CLINICAL SCIENCE

Clinical evaluation of the flotrac/vigileo™ system for continuous cardiac output monitoring in patients undergoing regional anesthesia for elective cesarean section: a pilot study

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BACKGROUND: Spinal anesthesia for cesarean delivery may cause severe maternal hypotension and a decrease in cardiac output. Compared to assessment of cardiac output via a pulmonary artery catheter, the FloTrac/Vigileo™ system may offer a less invasive technique. The aim of this study was to evaluate cardiac output and other hemodynamic measurements made using the FloTrac/Vigileo™ system in patients undergoing spinal anesthesia for elective cesarean section.

METHODS: A prospective study enrolling 10 healthy pregnant women was performed. Hemodynamic parameters were continuously obtained at 15 main points: admission to surgery (two baseline measurements), after preload, after spinal anesthesia administration and 4 time points thereafter (4, 6, 8 and 10 min after anesthesia), at skin and uterine incision, newborn and placental delivery, oxytocin administration, end of surgery, and recovery from anesthesia. Hemodynamic therapy was guided by mean arterial pressure, and vasopressors were used as appropriate to maintain baseline values. A repeated measures ANOVA was used for data analysis.

RESULTS: There was a significant increase in heart rate and a decrease of stroke volume and stroke volume index up to 10 min after spinal anesthesia ($P < 0.01$). Importantly, stroke volume variation increased immediately after newborn delivery ($P < 0.001$) and returned to basal values at the end of surgery. Further hemodynamic parameters showed no significant changes over time.

DISCUSSION AND CONCLUSIONS: No significant hemodynamic effects, except for heart rate and stroke volume changes, were observed in pregnant women managed with preload and vasopressors when undergoing elective cesarean section and spinal anesthesia.

KEYWORDS: FloTrac/Vigileo™; Cardiac output; Stroke volume; Cesarean section; Spinal anesthesia.

Auler Junior JC, Torres MLA, Cardoso MM, Tebaldi TC, Schmidt A. Kondo MM, Zugaib M. Clinical evaluation of the flotrac/vigileo™ system for continuous cardiac output monitoring in patients undergoing regional anesthesia for elective cesarean section: a pilot study. Clinics. 2010;65(8):793-798.

Received for publication on May 16, 2010; **First review completed on** May 16, 2010; **Accepted for publication** May 25, 2010

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INTRODUCTION

Cardiac output (CO) is routinely monitored in critically ill patients with the primary goal of maintaining adequate tissue perfusion.[1] In most patients in the surgical setting, thermodilution using a pulmonary artery catheter (PAC) is still the most frequently applied technique and has generally been accepted as the clinical gold standard.[1] However, the value of the PAC has been questioned in recent years, and its impact on outcome is controversial.[1,2] More recently, several less-invasive techniques that avoid the risks associated with the PAC have become available for routine CO monitoring.[3,4] These devices include continuous monitors that use arterial pressure waveform analysis to estimate CO and other hemodynamic parameters.[5-8]

Recently, a new continuous arterial pulse-wave analysis device that does not require external calibration, thermodilution or dye dilution has become available.[9,10] The FloTrac/Vigileo™ system (Edwards Lifesciences, Irvine, CA, USA) obtains the pressure wave signal from any standard peripheral arterial line, and the standard deviation

of the pulse pressure is empirically correlated with the stroke volume based on patient demographic characteristics (age, gender, body height, and weight) after automatic adjustment for actual vascular compliance.[9,10] Early validation studies for this device showed conflicting results.[11-13] Thus, the FloTrac/Vigileo™ software and its underlying algorithm were revised, and improved versions have recently become available for clinical use.[14,15]

Spinal anesthesia for cesarean delivery may cause severe maternal hypotension and a decrease in CO and blood flow to the placenta.[16,17] Prevention of hemodynamic instability during cesarean delivery during spinal anesthesia has been the aim of several studies aiming to minimize fetal and maternal morbidity. Most studies have used noninvasive monitoring devices to evaluate hemodynamic responses related to spinal anesthesia in the obstetric setting.[17,18] Consequently, the actual hemodynamic responses to spinal anesthesia for cesarean delivery (i.e., CO and systemic vascular resistance changes) are still poorly understood, especially in patients displaying cardiovascular disorders such as preeclampsia. Considering the pivotal role of the strict control of spinal anesthesia-related hemodynamic changes in pregnant patients and the recent advances in minimally invasive hemodynamic monitoring, this study was designed to detect and evaluate hemodynamic responses to delivery, vasopressors, and oxytocin in healthy pregnant women undergoing elective cesarean section following spinal anesthesia using the new FloTrac/Vigileo™ monitoring system.

METHODS

Subjects

A prospective observational study of adult pregnant women at term was performed in a tertiary care hospital in Brazil. The protocol was evaluated and approved by the institution's research and ethics committee. Written informed consent was obtained from all patients. In this study, 10 consecutive healthy pregnant women were enrolled with ages ranging from 18 to 25 years. Exclusion criteria were as follows: patient refusal, patients younger than 18 years, chronic arterial hypertension, twin pregnancy, active labor, heart or pulmonary disease, preoperative dysrhythmias, cognitive impairment or difficulty in understanding verbal commands, or presentation with absolute or relative contra-indications to regional anesthesia. All patients underwent preoperative transthoracic echocardiography, and no valvular dysfunctions were documented. Patients displaying reduced ventricular function or signs of pulmonary artery hypertension were also excluded.

Anesthesia procedure and CO monitoring

Antepartum management, anesthesia and postoperative management followed institutional standards. Patients received no premedication. In the operating room, routine monitoring was applied (Philips IntelliVue™ Monitoring, Philips Medical Systems, Andover, MA, USA), including pulse oximetry and 5-lead electrocardiography, and a 16-G catheter was inserted into right cephalic vein. Routine access to the left radial artery was established and connected to the Vigileo™ monitor (Edwards Lifesciences, Irvine, CA; software version 1.07) via the FloTrac™ pressure transducer. Patient data (age, gender, body weight, and height) were entered, and after checking the arterial line waveform fidelity, the system was zeroed and CO measurement initiated. The CO was recorded continuously during the perioperative period. Intravenous crystalloid preload (lactated Ringer's solution, 10 ml/kg^{-1}) was rapidly infused and initiated immediately before lumbar puncture. No further fluids were administered unless excessive hemorrhaging occurred. All patients received 10 mg (2 ml) hyperbaric 0.5% bupivacaine plus 15 μg fentanyl and 80 μg morphine sulfate administered at the L_3–L_4 interspace using a 27-G Whitacre needle. After spinal anesthesia, patients were in the supine position with 20° of left lateral tilt throughout the entire study period to minimize aortocaval compression. Block height was assessed using cold sensitivity to 70% ethanol solution. All patients received supplemental oxygen by nasal catheter until delivery.

The FloTrac/Vigileo™ system needs no external calibration and provides continuous cardiac output measurements from the arterial pressure wave. The Vigileo™ (Software version 1.07) records hemodynamic variables at 20-s intervals and performs calculations on the most recent 20 s of data. The system calculates the stroke volume (SV) using arterial pulsatility (standard deviation of the pulse pressure over a 20-s interval), resistance, and compliance. The CO is calculated as follows: CO = heart rate × SV [SV = K × pulsatility]. *K* is a constant that represents arterial compliance and vascular resistance and is derived from a multivariate regression model. The rate of adjustment of *K* was 1 min (Software 1.07). Pulsatility is proportional to the standard deviation of the arterial pressure wave over a 20-s interval.

Study protocol

Hemodynamic measurements included recordings of heart rate, mean arterial pressure (MAP), central venous pressure (CVP), cardiac output (CO), cardiac index (CI), stroke volume (SV), stroke volume index (SVI), stroke volume variation (SVV), and systemic vascular resistance (SVR). All hemodynamic data were recorded by an observer not involved in the routine management of the patient at predefined time points. Hemodynamic parameters were continuously obtained and analyzed at 15 main time points: admission to the surgery room (two baseline measurements regarding dorsal and lateral position – T_0 and T_1), after a volume preload of lactated Ringer's solution 10 ml/kg^{-1} (T_2), immediately after spinal anesthesia administration (T_3) and 4 time points thereafter (4, 6, 8 and 10 min after spinal anesthesia – T_4 through T_7), during skin incision (T_8), uterine incision (T_9), newborn delivery (T_{10}), placental delivery (T_{11}), immediately after oxytocin administration (T_{12}), end of surgery (T_{13}), and at recovery from spinal anesthesia (T_{14}). Systemic vascular resistance was calculated according to the following formula: systemic vascular resistance = (MAP − CVP) × 79.9/CO. Hemodynamic therapy was guided by MAP values, and vasopressors (metaraminol) were used as appropriate to maintain baseline arterial pressure values. The MAP value for the purposes of calculation of target blood pressures for vasopressor administration was recorded as the mean of three consecutive readings not differing from one another by more than 10% and taken before sitting up for the induction of anesthesia. If MAP decreased by up to 20% from baseline, a bolus of metaraminol 0.2 mg was administered every minute to maintain MAP within 20%

of the baseline value. If MAP decreased by more than 20% from baseline, a bolus of metaraminol 0.4 mg was administered every minute until the blood pressure recovered to within 20% of baseline.

Further interventions were as follows: immediately after delivery, 2-U oxytocin diluted in 10 ml saline solution was intravenously administered over a period of 60 s. Thereafter, a separate infusion of 20-U oxytocin in saline solution was started at 5 U/h^{-1} over 4 hours. Intravenous cefazolin (2 g) was slowly administered immediately after umbilical cord clamping. Intraoperative maternal blood loss was estimated from suction bottle measurement and checking of swabs at the end of the procedure.

Statistical analysis

Data were stored in EPI-INFO (software version 6.0) and analyzed by Statistical Package for the Social Sciences (SPSS) (version 15.0) for Windows (registered trademark). All data are expressed as means ± standard error of the mean (SEM) unless otherwise stated. Data were submitted to Kolmogorov-Smirnov and Bartlett tests for normality evaluation. Hemodynamic variables for each time interval were compared with the baseline by analysis of variance (ANOVA) for repeated measurements. If the ANOVA revealed a significant interaction, *post hoc* analysis was performed using the Bonferroni multiple comparisons test when applicable. $P < 0.05$ was considered to represent a statistically significant difference.

RESULTS

Ten consecutive pregnant women with a mean age of 22.4 years (range 18–25 years), a body mass index (BMI) of 29.4 ± 4.1 kg/m^{-2}, and a body surface area (BSA) of 1.65 ± 0.06 kg/m^{-2} as well as preserved left ventricular function and sinus rhythm who were undergoing elective cesarean section were enrolled. All patients completed the study and underwent uneventful surgical procedures, achieving a maximum block height at the T_4 dermatome level. There were no block failures, and no patients displayed blood loss greater than 500 ml. The mean surgery time was 75 ± 12 min, and the measurement period was uneventful for all patients. A total of 8 of 10 patients received metaraminol for MAP restoration; the mean total dose of metaraminol was 1.6 ± 0.2 mg/patient.

Table 1 displays the average hemodynamic data at the defined time intervals. Cardiac output and cardiac index remained stable throughout the procedure and after recovery from spinal anesthesia ($P = 0.24$ and 0.25, respectively). There was a significant increase in HR and a decrease of SV and SVI up to 10 min after spinal anesthesia ($P < 0.01$). Importantly, the SVV increased immediately after newborn delivery ($P < 0.001$) and returned to basal values at the end of surgery. However, no significant effects on CVP ($P = 0.09$) or SVR were observed ($P = 0.75$). Mean arterial pressure assessed by FloTrac/Vigileo™ system also showed no significant changes over time ($P = 0.08$).

DISCUSSION

This observational study describes maternal hemodynamic responses to spinal anesthesia for cesarean delivery in 10 healthy women, evaluated using the FloTrac/Vigileo™ system. This study demonstrated that spinal

Table 1 - Hemodynamic data obtained at each time point.

	T_0	T_1	T_2	T_3	T_4	T_5	T_6	T_7	T_8	T_9	T_{10}	T_{11}	T_{12}	T_{13}	T_{14}	*P*
HR (beats/min)	84(3)	84(4)	86(3)	89(7)	100(6)[a]	103(6)[b]	92(7)[c]	82(7)	79(3)	69(2)	75(4)	82(4)	79(3)	71(3)	67(2)	0.0001
MAP (mm Hg)	97(3)	92(7)	100(3)	97(2)	88(2)	82(3)	81(4)	87(5)	93(4)	89(6)	100(5)	94(3)	97(6)	93(5)	99(6)	0.0829
CVP (mm Hg)	16(1)	21(3)	18(1)	18(1)	14(1)	14(1)	13(1)	16(2)	15(1)	18(2)	20(3)	16(2)	16(2)	15(2)	16(2)	0.0855
CO ($L.min^{-1}$)	5.5(0.3)	6.2(0.5)	6.3(0.4)	5.6(0.2)	5.4(0.2)	5.0(0.2)	4.8(0.3)	4.6(0.3)	5.8(0.8)	5.1(0.2)	5.5(0.4)	5.9(0.4)	5.5(0.4)	5.3(0.2)	5.7(0.3)	0.2396
CI ($L.min^{-1}.m^2$)	3.3(0.2)	3.7(0.3)	3.7(0.2)	3.2(0.2)	3.2(0.1)	3.0(0.1)	3.0(0.2)	2.9(0.1)	3.5(0.5)	3.0(0.1)	3.3(0.3)	3.6(0.3)	3.3(0.3)	3.2(0.1)	3.4(0.1)	0.2490
SV (ml/beat)	73(4)	78(4)	70(3)	59(3)[d]	53(3)[d]	56(3)[d]	57(5)[d]	59(5)[d]	73(7)	78(5)	75(5)	75(4)	70(4)	74(3)	86(5)	0.0001
SVI ($ml.bat.m^2$)	42(2)	46(2)	42(2)	35(1)[d]	32(2)[d]	33(2)[d]	34(3)[d]	36(3)[d]	44(5)	46(3)	45(4)	45(2)	42(2)	44(2)	51(3)	0.0001
SVR ($dynes.s.cm^{-5}$)	1259(26)	1001(93)	1099(94)	1115(72)	1120(55)	1120(48)	1223(93)	1284(99)	1134(64)	1198(83)	1260(145)	1074(76)	1287(96)	1199(42)	1200(59)	0.7457
SVV (%)	15.0(3)	14.6(3)	7.3(1)	11.9(1)	14.1(2)	12.5(1)	10.7(1)	11.2(1)	10.1(1)	10.5(1)	27.0(4)[e]	17.9(2)[f]	17.3(2)[f]	11.6(1)	11.3(1)	0.0001

Data are means ± SEM. Statistical analysis used repeated measures ANOVA + Bonferroni *post hoc* multiple comparisons test; T_0: baseline (dorsal position); T_1: baseline (lateral position); T_2: immediately after volume preload; T_3: immediately after spinal anesthesia; T_4 to T_7: 4, 6, 8, and 10 min after spinal anesthesia; T_8: skin incision; T_9: uterine incision; T_{10}: newborn delivery; T_{11}: placental delivery; T_{12}: immediately after oxytocin administration; T_{13}: end of surgery; T_{14}: recovery from spinal anesthesia.

[a] $P < 0.01$ compared to T_9, T_{13} and T_{14}

[b] $P < 0.01$ compared to T_9, T_{10}, T_{13} and T_{14}

[c] $P < 0.05$ compared to T_{14}

[d] $P < 0.01$ compared to T_2 and T_{14}

[e] $P < 0.001$ compared to T_0–T_9, T_{13}, T_{14}; $P < 0.05$ compared to T_{12}; and

[f] $P < 0.05$ compared to T_2.

anesthesia was associated with hemodynamic stability in obstetric patients undergoing cesarean section, as no significant hemodynamic effects (except for heart rate and stroke volume changes) were observed in pregnant women managed with crystalloid preload and vasopressors. Additionally, we demonstrated that the FloTrac/Vigileo™ system is a reliable method for monitoring hemodynamic responses to spinal anesthesia in pregnant patients, although it should be compared to other methods in future studies. This minimally invasive device designed to measure CO- and SV-related parameters may be considered to further improve hemodynamic control and outcomes in obstetric anesthesia.

Monitoring of cardiac performance is important to either confirm diagnosis or guide therapy in patients undergoing major surgery or critically ill patients in the intensive care unit.[1] The invasive technique of pulmonary artery catheterization has been used to optimize hemodynamics.[1,2] Recently, less-invasive devices to measure CO have become available. These techniques include transthoracic bioimpedance, pulse dye densitometry, esophageal Doppler, transesophageal echocardiography and arterial pulse-wave analysis. Methods based on pulse-wave analysis have become increasingly accepted and gradually introduced into clinical practice.[5-10] Commercially available devices include the PiCCOsystem (PiCCO™, Pulsion Medical Systems) and the LiDCO-system (LiDCO™, LiDCO Ltd.), which both require invasive calibration by either transpulmonary thermodilution or lithium dilution after a certain time to compensate for interindividual differences in vascular compliance.[19] The FloTrac/Vigileo™ system offers the possibility of uncalibrated, continuous CO measurements on the basis of arterial waveform analysis combined with simple usability. In this study, we used the software version 1.07, which records hemodynamic variables at 20-s intervals. More recent software versions have improvements consisting of more frequent recalculation of an internal variable estimating vascular tone combined with a reduction of pulse-wave detection noise. Notably, this study was designed to evaluate the ability of the FloTrac/Vigileo™ system to detect hemodynamic variations during cesarean section procedures under spinal anesthesia and to speculate about the main mechanisms involved in these hemodynamic changes. Considering these goals and the regular use of non-invasive hemodynamic monitoring methods for pregnant women undergoing cesarean section, we did not compare the FloTrac/Vigileo™ system to gold standards such as the pulmonary artery catheter or transesophageal echocardiography.

The optimal anesthetic technique and hemodynamic monitoring for cesarean delivery in both healthy patients and women displaying cardiovascular diseases such as preeclampsia still remains controversial.[20,21] Most studies have focused on changes in blood pressure and heart rate as the key hemodynamic variables representing maternal CO during spinal anesthesia for cesarean delivery.[22,23] Although heart rate and blood pressure measurements are of significant value in assessing the safety of an anesthetic technique, the true goal of spinal anesthesia for cesarean delivery is to maintain maternal CO and uteroplacental blood flow. In healthy patients, the maximum change in CO has been shown to correlate better to uteroplacental blood flow than to upper arm blood pressure.[24] More recently, Dyer et al.[17] tested the hypothesis that continuous monitoring of CO in patients with severe preeclampsia during spinal anesthesia for cesarean delivery would give better information on the uteroplacental blood flow than determination of the mean radial artery blood pressure. It was found that CO, as inferred from pulse-wave analysis, did not decrease significantly from baseline if the mean radial artery blood pressure was maintained at baseline levels with intermittent vasopressors; therefore, it was concluded that spinal anesthesia was associated with clinically insignificant changes in CO. The study by Dyer and colleagues[17] used the LiDCO™ system, a method based on aortic pulse-wave analysis, to examine rapid changes in cardiovascular variables associated with spinal anesthesia, vasopressors, and oxytocin during cesarean section. However, this method of CO assessment has not been recommended during hemodynamic instability and has been shown to produce CO assessment errors during cardiac surgery.[25]

Notably, none of the above waveform-related methods (FloTrac/Vigileo™ or LiDCO™ system) are validated for evaluation of hemodynamic changes during spinal anesthesia and cesarean delivery. The results of these techniques with respect to reproducibility and accuracy are not uniform.[11-13,19] Whether they can guide therapy better than routine measurement of blood pressure remains to be determined. These additional methods for continuous monitoring of CO may herald a new era in which we focus on blood flow instead of blood pressure as the key hemodynamic variable in obstetric anesthesia.[26] This will provide more information and ultimately a better understanding of the hemodynamic changes in pregnant women and spinal anesthesia-related hemodynamic responses. The acquisition of such knowledge may improve our management with respect to the choice of fluids and vasopressors.[27]

Pulse-wave analysis has been used in careful investigations of cardiovascular responses during pregnancy. The first cardiovascular alteration during pregnancy is the increase in arterial compliance that starts in the first trimester.[23] Additionally, peripheral vascular resistance decreases moderately throughout gestation, followed by an increase in CO, HR, SV and aortic distensibility, a decrease in peripheral vascular resistance and an increase in left ventricular wall thickness from the second trimester to the end of pregnancy.[28] Notably, Dyer et al.[17] found that CO remained stable throughout cesarean delivery, except for in the period after oxytocin bolus administration (2.5 U). In the present study, however, no significant effects regarding CO or other hemodynamic parameters (except for SVV) were observed after oxytocin administration. The response to oxytocin observed by Dyer et al.[17] was more pronounced than that observed in a recent protocol using thoracic bioimpedance, in which a high-dose oxytocin regimen was used (5 or 10 U oxytocin administered as a rapid bolus).[29] Therefore, it is tempting to speculate that these differences may be related to the low-dose and/or slow-infusion oxytocin regimen used in the present protocol or even to the absence of cardiovascular comorbidities. Considering that oxytocin may cause transient profound hypotension and tachycardia[17] and that the ED_{95} for oxytocin in elective cesarean section has been shown to be around 0.35 U,[30] consideration should be given to administering this drug by slow, titrated, and diluted intravenous infusion.

In the present study, there was a significant decrease of SV and SVI after spinal anesthesia. However, this effect was likely physiologically compensated by an increase in HR.

Central venous pressure, SVR and MAP showed no significant changes over time. These results were not compared to previous LiDCO™ results in women displaying preeclampsia, where both MAP and SVR decreased significantly from the time of the adoption of the supine position until the end of surgery. Consequently, in the study by Dyer and colleagues[17], spinal anesthesia was associated with significant afterload reduction and minimal CO changes. We speculate that our results may be related to a prompt and more effective correction of MAP values by application of the vasopressor metaraminol, which ultimately produced CO maintenance throughout the procedure. Although vasopressors such as metaraminol and phenylephrine (α_1-agonists), rather than ephedrine, have been recommended for treating spinal anesthesia-related hypotension,[31] further studies are required to establish, from both the maternal and fetal points of view, the best agent to restore maternal MAP. A recent study showed that a bolus of phenylephrine reduced maternal CO and decreased CO to a greater extent than ephedrine during elective spinal anesthesia for cesarean delivery.[32] Interestingly, CO changes were correlated with heart rate changes after vasopressor administration, emphasizing the importance of heart rate as a surrogate indicator of CO. However, phenylephrine was more effective than ephedrine for counteracting hemodynamic responses to oxytocin.[32] Future studies should address these issues using waveform analysis combined with methods for observation of uteroplacental perfusion.

Fluid response prediction is difficult in spontaneously breathing patients. Because the swings in intrathoracic pressure are minor during spontaneous breathing, hemodynamic parameters like SVV are usually small.[31] However, in the present study, the SVV increased immediately after newborn delivery and returned to basal values at the end of surgery. Notably, in spontaneously breathing, hemodynamically unstable patients, Soubrier et al.[33] found a sensitivity and specificity of 47% and 92%, respectively, for predicting fluid responsiveness for SVV. However, emerging data suggest that the application of some measures such as forceful inspiration and expiration, Valsalva maneuvers or expiratory resistors are capable of magnifying the ability of SVV to predict fluid responsiveness.[31,34] It remains unclear whether optimized methods to measure SVV could be of value for prediction of fluid responsiveness in the obstetric setting, and new studies are thus warranted.

In summary, this study provides additional evidence that the FloTrac/Vigileo™ system can be used for CO measurement as it was consistent when tested in patients undergoing spinal anesthesia in an obstetric setting. To our knowledge, this study is the first to test this pulse-wave analysis method in an obstetric setting. No significant hemodynamic effects (except for heart rate and stroke volume changes) were observed in pregnant women managed with crystalloid preload and vasopressors undergoing elective cesarean section and spinal anesthesia. New studies addressing the monitoring of cardiac output and stroke volume parameters with respect to outcomes in obstetric patients are warranted. A better understanding of perioperative hemodynamic responses in obstetrics may contribute to a significant reduction in maternal and neonatal morbidity. The use of minimally invasive methods such as the FloTrac/Vigileo™ system in pregnant women presenting with significant cardiovascular disorders should be considered and could be a main target for future studies.

ACKNOWLEDGEMENTS

This research was supported by CEDAR – Centro de Estudos de Anestesiologia e Reanimação.

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