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CLINICAL ARTICLE

Bakri balloon during cesarean delivery for placenta previa

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ABSTRACT

Objective: To determine if the use of a Bakri balloon at cesarean delivery (CD) for placenta previa is associated with a reduced need for additional surgical or pharmacologic measures and less blood loss than usual practices. *Methods:* In a randomized controlled trial, 52 women undergoing CD for placenta previa were randomly allocated 1:1 into an intervention arm (prophylactic Bakri balloon immediately following placental delivery) or a control arm (use of any usual surgical/pharmacologic measures to achieve hemostasis). The primary outcomes were a clinician's decision to undertake further intervention to control bleeding, and the difference between preoperative and postoperative hemoglobin levels. *Results:* Although fewer women in the intervention group required additional measures to achieve hemostasis during CD, the difference between the groups was not significant (relative risk 0.54; 95% confidence interval, 0.19–1.57). The change in hemoglobin level among women in the intervention arm was also similar to that among controls (2.3 g/dL; 95% confidence interval, −4.4 to 8.9). *Conclusion:* The prophylactic use of a Bakri balloon at CD for placenta previa tended to be of benefit, with no evidence of harm or patient dissatisfaction, but the need for additional medical/surgical measures to control blood loss was not significantly reduced.

Australian New Zealand Clinical Trials Registry: ACTRN12613000348752.

1. Introduction

Approximately 1 in every 250 births is complicated by placenta previa [1], where the placenta is implanted entirely or partly in the lower uterine segment. Placenta previa may be subclassified using ultrasound scan to be "major" (implanted across the cervix) or "minor" (not implanted across the cervix) [2]. In most instances, a major placenta previa necessitates a cesarean delivery (CD). Given the rising trend toward birth by CD [3,4] and the known association between previous birth by CD and placenta previa [5], this is becoming an increasingly common complication of pregnancy.

Although there are risks associated with all births by CD, when performed in the setting of placenta previa, surgery can be very difficult. Given the poor contractility of the lower segment, CD in this situation is associated with increased risks of bleeding both during and after the operation [6]. Additional surgical procedures to control bleeding are sometimes required, including hysterectomy. Approximately 10% of CDs for placenta previa require an intraoperative or postoperative blood transfusion [7]. Strategies that will reduce the chance of excessive intraoperative/postpartum bleeding in this patient group are clearly desirable.

A Bakri Postpartum Balloon (Cook Medical; Bloomington, IN, USA) is an intrauterine balloon positioned in the uterus and inflated with saline. Its effect may be attributable to a pressure (tamponade) effect on the endometrial cavity or alternatively result from increased hydrostatic pressure in close proximity to the uterine arteries [8]. The catheter also allows drainage of blood to enable clinicians to measure blood loss. There is reasonable evidence supporting its use in the management of postpartum hemorrhage, often when other measures have failed and conservative management is warranted [9,10].

Balloon tamponade catheters have been used in the setting of a CD for placenta previa [11]. There are, however, very limited data specifically supporting the use of the Bakri balloon in the setting of a CD for placenta previa (5 case series including a total number of 26 women [12–16]), and there are no data with respect to the prophylactic use of the Bakri balloon or another balloon at the time of CD for placenta previa. The use of an intrauterine balloon catheter prophylactically at the time of CD may provide a significant benefit in reducing blood loss and avoiding the need for other more extensive surgical procedures.

2. Materials and methods

A randomized controlled trial was undertaken at Mater Health Services, Brisbane, Australia, between October 1, 2009, and November 30, 2012. The trial received ethics approval from the Mater Health Services Human Research Ethics Committee. Potential participants were identified by the research midwife and, following a consultation

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with an obstetrician or obstetric registrar, eligible women were provided written information about the trial. All women with a live singleton pregnancy at or beyond 24 + 0 weeks undergoing CD in the setting of a known low-lying placenta/placenta previa (leading edge of placenta less than 20 mm from the cervical os) were considered eligible for inclusion in the study. An ultrasound scan was required to confirm the placental location a maximum of 2 weeks prior to the planned CD date. Women with a suspected placenta accreta, congenital abnormalities of the uterine cavity, or submucosal uterine fibroids greater than 5 cm and those aged less than 18 years were ineligible to enroll.

The participants were randomly allocated 1:1 into an intervention arm (prophylactic use of the Bakri balloon immediately following delivery of the placenta at the time of CD) or a control arm (use of any/all usual surgical and/or pharmacologic measures to achieve hemostasis during CD). Randomization into the 2 study arms was according to a computer-generated random allocation list. Sealed opaque envelopes were prepared by Mater Medical Research Institute, Brisbane, Australia, and opened by the research midwife after obtaining written consent. Given the nature of the proposed intervention (presence or absence of an intrauterine balloon device), it was not possible to blind either clinicians or women to their allocation.

Following delivery of the infant at CD, 1 g of cefazolin and 5 IU of synthetic oxytocin were administered intravenously and the placenta was removed by controlled cord traction. Clinicians were instructed to wait until signs of separation before applying traction to the cord, except in the setting of significant bleeding. Following delivery of the placenta, the cavity was manually explored and a synthetic oxytocin infusion (20 U in 1000 mL of Hartmann solution at 250 mL/hour) was commenced and continued until 4 hours after birth. A further dose of cefazolin (1 g) was administered intravenously at 12 hours post-birth.

For women randomized to the intervention arm, a Bakri balloon was prophylactically placed immediately following delivery of the placenta at the time of CD. After removal of the stopcock from the inflation port at the end of the device, the balloon was placed (uninflated) in the uterine cavity. With the woman in the Trendelenburg position, and using a long Harrison forceps, the inflation port end of the balloon device was fed through the cervix from above and retrieved by an assistant vaginally. Following the first-layer closure of the uterine incision, 100 mL of sterile water was inflated into the Bakri balloon to ensure the balloon remained in the cavity. After 2-layer uterine closure, the balloon device was further inflated (up to a maximum total instilled volume of no more than 500 mL) until the uterus was considered "firm." In the event that the clinician was concerned about ongoing bleeding, any and all alternative surgical and/or pharmacologic measures of achieving hemostasis could now be employed. This included (but was not limited to) the use of misoprostol, ergometrine, prostaglandin-F2α, deflating the balloon and suturing the placental bed/B-Lynch/another compression suture, ligation of the uterine/ovarian/internal iliac arteries, and hysterectomy. At conclusion of the CD, the surgeon performed a digital vaginal examination to confirm that the balloon was in the uterine cavity, and a 1-inch vaginal pack soaked with povidone-iodine was placed to reduce the risk of the balloon being expelled into the vagina. The urethral Foley catheter remained in situ until the Bakri balloon was removed. The balloon remained in situ for no less than 17 hours and no more than 23 hours. Subsequent vaginal loss was recorded up to 36 hours post-birth.

For women randomized to the control arm, the clinician was free to employ any and all alternative surgical and/or pharmacologic measures of achieving hemostasis after delivery of the placenta (as described earlier), including the option of a Bakri balloon. A 2-layer uterine closure was then performed.

The 2 primary outcome measures were a clinician's decision to undertake further intervention to control bleeding, and the difference between preoperative and postoperative hemoglobin concentrations. Secondary outcome measures were the specific surgical and/or pharmacologic measures of achieving hemostasis, number of units of red blood cells transfused, intraoperative and postpartum estimated blood loss, endometritis within the first 4 weeks postpartum, return to theater during the hospital admission, admission to the intensive care unit, pain scores (in recovery and then 4 times daily until 24 hours after birth), and patient satisfaction.

Blood loss was estimated using a combination of measured loss in the Bakri balloon drainage bag and/or intra-abdominal drains, estimated loss as documented by the treating practitioner in the medical record and/or observation sheets, and estimated loss based on descriptions of vaginal loss (scant, light, moderate, heavy) on the woman's pad, "bluey," and vaginal pack (as per Bose et al. [17]). The diagnosis of endometritis was made if antibiotics were administered beyond 24 hours post-birth and the treating clinician documented "endometritis" in the case notes; if antibiotics were administered following hospital discharge because of heavy bleeding, discharge, and/or lower abdominal pain; or if antibiotics were administered beyond 24 hours post-birth in the absence of evidence of a urinary tract infection, breast infection, chest infection, or wound infection. Patient satisfaction was determined by survey administered by a different research officer (blinded to treatment allocation) by phone at approximately 7 days post-birth.

Assuming a type-1 error of 0.05 and a power of 80%, a sample size of 50 women per group was calculated to detect: (1) a 20% absolute decrease in the proportion of women requiring further hemostatic intervention (25% in the control arm versus 5% in the intervention arm), and (2) a 1-g/dL difference between the preoperative and postoperative hemoglobin concentrations (from 12 g/dL to 10 g/dL in the control arm versus 12 g/dL to 9 g/dL in intervention arm). To recruit this number of women, a 3-year inclusion period was anticipated. After almost 3 years, and having recruited 52 women to the trial, an interim analysis was undertaken and a decision made to cease enrollment, having considered the feasibility of continuing recruitment to reach an adequate sample size.

Statistical analyses of primary and secondary end points were performed according to the intention-to-treat principle, using Stata/SE 9.2 (StataCorp; College Station, TX, USA). Proportional data were compared using the χ^2 and Fisher exact tests, and continuous data were compared using the t test. $P < 0.05$ was considered statistically significant.

3. Results

Between October 1, 2009, and November 30, 2012, 83 women underwent CD for placenta previa at Mater Mother's Hospital, and all 83 were identified and considered for enrollment in the present study. Of these, 8 women did not meet the inclusion criteria and a further 21 declined to participate. Following randomization, 2 women were excluded after a subsequent ultrasound scan indicated, and subsequent histology confirmed, a diagnosis of placenta accreta. In total, 52 women undergoing a CD in the setting of placenta previa were included in the present study (Fig. 1). The groups were similar across all baseline variables except parity (Table 1). Significantly more women randomized to the control group were nulliparous than those randomized to the prophylactic Bakri balloon group (48.2% versus 16.0%; $P = 0.019$).

Although there was a trend toward fewer women in the prophylactic Bakri balloon group requiring additional measures to achieve hemostasis during CD, there was no statistically significant difference between the groups (RR 0.54; 95% CI, 0.19–1.57), even when controlled for parity. Post-hoc subgroup analyses were undertaken to better define particular patient cohorts where the data supported the prophylactic use of a Bakri balloon at the time of CD. Although numbers in the subgroups were small, there was a similar trend favoring the prophylactic use of a Bakri balloon in the settings of preterm CD, major placenta previa, and emergency CD. There was no instance of intraoperative blood transfusion and no difference in the change in hemoglobin level between women receiving a prophylactic Bakri balloon compared with controls, overall or in any subgroup (Table 2).