Original Research

Intrauterine Balloon Tamponade for Severe Postpartum Hemorrhage

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OBJECTIVE: To compare the rates of invasive procedures (surgical or vascular) for hemorrhage control between a perinatal network that routinely used intrauterine balloon tamponade and another perinatal network that did not in postpartum hemorrhage management.

METHODS: This population-based retrospective cohort study included all women (72,529) delivering between 2011 and 2012 in the 19 maternity units in two French perinatal networks: a pilot (in which balloon tamponade was used) and a control network. Outcomes were assessed based on discharge abstract data from the national French medical information system. General and obstetric characteristics were included in two separate multivariate logistic models according to the mode of delivery (vaginal and cesarean) to estimate the independent association of the network with invasive procedures.

RESULTS: Invasive procedures (pelvic vessel ligation, arterial embolization, hysterectomy) were used in 298 women and in 4.1 per 1,000 deliveries (95% CI 3.7–4.6). The proportion of women with at least one invasive procedure was significantly lower in the pilot network (3.0/1,000 vs 5.1/1,000, $P<.01$). Among women who delivered vaginally, the use of arterial embolization was also significantly lower in the pilot than the control network (0.2/1,000 vs 3.7/1,000, $P<.01$) as it was for those who delivered by cesarean (1.3/1,000 vs 5.7/1,000, $P<.01$). After controlling for potential confounding factors, the risk of an invasive procedure among women who delivered vaginally remained significantly lower in the pilot network (adjusted odds ratio [OR] 0.14, 95% CI 0.08–0.27), but not for women who delivered by cesarean (adjusted OR 1.19, 95% CI 0.87–1.61).

CONCLUSION: The use of intrauterine balloon tamponade in routine clinical practice was associated with a significantly lower use of invasive procedures for hemorrhage control among women undergoing vaginal delivery.

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Severe postpartum hemorrhage occurs in 1–2% of deliveries in high-income countries and its frequency is increasing.[1,2] Postpartum hemorrhage is among the most common causes of pregnancy-related death worldwide,[3] notably in the United States[4] and Europe.[5] It remains the leading cause of maternal mortality in France, where it is responsible for 18% of maternal deaths; moreover, 90% of these deaths from postpartum hemorrhage are considered avoidable.[6] The initial treatment of severe postpartum hemorrhage involves uterine massage and uterotonic drugs. When these first-line treatments fail, second-line therapies, including invasive procedures such as arterial embolization, uterine compression sutures, pelvic vessel ligation, and hysterectomy, can be used individually or in combination.[7–10]

Intrauterine balloon tamponade has emerged as a widely recommended technique to avoid invasive procedures.[11,12] This noninvasive procedure is effective for the management of postpartum hemorrhage with a success rate from 83% to 86% according to two recent publications.[13,14] Only two before-and-after studies investigated changes in invasive procedure

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rates after adding intrauterine balloon tamponade to a protocol for the management of severe postpartum hemorrhage.[13,15] The main limitation of the few published prospective cohort studies is the lack of a control group.[16] Therefore, the objective of this population-based cohort study was to compare the rates of invasive procedures for hemorrhage control between a perinatal network that routinely used intrauterine balloon tamponade and another perinatal network that did not use intrauterine balloon tamponade in postpartum hemorrhage management.

MATERIALS AND METHODS

This is a population-based retrospective cohort study that included all women who gave birth in two perinatal networks in France during 2011 and 2012. The first (pilot) network comprises 10 maternity units, including four level 1 units (no facilities for neonatal care) and five level 2 units (with a neonatal care unit) organized around one level 3 unit (referral center with an onsite neonatal intensive care unit). Half of the hospitals were private and half public. The second (control) perinatal network comprises nine maternity units including two level 1 units and five level 2 units organized around two level 3 units. Four of these hospitals were private and the other five public. In both networks, vascular embolization was available only at the level 3 units. The control and pilot perinatal networks are geographically close with similar mixes of private and public institutions and similar levels of social and economic development.

The pilot network began using intrauterine balloon tamponade in its standard practice in 2010. The control network did not use intrauterine balloon tamponade during the study period.

Abstracts from the institutions participating in the two networks were extracted from the French national database (Programme de Médicalisation des Systèmes d'Information [PMSI], a national administrative database initially designed to analyze hospital activity and contribute to the strategic elaboration of facility plans and financial management). We selected hospitalizations of women of reproductive age (12–55 years) from the International Classification of Diseases, 10th Revision (ICD-10) code Z37, called "birth outcome." Women who gave birth outside either network but transferred into the network after delivery were excluded as were those who gave birth within one of the networks and then transferred out.

Maternity units in both networks followed the French national clinical guidelines for postpartum hemorrhage management applicable at that time, published in 2004 and including the following steps[17]: 1) active management of the third stage of labor including prophylactic injection of 5 or 10 international units oxytocin after delivery of the anterior shoulder in vaginal births or immediately after birth in cesarean deliveries, early clamping of the umbilical cord, and controlled cord traction; 2) manual removal of the placenta, without delay in the case of hemorrhage or after 20 minutes in the absence of bleeding in vaginal births; 3) with excessive bleeding, manual removal of any retained placental tissue, search for and treatment of any obvious bleeding in any episiotomy or tear, and then administration of additional oxytocin (10 international units); 4) with continued bleeding, intravenous infusion of sulprostone (prostaglandin E2 analog); and 5) if prostaglandin infusion is not effective, an invasive procedure: uterine artery embolization, or surgical arterial ligation, compressive uterine sutures, or hysterectomy. The maternity units of the pilot network, however, modified the French guidelines in April 2010 to require that intrauterine balloon tamponade be used before any invasive procedure in immediate hemorrhages resulting from uterine atony unresponsive to sulprostone after vaginal delivery or delayed postpartum hemorrhage as a result of uterine atony unresponsive to sulprostone after cesarean delivery, that is, before step 5.

Invasive surgical procedures were recommended if medical treatment failed during a cesarean delivery. The network had previously assessed efficacy and tolerability of intrauterine balloon tamponade as an initial second-line treatment of postpartum hemorrhage.[12,13] In 2011–2012, 86% of the intrauterine balloon tamponades used the Bakri balloon. The Belfort–Dildy Obstetric Tamponade System, tradenamed the "ebb" balloon, became available in France only recently and was used only in the level 3 hospital. This has been described elsewhere.[13] The health care personnel had all undergone identical training; all had followed a two-part educational intervention conducted in the pilot network and described elsewhere.[13]

Maternity units produce a discharge abstract listing the principal and associated diagnoses of patients determined at discharge and coded according to ICD-10, and procedures performed during the hospital stay, according to the French Common Classification of Medical Procedures. Information in these abstracts is anonymous and covers both administrative and medical data. All of these abstracts are included in PMSI, the French medical information system. The very good quality of the French hospital database has been evaluated previously and has enabled us to carry out several epidemiologic studies

concerning hospitalized patients in France.[18–22] The main outcome was the rate of invasive procedures for hemorrhage control, expressed as the number of women treated for postpartum hemorrhage by arterial embolization or surgery (pelvic vessel ligation or hysterectomy) divided by the total number of deliveries in the two perinatal networks in France during calendar years 2011 and 2012.

Mode of delivery, uterine artery embolization, pelvic vessel ligation, hysterectomy, and blood transfusion were identified by French Common Classification of Medical Procedures codes. Severe postpartum hemorrhage was defined by the need for such an invasive procedure. Obesity (defined by a body mass index [calculated as weight (kg)/[height (m)]^2] of 30 or greater), previous cesarean delivery, multiple gestation, disseminated intravascular coagulation, a diagnosis of primary postpartum hemorrhage, and sepsis assessed by the medical staff were identified by the appropriate ICD-10 codes.[18,23,24] Multiple pregnancies were counted only once, whatever the number of fetuses.

The National Committee for Data Protection (Commission Nationale de l'Informatique et des Libertés, registration number 1576793) approved the study, which was conducted in accordance with French legislation. Because the study provided standard care in both networks and because the data set contained no information that could enable patient identification, the study was exempt from informed consent requirements. Because this study used an anonymized database and had no influence on patient care, ethics committee approval was not required. The data from the PMSI database was transmitted by the national agency for the management of hospitalization data (ATIH number 2015-111111-47-33).

Descriptive data were expressed as counts and percentages for qualitative variables and as means and SDs for continuous variables. A Pearson χ^2 or a Fisher exact test was used to compare the qualitative variables between the pilot and control networks, and a Student t or a Mann-Whitney test was used to compare quantitative variables. General and obstetric characteristics with a P value $<.20$ in these univariate analyses were included in two separate multivariate logistic models according to mode of delivery (vaginal and cesarean) to estimate the independent influence of the network on invasive procedures. The reliability of the models was assessed with the Hosmer–Lemeshow goodness-of-fit test. A first sensitivity analysis was conducted by keeping only patients who gave birth in a level 3 unit and excluding secondary transfers to these units. A second sensitivity analysis restricted to hemorrhage resulting from atony was performed. For this purpose, we excluded all deliveries associated with one of the following diagnoses: placenta previa (ICD-10 code O44), abruptio placenta (ICD-10 code O45), uterine rupture (ICD-10 codes O710 and O711), amniotic fluid embolism (ICD-10 code O881), and severe perineal lacerations (ICD-10 codes O702 and O703). Statistical analyses were performed with SAS 9.3. All hypotheses were tested at the two-tailed significance level of .05.

RESULTS

During the study period, 72,529 women delivered in the two perinatal networks (Fig. 1), of whom 298 (4.1/1,000; 95% CI 3.7–4.6) had at least one invasive procedure. Maternal age and percentages of vaginal delivery among nulliparous women, cesarean deliveries, operative vaginal deliveries, and primary postpartum hemorrhage were significantly higher in the pilot network, whereas percentages of obesity, previous

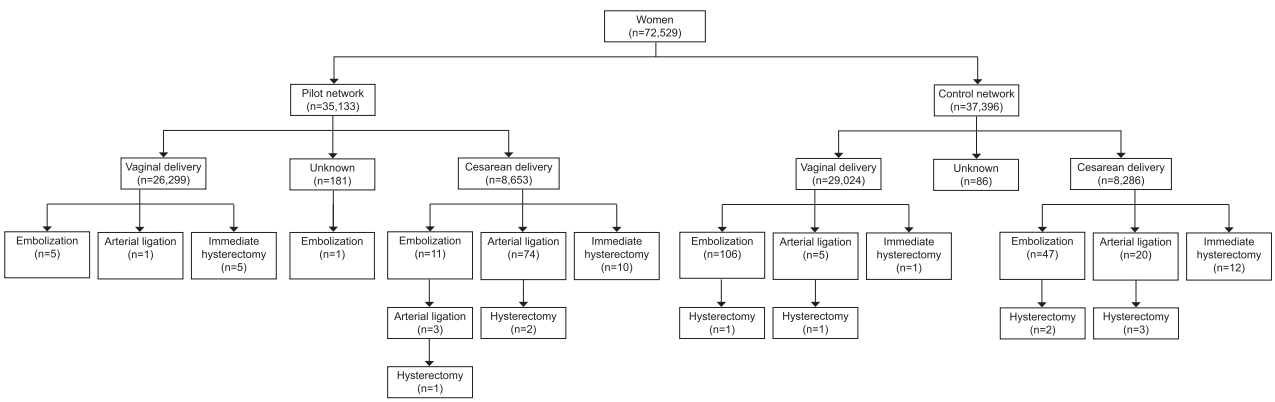

Fig. 1. Description of the study population by mode of delivery and invasive procedures.
Revert. Balloon Tamponade for Postpartum Hemorrhage . Obstet Gynecol 2018.

cesarean deliveries, management of retained products, blood transfusion, and public hospital deliveries were significantly higher in the control network. Percentages of preterm birth, multiple pregnancy, and sepsis were similar in both networks (Table 1).

The use of arterial embolization in the pilot network was lower than that in the control network (0.5/1,000 vs 4.1/1,000, $P<.01$) and the overall use of arterial ligation was higher (2.2/1,000 vs 0.7/1,000, $P<.01$; Table 2). Finally, the overall rate of women with at least one invasive procedure was significantly lower in the pilot network (3.0/1,000 vs 5.1/1,000, $P<.01$; Table 2). Among women with vaginal delivery, the arterial embolization rate was lower in the pilot network (0.2/1,000 vs 3.7/1,000, $P<.01$), whereas the rate of surgical procedures was similar in both networks (Table 2). Among women undergoing cesarean delivery, the embolization rate was significantly lower in the pilot network (1.3/1,000 vs 5.7/1,000, $P<.01$), but the rate of at least one surgical procedure was significantly higher (10.1/1,000 vs 4.1/1,000, $P<.01$); the rate of invasive procedures did not differ significantly (11.0/1,000 vs 9.5/1,000, $P=.35$; Table 2).

Invasive procedures correlated significantly with the mode of delivery. There were also interactions between mode of delivery and the other factors. Therefore, two separate multivariate logistic regressions were performed, one for vaginal deliveries and one for cesarean deliveries. More than 110 invasive procedures were used, either in vaginal deliveries or cesarean deliveries. We could thus include up to 11 variables in the models. Among women with vaginal delivery, the pilot network was significantly associated with a lower risk of an invasive procedure (adjusted odds ratio [OR] 0.14, 95% CI 0.08–0.27), whereas, for women undergoing cesarean delivery, the risk of such a procedure did not differ between the networks (Table 3).

The first sensitivity analysis, which only included patients who gave birth in level 3 units, gave similar results for vaginal (adjusted OR 0.08, 95% CI 0.03–0.22) and cesarean deliveries (adjusted OR 0.68, 95% CI 0.42–1.08). In the second sensitivity analysis, which was restricted to hemorrhage resulting from atony, we found similar results: the pilot network was still significantly associated with a lower risk of an invasive procedure for vaginal deliveries (adjusted OR 0.13, 95% CI 0.07–0.25), whereas, for women undergoing cesarean delivery, the risk of such a procedure did not differ between the networks (adjusted OR 1.17, 95% CI 0.84–1.63).

DISCUSSION

In this population-based study of two perinatal networks, which included 19 maternity units and 72,529 women giving birth in 2011–2012, the rate of invasive procedures was significantly lower in the pilot

Table 1. General and Obstetric Characteristics of Women in the Two Perinatal Networks

Characteristic	Pilot Network (n=35,133)	Control Network (n=37,396)	*P*
Maternal age (y)	30.6±5.1	29.9±5.3	<.01
Obesity (BMI 30 kg/m² or greater)	969 (2.8)	1,180 (3.2)	<.01
Gestational age at delivery (wk)*	39 0/7±2 1/7	39 0/7±2 1/7	.20
Preterm birth*	2,206 (6.3)	2,386 (6.4)	.73
Nulliparous with vaginal delivery*	10,893 (41.5)	11,503 (39.7)	<.01
Previous cesarean delivery	1,715 (4.9)	2,061 (5.5)	<.01
Cesarean delivery	8,653 (24.8)	8,286 (22.2)	<.01
Operative vaginal deliveries	4,594 (13.1)	4,535 (12.2)	<.01
Multiple pregnancy*	570 (1.6)	610 (1.6)	.92
Postpartum hemorrhage	1,571 (4.5)	1,540 (4.1)	.02
Coagulation disorder or DIC	94 (0.3)	55 (0.2)	<.01
Management of retained products	1,444 (4.1)	1,697 (4.5)	<.01
Blood transfusion	184 (0.5)	265 (0.7)	<.01
Sepsis	1,020 (2.9)	1,161 (3.1)	.11
Maternal death	1 (0.0)	3 (0.0)	.63
Deliveries in a public maternity unit	22,721 (64.7)	26,669 (71.3)	<.01
Deliveries by level of care			<.01
3	8,911 (25.4)	15,116 (40.4)	
2	18,938 (53.5)	15,629 (41.8)	
1	7,284 (20.7)	6,651 (17.8)	

BMI, body mass index; DIC, disseminated intravascular coagulation.
Data are mean±SD or n (%) unless otherwise specified.
* Missing data (0.05%).

Table 2. Rates of Invasive Procedures in the Two Perinatal Networks

	Pilot Network	Control Network	P*
Total cohort	35,133	37,396	
Embolization	17 (0.5 [0.3–0.7])	153 (4.1 [3.5–4.7])	<.01
Arterial ligation	78 (2.2 [1.7–2.7])	25 (0.7 [0.4–1.0])	<.01
Hysterectomy	18 (0.5 [0.3–0.7])	20 (0.5 [0.3–0.7])	.89
Women with at least 1 surgical procedure	93 (2.6 [2.1–3.1])	41 (1.1 [0.8–1.4])	<.01
Women with at least 1 invasive procedure	107 (3.0 [2.4–3.6])	191 (5.1 [4.4–5.8])	<.01
Vaginal deliveries	26,299	29,024	
Embolization	5 (0.2 [0.03–0.4])	106 (3.7 [3.0–4.4])	<.01
Women with at least 1 surgical procedure	6 (0.2 [0.03–0.4])	7 (0.2 [0.04–0.4])	.68
Women with at least 1 invasive procedure	11 (0.4 [0.2–0.6])	112 (3.9 [3.2–4.6])	<.01
Cesarean deliveries	8,653	8,286	
Embolization	11 (1.3 [0.5–2.1])	47 (5.7 [4.1–7.3])	<.01
Women with at least 1 surgical procedure	87 (10.1 [8.0–12.2])	34 (4.1 [2.7–5.5])	<.01
Women with at least 1 invasive procedure	95 (11.0 [8.8–13.2])	79 (9.5 [7.4–11.6])	.35

Data are n (per 1,000 [95% CI]) unless otherwise specified.
* Pearson χ^2 or a Fisher exact test.

network, which routinely used intrauterine balloon tamponade, than in the control network. After adjustment for the women's general and obstetric characteristics and for organizational factors, the pilot network was significantly associated with a lower risk of invasive procedures among women undergoing vaginal delivery but not those undergoing cesarean delivery. In a sensitivity analysis restricted to hemorrhages resulting from atony, we found similar results.

Publication of the French guidelines for postpartum hemorrhage management in 2004 led to an increase in embolization rates in an attempt to reduce maternal mortality by obstetric hemorrhage, which was especially high: 1.6 per 100,000 live births in 2007–2009.[25] The results of cohort studies in the general population show more frequent recourse to second-line treatments in France than in other industrialized countries.[26,27] This finding suggests a flaw in the management of postpartum hemorrhage before any invasive treatments.[28,29]

In a before-and-after study conducted in a single French maternity unit, Laas et al[13] showed that including intrauterine balloon tamponade in a protocol for the management of severe postpartum hemorrhage resulted in a significant decrease in the embolization rate after vaginal delivery. More recently, using a similar design, Gauchotte et al[15] confirmed that intrauterine balloon tamponade significantly reduced the need for interventional radiology or surgery for postpartum hemorrhage. Our results from a large population-based cohort study with a control group reinforce the conclusions of these two studies for vaginal

Table 3. Multivariate Regression—Factors Associated With Invasive Procedures by Mode of Delivery in the Perinatal Networks*

	Vaginal Deliveries			Cesarean Deliveries		
Variable	Adjusted OR	95% CI	P	Adjusted OR	95% CI	P
Pilot vs control network	0.14†	0.08–0.27	<.01	1.19‡	0.87–1.61	.27
Maternal age (per y)	1.00	0.97–1.03	.93	1.06	1.03–1.09	<.01
Obesity	1.51	0.70–3.26	.30	1.78	1.03–3.09	.04
Level of care			<.01			<.01
Level 2 vs 1	1.07	0.47–2.41	.88	2.11	1.21–3.68	<.01
Level 3 vs 1	5.22	2.53–10.78	<.01	2.70	1.54–4.75	<.01
Gestational age (per wk)	1.06	0.96–1.17	.26	0.92	0.88–0.96	<.01
Prior cesarean delivery	1.44	0.66–3.10	.35	1.58	1.07–2.33	.02

OR, odds ratio.
* Only those variables that were significant in at least one of the two final models were included.
† Crude OR 0.11 (0.06–0.19), P<.01.
‡ Crude OR 1.14 (0.85–1.54), P=.39.

deliveries. We did not find the same results for cesarean deliveries because intrauterine balloon tamponade may have been used less frequently or perhaps more readily after the cesarean delivery in cases of severe delayed postpartum hemorrhage.

The strength of this population-based study lies in the accuracy of data from French hospitals and the fact that, in France, 99.6% of births take place in hospitals.[30] A comparison of these discharge data with data from birth certificates (civil registry) showed that the PMSI included 99.6% of live births in France and was thus almost completely exhaustive.[18] Moreover, Chantry et al[24] examined 30,607 deliveries in the medical records of four teaching hospitals and compared them with the PMSI. They demonstrated that these procedures are recorded accurately: the positive predictive value of the PMSI was 97.6 (95% CI 92.4–100.0) for arterial ligation and reached 100.0% for both embolization and hysterectomy. Furthermore, the rate of hysterectomy resulting from severe postpartum hemorrhage in these two perinatal networks was similar to that reported in France as a whole (4.9/10,000 deliveries; 95% CI 3.8–6.2) and in the United Kingdom (4.1/10,000 deliveries; 95% CI 3.6–4.5).[25]

This study has several limitations. Uterine compression sutures are not coded by the French Common Classification of Medical Procedures, but because they often precede or are associated with arterial ligation, we believe that including them would not have increased the number of patients treated with at least one surgical procedure. Furthermore, this limitation does not affect the comparability of the two networks, because the absence of coding resulting from national rules affected both networks equally. Because intrauterine balloon tamponade was not coded either, we could not use medicoadministrative data to estimate the number of intrauterine balloon tamponades in the pilot network. However, in a previous publication of ours, we reported that 175 intrauterine balloon tamponades were performed during the years 2011 and 2012.[14] The high rate of arterial embolization in the control network, higher than that found in a prospective population-based observational study[25] conducted in 2004–2006 in France (1.2/10,000 deliveries), is another limitation. This difference is probably explained by the potential effect of the French guidelines for clinical practice published in 2004, which encouraged the use of arterial embolization,[17] and by the greater availability of embolization in the control network associated with a high number of deliveries in level 3 hospitals. Even if these networks are not perfectly comparable, these differences were taken into account during the statistical analyses with adjustments for confounding factors such as the characteristics of the women and major organizational factors such as the level of the unit.

In conclusion, this large population-based study compared the different routine clinical practices of two perinatal networks for the second-line management of severe postpartum hemorrhage. Our results seem to confirm the association between intrauterine balloon tamponade and a significantly lower rate of invasive procedures among women undergoing vaginal delivery.

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