Simulation-based training and standardised protocol for preventing massive transfusion in postpartum haemorrhage: a regional retrospective cohort study

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Abstract

Objective: To evaluate obstetrical providers' behaviours and maternal outcomes of women transferred with postpartum haemorrhage before and after introduction of a simulation-based training programme and standardised protocol Design: A retrospective cohort study Setting: All institutes operating deliveries in Satsuma Peninsula, Kagoshima Prefecture, Japan Population and Sample: Patients transferred with postpartum haemorrhage to Kagoshima City Hospital or Kagoshima University Hospital were included. Data collected before (period 1: 2015–2017) and after (period 2: 2018–2020) programme initiation were compared. There were 72 and 131 patients during periods 1 and 2. Methods: Data from medical records were used to compare providers' behaviours and outcomes between the two periods. Main outcome measures: Effectiveness of the simulation-based training and standardised protocol in postpartum haemorrhage, change in providers' behaviours, and maternal outcomes, including massive blood transfusion Results: Changes in providers' behaviours were observed after the programme. The rate of shock index recording increased from 9.7% to 36.6% ($p<0.001$), and the rate of using intravenous lines [?]20 gauge increased from 91.7% to 100% ($p=0.0017$). The mean shock index on arrival significantly decreased from 0.85 to 0.77 ($p<0.05$). The massive transfusion (red blood cells [?] 10 units) rate significantly decreased from 43.1% to 26.0% ($p<0.05$). Clinical factors related to massive transfusion were programme attendance, blood loss, and coagulopathy. Programme attendance reduced the risk of massive transfusion, while blood loss [?]2,200 g increased the risk. Conclusions: Introducing the simulation-based training programme and using a standardised protocol changed the providers' behaviours and decreased the massive transfusion rate for postpartum haemorrhage.

Introduction

Postpartum haemorrhage (PPH) is the leading cause of maternal mortality and severe morbidity worldwide.[1] In addition, increasing incidences of PPH have been reported in developed countries.[2-4] It is widely recognised that earlier awareness of exacerbation of vital signs using the shock index (SI), proper initial treatment, earlier transfer to tertiary hospitals, and good intra- and inter-hospital relationships can improve maternal clinical outcomes.[5-13] Surprisingly, 95% of maternal deaths due to PPH had some chance of preventability, and 70% of deaths had a good-to-strong chance of preventability.[14]Although simulation-based training does not supplant on-the-job training, it is believed to play an important role for maternal outcome improvement. Thus, clinical guidelines and standardised protocols are recommended to prevent adverse outcomes.[15] Although several studies reported that teamwork and communication improved clinical outcomes for PPH, there is not enough evidence that these programmes equally improve maternal outcomes.[15-18] To assess the effectiveness of simulation-based training, the Kirkpatrick model is useful (level 1: reaction, level 2: learning, level 3:

behaviour, and level 4: results).[19] Previous reports revealed the effectiveness of level 3, but there is still a lack of compelling evidence about the effectiveness of level 4.[8,13,17]

In Japan, the frequency of maternal deaths due to PPH reduced from 29% in 2010 to 7% in 2017.[20] They concluded that simulation-based training: the Japan Maternal Emergency Life-saving Course (J-MELS) contributed to reduced maternal deaths.[20] In Japan, 46% of deliveries occur in private clinics that are operated by one or two obstetricians.[21] Once PPH occurs, the women are transferred to tertiary hospitals. Half of the reported maternal deaths are women who delivered in private clinics and were transferred to tertiary hospitals because of maternal crises. Thus, team bundles in intra- and inter-hospitals are important to avoid preventable deaths. Since 2017, the Kagoshima Association of Obstetricians and Gynaecologists has recommended that obstetrical providers complete the J-MELS programme and enabled clinicians to use the same standardised protocol. This movement was broadcasted by instructors in Kagoshima City Hospital and Kagoshima University Hospital. We expected this initiative would lead to earlier awareness of maternal crises and an earlier decision regarding maternal transfer, subsequently leading to improved maternal outcomes. To assess the efficacy, this study aimed to evaluate providers' behaviours and the maternal outcomes for patients who were transferred to the Kagoshima City Hospital and Kagoshima University Hospital with PPH before and after providers attended the J-MELS.

Methods

Study design, training programme, and population

This retrospective cohort study was conducted at the Kagoshima City Hospital and Kagoshima University Hospital. Both hospitals serve as tertiary referral centres in the Kagoshima Prefecture, especially in the Satsuma Peninsula. Both hospitals are located in Kagoshima City, the capital of the Kagoshima Prefecture. Almost all severe cases of PPH in the Satsuma Peninsula are transferred to these two hospitals. In the Satsuma Peninsula, there are approximately 10,000 deliveries per year that are performed in 23 private clinics and five hospitals.

In September 2017, the J-MELS programme was distributed to all private clinics and hospitals performing deliveries. As a result, all the 28 clinics and hospitals in the region were involved in the programme with at least one provider in each institution having complete the programme by 2019. Overall, 229 participants (64 obstetricians and 165 midwives and nurses) attended the programme during this period. The J-MELS programme, emphasised the importance of (1) monitoring patients' vital signs (blood pressure, heart rate, SI, saturation of percutaneous oxygen [SpO_2], respiratory rate, and consciousness) during and after delivery to allow earlier recognition of PPH, (2) administering a high concentration of oxygen in PPH, and (3) using more than two routes for intravenous (IV) injection lines [?]20 gauge in PPH and stating clearly the standardised protocol for deciding maternal transfer: once maternal vital signs worsened to (1) SI $>$ 1.0 with continuous haemorrhage, (2) SI $>$ 1.5, (3) SpO2 $<$ 95% (room air), (4) tachypnoea or forced breathing, and (5) disturbance of consciousness. One goal of this programme was to achieve earlier awareness of PPH and earlier maternal transfer to tertiary hospitals, which can lead to earlier advanced treatment at a referral hospital, before the collapse of circulation and disseminated intravascular coagulation (DIC), and ultimately prevent maternal death.

We screened patients who were transferred to either the Kagoshima City Hospital or Kagoshima University Hospital for PPH from January 2015 to December 2020. Because no patient opted out from the study, all patients were included.

Data collection

The primary outcome was to investigate the efficacy of the programme by comparing the change in the obstetrical providers' behaviours and the maternal outcome before and after the providers attended the programme. The data were compared before (period 1: 2015–2017) and after (period 2: 2018–2020) introducing the J-MELS.

All data were collected from the patients' medical records. The baseline characteristics of all patients,

including maternal age, body mass index at delivery, parity, mode of conception, and mode of delivery, were collected. To assess providers' behavioural changes at the referring hospitals, the existence of an SI record, oxygen administration, the use of more than two IV routes with lines [?]20 gauge, amount of blood loss, and time from delivery to maternal transfer were evaluated. To assess the maternal outcome, the maternal SI, disturbance of consciousness, body temperature, haemoglobin (Hb) level, and platelet (Plt) counts on arrival were recorded. In addition, massive transfusion (packed red blood cell transfusion [?]10 units), hysterectomy, interventional radiology (IVR), and maternal death were evaluated. If one provider (obstetrician, midwife, or nurse) attended the programme at the time of transfer, the institution of the provider was also considered to be part of the programme.

Missing data

For all covariates, complete case analysis was performed as there was no missing data. Although there was one missing data point for SI on arrival, complete case analysis was performed, as accounted for <1% of the total study population.

Core outcome sets

The core outcome was to investigate the efficacy of the programme by comparing the change in obstetrical providers' behaviours and maternal outcomes before and after programme attendance. Data from before (period 1: 2015–2017) and after (period 2: 2018–2020) introducing the J-MELS were compared.

Statistical analysis

First, the inter-group comparisons were analysed to confirm the validity of the simulation-based training at Kirkpatrick level 3. Second, the relationship between programme attendance and massive transfusion was analysed to confirm the validity of the programme at Kirkpatrick level 4. Receiver operating characteristic (ROC) curve analysis of massive blood transfusion and the amount of blood loss at the referring hospitals was performed to determine the cut-off level of massive blood transfusion and to analyse the relationship between massive blood transfusion and programme attendance. Inter-group comparisons were performed using the Student t-test and nonparametric test for continuous variables (maternal age, body mass index at delivery, parity, SI, amount of blood loss, time from delivery to maternal transfer, body temperature, and Hb level on arrival) or the Fisher's exact test for nominal variables (mode of conception, mode of delivery, oxygen administration, existence of an SI record, use of more than two IV routes with lines [?]20 gauge, unconsciousness, massive transfusion, hysterectomy, IVR use, and maternal death). Relationships between massive blood transfusion and other variables were analysed using logistic regression analysis. A p-value of <0.05 was considered statistically significant. All statistical analyses were performed using EZR (version 1.54, Saitama Medical Center).[22]

Ethics approval

This study was conducted with the approval of the institutional review boards of Kagoshima City Hospital (number [no.]: 2020-62) and Kagoshima University Hospital (no. 200289), and in accordance with the 2013 Declaration of Helsinki. We announced this study in displays and the homepage in each hospital and provided an optout option for patients.

Funding

None.

Results

From January 2015 to December 2020, 203 women were transferred to either of Kagoshima City Hospital or Kagoshima University Hospital because of PPH. No patients were excluded from this study. There were 31,865 births in the Satsuma Peninsula during period 1 and 28,715 during period 2, with an overall decrease of about 10% in period 2. There were 72 patients transferred for PPH during period 1 and 131 transferred for PPH during period 2, representing an overall increase in PPH of 80%. The course completion rate increased

from 12.5% to 96.9% between the periods. Two of the 28 clinics and hospitals in Satsuma Peninsula did not participate in the programme until 2020; however, neither clinic had transferred patients with PPH to our hospitals after 2018. The demographics and maternal characteristics are shown in Table S1. Although maternal age significantly increased from 31.1 ± 5.1 years in period 1 to 34.0 ± 5.2 years in period 2 ($p < 0.001$), other factors, including the rates of primary disease, did not change significantly, aside from the incidence of placental abruption.

The providers' behavioural changes at the referring hospitals are presented in Table 1. The SI recording rate significantly increased from 9.7% to 36.6% between the two periods ($p < 0.001$), and the rate of using IV lines [?] 20 gauge increased from 91.7% to 100% between the two periods ($p = 0.00173$). The rate of securing multiple IV routes and oxygen administration did not change. The mean time from delivery to maternal transfer decreased from 150 (range, 88–260) minutes to 130 (range, 73–215) minutes, and the mean amount of blood loss at the referring hospitals decreased from 2,000 (range, 1,500–2,720) g to 1,927 (range, 1,100–2,370) g, although these changes were not statistically significant. Nevertheless, these improvements indicate the effectiveness of the programme at Kirkpatrick level 3.

Patients' vital signs, laboratory data on arrival, and clinical outcomes are shown in Table 2. As expected, the mean SI on arrival significantly decreased from 0.85 (range, 0.72–1.05) to 0.77 (range, 0.65–0.93) ($p = 0.0345$) (Figure 1). The Hb level (7.5 +- 2.4 g/dL and 8.0 +- 2.3 g/dL, respectively) and Plt counts (14.3 +- 6.8 x 10^4/μL and 15.8 ± 7.1 × 10^4/μL, respectively) improved between periods 1 and 2, but not significantly. Although the rates of both impaired consciousness (11.1% and 6.9%) and hypothermia (body temperature <36 ^{o}C) (9.7% and 3.8%) decreased between periods 1 and 2, these findings were also not significant.

The maternal outcomes are presented in Table 3. The occurrence of hysterectomy, IVR, and maternal death did not differ between the two periods. Two maternal deaths were caused by amniotic fluid embolism (AFE). Between the two periods, the rate of massive transfusion (red blood cells [RBC] [?] 10 units) significantly decreased from 43.1% to 26.0% ($p = 0.018$), indicating the effectiveness of the programme at Kirkpatrick level 4.

Clinical factors related to massive transfusion (RBC [?] 10 units) are shown in Tables S2 and 4. There were positive relationships between massive transfusion and the amount of blood loss at the referring hospitals and a negative relationship between massive transfusion and completion of the J-MELS programme. Coagulopathy (placental abruption, AFE, and DIC), a main cause of PPH, was a risk factor for massive transfusion. The ROC curve between blood loss at the referring hospitals and massive transfusion is presented in S3. The cut-off level of blood loss at the referring hospitals for massive transfusion was 2,200 g (sensitivity: 77.8%, specificity: 69.8%, area under the ROC curve: 0.774, 95% confidence interval [CI]: 0.699–0.849). Logistic regression analysis showed that the J-MELS programme effectively decreased the risk of massive transfusion (OR: 0.29, 95% CI: 0.14–0.62); additionally, blood loss [?]2,200 g at the referring hospitals increased the risk of massive transfusion (OR: 8.59, 95% CI: 4.14–17.8), and the same result was shown for coagulopathy as the main cause of PPH (OR: 5.60, 95% CI: 1.74–18.0), as presented in Table 4.

Discussion

Main findings

Similar to previous reports,[13,15-17] our study showed that the J-MELS programme was effective at Kirkpatrick level 3. Although the SI on arrival significantly improved and cases of massive transfusion significantly decreased, the occurrence of hysterectomy, IVR, and maternal death did not differ between the two periods.

Changes in providers' behaviours were observed, such as increased rates of SI recording and using IV lines [?]20 gauge, which might have resulted in earlier administration of first aid measures such as transfusion of extracellular fluid to maintain circulation. The increased number of maternal transfers, lower amount of blood loss at the referring hospitals, and shorter time to transfer between the two periods in our study indicate the effectiveness of the programme, which emphasises the importance of earlier awareness of the occurrence of PPH and earlier transfer using the same standardised protocol. Moreover, earlier awareness,

application of first aid measures, and transfer might have resulted in the improvement of the maternal SI on arrival. The implementation of earlier awareness and earlier transfer procedures to prevent maternal collapse and DIC was the goal of the simulation-based training. This goal was achieved to some degree. The decrease in the massive transfusion rate indicates the effectiveness of the programme at Kirkpatrick level 4. The results of logistic regression analysis support the independent effectiveness of the programme in terms of a reduction in the rate of massive transfusion (OR 0.29); an earlier transfer leads to a better maternal status on arrival, a lower amount of blood loss, an earlier administration of advanced treatment, such as IVR, and reduction of massive transfusion. The results of logistic regression analysis also showed that completing the J-MELS programme independently decreased the risk of massive transfusion. We concluded that our attempt to have practitioners from all clinics participate in the programme and use the same standardised protocol was successful in changing providers' behaviours and decreasing the rate of massive transfusion. This study is one of the valuable studies that evaluated the efficacy of a regional attempt to encourage obstetrical providers to attend simulation-based training and use a standardised treatment protocol. An earlier decision of maternal transfer can achieve a lower rate of massive transfusion. However, to evaluate whether this truly decreases maternal death, further study with a greater number of included patients is essential.

Strength and limitations

The strength of this study is that it could be considered a regional cohort study. Given the established systems of centralisation in Satsuma Peninsula, most severe PPH cases, with rare exceptions, are transferred to either of the two hospitals included in this study.

This study has some limitations that must be acknowledged. First, this study included multiple facilities and the number of providers who attended the programme differed in each facility; thus, there may be some differences in the estimated blood loss and first aid for PPH at each facility. Obstetricians tended to underestimate the amount of blood loss.[23] Thus, the recruitment of more patients and the study being conducted after all providers have completed the J-MELS programme are desirable. However, to overcome this problem, we used the SI in our analysis in addition to the amount of blood loss. The SI has been reported to be a useful predictor for early awareness of severe PPH.[9,24-26] In this study, the median SI on arrival decreased from 0.85 in period 1 to 0.77 in period 2. This fact supports the lower blood loss at the referring hospitals in period 2 than in period 1. Hence, the amount of blood loss at the referring hospitals is considered to be reliable.

Second, this study may not have included mild cases in period 1; thus, the improvement observed could be explained by the increase of mild cases of PPH in period 2. Interpretation

In the J-MELS programme, an earlier transfer was the emphasised point, and over triage was tolerated. However, the fact that the cases of hysterectomy and IVR did not decrease indicated that the increase in mild cases was not the only reason for the improvement observed. This result indicates that the occurrence of severe PPH in this area may be increasing. There have been some reports of increases in severe cases of PPH.[2-4,27-29] In the United States, the frequency of PPH with transfusion increased three-fold from 1999 to 2008.[3] Advanced maternal age ([?]35 years) is another risk factor for PPH. The mean maternal age increased from 31.1 years to 34.0 years between the two periods. These facts indicate that not only mild PPH transfers increased but the occurrence of PPH also increased. Therefore, the reduction in the massive transfusion rate may be the effect of the J-MELS programme. In Japan, the frequency of maternal deaths due to PPH decreased from 29% in 2010 to 7% in 2017.[20] Because our study population was small, we could not confirm the reduction of maternal death, but there was a reduction in the massive transfusion rate among cases of inter-hospital transfer. The simulation-training programme changed providers' behaviours and led to a decrease in the rate of massive transfusion. Although further study is needed, such training will have the potential to decrease maternal death in women with severe PPH instead of the recent trend of increasing maternal PPH.

Conclusions

Our initiative to have obstetrical providers from all obstetrical institutions attend the simulation-based training programme and use a standardised protocol for the treatment of PPH resulted in changes in providers' behaviours and a decrease in cases requiring massive transfusion.

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Disclosure of interests

The authors report no conflict of interest. All authors have completed the ICMJE uniform disclosure form.

CRediT authorship contribution statement:

Y.O.: Conceptualisation, Data curation, Formal analysis, Project administration, Writing-Original draft preparation; T.H.: Conceptualisation, Methodology, Writing-Review and editing; T.M.: Conceptualisation, Methodology, Writing-Review and editing; Y.N.: Investigation; Tomonori Hamada: Data curation, Project administration; H.T.: Conceptualisation, Writing-Review and editing; N.K.: Conceptualisation, Writing-Review and editing; Y.T.: Conceptualisation, Writing-Review and editing; H.K.: Resources, Writing-Review and editing; M.K.: Conceptualisation, Methodology, Writing-Review and editing, Supervision

Details of Ethics Approval

This study was approved by the institutional review boards of Kagoshima City Hospital on January 21 2021 (number [no.]: 2020-62) and Kagoshima University Hospital on March 24, 2021 (no. 200289), and was conducted in accordance with the 2013 Declaration of Helsinki. We announced this study in displays and the homepage of each hospital and provided an optout option for patients. The STROBE statement was followed.

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Table/Figure Captions

Table 1. Behaviours of obstetrical providers at the referring hospitals

Table 2. Vital signs and laboratory data on arrival

Table 3. Maternal outcomes

Table 4. Results of logistic regression analysis of factors for massive blood transfusion

S1. Demographic, obstetrical, and clinical characteristics

S2. Clinical factors and massive blood transfusion

S3. Receiver operating characteristic curve between massive blood transfusion, blood loss at the referring hospital, and shock index

Area under the receiver operating characteristic curve: 0.774, 95% confidence interval: 0.699–0.849, sensitivity: 77.8%, specificity: 69.8%

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