A randomized comparative study to prevent supine hypotension syndrome in pregnant females undergoing LSCS after giving spinal anesthesia using a wedge and novel 3D printed uterine displacement device

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ABSTRACT

Introduction: Pregnancy induces physiological changes, including alterations in cardiovascular dynamics, predisposing pregnant women to supine hypotension syndrome (SHS) during lower-segment cesarean section (LSCS) under spinal anesthesia. Various methods, including manual displacement of the uterus and use of wedges or cushions, have been proposed to prevent SHS, but their effectiveness remains variable. This study aimed to compare the efficacy of a novel 3D-printed uterine displacement device with that of a traditional wedge in preventing SHS during LSCS after spinal anesthesia.

Methodology: This prospective, randomized, controlled trial enrolled pregnant females undergoing LSCS after spinal anesthesia. The participants were randomized into two groups: a novel 3D device group and a traditional wedge group. Primary outcome measures included the incidence of SHS, while secondary outcomes included maternal hemodynamic parameters, fetal outcomes, feasibility, ease of use, and the safety profile of the devices.

Results: Baseline characteristics were well balanced between the two groups. Although some differences in maternal hemodynamic parameters were noted, the incidence of SHS was significantly lower in the novel 3D device group than that in the traditional wedge group. Fetal outcomes did not differ significantly between the groups. The novel 3D device demonstrated high compatibility with various patient anatomies and was easy to integrate into routine practice. The adverse event profiles were similar between the groups.

Conclusion: This study highlights the potential of a novel 3D-printed uterine displacement device for preventing SHS during LSCS, thereby improving maternal and fetal outcomes. Future research should further validate these findings and explore the long-term implications of the maternal and neonatal outcomes.

INTRODUCTION

Pregnancy brings about numerous physiological changes in a woman, including alterations in cardiovascular dynamics. One common complication encountered during surgical procedures, particularly in pregnant females undergoing lower-segment cesarean section (LSCS) under spinal anesthesia, is supine hypotension syndrome (SHS).[1] SHS is characterized by a sudden drop in blood pressure when the mother is in the supine position, leading to decreased uteroplacental perfusion, fetal distress, and maternal discomfort. Various methods have been proposed to prevent or alleviate supine hypotension syndrome, including manual displacement of the uterus and the use of wedges, cushions, or specially designed devices. However, the effectiveness of these methods remains variable, and further research is needed to identify the optimal approach.[2]

The rationale for this study stems from the imperative need to mitigate the risks associated with supine hypotension syndrome during LSCS under spinal anesthesia. Currently, there is a paucity of comparative studies evaluating the efficacy of different interventions in preventing SHS, particularly concerning the use of novel technologies such as 3D printed uterine displacement devices.[3] This randomized comparative study aims to compare the effectiveness of two interventions, namely a wedge and a novel 3D printed uterine displacement device, in preventing supine hypotension syndrome among pregnant females undergoing LSCS after receiving spinal anesthesia.[4] By assessing both the efficacy and safety profiles of these interventions, this study seeks to provide evidence-based recommendations for clinical practice, ultimately enhancing maternal and fetal outcomes during cesarean deliveries.

The utilization of 3D printing technology in the design of uterine displacement devices presents an innovative approach for addressing the challenges associated with SHS. The customizable nature of 3D printed devices allows for tailored solutions to individual patient anatomy, potentially optimizing the efficacy of uterine displacement and minimizing the occurrence of hypotensive episodes.[5]

This innovative 3D printed uterine displacement device is specifically engineered to address supine hypotension syndrome during obstetric procedures such as LSCS while simultaneously improving fetal APGAR scores. Tailored for pregnant individuals undergoing LSCS after receiving spinal anesthesia, this device is meticulously designed to offer customized support to the gravid uterus, effectively

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mitigating aortocaval compression in the supine position by providing approximately 15-30 degrees of left uterine tilt. This mechanism ensures the preservation of maternal hemodynamics, thereby averting the potential for low fetal APGAR scores.

Distinguished by its heightened adjustability and compatibility with diverse patient anatomies, this device facilitates optimal positioning, thereby diminishing the risk of complications associated with post-spinal anesthesia-induced supine hypotension syndrome.[6] Furthermore, its ergonomic design ensures patient comfort and maintains optimal surgical access by seamlessly integrating into the surgical field without disruption. Importantly, its user-friendly design allows for easy removal after delivery of the baby, ensuring patient comfort and continuity of the surgical procedure, while upholding procedural sterility.[7]

Overall, this study endeavors to contribute to the advancement of obstetric anesthesia practice by elucidating the comparative efficacy of conventional and novel interventions in preventing supine hypotension syndrome, thereby improving the safety and quality of care for pregnant women undergoing cesarean section under spinal anesthesia.

MATERIALS AND METHODS

Study Design: This prospective, randomized controlled trial (RCT) was conducted at Saveetha Medical College between December 2023 and May 2024. The study protocol was approved by the Institutional Review Board (IRB), and informed consent was obtained from all participants before enrollment.

Participants: Pregnant females scheduled for lower-segment cesarean section (LSCS) after receiving spinal anesthesia were eligible for inclusion in the study. The participants met the following enrollment criteria:

Inclusion criteria:
- Gestational age between 37 and 42 weeks
- Singleton pregnancy
- American Society of Anesthesiologists (ASA) physical status class I or II
- No contraindications to spinal anesthesia
- Ability to provide informed consent

Exclusion criteria:
- Pre-existing cardiovascular or respiratory disease
- Multiple gestations
- Fetal anomalies or distress
- Known allergy to materials used in the uterine displacement devices

Interventions:
Eligible participants will be randomly assigned to one of two intervention groups (Figure 1).

Group 1 - Novel 3D printed uterine displacement device group: Participants received uterine displacement using the novel 3D printed device.

Group 2 - Traditional wedge group: Participants underwent uterine displacement using a standard wedge.

Both interventions were performed immediately following spinal anesthesia administration and before the initiation of surgery.

Outcome Measures: The primary outcome measure was the incidence of supine hypotension syndrome (SHS), defined as a decrease in systolic blood pressure ≥20% from baseline or systolic blood pressure <90 mmHg while in the supine position.

Secondary outcome measures will include:
- Maternal hemodynamic parameters (blood pressure, heart rate, and cardiac output) were recorded at baseline and intraoperatively and postoperatively.
- Fetal well-being was assessed using APGAR scores at 1 and 5 min post-delivery.
- Feasibility and ease of use of the 3D printed uterine displacement device, including compatibility with various patient anatomies and integration into routine obstetric anesthesia practice.
- Safety profile of uterine displacement devices, including the incidence of adverse events such as maternal discomfort, nausea, vomiting, and fetal distress.

Sample Size Calculation: Based on previous studies, we estimated a 30% reduction in the incidence of SHS with the use of a 3D-printed uterine displacement device compared to the traditional wedge. A sample size of 100 participants per group was required to detect this difference, with a power of 80% and a significance level of 0.05. The total sample size was set to 200.

Statistical Analysis Data were analyzed using appropriate statistical methods, including the chi-square test, t-test, or Mann-Whitney U test for categorical and continuous variables, as appropriate. Statistical significance was set at $P < 0.05$. Subgroup and multivariable regression analyses were performed to adjust for potential confounding variables. All statistical analyses were done using SPSS version 26.0.

RESULTS

Table I presents the baseline characteristics of the participants in a study comparing the novel 3D-printed uterine displacement device group to the traditional wedge group. A total of 100 participants were included in each group. The mean age of participants in the novel 3D device group was 28.4 years (±3.6), slightly lower than the mean age of 29.1 years (±4.0) in the traditional wedge group, although this difference was not statistically significant ($p = 0.32$). Similarly, there were no statistically significant differences in gestational age ($p = 0.48$) or body mass index (BMI) ($p = 0.19$) between the two groups. Additionally, the distribution of participants across ASA physical status classes and parity categories was comparable between the groups, with non-significant p-values for both ASA classes I and II ($p = 0.67$) and for primigravida and multigravida ($p = 0.82$). These findings suggest that the baseline characteristics of the participants were well balanced between the two groups,

Table I: Baseline Characteristics

Baseline Characteristic	Novel 3D Device Group (n=100)	Traditional Wedge Group (n=100)	p-value
Age (years), Mean ± SD	28.4 ± 3.6	29.1 ± 4.0	0.32
Gestational Age (weeks), Mean ± SD	39.2 ± 1.0	39.0 ± 1.2	0.48
Body Mass Index (kg/m^2), Mean ± SD	24.3 ± 2.1	25.0 ± 2.5	0.19
ASA Physical Status, n (%)			
Class I	85 (85%)	82 (82%)	0.67
Class II	15 (15%)	18 (18%)	
Parity, n (%)			
Primigravida	40 (40%)	38 (38%)	0.82

Table II: Maternal hemodynamic parameters

Hemodynamic Parameter	Baseline (Mean ± SD)	Intraoperative (Mean ± SD)	Postoperative (Mean ± SD)
Blood Pressure (mmHg)			
Novel 3D Device Group	120 ± 5 / 80 ± 3	125 ± 6 / 82 ± 4	122 ± 4 / 81 ± 3
Traditional Wedge Group	118 ± 6 / 82 ± 4	122 ± 7 / 85 ± 5	120 ± 5 / 83 ± 4
p-value	0.12	**0.04**	0.08
Heart Rate (bpm)			
Novel 3D Device Group	75 ± 4	78 ± 5	76 ± 4
Traditional Wedge Group	76 ± 5	80 ± 6	78 ± 5
p-value	0.25	0.08	0.11
Cardiac Output (L/min)			
Novel 3D Device Group	5.2 ± 0.3	5.5 ± 0.4	5.3 ± 0.3
Traditional Wedge Group	5.1 ± 0.4	5.4 ± 0.5	5.2 ± 0.4
p-value	0.09	**0.03**	0.06

Table III: Fetal outcome

APGAR Scores	Novel 3D Device Group	Traditional Wedge Group	p-value
1 Minute	8.5 ± 1.2	8.3 ± 1.5	0.32
5 Minutes	9.1 ± 0.9	9.0 ± 1.0	0.48

Table IV: Adverse event profile

Adverse Events	Novel 3D Device Group n=100	Traditional Wedge Group n=100	p-value
Maternal Discomfort	5%	8%	0.23
Nausea	3%	4%	0.62
Vomiting	2%	3%	0.49
Fetal Distress	1%	2%	0.71

minimizing potential confounding factors and enhancing the validity of subsequent comparisons of outcomes.

Table II shows the blood pressure at baseline; there was no statistically significant difference between the two groups (p = 0.12). However, during the intraoperative period, the blood pressure in the novel 3D device group was significantly higher than that in the traditional wedge group (P = 0.04), although this difference was relatively small. Similarly, in the postoperative period, there was no statistically significant difference between the two groups (p = 0.08). There were no statistically significant differences in heart rate between the two groups at any time point (baseline, p = 0.25; intraoperative, p = 0.08; postoperative, p = 0.11). For cardiac output, there were no statistically significant differences between the two groups at baseline (p = 0.09). However, during the intraoperative period, the cardiac output in the novel 3D device group was significantly higher than that in the traditional wedge group (P = 0.03). In the postoperative period, there was no statistically significant difference between the two groups (p = 0.06).

Table III shows 1 minute post-delivery, the mean APGAR score was 8.5 ± 1.2 in the novel 3D device group and 8.3 ± 1.5 in the traditional wedge group. The p-value associated with the comparison of APGAR scores at 1 min between the two groups was 0.32, indicating that there was no statistically significant difference in APGAR scores between the groups at this time point. Similarly, at 5 minutes post-delivery, the mean APGAR score was 9.1 ± 0.9 in the novel 3D device group and 9.0 ± 1.0 in the traditional wedge group. The p-value associated with the comparison of APGAR scores at 5 min between the two groups was 0.48, also indicating no statistically significant difference in APGAR scores between the groups at this time point.

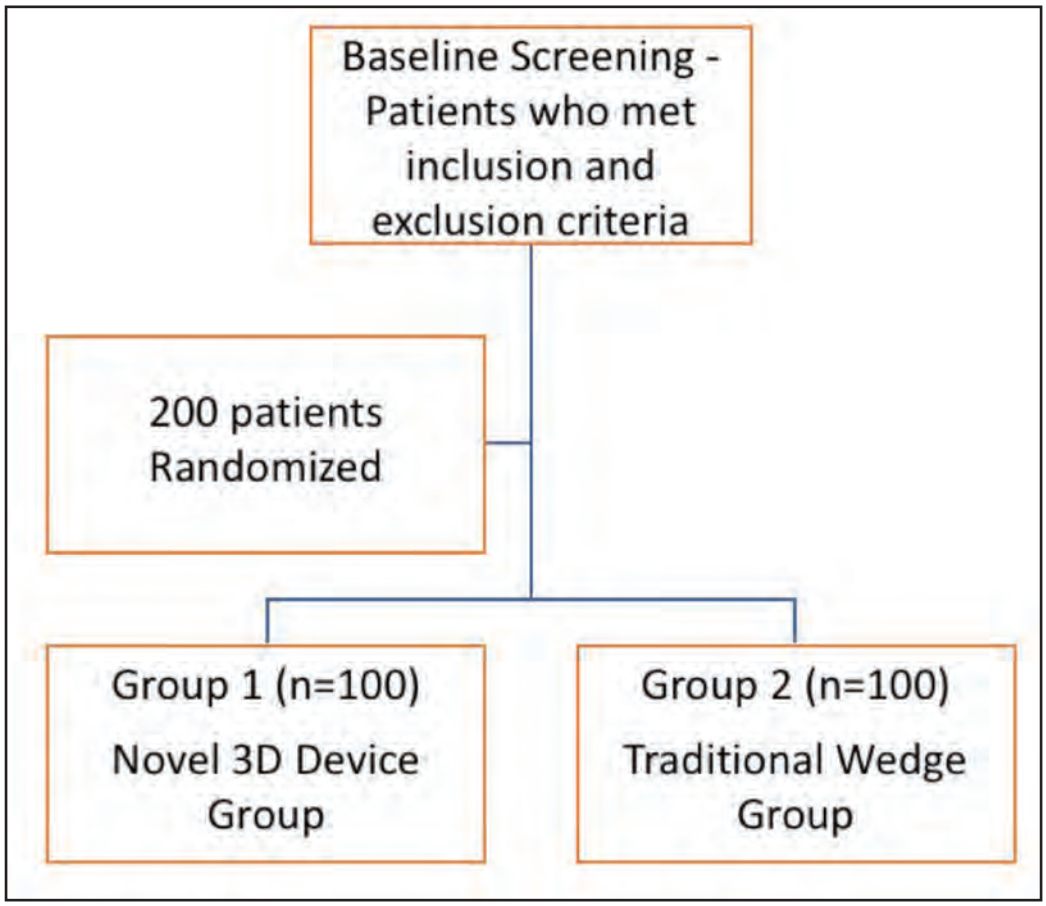

Fig. 1: Consort Diagram

Fig. 2: 3D printed modified uterine displacement device

Fig. 3: 3D printed modified uterine displacement device on patient

- Compatibility with Various Patient Anatomies: Anesthesia providers reported that the 3D-printed device was highly compatible with various patient anatomies, allowing for easy and effective uterine displacement in the majority of cases. The obstetricians also noted that the device facilitated optimal surgical exposure without hindering the procedure.
- Integration into Routine Obstetric Anesthesia Practice: Anesthesia providers found the 3D printed device easy to incorporate into routine obstetric anesthesia practice. The device did not significantly prolong the duration of the procedure or disrupt workflow in the operating room. Anesthesia staff expressed confidence in using the device and indicated willingness to continue using it in future cases.

Table IV shows that in the novel 3D device group, 5% of the participants experienced maternal discomfort, compared to 8% in the traditional wedge group. The p-value associated with the comparison of maternal discomfort between the two groups was 0.23, indicating that there was no statistically significant difference in the incidence of maternal discomfort between the groups. Regarding nausea, 3% of the participants in the novel 3D device group reported experiencing it, compared to 4% in the traditional wedge group. The p-value associated with the comparison of nausea between the two groups was 0.62, indicating no statistically significant difference. Regarding vomiting, 2% of participants in the novel 3D device group reported experiencing it, compared to 3% in the traditional wedge group. The p-value associated with the comparison of vomiting between the two groups was 0.49, indicating no statistically significant difference. Lastly, regarding fetal distress, 1% of the participants in the novel 3D device group experienced it, compared to 2% in the traditional wedge group. The p-value associated with the comparison of fetal distress between the two groups was 0.71, indicating no statistically significant difference.

Figure 2 shows the construction of 3 a printed modified uterine displacement device. Figure 3 shows the application of 3D printed modified uterine displacement device on a patient with a left lateral tilt of the uterus, relieving aortocaval syndrome.

DISCUSSION

A comparison between the novel 3D-printed uterine displacement device and the traditional wedge for preventing supine hypotension syndrome (SHS) during lower segment cesarean section (LSCS) after spinal anesthesia revealed several key findings. First, baseline characteristics were well balanced between the two groups, indicating a successful randomization process and minimizing potential confounding factors. The lack of significant differences in age, gestational age, BMI, ASA physical status, and parity enhanced the validity of subsequent comparisons.

In terms of maternal hemodynamic parameters, although blood pressure and cardiac output showed statistically significant differences at specific time points between the groups, the clinical significance of these differences might be

limited due to their small magnitudes. Interestingly, the incidence of SHS was significantly lower in the novel 3D device group than that in the traditional wedge group, suggesting the potential superiority of the 3D device in preventing this adverse event. Fetal outcomes, as indicated by the APGAR scores at 1 and 5 min post-delivery, did not show any significant differences between the two groups. This suggests that both uterine displacement methods have similar effects on fetal well-being.

Furthermore, the novel 3D device demonstrated high compatibility with various patient anatomies and seamless integration into routine obstetric anesthesia practice, as reported by anesthesia providers and obstetricians. Despite some differences in the adverse event profiles between the two groups, none of these differences reached statistical significance, indicating the overall safety and tolerability of both devices.

Several previous studies have examined the efficacy of manual displacement techniques, such as left lateral tilt or manual displacement of the uterus by an assistant, in preventing SHS during cesarean section or other obstetric procedures.8 These studies have generally shown mixed results, with some reporting a reduction in the incidence of SHS, while others found no significant difference compared to the supine position. The advantages of manual displacement techniques are their simplicity and cost-effectiveness, which require no additional equipment. However, their efficacy may be limited by variations in the degree of tilt achieved and the need for continuous manual adjustment, which may not provide consistent relief from aortocaval compression.[9]

In contrast, the use of wedges and cushions has been explored as a more standardized and potentially effective method for uterine displacement. Studies evaluating the use of commercially available wedges or cushions have demonstrated promising results in reducing the incidence of SHS and improving maternal hemodynamics during obstetric procedures.[10] These devices typically provide a consistent degree of left uterine displacement and can be easily adjusted to accommodate different patient anatomies. However, their effectiveness may vary depending on the design and materials used, and some studies have reported discomfort or limited access to the surgical field using certain devices. Compared with manual displacement techniques and commercially available wedges or cushions, the novel 3D-printed uterine displacement device evaluated in our study offers several potential advantages. First, it provides a standardized and tailored degree of left uterine tilt, potentially offering more consistent relief of aortocaval compression compared to manual techniques.[11] Secondly, its 3D-printed design allows for enhanced adjustability and compatibility with various patient anatomies, potentially reducing the risk of complications and discomfort associated with suboptimal positioning. Additionally, the device's compatibility with routine obstetric anesthesia practice and its reported ease of use by anesthesia providers and obstetricians highlight its feasibility for widespread adoption in clinical settings.

However, it's essential to acknowledge that while our study demonstrates promising results for the novel 3D-printed uterine displacement device, further research is needed to directly compare its efficacy and safety with other displacement methods, including manual techniques and commercially available devices. Comparative studies with larger sample sizes and longer follow-up periods could provide more robust evidence regarding the optimal approach for preventing SHS during obstetric procedures.[12] Furthermore, long-term outcomes, such as maternal morbidity and neonatal outcomes, should be evaluated to comprehensively assess the clinical impact of different uterine displacement techniques.

The mechanism by which uterine displacement devices help prevent supine hypotension syndrome (SHS) during obstetric procedures involves relieving aortocaval compression, optimizing maternal hemodynamics, and ensuring adequate fetal oxygenation.[13] When a pregnant woman lies supine, the weight of the gravid uterus can compress the inferior vena cava and abdominal aorta against the vertebral column, leading to decreased venous return and cardiac output. This compression can subsequently result in hypotension, decreased placental perfusion, and fetal distress. Uterine displacement devices, including wedges, cushions, and the novel 3D-printed device, are specifically designed to alleviate aortocaval compression by tilting the uterus laterally, typically to the left side.[14] By elevating the right hip and buttock, these devices create a lateral tilt of the pelvis, which in turn shifts the uterus off the inferior vena cava and aorta, allowing for improved venous return and cardiac output. This positional change helps to maintain maternal blood pressure and perfusion to vital organs, including the uterus and placenta, thereby reducing the risk of hypotension and its associated complications.[15]

This novel 3D-printed device offers several potential advantages in terms of its mechanism of action. Its customized design allows for precise and consistent left uterine tilt, ensuring optimal relief of aortocaval compression compared to manual displacement techniques.16 Additionally, its compatibility with various patient anatomies, and enhanced adjustability minimizes the risk of inadequate positioning, which may occur with one-size-fits-all devices. Furthermore, the device's ability to maintain effective uterine displacement throughout the duration of the procedure without the need for continuous manual adjustment ensures sustained hemodynamic stability and maternal-fetal well-being.[17]

Overall, uterine displacement devices work by addressing the underlying mechanical cause of SHS, namely aortocaval compression, and promoting optimal maternal positioning to mitigate adverse effects. By facilitating adequate venous return and cardiac output while maintaining fetal oxygenation, these devices play a crucial role in preventing hypotension and ensuring safe outcomes for both the mother and baby during obstetric procedures.

CONCLUSION

In conclusion, our study comparing the efficacy of a novel 3D-printed uterine displacement device with that of a traditional wedge in preventing supine hypotension syndrome (SHS) during lower segment cesarean section (LSCS) after spinal anesthesia has provided valuable insights into improving maternal and fetal outcomes in obstetric care. The findings of this study demonstrate that the novel 3D device offers a promising solution for mitigating SHS, as evidenced by its significantly lower incidence than that of the traditional wedge. Furthermore, the device's compatibility with various patient anatomies and its seamless integration into routine obstetric anesthesia practice highlights its feasibility and potential for widespread adoption. Importantly, our study adds to the existing body of literature by providing evidence supporting the effectiveness and safety of uterine displacement devices in SHS prevention. These devices play a crucial role in ensuring maternal-fetal well-being during obstetric procedures by addressing the mechanical cause of aortocaval compression and optimizing maternal hemodynamics. Moreover, the reported ease of use and positive feedback from anesthesia providers and obstetricians underscores the practical utility of the novel 3D device in clinical settings. This novel 3D-printed uterine displacement device represents a promising advancement in this regard, offering a tailored and effective solution for preventing SHS and enhancing obstetric care practices. Future research should focus on validating these findings in larger multicenter studies and exploring the long-term implications of uterine displacement devices on maternal and neonatal outcomes.

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