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International Journal of Gynecology and Obstetrics xxx (2014) xxx-xxx



Contents lists available at ScienceDirect

International Journal of Gynecology and Obstetrics



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journal homepage: www.elsevier.com/locate/ijgo

1 CLINICAL ARTICLE

² Severe maternal morbidity and near miss due to postpartum hemorrhage

in a national multicenter surveillance study

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11 ARTICLE INFO

12 Article history:

- 13 Received 1 April 2014
- Received in revised form 21 August 2014Accepted 23 October 2014
- 15 Accepted 25 October 201
- 16 Keywords:
- Maternal near miss
 Postpartum hemorrhage
- 19 Retained placenta
- 20 Severe maternal morbidity
- 21 Tissue lacerations
- 22 Uterine atony

ABSTRACT

Objective: To assess the occurrence of severe maternal complications owing to postpartum hemorrhage (PPH)23and its associated factors. Methods: A secondary analysis of data from a multicenter cross-sectional prospective24surveillance study included 9555 cases of severe maternal morbidity at 27 centers in Brazil between July 200925and June 2010. Complications of PPH, conditions of severity management, and sociodemographic and obstetric26characteristics were assessed. Factors independently associated with severe maternal outcome (SMO) were27identified using multiple regression analysis. Results: Overall, 1192 (12.5%) of the 9555 women experienced com-28plications owing to PPH (981 had potentially life-threatening conditions, 181 maternal near miss, and 30 had29died). The SMO ratio was 2.6 per 1000 live births among women with PPH and 8.5 per 1000 live births among30women with other complications. Women with PPH had a higher risk of blood transfusion and return to the31operating theater than did those with complications from other causes. Maternal age, length of pregnancy, pre-32ary to PPH. Conclusion: PPH frequently leads to severe maternal morbidity. A surveillance system can identify the34main causes of morbidity and could help to improve care, especially among women identified as being at high35risk of PPH.36

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42 1. Introduction

Postpartum hemorrhage (PPH) is a leading cause of maternal morbidity and mortality worldwide, but is of particular concern in lowand middle-income countries [1]. In such regions, PPH is estimated to account for one-quarter to one-third of all maternal deaths [2,3]. For each reported maternal death, approximately 20 women survive but go on to experience the consequences of related morbidities [3], creating a large social and economic burden.

Most cases of PPH are caused by uterine atony [4]. Consequently, key
 risk factors for PPH include situations that overdistend the uterus, labor
 induction and augmentation, previous cesarean delivery, hypertensive
 disorders of pregnancy, fibroids, placenta previa, and coagulopathy [4].
 In the past 15 years, an increase in the incidence of PPH–even in
 high-income countries—has been shown in several independent studies

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[5–8]. This observation probably reflects multifactorial causes, such as 56 advanced maternal age, obesity, comorbidities, multiple pregnancy, 57 ethnic origin, and rising rates of cesarean delivery [5–8]. 58

The classic definition of PPH is based on the estimated volume of 59 blood loss that occurs either during delivery or within 24 hours of deliv-60 ery [9]. Nevertheless, use of this definition can be challenging in clinical 61 practice, and diagnosis is usually made by visual estimation of blood 62 loss, suggesting that PPH might actually be underdiagnosed [10,11]. 63 This inaccuracy in blood-loss estimation has triggered efforts to deter-64 mine the global incidence of PPH [4], and to identify clinical signs that 65 might objectively relate to blood loss, such as the shock index [12]. 66 Depending on the presence of pre-existing conditions (e.g. anemia), un-67 treated PPH can lead to hypovolemic shock, multiorgan dysfunction, 68 and maternal death [13]. Therefore, timely and accurate identification 69 of this complication is crucial to ensure that appropriate interventions 70 are initiated (e.g. drugs, surgery, and referral) and that adverse out-71 comes are avoided [14].

For many years, interest in PPH was focused on the evaluation of risk 73 factors, prevention, and treatment [9]. Other studies have tried to un-74 derstand the reasons for substandard care in PPH [8], accurate diagnosis 75

http://dx.doi.org/10.1016/j.ijgo.2014.08.023

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Please cite this article as: Rocha Filho EA, et al, Severe maternal morbidity and near miss due to postpartum hemorrhage in a national multicenter surveillance study, Int J Gynecol Obstet (2014), http://dx.doi.org/10.1016/j.ijgo.2014.08.023

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[12], and identification of potentially severe cases. To date, few studies
 have collected consistent prospective data on severe maternal morbid ity owing to PPH. The Brazilian Network for Surveillance of Severe
 Maternal Morbidity Study Group previously conducted a multicenter
 cross-sectional survey of severe maternal morbidity in Brazil [15].

The aim of the present study was to perform a secondary analysis of data from this survey, focusing on risk factors for severe maternal morbidity secondary to PPH, using WHO criteria for potentially life-threatening conditions (PLTC), maternal near miss (MNM), and maternal death [16].

86 **2. Materials and methods**

87 A cross-sectional prospective surveillance study was conducted between July 1, 2009, and June 30, 2010, at 27 referral obstetric units locat-88 ed throughout Brazil. An investigator and a coordinator were present at 89 each center. Among all deliveries in these institutions during the 1-year 90 91 period, 9555 women with severe maternal morbidity were identified; cases of PLTC, MNM, and maternal death were identified using WHO 92criteria [16–18]. Approval was obtained from the National Council for 93 Ethics in Research and the institutional review boards of participating 94 95units. The need for informed consent was waived because study data 96 were collected from medical records and the women were enrolled either after hospital discharge or death. 97

Sample size for the multicenter cross-sectional survey was originally
 estimated using a theoretical incidence of MNM of approximately 10
 cases per 1000 live births [16], considering this measure was the main
 primary outcome of the study. Approximately 75 000 deliveries were
 predicted to occur at the 27 centers during the study period, so 750
 cases of MNM would be expected.

104 The medical records of women who were admitted to participating 105units for delivery or any pregnancy-related issue were reviewed by 106local researchers immediately after hospital discharge. To obtain clinical information on women who had transferred away from one of the study 107units, local researchers contacted the receiving healthcare units to 108 establish the patients' outcomes. Information was also obtained for 109women who had died. If required, information was also obtained from 110 prenatal records or directly from the healthcare team. 111

Data collection was performed using a paper form that also collected 112 information about adequacy of health care and any delays in receiving 113 appropriate care. These data were then transferred by local researchers 114 115 to electronic forms hosted on the Brazilian Network for Surveillance of Severe Maternal Morbidity Study Group website, located within the 116 institutional web page of the coordinating center (University of 117 Campinas, Campinas, Brazil). Completed electronic forms were sent 118 to a central database using OpenClinica version 3.0 (https://www. 119 120openclinica.com/), a specialized platform designed to manage clinical studies. Further methodological details are available elsewhere 121 122[15.19.20].

An operating manual was developed and provided to all investiga-123tors and coordinators for training purposes before data collection com-124125menced to ensure systematic quality control. Initially, each local 126coordinator reviewed the forms, checked for errors, and searched for any missing data. Then, the local investigator performed a second re-127view to identify possible inconsistencies. Finally, the national coordina-128tors checked the database, identified possible inconsistencies, and sent 129an error report to participating centers, which were required to respond 130and correct all information [19]. 131

Constant auditing was conducted using a set of validation and cross-132checking rules as part of the online data management. Participating 133 units and researchers from the coordinating center underwent a sys-134tematic evaluation of possible delays and deficiencies in the quality of 135care and health-system inadequacy, with data on interhospital transfer, 136 patient refusal in accepting treatment, and lack of equipment or 137 medication. Overall, the delays and deficiencies identified were opera-138 139 tionally defined as a substandard care. Hemorrhagic complications were systematically investigated and included prepartum and intra- 140 partum hemorrhage, PPH, complicated ectopic pregnancy, abortion, or 141 other severe hemorrhage (e.g. wound hematoma). 142

In the present secondary analysis, data were used for women with 143 obstetric complications. They were initially divided by whether the 144 complications were due to PPH or another cause. The prevalences of 145 PLTC, MNM, and maternal death were calculated and compared be-146 tween the two subgroups. Health indicators related to maternal mor-147 bidity and mortality were estimated according to WHO criteria [16]. 148 These indicators included the MNM ratio, the severe maternal outcome (SMO) ratio (defined as the sum of MNM plus maternal death), the ratio of MNM to maternal death, the mortality index, and the maternal mor-151 tality ratio (MMR).

Data were analyzed using SPSS version 20.0 (IBM, Armonk, NY, USA) 153 and Epilnfo version 3.5.3 (CDC, Atlanta, GA, USA). The prevalence ratio 154 (PR) was adjusted for the cluster effect of the design. This correction 155 was used because each participating center was considered as a cluster, 156 and the correspondent heterogeneity in each variable among clusters 157 was adequate [20,21]. Sociodemographic and obstetric factors potentially associated with worse outcomes among women with PPH were 159 evaluated by comparing women with PLTC with those with SMO. Finally, multiple Poisson regression analysis was used to identify factors 161 independently associated with SMO secondary to PPH. P < 0.05 was considered statistically significant.

3. Results

Among the 9555 women with severe complications in pregnancy, 165 delivery, or the postpartum period, 8645 (90.5%) had PLTCs, 770 (8.1%) 166 had MNM, and 140 (1.5%) died. PPH affected 1192 (12.5%) women, 167 most of whom had PLTCs (Fig. 1, Table 1). Uterine atony was the most frequently diagnosed condition in women with PPH (Table 1). Causes other 169

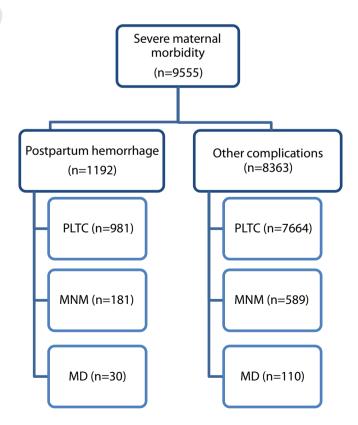


Fig. 1. Schematic of the women with severe maternal morbidity owing to postpartum hemorrhage or other causes according to the final outcome. Abbreviations: PLTC, potentially life-threatening condition; MNM, maternal near miss; MD, maternal death.

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