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Research article

Maternal care bundle: The effect of a multimodal approach on the prevention of maternal hypotension following spinal anesthesia in parturients undergoing elective or urgent cesarean section



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ABSTRACT

Background and Aim: Many techniques to prevent spinal induced hypotension in cesarean section have been advocated; but no one technique proved to be totally effective. The aim of this cohort interventional study was to investigate the efficacy of application of multimodal approach to decrease the incidence of hypotension (defined as mean arterial blood pressure ≤60 mmHg) following spinal anesthesia in parturients undergoing elective or urgent cesarean section.

Patients and Methods: In this prospective cohort interventional study, 159 American Society of Anesthesiologists (ASA) classification I-II parturients undergoing elective or urgent cesarean section were enrolled. All patients received maternal care bundle which consisted of; fixed low dose of bupivacaine (7.5 mg + fentanyl 25 µg), coloading with 15 ml/kg lactated Ringer's, placement of the patient in the supine wedged position, administration of 9 mg ephedrine sulphate IV after intrathecal injection and placement of graduated compression stockings (GCS) in the elevated leg position >45° and maintaining leg elevation at 20° following application of GCS. Demographic data, spinal anesthetic technique variables, fluid intake and urine output were documented. Mean arterial blood pressure, heart rate and oxygen saturation were recorded at baseline T0 (before spinal anesthesia administration), T1 (5 min following intrathecal injection of local anesthetics), T2 (15 min), T3 (30 min) and at T4 (end of procedure prior to PACU transfer). Total dose of ephedrine and any complication was documented.

Results: Incidence of hypotension after 5 min (T1) was 17.6%, at 15 min (T2) was 3.8% and at 30 min (T3) was 5%.

Conclusions: The application of a maternal care bundle had significantly decreased the incidence of spinal induced hypotension in parturient undergoing elective or urgent Cesarean delivery.

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1. Introduction

Despite evidence demonstrating that major maternal and fetal complications associated with general and regional anesthesia are similar, however, evidence suggests that the use of regional mainly spinal - anesthesia is increasing and the use of general anesthesia is declining [1]. Subarachnoid block is a common technique for cesarean section as it is easy to perform and provides a rapid-onset, dense motor block. It is usually not associated with maternal or fetal risk for local anesthetic toxicity [1], but it is frequently associated with hypotension and its incidence varying from 70% to 80%, this hypotension may be deleterious to both parturient and fetus [2]. Maternal hypotension is a physiologic response of spinal block due to sympathectomy resulting from the neuroaxial blockade. Physiological changes associated with pregnancy may exacerbate sympathectomy mediated hypotension with subsequent maternal and fetal complications. Several mechanisms for hypotension had been postulated, compression of the vena cava by gravid uterus impeding venous return, venous pooling of blood in the lower legs, leading to decreased venous return and reduced cardiac output [3,4]. Many preventive measures are currently used to prevent or minimize hypotension, including vasopressor administration, left uterine displacement, crystalloids or colloid preloading or coloading, and elastic compression stocking onto the lower limbs [5,6]. No single intervention was capable of preventing maternal hypotension [5].

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In this cohort interventional study, we hypothesized that combining prophylactic methods (Maternal Care Bundle i.e. low fixed dose of bupivacaine, coloading, preemptive use of vasopressors, patient positioning, and leg compression) would be of more value than single intervention in preventing maternal hypotension.

2. Patients and methods

Following approval from Ethics and research committee of anesthesia department, faculty of medicine, Cairo University, an informed written consent was signed by each patient included in the study. Patients received single shot spinal anesthesia for cesarean delivery were subjected to group of prophylactic therapies aiming to minimize post spinal anesthesia mediated maternal hypotension. This study was carried out in the period of June to November 2015; in obstetrics operating theatre department, Cairo University hospitals. All parturients coming for elective or urgent cesarean delivery with American Society of Anesthesiologists grade I-II were included. Exclusion criteria include; any contraindication to spinal anesthesia, preeclampsia and uncontrolled hypertension. Following enrollment, and on arrival to operating theater full monitoring with non-invasive blood pressure, ECG and pulse oximetry were applied, wide bore cannula 16G was also inserted under local anesthesia; prior to administration of spinal anesthesia. The study was designed to analyze the effect of implementation of the maternal care bundle which consisted of; fixed low dose of bupivacaine $(7.5 \text{ mg} + \text{fentanyl } 25 \mu\text{g})$, coloading with 15 ml/kg lactated Ringer's, placement of the patient in the supine wedged position, administration of 9 mg ephedrine sulphate IV after intrathecal injection and placement of graduated compression stockings (GCS) in the elevated leg position >45° and maintaining leg elevation at 20° following application of GCS. Spinal block was performed in the sitting position under complete aseptic precautions. All patients were assessed for motor block using modified Bromage scale [8] and sensory level using pin prick method in the midclavicular line bilaterally. Bromage score for motor block was estimated as follow: Bromage 3: unable to move feet or knees, Bromage 2: able to move feet only, Bromage 1: just able to move knees, Bromage 0: full flexion of knees and feet. Patient demographics, spinal anesthetic technique variables, fluid management and urine output were documented. Mean arterial blood pressure, heart rate and oxygen saturation (SpO₂) were recorded at baseline T0 (before spinal anesthesia administration), T1 (5 min following intrathecal injection of local anesthetic), T2 (15 min following intrathecal injection), T3 (30 min following intrathecal injection) and at T4 (at end of procedure prior to PACU transfer). Hypotensive episode defined as mean arterial blood pressure ≤60 mmHg was documented and managed with increments of 5 mg ephedrine sulphate, total doses of ephedrine sulphate were recorded. Episodes of bradycardia were also documented with timing and total amount of administered atropine was recorded. Nausea and vomiting incidence was also documented. Compliance to maternal care bundle was recorded as yes or no for each bundle item. Patients were considered compliant only when they were adhering to all 6 items. Patients were considered noncompliant if they did not adhere to one or more of the proposed 6 items.

Statistical analysis: Data were coded and entered using the statistical package SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 22. Data was summarized using mean, standard deviation, minimum and maximum in quantitative data and using frequency (count) and relative frequency (percentage) for categorical data. P-values less than 0.05 were considered as statistically significant. Sample size: It was a time limited study; we included 159 Parturients, if the number was less than 100 subjects the study would be extended.

3. Results

One hundred and sixty three patients were enrolled in the study, 3 patients experienced failure to establish adequate spinal anesthesia level and proceeded to general anesthesia, and one patient was excluded due to complicated cesarean section (placenta accreta). Total number of patients enrolled after exclusion of the previous 4 patients was 159 patients (Fig. 1). Mean age of patients enrolled was 28.82 years and duration of surgery ranged from 30 to 90 min. Table 1 showing the variables and characteristics of spinal anesthesia, ASA classification, anesthesiologist and surgeon experience. Total incidence of hypotension was 42 patients with percentage of 26.4% throughout the whole duration of surgery; incidence of hypotension after 5 min (T1) was 17.6%, at 15 min (T2) was 3.8% and at 30 min (T3) was 5% (Table 2), incidence of bradycardia was 2.5%. There was a clear relation between nausea and hypotension at 5 min (T1) and 15 min (T2) expressed in P value of <0.001 and 0.008 respectively. The same regarding the relation between hypotension and vomiting, the P value was significant of 0.001 at both T1 and T2. Mean arterial blood pressure trends are shown in Fig. 2, and mean heart rate trends are shown in Fig. 3 at different time points. Table 3 shows side effects and Table 4 shows total ephedrine, atropine, fluid volume administrated and urine output.

4. Discussion

This is the first study that conducted the maternal care bundle to prevent spinal induced hypotension in parturients undergoing cesarean section. The main finding of this study showed significant reduction of the incidence of hypotension.

With the implementation of the maternal care bundle, the incidence of hypotension had decreased significantly to 26.4% in the whole procedure. This technique had a low incidence of maternal nausea where it was 16.9%, and vomiting where it was 9.4%.



Fig. 1. Flow diagram of participants. CS: cesarean section.

Table 1

Variables and characteristics of spinal anesthesia, ASA classification, anesthesiologist and surgeon experience.

		Count	Percentage (%)
(ASA) classification	asa i	149	93.7
	Asa ii	10	6.3
Status	Elective	84	52.8
	Urgent	75	47.2
Position	Sitting	159	100.0
Approach	Midline	43	27.0
	Paramedian	116	73.0
Space	L2-3	3	1.9
	L3-4	147	92.5
	L4-5	9	5.7
Needle gauge	22G	91	57.2
	25G	60	37.7
	27G	8	5.0
Туре	Quincke	159	100.0
Anesthesiologist experience	Assistant lecturer	7	4.4
	Year 1 residency	16	10.1
	Year 2 residency	3	1.9
	Year 3 residency	133	83.6
Number of Attempt	1	125	78.6
	2	25	15.7
	3	6	3.8
	4	3	1.9
CSF	Blood stained	10	6.3
	Clear	149	93.7
Flow	Acceptable	157	98.7
	Fair	2	1.3
Barbotage	Yes	159	100
Surgeon's experience	Assistant lecturer	27	17.0
	Lecturer	5	3.1
	Resident	127	79.9

Data presented as counts and percentages. ASA: American Society of Anesthesiologists, CSF: cerebrospinal fluid.

Table 2

Hypotension at different time points.

	Count	Percentage (%)
T1 hypotension	28	17.6
T2 hypotension	6	3.8
T3 hypotension	8	5.0
T4 hypotension	0	0

Data are presented as counts and percentages. T1 (5 min following intrathecal injection), T2 (15 min following intrathecal injection), T3 (30 min following intrathecal injection) and at T4 (at end of procedure prior to PACU transfer).

Kol et al. [9] designed a randomized, double-blinded study to determine the efficacy and safety of 0.5 mg/kg intravenous ephedrine for the prevention of hypotension during spinal anesthesia for cesarean section. Patients were randomly assigned into two groups: ephedrine group (n = 21) and control group (n = 21). All patients received intravenous preload of 15 ml/kg lactated Ringer's solution. Shortly after the intrathecal injection, ephedrine 0.5 mg/kg or saline was injected intravenously. They found that there was significant lower incidence of hypotensio in the ephedrine group compared with the control group (38.1% versus 85.7% respectively). So the use of ephedrine with other items of the maternal care bundle had significantly decreased the incidence of hypotension.

In consistent with the current study; Leo et al. [10] conducted a randomized comparison of low doses of hyperbaric bupivacaine in combined spinal-epidural anesthesia for cesarean delivery on 60 women were randomly assigned to one of the 3 groups receiving



Fig. 2. Trends of MAP over time points. Data are presented as mean and standard deviation. T1 (5 min following intrathecal injection), T2 (15 min following intrathecal injection), T3 (30 min following intrathecal injection) and at T4 (at end of procedure prior to PACU transfer). MAP: mean arterial blood pressure, PACU: post anesthesia care unit.



Fig. 3. Trends of HR over time points. Data are presented as mean and standard deviation. T1 (5 min following intrathecal injection), T2 (15 min following intrathecal injection), T3 (30 min following intrathecal injection) and at T4 (at end of procedure prior to PACU transfer). HR: heart rate, PACU: post anesthesia care unit.

Tabl	e 3
Side	effects.

Side effects	Count (n = 159)	Percentage (%)
Hypotension	42	26.4
Bradycardia	4	2.5
Nausea	27	17.0
Vomiting	15	9.4

Data are presented as counts and percentages.

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Ephedrine, Atropine doses, fluid volume and urine output.

Parameter	Mean ± SD	Minimum	Maximum
Ephedrine dose (mg)	3.21 ± 5.91	0.00	21.00
Atropine dose (mg)	0.01 ± 0.07	0.00	0.50
Fluid volume (ml)	2166.67 ± 371.73	1500.00	3500.00
Urine output (ml)	154.91 ± 70.64	75.00	500.00

Data represented as mean, SD (standard deviation), minimum and maximum.

7 mg, 8 mg, or 9 mg hyperbaric bupivacaine combined with 100 µg of morphine and intravenous hydroxyethyl starch 15 ml/ kg and concluded that the lowest dose of hyperbaric bupivacaine was 7 mg that provided equally rapid onset and effective anesthesia for cesarean delivery while reducing the incidence of hypotension compared with 8 and 9 mg; the incidence of hypotension was 30% in the group received 7 mg bupivacaine, 55% in the group received 8 mg and 70% in the group received 9 mg.

In contrast to this study; van Bogaert [11] found that leg elevation alone did not prevent spinal induced hypotension in patients undergoing elective cesarean section. He randomly allocated 82 patients to one of 4 groups: raising, wrapping, raising and wrapping of the legs and no intervention, he concluded that wrapping of the legs at spinal block for Cesarean section is recommended to reduce hypotension. But he studied that technique on a small number of patients.

Also, in consistent with the current study; Oh et al. [12] compared coload versus preload in 60 parturients undergoing cesarean delivery under spinal anesthesia, they randomized the patients into 2 groups; coload group, received 15 ml/kg of crystalloid after intrathecal drug injection and preload group, received 15 ml/kg of crystalloid before intrathecal drug injection; they found that the incidence of hypotension was higher in preload group (83%) than coload group (53%).

In line with this study; Vercauteren et al. [13] used a multimodal technique to prevent spinal induced hypotension in cesarean delivery where they used low dose bupivacaine, prophylactic low dose ephedrine and preload. They conducted a double blind randomized study on 50 parturients undergoing elective cesarean section under spinal epidural anesthesia; the patients were randomly allocated to 2 groups; one group received 5 mg ephedrine the other group received saline. Spinal anesthesia was performed with low dose hyperbaric bupivacaine 6.6 mg combined with sufentanil 3.3 µg as part of a combined spinal-epidural technique in all patients. All patients received 1000 mL of lactated Ringer's solution and 500 mL of hydroxyethyl starch 6% before the spinal injection. They found that the incidence of hypotension was more in the placebo group (58% vs 25%, P < 0.05) compared to the ephedrine group; but we used coloading not preloading.

Limitations to this study that we did not evaluate the neonatal outcome; also we did not know which technique was more effective in preventing hypotension in this multimodal technique. Another limitation of the study is that the study did not include comparative group to prove the effect of applying the whole bundle of care on spinal hypotension. Conclusions: maternal care bundle is highly recommended to decrease the incidence of spinal induced hypotension in parturients undergoing cesarean section.

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