BJA

*British Journal of Anaesthesia*, 117 (3): 316–23 (2016)

**doi: 10.1093/bja/aew268**
Cardiovascular

# Validation of non-invasive arterial pressure monitoring during carotid endarterectomy

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## Abstract

**Background:** Patients undergoing carotid endarterectomy require strict arterial blood pressure (BP) control to maintain adequate cerebral perfusion. In this study we tested whether non-invasive beat-to-beat Nexfin finger BP ($BP_{fin}$) can replace invasive beat-to-beat radial artery BP ($BP_{rad}$) in this setting.

**Methods:** In 25 consecutive patients (median age 71 yr) scheduled for carotid endarterectomy and receiving general anaesthesia, $BP_{fin}$ and $BP_{rad}$ were monitored simultaneously and ipsilaterally during the 30-min period surrounding carotid artery cross-clamping. Validation was guided by the standard set by the Association for the Advancement of Medical Instrumentation (AAMI), which considers a BP monitor adequate when bias (precision) is <5 (8) mm Hg, respectively.

**Results:** $BP_{fin}$ *vs* $BP_{rad}$ bias (precision) was −3.3 (10.8), 6.1 (5.7) and 3.5 (5.2) mm Hg for systolic, diastolic, and mean BP, respectively. One subject was excluded due to a poor quality BP curve. In another subject, mean $BP_{fin}$ overestimated mean $BP_{rad}$ by 13.5 mm Hg.

**Conclusion:** Mean $BP_{fin}$ could be considered as an alternative for mean $BP_{rad}$ during a carotid endarterectomy, based on the AAMI criteria. In 23 of 24 patients, the use of mean $BP_{fin}$ would not lead to decisions to adjust mean $BP_{rad}$ values outside the predefined BP threshold.

**ClinicalTrials.gov:** NCT01451294.

**Key words:** carotid endarterectomy; measurement techniques, arterial pressure; Nexfin; non-invasive continuous arterial pressure measurement

In patients with a high-grade symptomatic stenosis of the internal carotid artery, carotid endarterectomy (CEA) is the recommended treatment to prevent future cerebrovascular events.[1 2 3] Reduced flow through carotid arteries often leads to impaired cerebral autoregulation, implying that cerebral perfusion becomes dependent on blood pressure.[4 5] Therefore, strict arterial blood pressure (BP) control has to be maintained perioperatively and it is recommended to monitor BP beat-to-beat via a catheter placed in an artery. Arterial cannulation is invasive, sometimes time-consuming and painful. Complications, although rare, include local infection, sepsis, pseudoaneurysm, and thrombosis.[6] Although anaesthetists and some other doctors are trained in

**Accepted:** June 30, 2016

**Editor's key points**

- Strict BP control traditionally requires direct arterial cannulation and monitoring.
- At least one non-invasive device estimates BP using a finger cuff and photoplethysmography.
- This study found that non-invasive estimation of mean BP was in close agreement with invasive BP.
- Non-invasive beat-to-beat monitoring is likely to be a suitable option in selected cases.

arterial cannulation, the first attempt using palpation has a success rate of <50% and sometimes cannulation still fails despite the use of ultrasound.[7]

Nexfin (Edwards Lifesciences, Irvine, CA, USA) is a device enabling continuous beat-to-beat non-invasive BP monitoring, using the finger cuff technology proposed by Peňáz in 1973.[8] Previous studies found that the Nexfin photoplethysmograph is reliable in pregnancy, in children, in patients undergoing cardiovascular surgery, and in those with vascular disease, hypertension, or tachycardia.[9–14] Recently, however, two studies concluded that it cannot sufficiently replace invasive BP monitoring in critically ill patients.[15 16]

The criteria for validating beat-to-beat BP devices are subject to ongoing debate. The international standard for non-invasive sphygmomanometers from the Association for the Advancement of Medical Instrumentation (AAMI),[17] which is the most used standard with guidelines to validate intra-arterial measurement devices, is not intended for validation of non-invasive continuous beat-to-beat BP monitors. The AAMI does not standardize how many and which beats or time periods should be analyzed.[16] To validate Nexfin in patients undergoing a CEA, we used the AAMI's standard, but we also analysed whether wrong clinical decisions would be made to maintain cerebral perfusion when non-invasive BP monitoring replaced invasive BP monitoring.

## Methods

### Patients

Patients included in the current study were originally included in the PEPPER trial, a study that aimed to assess the effect of two routinely used vasopressors (phenylephrine and ephedrine) on the cerebral haemodynamics during CEA.[18] This study was approved by the Medical Research Ethics Committee of the University Medical Center, Utrecht. The protocol of the PEPPER trial[17] was published in the trial register (ClinicalTrials.gov: NCT01451294). All subjects received verbal and written explanations of the objectives and the techniques of measurement, as well as the risks and benefits associated with the study, and subsequently provided written informed consent in accordance with the Helsinki Declaration.

### Measurements

All patients received standard monitoring [electrocardiography, end-tidal carbon dioxide, non-invasive BP, with an upper arm cuff of which the size was adapted to body weight and posture, and pulse oximetry by a Datex Ohmeda S/5 system (GE Healthcare, Waukesha, WI, USA)]. Invasive beat-to-beat BP was monitored with an artery line (Arbocath 20 G; Hospira, Lake Forest, IL, USA) placed in the radial artery ipsilateral to the upper arm cuff ($BP_{rad}$). To ensure reliable data, the radial artery catheter was flushed, the pressure bag was pressurized and maintained at 300 mm Hg, zero-referencing was performed, and the pressure transducer was zeroed at the level of the right atrium and maintained at all times during surgery.

Non-invasive beat-to-beat finger BP ($BP_{fin}$) was measured using the Nexfin system (Edwards Lifesciences, Irvine, CA, USA). Nexfin measures by photoelectric plethysmography and servo-controlled cuff pressure as proposed by Peňáz.[8] A detailed description has been previously published.[10] The finger cuff, the size of which was selected to fit the size of the finger, was placed on the mid-phalanx of either the ring finger or the middle finger ipsilateral to the radial artery line and upper arm cuff. To detect changes in finger arterial physiology, a built-in expert system (Physiocal)[19] tracks the unloaded diameter of the finger artery to establish and adjust the arterial unloaded volume at least once every 70 heartbeats. According to the Nexfin operator's manual, a Physiocal interval >30 beats indicates stable and reliable pressure measurement.[20] The 'heart reference system', with which the Nexfin is equipped, was not used because all patients were in the supine position and had their hands at their side during the entire procedure.

As per our local standard of care for CEA procedures with selective carotid clamping, changes in brain perfusion were monitored with electroencephalography (EEG; Micromed, Treviso, Italy) and ipsilateral transcranial Doppler to determine middle cerebral artery blood flow velocity (DWL; Multidop X4, Sipplingen, Germany).

### CEA protocol

The CEA procedure was performed in a tertiary referral vascular centre by an experienced vascular surgeon or a surgical resident under supervision. All patients underwent their CEA under general anaesthesia. Before the start of the surgical procedure an upper and lower threshold of BP was determined. This threshold was based on the average oscillometric upper arm BP measurements determined on the day of admission. Induction of anaesthesia was achieved with sufentanil (0.3–0.7 $\mu g\,kg^{-1}$) and propofol (0.5–2 $mg\,kg^{-1}$) and muscle relaxation was achieved with rocuronium (0.3–0.5 $mg\,kg^{-1}$). After 3 min the trachea was intubated and anaesthesia was maintained with sevoflurane at 0.5–1.0 minimum alveolar concentration.

A total of 5000 IU of heparin was administered intravenously approximately 3 min before cross-clamping the carotid artery. An intraluminal shunt was placed selectively in case of EEG asymmetry or a decrease of >60% of the ipsilateral middle cerebral artery blood velocity measured with TCD.[21]

To preserve cerebral perfusion, mean radial artery BP was kept between 100 and 120% of the awake BP level until the carotid artery was unclamped. Therefore vasoactive medication such as ephedrine, phenylephrine, and/or norepinephrine had to be administered intravenously in various dosages to all patients.

Sevoflurane administration was discontinued at the end of the procedure; when spontaneous respiration had returned, the trachea was extubated. Subsequently the patients were transferred to the recovery room for observation time of at least a 6 h.

### Data analysis

Both the $BP_{rad}$ curve (100 Hz) derived from the Datex Ohmeda S/5 monitoring system (GE Healthcare) and the $BP_{fin}$ curve (200 Hz) were stored on hard disk for offline analysis. The $BP_{fin}$ curve underwent 'waveform reconstruction' by using an algorithm to reconstruct the digital artery waveform to the brachial artery waveform.[20] The algorithm corrects for the decrease in diastolic