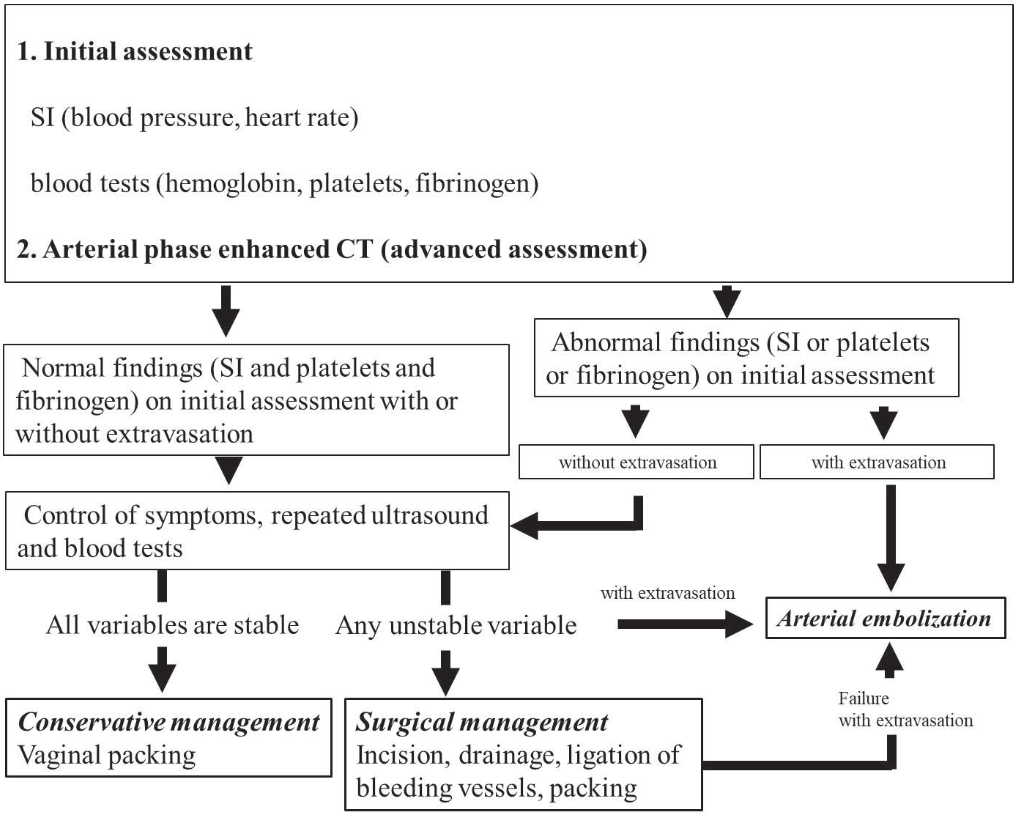

Fig. 3. Suggested treatment algorithm for PGHA.
SI, shock index.

PPH (the causes of which were not described) and invasive procedures, including AEM, hemostatic suture with laparotomy (of the uterus or the pelvic vessels), and hysterectomy. These results provide strong support for the present findings.

The strong points of the present study are that a relatively large number of patients was used to evaluate each treatment modality; it is the first report to evaluate each treatment modality for the management of PGHA using various clinical findings (SI, platelet count, fibrinogen level, and contrast-enhanced CT); and it clearly showed the differences in clinical findings among the treatment methods. A limitation of this study is its retrospective, single-center design.

In conclusion, the present results revealed hypotension (systolic blood pressure < 100 mmHg), SI, platelet count, fibrinogen level, and CT findings as helpful and valuable for selecting the treatment method for PGHA. A treatment algorithm is proposed for the management of PGHA, specifically for use at the time of initial evaluation of women admitted to tertiary hospitals (Fig. 3). Further evaluation of this algorithm in multiple institutions is needed.

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Conflict of Interest

The authors declare no conflict of interest.

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