Aim: Several devices are used for balloon tamponade. In Japan, metreurynters are widely used for cervical ripening; however, there is little evidence for their use in hemostatic uterine balloon tamponade. This study aimed to assess the non-inferiority of metreurynters as the balloon device for obstetric hemorrhage.

Methods: Medical charts of all patients with obstetric hemorrhage of more than 1,000 ml who underwent balloon tamponade with metreurynters were retrospectively reviewed for five years at a tertiary referral university hospital.

Results: A total of 89 uterine balloon tamponade cases were identified from medical records. Of these, 66 cases involved term postpartum hemorrhage (PPH) within 24 h after delivery (PPH group) and 23 involved other types of cases (other group), including cesarean scar pregnancy, cervical pregnancy, retained placenta, and others. In the PPH group, the average hemostasis rate was 93.9%, whereas the rate was 91.3% in the other group. Seven cases failed to achieve hemostasis with balloon tamponade only and required additional treatment. There were no adverse events related to balloon tamponade using metreurynters.

Conclusions: Metreurynters used for balloon tamponade were non-inferior to Bakri balloons in hemostasis and complication rates, suggesting they are effective and appropriate for the management of obstetrical hemorrhage.

Introduction

Obstetric hemorrhage is a life-threatening event that can lead to postpartum hemorrhage (PPH), traditionally defined as bleeding of more than 500 ml. PPH accounts for a large proportion of maternal deaths worldwide, as well as in Japan. Since PPH can quickly lead to maternal morbidity, it requires rapid and appropriate treatment. Other than PPH, post abortion hemorrhage, cesarean scar pregnancy (CSP), and cervical ectopic pregnancy (CP) are also potentially life-threatening events.

In cases of massive obstetrical hemorrhage, conventional methods such as bimanual uterine compression and administration of uterotonic agents are used to achieve hemostasis. When these methods fail, the historical approach of using a tamponade effect to control PPH involved packing the uterus with sterile gauze. Subsequently, uterine balloon tamponade was introduced as a modality for treating PPH. Various types of balloon catheters have been introduced, including the Bakri balloon, the Sangstaken-Blakemore esophageal catheter, the Rush urological balloon, various condom catheters, and the Foley balloon catheter. Obstetricians now typically prefer intrauterine balloons to uterine packing in order to manage PPH. Indeed, the Japan Association of Obstetricians and Gynecologists recommends a balloon tamponade test for PPH. Furthermore, organizations such as the World Health Organization (WHO), the International Federation of Gynecology and Obstetrics (FIGO), the American Congress of Obstetricians and Gynecologists (ACOG), and the Royal College of Obstetricians and Gynaecologists (RCOG) have recommended intrauterine balloons as the first-line hemostatic treatment for PPH.
In Japan, metreurynters are widely used to induce labor and for mechanical maturation of the cervix. Thus, Japanese obstetricians are accustomed to handling metreurynters, which are commonly used at delivery facilities. However, no studies have addressed their effectiveness as balloons for intrauterine tamponade. Accordingly, this study retrospectively assessed hemostasis outcomes and ineffective hemostasis cases in order to clarify the hemostatic effect of metreurynters.

### Materials and methods

At our institution, metreurynters (Fuji-Metro; Fuji Latex Co., Ltd., Tochigi, Japan and Mini-Metro; Soft Medical Co., Ltd., Tokyo, Japan) have been used as balloons for intrauterine tamponade since April 2009 for first-line mechanical hemostasis of PPH. A retrospective review of medical charts of all patients who underwent balloon tamponade with metreurynters between April 2009 and April 2014 at Juntendo University Hospital was conducted. Hemostasis success rate, volume of balloon inflation, and patient characteristics were assessed. Hemostasis rate was considered the primary outcome, and complication rate was considered the secondary outcome.

This study was approved by the Clinical Investigation Ethics Committee of Juntendo University.

### Balloon tamponade

For cases of persistent massive hemorrhage (> 1,000 ml) even after conventional treatments such as bimanual uterine compression and administration of uterotonic agents, a balloon tamponade test was performed as follows. A metreurynter was used as the balloon device, except in cases of latex allergy. Based on the volume of the uterine cavity, two metreurynters were available: the Fuji-Metro, with a maximum volume of 150 ml, and the Mini-Metro for cervical ripening, which has a maximum volume of 40 ml.

With transabdominal ultrasound guidance, the balloon was inserted into the uterine cavity as a balloon catheter and inflated with enough saline to both prevent the device from falling into the vagina and to achieve hemostasis. For cesarean section cases, metreurynters pre-inflated with 50 ml of sterile saline were inserted into the lower uterine segment from the incision site of the uterus with the shafts passed through the cervical canal. Subsequently, the balloon was inflated with 50–150 ml of saline vaginally until hemostasis was achieved, after closure of the uterine incision.

After insertion of the balloon, vital signs and vaginal bleeding were serially monitored. Moreover, the absence of retained lochia or intrauterine hematoma was confirmed by transabdominal ultrasound. The balloon was removed about 24 h after insertion. During this time, uterotonic drugs were also administered.

Prior to balloon tamponade, verbal informed consent was obtained in every case following an explanation of the situation and the necessity for intrauterine balloon tamponade.

### Results

A total of 89 cases were identified from medical records. There were 66 cases in the PPH group in which balloon tamponade was used within 24 h after delivery, and 23 cases in the other group, including CSP, CP, retained placenta, and others.

Table 1 shows the details of bleeding amount within 24 h after delivery, hemostasis success rate, and amount of balloon inflation in the PPH group. There was one case of acute fatty liver of pregnancy with disseminated intravascular coagulation (DIC). Three other cases were followed; two cases of recurrent bleeding after transcatheter arterial embolization (TAE) and one case of pregnancy with idiopathic thrombocytopenic purpura (ITP). The mean hemostasis rate was 93.9%, and the median amount of balloon inflation was 120 ml (80 to 150 ml).

Table 2 provides the details of bleeding amount, hemostasis success rate, and amount of balloon inflation for the other group. Among cases of retained placenta, bleeding for more than 24 h after delivery was observed in three cases in the first and second trimesters, and eight cases in the third trimester. Three other cases were followed, including two cases of atomic bleeding after miscarriage in the second trimester and one case of placental abruption in the second trimester. The mean hemostasis rate was 91.3%. The median amount of balloon inflation was 15 ml in the first trimester (10 to 35 ml), 40 ml in the second trimester (20 to 40 ml), and 40 ml in the third trimester (10 to 120 ml).

There were four and two cases of balloon tamponade failure in the PPH group and the other group, respectively. Table 3 shows the details of these cases. A second surgery was performed for a case with ruptured sutures postcesarean section, and complete hemostasis was achieved in the remaining five cases after TAE. There were no adverse events related to balloon tamponade using metreurynters.

### Discussion

A satisfactory hemostasis rate with balloon tamponade was achieved using metreurynters in the PPH group, which is consistent with previous reports. This success rate was similar to rates with other treatment methods, including embolization and uterine compression.
sutures. In addition, the present hemostasis results using small metreuyneters are consistent with previous studies showing the effectiveness of Foley balloon catheters for local treatment of CSP and CP.

With regard to the volume of balloon inflation, different volumes have been reported depending on balloon shape: Bakri, 500 ml; Sengstaken-Blakemore, 120–370 ml; Rusch, 240–1,000 ml; and Condom, 200–500 ml. The required volumes of saline depend on both balloon shape and uterine capacity. In the PPH group, cases of atonic bleeding, placenta previa/low-lying placenta, and incomplete laceration of the isthmus, where 100% hemostasis rates were achieved, required a median volume of only 120 ml, suggesting that less saline than required for the Bakri balloon was sufficient to achieve hemostasis. These findings were supported by Georgiou who demonstrated a curvilinear relationship between intraluminal pressure and balloon volume, with only a small amount of saline required to achieve hemostasis.

Moreover, the Bakri balloon is priced at JPY29000, whereas metreuyneters cost JPY3200 for the Fuji-metro and JPY1500 for the Mini-metro. Thus, metreuyneters are substantially less expensive than Bakri balloons.

### Conclusion

Metreuyneters used for balloon tamponade were non-inferior to Bakri balloons in terms of hemostasis success and complication rates, and are substantially less expensive. Our findings suggest that metreuyneters are effective and appropriate for the management of obstetrical hemorrhage.

### Acknowledgements

None.
Conflict of Interest

None.

References