Original Article
Does uterine gauze packing increase the risk of puerperal morbidity in the management of postpartum hemorrhage during caesarean section: a retrospective cohort study

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Abstract: Background: To compare the outcomes especially the puerperal morbidity of uterine gauze packing (UGP) with those of uterine balloon tamponade (UBT) in the management of postpartum hemorrhage (PPH) during caesarean section (c-section). Methods: It was considered success as no requirement for either a further therapy or hysterectomy for PPH. The postpartum infection risk was pragmatically measured as puerperal morbidity. Results: The identified PPH subjects were subdivided into two groups for comparison, in which UGP or UBT was used as second-line therapy for women undergoing c-sections between January 2010 and September 2014. Of the 318 c-section subjects initially treated by basic managements for expected PPH, 99 cases underwent UGP and 66 UBT as the second-line therapies to stop persistent bleeding. The success rates of the UGP and UBT groups were 90.91 and 87.88%, respectively. Only one patient in UBT group resorted to hysterectomy. The respective rates of puerperal morbidity were 10.10 and 13.64%, with risk ratio of 0.74 (95% CI: 0.32, 1.72). There were no significant differences between the two groups even after the adjustment for potential confounding factors. Conclusion: UGP appears to be effective in treating PPH during c-section without an observed increase in the risk of potential postpartum infection when compared with UBT. UGP could be recommended as routine for patients who are not responding to conventional basic therapies in addressing PPH, along with the provision of appropriate training.

Keywords: Postpartum hemorrhage, caesarean section, postpartum infection, uterine gauze packing, uterine balloon tamponade

Introduction

Obstetric hemorrhage is one of the most serious complications during delivery. It accounts for one quarter of the major direct causes of maternal deaths globally [1], while it rises up to nearly one third in Africa and Asia [2]. The risk of hemorrhage during caesarean section (c-section) was significantly higher compared to that of vaginal delivery [3, 4]. Postpartum hemorrhage (PPH), the most common form of obstetric hemorrhage, has been an increasing concern with the increase inc-section rate in many countries, including China. The well-known major causes of PPH are uterine atony, placental factors, lacerations, and coagulation disorders. Hemorrhage often occurs suddenly and unpredictably with high volume bleeding in a short period of time, which may be life threatening to the puerpera if it cannot be dealt with rapidly and adequately. If there is persistent bleeding despite treatment with the first-line conventional basic measurements such as uterotonic drugs and other conservative interventions, second-line intervention should be used without further delay [5, 6]. The second-line measures include surgical, radiological or new medical therapies, such as recombinant activated factor VIIIa (rFVIIa) [5]. Because hysterectomy is associated with major complications and sterility, active attempts have been made to introduce conservative surgical measures to avoid such last resort. UBT, one of conservative surgical interventions, has been added to the treatment modalities of PPH [7, 8]. As for UGP, which is another conservative procedure, although it is a readily available and inexpensive measure for the management of
UGP without increasing the risk of potential postpartum infection

Figure 1. Flowchart of recruitment and study profile. *The first-line conventional treatments included uterotonic agents, massage and manual compression.

PPH, it was questioned and criticized because of the potential risk of postpartum infection, uterine trauma, and ineffective packing [9, 10]. While some recent case reports have indicated that uterine packing is a safe and effective technique for controlling intractable hemorrhage [11, 12]. Little evidence within the obstetrical literature has filled the knowledge gaps and addressed the concerns of more postpartum infection resulting from uterine packing for the management of obstetrical hemorrhage. As few studies have addressed the comparative effectiveness and potential infection risk of UGP in the clinical setting, we performed a retrospective cohort study to compare the outcomes of UGP with those of UBT, in particular, to explore whether UGP will increase the infection risk in the management of PPH during c-section.

Material and methods

Sample

A total of 62,667 cases were scheduled to deliver between January 1, 2010 and September 31, 2014 at the International Peace Maternity and Child Health Hospital, which is a tertiary university teaching hospital. All of the PPH subjects during c-sections were systematically evaluated by two experienced obstetricians. Among the 30,807 c-section cases, 318 cases were initially treated by conventional basic management for expected PPH, i.e., an estimated blood loss of over 500 ml within the first 24 h of delivery according to the traditional World Health Organization definition of primary PPH [6, 13]. Hospital electronic medical record sand clinical data from the Department of Obstetrics including notes by physicians and/or nurses concerning the hospitalization were reviewed to identify the study population. The inclusion criterion in this study was the PPH cases delivering via c-section used UGP or UBT as the second-line therapy for PPH after failure of initial conventional measures to stop bleeding. The conventional basic treatments included uterotonic agents, massage and manual compression. Usually, the routine administration of uterotonic agents included oxytocin 10 iu intramuscularly and 20...
UGP without increasing the risk of potential postpartum infection

Table 1. Clinical characteristics of patients with PPH during c-section

<table>
<thead>
<tr>
<th>Variable</th>
<th>UGP (n=99)</th>
<th>UBT (n=66)</th>
<th>χ²</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (year)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;35</td>
<td>68 (68.69%)</td>
<td>53 (80.30%)</td>
<td>2.7324</td>
<td>0.0983</td>
</tr>
<tr>
<td>≥35</td>
<td>31 (31.31%)</td>
<td>13 (19.70%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gestational age (week)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;37</td>
<td>27 (27.27%)</td>
<td>17 (25.76%)</td>
<td>0.0465</td>
<td>0.8293</td>
</tr>
<tr>
<td>37-42</td>
<td>72 (72.73%)</td>
<td>49 (74.24%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birth weight (g)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;4000</td>
<td>79 (79.80%)</td>
<td>47 (71.21%)</td>
<td>1.6173</td>
<td>0.2035</td>
</tr>
<tr>
<td>≥4000</td>
<td>20 (20.20%)</td>
<td>19 (28.79%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood loss (ml)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>500-1000</td>
<td>58 (58.59%)</td>
<td>42 (63.64%)</td>
<td>0.4231</td>
<td>0.5154</td>
</tr>
<tr>
<td>≥1000</td>
<td>41 (41.41%)</td>
<td>24 (36.36%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operative time (min)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤50</td>
<td>29 (29.29%)</td>
<td>34 (51.52%)</td>
<td>8.2851</td>
<td>0.0040</td>
</tr>
<tr>
<td>&gt;50</td>
<td>70 (70.71%)</td>
<td>32 (48.48%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>77 (77.78%)</td>
<td>49 (74.24%)</td>
<td>0.2742</td>
<td>0.6005</td>
</tr>
<tr>
<td>≥2</td>
<td>22 (22.22%)</td>
<td>17 (25.76%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fetus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>85 (85.86%)</td>
<td>50 (75.76%)</td>
<td>2.7160</td>
<td>0.0993</td>
</tr>
<tr>
<td>2</td>
<td>14 (14.14%)</td>
<td>16 (24.24%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Main Cause of bleeding</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uterine inertia</td>
<td>19 (19.19%)</td>
<td>40 (60.61%)</td>
<td>29.5667</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Placental factors</td>
<td>80 (80.81%)</td>
<td>26 (39.39%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: UGP, Uterine gauze packing; UBT, Uterine balloon tamponade; IQR, interquartile range.

iu intravenous infusion (4 ml/min running at 240 mL/hour), 100 μg carbettocin intramuscularly, 250 μg carboprost tromethamine intramuscularly. A total of 165 cases were finally included in the study; 99 patients underwent UGP and 66 UBT (Figure 1). Characteristics of the patients such as age, parity, gestational weeks, fetal number, and cause of hemorrhage were collected and reviewed. The Institutional review board approval from International Peace Maternity & Child Health Hospital, Shanghai Jiaotong University School of Medicine was obtained to conduct the retrospective cohort study on 26 February 2013. The approval registration number is GLW-2013.

Measures and definitions

Management procedures of UGP [14]: The sterile gauze used was approximately 2 m long and 3 cm wide and was prepared preoperatively in our hospital. It was soaked with iodophor and then wrung out. The uterine cavity was packed with the gauze through the hysterotomy, with one end of the gauze passed through the cervix into the vagina for subsequent removal. The gauze should be packed uniformly side to side and packed completely and tightly in uterine cavity before suturing the uterine incision. Attention should be paid to ensure that there is no active bleeding and to prevent suturing the gauze while closing the uterine incision. The gauze was removed after 12 to 24 h when hemostasis had been achieved. The gauzes should be removed gradually and manual compression on the fundus of the uterus should be provided simultaneously to achieve the desired effect of pressurization.

Management procedures of UBT: The UBT used in our hospital was Bakri balloon (Cook Medical, Bloomington, IN, USA). The distal end of the balloon shaft was pulled through the cervix into the opened uterus. After the balloon was inflated with approximately 100 ml of sterile saline solution, the hysterotomy incision was closed carefully to avoid damage to the balloon. The balloon was then inflated with a total amount of sterile saline solution usually ranging from 150 to 350 ml conforming to the size of the uterine cavity. The drainage port of the balloon was connected to a fluid collection bag to monitor
UGP without increasing the risk of potential postpartum infection

Table 2. Outcome comparison between the two groups

<table>
<thead>
<tr>
<th>Outcome</th>
<th>UGP (n=99)</th>
<th>UBT (n=66)</th>
<th>RR (95% CI)</th>
<th>χ²</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success</td>
<td>Yes</td>
<td>90 (90.91%)</td>
<td>58 (87.88%)</td>
<td>1.04</td>
<td>0.391</td>
</tr>
<tr>
<td></td>
<td>No*</td>
<td>9 (9.09%)</td>
<td>8 (12.12%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Puerperal Morbidity</td>
<td>Yes</td>
<td>10 (10.10%)</td>
<td>9 (13.64%)</td>
<td>0.74</td>
<td>0.4828</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>89 (89.90%)</td>
<td>57 (86.36%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: UGP, Uterine gauze packing; UBT, Uterine balloon tamponade; RR, Risk Ratios, i.e., ratios of success/morbidity rate were used as a measure of association between outcome and treatment. *Among the 17 cases of failure, 16 of them were subsequently treated by transarterial embolisation, and only one patient in the UBT group required hysterectomy.

Table 3. Multivariate logistic regression analysis of puerperal morbidity

<table>
<thead>
<tr>
<th>Variables</th>
<th>Odds Ratio (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment (UGP vs. UBT)</td>
<td>0.47 (0.16, 1.40)</td>
<td>0.1741</td>
</tr>
<tr>
<td>Operative time (&gt;50 min vs. ≤50 min)</td>
<td>1.58 (0.55, 4.57)</td>
<td>0.3960</td>
</tr>
<tr>
<td>Cause of bleeding (placental factors vs. uterine inertia)</td>
<td>2.23 (0.68, 7.27)</td>
<td>0.1830</td>
</tr>
</tbody>
</table>

Note: UGP, Uterine gauze packing; UBT, Uterine balloon tamponade.

hemorrhage. The balloon was kept inflated for 12-24 h with careful monitoring.

Post-operative treatments and observation indexes: all of the subjects were infused with oxytocin and treated routinely with prophylactic antibiotics such as cefuroxime sodium. Clinical parameters such as vital signs and uterine bleeding were strictly monitored. 1. Definition of success: procedure of UGP or UBT was considered successful as no requirement for either a further therapy (such as embolisation, rFVIIa, intra-arterial balloon occlusion and pelvic vessel ligation) to treat PPH or hysterectomy [5]. 2. Postpartum infectious risk: it was measured as a surrogate endpoint i.e. puerperal morbidity: fever of 38°C and higher on any 2 of the first 10 days (measured 4 times each day with an interval of more than 4 h) following delivery exclusive of the first 24 h. 3. Other observation indexes: 1) operation duration; 2) blood loss during surgery and within 24 h after birth, which was routinely estimated by weighing method.

Statistical analysis

Statistical analyses were performed with SAS version 9.3 (SAS Institute, Cary, NC, USA). Data were expressed as median (IQR, interquartile range) for continuous variables and percentage for categorical variables. Comparisons between two groups were made by Chi-square test or Fisher’s exact test when appropriate. Logistic regression model was conducted to adjust for potential confounders, which were clinically relevant and readily available from routine health records. All statistical tests were 2-sided, with statistical significance defined as P<0.05.

Results

As shown by the study flowchart (Figure 1), 165 women eligible to meet the study criteria were included from January 2010 to September 2014. The characteristics of the 99 UGP cases and 66 UBT controls are presented in Table 1. The median age of women in both groups was a little older than 30 years. The UGP group tended to have older subjects (over 35 years) and longer operative durations than UBT group. Subjects in both groups had a similar distribution of parity, gestational weeks, number of fetus and birth weight. Women in both groups had similar median and interquartile regarding blood loss, and nearly half of them were minor PPH (blood loss 500-1000 mL). The leading cause of PPH in the UBT group was uterine atony, which accounted for 60.61%. While placental factors (such as placenta previa, placenta accrete and placenta adherence) were the most common causes of PPH for the UGP group accounting for 80.81%. There were significant differences in operative duration and the hemorrhage causes between the two groups, and the details are listed in Table 1.

The success rates for hemostasis and occurrences of postpartum infection did not differ significantly between the groups (Table 2). The UGP group was effective in 90 cases, and the UBT group in 58 cases. The success rates of UGP and UBT were 90.9 and 87.9%, respectively. Eight out of 66 patients (12.1%) in the UBT group failed to stop bleeding excessively, while 9 out of 99 patients (9.1%) required further interventions after UGP. Only one patient in the UBT group required hysterectomy, and uterine artery embolization was subsequently employed for the other 16 patients to effectively control of excessive bleeding [15].
UGP without increasing the risk of potential postpartum infection

There were no significant differences for the puerperal morbidity between the two groups (Table 2). The rates of puerperal morbidity were 10.1 and 13.6% for UGP and UBT, respectively. The risk ratio (RR) of UGP to UBT was 0.74 (95% CI: 0.32, 1.72). Multivariate logistic regression analysis was performed to adjust the potential confounding factor i.e. operative time and causes of PPH, among which puerperal morbidity was taken as outcome. The details are listed in Table 3. The results indicated that adjustments do not significantly alter the interpretation of the crude RR of treatments.

Discussion

Main findings

The results of this study show that UGP was effective in treating PPH during c-section without increasing the potential risk of postpartum infection when compared with UBT. There were no significant differences between the two groups even after the adjustment for potential confounding factors.

Strengths and limitations

Our study attempted to compare outcomes of the use of UGP and UBT for PPH in real clinical setting, which would provide valuable insights into the usage and comparative effectiveness of the two second-line treatments of PPH. Puerperal morbidity can be relatively quickly and easily measured, which is generally accepted among clinicians as a sign of postpartum infection. However, the results should be viewed with a critical eye of caution given the limitations of surrogate indicator to predict real clinical endpoint. Limitations of our study were also those inherent to retrospective observational studies. The multivariate logistic regression could only adjust the known confounders, not the unmeasured ones, which may be addressed simultaneously by other approaches such as randomized control trial. Thus far, however, no RCTs have been identified on the use of uterine tamponade for the treatment of PPH [17]. However, the use of uterine packing for control of PPH has fallen out of favor compared to another conservative surgical intervention UBT, which is currently more commonly used but also more expensive. Despite the controversial issue of UGP being a risk factor for postpartum infection, uterine trauma, concealed hemorrhage and ineffective packing [9, 11], the literature regarding the effect of UGP on postoperative infection is either scarce or inconclusive. The results of our study would add to our understanding of addressing such issue.

Interpretation of our findings depends on the definition of PPH and measures of postpartum infection. The definition of PPH is somewhat arbitrary. PPH has been most commonly defined as bleeding within 24 h in excess of 500 mL after vaginal delivery or 1000 mL after c-section [18]. We adopted the traditional World Health Organization definition of primary PPH, i.e., all blood losses over 500 mL from the genital tract within 24 h of the birth of a baby, which is in line with some current practice guidelines. PPH would be minor (500-1000 mL) or major (more than 1000 mL). As the estimated blood loss before UBT varied widely in former reports-from 550 to 5000 mL [19], UGP and UBT are applicable to both minor and major PPH in our routine practice. Therefore, the definition of PPH employed here is well appropriate for our particular purpose for comparison of the two approaches as second-line therapies in real-world settings.

There has been no consistent application of a standard definition for postpartum infection. Some studies focus on fever, wound complications, and endomyometritis [20, 21]. While other studies define it as a composite infectious outcome including endometritis, urinary tract infection, wound infection, and pneumonia [22, 23]. It was reported that postpartum maternal infections during c-section occurred at a rate of 4 to 46% [23-25]. Different criteria to diagnose infection, different characteristics of the population studied, and different time-points of evaluation will explain some of the variability in the incidence in various studies [26-28]. We pragmatically measured the risk of postpartum infection in our study as puerperal morbidity, which would be practically measurable in routine clinical settings and represent a clinically important event. From a clinical per-
UGP without increasing the risk of potential postpartum infection

spective and taking into account previous reports [21, 29, 30], we believe that our definition could be an appropriate index, which met our initial needs to compare the infection risk of two treatments for PPH in the usual clinical setting.

At baseline, the UGP group appeared to have longer operative time and higher proportion of placental factors causing bleeding compared to the UBT group. The surgical duration has been commonly accepted as a risk factor for infection, placental factors carry more risk for infection than uterine inertia. Therefore, the crude risk ratio of 0.74 in our study might be biased estimation in favor of the UBT group. However, the adjusted RR resulting from multivariate logistic regression was in line with the crude RR, which indicated that adjustments did not significantly alter the interpretation of the crude RR of treatments.

In the present study, high overall success rates were found for hemostasis, 91% in the UGP group and 88% in the UBT group. This finding is in agreement with previous reports, and the success rates reported in the literature range from 70 to 100% [6]. Although UGP appears to achieve a similar effectiveness of UBT, it does not have been recommended for the treatment modalities of PPH as UBT. The main reason for the limited use of UGP may be attributed to the misunderstanding of UGP and lack of trained, skilled physicians. In fact, the use of uterine packing for control of PPH became a lost skill to most obstetrician after the 1950s [7, 10, 31]. The training and experience of the physician or midwife may significantly influence the therapeutic pathway in the management of PPH.

Admittedly, strategies to be adopted with regard to PPH in developing countries may differ from those routinely practiced in developed countries because of different health care systems. While a case report and a case series study recently showed that UGP of chitosan-covered gauze is a promising option in the treatment of severe PPH, which is suitable not only for resource-poor countries but also for developed countries [32, 33]. UGP is less popular although the concerns of postpartum infection resulting from UGP have not been confirmed by solid evidence. The guideline development group of the “WHO recommendations for the prevention and treatment of postpartum haemorrhage” identified important knowledge gaps and research questions that need to be addressed through primary research [6]. Among these research questions, “What are the effects of uterine balloon or tamponade in the treatment of PPH?” should be continually assessed and tested in a wider population to determine the most suitable approach for a particular setting.

Conclusion

The results of this study indicate that UGP could be effective in addressing PPH during c-section without increasing the risk of postpartum infection when compared with UBT. Our results indicate that UGP could be added to the treatment modalities of PPH along with the provision of appropriate training. Taking into account its availability and low-cost, UGP would be used as the primary second-line therapy for PPH, especially in resource-poor settings. Further prospective observational studies or RCTs are needed to provide conclusive results on the optimal use of various uterine tamponade technologies for the management of PPH in different settings.

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Disclosure of conflict of interest

None.

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References


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