The Nexfin™ device for continuous non-invasive arterial pressure monitoring is a successor of the Finapres™ device and is based upon similar technology.

The Nexfin™ device has proved to be reliable in adult subjects.

In this study of a paediatric adaptation of the Nexfin™ monitor, it reported arterial pressure values that accurately reflected intra-arterial values and accurately tracked arterial pressure changes.

The Nexfin™ device could not record the arterial pressure on several patients and further development may be of value.

In children undergoing major surgery, significant changes in arterial pressure may result in decreased organ perfusion and tissue damage. Routinely, non-invasive arterial pressure (NIAP) measurement using the automatic oscillometric technique with an upper arm inflatable cuff is used during anaesthesia. NIAP measurement is an easy, relatively fast, non-invasive but intermittent technique. Therefore, NIAP is less suitable for monitoring patients with (possible) rapid changes in arterial pressure. Also NIAP measurements may be less reliable compared with intra-arterial pressure (IAP) measurement.

IAP measurement using an intra-arterial catheter is commonly used during major surgery and in critically ill patients. IAP provides a reliable and continuous arterial pressure measurement and also allows for blood sampling. However, arterial catheter placement in children is undesirable before induction of anaesthesia, can be time-consuming, and requires extensive experience. In addition, the method is associated with a small risk of bleeding, infection, and distal limb ischaemia. For these reasons, NIAP is still frequently used in small children.
Arterial pressure can be continuously monitored using an inflatable cuff around the finger using the Nexfin™ device (BMEYE, Amsterdam, The Netherlands). The Nexfin™ device is the improved and further developed successor of the former Finapres™ device (Ohmeda, USA) and is based upon similar technology. This non-invasive finger arterial pressure (FAP) measurement method has been widely studied and has proven to be feasible and reliable in adult subjects. 7, 8 Accuracy and precision of Nexfin™ in adult patients are compatible with the standards of the Association for the Advancement of Medical Instrumentation (AAMI) that allow a maximum bias of 5 mm Hg and a maximal standard deviation of 8 mm Hg. 9–10

The former Finapres device has previously been studied in children using cuffs originally designed for adults. In these studies, there was a significant measurement bias compared with IAP, but the Finapres accurately tracked short-term arterial pressure changes. 11–13

Recently, a research prototype with special adaptations for use in the paediatric population (Nexfin-paediatric) was developed by the company that develops the Nexfin™ device and, in the past, also developed the Finapres device (BMEYE, Amsterdam, The Netherlands). In two recent studies, the accuracy of this new prototype for measuring arterial pressure in critically ill children under haemodynamic stable conditions was shown to be acceptable compared with IAP. 14, 15

The goal of the present study was to assess the accuracy of Nexfin-paediatric in detecting rapid arterial pressure changes in young children undergoing congenital cardiac surgery.

Methods

Subjects

We included 13 children undergoing congenital cardiac surgery. In all children, IAP monitoring was part of their routine anaesthetic management. Non-invasive FAP measurements were only used for research purposes and not for clinical decision-making. Because of the non-invasive and observational design of adding FAP measurements, the local ethics committee approved the study protocol and waived the need for informed consent. We chose this patient group because of the availability of IAP in all children and the magnitude of the expected arterial pressure changes.

Anaesthesia

Premedication consisted of the rectal administration of midazolam 0.3–0.5 mg kg⁻¹. Induction of anaesthesia was performed using inhaled sevoflurane (3–8%). General anaesthesia was instituted using continuous inhaled sevoflurane (~3%) and midazolam (range 0.2–0.3 mg kg⁻¹) in combination with fentanyl boluses (range 1–5 µg kg⁻¹) or continuous infusion (0.1 µg kg⁻¹ min⁻¹) at the discretion of the attending anaesthetist. Muscle relaxation was achieved using pancuronium 0.2 mg kg⁻¹. The trachea was intubated using a 3.5–6 mm cuffed tracheal tube (Mallinckrod, Hazelwood, MO, USA), and the lungs were mechanically ventilated in a volume-controlled mode using tidal volumes of ~6–10 ml kg⁻¹ (Aestiva, Datex-Ohmeda, Madison, WI, USA).

Normocapnia, guided by capnography, was achieved by adjusting the respiratory frequency or tidal volume to maintain an end-tidal CO₂ tension between 4 and 5 kPa. At the end of the surgical procedure, all children were admitted to the paediatric intensive care unit. Children were routinely monitored using EKG, IAP, transcutaneous arterial oxygen saturation, capnography, core temperature, skin temperature, and central venous pressure.

Non-invasive arterial pressure measurement

The Nexfin-paediatric is a research prototype that provides continuous, non-invasive FAP in children. Both the former Finapres device and the new prototype are based upon the volume-clamp principle of Peñaz in combination with the Physiocal criteria of Wesseling. 16–18 The device uses an inflatable finger cuff with a built-in photoplethysmograph (Fig. 1). The pressure in the finger cuff is controlled by a fast reacting servo system. The setpoint of the servo is determined by the Physiocal criteria and is dependent on the visco-elastic properties of the wall of the finger arteries. The Physiocal criteria drive the calibrating procedure of the device. This calibrating procedure is performed automatically and is activated frequently at the start of the measurement; its frequency declines when a more stable signal is detected. With this method, the finger cuff never occludes the finger arteries, which means that the blood flow to the finger is maintained under all circumstances. The pressure in the inflatable cuff closely resembles the FAP. FAP is physiologically lower than arterial pressure measured at the brachial level, which is the most common site of arterial pressure readings. Also the waveform characteristics are different. 19

To solve this discrepancy, a software algorithm can be used which converts the FAP to a reconstructed brachial artery pressure waveform (reBAP). 8, 21, 22 In adults, reBAP is

Fig 1 Example of a prototype finger cuff applied in a child of 2.5 yr (11 kg) with finger circumferential of 3.5 cm.
Invasive arterial pressure measurement

After induction of anaesthesia, a 22 or 24 G catheter was inserted and connected, using standard low compliant tubing, to a disposable pressure transducer (Edwards Lifesciences, Irvine, CA, USA). The attending paediatric cardiac anaesthetist chose the site of insertion based upon clinical judgement. The radial and femoral arteries were the preferred sites. The brachial artery was only used when other routes were unsuccessful. The pressure transducer was zeroed to ambient air pressure and positioned at the level of the mid-axillary line. Air bubbles were flushed from the system before data collection. The IAP measurement was checked for quality by visually inspecting the waveform and performing a square wave test. With this test, under-damped (extra oscillations) or over-damped (slowed upstroke and loss of oscillations) pressure systems can be identified. Routine monitoring was instituted using the HP Merlin CMS monitoring system (originally a product of HP, Irvine, CA, USA; nowadays: Philips, Eindhoven, The Netherlands). The monitor output signal was connected to the Nexfin-paediatric pressure measurement device, which enabled the registration of the arterial curve with 200 Hz sampling rate.

Recording of IAP and FAP

After IAP was obtained, an appropriate size finger cuff was placed on the middle phalanx of the second or third finger, preferably according to the guidelines provided by the manufacturer. In the child with a brachial arterial catheter, the cuff was placed on the contralateral hand. In five children with a radial artery catheter, the cuff was also placed on the contralateral side in all but one. When a femoral arterial catheter was used either hand could be taken for finger cuff placement. The same observer (C.M.H.) applied the finger cuff in all experiments.

An attempt to acquire FAP was defined as a procedure to apply or reapply the finger cuff and start the device until an acceptable finger arterial curve appeared on the screen and the Physiocal calibrating procedures were infrequent. The quality of the FAP curve was the primary consideration and resemblance with the IAP curve was not checked since reconstruction of the FAP signal to reBAP was not performed at this stage.

The hand was fixed at the mid-axillary level to prevent any hydrostatic level errors. FAP and IAP were simultaneously and continuously recorded using the prototype device during the whole course of the surgical procedure, with exception of the period on cardiopulmonary bypass (CPB). Although measurement of FAP is possible during CPB, this was not the goal of this study.

Core temperature and temperature of the palm of the hand to which the finger cuff was attached were constantly monitored. The hand and fingers were checked regularly for signs of tissue hypoxia or other side-effects.

Data comparison

As noted above, data were analysed offline. We compared IAP and reBAP measurements of absolute arterial pressure levels during a 10 s control period after onset of a recording session. To determine the ability of reBAP to track arterial pressure changes, we identified the four largest changes in IAP during each surgical procedure. This was done by analysing the complete IAP recording afterwards for the whole procedure without knowing the reBAP data. For each patient, we searched for large changes in mean arterial pressure (MAP) regardless of whether these changes were an increase or a decrease in arterial pressure. In order to select only rapid changes, we also searched only for changes that occurred within a 5 min time frame. Eventually, the four largest changes in MAP that occurred within a 5 min time interval were eligible for further analysis. At last, we compared the arterial pressure values acquired with IAP with the values of reBAP during a 10 s period just before and after an arterial pressure change occurred.

Statistical analysis

To assess the adequacy of reBAP in determining absolute arterial pressure levels, we compared reBAP and IAP and calculated bias (reBAP−IAP) and limits of agreement (LOA) (1.96×SD) using the Bland–Altman method. Only one measurement per patient was used for comparing absolute values. To determine the accuracy of tracking arterial pressure changes, we compared the IAP changes with the changes in reBAP using the Pearson correlation coefficient and the Bland–Altman analysis for multiple measurements per subject. Data were checked for normal distribution using the Kolmogorov–Smirnov test. The influence of
vasoactive drugs on the mean bias was checked using Student’s t-test.

The primary goal of this study was to compare changes in arterial pressure as measured by reBAP and IAP. Therefore, we considered a correlation coefficient between changes in reBAP and IAP of 0.9 or greater significant. At the same time, a value of 0.7 (or less) would be unacceptable. When using a significance level of 0.05 and a power of 0.9, this would require a sample size of 31.7. Since we planned to analyse the four greatest changes in arterial pressure per patient, this would result in eight children. Because of uncertainties with respect to technical aspects, we included five more children (total 13).

Calculations and data management were performed using Excel for windows (Office 2007, Microsoft, Seattle, WA, USA). Statistical calculations were performed with MedCalc 11 (MedCalc Software, Mariakerke, Belgium).

**Results**

Thirteen children (ASA classes II–IV) with a median age of 11 months undergoing congenital cardiac surgery were included in the study. All patients had an adequate IAP signal. In three children, no FAP curve could be obtained even after multiple attempts with different sized cuffs on different fingers. These children were not different from the other 10 concerning type of surgery, baseline arterial pressure, heart rate, or hand temperature. The overall success rate was therefore 76%. Patient characteristics are described in Table 1.

On average, we needed five attempts for each patient (range 1–22) to obtain an acceptable FAP signal. A total of 1100 min of simultaneous arterial pressure registration was recorded with a mean of 106 min (range 50–180 min) per patient. Eventually, data from 10 patients were eligible for further analysis including the four largest arterial pressure changes per patient, and this resulted in 40 data points for analysis.

During anaesthesia, the mean MAP value measured intraarterially was 59.5 mm Hg (range 28.4–106.6 mm Hg). An example of an individual tracing of reBAP and IAP is shown in Figure 2.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (month)</th>
<th>Weight (kg)</th>
<th>Vasoactive drugs</th>
<th>Procedure</th>
<th>FAP measurement successful</th>
<th>Temperature of the hand (°C)</th>
<th>IAP, mean (range) (mm Hg)</th>
<th>IAP catheter site</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>47</td>
<td>15</td>
<td>k</td>
<td>PA</td>
<td>Yes</td>
<td>35.6</td>
<td>42.5 (48.5–110.2)</td>
<td>rad</td>
</tr>
<tr>
<td>2</td>
<td>33</td>
<td>12</td>
<td>—</td>
<td>Fallot</td>
<td>Yes</td>
<td>33.9</td>
<td>46.9 (33.2–63.5)</td>
<td>fem</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>5</td>
<td>d</td>
<td>VSD</td>
<td>Yes</td>
<td>37</td>
<td>67.2 (41.7–89.7)</td>
<td>fem</td>
</tr>
<tr>
<td>4</td>
<td>90</td>
<td>31</td>
<td>—</td>
<td>Ross procedure</td>
<td>Yes</td>
<td>36.4</td>
<td>63.7 (36.2–88.0)</td>
<td>rad</td>
</tr>
<tr>
<td>5</td>
<td>44</td>
<td>13</td>
<td>—</td>
<td>ASD</td>
<td>Yes</td>
<td>32.9</td>
<td>64.6 (36.5–77.5)</td>
<td>rad</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>4</td>
<td>m, n, d</td>
<td>VSD</td>
<td>No</td>
<td>33</td>
<td>54.2 (43.2–68.2)</td>
<td>fem</td>
</tr>
<tr>
<td>7</td>
<td>4</td>
<td>4</td>
<td>—</td>
<td>VSD</td>
<td>No</td>
<td>35</td>
<td>54.8 (38.0–70.7)</td>
<td>fem</td>
</tr>
<tr>
<td>8</td>
<td>23</td>
<td>15</td>
<td>m, f</td>
<td>Fontan</td>
<td>Yes</td>
<td>35.5</td>
<td>43.8 (35.0–54.0)</td>
<td>fem</td>
</tr>
<tr>
<td>9</td>
<td>3</td>
<td>4</td>
<td>m</td>
<td>VSD</td>
<td>No</td>
<td>33</td>
<td>49.2 (30.8–64.2)</td>
<td>fem</td>
</tr>
<tr>
<td>10</td>
<td>37</td>
<td>12</td>
<td>m, f</td>
<td>Fontan</td>
<td>Yes</td>
<td>34.7</td>
<td>53.3 (33.0–68.8)</td>
<td>brach</td>
</tr>
<tr>
<td>11</td>
<td>2</td>
<td>4</td>
<td>m, n, d</td>
<td>VSD</td>
<td>Yes</td>
<td>31.1</td>
<td>41.0 (19.7–87.2)</td>
<td>rad</td>
</tr>
<tr>
<td>12</td>
<td>8</td>
<td>7</td>
<td>e</td>
<td>Glenn</td>
<td>Yes</td>
<td>34.4</td>
<td>54.9 (35.0–67.0)</td>
<td>fem</td>
</tr>
<tr>
<td>13</td>
<td>11</td>
<td>10</td>
<td>m</td>
<td>Fallot</td>
<td>Yes</td>
<td>30.6</td>
<td>55.5 (36.7–67.0)</td>
<td>rad</td>
</tr>
</tbody>
</table>
Compared with IAP, reBAP underestimated systolic arterial pressure (SAP) by 8.9 mm Hg with LOA ± 20, overestimated diastolic arterial pressure (DAP) with bias of 1.8 mm Hg (LOA ± 11), and overestimated MAP with a bias of 0.3 mm Hg (LOA ± 9.3).

The bias between the two measurement methods was not significantly correlated to body weight, hand temperature, or core temperature with a correlation of $r^2 = 0.53$ (95% CI $0.86$ to $0.14$), $0.08$ (95% CI $-0.74$ to $0.66$, and $-0.24$ (95% CI $-0.84$ to $0.62$) respectively. There was no difference in bias between IAP measured at the radial artery and reBAP or IAP measured at the femoral artery and reBAP.

Changes in arterial pressure measured with reBAP and IAP were highly correlated with $r^2$ of 0.96 for SAP, 0.97 for DAP, and 0.98 for MAP. The changes in MAP are shown in Figure 3. reBAP tracked changes in IAP with a mean bias for SAP, DAP, and MAP of 0.0 (SD 5.8), 0.1 (SD 2.8), and 0.2 mm Hg (SD 2.7), respectively (Fig. 4).

**Discussion**

Our study demonstrates that reBAP measured with the prototype Nexfin-paediatric is capable of tracking arterial pressure changes in children undergoing congenital cardiac surgery. Although several previous studies have been performed in children using the former Finapres device, this is the first study to use finger cuffs and physiological software especially designed for small children during major surgery. The accuracy of reBAP in determining absolute arterial pressure was comparable with a previous study performed in critically ill children.\(^\text{14}\)

Unfortunately, in almost 25% of patients, a FAP signal was not obtainable after induction of anaesthesia. This is different from previous studies performed in small children admitted to an ICU and from studies in adult patients where reBAP shows a success rate of 97%.\(^\text{8-15,26}\) Besides a lower success rate, the absolute difference between reBAP and IAP was comparable with the previous study.\(^\text{14}\) DAP and MAP were adequately reflected by reBAP, but there was a 9 mm Hg underestimation of SAP.

The lower success rate may be explained by the use of volatile anaesthetics, the occurrence of core hypothermia, and a decreased environmental temperature in the operating theatre. Volatile anaesthetics may reduce peripheral blood flow.\(^\text{27}\) However, after induction, intraarterial diastolic pressure decreased to an average of 46 mm Hg which was only slightly lower than the pressures measured in previous studies. Core hypothermia, which commonly occurs during surgery, causes vasoconstriction in digital arteries, which reduces blood flow. The use of sevoflurane impairs this thermoregulatory response, lowering the threshold for peripheral vasoconstriction to 35.1°C.\(^\text{28}\) However, hand temperature was not significantly lower in those patients where a non-invasive signal was unobtainable.
When assessing the accuracy of a new measuring device, one has to ensure an appropriate ‘gold standard’ for comparison. When a gold standard does not exist, a new method has to be compared with the next best method. In this particular study, we used the intra-arterially measured arterial pressure. However, the adequacy of the IAP, systolic pressure in particular, is affected by the quality of the pressure waveform. Therefore, measurement discrepancies between reBAP and IAP may also result from measurement errors in IAP, although an adequate IAP signal was obtainable in every patient.

A limitation of this study is the use of different catheter insertion sites for the measurement of IAP, although we were unable to detect significant differences in bias between various arterial catheter insertion sites. Also, there was no relationship between bias on the one hand and core temperature, hand temperature, or the use of vasoactive drugs on the other.

Despite a recording period of several hours, we did not encounter any side-effects. This is in agreement with previous studies in children.

The research prototype type and the paediatric finger cuffs need further development for clinical use in a next version of this device. Also, this version of the software algorithm for reconstructing the brachial arterial signal is designed for adults. Although it performed acceptably in an earlier paediatric study, a further improved version for a paediatric population is currently under construction.
Further improvement is based upon the different elastic properties of arteries in children compared with adults.\textsuperscript{19} Thereafter, more research is needed to evaluate the accuracy of this new technique in children.

With regard to the commercially less interesting paediatric market, this development poses a challenge to every manufacturer.

In adults, the Nexfin technology is capable of measuring cardiac output using a reconstructed brachial arterial pressure curve; this may be a valuable adjunct to Nexfin-paediatric.\textsuperscript{30,31} Also, the reBAP signal could be used for determining fluid status using arterial pressure variations.\textsuperscript{32} In certain cases where a fast continuous technique is vital, such as emergency medicine, anaesthesia, and critical care medicine, a non-invasive finger sensor device could prove to be effective. Also, given the non-invasive nature of the measurement, this continuous technique could be valuable for research purposes.

Continuous non-invasive reconstructed brachial arterial pressure from FAP adequately reflects IAP changes in children during cardiac surgery. However, the measurement in the operating theatre using this prototype can, at the present state of development, still be time-consuming and has a significant failure rate. With further development, this technology could be useful for monitoring arterial pressure in children in the clinical setting.

Conflict of interest

O.S. is a former employer of BMEYE. J.J.S. is Chief Technology Officer of BMEYE.

Funding

The research prototype Nexfin-paediatric device was supplied by the BMEYE company. No further funding was received.

References


3 Pace NL, East TD. Simultaneous comparison of intraarterial, oscillometric, and finapres monitoring during anesthesia. \textit{Anesth Analg} 1991; \textbf{73}: 213–20

4 Movius AJ, Bratton SL, Sorensen GK. Use of pulse oximetry for blood pressure measurement after cardiac surgery. \textit{Arch Dis Child} 1998; \textbf{78}: 457–60


6 Scheer B, Perel A, Pfeiffer UJ. Clinical review: complications and risk factors of peripheral arterial catheters used for hemodynamic monitoring in anaeesthesia and intensive care medicine. \textit{Crit Care} 2002; \textbf{6}: 199–204

7 Silke B, McAuley D. Accuracy and precision of blood pressure determination with the Finapres: an overview using re-sampling statistics. \textit{J Hum Hypertens} 1998; \textbf{12}: 403–9


9 Association for the Advancement of Medical Instrumentation (AAMI). \textit{Manual, Electric or Automated Sphygmomanometers}, 2003


12 Drouin E, Gournay V, Calamel J, Mouzard A, Rozé JC. Feasibility of using finger arterial pressure in neonates. \textit{Arch Dis Child Fetal Neonatal Ed} 1997; \textbf{77}: F139–40

13 Triedman JK, Saul JP. Comparison of intraarterial with continuous noninvasive blood pressure measurement in postoperative pediatric patients. \textit{J Clin Monit} 1994; \textbf{10}: 11–20


16 Penaz J. Photoelectric measurement of blood pressure, volume, and flow in the finger. 10th International Conference of Medical Biology and Engineering. Dresden, Germany, 1973

17 Wesseling KH, Settels WB, Klawer WH. On the indirect registration of finger blood pressure after penaz. \textit{Funct Biol Med} 1982; \textbf{1}: 245–50


25 Bland JM, Altman DG. Agreement between methods of measurement with multiple observations per individual. \textit{J Biopharm Stat} 2007; \textbf{17}: 571–82

26 Turner RJ, Gatt SP, Kam PCA, Ramzan I, Daley M. Administration of a crystalloid fluid preload does not prevent the decrease in arterial blood pressure after induction of anaesthesia with propofol and fentanyl. \textit{Br J Anaesth} 1998; \textbf{80}: 737–41


