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Accuracy of blood transfusion in postpartum hemorrhage to assess maternal morbidity

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ABSTRACT

Objective: To measure the accuracy of blood transfusion (timing and number of blood units) in postpartum hemorrhage (PPH) in a perinatal network.
Study design: (1) The ANONYMAT software system was used for anonymization and linkage of two large stand-alone databases, the Burgundy Perinatal Network (BPN) and the National Blood Centre (EFS) databases, which contain, respectively, clinical data from hospital discharges and information concerning any blood transfusion in France (considered as the gold standard database for identifying any transfusion). (2) Identification of prescriptions of at least one red blood cell (RBC) unit at the day of delivery (≥22 weeks) and up to 42 days, with manual reviewing of medical records in case of discordant recording. (3) Assessing the sensitivity and positive predictive value of data from the BPN database.
Results: Among the 9736 women receiving at least one blood product dispensed between 01/01/2006 and 12/31/2007 and the 35,779 women who delivered, 233 women (0.65% of deliveries) received at least one RBC unit for post partum hemorrhage. In the BPN database according to the type of hospital stay in our perinatal network (delivery stay only, delivery and post-delivery stays), sensitivity and positive predictive value for RBC transfusion ranged from 61.4% (55.1–67.6) to 67.8% (61.8–73.8) and 82.2% (76.5–87.9) to 83.2% (77.8–88.5), respectively. Linkage of both BPN and EFS databases allowed accurate recording of all but one RBC transfusion.
Conclusion: Our approach allowed 100% electronic recording of PPH requiring blood transfusion, making it an important sentinel event of maternal morbidity to assess the perinatal network.

1. Introduction

Health care improvement, either at a hospital-network or at a nationwide level, depends upon regular assessment of one or many reliable criteria. Selection of a criterion is based on its ability to predict adverse birth outcomes, its reproducibility, its low but sufficient incidence and the exhaustiveness of its recording in electronic databases [1,2].

The maternal mortality ratio in high-income countries (10 per 100,000 live births) is too small for regular evaluation of perinatal networks [1,3]. Regarding maternal morbidity, the use of a single criterion might be of limited value either because of poor reproducibility [4] or because of strong disparities in health facilities and hospital network organization likely to influence medical practices [5]. Furthermore, additional weakness might be introduced by poor accuracy of electronic data recording [6–8]. Using postpartum hemorrhage requiring red blood cell transfusion (PPH-RBT) as a marker of severe maternal morbidity confers the advantage of combining, within the same database, information on both a condition, i.e. postpartum hemorrhage, and a procedure, i.e. transfusion [8,9]. Unlike composite maternal morbidity indicators (such as life threatening "near-miss episodes" during childbirth) [5,7,8], our approach allows us to combine the power of two large stand-alone databases. The incidence of PPH-RBT is high enough (0.45–1.86%) [10–12] to serve as a marker of the quality of maternity care and low enough to allow a systematic review of medical records.

Our goal was twofold: (i) to assess red blood cell transfusion for postpartum hemorrhage (PPH) in an exhaustive electronic tool

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allowing perinatal networks to assess on a regular basis medical practices using PPH-RBT as the target event, and (ii) to assess time for transfusion and number of blood units administered within the 42 days following delivery in order to go into further clinical details of transfusion-based obstetrical assessment.

2. Materials and methods

For our study, PPH included early PPH (>500 ml for vaginal birth and >1 l for a cesarean section within 24 h after the birth of a baby) and secondary PPH (defined as abnormal or excessive bleeding from the birth canal between 24 h and 12 weeks postnatally). In order to conform with the definition of maternal mortality, however, we limited the time period to 42 days after delivery. Since we had the date but not the hour of birth, early PPH was defined not by the first 24 h but by considering the day and the day after delivery. According to Waterstone et al. [10], severe postpartum hemorrhage is defined as follows: estimated blood loss >1500 ml, peripartum fall in hemoglobin concentration ≥40 g/l or acute transfusion of 4 or more units of blood.

2.1. Study population

This study included all deliveries occurring in the Burgundy region of France between January 1st 2006 and December 31st 2007. It consisted of the cross-analysis of two prospective databases, the Burgundy Perinatal Network (BPN) database, which contains clinical data from hospital discharges, and the National Blood Centre (EFS) database, which contains information concerning any blood transfusion in France. The distribution of the study population is presented in Fig. 1.

2.2. Data collection and anonymization procedure

The BPN database included hospital discharge databases of the 18 public and private hospitals of the Burgundy region [13]. The BPN database combined information of both a condition, i.e. postpartum hemorrhage, and a procedure, i.e. transfusion.

The EFS is the only institution authorized to collect, store and deliver blood products. The EFS is committed to trace any single blood unit dispensed and transfused. It has a highly reliable and

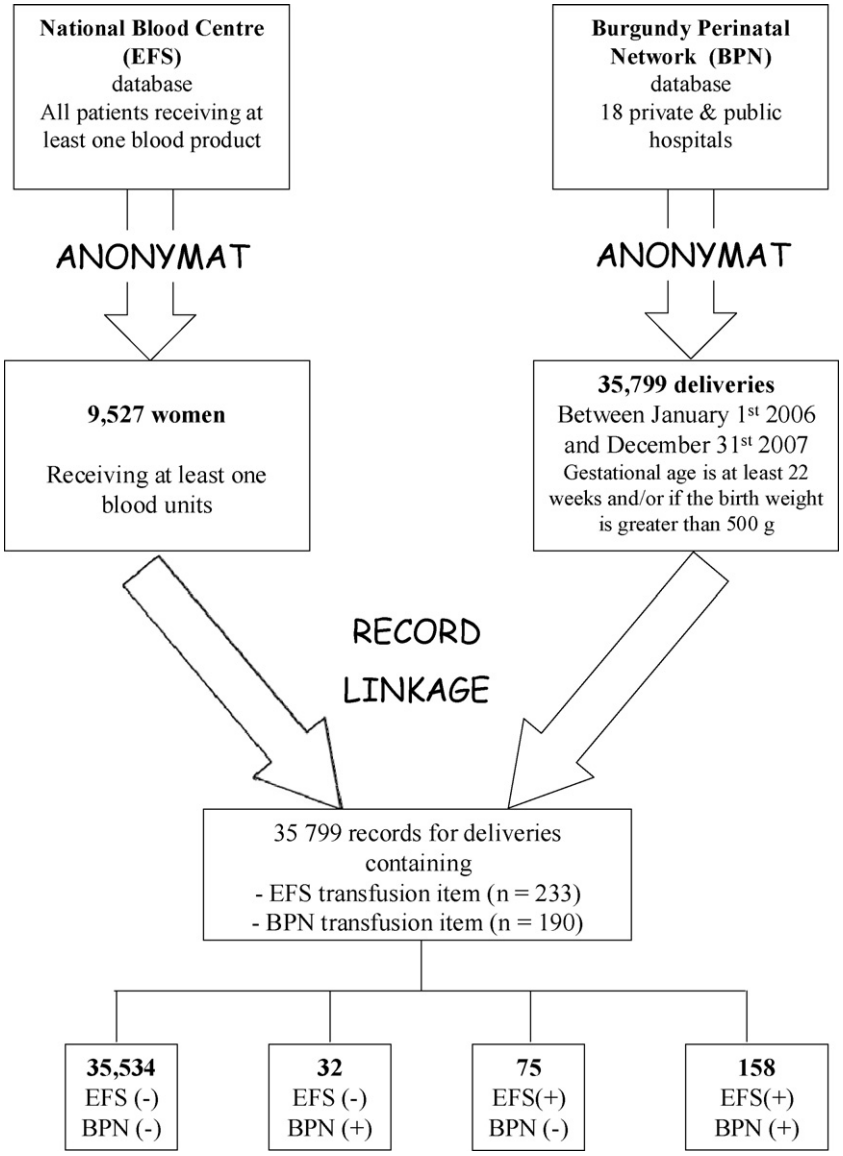

Fig. 1. Flow chart showing the study design. BPN+ and EFS+ mean electronic recording of transfusion in the Burgundy Perinatal Network and in the French Blood Centre databases, respectively. BPN− and EFS− mean the absence of such recording. EFS transfusion item (n = 233) corresponds to delivered women recorded in EFS database. BPN transfusion item (n = 190) corresponds to women recorded in BPN database independently of being transfused or not.

exhaustive database. Nevertheless, it does not record any clinical information, making the association between blood unit dispensing and a specific medical condition unfeasible. The EFS database contains two items of information: (i) amount and nature of blood products administered and (ii) hospital department in charge of the patient at the time of blood product dispensing. For the study purpose, the EFS data collection was restricted to women. These two databases were rendered anonymous using ANONYMAT software [14] before being sent from each hospital and from the EFS, as usually done for the annual assessment of our perinatal network's performance by the regional audit committee [14,15]. This software, based on the Standard Hash Algorithm, ensures the irreversible transformation of independent fields (including maiden names, first names and dates of birth) to obtain a strictly anonymous code, but always the same one for a given mother [14]. Linkage is carried out on files that are rendered anonymous and not directly on nominative data.

2.3. Data validation and file linkage

In order to validate cross-linked data provided by the BPN and the EFS databases from different hospital stays and delivery of blood units, an on-site medical record verification was performed for every discordant record between both databases. The codes we used for BPN were: code Z51.30 from the International Classification of Diseases (ICD-10) which corresponds to labile blood product transfusion and/or codes from the French classification of common medical acts (CCAM): FELF001, FELF004 and FELF011 for red blood cell units transfusion; FELF003 and FELF006 for labile blood products excluding red blood cell units. For EFS, specific codes corresponding to the same items were utilized.

This study was approved by the National Commission for Data Protection (CNIL #136 3158).

2.4. Analysis protocol

We used a two-step procedure. The first step consisted of assessing sensitivity and positive predictive value of the electronic recording for "red blood cell transfusion" in the BPN database for (i) every hospital stay including delivery and (ii) hospital stay including delivery and every other stay up to 42 days post-delivery either in obstetric departments (same or different establishment) or in the single intensive care unit (ICU) in Dijon teaching hospital of Burgundy after post-delivery transfer of the mother.

To better assess health care system organization, we took into account not only hospital stay including delivery (group A) but also group A plus ICU stay in the level III hospital after delivery (group B) and lastly, group B plus postpartum stay in obstetric departments with or without inter-hospital transfer (group C).

As a sensitivity analysis and in order to assess coding accuracy according to the level of hospital (levels I, II and III depending on pediatric and maternal care), a second set of analysis was restricted to the level III hospital, a teaching hospital which concentrated the most important part of PPH-RBT for the stays including delivery plus postpartum stays after transfer from a level I or II hospital (group D) and at last group D plus postpartum ICU stays (group E).

It might be argued that one red blood cell (RBC) unit transfusion might not reflect a true severe PPH and that coding accuracy in hospital discharge databases might be high enough in the most severe cases. Hence our second step consisted of studying two subgroups of women who experienced a more severe postpartum hemorrhage based on both the number of blood units (with a threshold value of 4 RBC units) and the timing for transfusion (within or after the first 24 h following delivery). The first subgroup restricted the analysis to early PPH. The second subgroup restricted the analysis to early and severe PPH based on both the number of blood units and the timing of transfusion.

2.5. Statistical analysis

Qualitative variables were expressed as percentages. A transfusion collected in the EFS database was considered as the gold standard. The sensitivity (Se), positive predictive value (PPV), and their confidence intervals at 95% (95%) were estimated. The agreement between the two methods of data collection was measured using the kappa coefficient. All hypotheses were tested bilaterally at the alpha level of 0.05. Analyses were performed using the SAS 9.1 software (SAS Institute Inc.). Concordance was considered to be excellent for kappa coefficients between 1 and 0.80, good between 0.80 and 0.60, moderate between 0.60 and 0.40 and poor for values below 0.40 [16].

3. Results

In Burgundy, during the study time period, 35,799 women delivered and 9736 women received a dispensed blood product (with 9527 being red blood cell units). Among the 35,799 delivering women, transfusion using either the BPN or the EFS databases was recorded in 265 cases. Two hundred and 33 women (233/265: 87.9% and 233/35,799: 0.65%) received at least one blood unit after delivery either during hospital stay for delivery or up to 42 days post-delivery whether they had been transferred from one hospital to the other or from any obstetric department to the ICU (Table 1).

Among these 233 cases, 158 (67.8%) were recorded in both BPN and EFS databases.

There were 31 transfusion cases (31/233: 13.3%) recorded in the BPN database but not retrieved from the EFS database. For one case, a failure of our anonymization procedure in relation with a very complex family name (i.e. one technical failure out of 35,799 deliveries and 9736 blood units dispensed) was noticed. The 30 remaining cases were due to miscoding of the discharge abstract in the BPN database (platelet or fresh-frozen plasma without red blood cell unit transfusion, 17 cases; fibrinogen and/or macromolecules and/or prostaglandin administration for bleeding without blood unit transfusion, 13 cases).

There were 75 transfusion cases (75/233: 32.2%) not recorded in the BPN database. Failure was due either to miscoding or to a transfusion being performed outside the obstetric department (during interventional radiology, during transfer or in the ICU) or in another hospital (new hospital stay without delivery).

Table 1
Electronic recording of transfusion, at least one blood unit, by the Burgundy Perinatal Network (B) and the French Blood Centre (F).

	B−/F−	B−/F+	B+/F−	B+/F+	Total	Sensitivity (95% CI)	PPV (95% CI)	Kappa	Total B+	Total F+
A	35,535	90	31	143	35,799	61.4% (55.1–67.6)	82.2% (76.5–87.9)	0.70 (0.65–0.75)	174	233
B	35,534	83	32	150	35,799	64.4% (58.2–70.5)	82.% (76.9–87.9)	0.72 (0.67–0.77)	182	233
C	35,534	75	32	158	35,799	67.8% (61.8–73.8)	83.2% (77.8–88.5)	74 (0.70–0.79)	190	233

B+ and F+ mean electronic recording of transfusion in the Burgundy Perinatal Network and in the French Blood Centre databases, respectively. B− and F− are for the absence of such recording. A = hospital stays including delivery. B = A + ICU stays in the level 3 hospital following delivery. C = B + post-partum stays (with or without inter-hospital transfer). PPV: predictive positive value. CI: confidence intervals.

Table 2
Electronic recording of transfusion, at least one blood unit, in the only level 3 hospital of the Burgundy Perinatal Network (B) and the French Blood institution (F).

	B−/F−	B−/F+	B+/F−	B+/F+	Total	Sensitivity (95% CI)	PPV (95% CI)	Kappa	Total B+	Total F+
D	4623	15	10	42	4690	73.7% (62.3–85.1)	80.8% (70.1–91.5)	0.77 (0.68–0.86)	52	57
E	4622	12	11	45	4690	78.9% (68.4–89.5)	80.4% (70.0–90.8)	0.79 (0.71–0.88)	56	57

B+ and F+ mean electronic recording of transfusion in the Burgundy Perinatal Network and in the National Blood Centre databases, respectively. B− and F− are for the absence of such recording. D = hospital stays including delivery + post-partum stays after transfer from another hospital. E = D + ICU stays. PPV: predictive positive value. CI: confidence intervals.

Table 3
Timing and severity of post partum hemorrhage (PPH). 233 women received at least one blood unit with or without platelet units and fresh frozen plasma.

		Day of PPH	
		Delivery day or day after	Following days until 42 days
Blood unit	Less than 4 units	116	35
	4 Units or more	75	7
	Number of deliveries	191	42

Manual review of medical charts in cases of discordant recording between both databases showed that sensitivity for blood unit transfusion was 100% in the EFS database and ranged from 61.4% (95%CI: 55.1–67.6%) to 67.8% (95%CI: 61.8–73.8%) in the BPN database with a positive predictive value of 82.2% (95%CI: 76.5–87.9%) to 83.2% (95%CI: 77.8–88.5%) according to the type of hospital stay considered (Table 1). Sensitivity and positive predictive value (PPV) of transfusion recording were found to be significantly better in the level III hospital. The sensitivity values were 73.7% (95%CI: 62.3–85.1%) and 78.9% (95%CI: 68.4–89.5%) for groups D and E, respectively, and the PPV were 80.8% (95%CI: 70.1–91.5%) and 80.4% (95%CI: 70.0–90.8%) for groups D and E, respectively (Table 2).

When the analysis was restricted to the most severe cases (4 units or more; 82/35,799: 0.23) (Table 3), we found that by restricting the analysis to either early PPH (191/233 cases, 81.9%) or early PPH requiring transfusion of at least 4 RBC units (75/233, 32.2%) sensitivity was only marginally improved: 70.2% (95%CI: 63.7–76.6%) and 74.7% (95%CI: 64.9–84.5%), respectively (Table 4).

Regarding transfusion in the following days until 42 days (Table 3), 34 out of 42 were transfused during the period of hospital stay following delivery, because they did not tolerate anemia that occurred subsequent to early PPH. Eight out of 42 required new hospitalization after their hospital discharge: seven out of 42 between day 10 and day 20 and only one between day 21 and day 42. For these 8 patients, sepsis and/or intra-uterine retention were the causes of bleeding.

4. Comment

The key finding of our study is that despite combining both diagnosis and procedure criteria, recording of PPH-RBT using the BPN hospital discharge summary database had a poor sensitivity under an acceptable threshold value of 80%. Only 61.4% (all hospital stays for delivery) to 78.9% (all hospital stays in the level III hospital including the ICU) of the cases were captured. On the contrary, linkage of the two large and stand-alone BPN and EFS databases, using ANONYMAT software, allowed an accurate electronic recording of all but one case of PPH-RBT.

Accuracy of the BPN recording was increased when patient history was considered not only during hospital stay for delivery but also included maternal transfers to the tertiary care center or to the intensive care unit or readmissions within 42 days after delivery (sensitivity: 61.4–67.8%). Sensitivity was increased when either early (70.2%) or early and severe (74.7%), i.e. requiring at least 4 blood units, PPH-RBT was considered.

As postpartum hemorrhage has been described to have increased by about 25% between 1994 and 2006 [17] and because pregnancy-related bleeding remains not only one of the leading causes of maternal death [1,18] but also one of the most preventable causes of death, it is of great value to establish an accurate electronic recording. One strength of our study is that our data are likely to reflect the true prevalence of PPH-RBT as our prevalence of PPH requiring at least one RBC transfusion was 0.65% and 0.23% for those requiring transfusion of at least 4 red blood cell units. This is in good agreement with the available literature where the prevalence of PPH-RBT ranges from 0.19% to 0.91% according to the number of blood units used to define it [9,10,19–21]. The only severe PPH we did not record were exceptional hysterectomy or arterial embolization procedures without transfusion.

Our data, like those published in the literature, indicated that using only the discharge database underestimated maternal morbidity. Zwart et al. described a 35% underreporting of major obstetric hemorrhage [12] and several other reports showed that sensitivity in routinely collected population health datasets is quite low, even for severe medical condition such as postpartum hysterectomy (∼25%) [5] and hypertension (∼64%) (22), and ranges from 25% to 100% for blood transfusions for postpartum hemorrhage [8,23]. Sensitivity for severe maternal morbidity through electronic datasets can be substantially improved when adding other items, either diagnostic or therapeutic, as has been suggested in previously published studies on severe maternal morbidity or "near-miss" [6,9,10,19–22,24–26]. Even in this case, however, sensitivity was reported to reach only 71% in the study published by Zwart et al. [20], suggesting that this method of combined outcomes might still be of poor efficacy for an appropriate assessment of health care networks.

We have confirmed the utility of the ANONYMAT software that makes identification anonymous and allows linking of different databases in an exhaustive way. Linkage of these two population-based databases using this software confers the advantage of adding complementary clinical data to a truly exhaustive recording of blood dispensation, as has been verified by manual review of

Table 4
Sensitivity for early PPH (occurring on the day of delivery or the day after) and early severe PPH (early PPH requiring transfusion of at least 4 RBC units).

	B−/F−	B−/F+	B+/F−	B+/F+	Total	Sensitivity (95% CI)	Total F+
Early PPH	35,552	57	56	134	35,799	70.2% (63.7–76.6)	191
Early and severe PPH	35,590	19	134	56	35,799	74.7% (64.9–84.5)	75

B+ and F+ mean electronic recording of transfusion in the Burgundy Perinatal Network and in the National Blood Centre databases, respectively. B− and F− are for the absence of such recording.

obstetric medical records throughout the Burgundy region. This indicator, PPH-RBT, should be reproducible across networks and all types of obstetric unit, providing that within the hospital discharge databases, the date of delivery and gestational age at delivery are known as is the case in France since 2010. Being able to accurately record the number of women receiving blood transfusion between 22 weeks of amenorrhea and 42 days post-delivery, with details on the timing, the number and the type of blood products administered allows a good evaluation of pregnancy-related bleeding including appropriateness of medical management and health care system organization. This sentinel event, PPH-RBT, should also improve recording of severe maternal complications or invasive procedures that have repeatedly been shown to be either underestimated or unknown by obstetricians (such as postpartum hysterectomy, artery embolization, ICU stay or death) [10].

Hence, using our approach, PPH-RBT appears to be a powerful marker of severe maternal morbidity that can be used as a simple and reliable sentinel event to assess quality of medical care and health-care system organization. Our model can be reproduced worldwide as many countries have: (i) hospital discharge summary databases and (ii) national or several regional blood center databases.

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