Research Article

## Comparison of the Incidence of Maternal Hypotension during Elective Cesarean Delivery under General Anesthesia using the LMA Supreme between Left Lateral Table Tilt and Supine Position: A Randomized Controlled Trial

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#### **ABSTRACT**

**Background:** Current recommendations for term women undergoing cesarean delivery with general anesthesia include maintenance of left lateral tilt for uterine displacement until delivery. No randomized controlled trial on the effect of the maternal position on blood pressure during elective cesarean delivery under general anesthesia has been investigated.

**Methods:** One hundred parturients who underwent cesarean delivery under general anesthesia with an LMA were randomized to the supine group (n=50) or 15° left tilt group (n=50). The primary outcome was the incidence of hypotension (defined as an SBP was less than 80% of baseline from the induction to delivery or SBP less than 90 mmHg).

**Results:** The primary outcome was the incidence of hypotension and the incidence of hypotension of left tilt group and supine group were 2% and 10% respectively and there was no significant difference (P=0.09). The secondary outcome of the first-insertion attempt success rate of SLMA was the same in both groups: 100%. Time to effective ventilation was 22.4+1.8 s for the left tilt group and 22.3+1.6 s for the supine group and there was no significant difference (P=0.64). Time from induction to delivery was  $8.8 \pm 1.2$  min for the left tilt group and  $8.4 \pm 1.1$  min for the supine group and there was no significant difference (P=0.17). There were no significant differences in APGAR scores at 1 and 5 min and umbilical artery cord pH between the two groups. And we did not find regurgitation or aspiration in any of the parturients.

**Conclusions:** There was no significant difference between the maternal supine position and left tilt position at the incidence of hypotension during elective cesarean delivery with general anesthesia in healthy term women.

Keywords: Cesarean delivery; General anesthesia; Left lateral table tilt; The LMA supreme

#### INTRODUCTION

Currently, spinal anesthesia is the first choice for cesarean section. Hypotension following spinal anesthesia for cesarean section can occur in up to 80% of women without prophylactic measures and can cause nausea and vomiting, if hypotension is not corrected, it can be a risk for the mother and foetus. However, some parturients need general anesthesia. Current recommendations for term women undergoing cesarean delivery with general anesthesia include maintenance of the left lateral

tilt for uterine displacement until delivery, based on the premise that the supine position will result in aortocaval compression, maternal hypotension and fetal compromise. Crawford et al. reported that 150 parturiens undergoing elective cesarean delivery with general anesthesia and superior neonatal clinical and acid-base status were found in women who were tilted. Several reports have shown that using laryngeal mask airways is safe during elective cesarean delivery under general anesthesia. The LMA Supreme (SLMA) is a single-use LMA with a double lumen design that allows separation of the respiratory tract and

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the alimentary tract, reducing the risk of aspiration. No randomized controlled trial on the effect of maternal position on blood pressure during elective cesarean delivery under general anesthesia has been investigated [1].

#### MATERIALS AND METHODS

This study was approved by the Institutional Review Board at the Quanzhou Macare Women's Hospital in China. All parturients provided written informed consent prior to study participation. The study was registered in the Chinese Clinical Trial Registry (ChiCTR2100053698, registered on November 27, 2021).

From December 2021 through October 2022, we recruited American Society of Anesthesiologists' physical status II parturients who were scheduled for elective cesarean delivery and who preferred general anesthesia at Quanzhou Macare Women's Hospital, aged 18 to 50 years, non-laboring, at term with singleton uncomplicated pregnancies and fasted for at least six The exclusion criteria were pregnancy-induced hypertension, diabetes mellitus, uterine abnormalities (e.g., large fibroids, bicornuate uterus), potentially difficult airways (Modified Mallampati grade 4, upper respiratory tract or neck pathology), gastroesophageal reflux disease, Body Mass Index (BMI) ≥ 35 kg/m<sup>2</sup>, fetal intrauterine growth restriction and alcoholism or illicit drug use. The number of deliveries in our hospital ranges from 60-80 per month, with a cesarean section rate of 35-45% and approximately 80% of the parturients choose general anesthesia due to personal preference [2].

The majority of cesarean deliveries at Quanzhou Macare Women's Hospital are performed under general anesthesia using the LMA Supreme (SLMA). The size of the SLMA used was choosed by recommendations of the manufacturer. However, the attending anesthesiologist can choosed a more appropriate size based on the parturient's weight, BMI and mouth opening. Four anesthesiologists with more than ten years of experience with the SLMA participated in the trial.

Once the parturients were enrolled, they were randomized into 2 groups and allocation was concealed using sealed opaque envelopes prepared by a statistician. The two groups were the Left tilt Group (LG) and Supine group (SP). The parturients and anesthesiologists were not blinded to the assigned group and the data were collected by an independent person.

Parturients were given 50 mg of ranitidine intravenously one hour before surgery. In the operating room, we kept the surgical table horizontally with the SG and with the LG, the surgical table was turned to 15° of left lateral tilt. Electrocardiogram, pulse oximetry, capnography and noninvasive blood pressure measurements were applied to the parturient. Blood pressure was measured every 2 minute on the right arm for a total of three measurements. The mean of the three measurements was the baseline blood pressure. The baseline blood pressure in the LG was obtained in the left tilt position [3].

In the left tilt group, a wide webbing strap was used to hold the parturient across the upper thighs and chest. With these provisions, we found that patients could be held securely in the

left-tilt position. The incline of the surgical table was verified by a digital inclinometer (DL294002, Deli company, China).

In the LG, after the uterine incision, the surgical table was turned horizontally to facilitate the application of fundal pressure by an assistant and access to the head of the neonate by the primary obstetrician during delivery. When fundal pressure was applied during surgery, positive pressure ventilation was briefly halted to reduce the risk of gastric insufflation.

Preoxygenation for three minutes, a coload of 10 ml/kg lactated Ringer's solution was administered during 5 to 10 min, all paturients received a modified rapid sequence induction with intravenous propofol 2 mg/kg followed by rocuronium 1.0 mg/kg. Cricoid pressure was not applied in our study. One minute after induction, the SLMA was inserted using the technique described by the manufacturer. The ability to ventilate was confirmed as evidenced by the presence of carbon dioxide trace on capnography. Following successful SLMA placement, a pre-mounted #14 gastric tube was advanced through the gastric drainage channel, then the suction begun. After two attempts, if the placement of SLMA was still failed or more than 80 sec or when desaturation occurred (SpO<sub>2</sub><92%), the paturient's airway was secured using direct laryngoscopy and tracheal intubation. Parturients were ventilated (volume controlled) with a tidal volume of 6 to 10 mL/kg at 10 to 16 breaths/min, targeting an end-tidal carbon dioxide concentration of 35 mmHg to 45 mmHg. Maintenance of general anesthesia was achieved with 1.5 to 2.0% sevoflurane in a 50% mix of nitrous oxide and oxygen. 1 minute after the use of sevoflurane, the obstetrician started the operation [4].

BP was measured every minute after induction and we recorded the SBP and Heart Rate (HR) every minute until delivery. If the SBP was less than 80% of the baseline value or less than 90 mmHg, BP was measured again immediately. If the SBP was still less than 80% of the baseline value or less than 90 mmHg, the phenylephrine 50 ug was given intravenously. One minute later, if the SBP was still less than 80% of baseline, then phenylephrine 100 ug was given intravenously. After the use of 100 ug phenylephrine, if the SBP was still less than 80% of baseline, any other measures could be used including ephedrine, epinephrine, additional intravenous fluid or more rapid delivery and if the patient was supine, the surgical table could be tilted to the left lateral tilt. If the maternal HR was less than 40 beats/min, 0.5 mg of atropine was given intravenously.

After delivery, intravenous opioids and oxytocin were administered, sevoflurane was turned to 1% and BP was measured every 5 minutes. At the end of surgery, reversal of muscle paralysis was given, then suctioning and removal of the orogastric tube were performed. After achieving adequate spontaneous respiration and consciousness, the SLMA was removed and inspected.

The primary outcome was the incidence of hypotension (defined as an SBP less than 80% of the baseline or SBP less than 90 mmHg from the induction to delivery).

The secondary outcomes included the following:

- The first-insertion attempt success rate of the SLMA (We defined an insertion attempt as the insertion and complete.
- Removal of the airway device and recorded the number of attempts required.
- The incidence of regurgitation (defined as gastric contents identified in the mouth with pH<4) and the incidence of aspiration (defined as gastric contents identified on the inner bowl of the SLMA with pH<4).
- Umbilical artery cord pH.
- Neonatal Apgar scores [5].

#### Statistical analysis

Primary outcome measures of the incidence of hypotension and secondary outcomes, namely the first-insertion attempt success rate of the SLMA, incidence of regurgitation and incidence of aspiration were treated as categorical data. The secondary outcomes, including time to effective ventilation, umbilical artery cord pH and Apgar score, were compared by unpaired t tests.

Categorical data were analysed using the *Chi-square* test or Fisher's exact test. Significance level was set at p-value<0.05 and all tests were two-sided.

Datas were analysed using IBM SPSS 22.0 software (Armonk, NY, USA).

The incidence of hypotension was approximately 20% in late pregnancy when the parturients were in supine position, as reported in prior studies. The incidence of hypotension in the left tilt group was zero under general anesthesia. For a two-tailed analysis with  $\alpha$  0.5 and 90% power, we calculated a sample size of 47 per group. We therefore aimed to enroll 50 patients per group.

### **RESULTS**

First, our study plan was from December 2021 to May 2022. However, we did not obtain enough ideal cases and the study

**Table 1:** Maternal demographics.

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	Left tilt group (n=50)	Supine group (n=50)	P value		
Age (Yr)	30.8 ± 4.0	31.2 ± 3.8	0.59		
Height (Cm)	161.4 ± 4.4	161.3 ± 4.5	0.93		
Weight (Kg)	69.8 ± 9.0	69.5 ± 8.6	0.88		
BMI (kg/m <sup>2</sup> )	26.8 ± 3.1	26.7 ± 3.2	0.94		
Gestational age (wk)	38.4 ± 0.8	38.3 ± 0.8	0.92		

Note: The values represent mean ± SD. Continuous variables were compared by unpaired t test, BMI=Body Mass Index

#### Maternal haemodynamic parameters

Blood pressure data are presented in Table 2. Baseline SBP was similar between groups: Blood pressure was  $118 \pm 8$  mmHg for the left tilt group and  $119 \pm 9$  mmHg for the supine group (P=0.26). From induction to delivery, the SBP changed from

parturients between December 2021 and October 2022. There were 9 parturients who did not give consent and 11 parturients did not meet the recruitment criteria. Among the 11 parturients, 9 parturients were excluded because of elevated SBP in the operating room before anesthesia and 2 parturients were excluded because they fasted for less than 6 hours. A total of 100 parturients were randomized (left tilt, n=50; supine, n=50) and there was no withdrawal or dropout (Figure 1) [6].

was extended to October 2022. Finally, we screened 120

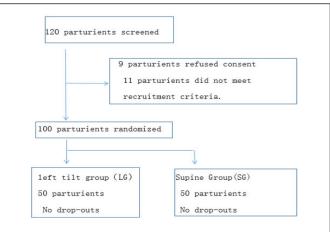


Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

#### Maternal demographics

There were no significant differences in maternal age, height, weight, BMI and gestational age between groups (Table 1).

-19.2% to 21.3% in the left tilt group and the SBP changed from -19.4% to 20.2% in the supine group. There was no SBP less than 80% of baseline from the inducion to delivery. However, there was one case (2%) which SBP was less than 90 mmHg at 1 min after induction in the left tilt group and five cases (10%) which SBP were less than 90 mmHg at 1 min after induction in

the supine group. In the six cases which SBP were less than 90 mmHg, the lowest SBP was 87 mmHg.

The primary outcome was the incidence of hypotension and the incidence of hypotension were 2% in the left tilt group and 10% in the supine group respectively, but there was no significant difference (P=0.09). After induction, compare to baseline, SBP was significantly lower at 1 min, with an average of 15% and 14.7% between the two groups, but there was no significant difference (P=0.52). No phenylephrine was given in any case, because after SBP was remeasured, they were all more than 90 mmHg.

Heart rates are presented in Table 2. Baseline HR was similar between the groups: Heart rate was  $85 \pm 5$  mmHg for the left tilt group and 85 ± 6 mmHg for the supine group (P=0.98). After induction, compared to the baseline, HR was significantly greater in 4 min, with average of 27.3% and 28.5% between the two groups, but there was no significant difference (P=0.18). No atropine was given in any case [7].

**Table 2:** Maternal haemodynamic parameters.

Left tilt group (n=50)	Supine group (n=50)	P value
118 ± 8	119 ± 9	0.26
(-19.2, 21.3)	(-19.4,20.2)	
1 (2%)	5 (10%)	0.09
85 ± 5	85 ± 6	0.98
	118 ± 8 (-19.2, 21.3) 1 (2%)	118 ± 8

Note: Values are presented as frequency (%), mean ± SD

The anaesthetic outcomes and foetal and neonatal outcomes are presented in Table 3. The secondary outcome of the firstinsertion attempt success rate of the SLMA was the same in both groups: 100%. No case need second insertion of SLMA. Time to effective ventilation was 22.4+1.8 s for the left tilt group and 22.3+1.6 s for the supine group and there was no significant difference (P=0.64). Time from induction to delivery was  $8.8 \pm$ 1.2 min for the left tilt group and 8.4  $\pm$  1.1 min for the supine group and there was no significant difference (P=0.17). There were no significant differences in APGAR scores at 1 and 5 min and umbilical artery cord pH between two groups. And we did not find regurgitation or aspiration in all the parturients.

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Table 3: Anesthetic and foetal and neonatal outcomes.

	Left tilt group (n=50)	Supine group (n=50)	P value
First-insertion attempt success rate of SLMA (%)	100	100	
Time to effective ventilation (s)	22.4 ± 1.8	22.3 ± 1.6	0.64
pH of SLMA surface	7.0 ± 0.1	7.1 ± 0.2	0.56
APGAR score 1 min	8.4 ± 0.5	8.3 ± 0.5	0.23
APGAR score 5 min	9.9 ± 0.2	9.9 ± 0.1	0.17
Umbilical artery cord	7.27 ± 0.02	7.28 ± 0.01	0.14
Induction to delivery	8.8 ± 1.2	8.4 ± 1.1	0.17

#### **DISCUSSION**

The key finding in our study was that although the incidence of hypotension was higher in supine position (10%) than left tilt position (2%) during elective cesarean delivery with general anesthesia in healthy term women, but there was no significant difference(P=0.09). Crawford, et al. reported 150 parturiens undergoing elective cesarean delivery with general anesthesia using endotracheal intubation, 63 of whom were tilted 15° (for the convenience of the surgeons, most of the parturients were tilted to the right), 87 of whom were supine and superior neonatal clinical and acid-base status was found in women who were tilted, but did not mention of randomization or maternal hemodynamics. Why left uterine displacement did not have obvious effect on the maternal and neonatal outcomes in our study after Crawford et al. found a significant effect, the reasons may be following: The performance of modified rapid sequence induction and one minute later the insertion of SLMA was performed, the insertion of SLMA would stimulate stress hormones and increase the BP; The lower ventilatory pressures associated with positive pressure ventilation with the LMA compared to endotracheal intubation improve pre-load enough that the benefits of left uterine-displacement are not required; Crawford et al. used a wedge, maybe there is better displacement with a wedge than a table tilt; the Crawford study had less strenuous exclusion criteria compared to our study (e.g., any woman with a BMI over 35 was excluded), maybe the exclusion criteria from our study excluded some potential parturients who may have benefited from left uterine displacement; The Crawford study used left and right uterine displacement (for the convenience of the surgeons, most of the parturients were tilted to the right), maybe right uterine displacement is more effective in some circumstances like breech presentations according to Y Hirabayashi, et al. report [9].

To our knowledge, this is the first randomized controlled clinical trial that investigated the effects of maternal position on blood pressure during sLMA use for cesarean delivery with general anesthesia. Many clinical trials compared maternal tilt versus the supine position during cesarean section with general anesthesia from the 1970's, but none of them both mentioned randomization and maternal haemodynamics. Ansari et al., reported that 30 parturiens with cesarean delivery using general anesthesia were divided into "table tilted (10° left tilt position)" and "table not tilted", none of them developed hypotension. Downing et al. reported 100 parturiens with elective cesarean section under general anesthesia were divided at random into two groups, 50 tilt (10°) and 50 supine, no mention of maternal haemodynamics or vasopressor use. Matorras et al. reported performing the cesarean section in emergent cases under general anesthesia in partial lateral position had no advantages for the mother or the fetus, but this report did not mention hypotension or vasopressor use during surgery.

The tilt group in our study were all towords to the left side and it surely bring some inconvenience for the surgeons. The time from induction to delivery for the left tilt group was 24 s longer than the supine group, but there was no significant difference. It took more time to delivery the baby for the left tilt group, possibly because all of our obstetricians stood on the right side

of the patient when operating and the left tilt position made it more difficult for the obstetricians to operate in the left tilt position than in the supine position.

The first-insertion attempt success rate of the SLMA in our study was 100% in each group, which is comparable to other studies which range from 98 to 99.1% using the SLMA for cesarean section.

The time to effective ventilation was 22.4+1.8 s for the left tilt group and 22.3+1.6 s for the supine group. Parturient's position was not associated with a significant difference in the time to effective ventilation.

Parturients are considered to be at higher risk for gastric regurgitation and pulmonary aspiration. However, we did not find any clinical evidence of regurgitation or aspiration in our study. It could be attributed to second generation LMA could provide a better pharyngeal seal that prevents stomach insufflation and regurgitated gastric contents from entering the airway. Our results was similar with previous studies.

Fetal outcomes were similar between the two groups and the outcomes were satisfactory. Several studies have shown similar fetal outcomes with general anesthesia.

There are several limitations in this study. First, all women were no laboring and healthy and it is unknown whether our findings apply to laboring parturients or parturients with complicated conditions such as preeclampsia or morbid obesity. Second, high risk parturients were excluded to reduce the risk of gastric regurgitation or aspiration and all parturients were fasted for at least 6 hours. Thus, it is unknown whether our findings apply to obstetric populations deemed to be at high risk of regurgitation or aspiration. Third, the mean BMI in our study was lower than that in other studies and the results may be different for parturients with different ethnic backgrounds. Fourth, this study involved very experienced anesthesiologists, each with more than ten years of experience in using the SLMA and the findings may not apply to hospitals where the use of the SLMA is less common [10].

#### **CONCLUSION**

We found that there was no significant difference between the maternal supine position and left tilt position at the incidence of hypotension during elective cesarean delivery with general anesthesia in healthy term women. These figures are remarkable and call for confirmation by other researchers.

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# AVAILABILITY OF DATA AND MATERIALS

The datasets generated and analysed during the current study are available from the corresponding author on reasonable request.

#### **AUTHOR'S CONTRIBUTION**

**Xinghui Huang:** Study design, data collection, data analysis, revising the article critically for important intellectual content and final approval of the version to be submitted.

**Weiyu Yao:** Study design, data collection, patient recruitment and final approval of the version to be submitted.

Qianlin Xie: Data collection, patient recruitment and final approval of the version to be submitted.

**Qunjie Li:** Data analysis, revising the article and final approval of the version to be submitted. All authors read and approved the final manuscript.

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