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Efficacy of Prophylactic Antibiotics in Bakri Intrauterine Balloon Placement: A Single-Center Retrospective Analysis and Literature Review

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Abstract

Objective Bakri intrauterine balloon (BIUB) placement is an effective treatment for postpartum hemorrhage (PPH). This study aims to evaluate the risk of infection during BIUB placement.

Study Design Data for all deliveries ($n = 2{,}144$) at our institution between January 2014 and March 2018 were retrospectively reviewed. Patients diagnosed with PPH ($n = 758$) were included in our analysis, further divided into BIUB ($n = 80$) and non-BIUB groups ($n = 678$), and subdivided into vaginal delivery (VD), elective cesarean delivery (CD), and emergency CD groups. Postpartum endometritis rate was compared in each group. A single dose of prophylactic antibiotics was administered for BIUB placement in the VD group. In the CD groups, antibiotics were administered preoperatively once, and no additional antibiotics for BIUB placement were administered. To obtain an antibiotics administration protocol to be applied during BIUB placement, we electronically searched the PubMed and Scopus databases.

Results No significant differences were observed in endometritis rates between BIUB and non-BIUB groups of all groups. In the literature review, of 27 suitable publications identified, multiple doses of antibiotics were administered in 17 (62.9%) studies and none investigated the efficacy of a protocol for antibiotic.

Conclusion Our protocol might be effective and sufficient in preventing postpartum BIUB placement-related endometritis.

Keywords
- Bakri balloon
- balloon tamponade
- complication
- endometritis
- prophylactic antibiotics
- postpartum hemorrhage

Postpartum hemorrhage (PPH) is a leading cause of maternal death.[1] Treatment strategies include the use of uterotonics (e.g., oxytocin), intrauterine balloon tamponade, uterine compression sutures, interventional radiology, uterine artery ligation, and hysterectomy.[1–5] Bakri first described the effectiveness of intrauterine balloon tamponade for the treatment of PPH during cesarean delivery (CD) in patients with low-lying placentas in 1992.[6] Since then, various methods of intrauterine balloon tamponade have been proposed and have yielded good outcomes, with hemostasis rates generally exceeding 80%.[7–11]

The Bakri intrauterine balloon (BIUB; Cook Medical, Bloomington, IN) is a uterine-specific tamponade balloon with proven effectiveness.[12,13] Although some authors have indicated that balloon placement can cause infection,[14,15] the

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infection rates among women requiring BIUBs have never been described, and little is known about the benefit of prophylactic antibiotic protocols.

The aim of the present study was to evaluate the risk of infection, particularly endometritis, and the effectiveness of a prophylactic antibiotic protocol. It was expected to provide useful information to obstetricians who use BIUB for PPH.

Materials and Methods

Study Design

In this retrospective analysis, we reviewed data from the deliveries at Osaka University Hospital, Osaka, Japan, between January 2014 and March 2018. The study was approved by the Osaka University Ethics Committee (approval 18130, approved on August 1, 2018). Informed consent was not required from patients because of the retrospective nature of the analysis, which was based on computerized data and anonymous selection criteria.

Patients diagnosed with PPH who had cumulative blood loss greater than or equal to 1,000 mL according to the American College of Obstetricians and Gynecologists (ACOG) definition[1] were primarily divided into BIUB and non-BIUB groups, and were further divided into vaginal delivery (VD), elective CD (el-CD), and emergency CD (em-CD) groups.

Among these, we evaluated the following clinical characteristics and outcomes: maternal age at delivery, gravidity and parity, length of pregnancy at delivery, status of Group B *Streptococcus* (GBS) in vaginal swab within 4 weeks of delivery, rate of premature membrane rupture, percentage using an intrauterine pressure catheter, rate of manual removal of placenta, indication for CD groups only, total blood loss during delivery, rate of blood transfusion, rate of chorioamnionitis (CAM), time from delivery to BIUB placement, blood loss from delivery to BIUB placement, BIUB volume, blood loss duration during BIUB placement, duration of BIUB placement, and additional surgical treatments used to control PPH. We defined CAM as being confirmed by histopathological analysis in this study. We excluded patients who were administered antibiotics in a manner different to our protocol, together with patients diagnosed with CAM.

Procedures

Our protocol for antibiotic prophylaxis in cases requiring BIUB is shown in ►**Fig. 1**. In the VD group, we administered a single dose of prophylactic antibiotics (e.g., ampicillin 2 g or cefazolin 1 g) intravenously before BIUB insertion. In the CD groups, we administered antibiotics (e.g., ampicillin 2 g or cefazolin 1 g) preoperatively once, and no additional antibiotics were administered unless intraoperative bleeding

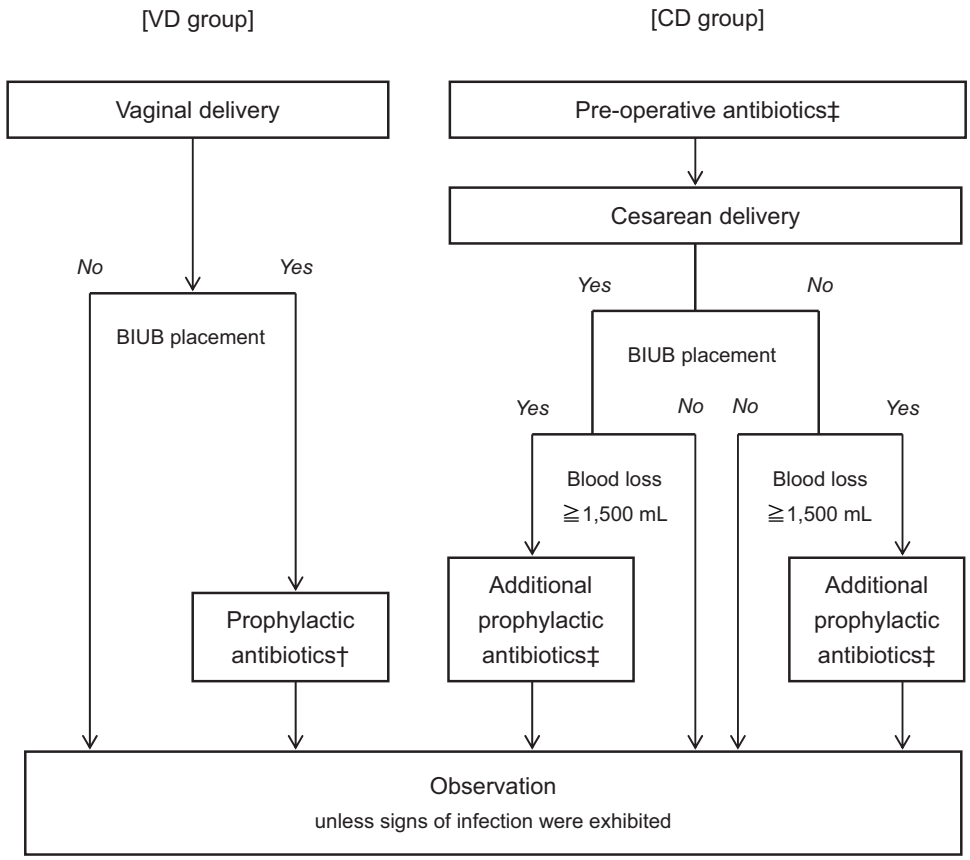

Fig. 1 Prophylactic antibiotic protocol used in this study. † In the VD group, a single prophylactic dose of antibiotic was administered before balloon insertion, aiming to prevent endometritis due to BIUB placement. ‡ In the CD groups, antibiotics were administered preoperatively and when blood loss exceeded 1,500 mL, consistent with the aim to decrease surgical site infection, regardless of whether the BIUB was placed. No additional antibiotics were administered in either group after the procedure if there were no signs of infection. BIUB, Bakri intrauterine balloon; CD, cesarean delivery; VD, vaginal delivery.

exceeded 1,500 mL. Additional antibiotics were administered according to the ACOG recommendations.[1] Therefore, we did not add any antibiotics regardless of BIUB placement in CD cases. In all groups, no additional antibiotics were given during BIUB placement unless there were signs of infection.

The BIUB was placed transvaginally through the cervix in VD and CD cases and transabdominally through the cesarean uterine incision in some CD cases. Gauze was packed into the vagina to prevent prolapse of the BIUB from the uterus in all cases. If bleeding was controlled after balloon inflation, the balloon tamponade was kept in place for 12 to 24 hours.

Postpartum endometritis was defined as fever $\geq$38°C beginning >24 hours or continuing at least 24 hours after delivery plus fundal tenderness, with no other recognized cause of fever, according to the definition of the Centers for Disease Control and Prevention (CDC).[16]

Outcomes

The primary outcome was to determine the postpartum endometritis rate comparing those cased with BIUB and non-BIUB in each group. The secondary outcome was to investigate the rates of other complications, such as uterine perforation and cervical trauma, caused by BIUB placement.

Literature Review

We performed a literature review to discuss the effectiveness of prophylactic antibiotic use in women requiring a BIUB. This involved an electronic search of the PubMed (https://www.ncbi.nlm.nih.gov/pubmed/) and Scopus (https://www.scopus.com) databases from April 1992 to August 2018 with some modification of the previous method.[17,18] Review articles and articles in languages other than English were excluded. The search strategy included the keywords specific to Bakri balloon in each database.

The search strategy used keywords that were specific to each database and included the following terms: "Bakri balloon," "antibiotics," "PPH," "endometritis," or "infection." The keywords were used in various combinations. All articles referring to Bakri balloons were screened, and we excluded studies that did not describe antibiotic use. A flow diagram of the literature search is presented in ►**Supplementary Material S1** (available online only).

Statistical Analysis

We performed the statistical analysis using JMP Pro version 14.0.0 (SAS Institute, Cary, NC). Continuous variables were analyzed using the *t*-test, and categorical variables were analyzed using Chi-square test or Fisher's exact test. A p value of <0.05 indicated statistical significance.

Results

Retrospective Study of BIUB and Antibiotic Use

There were 2,144 deliveries in the study period. Total 100 cases diagnosed with CAM were excluded. We also excluded 14 patients with BIUB who received antibiotics that were not given in accordance to our protocol. As a result, among 2,144 deliveries in the study period, we identified 758 women diagnosed with PPH ($\geq$1,000 mL), of which 80 were treated with BIUB for hemostasis. There were 678 cases of PPH without BIUB and investigated as a control group. The BIUB group was further divided into 32 (40.0%), 28 (35.0%), and 20 (25.0%) patients in the VD, el-CD, and em-CD groups, respectively; the corresponding numbers in the non-BIUB group were 243 (35.8%), 235 (34.7%), and 200 (29.5%), respectively.

Patient characteristics are summarized in ►**Table 1**. The groups did not differ significantly in terms of baseline characteristics except for median maternal age (BIUB group: 36 vs. non-BIUB group: 35, $p = 0.049$), median maternal body mass index (BIUB group: 24.2 vs. non-BIUB group: 24.9, $p = 0.0058$), and frequency of placental abnormalities (BIUB group: 33.3% vs. non- BIUB group: 15.9%, $p = 0.0047$).

The clinical outcomes of the BIUB group are shown in ►**Table 2**. Almost 90% of patients received prophylactic ampicillin (ABPC) (2 g) or cefazolin (1 g), while the remaining 10% received gentamicin, clindamycin , sulbactam/ABPC (SBT), or ceftriaxone. This is because the 10% were suspected of having penicillin allergy or were chosen by the clinician's preference. However, all antibiotic drugs were administered as a single dose. The uterus preservation rate was 92.5% (74/80). Median total blood loss, transfusion rate, and endometritis rate among the VD, el-CD, and em-CD groups are shown in ►**Table 3**. We observed no significant difference in the rate of postpartum endometritis between the BIUB and non-BIUB groups in either the VD group (3.1% [1/32] vs. 2.1% [5/243], $p = 0.53$), the el-CD group (7.1% [2/28] vs. 3.8% [9/235], $p = 0.33$), or the em-CD group (10.0% [2/20] vs. 12.5% [25/200], $p = 1.00$).

►**Supplementary Materials S2** and ►**S3** (available online only) show the results of the analysis for all patients who delivered at our institution during the study period, including non-PPH patients with blood loss of 1,000 mL or less. As was the case with PPH patients, there was no significant difference in the rate of endometritis between the BIUB and non-BIUB groups.

Literature Review

As outlined in ►**Supplementary Materials S1** and ►**S4** (available online only), the electronic literature search revealed 152 articles, and the studies referring to prophylactic antibiotic use in BIUB placement are shown in ►**Table 4** (27 articles). The prophylactic antibiotics used included cephradine (one article), cephazolin (two articles), a combination of multiple antibiotics (four articles), and broad-spectrum antibiotics (nine articles). Total 10 of the articles did not provide details about the kind of antibiotics used.

Prophylactic antibiotics were reportedly given as a single dose in one article and as multiple doses in 17 articles, but no details about dosing frequency were reported in nine articles. The dose and duration of antibiotic use also varied according to the institution. Finally, although 152 articles described the use of BIUBs, none of them investigated or discussed the use of antibiotic prophylaxis protocols.

Table 1 Demographic characteristics for women with or without Bakri intrauterine balloon (cases of blood loss ≥1,000 mL)

	BIUB group	non-BIUB group	*p*-Value
Number of cases	80	678	
Maternal age (y)			
Median (range)	36 (25–44)	35 (18–53)	0.049[a]
Maternal body mass index at delivery			
Median (range)	24.2 (18.5–36.7)	24.9 (16.5–50.7)	0.0058[a]
Parity, *n* (%)			
Primipara (0)	31 (38.8)	277 (40.9)	0.81[c]
Multipara (1≦)	49 (61.2)	401 (59.1)	
Length of pregnancy at delivery (wk)			
Median (range)	38 (24–41)	38 (29–42)	0.54[a]
Preterm delivery <37 weeks, *n* (%)	16 (20.0)	126 (18.6)	0.76[c]
Modes of delivery, *n* (%)			
Vaginal delivery	32 (40.0)	243 (35.8)	0.46[c]
Elective cesarean delivery	28 (35.0)	235 (34.7)	1.00[c]
Emergency cesarean delivery	20 (25.0)	200 (29.5)	0.44[c]
GBS-positive, *n* (%)	7 (8.8)	102 (15.0)	0.18[c]
PROM, *n* (%)	8 (10.0)	55 (8.1)	0.52[c]
Placement of an IPC, *n* (%)	5 (6.3)	47 (6.9)	1.00[c]
Manual removal of placenta, *n* (%)	7 (8.8)	29 (4.3)	0.091[c]
Indication for CD, *n* (%)			
Previous CD and myomectomy	12 (25.0)	163 (37.5)	0.11[c]
Non-reassuring FHR	5 (10.4)	52 (11.9)	1.00[c]
Labor arrest and induction failure	4 (8.3)	70 (16.1)	0.21[c]
Placental abnormalities[b]	16 (33.3)	69 (15.9)	0.0047[c]
Abnormalities of UCI	0 (0)	5 (1.1)	1.00[c]
Multiple pregnancy	3 (6.3)	17 (3.9)	0.44[c]
Malpresentation	3 (6.3)	29 (6.7)	1.00[c]
Others	5 (10.4)	30 (6.9)	0.38[c]

Abbreviations: BIUB, Bakri intrauterine balloon; GBS, Group B Streptococcus; FHR, fetal heart rate; IPC, intrauterine pressure catheter; PROM, premature rupture of the membranes; UCI, umbilical cord insertion.
[a]*p* value from *t*-test of differences between BIUB and non-BIUB groups.
[b]Placenta previa and low-lying placenta cases.
[c]*p* value from Fisher's exact test of differences between BIUB and non-BIUB groups.

Table 2 Clinical outcomes of the Bakri intrauterine balloon group

	BIUB group (*n* = 80)
Time between delivery and BIUB placement (h)	
Median (range)	1.21 (0.15–8.0)
Blood loss at insertion of BIUB placement (mL)	
Median (range)	1,765 (900–5,571)
Volume of water infused in BIUB (mL)	
Median (range)	200 (70–500)
Estimated blood loss during BIUB placement (mL)	
Median (range)	140 (4.0–5,430)
Duration of BIUB placement (h)	
Median (range)	21.0 (0.33–27.0)
Additional treatment	
Blood transfusion, *n* (%)	50 (62.5)
Interventional radiology, *n* (%)	11 (13.8)
Uterine compression suture, *n* (%)	6 (7.5)
Hysterectomy, *n* (%)	6 (7.5)
Complications	
Failure of tamponade, *n* (%)	2 (2.5)
Endometritis, *n* (%)	5 (6.3)
Uterine perforation by BIUB placement, *n* (%)	0 (0)
Cervical trauma by BIUB placement, *n* (%)	0 (0)
Type of antibiotics used as prophylaxis, *n* (%)	
ABPC 2 g	41 (51.3)
CEZ 1 g	32 (40.0)
ABPC 2 g + GM 200 mg	2 (2.5)
ABPC 2 g + CLDM 600 mg	1 (1.2)
ABPC 2 g + CLDM 600 mg + GM 200 mg	1 (1.2)
GM 240 mg + CLDM 600 mg	1 (1.2)
SBT/ABPC 1,500 mg	1 (1.2)
CTRX 1 g	1 (1.2)

Abbreviations: ABPC, ampicillin; BIUB, Bakri intrauterine balloon; CEZ, cephazolin; CLDM, clindamycin; CTRX, ceftriaxone; GM, gentamicin; SBT/ABPC, sulbactam/ampicillin.

Discussion

The key findings of our study are that a single dose of prophylactic antibiotics in VD cases, and no additional antibiotics in CD cases, for BIUB placement might be effective and sufficient to prevent postpartum endometritis related to BIUB placement. Moreover, our literature review revealed that our study is the first to evaluate the risk of endometritis in BIUB placement and multiple doses of antibiotics were administered in approximately 65% of articles during BIUB placement.

Ever since its effectiveness was confirmed,[12,13] BIUB has been widely incorporated as a standard option for the conservative management of PPH.[1] As BIUB utilization continues to increase, obstetricians must pay greater attention to the associated risks and complications. Previous studies have reported several complications and adverse events associated with BIUB. They include uterine perforation or cervical trauma during balloon placement, failure of tamponade due to a

Table 3 Comparison of blood loss, blood transfusion rate, and endometritis rate by mode of delivery (cases of blood loss ≥1,000 mL)

	BIUB group	non-BIUB group	*p*-Value
Number of cases	80	678	
Median of total blood loss, mL (range)			
Vaginal delivery	2,233 (1,025–7,970)	1,255 (1,000–7,400)	0.0001[a]
Elective cesarean delivery	2,250 (1,081–3612)	1,255 (1,000–8,470)	0.0001[a]
Emergency cesarean delivery	2,252 (1,012–4,500)	1,250 (1,000–8,972)	0.15[a]
Blood transfusion, *n* (%)			
Vaginal delivery	19/32 (59.4)	26/243 (10.7)	<0.0001[b]
Elective cesarean delivery	18/28 (64.3)	18/235 (7.7)	<0.0001[b]
Emergency cesarean delivery	13/20 (65.0)	32/200 (16.0)	<0.0001[b]
Endometritis, *n* (%)			
Vaginal delivery	1/32 (3.1)	5/243 (2.1)	0.53[b]
Elective cesarean delivery	2/28 (7.1)	9/235 (3.8)	0.33[b]
Emergency cesarean delivery	2/20 (10.0)	25/200 (12.5)	1.00[b]

Abbreviation: BIUB, Bakri intrauterine balloon.
[a]*p* value from *t*-test of differences of blood loss between BIUB and non-BIUB groups.
[b]*p* value from Fisher's exact test of differences in the rate of blood transfusion and endometritis between BIUB and non-BIUB groups.

broken balloon or inadequate inflation, uterine rupture due to excessive inflation, and infection.[18]

The rates of many of these complications may be reduced by using ultrasound guidance for device insertion: the Matsubara–Nelaton's method[21,22] and the tamponade test.[23,24] However, it is unclear whether these procedures lower infection rates. Considering infections such as postpartum endometritis complication of BIUB,[14,15] it is surprising that there has been little discussion of the rate of infection or the use of prophylactic antibiotics in the literature.

According to our review of the effectiveness of prophylactic antibiotics, 17 (65.4%) out of 27 publications used multiple doses of antibiotics. We found that the type, frequency, dose, and duration of antibiotics varied according to the institution, and no previous study had compared antibiotic regimens for preventing endometritis. Although we wanted to investigate the rate of endometritis according to antibiotic regimen, only 11 (40.7%) out of 27 studies mentioned the rate of endometritis and none had investigated the rate of endometritis in the BIUB and non-BIUB groups.

The World Health Organization has stated that inappropriate antibiotic use contributes to antibiotic resistance, threatening our ability to treat common infectious diseases, and resulting in prolonged illness, disability, death, and increased healthcare costs.[25] All antibiotic use should therefore be based on rigorous evidence, including the prophylactic use of antibiotics in BIUB placement. We conducted this retrospective analysis to evaluate the risk of infection and the effectiveness of the protocol we used for antibiotic prophylaxis in women treated for PPH by BIUB.

Our antibiotics protocol was not associated with excessive events of endometritis related to BIUB usage. Since only a few patients were included with a BIUB without prophylactic antibiotics at our institution, we could not compare the endometritis rate between patients who did and did not receive antibiotics. In the CD groups, we administered antibiotics preoperatively, and when blood loss exceeded 1,500 mL as part of the routine strategy to prevent surgical site infections, according to the ACOG recommendations.[26,27] Although it is conceivable that the rate of endometritis in patients receiving BIUBs may not increase without prophylactic antibiotic use, we were at least able to show that a single-dose of prophylactic antibiotics might be effective in preventing an infection.

A major strength of the present study is that we formally evaluated both the risk of endometritis associated with BIUB placement, and the effectiveness of prophylactic antibiotic therapy. This was then supported with data from a literature review of antibiotic use for BIUB placement. Second, we found that multiple doses of antibiotics were administered in approximately 65% of articles. We believe that our data are useful for reducing the use of antibiotics without an increased rate of infection.

Our study included several limitations. One is that this was only a single-center retrospective study with small sample size; unmeasured bias may exist in the analysis. To ensure the safe and effective use of BIUBs for PPH, larger studies are needed. Second, we could not match the patient's characteristics between BIUB and non-BIUB cases well. Small sample size did not allow us to perform propensity score matching; thus, we selected the PPH cases to reduce the bias of hemorrhage. We are aware this is not an ideal method; however, we believe it is an acceptable method.

Third, we could not investigate the risk of endometritis in cases without antibiotic administration. To clearly show that our antibiotics protocol is sufficient to prevent infection, we should conduct the study as follows; comparing two study groups in which one receives antibiotics and the other does

Table 4 Summary of the literature regarding prophylactic antibiotic use for BIUB placement

Author Reference	Year	Study design	No.	Type of antibiotics	Dose and frequency	Duration of antibiotic	The rate of infection n (%)
Wang D (S1)	2018	Prospective	407	NR	NR	NR	0 (0)
Zeng C (S2)	2017	Retrospective	27	BS	MD	48 hours after delivery	NR
Mathur M (S3)	2018	Retrospective	49	NR	MD	During balloon placement	NR
Soyama H (S4)	2017	Retrospective	50	NR	Twice	At the beginning of CD,12 hours after CD	0 (0)
Darwish AM (S5)	2018	RCT	33	CED 1 g	Every 12 hours, DIV (MD)	24 hours after balloon placement	0 (0)
Abraham C (S6)	2017	Case report	1	NR	MD	During balloon placement (24 hours) houthours hours)	0 (0)
Revert M (S7)	2017	Prospective	226	AMPC/CVA + GM	MD	48 hours after delivery	1 (0.44)
Cho HY (S8)	2015	Retrospective	64	CEZ 1 g	Every 12 hours, DIV (MD)	During balloon placement (24 hours)	NR
Vintejoux E (S9)	2015	Retrospective	36	NR	Single-dose	–	NR
Alkis I (S10)	2015	Retrospective	47	BS	NR	NR	NR
Cengiz H (S11)	2015	Case report	1	BS	MD	During balloon placement (24 hour)	NR
Kaya B (S12)	2014	Prospective	45	BS	NR	NR	0 (0)
Beckmann MM (S13)	2014	RCT	25	CEZ 1 g	DIV (Twice)	At the delivery and 12 hours after delivery	0 (0)
Kavak SB (S14)	2013	Prospective	7	BS	NR	NR	NR
Vrachnis N (S15)	2013	Retrospective	18	NR	NR	NR	0 (0)
Patacchiola F (S16)	2012	Retrospective	16	BS	NR	NR	0 (0)
Laas E (S17)	2012	Retrospective	43	AMPC/CVA + GM	MD	48 hours after delivery	1 (2.3)
Karateke A (14)	2012	Case report	1	NR	MD	During balloon placement (26 hour)	NR
Diemert A (S18)	2012	Retrospective	20	BS	MD	During balloon placement (24 hour)	0 (0)
Khalil MI (S19)	2011	RCT	50	BS	MD	48 hours after delivery	NR
Arduini M (S20)	2010	Retrospective	9	ABPC/SBT 3 g	Every 12 hours, DIV (MD)	NR	NR
Georgiou C (S21)	2010	Case study	2	CEZ + CEX + MNZ	[a]	CEZ: 24 hours, CEX + MNZ: 4 days	NR
Majad H (S22)	2009	Case report	1	TAZ/PIPC + OAT	MD	NR	NR
Vitthala S (S23)	2009	Retrospective	15	BS	NR	NR	NR
Nelson WL (S24)	2007	Retrospective	5	NR	MD	During balloon placement	NR
Tahaoglu AE (S25)	2017	Retrospective	42	NR	NR	NR	NR
Agrawal R (S26)	2011	Case report	1	NR	NR	NR	NR

Abbreviations: ABPC/SBT, ampicillin/sulbactam; BIUB, Bakri intrauterine balloon; BS, Broad-spectrum; CD, cesarean delivery; CED, cephradine; CEX, cephalexin; CEZ, cephazolin; CVA/AMPC, clavulanic acid/amoxicillin; DIV, drip intravenous; GM, gentamicin; MD, multiple-dose; MNZ, metronidazole; No., number of cases; NR, not reported; OA, oral administration; OAT, oral antibiotics; RCT, randomized control trial; TAZ/PIPC, tazobactam/piperacillin.

[a]CEZ 1 g, every 12 hours, DIV + CEX 1500 mg/day, OA + MNZ 1,500 mg/day, OA.

not receive antibiotics in the prospective or randomized control study. Fourth, the relationship between rate of infection and details of antibiotics (regimen and administered cycle) was not available in most previous studies making regimen-specific discussion not feasible.

In conclusion, we found no association between endometritis and the placement of a Bakri Balloon for PPH among different modes of delivery. We also conclude that antibiotic prophylaxis may be helpful in preventing this infection. However, more robust studies like randomized control trials are needed to clarify the link between the use of antibiotics as prophylaxis for procedures, such as a Bakri balloon placement and prevention of infection.

Authors' Contribution

Y.N., S.M., Y.K., M.E., A.K., and T.T. contributed to study conception and design, data collection, and drafting of the manuscript. M.E., T.T., and T.K. investigated the articles identified in the literature search. A.K. performed an extensive revision of the revised manuscript. T.K. conceived the study, provided general supervision, helped draft the manuscript, and gave final approval for publication of the manuscript. All authors read and approved the final version of the manuscript.

Conflicts of Interest

The authors declare no conflicts of interest or relevant financial relationships associated with the present study.

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