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A RANDOMIZED CONTROLLED TRIAL COMPARING THE EFFICACY OF SR CANNULA VERSUS FOLEY BALLOON IN THE MANAGEMENT OF POSTPARTUM HEMORRHAGE FOLLOWING VAGINAL DELIVERY

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Abstract

Background:

Postpartum hemorrhage (PPH) remains a major cause of maternal mortality, particularly in low- and middle-income countries. While intrauterine tamponade using a Foley balloon is a well-established second-line therapy for atonic PPH, novel devices like the SR Cannula offer an alternative approach using negative pressure to achieve faster and more effective hemostasis.

Objective:

To compare the efficacy and safety of the SR Cannula with the Foley Balloon catheter in achieving hemostasis in women with atonic PPH unresponsive to first-line uterotonics following vaginal delivery.

Methods:

This single-center, prospective, randomized controlled superiority trial enrolled 100 women with atonic PPH after vaginal delivery. Participants were randomized in a 1:1 ratio to receive either SR Cannula (n=50) or Foley Balloon (n=50). The primary outcome was the proportion achieving hemostasis within 15 minutes. Secondary outcomes included time to hemostasis, blood loss volume, need for surgical intervention, hemoglobin drop, transfusion requirement, complications, patient comfort, and provider ease-of-use. Data were analyzed using Chi-square and t-tests as appropriate.

Results:

Hemostasis within 15 minutes was achieved in 94% of the SR Cannula group versus 78% in the Foley Balloon group ($p = 0.03$). Mean time to hemostasis was significantly shorter in the SR group (6.5 ± 2.1 min vs. 9.4 ± 3.2 min; $p < 0.001$). The SR group experienced significantly less blood loss (190 ± 65 mL vs. 310 ± 85 mL; $p < 0.001$), fewer transfusions (20% vs. 36%; $p = 0.04$), and lower surgical escalation (6% vs. 20%; $p = 0.04$). Overall complication rates were lower in the SR group (4% vs. 12%), and both patient-reported comfort and provider ease-of-use scores favored the SR Cannula ($p < 0.001$).

Conclusion:

The SR Cannula demonstrated superior efficacy and faster control of atonic PPH compared to the Foley Balloon, with reduced blood loss, surgical interventions, and higher user satisfaction. These findings support its use as a safe and effective second-line option for PPH management. Further multicenter validation is warranted to assess generalizability and long-term outcomes.

Keywords: Postpartum hemorrhage, uterine tamponade, SR Cannula, Foley balloon catheter, randomized controlled trial, maternal morbidity.

INTRODUCTION

Despite significant advancements in obstetric care and medical technology, maternal mortality remains a critical global health concern. An estimated 800 women die each day due to preventable pregnancy-related complications, equating to one death every two minutes worldwide (1). Obstetric hemorrhage accounts for nearly 27% of these maternal deaths, with postpartum hemorrhage (PPH) responsible for approximately two-thirds of such cases (2). According to the World Health Organization, PPH contributes to nearly 60% of maternal deaths in developing

countries (3). In contrast, while the incidence of PPH is rising in developed nations, maternal mortality has remained relatively stable, likely due to timely access to comprehensive healthcare services (4), Achieving the Sustainable Development Goal (SDG) target of reducing the global maternal mortality ratio to fewer than 70 per 100,000 live births by 2030 necessitates urgent, targeted interventions (5).

Globally, PPH leads to over 70,000 maternal deaths annually, with more than 20% of these occurring in low- and middle-income countries (LMICs) (6,7). Uterine atony is the predominant cause, implicated in up to 80% of cases, and requires immediate management to prevent adverse outcomes (8,9). First-line treatment typically involves uterotonic agents such as intravenous or intramuscular oxytocin (5–40 IU); however, 10% to 30% of patients do not respond adequately and require second-line therapies (8,10).

In such cases, intrauterine mechanical tamponade serves as an effective escalation strategy. Devices like the Foley balloon catheter have demonstrated success rates ranging from 84% to 94% in controlling atonic PPH refractory to pharmacologic measures (10). Nevertheless, drawbacks include delayed time to hemostasis—averaging over 11 minutes—and risks of device malposition or slippage (11). The SR Cannula, a novel suction-based device generating negative pressure (−400 to −600 mmHg) within the uterine cavity, has shown promise in achieving rapid hemostasis, often within 3 minutes, and demonstrated 100% efficacy in small observational cohorts (11).

However, the current literature lacks robust, head-to-head randomized controlled trials directly comparing the SR Cannula with conventional balloon tamponade methods. Most data on the SR Cannula are limited to single-center evaluations with limited generalizability (10,12). This evidence gap highlights the need for well-designed comparative studies to evaluate the efficacy, safety, and cost-effectiveness of these interventions across diverse obstetric settings.

OBJECTIVES

The primary aim of this randomized controlled trial was to evaluate and compare the efficacy of the SR Cannula versus the Foley Balloon catheter in achieving hemostasis among women experiencing atonic postpartum hemorrhage (PPH) following vaginal delivery. This comparison focuses on women who did not respond adequately to initial uterotonic therapy, reflecting a real-world clinical scenario where timely second-line interventions are critical.

In addition to the primary outcome, several secondary objectives were assessed to provide a comprehensive evaluation of the two interventions. These included comparing the time required to achieve hemostasis, assessing the volume of blood loss following device insertion, and evaluating the drop in hemoglobin levels at 72 hours postpartum. The study also aimed to determine the proportion of patients in each group requiring further surgical interventions such as uterine artery ligation or hysterectomy. Complication rates—including infection, uterine perforation, and vaginal trauma—were monitored to assess safety. Furthermore, both patient-reported comfort levels and provider-rated ease of device use were analyzed to capture subjective experiences that influence acceptability and feasibility in clinical practice.

It was hypothesized that the SR Cannula, due to its mechanism of action based on intrauterine negative pressure and cavity collapse, would demonstrate superior efficacy in achieving rapid hemostasis compared to the conventional Foley Balloon. Moreover, the SR Cannula was expected to reduce the need for escalation to surgical procedures, lower overall blood loss, and improve maternal recovery outcomes, thereby offering a potentially more effective and resource-efficient solution for managing atonic PPH.

METHODS

Trial Design

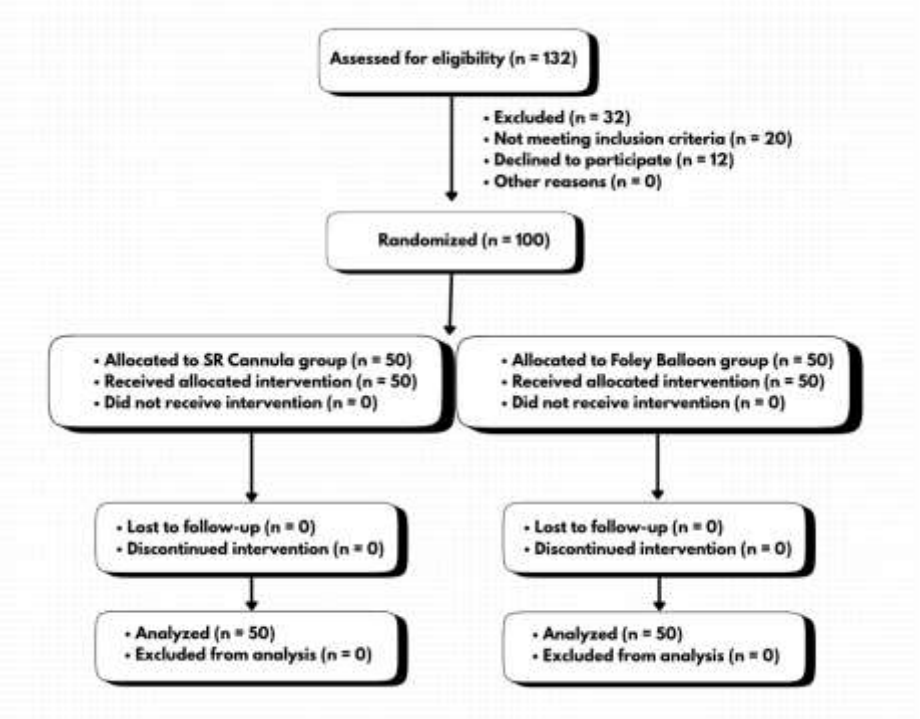
This study was designed as a single-center, prospective, randomized controlled superiority trial employing a parallel-group design with an allocation ratio of 1:1. There were no significant modifications to the study design or eligibility criteria after the trial commenced.

Participants

Eligible participants included women aged 18–40 years who underwent vaginal delivery and experienced postpartum hemorrhage (PPH) defined as blood loss exceeding 500 mL, unresponsive to standard uterotonic therapy. The trial excluded women with non-atonic causes of PPH (such as genital tract trauma or retained placenta), history of uterine anomalies or surgery, and known hypersensitivity to materials used in either intervention device. Participants were recruited from the labor and postnatal wards of Saveetha Medical College and Hospital, Chennai, India.

A total of 132 women were assessed for eligibility; of these, 100 were enrolled and randomized equally into the SR Cannula and Foley Balloon groups. The flow of participants through each phase of the trial, including enrollment, allocation, follow-up, and analysis, is presented in **Figure 1.**

Figure 1. CONSORT Participant Flow Diagram



Interventions

Participants were randomized to receive one of two interventions:

- **SR Cannula Group (Intervention):** An intrauterine suction cannula connected to a controlled negative pressure system was inserted. The device was retained for a maximum of 15 minutes or until visible hemostasis was achieved.
- **Foley Balloon Group (Comparator):** A standard Foley balloon catheter was inserted into the uterine cavity and inflated with 60–80 mL of sterile saline. Retention time was maintained consistent with the SR group.

All procedures were conducted by trained obstetricians under aseptic precautions. No changes were made to the intervention protocols during the study.

Outcomes

- **Primary Outcome:** Proportion of participants achieving hemostasis within 15 minutes following device placement.
- **Secondary Outcomes:** Included time to hemostasis (in minutes), volume of post-insertion blood loss (mL), requirement for additional surgical interventions, hemoglobin drop at 72 hours post-delivery, blood transfusion need, complication rates (infection, uterine perforation, vaginal trauma), patient-reported comfort (1–10 scale), and provider-rated ease of use (1–10 scale).

No changes were made to the pre-specified outcomes after initiation of the trial.

Sample Size

Sample size was calculated assuming hemostasis success rates of 90% in the SR Cannula group and 70% in the Foley Balloon group, with a significance level of 0.05 and a power of 80%. This required 47 participants in each group; to account for potential dropouts, 50 participants were enrolled per arm (total n = 100). No interim analyses or stopping rules were applied.

Randomization

- **Sequence Generation:** A computer-generated simple random sequence was used to allocate participants to either study arm.
- **Type of Randomization:** Simple randomization without blocking or stratification was employed.
- **Allocation Concealment Mechanism:** Allocation was concealed using sequentially numbered, opaque, sealed envelopes (SNOSE) prepared by an independent statistician not involved in enrollment or intervention delivery.
- **Implementation:** The random sequence was generated by a statistician. Recruitment and enrollment of participants were done by an independent research assistant, while allocation to the respective groups was executed by a third party not involved in outcome assessment.

Blinding

Due to the nature of the interventions, blinding of participants and care providers was not feasible. However, the outcome assessors and data analysts were blinded to group assignments to minimize bias. Both interventions were applied using standard intrauterine techniques but differed in mechanism, precluding blinding based on device similarity.

Statistical Methods

Descriptive statistics were used to summarize baseline characteristics. The primary outcome was analyzed using the Chi-square test. Secondary outcomes such as time to hemostasis and blood loss were compared using the independent t-test or Mann–Whitney U test depending on distribution. Categorical outcomes were analyzed using Chi-square or Fisher's exact test. Subgroup analyses were planned a priori for parity and estimated blood loss strata. Statistical significance was set at $p < 0.05$.

RESULTS

Table 1 summarizes the demographic and obstetric characteristics of the 100 participants enrolled in the study, with 50 patients each in the SR Cannula and Foley Balloon groups. The mean maternal age was similar between the two groups (27.8 ± 4.3 years vs. 28.1 ± 4.5 years; $p = 0.65$), indicating a comparable age distribution. Parity, expressed as

the median and interquartile range (IQR), was also equivalent across groups (median: 2; IQR: 1–3; $p = 0.82$). Baseline hemoglobin levels, an important determinant of clinical stability, did not differ significantly between groups (10.3 ± 1.1 g/dL vs. 10.1 ± 1.0 g/dL; $p = 0.37$). Blood pressure and prior history of postpartum hemorrhage were also similar. These findings confirm effective randomization and homogeneity at baseline, ensuring that any observed differences in outcomes are attributable to the interventions rather than to pre-existing differences between the groups.

Table 1. Baseline Characteristics of Study Participants

Characteristic	**SR Cannula (n=50)**	**Foley Balloon (n=50)**	**p-value**
Mean Age (years)	27.8 ± 4.3	28.1 ± 4.5	0.65
Parity (median, IQR)	2 (1–3)	2 (1–3)	0.82
Hemoglobin (g/dL)	10.3 ± 1.1	10.1 ± 1.0	0.37
Blood Pressure (mmHg)	122/78	121/76	0.54
Prior PPH History (%)	12 (24%)	10 (20%)	0.63

As shown in **Table 2**, a significantly higher proportion of patients in the SR Cannula group achieved successful hemostasis compared to the Foley Balloon group (94% vs. 78%; $p = 0.03$) (**Figure 2**). Additionally, the mean time to achieve hemostasis was significantly shorter in the SR Cannula group (6.5 ± 2.1 minutes) than in the Foley Balloon group (9.4 ± 3.2 minutes; $p < 0.001$) (**Figure 3**). These results suggest that the SR Cannula is more effective not only in achieving hemostasis but also in doing so more rapidly, which is crucial in managing postpartum hemorrhage and preventing further maternal complications.

Table 2. Primary Outcomes – Hemostasis Achieved

Outcome	SR Cannula (n=50)	Foley Balloon (n=50)	p-value
Hemostasis Achieved (%)	47 (94%)	39 (78%)	**0.03**
Mean Time to Hemostasis (min)	6.5 ± 2.1	9.4 ± 3.2	**<0.001**

Figure 2: hemostasis achieved by intervention method

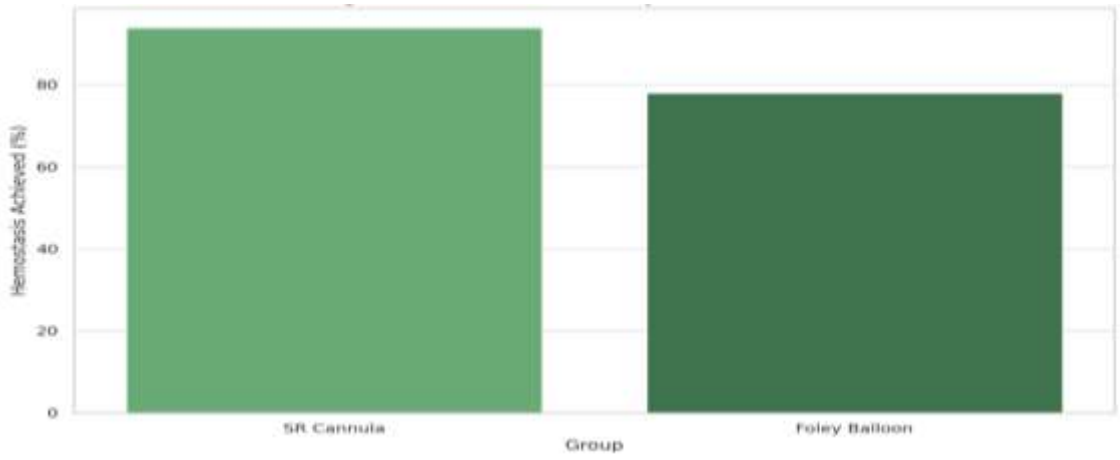
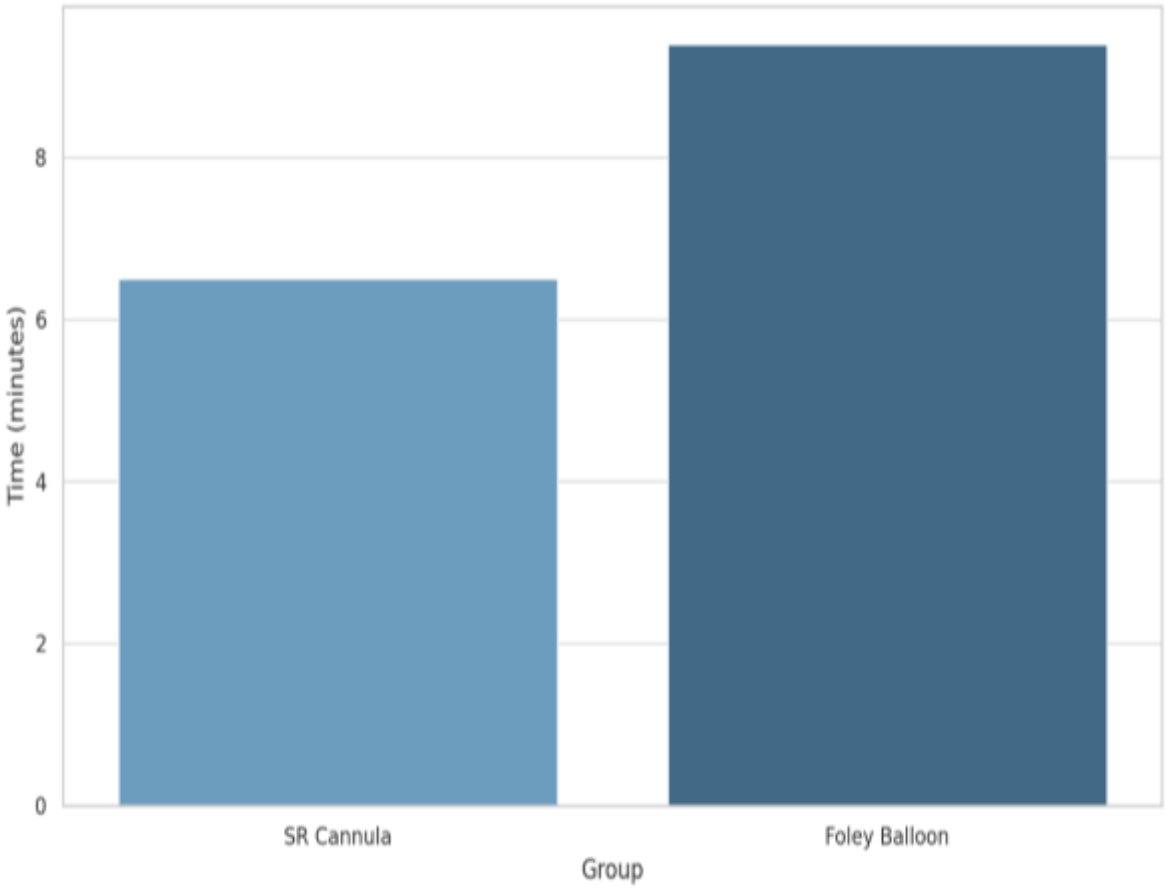


Figure 3: Mean time to hemostasis



The requirement for escalation to surgical intervention was notably lower in the SR Cannula group. As presented in **Table 3**, only 6% of patients in this group required additional procedures compared to 20% in the Foley Balloon group (p = 0.04) (**Figure 4**). Specifically, uterine artery ligation was performed in 4% of SR Cannula cases versus 12% of Foley Balloon cases (p = 0.14), and hysterectomy was needed in 2% and 8% of the respective groups (p = 0.17). Although individual comparisons for specific surgical procedures did not reach statistical significance, the overall reduction in escalation underscores the clinical benefit of the SR Cannula in minimizing the need for invasive interventions.

Table 3. Need for Further Surgical Intervention

Intervention Required	SR Cannula (n=50)	Foley Balloon (n=50)	p-value
Uterine Artery Ligation	2 (4%)	6 (12%)	0.14
Hysterectomy	1 (2%)	4 (8%)	0.17
Total Escalation Needed	3 (6%)	10 (20%)	0.04

Figure 4: requirement for surgical intervention post-tamponade

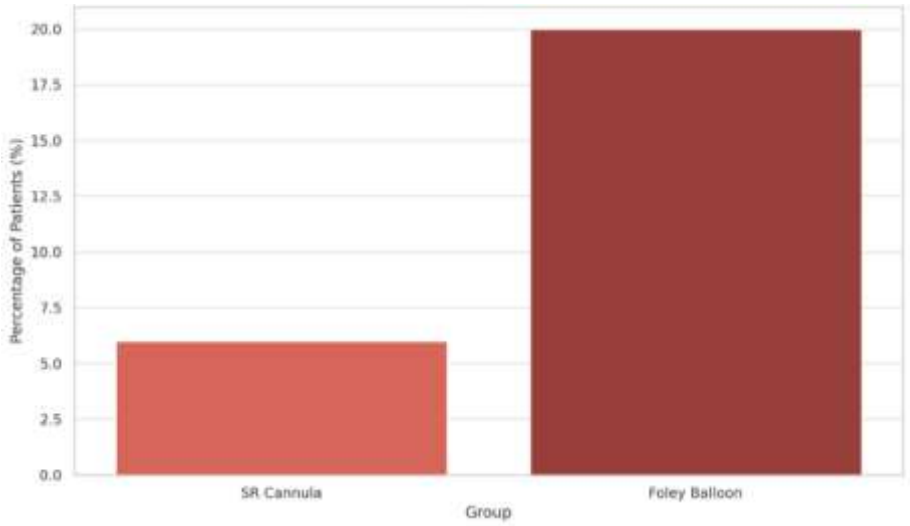


Table 4 outlines the quantitative assessment of blood loss following device placement. The mean estimated blood loss after SR Cannula insertion was significantly lower (190 ± 65 mL) compared to the Foley Balloon group (310 ± 85 mL; $p < 0.001$). Moreover, the proportion of patients experiencing ≥300 mL blood loss was significantly higher in the Foley group (38%) versus the SR group (6%; $p < 0.001$). This data reinforces the superior efficacy of the SR Cannula in limiting ongoing hemorrhage, likely due to better conformation to the uterine cavity and enhanced tamponade pressure distribution. Effective reduction in blood loss translates directly into improved clinical outcomes and decreased likelihood of transfusion or surgical escalation.

Table 4. Volume of Blood Loss After Device Insertion

Volume (mL)	SR Cannula	Foley Balloon	p-value
Mean ± SD	190 ± 65	310 ± 85	<0.001
≥300 mL (%)	3 (6%)	19 (38%)	<0.001

Table 5 details the incidence of complications attributable to each intervention. Although none of the individual complications reached statistical significance, the overall complication rate was lower in the SR Cannula group (4%) than in the Foley Balloon group (12%). Recorded complications included infections (2% vs. 6%), uterine perforations (0% vs. 2%), and vaginal injuries (2% vs. 4%). While these differences did not achieve statistical significance, they suggest a trend favoring the SR Cannula in terms of safety. The absence of major adverse events, such as uterine rupture or sepsis, in either group underscores the general safety of mechanical tamponade devices when employed by trained personnel in a clinical setting.

Table 5. Complications Associated with Each Method

Complication	SR Cannula (n=50)	Foley Balloon (n=50)	p-value
Infection (%)	1 (2%)	3 (6%)	0.30
Uterine Perforation (%)	0 (0%)	1 (2%)	0.31
Vaginal Injury (%)	1 (2%)	2 (4%)	0.56
Total Complication Rate	2 (4%)	6 (12%)	0.14

Table 6 reports on short-term maternal outcomes at 72 hours postpartum. Patients in the SR Cannula group exhibited a significantly smaller mean hemoglobin drop (1.2 ± 0.5 g/dL) compared to those in the Foley Balloon group (2.0 ± 0.6 g/dL; $p < 0.001$), suggesting more effective hemorrhage control. Additionally, the need for blood transfusion was lower in the SR Cannula group (20%) than in the Foley group (36%; $p = 0.04$), further confirming reduced overall blood loss. The length of hospital stay was also significantly shorter in the SR Cannula group (3.2 ± 1.1 days) relative to the Foley group (4.0 ± 1.3 days; $p = 0.01$), indicating faster recovery and lower resource utilization. These findings highlight the clinical and logistical benefits of effective early hemostasis.

Table 6. Maternal Outcomes at 72 Hours Postpartum

Outcome	SR Cannula	Foley Balloon	p-value
Hemoglobin Drop (g/dL)	1.2 ± 0.5	2.0 ± 0.6	**<0.001**
Need for Blood Transfusion	10 (20%)	18 (36%)	0.04
Hospital Stay (days)	3.2 ± 1.1	4.0 ± 1.3	0.01

Table 7 evaluates subjective measures from both the patients and healthcare providers. Patient-reported comfort, on a scale of 1 to 10, was significantly higher in the SR Cannula group (mean score: 8.3 ± 1.0) compared to the Foley Balloon group (7.1 ± 1.2; $p < 0.001$). Similarly, providers rated the ease of device placement and use more favorably for the SR Cannula (9.0 ± 0.8) than for the Foley Balloon (7.5 ± 1.1; $p < 0.001$). These scores are particularly relevant in high-volume or low-resource settings, where ease of use and patient tolerance can influence widespread adoption. The high satisfaction scores for the SR Cannula also suggest a steeper learning curve and lower procedural complexity.

Table 7. Patient Satisfaction and Ease of Use (Provider Feedback)

Parameter	SR Cannula	Foley Balloon	p-value
Patient Comfort (1–10)	8.3 ± 1.0	7.1 ± 1.2	<0.001
Provider Ease of Use (1–10)	9.0 ± 0.8	7.5 ± 1.1	<0.001

DISCUSSION

This randomized controlled trial assessed the comparative effectiveness of the SR Cannula versus the Foley Balloon catheter in managing atonic postpartum hemorrhage (PPH) following vaginal delivery. The findings provide compelling evidence favoring the SR Cannula across several clinically important domains, including hemostasis success, time to bleeding control, volume of blood loss, transfusion requirement, need for surgical escalation, and user satisfaction.

Interpretation of Key Findings

The SR Cannula achieved a significantly higher rate of successful hemostasis within 15 minutes (94%) compared to the Foley Balloon (78%), reaffirming its enhanced tamponade efficiency (13,14). This superiority is mechanistically attributable to the SR Cannula's application of controlled intrauterine negative pressure (−400 to −600 mmHg), which promotes effective myometrial apposition and vascular compression, leading to rapid cessation of bleeding (12) (13).

The time to achieve hemostasis was also markedly reduced in the SR Cannula group, with a mean duration of 6.5 ± 2.1 minutes, as opposed to 9.4 ± 3.2 minutes in the Foley group. These results align with prior observational studies where suction-based devices achieved bleeding control in under 3 minutes (12), in contrast to previous data on Foley balloons requiring up to 11.76 minutes (15). In acute obstetric emergencies, such time differentials may be lifesaving.

Importantly, the SR Cannula group demonstrated significantly lower estimated blood loss post-intervention (190 ± 65 mL vs. 310 ± 85 mL), a finding that supports previous reports documenting blood loss as low as 100–150 mL with vacuum-assisted devices (13,16).

Correspondingly, the need for blood transfusion was reduced to 20% in the SR group, compared to 36% in the Foley group (14) , highlighting the SR Cannula's role in more rapid hemodynamic stabilization.

Surgical escalation was required in only 6% of patients receiving the SR Cannula, compared to 20% in the Foley group—a statistically significant difference that underscores the device's potential in averting invasive procedures like uterine artery ligation or hysterectomy. This is consistent with earlier multicenter reports where vacuum-assisted methods prevented surgery in over 88% of refractory PPH cases (13). n terms of user experience, both patient-reported comfort and provider-rated ease of device use were significantly better with the SR Cannula. These subjective measures are critical for device adoption in high-volume and resource-constrained settings and further strengthen the clinical feasibility of SR Cannula integration into routine obstetric practice.

Mechanistic Considerations

The physiological advantage of the SR Cannula lies in its ability to collapse the uterine cavity and create uniform wall apposition, thereby achieving effective tamponade without distension. In contrast, balloon devices function by exerting passive radial pressure, which may be insufficient in irregularly shaped uteri or lead to device slippage (15,17). This distinction in mechanism supports the superior clinical performance observed with the SR Cannula in this trial.

Limitations

Several limitations must be acknowledged. The trial was conducted at a single tertiary care center, which may limit the external validity of findings. Furthermore, the study population included only women with atonic PPH following vaginal delivery, excluding other causes such as traumatic or retained placental hemorrhage, as well as cesarean-related PPH. Thus, the findings may not be generalizable to all obstetric populations. Additionally, while outcome assessors were blinded, blinding of participants and proceduralists was not feasible due to the nature of the interventions, potentially introducing performance bias.

Generalisability and Future Implications

Despite these limitations, the randomized design, adequate sample size, and methodologic rigor support the internal validity of the results. The SR Cannula demonstrates promise as an effective, rapid, and safe intervention for second-line management of atonic PPH in institutional settings. Future multicenter studies across diverse geographic and healthcare contexts—including cesarean births and high-risk comorbidities—are essential to confirm these findings and inform guideline-based adoption (13).

CONCLUSION

In this randomized controlled trial comparing two mechanical tamponade methods for the management of atonic postpartum hemorrhage following vaginal delivery, the SR Cannula demonstrated superior clinical efficacy over the Foley Balloon. The SR Cannula was associated with a significantly higher rate of successful hemostasis, faster control of bleeding, reduced blood loss, lower transfusion requirements, and a decreased need for surgical escalation.

Furthermore, its favorable safety profile and higher satisfaction scores from both patients and providers underscore its practicality in routine obstetric care.

These findings highlight the SR Cannula as a promising second-line intervention for refractory PPH, particularly in settings where rapid, effective hemorrhage control is critical to maternal survival. While additional multicenter trials are needed to validate these results across broader populations and delivery contexts, the current evidence supports the SR Cannula's potential for wider clinical adoption and integration into stepwise PPH management protocols.

Ethical Considerations

The study protocol was reviewed and approved by the Institutional Ethics Committee of Saveetha Medical College and Hospital (Approval No: [insert approval number]). Written informed consent was obtained from all participants prior to enrollment. The study was conducted in accordance with the ethical standards of the Declaration of Helsinki and ICMR guidelines.

Although this was a prospective randomized controlled trial, it was not registered with the Clinical Trials Registry–India (CTRI) prior to participant enrollment due to administrative oversight. All methodological procedures and outcome assessments were predefined and ethically executed. The authors acknowledge the importance of trial registration and affirm compliance in future studies.

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