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Severe postpartum haemorrhage after vaginal delivery: a statistical process control chart to report seven years of continuous quality improvement

Corinne Dupont [a,*], Pauline Occelli [b], Catherine Deneux- Tharaux [c], Sandrine Touzet [b], Antoine Duclos [b], Marie- Hélène Bouvier-Colle [c], René-Charles Rudigoz [a], Cyril Huissoud [d]

[a] Réseau périnatal Aurore – Hôpital de la Croix Rousse, Université Lyon 1, EAM 4128, laboratoire Santé, Individu, Société , faculté de médecine Laënnec, 69372 Lyon, France
[b] Hospices Civils de Lyon, Pôle Information médicale Evaluation et recherche; Université Lyon 1, Lyon, France
[c] Inserm U953 Recherche épidémiologique en Santé périnatale Santé des femmes et des enfants, Paris
[d] Réseau périnatal Aurore – Hôpital de la Croix Rousse, Université Lyon 1, INSERM U846, Stem Cell and Brain Research Institute, Lyon, France

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ABSTRACT

Severe postpartum haemorrhage after vaginal delivery: a statistical process control chart to report seven years of continuous quality improvement

Objective: To use statistical process control charts to describe trends in the prevalence of severe postpartum haemorrhage after vaginal delivery. This assessment was performed 7 years after we initiated a continuous quality improvement programme that began with regular criteria-based audits

Study Design: Observational descriptive study, in a French maternity unit in the Rhône-Alpes region.

Intervention: Quarterly clinical audit meetings to analyse all cases of severe postpartum haemorrhage after vaginal delivery and provide feedback on quality of care with statistical process control tools. Main outcome measures: The primary outcomes were the prevalence of severe PPH after vaginal delivery and its quarterly monitoring with a control chart. The secondary outcomes included the global quality of care for women with severe postpartum haemorrhage, including the performance rate of each recommended procedure. Differences in these variables between 2005 and 2012 were tested.

Results: From 2005 to 2012, the prevalence of severe postpartum haemorrhage declined significantly, from 1.2% to 0.6% of vaginal deliveries ($p < 0.001$). Since 2010, the quarterly rate of severe PPH has not exceeded the upper control limits, that is, been out of statistical control. The proportion of cases that were managed consistently with the guidelines increased for all of their main components.

Conclusion: Implementation of continuous quality improvement efforts began seven years ago and used, among other tools, statistical process control charts. During this period, the prevalence of severe postpartum haemorrhage after vaginal delivery has been reduced by 50%.

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Introduction

The rate of postpartum haemorrhages (PPH) has increased in recent years in many developed countries, including the United States [1,2], Canada [3], Australia [4], Norway [5], and Ireland [6]. In particular, PPH due to uterine atony has contributed to this rise, although the reasons for this remain unclear [3,4,7–9]. Neither a change in the frequency of risk factors associated with patient characteristics nor trends in risk factors associated with practices explain this increase [9]. In France, severe PPH is the leading cause of maternal mortality and, according to the national committee of experts, around 80% of these deaths may be avoidable [10] .

Different quality improvement programmes (QIPs) aimed at improving the medical care of women giving birth have been shown to be effective in obstetrics. These include audits with feedback to the staff, reminders at the moment of prescriptions, and multifaceted intervention programmes [11]. Similar initiatives in the area of PPH have been described and reported to improve the process of care and PPH rates in several maternity units [12]. Other initiatives have been reported or in a single facility [13] or have

* Corresponding author at: Hospices civils de Lyon, Laboratoire Reseau perinatal Aurore Hôpital de la Croix Rousse 69004 Lyon, France. Tel.: +33 68234876; fax: +33 472004163.
E-mail address: Corinne.dupont@chu-lyon.fr (C. Dupont).

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improved only the process but not the PPH rates [14]. These programmes have been applied for periods ranging from 12 to 36 months, with follow-up and assessment either immediately afterwards or at most a year later. Nonetheless, it is sometimes difficult to make the effectiveness of these multifaceted intervention programmes last over time [15]. The concepts of sustainability applied by various authors differ in their definition, methods of measurement (qualitative or quantitative), quantification, and expression of results [16,17]. To our knowledge, no study has assessed the long-term effects of such programmes in obstetrics and, more precisely, for the management of PPH.

Studying the variations of clinical practices and outcomes over time improves our understanding of the factors involved. This in turn makes it possible to determine the most useful actions to implement.

Statistical process control (SPC) is based on a graphical method that can analyse the behaviour of one or more process indicators as part of a continuous QIP [18]. This method is widely applied in healthcare and has recently been applied in the field of obstetrics [19,20] but not to the PPH rate. In 2010, our level 3 maternity ward integrated SPC into the QIP. Since 2005, we began to monitor, analyse, and understand the variations in the rates of severe PPH [21]. The rate of severe PPH fell between 2005 and 2008 [21].

The objective of this study was to describe the course of the rate of severe PPH after vaginal deliveries, seven years after the QIP began, with graphical statistical process control charts.

Methods

Setting

The study took place from 2005 through 2012 in the level 3 maternity ward of La Croix Rousse Hospital (Lyon), which currently has approximately 4000 deliveries per year. In 2012, the professional staff included 74 full-time equivalent midwives, 19 obstetricians (6 hospital staff physicians, 3 chief residents (senior specialist registrars), 10 associated physicians), and 8 interns.

The source population included all women who gave birth in the maternity ward between 2005 and 2012. The frequency of each of the following risk factors for PPH was measured annually for all women: past caesarean (or other uterine scar), multiple pregnancy, placenta praevia, mode of delivery (spontaneous vaginal delivery, instrumental vaginal delivery, that is, by vacuum or forceps, or caesarean), macrosomia (>4000 g), and episiotomy.

The study population comprised all women with a vaginal delivery ($n = 21{,}822$). In 2005, the hospital implemented systematic prospective identification of all cases of severe PPH after vaginal delivery.

Indicator

Severe PPH was defined by the presence of at least one of the following criteria: blood loss greater than 1500 mL, or transfusion with concentrated red cells, or treatment of haemorrhage by radiologic embolization, or conservative surgical treatment, or hysterectomy, or transfer to the critical care department, or intrapartum haemoglobin loss of 4 g/dL or more, or death due to PPH. The rate of severe PPH after vaginal delivery is the ratio of the number of patients with a severe PPH to the number with a vaginal delivery during the same period.

Blood collector bags were systematically used to measure postpartum bleeding

The continuous QIP began in 2005 and took place in three consecutive stages. It began by combining a clinical audit with quarterly audits of morbidity and mortality from severe PPH [21] . The second stage of the continuous QIP started in 2008, when we began applying special data collection procedures to these cases: summary forms are completed by the obstetric team during daily staff meetings (see Appendix 1). During the quarterly audits, the team defines the quality of the care provided to each as optimal, suboptimal, or not optimal [21], in accordance with the French clinical practice guidelines for PPH [22]. It was considered optimal if four key steps were taken in the following time periods after diagnosis of a haemorrhage: call to the senior physician <10 min, performance of a manual uterine examination or manual removal of the placenta <15 min, administration of oxytocin as a first-line treatment and of sulprostone in the 30 min after the PPH diagnosis if atony persisted. It was considered not optimal if at least one of these stages was not performed. It was considered suboptimal if at least one of these stages was not performed within recommended time period or if a minor element was omitted, such as verification of lower genital tract or rapid suturing of soft-tissue wounds.

The third stage of the continuous QIP began in 2010, when we added to it a quarterly monitoring of the severe PPH rate, inspired by the specific methods developed by the French Health Authority (Haute Autorité de Santé, HAS) for application of SPC in French healthcare facilities [18].

Graphical SPC chart

The SPC tool applied here to monitor the behaviour of the indicator is composed of a graphical control chart together with a tracking log. This chart has a central line (CL) and two limits, a lower control limit (LCL) and an upper control limit (UCL), plotted at a given number of standard deviations from the central line. These 3 lines are calculated according to the validated mathematical formula currently applied by the HAS [18]. The indicator values are reported chronologically in this chart. The continuous QIP endeavours to reduce the variability of the process results. A system or process is said to be in statistical control when the value of the indicator changes only within the control limits. Crossing a limit expresses the presence of a cause that must be identified, corrected and used for future improvement.

For this study, based on prospectively collected data about the severe PPHs occurring after vaginal delivery, a control chart was established retrospectively for the 2005–2009 period and prospectively beginning in 2010 [18]. A p-chart (for proportion/percentage) was used to monitor this qualitative binary variable (presence or absence of severe PPH) with variously sized populations of women with vaginal deliveries, depending on the quarter. In view of the frequency of the cases, this monitoring took place quarterly. According to a consensus of local experts, obstetricians, anaesthetists and midwives, and in the absence of available data in the literature, the central line was set at 0.5% based on the mean rate observed from 2008 through 2010. A single standard deviation around the central line was tolerated for the UCL and LCL, in view of the severity of the cases. These limits were calculated for each quarter (as detailed in Appendix 2). The process of care was considered in statistical control if the severe PPH rate remained between the UCL and the LCL.

Statistical analyses

Between 2005 and 2012, the annual frequency of the characteristics of all women in the source population and of those with severe PPH, as well as the compliance of care practices, were compared by a chi-2 test for trend. The threshold of significance was set at 5%. The statistical analyses were performed with EPIINFO.

A segmented linear regression of the number of severe PPHs according to time was performed to demonstrate a change in the

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