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Monitoring of postpartum haemorrhage through current information flows in Trentino Region, Italy

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ABSTRACT

Objective. Postpartum haemorrhage (PPH) is the leading cause of maternal mortality and severe morbidity worldwide. Primary postpartum haemorrhage for spontaneous deliveries is defined as the loss of more than 500 mL of blood within 24 hours of childbirth, whereas for caesarean deliveries, it is considered as loss of more than 1,000 mL of blood.

The objective is monitoring the risk of PPH in Trentino Region (North-East Italy).

Materials and Methods. The distribution of primary PPH was analysed for the two types of delivery in terms of maternity facility characteristics, mother's characteristics, labour and delivery characteristics. Event outcomes for the mother were also analysed (hospitalization, hysterectomy, blood product transfusions and fatality).

Results. In the 2011-2016 period, there were 27,460 deliveries in the maternity facilities of Trentino region with an average overall prevalence of primary PPH of approximately 15%. The multivariate logistic regression analysis identified the significant independent predictors of primary PPH were age and nationality of the mother, parity, gestational age, medically assisted procreation, multiple births, neonatal weight, pregestational Body Mass Index, type of labour, maternal health concerns during pregnancy and tears and/or episiotomy.

Conclusions. A PPH monitoring system using integrated current information flows could help the local health service and sector professionals to keep the phenomenon under control and monitor the quality of clinical practice.

INTRODUCTION

Postpartum haemorrhage (PPH) is the leading cause of maternal mortality and severe morbidity worldwide. The condition is thought to be responsible for approximately a quarter of deaths that occur during pregnancy, childbirth or the puerperal period [1]. It is estimated that it affects 26 in every 100 women who give birth in Africa and 13 in every 100 in Europe and North America [2].

Several studies have reported, over the past two decades, an increase in the incidence of PPH in

industrialised countries, associated not only with the greater attention dedicated to the issue or improvements in data acquisition, but also with the changes in the characteristics of the mothers and of birth practices, in particular a more extensive use of Caesarean sections and induced labour [3-8].

Many studies have furthermore suggested that the majority of deaths associated with PPH could have been avoided by earlier and more appropriate diagnosis and treatment [9-13].

This has been confirmed also in Italy, on the basis of the confidential investigations performed

as part of the maternal death surveillance system headed by the Italian Institute of Health in partnership with some regional authorities. This experience demonstrated that, between 2013 and 2015 more than half of all cases of maternal death due to PPH were associated with sub-standard care [14]. Given the frequency of the phenomenon and its potential implications on female health, a systematic surveillance of PPH through current information flows could be recommended. This could also facilitate, at a local level, the implementation of specific confidential investigations with potential positive returns in terms, for example, of greater awareness amongst healthcare professionals, of an increase in evidence-based operational practices and, above all, of the capacity for various services to interact and communicate all aspects with a non-negligible impact on birth outcomes [14].

On the other hand, it should be noted that the registration of the PPH is not provided by the ministerial model of the Birth Assistance Certificate (CedAP), which pursuant to Ministerial Decree no. 349 of July 16, 2001, represents the primary and mandatory tool for monitoring the birth event [15]. Unlike what happens in all other Italian regions, the occurrence of PPH is recorded in the CedAP used in the province of Trento (north-east Italy). The data on the prevalence of PPH, overall and by single maternity unit, have been disseminated since 2011, through the annual birth report, by the Clinical and Evaluational Epidemiology Service of the Provincial Health Authority of Trento (APSS). This observational study retrospectively analyzes, on the basis of what has been recorded by the provincial model of the CedAP, the trend of PPH in the births that took place in the maternity units of the province of Trento between 2011 and 2016. Maternal and obstetric factors associated with the occurrence of PPH are also analyzed.

On 31 December 2016, six maternity units were active in the province of Trento, two hubs (Trento and Rovereto) and four spokes. Among these, the maternity unit of Trento registers 2,400 births per year, Rovereto 1,200 births per year.

MATERIALS AND METHODS

Information regarding the occurrence and entity of blood loss is recorded in the "placenta removal" section of the CedAP used in the province of Trento. The accuracy and reproducibility of blood loss measure-

ments is defined, together with all the criteria for the management of the event, in the Guidelines issued by the Provincial Health Authority's Mother & Child Department in 2010 and reviewed in 2013 [16]. More specifically, blood loss estimates are based on the use of transparent graduated collection bags, combined with an assessment of the clinical signs (palpitations, dizziness, asthenia, palpitations, confusion, hunger, air, syncope) and symptoms of hypovolemia (hypotension, tachycardia, oliguria, O₂ saturation < 95%) and the degree of shock [17]. According to the APSS protocol, the prevention of PPH is based on the identification, in the different stages of pregnancy, of pregnant women at risk, on the active management of the III stage of labour, through the Brandt Andrews maneuver and prophylaxis with uterotonic drugs and in caesarean section with the use of intravenous oxytocin after extraction of the fetus. The shock index and blood parameters are taken into account for defining the need for transfusion. In particular transfusion of concentrated red blood cells is expected if Hb < 6 g / dL (≤ 9 g/dL in the third trimester), if the estimated blood loss is > 1500 cc and the underlying cause has not yet resolved, if the patient is tachycardic. Plasma transfusion is expected if INR / PT > 1.5; platelet transfusion is expected if platelets are < 50,000 with bleeding or if < 20,000 without bleeding. Cryoprecipitate transfusion is expected if fibrinogen < 75-100 mg/dl- The Bakri Balloon can be used in case of refractory bleeding to medical treatments and other conservative treatments, both after vaginal birth and after caesarean section. The transfer of the patient from the spokes centers to the hubs centers will take place when the patient is hemodynamically stable, assisted by helicopter rescue. The annual provincial data of the CedAP, have been recorded on electronic media by midwives at each maternity unit. The database of the CedAP was used to calculate, for the 2011-2016 period, the blood loss associated with spontaneous vaginal deliveries and Caesarean deliveries for all the province's maternity facilities. This produced an estimate of primary postpartum haemorrhage for spontaneous deliveries and C-sections, taking into account that primary postpartum haemorrhage for vaginal deliveries is defined as the loss of more than 500 mL of blood within 24 hours of childbirth, whereas for Caesarean deliveries, it is considered as loss of more than 1,000 mL of blood, as indicated by Mousa and Alfirevic [18]. The conventional definition of PPH, based on estimated blood loss contemplates two degrees (minor and major) according to the entity of the blood loss: a) minor PPH when blood loss is

between 500 and 1000 mL and; b) major PPH when > 1000 mL of blood is lost. Major haemorrhage can in turn be classified as moderate (1000-2000 mL) or severe (more than 2000 mL) [19].

The distribution of primary postpartum haemorrhage was analysed for the two types of delivery in terms of the following variables: maternity facility characteristics (maternity unit registering 1,000 births or more per year *vs* < 1,000 births), mother's characteristics (age, nationality, qualification, pregestational Body Mass Index [BMI], parity, medically assisted procreation [MAP] and maternal health concerns), labour characteristics (spontaneous/induced) and delivery characteristics (multiple/singleton births, gestational age, presentation of the newborn, neonatal weight, perineum, episiotomy and vaginal tears). The associations were analysed in an initial phase according to a bivariate model, using the Chi-squared test and Fisher's exact test (significant with p -value ≤ 0.05). Subsequently, two multiple logistic regression analyses were performed, using primary PPH as the dependent variable, for spontaneous deliveries alone and Caesarean sections alone, respectively. The predictors analysed were the previously mentioned characteristics of the mother, labour and delivery, adjusted by the year of birth, maternity facility (< 1000 *vs* ≥ 1000 births per year) and number of births (singleton *vs* multiple births). The mother's pregestational BMI (expressed in kg/m²) was broken down into four classes: underweight for values under 18.50, normal weight for values in the range 18.50-24.99, overweight between 25.00 and 29.99 and obesity for values of 30.00 and over.

The risk associated with the presence of maternal health concerns was also considered using the information on the pregnancy acquired with the CedAP: no risk was attributed if the pregnancy was physiological, a mild risk was attributed if the woman had only one health concern (of every kind, pre-existing or occurring in the index pregnancy), a moderate risk with two comorbidities, and a high risk with three or more comorbidities.

Event outcomes for the mother were also analysed by performing a record linkage between the CedAP database and the hospital discharge record database, using the year of birth and tax code (where available) as the linkage key; the few cases of women who gave birth to two or more babies the same year were managed independently. The type of intervention, Intensive Care Unit (ICU) admission, duration of hospitalisation and type of discharge were subsequently analysed. The details of the major events (hysterec-

tomy) were analysed using the hospital information system, which is an electronic repository collecting the analytical data of all user contacts with the provincial health services. The occurrence of long-term major consequences for the mother (death of the mother) was evaluated by analysing live status one year after the PPH event, by consulting the health registry.

RESULTS

In the 2011-2016 period, there were 27,460 deliveries in the maternity facilities of the province of Trento, for a total of 27,963 births (27,886 live and 77 still births). Between 2011 and 2016, there was a 14% decrease in the number of deliveries and births, equal to - 2.4%/year with a parallel reduction in the number of maternity facilities in the province from 7 to 5 by the end of 2016. On average, 24.6% of deliveries were Caesarean sections, with a decreasing trend between 2011 (25.6%) and 2016 (20.6%). On average, 74.1% of Caesarean sections were elective and the remainder were performed in urgency/emergency. The average proportion of operative vaginal deliveries was 5.4%. The data on blood loss in the puerperium has been reported in the CedAP database in 98.3% of cases. The highest proportion of missing values is recorded for elective C-sections (6.1%), followed by the 4.5% for C-sections during labour, while the lowest proportion is for spontaneous deliveries (0.4%). The two hub hospitals showed the lowest proportion of missing values (0.9%), while the spokes 3.6%.

The blood loss breakdown (by quantity), per type of delivery and per year is provided in figure 1 (for spontaneous deliveries) and in figure 2 (for Caesarean sections). Mean blood loss was 289 mL (SD = 283 mL) for spontaneous vaginal deliveries and 408 mL (SD = 267 mL) for Caesarean deliveries. There were no statistically significant differences in the blood loss class breakdown between one year and another for both delivery types. The proportion of blood loss greater than 1000 mL remains below 3% in each year and for each type of birth. This proportion respects the standard agreed between maternity units and APSS.

The time trend for the prevalence of PPH for spontaneous and Caesarean deliveries is described in **Figure 3**. The average overall prevalence is approximately 10% and appears to be more or less stable over the study period, decreasing slightly for spontaneous deliveries and increasing slightly for Caesarean deliveries.

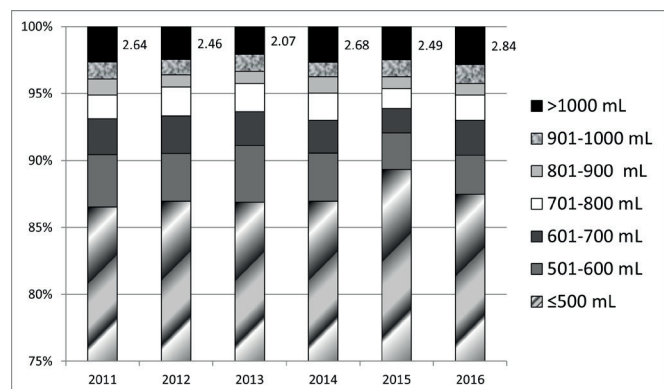


Figure 1. Province of Trento. Blood loss for spontaneous deliveries. Percentage weight of blood loss classes, per single year. Period: 2011-2016.

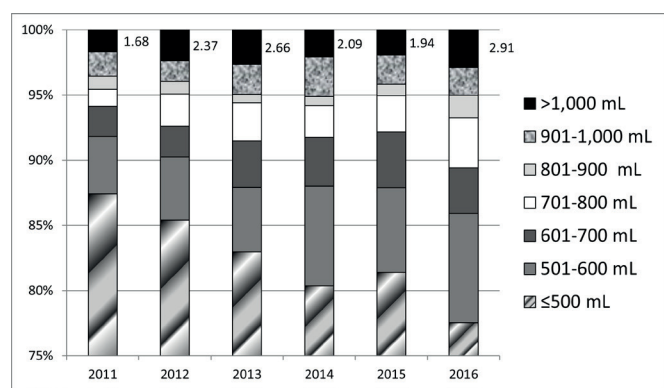


Figure 2. Province of Trento. Blood loss for Caesarean deliveries. Percentage weight of blood loss classes, per single year. Period: 2011-2016.

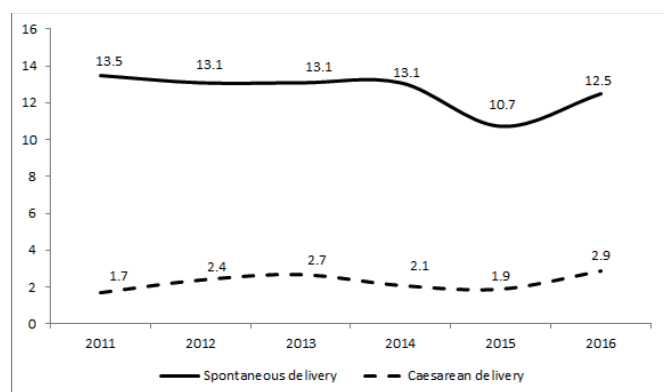


Figure 3. Province of Trento. Prevalence of primary postpartum haemorrhage, for spontaneous and Caesarean deliveries, per single year. Period: 2011-2016.

Table 1 A, B shows the data acquired by analysing the characteristics of the mother, labour and delivery in association with the occurrence of primary PPH, separately for spontaneous and caesarean deliveries. For spontaneous vaginal deliveries (Table 1 A), primary PPH was significantly associated with:

- parity: 14.8% amongst nulliparous mothers vs 10.7% amongst pluriparous mothers;
- gestational age: 12.8% amongst full-term deliveries vs 7.8% amongst pre-term deliveries;

- medically assisted procreation: a MAP showed a risk of PPH of 23.9%, compared to 12.4% of no MAP;
- neonatal weight: an increasing probability of PPH as the weight class of the infant increases, reaching the 26.8% for babies with a weight $\geq 4,000$ g;
- pregestational BMI: increase in primary PPH with an increase in BMI, with a PPH prevalence of 16.2% in obese women;
- multiple birth: with a proportion more than double in twin pregnancies;
- type of labour: 15.6% for induced labour vs 11.9% for spontaneous labour;
- maternal health concerns during pregnancy: as the risk of pregnancy complications increases, the proportion of PPH increases, from 12.1% for no risk to 21.9% for high risk (three or more comorbidities);
- tears and/or episiotomy: an intact perineum implied a 7.2% of risk in PPH, compared with a 20.7% for only episiotomy, an overall 30% in case of episiotomy and vaginal tears, 10.0% in case of only 1st degree tear, 16.7% in case of only 2nd degree tear and 30.2% in case of only 3rd degree tear.

As regards the mother’s characteristics, an increase in risk was observed with an increase in academic qualifications: 8.6% for mothers with a primary school diploma vs 13.6% for mothers with a university degree. As far as Caesarean deliveries are concerned (Table 1 B), statistically significant differences were observed in the proportion of primary PPH when the sample was stratified by the age of the mother (2.6% for mothers aged 35 and over vs 1.8% for mothers under 35), gestational age (4.9% for preterm births vs 1.7% in full-term births), type of Caesarean delivery (2.4% for elective caesareans vs 1.3% for those performed in labour), maternal health concerns during pregnancy, medically assisted procreation, multiple births and birth weight. An increased proportion of PPH was also observed amongst women of African, Asian or South American origin.

The multivariate logistic regression analysis (Table 2) identified the following variables as significant independent predictors of primary PPH in vaginal delivery: parity, with a higher risk in nulliparous, pregestational BMI, with a higher risk in obese, medically assisted procreation, neonatal weight $\geq 4,000$ g, induced or expedited labour, episiotomy and/or tearing, the maternal health concerns, multiple birth. More specifically, the probability of primary PPH adjusted for the other variables includ-

Table 1. (A) Distribution of frequencies (observed and percentages) of primary PPH in association with the characteristics of the mother, labour and delivery, for spontaneous deliveries. Associations analysed using the Chi-squared test. (B) Distribution of frequencies (observed and percentages) of primary PPH in association with the characteristics of the mother, labour and delivery for Caesarean deliveries. Associations analysed using the Chi-squared test.

Variable	Category	Spontaneous deliveries		
		Yes primary EPP	Total	P-value
Type of maternity unit	Hub (\geq 1,000 births per year)	1,752 (12.3%)	14,201	0.081
	Spoke ($<$ 1,000 births per year)	862 (13.2%)	6,529	
Parity	Nulliparous	1,427 (14.8%)	9,669	$<$ 0.0001
	Pluriparous	1,187 (10.7%)	11,061	
Age of the mother	15-34 years	1,856 (12.7%)	14,631	0.640
	\geq 35 years	758 (12.5%)	6,089	
Nationality of the mother	Italian	1,932 (12.6%)	15,331	0.831
	African	141 (12.1%)	1,168	
	Asian	95 (13.7%)	695	
	Eastern European	389 (12.6%)	3,093	
	Western European	13 (10.0%)	130	
	South-American	43 (14.5%)	296	
	North-American	1 (14.3%)	7	
Mother's qualification	Master's degree or higher	669 (13.6%)	4,914	0.016
	Short degree	223 (11.9%)	1,867	
	High school diploma	1,321 (12.5%)	10,595	
	Secondary school diploma	361 (12.5%)	2,880	
	Primary school diploma or lower	40 (8.6%)	464	
Pregestational BMI of the mother	Underweight	244 (11.3%)	2,152	$<$ 0.0001
	Normal weight	1,790 (12.3%)	14,576	
	Overweight	419 (14.1%)	2,980	
	Obese	153 (16.2%)	942	
Medically assisted procreation	Yes	93 (23.9%)	389	$<$ 0.0001
	No	2,521 (12.4%)	20,341	
Gestational age	$<$ 37 weeks	61 (7.8%)	780	$<$ 0.0001
	\geq 37 weeks	2,553 (12.8%)	19,950	
Multiple births	Yes	18 (30.5%)	59	$<$ 0.0001
	No	2,596 (12.6%)	20,671	
Type of labour	Spontaneous	1,965 (11.9%)	16,569	$<$ 0.0001
	Induced	649 (15.6%)	4,160	
Presentation of the newborn	Vertex	2,608 (12.6%)	20,673	0.635
	Other	6 (10.5%)	57	
Neonatal weight	$<$ 1,500 g	3 (5.9%)	51	$<$ 0.0001
	1,500-2,499 g	43 (6.3%)	683	
	2,500-3,999 g	2,238 (11.9%)	18,766	
	\geq 4,000 g	330 (26.8%)	1,230	
Perineum – Episiotomy – Vaginal tears	Intact perineum	442 (7.2%)	6,169	$<$ 0.0001
	Only episiotomy	431 (20.7%)	2,080	
	Episiotomy and 1 st degree tear	33 (28.2%)	117	
	Episiotomy and 2 nd degree tear	78 (31.1%)	251	
	Episiotomy and 3 rd degree tear	20 (32.3%)	62	
	Only 1 st degree tear	609 (10.0%)	6,123	
	Only 2 nd degree tear	950 (16.7%)	5,707	
	Only 3 rd degree tear	42 (30.2%)	139	
Risk associated with the presence of maternal health concerns	No risk	2,009 (12.1%)	16,620	$<$ 0.0001
	Mild risk	488 (14.4%)	3,388	
	Moderate risk	94 (15.2%)	617	
	High risk	23 (21.9%)	105	





(B)

Variable	Category	Caesarean deliveries		P-value
		Yes primary EPP	Total	
Type of maternity unit	Hub (≥ 1,000 births per year)	114 (2.4%)	4,676	0.007
	Spoke (<1,000 births per year)	29 (1.4%)	2,054	
Parity	Nulliparous	63 (2.0%)	3,224	0.352
	Pluriparous	80 (2.3%)	3,506	
Age of the mother	15-34 years	70 (1.8%)	3,929	0.021
	≥ 35 years	73 (2.6%)	2,799	
Nationality of the mother	Italian	97 (1.9%)	5,041	0.009
	African	18 (4.0%)	451	
	Asian	9 (4.1%)	222	
	Eastern European	12 (1.5%)	823	
	Western European	1 (2.3%)	44	
	South-American	6 (4.1%)	146	
	North-American	0 (0.0%)	1	
Mother's qualification	Master's degree or higher	35 (2.2%)	1,606	0.300
	Short degree	12 (2.5%)	476	
	High school diploma	65 (1.9%)	3,438	
	Secondary school diploma	24 (2.3%)	1,041	
	Primary school diploma or lower	7 (4.2%)	167	
Pregestational BMI of the mother	Underweight	6 (1.2%)	518	0.074
	Normal weight	87 (2.0%)	4,379	
	Overweight	35 (3.0%)	1,175	
	Obese	14 (2.3%)	607	
Medically assisted procreation	Yes	25 (6.0%)	418	< 0.0001
	No	118 (1.9%)	6,312	
Gestational age	< 37 weeks	48 (4.9%)	989	< 0.0001
	≥ 37 weeks	95 (1.7%)	5,741	
Type of Caesarean delivery	During labour	22 (1.3%)	1,721	0.0048
	Elective	121 (2.4%)	5,009	
Multiple births	Yes	36 (8.4%)	431	< 0.0001
	No	107 (1.7%)	6,299	
Type of labour	Spontaneous	15 (1.2%)	1,255	0.625
	Induced	14 (1.4%)	978	
Presentation of the newborn	Vertex	116 (2.1%)	5,533	0.729
	Other	27 (2.3%)	1,197	
Neonatal weight	< 1,500 g	8 (4.0%)	202	0.003
	1,500-2,499 g	27 (3.6%)	758	
	2,500-3,999 g	98 (1.8%)	5,405	
	≥ 4,000 g	10 (2.7%)	365	
Risk associated with the presence of maternal health concerns	No risk	71 (1.6%)	4,440	< 0.001
	Mild risk	53 (3.3%)	1,607	
	Moderate risk	15 (3.0%)	501	
	High risk	4 (2.2%)	182	

ed in the model was 18.5% higher for nulliparous women, 18.1% and 32.4% higher for mothers who were overweight and obese before the pregnancy, respectively, 93.1% higher in case of MAP, 3.5 times higher when the newborn has a weight ≥ 4,000 g

and 22.1% higher when labour was induced. The presence of both episiotomy and tearing (*vs* intact perineum) showed that the risk of PPH was almost 5 times greater for 1st degree tears, 5.2 times greater for 2nd degree tears and 4.7 times higher for 3rd de-

Table 2. Results of the multiple logistic regression analysis for spontaneous deliveries only evaluating the probability (OR) of primary PPH in relation to the characteristics of the mother, labour and delivery.

Variable	Category	OR*	Wald 95% C.I.		P-value
			Lower	Higher	
Type of maternity unit	Spoke (< 1,000 births per year)	1.000	-	-	0.268
	Hub (≥ 1,000 births per year)	0.946	0.857	1.044	
Parity	Pluriparous	1.000	-	-	0.0005
	Nulliparous	1.185	1.077	1.304	
Age of the mother	15-34 years	1.000	-	-	0.894
	≥ 35 years	1.007	0.911	1.112	
Mother's qualification	Primary school diploma or lower	1.000	-	-	0.162
	Secondary school diploma	1.360	0.958	1.931	
	High school diploma	1.287	0.885	1.872	
	Degree or higher	1.430	1.001	2.046	
Nationality of the mother	Italian	1.000	-	-	0.606
	African	0.995	0.816	1.214	
	Asian	1.128	0.891	1.429	
	Eastern European	1.044	0.922	1.183	
	Western European	0.708	0.393	1.277	
	South-American	1.270	0.907	1.779	
Pregestational BMI of the mother	Underweight	1.000	-	-	0.019
	Normal weight	1.041	0.900	1.205	
	Overweight	1.181	1.002	1.408	
	Obese	1.324	1.051	1.669	
Medically assisted procreation	No	1.000	-	-	< 0.0001
	Yes	1.931	1.500	2.485	
Gestational age	≥ 37 weeks	1.000	-	-	0.242
	< 37 weeks	0.837	0.621	1.127	
Type of labour	Spontaneous	1.000	-	-	0.0001
	Induced	1.221	1.103	1.352	
Presentation of the newborn	Other	1.000	-	-	0.628
	Vertex	1.245	0.514	3.016	
Neonatal weight	< 1,500 g	1.000	-	-	< 0.0001
	1,500-2,499 g	0.628	0.176	2.233	
	2,500-3,999 g	1.278	0.365	4.478	
	≥ 4,000 g	3.458	1.018	12.224	
Perineum – Episiotomy – Vaginal tears	Intact perineum	1.000	-	-	< 0.0001
	Only episiotomy	2.903	2.486	3.389	
	Episiotomy and 1 st degree tear	4.885	3.197	7.466	
	Episiotomy and 2 nd degree tear	5.186	3.867	6.955	
	Episiotomy and 3 rd degree tear	4.723	2.700	8.262	
	Only 1 st degree tear	1.363	1.196	1.552	
	Only 2 nd degree tear	2.337	2.065	2.645	
Risk associated with the presence of maternal health concerns	Only 3 rd degree tear	4.981	3.385	7.330	
	No risk	1.000	-	-	0.001
	Mild risk	1.211	1.079	1.359	
	Moderate risk	1.213	0.957	1.537	
High risk	1.798	1.091	2.961		
Multiple births	No	1.000	-	-	< 0.0001
	Yes	3.949	2.077	7.509	

*OR also adjusted by the year of birth.

gree tears. First-degree tearing alone was associated with a 1.4 times higher risk of primary PPH; 2nd degree tearing alone with a 2.3 times greater risk

and more severe (3rd degree) tears with a 5 times greater risk. Lastly, episiotomy alone was associated with a 2.9 times greater risk of primary PPH than

Table 3. Results of the multiple logistic regression analysis for Caesarean deliveries only evaluating the probability (OR) of primary PPH in relation to the characteristics of the mother, labour and delivery.

Variable	Category	OR*	Wald 95% C.I.		P-value
			Lower	Higher	
Type of maternity unit	Spoke (< 1,000 births per year)	1.000	-	-	0.880
	Hub (≥ 1,000 births per year)	1.037	0.645	1.669	
Parity	Pluriparous	1.000	-	-	0.970
	Nulliparous	1.007	0.694	1.462	
Age of the mother	15-34 years	1.000	-	-	0.082
	≥ 35 years	1.378	0.960	1.978	
Mother's qualification	Degree or higher	1.000	-	-	0.853
	High school diploma	0.910	0.590	1.401	
	Secondary school diploma	1.015	0.573	1.796	
	Primary school diploma or lower	1.315	0.529	3.264	
Nationality of the mother	Italian	1.000	-	-	0.046
	African	1.879	1.054	3.351	
	Asian	2.220	1.051	4.689	
	Eastern European	0.797	0.426	1.489	
	Western European	1.337	0.178	10.055	
	South-American	2.356	0.993	5.588	
Pregestational BMI of the mother	Underweight	1.000	-	-	0.298
	Normal weight	1.782	0.766	4.145	
	Overweight	2.307	0.942	5.651	
	Obese	1.936	0.715	5.243	
Medically assisted procreation	No	1.000	-	-	0.188
	Yes	1.471	0.828	2.615	
Gestational age	≥ 37 weeks	1.000	-	-	0.0007
	< 37 weeks	2.486	1.468	4.208	
Type of Caesarean delivery	During labour	1.000	-	-	0.089
	Elective	1.529	0.938	2.492	
Presentation of the newborn	Other	1.000	-	-	0.918
	Vertex	1.024	0.657	1.596	
Neonatal weight	< 1,500 g	1.000	-	-	0.058
	1,500-2,499 g	1.067	0.461	2.467	
	2,500-3,999 g	1.836	0.758	4.446	
	≥ 4,000 g	3.484	1.157	10.492	
Risk associated with the presence of maternal health concerns	No risk	1.000	-	-	0.078
	Mild risk	1.639	1.102	2.437	
	Moderate risk	1.275	0.691	2.352	
	High risk	0.805	0.277	2.336	
Multiple births	No	1.000	-	-	< 0.0001
	Yes	2.969	1.797	4.905	

*OR also adjusted by the year of birth.

an intact perineal status. The presence of maternal health concerns showed an increase in the risk of primary PPH ranging from 21.1% in the presence of a single health concern to 79.8% in the presence of 3 or more comorbidities. Multiple births were associated with a 4 times greater risk of primary PPH than singleton births. Finally, there seems to be an upward trend in risk of primary PPH through educational attainment, but this is not statistically significant in the multivariate analysis.

The multivariate logistic regression analysis (Table 3) identified the following variables as significant independent predictors of primary PPH in caesarean delivery: a gestational age of less than 37 weeks, the presence of maternal health concerns, a neonatal weight ≥ 4,000 g, multiple births and a foreign origin, especially for women from African and Asian countries. In the univariate analysis a statistically significant difference emerged in relation to the characteristics of the maternity units, with an

excess of primary PPH in the hubs compared to the spokes, but it was not confirmed in the multivariate analysis, adjusting for the other covariates.

The record linkage between the CedAP database and the birth discharge record database needed to analyse the outcomes resulted in a 94% match.

Outcomes of mothers with PPH after a caesarean delivery

Amongst the hospitalisations of mothers with PPH following a Caesarean delivery there were 3 cases of abdominal hysterectomy (2 pluriparous women and one nulliparous woman who had twins; one case recorded in 2011, one in 2013 and one in 2016). In two cases, abdominal hysterectomy had to be performed due to uterine atony with massive haemorrhage that could not be controlled by medical therapy and a uterine tamponade procedure; in the third case, it has due to a massive haemorrhage after premature rupture of membranes (PROM) with loss of consciousness during labour. Uterine/vaginal tear repair surgery was performed in 8 cases (equal to 5.6% of the sample of women with PPH following Caesarean delivery); repair surgery was performed for tearing of the perineum/other pelvic organs in 1 case (0.7% of the sample); and whole blood or blood product transfusions were performed in 18 cases (12.6% of the sample). There were 3 ICU admissions (2.1% of the sample); the average duration of hospitalisation was 4.9 days (SD = 2.3), which was significantly longer than the duration of hospitalisation for Caesarean deliveries without PPH of 3.9 days (SD = 1.4); no fatalities were recorded and 96.8% of the women were discharged to their home.

Outcomes of mothers with PPH after a vaginal delivery

Amongst the hospitalisations of mothers with PPH following a vaginal delivery there were 2 cases of abdominal hysterectomy (both pluriparous women who gave birth in 2014). Hysterectomy had to be performed due to placenta accreta after manual placenta removal followed by massive haemorrhage that did not respond to medical treatment. Uterine, vaginal or vulval tear repair surgery was performed in 1,137 cases (equal to 43.5% of the sample of women with PPH after spontaneous vaginal delivery); repair surgery was performed for tearing of the perineum/other pelvic organs in 540 cases (20.7% of the sample); an episiotomy was performed and

a vacuum was used for delivery in 314 cases (12.0% of cases); and whole blood or blood products were transfused in 93 cases (3.6% of the sample).

There were 3 ICU admissions (0.1%). Hospitalisation lasted an average of 3.3 days (SD = 1.1), compared to a duration of hospitalisation for spontaneous delivery without PPH of 3.0 days (SD = 1.1). The overall hysterectomy rate was 0.18/1000 births, of which 0.10 per 1000 spontaneous deliveries and 0.47 per 1000 Caesarean sections. No fatalities were recorded for the sample observed and 97.7% of the women were discharged to their home.

DISCUSSION

A certain degree of blood loss is a normal consequence of a vaginal or Caesarean delivery and this bleeding is usually reduced by a contraction of the myometrium and the activation of haemostatic factors in the decidua. Defects in these mechanisms, associated with systemic or local predisposing conditions or with reproductive tract tears induced by the delivery and/or birth procedures, can lead to heavy bleeding that can be difficult to control with conservative intervention alone [20-22]. Prevention, early identification of the risk factors, early and timely diagnosis and appropriate treatment are the most efficacious ways to minimise the clinical implications of postpartum haemorrhage, especially primary postpartum haemorrhage (PPH) occurring within 24 hours after delivery. The implementation of validated guidelines on the prevention and management of this problem safeguards the medical team and provides a guarantee for patients [14, 23]. The prediction and assessment of blood loss remain key for a prompt, effective management. The impact of the operational procedures relating to the management of PPH in the maternity units of the province of Trento can be assessed through the use of current information flows. The same medical and obstetric staff of the maternity units believed that the CedAP in use in the province of Trento could be the basic tool for recording the occurrence of PPH. The registration and quantification of PPH was also necessary for monitoring the specific activity indicators set by the APSS Directorate General for the maternity units: proportion of PPH/1000 birth, proportion of PPH > 1000 mL/1000 birth. The completeness of registration of the PPH in the maternity units of the province of Trento appears very good consid-

ering that the missing values are equal to 1.7% of the cases with higher values in case of caesarean section and in deliveries at the spokes centres. The blood loss classes show a proportional weight that does not substantially vary from one year to the next and in relation to the type of birth. The class of blood loss above 1000 mL remains in each year considered below 3% of the total, which represents the quality standard that the same maternity units have set themselves. This standard does not appear to be influenced by the concentration of provincial birth points during the period under study. Our study reports an average prevalence of PPH in all deliveries equal to 10%, 12.6% in vaginal deliveries and 2.3% in caesarean deliveries.

On the whole, the temporal trend of PPH in province of Trento appears to be quite stable and consistent with that reported in the literature [4-8]. The risk factors involved, which cannot always be identified, can be classified as maternal/antenatal factors or birth-related factors [24]. The risk factors analysed in this study are those that can be identified using the information provided in the CedAP used in the province of Trento. Specific risk factors, related to the placenta, such as placental abnormalities or placental abruption or to labour, such as lack of progression to stage II of labour or to a previous pregnancy with PPH are not recorded in the CedAP. This can be a limitation of the study. In any case, this kind of information is in the specific availability of each individual maternity units.

The risk factors for PPH associated with spontaneous delivery and identified by multiple analysis are consistent with those previously reported in the literature [5-8, 24, 25]. The maternal factors have a preponderant weight; this is the case for nulliparity, high BMI, medically assisted procreation, multiple deliveries and number of maternal comorbidities. Of these, it should be noted that 0.7% of the sample had preeclampsia/eclampsia, 0.2% pregestational diabetes, and a further 4.7% gestational diabetes. The birth-related factors also retain their importance and among these a significant weight must be attributed to fetal macrosomia, episiotomy and perineal tears. The level of education would appear to have an independent weight in the case of PPH associated with spontaneous deliveries, where the risk increases with the level of education. This association, rarely reported in previous studies, could be completely random, and perhaps also linked to a possible data recording error in the CedAP, considering that the

available evidence indicates a relationship more with a low than a high educational qualification [24, 25]. The only potentially controllable pre-natal factor is maternal BMI which can directly or indirectly affect the risk of PPH [26].

The risk factors for PPH associated with Caesarean deliveries are also consistent with the findings reported in the literature [5-8, 24, 25] and are mainly associated with maternal or antenatal conditions, such as a gestational age of less than 37 weeks, the number of births and the presence of maternal health concerns. Of these, preeclampsia/eclampsia (mild or severe) accounts for 4.9% of the sample, and insulin-dependent pregestational diabetes 2.8% of cases, in addition to 7.7% of women with gestational diabetes. Regarding maternal comorbidities, the risk trend appears to be positive for the mild and moderate risk categories, which show an OR of 1.63 and 1.27, respectively, compared to the high risk category, which shows a not statistically significant OR of 0.8. This apparent discrepancy could be explained by two possible factors: an extremely low number of women classified as high risk category who have undergone caesarean section and by possible completeness problems in registering the mothers' comorbidities. The nationality factor takes on an independent weight in the forms of PPH associated with Caesarean delivery and is significant amongst mothers from African and Asian countries, as reported by previous studies [5-8].

The recognition of the presence of specific antenatal risk factors, *i.e.* those related to the characteristics of the woman or the pregnancy, could be of use in the preventative choice of the most suitable or best-equipped maternity facility, within the context of a network cooperation [23, 25]. The management of postpartum haemorrhage requires a multidisciplinary approach to restore the haemodynamic conditions of the woman and, at the same time, identify and treat the causes of the bleeding [27, 28]. The availability of a specific guideline to which all the operators involved can refer also helps to contain the frequency of possible serious events.

In our study, as regards the severe maternal outcomes, there was a total of 6 ICU admissions and 5 postpartum hysterectomies, of which 3 cases followed Caesarean deliveries (2 cases of uterine atony and 1 case of massive haemorrhage after PROM and loss of consciousness during labour) and 2 cases followed vaginal delivery (2 cases of placenta

accreta following manual placenta removal). The incidence of emergency postpartum hysterectomy in our study was 0.18‰ amongst vaginal deliveries and 0.5‰ amongst Caesarean deliveries, putting it in the lowest part of the range reported in the literature of 0.5 to 1.0/1000 births [29-33]. No fatalities were observed. This fact demonstrates that the system is, on the whole, well able to manage postpartum haemorrhagic events. The implementation and review of specific guidelines for medical professionals may have made a significant contribution to this result and, indeed the province of Trento's obstetric care network is subject to regular audits. In particular, the specific objectives of a "clinical audit on the adequacy of obstetric practices" assigned by the Provincial Agency for Health Services to all maternity units and conducted in 2012-2013, included the monitoring of PPH incidence, through the audit of clinical cases. This specific PPH monitoring activity has been permanently included in the budget for all maternity facilities in the province of Trento since 2017. This was also consistent with the guidelines provided by AGENAS in 2017, which specifically suggest conducting clinical audits, within the various organisational settings and the system as a whole, as an efficacious practice for improving the management of PPH [23].

CONCLUSIONS

Postpartum haemorrhage (PPH) is the leading cause of maternal mortality and severe morbidity. Not only obstetric but also maternal or antenatal factors are recognized as risk factors for this condition. This can help the assistance network to plan the best birth path. It is therefore appropriate that the phenomenon be monitored as well as the response provided by the health services [34, 35]. In our experience it seems feasible a PPH monitoring system that uses current information flows starting primarily from CedAP, albeit with the information limits connected to this tool. This helps the Health Agency and the health workers to keep the phenomenon under control and monitor the quality of their clinical practice. It would be desirable for this monitoring activity to be made possible at the level of all Italian regions, by providing for a collection of data relating to the PPH, on the occasion of the next revision of the national CedAP model.

COMPLIANCE WITH ETHICAL STANDARDS

Authors contribution

S.P., R.P.: Conceptualization, draft of the initial manuscript. R.P.: check and correction of the data of the CedAP informative flow. R.P.: Data analysis. S.P., R.P., F.T.: Results interpretation and revision of the manuscript. All authors approved the final manuscript as submitted and agreed to be accountable for all aspects of the work.

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Study registration

N/A.

Disclosure of interests

All authors declare they have no conflicts of interest and they have no financial or personal relationships with other people or organizations that could inappropriately influence (bias) their work.

Ethical approval

The Ethical approval was not required as this observational study involved fully anonymized data. The data come from the CedAP informative flow and are routinely collected according to the Italian laws in force. This study is in line with the STROBE and RECORD Statements.

Informed consent

Informed consent was not collected for reasons of organizational impossibility attributable to the fact that the failure to consider the data referring to the estimated number of interested parties who cannot be contacted to inform them, compared to the total number of subjects intended to be involved in the research, would produce significant consequences for the study in terms of altering the relative results; this having regard, in particular, to the inclusion criteria provided for by the study, the methods of enrollment, the statistical number of the chosen sample, as well as the period of time elapsed from the moment in which the data relating to the interested parties were originally collected (as allowed

by privacy code Legislative Decree 196/2003, by the provision of the Privacy Guarantor n.85 of 1 March 2012 and the provision of the Privacy Guarantor n.146 of 5 June 2019).

Data sharing

Aggregate analyses are available on reasonable request to the corresponding author.

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