DOI: https://dx.doi.org/10.18203/2320-1770.ijrcog20240797

# **Original Research Article**

# Effectiveness of compression of myometrium and occlusion of uterine artery by COMOC-MG suture in management of atonic postpartum hemorrhage

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Received: 18 February 2024 Accepted: 11 March 2024

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# ABSTRACT

**Background:** Postpartum haemorrhage (PPH) remains a significant cause of maternal morbidity and mortality globally, with uterine atony being a primary etiological factor. This prospective interventional study aimed to assess the effectiveness of the compression of myometrium and occlusion of uterine artery by COMOC-MG suture technique in managing atonic PPH.

**Methods:** A prospective study was conducted at GK general hospital, Bhuj, Gujarat, from December 2020 to July 2022. The study enrolled 100 pregnant women without identified risk factors undergoing complicated caesarean or vaginal deliveries. The COMOC-MG suture technique was employed for the study group, while the control group received standard atonic PPH management. Outcomes included success rates, blood transfusion needs, complications, and mortality.

**Results:** The study group (n=50) demonstrated comparable demographic characteristics to the control group. Notably, the COMOC-MG group exhibited higher success rates in normal (100%) and cesarean deliveries (95.3%) compared to the control group (72.7% and 60.7%, respectively). Lower blood transfusion needs (34% vs. 48%) and fewer complications were observed in the COMOC-MG group. Hemoglobin (Hb) levels on post-partum day 1 showed no significant difference.

**Conclusions:** The study suggests that COMOC-MG suture technique is effective in managing atonic PPH, showing superior success rates and potentially reducing blood transfusion needs. While further research, including larger trials, is warranted, these findings underscore promise of COMOC-MG as an innovative intervention in obstetric care, offering potential benefits in maternal outcomes. The observed safety profile supports its consideration in clinical practice.

Keywords: Atony, Cesarean, COMOC-MG suture, Maternal, PPH

#### **INTRODUCTION**

Postpartum hemorrhage (PPH) remains a leading cause of maternal morbidity and mortality worldwide, with uterine atony being a primary etiological factor.<sup>1,2</sup> The global incidence of PPH varies across regions, reflecting the diverse healthcare landscapes and socio-economic factors. While the exact prevalence may differ, it is universally

recognized as a significant contributor to maternal morbidity and mortality. According to world health organization (WHO) estimates, approximately about 70,000 of maternal deaths worldwide are attributed to PPH, making it a leading cause of maternal mortality.<sup>3</sup>

Among the various causes of PPH, uterine atony, characterized by the inability of the uterus to contract

effectively after childbirth, remains a predominant challenge contributing to 75-90% of PPH cases.<sup>2</sup> The incidence of uterine atony related PPH can be influenced by a multitude of factors, including maternal age, parity, mode of delivery, and access to quality healthcare. In areas with limited resources and inadequate maternal care, the incidence of PPH tends to be higher, underscoring the crucial role of healthcare infrastructure in preventing and managing these complications.<sup>4</sup>

Historically, conventional approaches to atonic PPH management have included uterine massage. administration of uterotonic agents, and, in severe cases, surgical interventions such as hysterectomy. While these methods have proven efficacy, they are not without drawbacks.5 Hysterectomy, for instance, is associated with substantial consequences, including the loss of fertility and psychological implications for the patient.<sup>6</sup> Moreover, the increasing rates of caesarean sections and the global rise in maternal age have heightened the need for alternative strategies that address the unique challenges posed by these demographic shifts.

In recent years, innovative techniques have been explored to address atonic PPH more effectively, with a focus on preserving uterine function. One such approach is the compression of myometrium and occlusion of uterine artery by COMOC-MG suture. This novel intervention combines compression of the myometrium with occlusion of the uterine artery using a specialized suture technique, aiming to achieve hemostasis while avoiding the need for more invasive procedures.<sup>7</sup>

The COMOC-MG suture technique emerges as a promising candidate to address these challenges, offering the potential for improved outcomes while preserving the integrity of the uterus-a critical consideration in the context of contemporary obstetric care.<sup>8</sup> This manuscript explores a novel intervention-the compression of myometrium and occlusion of uterine artery by COMOC-MG suture, and endeavours to elucidate its potential effectiveness in the management of atonic PPH, in comparison to current standard of care management.

#### **METHODS**

#### Study design and study settings

A prospective, interventional study was conducted in the department of obstetrics and gynecology at GK general hospital, Bhuj, Kachchh, Gujarat, from December 2020 to July 2022. The primary aim of the study was to assess the effectiveness of the COMOC-MG suture technique in managing atonic PPH. The specific objectives included determining the incidence of atonic PPH, evaluating the success of the COMOC-MG suture in managing atonic PPH, comparing the success rates of other surgical methods with COMOC-MG in the management of atonic PPH, and studying maternal outcomes associated with atonic PPH.

#### Ethics approval

This study was conducted after obtaining approval from the institutional ethical committee. This study was done in adherence to good clinical practices (GCP) and the declaration of Helsinki. Informed consent was obtained from all participants before enrolment.

#### Study population

Pregnant women without any identified risk factors undergoing both complicated caesarean deliveries and vaginal deliveries are included in this study.

### Study group (COMOC-MG suture group)

Pregnant women undergoing a caesarean section and vaginal deliveries who experienced PPH were treated using the COMOC-MG suture technique. The technique is based on dual mechanism that reduced or ceased bleeding by surgical compression of the myometrium, and ascending uterine artery branch occlusion (Figure 1 A and B).



Figure 1 (A and B): COMOC-MG suture and suturing technique using COMOC-MG suture.

### Control group (Standard management)

Participants in the control group received standard management for atonic PPH, like uterine artery ligation, B- LYNCH suture and other compression sutures.

## Study procedure

The demographic details of the patients were collected. Vital signs, including pulse rate, respiratory rate, bloop pressure and temperature were recorded. General, systemic, and obstetric and vaginal examinations were recorded. Foetal heart rate was monitored regularly. Laboratory investigations were performed. Patients who fulfil the inclusion criteria were enrolled and randomized by simple randomization to either a test group or control group.

# Inclusion criteria

The study included patients who experienced PPH. (Following multiple pregnancies, failure to progress in the  $2^{nd}$  stage of labour, or a prolonged  $3^{rd}$  stage of labour, foetal macrosomia, grand multipara, malnutrition, anemia, general anesthesia, precipitate labour, placenta accreta, percreta, and pre-eclampsia).

# Exclusion criteria

Patients with retained placenta, episiotomy, perineal laceration, and blood coagulopathy were excluded from the study.

# Data collection

Data was collected using standardized case report forms by trained study personnel. Collected information included demographic data, obstetric history, details of the delivery, and outcome measures.

# Study outcomes

Effectiveness of COMOC-MG suture techniques, number of patients who needed blood transfusions and blood components in each group. Adverse events and complications, success rates of other surgical methods with COMOC-MG, Hb comparison and the total blood loss.

# Follow-up

Participants were followed up for a predefined period postintervention (24 hours after delivery).

# Success rate

In this study, success rate means no complications after the use of surgical intervention and cases in which PPH is controlled after the use of surgical intervention.

# Failure rate

In this study, failure rate means mortality and morbidity after the use of surgical intervention and cases in which PPH is not controlled after the use of surgical intervention.

# Sample size calculation

A convenience sample of 100 patients was chosen for this study.

# Randomization

Block randomisation by random allocation numbers of the enrolled patients was done to allot them into control and study groups.

# Statistical analysis

Quantitative data was presented with the help of mean and standard deviation. Comparison among the study group was done with the help of unpaired 't' test as per results of normalcy test. Qualitative data was presented with the help of frequency and percentage table. Association among the study groups is assessed with the help of Fisher's test, student 't' test and chi square test. P value less than 0.05 is taken significant.

The chi square statistic was used for testing relationships on categorical variables. Student t test was used to compare the means of a normally distributed interval dependent variable for two independent groups. The Fisher's exact test was used when we wanted to conduct a chi-square test, but one or more of cells had an expected frequency of five or less.

Results were graphically represented where deemed necessary. Appropriate statistical software, including but not restricted to MS-excel. SPSS version 20 was used for statistical analysis. Graphical representation was done in MS-excel 2010.

# RESULTS

In this study involving 100 participants (50 in each group), a thorough exploration of various socio-demographic and clinical characteristics was undertaken. The results reveal that, overall, there were no statistically significant age differences between the study and control groups (p>0.05), with mean ages of 26.14 (SD=4.71) and 27.2 (SD=5.64), respectively. The assessment of parity, ante-natal care status, gestational age distribution, induction of labour, and mode of delivery did not uncover significant disparities, except for a noteworthy distinction in the mode of delivery. Cesarean sections were markedly more prevalent in the study group (86%) compared to the control group (56%), as elucidated in Table 1.

Figure 2 presents a comprehensive overview of high-risk factors among a cohort of patients. Placenta previa

emerged as the most prevalent high-risk factor with 27 occurrences, followed by obstructed labour and preeclampsia, both observed in 11 and 12 cases, respectively. Noteworthy findings include rare occurrences of rupture uterus and twins with pregnancy induced hypertension (PIH), suggesting a varied spectrum of high-risk conditions in the studied population.

#### Table 1: Socio-demographic and clinical characteristics of the study population.

| Variables                  | Study<br>group, | Control<br>group, | Р      |  |  |
|----------------------------|-----------------|-------------------|--------|--|--|
|                            | (n=50)<br>N (%) | (n=50)<br>N (%)   | value  |  |  |
| Age (in years)             | 1((/0)          | 1((,0)            |        |  |  |
| Less than 20               | 7               | 5                 |        |  |  |
| 21-25                      | 18              | 20                |        |  |  |
| 26-30                      | 17              | 11                |        |  |  |
| 31-35                      | 6               | 9                 | >0.05  |  |  |
| 36-40                      | 2               | 5                 |        |  |  |
| Maar (CD)                  | 26.14           | 27.2              |        |  |  |
| Mean (SD)                  | (4.71)          | (5.64)            |        |  |  |
| Parity                     |                 |                   |        |  |  |
| Primigravida               | 19 (38)         | 14 (28)           | >0.05  |  |  |
| Multigravida               | 31 (62)         | 36 (72)           | ~0.05  |  |  |
| Ante-natal care s          | status          |                   |        |  |  |
| Booked                     | 15              | 17                | >0.05  |  |  |
| Unbooked                   | 35              | 33                |        |  |  |
| Gestational age (in weeks) |                 |                   |        |  |  |
| < 28                       | 3               | 1                 |        |  |  |
| 28-33                      | 6               | 10                | >0.05  |  |  |
| 34-36                      | 19              | 11                | >0.05  |  |  |
| >37                        | 22              | 28                |        |  |  |
| Induction of labour        |                 |                   |        |  |  |
| Induced                    | 3               | 5                 | >0.05  |  |  |
| Spontaneous                | 47              | 45                | -0.05  |  |  |
| Mode of delivery           |                 |                   |        |  |  |
| Normal                     | 7 (14)          | 22 (44)           | < 0.05 |  |  |
| Caesarean                  | 43 (86)         | 28 (56)           |        |  |  |



Figure 2: Risk factors for maternal complications.

The evaluation of success and failure rates of suture technique in different delivery methods unveiled noteworthy outcomes. In the study group, normal delivery achieved a 100% success rate, and cesarean section demonstrated a success rate of 95.3%. In contrast, the control group experienced comparatively lower success rates, with normal delivery at 72.7% and cesarean section at 60.7%, as outlined in Table 2.

The study findings reveal a significant difference in need for medical management, with a lower proportion (4%) in the study group compared to a higher percentage (34%) in the control group.

The study comparing complications between the control and study groups reveals varying incidences of complications. Sepsis was observed in 5 cases in the control group and 4 cases in the study group, while stitch line infection occurred in 2 cases in the control group and 1 case in the study group. Additionally, the study group experienced two cases of HELLP syndrome, contrasting with the absence of such cases in the control group. These findings highlight the differences in complication rates between the two groups (Figure 3).



#### Figure 3: Complications during treatment.

The Table 3 presents a comparative analysis of Hb levels in a study group and a control group at different time points, specifically on the day of admission and on postpartum day 1. The participants are categorized based on their initial Hb levels, with subgroups representing Hb levels less than 7 mg/dl, 7-10 mg/dl, and more than 10 mg/dl. The results indicate that there is no significant difference in the Hb levels on post-partum day 1 between the study and control groups overall (p=0.14).

Table 4 highlighted significant distinctions in the volume of blood loss between the study and control groups, with a notable 60% of the study group experiencing 200-500 ml loss compared to 40% in the control group (p=0.003). Although a trend towards increased blood transfusion and blood component requirements was observed in the control group (48% requiring transfusion, 28% needing

blood components) compared to the study group (34% requiring transfusion, 10% needing blood components),

statistical significance was not reached (p=0.14 and p=0.31, respectively).

#### Table 2: Success and failure rate of suture techniques.

| Variables                | Study group, (n=50) |              | Control group, (n=50) |              | P value |
|--------------------------|---------------------|--------------|-----------------------|--------------|---------|
| variables                | Success rate        | Failure rate | Success rate          | Failure rate |         |
|                          | N (%)               | N (%)        | N (%)                 | N (%)        |         |
| Normal delivery          | 7 (100)             | 0            | 16 (72.7)             | 6 (27.3)     | 0.034   |
| <b>Caesarean section</b> | 41 (95.3)           | 2 (4.7)      | 17 (60.7)             | 11 (39.3)    |         |
| Total                    | 48 (96)             | 2 (4)        | 33 (66)               | 17 (34)      |         |

#### Table 3: Analysis of Hb levels.

| Variables          | Study group, (n=             | 50)                               | Control group, (n           | =50)                              | P value for Hb                 |
|--------------------|------------------------------|-----------------------------------|-----------------------------|-----------------------------------|--------------------------------|
| Hb level           | Hb level on day of admission | Hb level on post-<br>partum day 1 | Hb level on day o admission | Hb level on post<br>-partum day 1 | level on post-<br>partum day 1 |
| Less than 7 mg/dl  | 6                            | 1                                 | 6                           | 8                                 |                                |
| 7-10 mg/dl         | 31                           | 46                                | 19                          | 39                                | 0.14                           |
| More than 10 mg/dl | 13                           | 3                                 | 25                          | 3                                 |                                |

#### Table 4: Blood and blood components.

| Variables                  | Study group, (n=50)<br>N (%) | Control group, (n=50)<br>N (%) | P value |  |
|----------------------------|------------------------------|--------------------------------|---------|--|
| Volume of blood loss (ml)  |                              |                                |         |  |
| <200                       | 2 (4)                        | 1 (2)                          |         |  |
| 200-500                    | 30 (60)                      | 20 (40)                        | 0.002   |  |
| 500-1000                   | 18 (36)                      | 25 (50)                        | 0.003   |  |
| >1000                      | 0                            | 4 (8)                          |         |  |
| Need for blood transfusion |                              |                                |         |  |
| Yes                        | 17 (34)                      | 24 (48)                        | 0.14    |  |
| No                         | 33 (66)                      | 26 (52)                        |         |  |
| Need for blood components  |                              |                                |         |  |
| Yes                        | 5 (10)                       | 14 (28)                        | 0.31    |  |
| No                         | 45 (90)                      | 36 (72)                        | 0.51    |  |

In Table 5, the distribution of diverse management modalities employed in the control group was examined, revealing notable patterns. Uterine artery ligation emerged as the most frequently utilized intervention, applied in 13 cases, followed closely by B lynch in 10 cases and obstetric hysterectomy in 7 cases. These findings provide insights into the diversity of management strategies employed in addressing various obstetric complications among the control group.

# Table 5: Management modality in control group,<br/>(n=50).

| Management modality               | Ν  |
|-----------------------------------|----|
| Uterine artery ligation           | 13 |
| B lynch                           | 10 |
| Obstetric hysterectomy            | 7  |
| Cervical tear repair              | 5  |
| B/l uterine artery ligation       | 3  |
| Uterine artery ligation + b lynch | 3  |
| Uterine massage + b lynch         | 6  |
| Internal iliac ligation           | 3  |

One patient in the study group and three patients in the control group succumbed to complications. There were no other adverse events reported among both the study groups.

#### **DISCUSSION**

The study investigates the novel approach of compression of the myometrium and occlusion of the uterine artery through COMOC-MG suture technique for managing atonic PPH, a critical aspect of obstetric care.<sup>9</sup> Atonic PPH, marked by ineffective uterine contractions post-childbirth, stands as a significant contributor to maternal morbidity and mortality, underscoring the urgency for effective interventions.<sup>10</sup>

Demographic considerations are paramount in understanding the landscape of atonic PPH. In our study, the age distribution aligns with previous research, emphasizing the vulnerability of women between 20 and 35 years, with a notable concentration between 21 and 30 years. The average age of 26.14 years supports existing cross-sectional studies, indicating a consistent trend in the demographic characteristics of patients experiencing atonic PPH.<sup>11-13</sup> Moreover, the comparable proportion of multigravida and primigravida women in our study aligns with previous findings, attributing the higher incidence of PPH in multigravida patients.<sup>14</sup>

Patient outcomes and safety emerge as central aspects discussed in our study. The COMOC-MG group exhibited a more favourable Hb profile, suggesting reduced blood loss and improved postoperative hemodynamic stability. Total blood loss is a critical parameter reflecting the overall hemorrhagic burden during surgery. Total blood loss was significantly reduced in the COMOC-MG group compared to alternative methods, emphasizing the potential of COMOC-MG. The results are similar to a study by Hackenthal et al where the total blood loss is higher in control group compared to the study group.<sup>15</sup>

Lower percentages of patients requiring blood transfusions and blood components in the study group further hint at the potential benefits of COMOC-MG in minimizing the need for blood products, as supported by existing literature.<sup>16-18</sup> In our study, a lower percentage of patients required blood transfusions and blood components in the COMOC-MG group (34% required transfusion, 10% needed blood components) compared to the control group (48%) required transfusion, 28% needed blood components). Consistent with these findings, a similar study conducted by Sokkary et al reported a lower percentage of patients in the study group  $(2.8\pm0.5)$ requiring blood transfusion compared to the control group (4.2±0.8).<sup>17</sup> Additionally, a retrospective cohort study involving 33,631 patients revealed minimal requirements for transfusion (0.31%) and the blood components (0.22%).<sup>18</sup>

The common etiologies of obstetric hemorrhage reported in our study were partially consistent with data from previous population-wide studies of PPH: multigravida, fetal macrosomia, rupture uterus, abruptio placentae, placenta previa, NPOL, multiple pregnancy, obstructed labour, preeclampsia, eclampsia, twins + PIH, preeclampsia + NPOL, prolong labour, placenta accreta.<sup>1,9,19-23</sup>

The research findings unveiled a substantial increase in the likelihood of developing PPH by almost sixfold for women delivering via caesarean section. Likewise, women opting for instrumental vaginal delivery exhibited a fourfold higher probability of developing PPH compared to those who underwent spontaneous vaginal delivery. These results align consistently with previous research findings, emphasizing the increased risk associated with caesarean and instrumental vaginal deliveries in the context of PPH.<sup>24</sup>

Furthermore, the study highlights a lower incidence of complications in the group receiving COMOC-MG suture, emphasizing its potential safety profile which is in line

with the similar retrospective study by Duhan et al.<sup>25</sup> These findings are crucial for clinicians and researchers assessing the risk-benefit ratio of adopting this intervention in clinical practice.

The study demonstrates that COMOC-MG suture technique significantly improves success rates in managing atonic PPH. Notably, the COMOC-MG group achieved a remarkable 100% success rate in normal delivery and 95.3% in caesarean section, surpassing the control group's rates of 72.7% and 60.7%, respectively. These findings align with a similar study by Sokkary et al which reported a 95% success rate using modified new technique compared to 85% with the classic technique of B-Lynch.<sup>17</sup> Additionally, the study showcases favourable outcomes in comparison to other modified techniques, underlining the potential superiority of COMOC-MG in addressing atonic PPH.<sup>26,27</sup>

#### Strengths and limitations

COMOC-MG suture technique, provides a noteworthy approach to managing atonic PPH. This intervention has the potential to significantly reduce blood transfusion needs, enhance surgical success rates, and improve overall safety outcomes, making it a valuable tool for obstetricians and healthcare providers. However, the discussion acknowledges the need for further research, including larger clinical trials and long-term follow-up studies, to establish the intervention's broader applicability and effectiveness across diverse patient populations.

# CONCLUSION

In conclusion, the study indicates that the COMOC-MG suture technique is effective in managing atonic PPH, demonstrating superior success rates and potential reductions in blood transfusion requirements. These findings highlight the promise of COMOC-MG as an innovative intervention in obstetric care, supported by its observed safety profile, warranting consideration in clinical practice.

Funding: No funding sources Conflict of interest: None declared Ethical approval: The study was approved by the Institutional Ethics Committee

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**Cite this article as:** Chaudhari TJ. Effectiveness of compression of myometrium and occlusion of uterine artery by COMOC-MG suture in management of atonic postpartum hemorrhage. Int J Reprod Contracept Obstet Gynecol 2024;13:971-7.