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Bakri balloon for the management of placenta previa

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Abstract: Introduction; Placenta previa is frequently associated with severe obstetric hemorrhage. Bakri balloon was used for the first time in 1992, and was approved as one of the primary support tools in treating PPH.
Objective; To evaluate the outcomes of uterine tamponade using a Bakri balloon for management of placenta previa during caesarean deliveries.
Methods; This is a retrospective study carried out in Maternity and Children Hospital (MCH), Madinah, Saudi Arabia, from September 2012 to September 2015. Outcomes include demographic characteristics of the participants, need for blood transfusion, failure of the balloon, need for further management, duration the balloon kept in, obstetric complications, neonatal morbidity, hospital course post-operative, follow up and progress afterward.
Results; Total number of placenta previa patients 225, of these 164 were operated, while, 47 were transferred to higher medical centre. Added to that, 14 patients were discharged against medical advice. 13 Bakri balloon were inserted intraoperative.
Conclusion; Bakri balloon was more effective in controlling bleeding and was associated with less maternal morbidity and mortality than not using the balloon.
This is the only study in the Middle East which study Bakri balloon for the management of placentaprevia.

Keywords: Placenta previa, Bakri balloon, uterine tamponade,maternal morbidity,Placenta accreta, retrospective study.

I. BACKGROUND

Placenta previa is an obstetric complication in which the placenta is inserted partially or wholly in the lower uterine segment[1]. It is associated with maternal mortality and significant increase in maternal morbidities including massive hemorrhage, infection, adjacent organ damage, and emergency hysterectomy[1, 2]. Placenta previa occurs in approximately 4.8 of every 1,000 deliveries[2]. Women with placenta previa often present with painless, bright red vaginal bleeding[3]. This commonly occurs around 32 weeks of gestation, but can be as early as late mid-trimester[4]. Exact cause of placenta previa is unknown. It is hypothesized to be related to abnormal vascularisation of the endometrium caused by scarring or atrophy from previous trauma, surgery, or infection[1, 2, 4, 5].

Normally, the placenta adheres only to the decidua basalis, thus it separates smoothly from the wall of the uterus after delivery[6, 7]. Placenta accreta exists when the chorionic villi penetrate through the decidua basalis into the myometrium. Morbidly adherent placenta is three types according to the degree of invasion of the placenta into the uterine wall. The placenta is called accreta when it invades the myometrium superficially. Placenta increta exists when the chorionic villi invade the myometrium more deeply. Placenta percreta involves invasion of the placenta to the uterine serosa, and this might involve other nearby organs such as the urinary bladder or rectum (Figure 1)[4, 8].

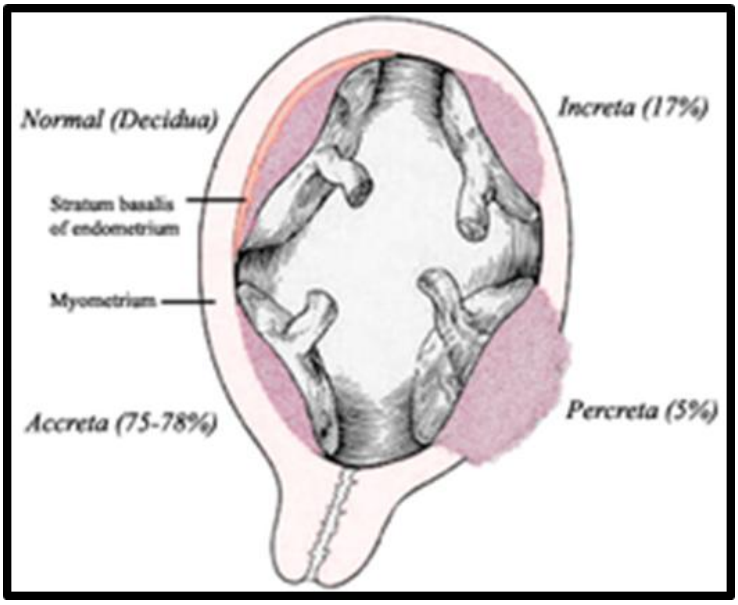

Figure1: Placental classifications

Incidence of adherent placenta is 1 in 2500 deliveries[9-11]. Currently, there is dramatic increase in the incidence of placenta previa and placenta accreta due to the increasing rate of cesarean delivery combined with increasing maternal age[7, 12, 13]. An important risk factor for placenta accreta is placenta previa in the presence of a uterine scar[8]. Placenta previa is an independent risk factor for placenta accreta[1]. Additional reported risk factors for placenta accreta include maternal age and multiparity, other prior uterine surgery, prior uterine curettage, uterine irradiation, endometrial ablation, Asherman's syndrome, uterine leiomyomata, uterine anomalies, hypertensive disorders of pregnancy, and smoking[11, 14, 15].

Placenta previa usually associated with uterine atony, bleeding from the lower flap of the uterine wall, and invasive placentation can cause postpartum hemorrhage[12, 16]. Intraoperative management options to control hemorrhage in placenta previa patients include bimanual uterine compression, implantation site compression with sutures, uterine arterial ligation, B lynch sutures, pelvic arterial embolization and hysterectomy. Added to that, leading to prolonged hospitalisation, admission to an intensive care unit and socio-economic costs[3, 9, 17].

Arterial ligation and different types of compression suture have a low success rate among inexperienced surgeons[3, 8]. Pelvic arterial embolization requires high medical costs and sophisticated facilities[5, 8]. On the other hand, hysterectomy has high morbidity and mortality rates and results in fertility loss. Therefore, other minimal to noninvasive procedures are needed to treat intraoperative and postpartum haemorrhage and preserve the uterus[4, 10, 18].

One of the earliest methods of achieving a tamponade effectwas by uterine packing[5, 18]. Sterile gauze was always used for uterine packing[5, 10]. Recently, balloon technology has been used to tamponade uterus to control haemorrhage[1, 10]. This involves inserting a rubber or silicone balloon into the uterine cavity and inflating the balloon with normal saline. The balloons include the Sengstaken–Blakemore tube, the Bakri balloon, the Rusch balloon, Foley catheters and the condom catheter balloon (Figure 2)[1, 2, 5].

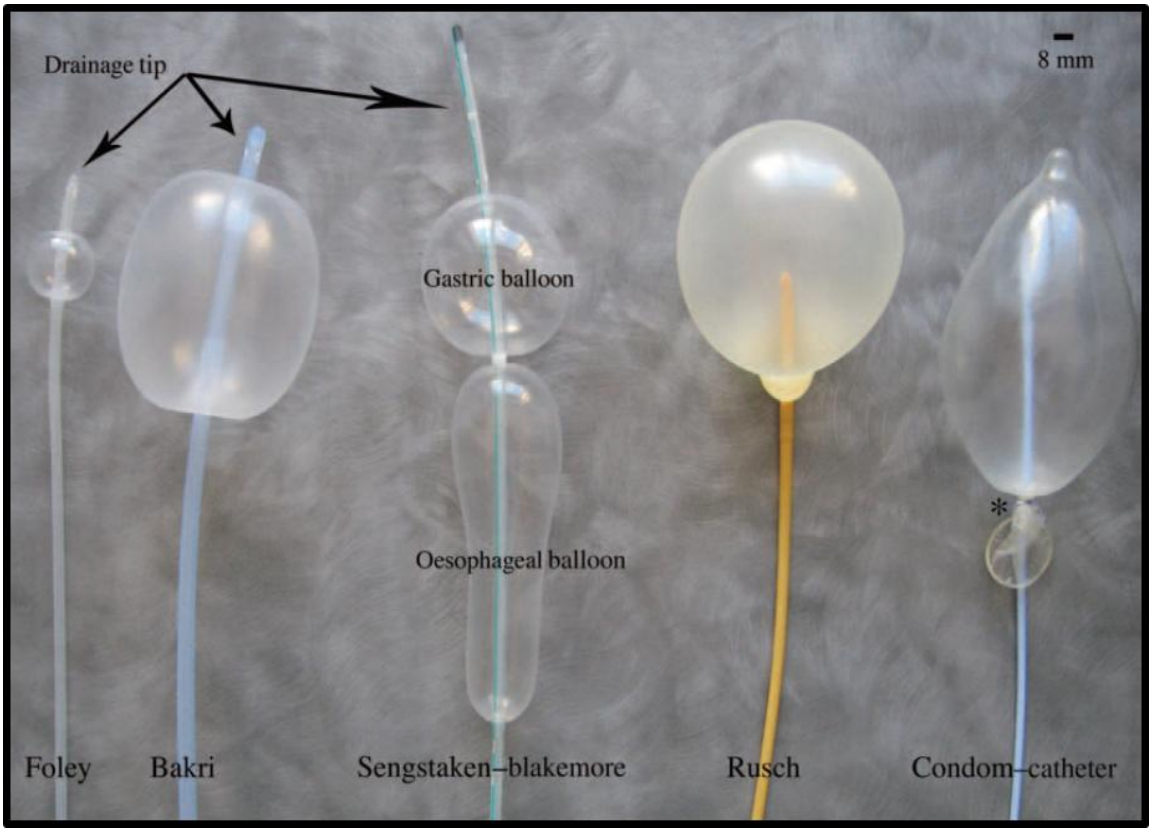

Figure 2: Types of balloon catheters for uterine tamponade

In 1992, Dr Younes Bakri introduced intrauterine balloon tamponade for the treatment of obstetric hemorrhage during cesarean delivery[1, 5, 7]. Both the International Federation of Gynaecology and Obstetrics (FIGO) and the International Confederation of Midwives (ICM) have approved the balloon as one of the primary support tools in treating PPH[5, 6]. A number of recent reports have described the successful use of balloon tamponadeto manage hemorrhage from the lower uterine segment due to placenta previaaccreta[3, 8, 19].

Bakri balloon is a silicone, obstetrical balloon of a 24-French, 54-cm long, silicone catheter with a filling capacity of 500-mL[5, 7]. Ductile shape allows it to conform to uterine anatomy and shape. Added to that, it allows for hemostatic cushion application and limits clot adhesion. The large diameter lumen in the shaft and multipored, nonabrasive tip allows for constant drainage, so an ongoing uterine hemorrhage does not go undetected post-application[5-7]. Once deflated, the Bakri Balloon is easily removed transvaginally without the need for an additional surgical procedure. It is usually kept for 24 hours, but may be removed sooner upon physician determination of hemostasis or the need to apply more aggressive treatment[5, 6].

The present study aimed to evaluate the outcomes of uterine tamponade using a Bakri balloonfor management in cases of placenta previa during caesarean deliveries.

II. METHODOLOGY

This is a retrospective study, carried out in Maternity and Children Hospital (MCH), Madinah, Saudi Arabia. Placenta previa patient records wereidentified and data extracted from placenta previapatient's recordsthat were operated in the hospital from September 2012 to September 2015. Due to the retrospective nature of the study, informed consent is not necessary but patient records were de-identified prior to analysis.This study was approved by Madinah MCH Research Committee.

Madinah MCH (MMCH) is a tertiary hospital where medical care is given free of charge. MCH cover the whole region of Madinah which is 151,990 km2 (58,680 mi2), with a total multi ethnic population of 1,977,933. MCH lies in Madinah which is the capital of the region and the second holiest city in Islam (Figure 3)[20]. MCH average number of deliveries is 15,000 per year, and caesarian section rate is 21%.

Figure 3: Madinah region

Placenta previa was defined as a condition where the placenta lies low in the uterus, while partially or completely covering the cervix. The patients were diagnosed with placenta previaby RIC5-9-D transvaginalprobe and C4-8-D transabdominal probe using Voluson E6 ultrasound system (GE Healthcare) inthe third trimester. Placenta accreta is diagnosed using gray scale ultrasound and the suggestive signs of placenta accreta were presence of placental vascular lacunae, loss of a sonolucent area, interruption of bladder-uterine serosa and visualization of a focal protruding mass between the placenta and bladder. Diagnosis were confirmed by Magnetic resonance imaging (MRI) within 1 week of the ultrasound and intraoperative.

All patients received general anesthesia for cesarean section. At the time of cesarean section, postpartum hemorrhage was initially managed with Oxytocin 10u IM and 40 units in 500ml normal saline at 125ml/hour if the uterus is relaxing intermittently. In refractory cases, 0.1 mg Carboprost trimthamine given intravenously. Second line of management if bleeding continued were to take figure 8 stitches in the bleeding site of the placental bed. In case of more than 1000 mL postpartum hemorrhage and uncontrolled bleeding by previous steps a third line of management is taken. The third line of management is B lynch. If failed, next is either abdominal backing, hysterectomy, or both depending on patient condition and obstetrician preference. Some of the obstetrician insert Bakri balloon as the third line of management and if failed they move to B lynch as fourth line and so on.

The Bakri balloon was inserted through the cesarean section incision or transvaginally according to cervical opening. After proper placement of the catheter, the balloon was partially inflated with 50–100 mL of sterile normal saline. After closure of the uterus and caesarian section scar balloon was further inflated up to 300-500 mL until the blood draining through catheter is significantly decreased. Post-balloon application, low-dose intravenous oxytocin infusion was maintained for 24 hours. The drainage amount was checked hourly for the first 6 hours and if < 100 mL/h, every 4 h thereafter. The decision to remove the drain was made the following day. Failure of Bakri balloon tamponade was defined as continuous uterine hemorrhage after proper placement and inflation of the balloon catheter, with the need for additional intervention to control the bleeding.

Outcomes include demographic characteristics of the participants (nationality, age, parity, gestational age at time of diagnosis and at time of caesarian section, and history of previous uterine operations), need for blood transfusion, failure of the balloon, need for further management, duration the balloon kept in, obstetric complications, neonatal morbidity, hospital course post-operative, follow up and progress afterward. Simple descriptive analysis will be used.

This study was approved by Madinah Maternity and Children Hospital Research and Ethical Committee.

III. RESULTS

Medical records reviewed and showed total number of deliveries for the study period is 39853 of these were caesarian section representing 29.53% of total number of deliveries (Table 1).

	Vaginal and instrumental delivery N (%)	Cesarean delivery N (%)	Total
1/9/2012-31/8/2013	9330 (68.43%)	4304 (31.57%)	13634
1/9/2013-31/8/2014	8524 (68.88%)	3850 (31.12%)	12374
1/9/2014-31/8/2015	10230 (73.89%)	3615 (26.11%)	13845
Total	28084 (70.47%)	11769 (29.53%)	39853

Table 1: Vaginal and caesarian deliveries during study period, N= number, % percentage.

Total number of placenta previa patients 225 during the study period, of these 164 were operated in the hospital, while, 47 were transferred to higher medical centre. Added to that, 14 patients were discharged against medical advice (DAMA) because they plan delivery in other hospital (Table 2).

	1/9/2012-31/8/2013 N (%)	1/9/2013-31/8/2014 N (%)	1/9/2014-31/8/2015 N (%)	Total N (%)
Total placenta previa	48	82	95	225
DAMA	5 (10.42%)	4 (4.89%)	5 (5.26%)	14 (6.22%)
Transferred	12 (25%)	16 (19.5%)	19 (20%)	47 (20.89%)
Operated	31 (64.58%)	62 (75.61%)	71 (74.74%)	164 (72.89%)

Table 2: Distribution of placenta previa patients

Of all placenta previa patients operated in the hospital, 13 Bakri balloon were inserted intraoperative to control bleeding post-delivery of the placenta (Table 3).

	1/9/2012-31/8/2013 N (%)	1/9/2013-31/8/2014 N (%)	1/9/2014-31/8/2015 N (%)	Total N (%)
Total operated placenta previa	31	62	71	164
With Bakri balloon	1 (3.23%)	6 (9.68%)	6 (8.45%)	13 (7.93%)
Without Bakri balloon	30 (96.77%)	56(90.32%)	65 (91.55%)	151 (92.07%)

Table 3: Included patients

For classification purposes Bakri balloon group will be called treatment group while the rest of the placenta previa patients will be referred to as control group. Demographic characteristics of Bakri balloon patients compared to the control group were indifferent (Table 4). Statistically significant difference in demographic results can be explained by the difference in number of participants in each group (Table 4).

		With Bakri balloon 13 N (%)	Without Bakri balloon 151N (%)	P
Patient age	18-25	2 (15.38%)	7 (4.64%)	0.1
	26-35	9 (69.23%)	132 (87.42%)	0.18
	36-45	2 (15.38%)	12 (7.95%)	0.07
Parity	PG	1 (7.69%)	1 (0.66%)	0
	P1	0	3 (1.99%)	0.01 (CI 0.002, 0.04)
	P2	1 (7.69%)	17 (11.26%)	0.88
	P3	4 (30.77%)	39 (25.83%)	0.04(CI -0.21, 0.3)
	P4	3 (23.08)	74 (49%)	0.25
	≥P5	4 (30.77%)	17 (11.26%)	0.19
Previous CS	None	1 (7.69%)	1 (0.66%)	0
	1	1 (7.69%)	3 (1.99%)	0.98
	2	5 (38.46%)	45 (29.8%)	0.08
	3	4 (30.77%)	83 (54.97%)	0.24
	>4	2 (15.38%)	19 (12.58%)	0.02(CI 0.17, 0.23)
Gestational age	28^{+0}-32^{+0} weeks	1 (7.69%)	8 (5.3%)	0.94
	32^{+1}-34^{+0} weeks	3 (23.08)	24 (15.89%)	0.07
	34^{+1}-37^{+0} weeks	7 (53.85%)	35 (23.18%)	0.3
	>37 weeks	2 (15.38%)	84 (55.63%)	0.4
Education	High school	2 (15.38%)	87 (57.62%)	0.42
	University	10 (76.92%)	60 (39.74%)	0.37
	Higher degree	1 (7.69%)	4 (0.26%)	0.97

Table 4: Participants demographic results

All participants delivered by cesarean section either emergency or elective (Table 5). Most of the participants were booked in MCH (Table 5). All participants were kept in intensive care unit (ICU) between 2 and 6 days (Table 5). All participants were transfused blood between 4-16 units (Table 5). None of the Bakri balloon group needed further management to control bleeding. The control group mostly did not need further management except 7 patients needed B lynch and 15 needed cesarean hysterectomy. Added to these patients, another 11 patients operated for placenta previa and suffered severe post-partum bleeding (PPH) and disseminated intravascular coagulopathy (DIC). These 11 patients received massive amount of blood transfusion and Bakri balloon was not inserted in them but they required hysterectomy and abdominal packing (using abdominal towels 10X10) for 24-48 hours. Further, they needed to be operated again to remove packs (Table 5). Among them, only one patient was lost on the fifth day post-operative in spite of all the effort to save her life (Table 5). Bakri balloon kept in 9 patients of the treatment group for 24 hours. On the other hand, it was kept for 48 hours in 4 patients.

		With Bakri balloon 13 N (%)	Without Bakri balloon 151 N (%)	P
Booking	Booked in MCH	9 (69.23%)	75 (49.67%)	0.19
	Booked else where	3 (23.08)	61 (40.4%)	0.17
	Unbooked	1 (7.69%)	15 (9.93%)	0.9
Type of CS	Emergency	5 (38.46%)	27 (17.88%)	0.2
	Elective	8 (61.54%)	124 (82.12%)	0.21
Need for Further management	B Lynch	0	7 (4.27%)	0.04 (CI0.01, 0.07)
	CS hysterectomy	0	15 (9.15%)	0.09
	PPH and DIC received hysterectomy, packing and reoperated	0	11 (6.71%)	0.07
	Death	0	1 (0.61%)	0.01(CI 0.005, 0.03)
Stay in ICU	1-2 days	11(84.62%)	29 (19.21%)	0.65
	3-4 days	2 (15.38%)	96 (63.58%)	0.48
	5-6 days	0	26 (17.21%)	0.17
Blood transfusion	1-4 units	8 (61.54%)	36 (23.84%)	0.37
	5-8 units	5 (38.46%)	78 (51.66%)	0.13
	8-12 units	0	33 (24.24%)	0.21
	12-16 units	0	4 (0.26%)	0.02 (CI 0.009, 0.05)

Table 5: results for type of CS, further management, stay in ICU and blood transfusion

Products of the pregnancy were mostly girls (Table 6). None of the babies died. Neonatal outcomes can be seen in (Table 6).

		With Bakri balloon 13 N (%)	Without Bakri balloon 151 N (%)	P
Sex	Boy	4 (30.77%)	69 (45.7%)	0.15
	Girl	9 (69.23%)	82 (54.3%)	0.15
Admission to NICU	Yes	6 (46.15%)	70 (46.36)	0.002(CI 0.001-0.28)
	No	7 (53.85%)	81 (53.64%)	0.003(CI 0.002-0.29)
Stay in NICU	Total	6	70	0.002(CI 0.001-0.28)
	>7 days	5 (83.34%)	20 (20.57%)	0.25
	7-14 days	1 (16.66%)	45 (64.29%)	0.7
	15-28 days	0	16 (15.14%)	0.11

Table 6: Neonatal outcomes

All participants were discharged from hospital in good condition and followed in the clinic after 6 weeks of the delivery and then after 12 weeks. Three participants returned within 18 months pregnant and they are booked and followed in the hospital. Of these three patients one patient of the Bakri balloon group came pregnant 12 weeks and on follow up. The other two pregnant patients were participants of the control group and both came at 13 weeks pregnancy and on follow up.

IV. DISCUSSION

Every obstetrician fears the day when one of his or her patients has a placenta previa and massive hemorrhage. We endeavor continuously to improve our ability to respond to this obstetric emergency. Placenta previa and its related postpartum hemorrhage is a major cause of pregnancy-related death in both developed and developing nations. One of the latest and greatest improvements in obstetrics care is the Bakri balloon. This simple silicon catheter with large balloon exerts pressure (tamponade) on the blood vessels to prevent bleeding and blood lose following removing the placenta in placenta previa patients. Usually following the removal of placenta in those patients there will be sever postpartum hemorrhage, and uterine atony. Many methods are used to control the bleeding in those patients and their success rate differs specially depending on the expertise of the surgeon. Bakri balloon is a simple pressure method to control the bleeding and needs a little training to learn how to apply it correctly and effectively.

Bakri balloon was first invented in 1992, but gained popularity and waswildly used in developed countries by the beginning of the new millennium. Within the next 10 years Bakri balloon most of the countries of the word start use the balloon and now a day it is an important tool available in most obstetrics wards worldwide. In Saudi Arabia, Bakri balloon available in almost all obstetrics wards but, its use is manly restricted to senior obstetricians.In MMCH Bakri balloon utilization is restricted to trained senior obstetricians and even those are not utilizing Bakri balloon enough because its use is relatively new to them. Added to that, using such a simple tool to manage one of the major diseases in obstetrics carry a major issue of apprehension. This may explain the low number of patients with Bakri balloon inserted to manage bleeding in them.

There is no available census on the incidence of placenta previa in Saudi Arabia but, for cultural reasons large family is desirable[9]. This lead to increase fertility rate and grand multiparity with increased incidence of recurrent caesarian section rates and following consequences. These consequences include placenta previa. In Madinah MCH the rate of placenta previa during the three years of the study was 5.6 per 1000 deliveries. When comparing MMCH rate with the international rate of 4.8 of every 1,000 deliveries, MMCH rate seems very high. This may be explained because this is a tertiary hospital serving the whole Madinah region.Internationally rates of placenta previa is on the rise and the rate in MMCH is the same[2, 11, 14].The rate of placenta previa was 3.5 per 1000 deliveries in the first year of the study and increased to 6.6 per 1000 deliveries in the second year of the studyand finally to 6.9 per 1000 deliveries in the last year of the study.

Because of cultural reasons not all women diagnosed and followed for placenta previa managed in the MMCH. Fourteen patients (6.22%) discharged against medical advice, while 47 patients (20.89%) were transferred to other hospitals either because they are seeking delivery between members of the family, seeking different medical advice or transferred to higher medical centre.

Regarding comparing patients who received no further management after insertion of Bakri balloon and the other group were patients received further management with no Bakri balloon.The difference for inexpert eye seems clear because with Bakri balloon there was no need for further management in any of the patients. Statistically this difference is not enough to be significant except in case of using B lynch which was more in the placenta previa group. This unclear difference can be explained by the small number of patient in both samples.

Maternal mortality is extremely dreadful but in case of placenta previa it is a fact. Placenta previa implicated in around 20% of maternal death from haemorrhage [21, 22]. During the period of the study one patient on the group without Bakri balloon unfortunately died on the fifth day and that was statistically significant.
The number of blood units transfused in the Bakri balloon group is 2-6 with an average of 3 while, in the other group it was 4-16 units with an average of 7 units, but, this was not statistically significant. The number of blood units transfused to Bakri balloon patients in literature ranges from 1 to 6 units with an average of 3 units, while it is 3-9 units and average of 6 units of blood in the general placenta previa population [1, 7, 10, 18].
During study period, no neonatal death occurred. In developed countries infant mortality rate due to placenta previa is 1.2% [23].Admission to NICU was statistically significant less in the Bakri balloon group. On the other hand, length of stay in the NICU was not statistically significant.
This is the only study on Bakri balloon for the management of placenta previa in the Middle East and the second largest in the world after Cho et al, 2015 [1].

V. CONCLUSIONS

In this retrospective study, Bakri balloon insertion for the management of bleeding during caesarean section in placenta previa patients was compared to not using the balloon. Bakri balloon was more effective in controlling bleeding and was associated with less maternal morbidity and mortality.Moreover, Bakri balloon was associated with less morbidity for the baby.
Bakri balloon is an effective, simple tool that provide immediate results with minimal complications for the management of bleeding during caesarean section in placenta previa patients. Bakri balloon should be considered as the second line treatment in massive uterine haemorrhages that are unresponsive to uterotonics.

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