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Blood pressure measurement during cesarean delivery

Evaluation of a beat-to-beat noninvasive device (Nexfin™)

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Abstract

Early detection of arterial hypotension during cesarean delivery under spinal anesthesia is important. This study aims to compare the validity of Nexfin™ as beat-to-beat noninvasive blood pressure monitoring with conventional intermittent oscillometric measurement of blood pressure during elective cesarean delivery.

This open prospective observational bicentric study was performed between January 2013 and December 2015. We simultaneously recorded arterial blood pressure with both techniques in pregnant women undergoing elective cesarean delivery under spinal anesthesia. The primary outcome was a Bland–Altman analysis of systolic blood pressure measurement comparing Nexfin™ and a conventional method. The secondary outcomes were the time to detect the first relevant hypotensive episode and the comparison of both devices using a four-quadrant graph.

One hundred and seventy-four parturients completed the study, and 2640 pairs of systolic blood pressure measurements were analyzed. Bias was -10 mmHg with upper and lower limits of agreement of -61 and +41 mmHg. In 73.9% of the cases, the two techniques provided the same information (normotension or hypotension), but the conventional method missed 20.8% of measurements, with Nexfin™ detecting 16.2% more hypotensive measurements. The median [25–75 percentiles] duration to detect the first hypotensive measurement was 331 [206–480] seconds for Nexfin™ and 440 [300–500] s for intermittent oscillometry ($P < .001$).

The agreement between Nexfin™ and an intermittent method for the measurement of systolic blood pressure was not in an acceptable range during cesarean delivery, although Nexfin™ may detect hypotension earlier than the standard method.

Trial registration: Clinicaltrials.gov identifier: NCT01732133; November 22, 2012

Abbreviations: BP = blood pressure, BPosc = intermittent oscillometric arm blood pressure, CNAP™ = continuous noninvasive arterial pressure device, CNBP = continuous and noninvasive blood pressure, SBP = systolic BP.

Keywords: arterial pressure, cesarean section, intraoperative, monitoring, monitoring, noninvasive

1. Introduction

To limit morbidity among pregnant women, the guidelines for elective cesarean delivery recommend avoiding general anesthesia.[1] Instead, spinal anesthesia is the preferred method in healthy parturients. However, the incidence of maternal hypotension has been reported in up to 74% of cases,[2] placing the mother and newborn at increased risk of adverse effects.[3,4] Close monitoring of the mother's blood pressure (BP) and immediate treatment of hypotension are strongly recommended.[5] Continuous monitoring of blood pressure with an invasive arterial line is generally not used in routine clinical care because of its possible undesirable effects[6] and is not recommended for routine births,[7] but

Editor: Chien-Kun Ting.

This work was sponsored by the Clinical Research Department of Hôpital Foch.

Declaration of Interest: Mathieu Bobet, Jona Joachim, Etienne Gayat, Agnès Bonnet, Kerstin Sievert, Carole Barnichon, Marc Fischler, and Morgan Le Guen have no interests to be declared.

The data that support the findings of this study are available from a third party, but restrictions apply to the availability of these data, which were used under license for the present study, and so are not publicly available. Data are available from the authors upon reasonable request and with permission of the third party.

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How to cite this article: Bobet M, Joachim J, Gayat E, Bonnet A, Sievert K, Barnichon C, Fischler M, Le Guen M. Blood pressure measurement during cesarean delivery: Evaluation of a beat-to-beat noninvasive device (Nexfin™). Medicine 2021;100:22(e26129).

Received: 31 March 2020 / Received in final form: 10 April 2021 / Accepted: 6 May 2021

http://dx.doi.org/10.1097/MD.0000000000026129

detection of hypotension under spinal anesthesia could be delayed or missed by intermittent oscillometric arm blood pressure (BPosc).

Devices allowing continuous noninvasive blood pressure (CNBP) could be useful in this situation. These devices were first described and developed by Penáz and colleagues 40 years ago.[8] For many years, these devices have been used with anesthesia during major surgery and in intensive care units for severely ill patients.[9,10] Studies have demonstrated a performance comparable to that of invasive arterial blood pressure measurement.[11–13] The easy-to-use Nexfin^{TM}, which incorporates photoplethysmographic technology that allows noninvasive beat-to-beat BP readings to be obtained via a single finger cuff, is one of these devices. To date, there are few publications on the use of Nexfin^{TM} in parturients. Akkermans et al demonstrated that this device has adequate accuracy for the measurement of blood pressure in a pregnant population,[14] and Sng et al used this device successfully within a closed-loop vasopressor automated system for the maintenance of hemodynamic stability during spinal anesthesia for caesarean delivery.[15]

We hypothesized that both blood pressure measurement techniques, continuous non-invasive and intermittent, would give concordant results during cesarean delivery, leading to consider the possibility of interchangeability.

2. Methods

This multicenter prospective study was approved by the Ethical Committee Ile de France VIII (July 10, 2012) and registered on the international platform www.clinicaltrials.gov (NCT017 32133). Written informed consent was obtained from all parturients participating in the trial with a specific justification related to the "protected population" (pregnancy), in accordance with French law. It was performed in one university hospital and in one private nonprofit hospital between January 2013 and December 2015.

2.1. Study population

Adult parturients (i.e., age $\geq$ 18 years) were consecutively enrolled if they had an uneventful pregnancy with a scheduled cesarean delivery under spinal anesthesia. The exclusion criteria used were as follows: contraindications for spinal anesthesia, multiple pregnancy, pathologies at the end of the pregnancy (HELLP syndrome, acute hepatic steatosis, emergency delivery) or limitations in the use of the Nexfin^{TM} (cardiac arrhythmia, obesity (body mass index $>$ 35 kg/m^2 at inclusion), or pathologies of the upper limbs (such as Raynaud's disease, or vascular stenosis).

2.2. Procedure

This study compared a routine monitor using BPosc (General Electric Healthcare, 78,530 Buc, France) and a continuous blood pressure monitor, the Nexfin^{TM}, which was originally distributed by BMEYE B.V. (Amsterdam, The Netherlands) and later by Edwards as ClearSight (Edwards Lifesciences LLC, Irvine, California). The Nexfin^{TM} is a noninvasive beat-to-beat BP measurement device that is based on the 'patch clamp' principle. It uses a finger cuff in which pressure is continuously adjusted during the systolic BP (SBP) and diastolic BP cycle so that the blood volume flowing through the finger arteries is held constant. Cuff pressure is therefore used to indirectly measure finger BP. An algorithm converts the raw beat-to-beat finger BP to brachial BP.[16]

Parturients fasted overnight except for clear drinks and received routine antacid prophylaxis before the surgery. At admission to the operating theater, the parturients were positioned in a supine position with a left lateral tilt; monitors included electrocardiogram, BPosc on the right arm, and pulse oximetry. An intravenous cannula was inserted into a forearm vein, and the Nexfin^{TM} finger cuff was applied to the middle phalanx of the second or third finger of the left hand. The automatic calibration with a heart reference system was performed with the patient in the supine position. Then, BPosc and CNBP monitoring were synchronized during the procedure via an analog input to a monitoring system.

Spinal anesthesia was performed at the L3-L4 or L4-L5 level with aseptic precautions in the sitting position using 2 ml of 0.5% hyperbaric bupivacaine mixed with 5 μg of sufentanil and 100 μg of morphine. Then, the parturient was placed in a 5–10-degree tilt-left supine position for cesarean delivery, and blood pressure was measured at 1-min interval. An intravenous infusion of 500 mL Ringer lactate in ten minutes was started during anesthetic administration. The spread of the sensory block was tested using a cold spray, and a block level at T5–T6 was considered satisfactory.

The first measurement of BP obtained once the parturient was placed on the operating table was considered the reference value for BPosc, while the baseline value for CNBP was its first measurement after calibration.

For both devices, arterial hypotension was defined as a 20% decrease in SBP from baseline (measured in the supine position by BPosc just before spinal anesthesia).[2] Continuous noninvasive BP measurements were blinded during the procedure. Any hypotension observed with BPosc between the induction of spinal anesthesia and delivery was treated with an intravenous bolus of phenylephrine (50–100 μg) or ephedrine (6–9 mg) based on the algorithm of each center. Some decisions were left to the investigator's discretion, such as treatment of dizziness, but no therapeutic decisions were made based on the Nexfin^{TM} device (data not available during the cesarean delivery).

2.3. Outcomes

The primary outcome was the agreement between Nexfin^{TM} and BPosc simultaneous measurements in arterial pressure. The secondary outcomes explore the maximal drops in SBP, the time needed to detect a significant drop in SBP defined by a 20% decrease from the baseline value, and the tolerance of the intermittent measurement of arterial blood pressure. Secondary outcomes also explored babies' well-being through the APGAR score and the blood gas on the umbilical cordon if available.

2.4. Recorded data

The following demographic characteristics of the pregnant women and their newborns were collected: age, weight, height, gestational weeks, indication for cesarean delivery, neonatal umbilical vein pH, and Apgar score at 1, 5 and 10 min. The tolerance of both devices was reported by the parturients based on a visual analogue scale (VAS; 0: extremely uncomfortable to 10: perfect). Any adverse event was collected, immediately analyzed, and declared to the health authorities if necessary.

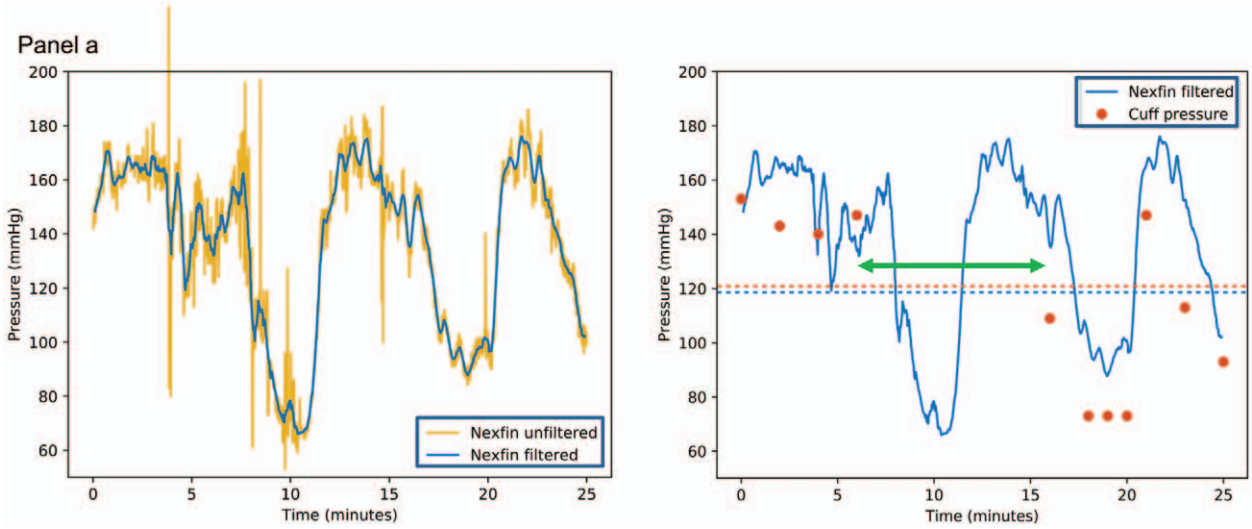

Figure 1. Typical recording of systolic blood pressure for an individual parturient, Panel a: - Yellow trace: original raw Nexfin data sampled at 1 Hz, - Blue trace: Nexfin data filtered using a 20-s centered moving average filter. Each point on the blue curve corresponds to the mean value of 20 s of data from the yellow curve. Panel b: - Blue trace: filtered Nexfin data (identical to Panel a), - Red circles: discontinuous blood pressure cuff measurements (cuff pressure or BPosc), - Dashed horizontal lines: predefined threshold of 80% of the baseline blood pressure. The blue dashed line and orange dashed line correspond to the thresholds for Nexfin and cuff pressure, respectively. - Green arrow: period during which BPosc gave no measurement.

Paired measurements were obtained using the Nexfin™ (CNBP) and the BPosc every minute from the end of spinal injection. To obtain a single CNBP value in parallel to the BPosc value, the data for CNBP were filtered. An average value surrounding the "minute of interest" was calculated over an interval of 20 + 20 consecutive seconds that corresponded to the median duration of the oscillometric measurement (Fig. 1).

2.5. Statistical analysis

According to Linnett,[17] a study aimed at comparing these two methods with an equivalent hypothesis requires at least 150 patients to yield a power of 90% and a bilateral risk of 5%. We decided to include 15% more parturients to forecast the risk of attrition; a total number of 174 was chosen.

Categorical variables are expressed as absolute values (percentages). Continuous variables are presented as mean ± SD if the distribution tested as normal using the Shapiro–Wilk test or as median [25–75 percentiles]. Comparisons were performed using a Chi-square test for categorical variables and independent Student's *t*-test or the Wilcoxon signed rank test for continuous variables as appropriate.

Time to occurrence of hypotension and maximal drops in blood pressure were compared using paired Student's *t*-test and the Wilcoxon signed rank test.

Pairs of simultaneous BP recordings (filtered CNBP and BPosc) were compared using the Bland–Altman method for repeated measures.[18]

Finally, we used a four-quadrant graph to determine the risk of making a decision based on the Nexfin™ versus an oscillometer. The x-axis displayed the BPosc, and CNBP was placed on the y-axis. For both devices, Zone A was the region located above 80% of the baseline (normotension), while Zone B was the region located under 80% of the baseline (hypotension). These regions corresponded, respectively, to a normal or low blood pressure value detected by both devices, and we considered both measurements to be similar because they led to the same clinical decision. Zones C and D indicate regions in which the difference between BPosc and CNBP was clinically significant and where the devices would therefore not suggest the same treatment (such as the administration of a vasopressor).

Data filtering and analysis were conducted using the Python Pandas library (version 0.19.2). All statistical analyses were conducted using R version 3.2.4 (R Core Team, 2016; R Foundation for Statistical Computing, Vienna, Austria).

The significance level was set to .05.

The data that support the findings of this study are openly available in the Dryad repository at https://datadryad.org/search [https://doi.org/10.5061/dryad.280gb5mpj].

3. Results

A total of 174 parturients were included nonconsecutively in the study from January 2013 to December 2015. Data for 14 parturients were not available. Finally, analysis was performed using data from 160 parturients (Fig. 2). The main characteristics of these parturients, their surgeries, vasoactive drug requirements and neonatal outcomes are reported in Table 1. In 50% of the cases, the indication for cesarean delivery was previous cesarean delivery, while abnormalities in fetal presentation (e.g., breech position) were the second indication in 30% of cases. The mother's convenience represented 8% of the indications, and the last 12% were miscellaneous indications (abnormalities of placenta implantation, poor conditions for a natural birth such as pelvic trauma, previous instrumental extraction, ...).

The median duration between spinal puncture and delivery was 20 [16–23] min. A total of 126 (79%) parturients with significant decreases in arterial pressure (> 20%) were diagnosed by the control method, and 94% received vasopressors with a median of 4 [2–5] boluses. The total dose of phenylephrine before delivery was 300 μg [150–450], and the total dose of ephedrine before delivery was 18 mg [12–30]. Some of the parturients

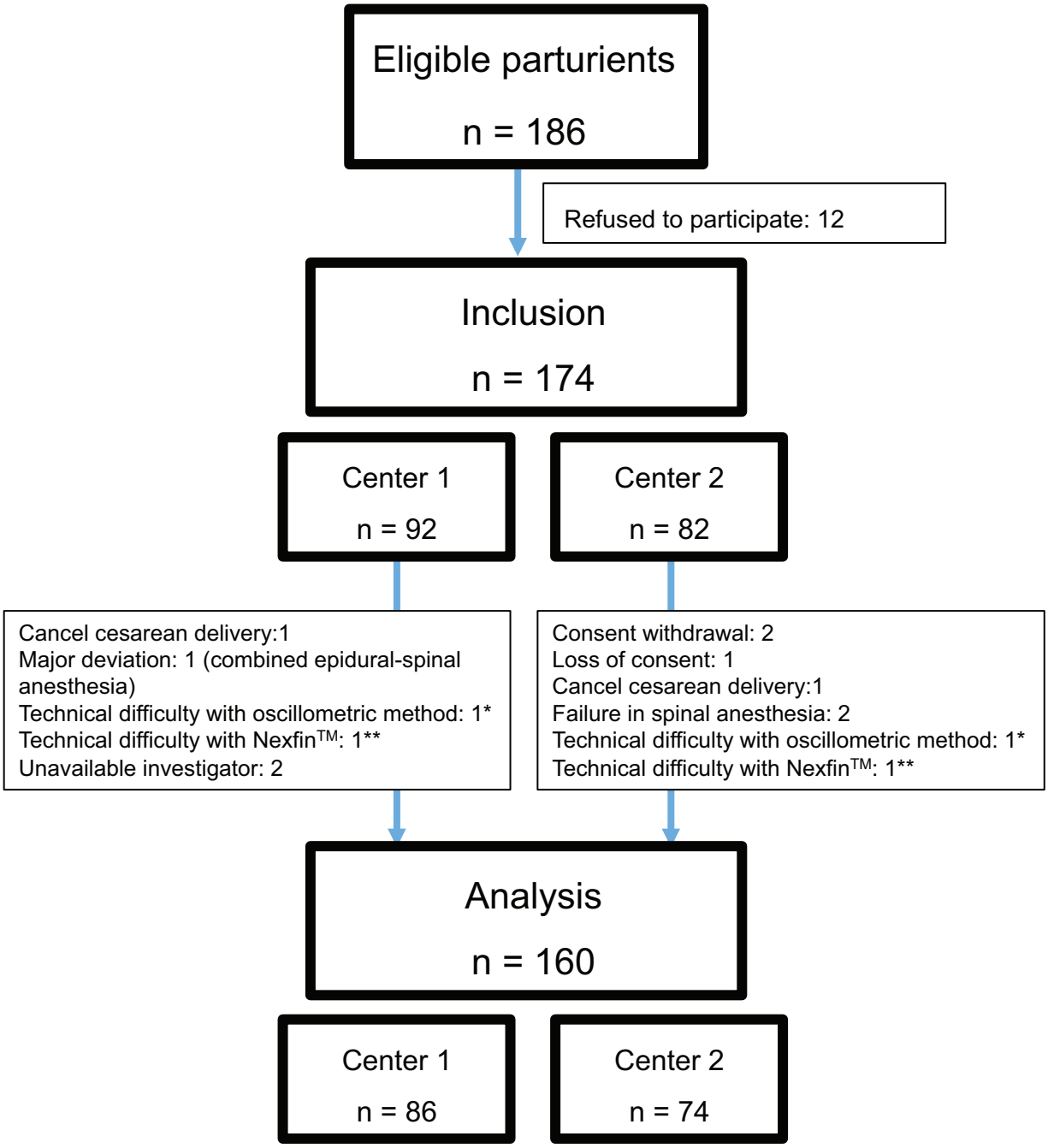

Figure 2. Flow chart, * wrong size of the cuff. ** problem of calibration due to change of position from dorsal to sitting positions.

received a systematic dose of a vasopressor (n = 8) before any blood pressure measurements were taken, while others were treated because of symptoms (e.g., dizziness, nausea or vomiting) without any contemporary hypotension.

A total of 3335 min were monitored with 695 missing values for BPosc and none for Nexfin™. Notably, during these blind periods of BPosc, 160 (23%) values measured by Nexfin™ were below 80% of the baseline value. Comparisons between the techniques included 2640 pairs of measurements, and the maximal drops in blood pressure measured by BPosc and CNBP were 32 [21–47] and 47 [29–61] mmHg, respectively ($P < .001$). The median durations to detect the first hypotensive episode were 331 [206–480] and 440 [300–600] s ($P < .001$) for the Nexfin™ and BPosc, respectively.

The Bland–Altman comparison demonstrated a systematic bias of -10 mmHg for Nexfin™, with limits of agreement from -61 to +41 mmHg (Fig. 3).

According to the four-quadrant graph, 73.9% of the paired SBPs were in Zones A and B, implying that the two methods simultaneously detected either normotension or hypotension. The BPosc would have resulted in treatment for hypotension that would have been undiagnosed by the CNBP in 9.9% of the cases

Table 1

Parturient characteristic data and neonatal outcomes (n = 160).

Maternal variables	
ASA I/II	126/34
Weight (kg)	75 ± 12
Height (cm)	165 ± 7
Age (years)	35 ± 4
Gestational age (weeks)	39 [35–41]
Spinal to delivery time (min)	20 [16–23]
First bolus of vasoactive drug (min)	2 [0–5]
Vasoactive drug boluses (number)	4 [2–5]
Neonatal outcomes	
Apgar score = 10 at 1 min	139 (87%)
Apgar score = 10 at 5 min	148 (93%)
Umbilical venous pH	7.32 [7.28 – 7.36]
Lactate concentration in the umbilical vein (mmol/L)	1.96 [1.63 – 2.50]

ASA = American Society of Anesthesiology.
Data are expressed as the mean ± SD or median [25–75 percentiles] for continuous data and as number (percentage) for categorical data.

(Zone C). The CNBP measurements would have led to the treatment of hypotension in 16.2% of cases that would not have been detected by BPosc (Zone D) (Fig. 4).

The diagnostic accuracy of Nexfin™ can also be evaluated as the percentage of parturients diagnosed as hypotensive by both methods (63.2%) and the percentage of those where the oscillometric method is faulty (35.3%), leaving 1.5% of the cases where it is the Nexfin™ that is faulty.

There was a significant difference in neonatal umbilical vein pH according to a threshold of vasopressor bolus above 4 ($P < .001$), with a lower pH indicated by a number exceeding 4, but there was no difference in Apgar scores at 1 min ($P = .803$). All the newborns except one had an Apgar score of 10 at the 10th min. The tolerance score measured by the VAS was 8.5 ± 1.8 for CNBP and 7.5 ± 2.0 for BPosc ($P < .001$).

No complications related to the use of the Nexfin™ device were observed during the study period.

4. Discussion

We investigated the performance of a continuous CNBP for detecting arterial hypotension during spinal anesthesia for cesarean delivery and compared the results with those obtained using routine intermittent measurement of BP by oscillometry. Notably, this study showed that

1. the intermittent traditional method (oscillometry) has data gaps unlike the continuous method (Nexfin™),
2. there was a longer delay in detecting hypotension with oscillometry, and
3. the agreement limits are too wide to suggest replacing oscillometry with the Nexfin™.

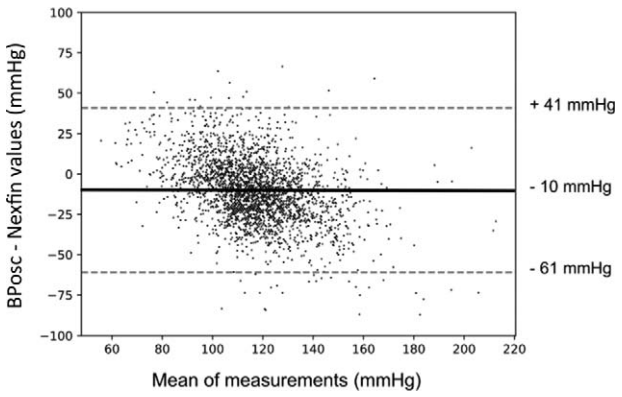

Figure 3. Bland–Altman analysis for repeated measures graphical representation of agreement in systolic blood pressure values between Nexfin (CNBP) and oscillometric arm blood pressure (BPosc). The bold horizontal line represents the bias, and the dotted lines represent the upper and lower limits of agreement.

Ilieş et al[12] previously compared the continuous noninvasive arterial pressure (CNAP) monitor with discontinuous automated oscillometric measurements obtained every three minutes during cesarean delivery under spinal anesthesia. The authors showed that SBP was detected at lower limits and that hypotensive periods were identified more often by continuous measurement than by standard monitoring every three minutes. In addition, the authors reported missing nearly 40% of all hypotensive episodes when using intermittent measurements. Furthermore, the authors suggested in their conclusion that CNAP might play a possible role in these surgeries and recommended an interval of one minute with oscillometry to limit undetected events. Our results are similar to these findings, even though we used this recommendation of measurement every minute. The number of values missed by oscillometry remains high (>20%) and suggests that care providers may miss the occurrence of a significant event in many cases. In this situation, clinical signs of hypotension, such as unconsciousness, dizziness, nausea, and vomiting,[19,20] are the only signs of alert, but they can also signify fetal hypoperfusion. Indeed, potential fetal side effects are caused by a reduction in uterine blood flow, which can produce a consequential reduction in the fetal oxygen supply, leading to acidosis and impaired Apgar scores.[3,21] This consequence was associated with a difference in pH in cases in which a vasopressor was repeatedly administered. This was supported in our cohort by an association with a low pH and more than four instances of bolus administration of vasopressor. Therefore, much effort has recently been devoted to evaluating prophylactic treatments for hypotension after spinal anesthesia. The incidence rate of hypotension remains high and could be reduced to some extent.[5] Although our clinical routine includes a volume coloaded with Ringer's solution and the rapid application of vasopressors, hypotension still occurred in 79% of our parturients and represented nearly 20% of the overall measurements despite this treatment. Therefore, this frequent event and the 20% of parturients lacking data with the oscillometric technique emphasize the need for a device that accurately measures this parameter. In this context, CNBP with Nexfin™ may represent a key component with no lack of data above 1 min and an earlier detection of major events. This accurate and continuous measurement may reduce the rate of symptomatic hypotension and potentially reduce the total number of administered boluses of vasopressors, which can affect materno-fetal circulation. On the other hand, the high rate of masked hypotension with oscillometry may question the validity of this older technique. This commonly used traditional technique was originally used to detect chronic arterial hypertension. Consequently, its performance for detecting a hypotensive event or sudden variation in arterial pressure is considered acceptable, but it is objectively questionable and has been demonstrated to be unacceptable in a critical care unit.[22] Moreover, the time interval before detection of a relevant event was significantly

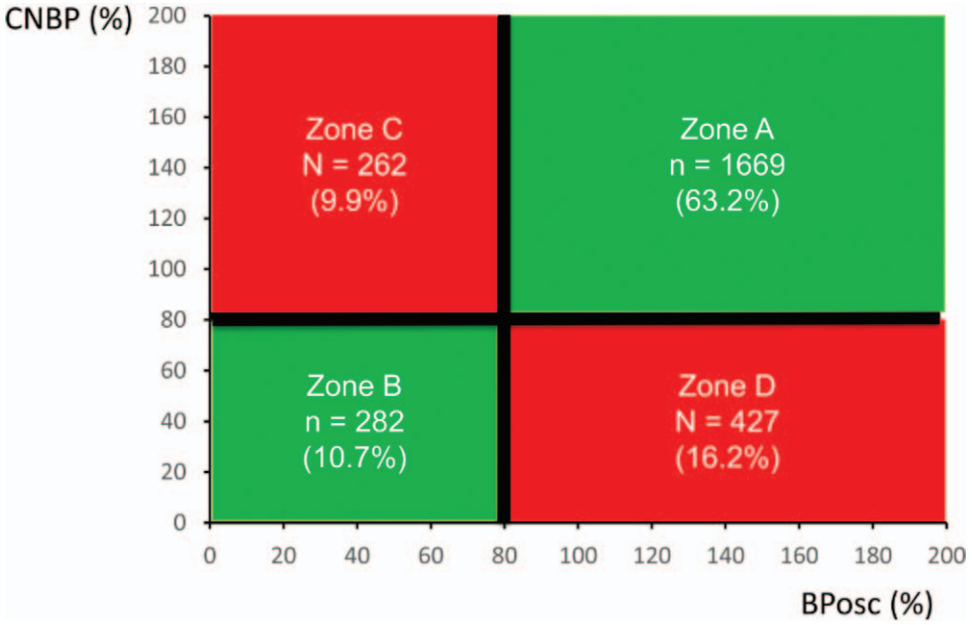

Figure 4. Four-quadrant representation of the performance of both devices for detecting hypotension BPosc: Intermittent oscillometric arm blood pressure. CNBP = Continuous noninvasive blood pressure. Zone A = data points above 80% of the baseline (normotension) for both devices. Zone B = data points under 80% of the baseline (hypotension) for both devices. Zones C and D = contradictory results between the devices that could have led to a different treatment.

reduced with Nexfin^{TM} (330 s versus 440 s for BPosc, with $P < .01$), and this gain may reduce the symptoms of hypotension or the delay before treatment. Its performance in this field was demonstrated by Juri et al in 40 cesarean deliveries where the administration of vasopressors was guided by CNBP or BPosc.[23] The authors showed a significant decrease in arterial hypotension and nausea in the CNBP arm: 0% versus 45% ($P < .001$) and 10% versus 45% ($P = .012$), respectively.

Concerning Nexfin^{TM}, we observed a relatively constant and unexpected bias of -10 mmHg, as shown in Figure 3. To explain this deviation, we constructed a model that included the influence of the tilt position, which potentially plays a role in differences in measurements obtained between the left and right arms after calibration in the supine position. This model partially explained the observed bias because a tilt of 5° increased the height of the arm with the brachial cuff by 10 cm and could have altered the value by 9 mmHg if we had used this position. However, the agreement limits were wide and could not be explained by any reasonable factor. This discrepancy was also described for other devices, such as CNAP^{TM} and was less important for Nexfin^{TM} in other studies.[24] We suspect that the change in position within a short period is a perturbing factor (calibration in the supine position, spinal anesthesia in the sitting position and cesarean delivery in the left tilt position). Juri et al observed a better agreement limit in a similar design, but spinal anesthesia was performed in a lateral position, and calibration of the CNBP was performed after puncture.[23] In any case, a continuous CNBP variation may alert the physician to make a decision, such as whether to exert control using the reference method, to wait or to administer prophylactic vasopressors.

This finding leads to an attempt at closed-loop feedback when using computer-controlled infusion. Ngan Kee et al performed the first trial using intermittent blood pressure measurements and concluded that this method produced no improvement in clinical outcome.[25] However, a closed loop performed using CNAP^{TM} resulted in an improvement in BP control and a lower incidence of nausea and vomiting than was observed for intermittent blood pressure measurements.[26,27] These results were replicated for Nexfin^{TM}[15] and remained true despite an apparent discrepancy between our study and the two previous studies. Our study compared the absolute values of systolic blood pressure between the Nexfin^{TM} and the BPosc, while this is the trend in the variation in the systolic blood pressure that has been analyzed in the algorithms of Sng et al.[15]

4.1. Limitations of the study

The limitations in the current study should be mentioned. The first point concerns the number of patients included. The standard approach is to calculate this number based on an expected difference between methods, its variance, and the alpha and beta risks. We choose to follow the advice from Linnett,[17] which recommends studying more than 150 patients to yield a power of 90% and a bilateral risk of 5% when comparing two methods. We studied data from 160 parturients, which translated to 2640 pairs of data. Second, some of our results could have been modified by the inflation and deflation of the brachial cuff every minute, which induces reactive hyperemia, and by the systemic changes in vasomotor tone produced by vasopressor drug boluses.[27,28] The third limitation concerns the definition of arterial hypotension which is variously described in the literature and we chose a well-accepted one as a 20% decrease of the baseline. Any other definition could have changed the performance of non-invasive blood pressure measurement.

In conclusion, our study shows that agreement between Nexfin^{TM} and the intermittent method of measuring systolic blood pressure is not in an acceptable range in parturients receiving spinal anesthesia for elective cesarean delivery. However, the Nexfin^{TM} device diagnosed hypotension earlier than intermittent oscillometry. Thus, these two methods could be

complementary, with the continuous method allowing early detection of hypotension and the oscillometric method providing confirmation.

Author contributions

Conceptualization: Mathieu Bobet, Etienne Gayat, Marc Fischler, Morgan Le Guen.
Data curation: Mathieu Bobet, Agnès Bonnet, Kerstin Sievert, Carole Barnichon, Morgan Le Guen.
Formal analysis: Mathieu Bobet, Jona Joachim, Etienne Gayat, Marc Fischler, Morgan Le Guen.
Investigation: Mathieu Bobet, Agnès Bonnet, Kerstin Sievert, Carole Barnichon, Morgan Le Guen.
Methodology: Jona Joachim, Etienne Gayat, Marc Fischler, Morgan Le Guen.
Project administration: Marc Fischler, Morgan Le Guen.
Supervision: Marc Fischler, Morgan Le Guen.
Visualization: Jona Joachim, Etienne Gayat, Marc Fischler, Morgan Le Guen.
Writing – original draft: Jona Joachim, Marc Fischler, Morgan Le Guen.
Writing – review & editing: Mathieu Bobet, Jona Joachim, Etienne Gayat, Agnès Bonnet, Kerstin Sievert, Carole Barnichon, Marc Fischler, Morgan Le Guen.

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