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Factors affecting blood pressure measurement validations

Submission date	Recruitment status	[ ] Prospectively registered
31/08/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/04/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/04/2020	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
It has been assumed that the differences between manual and automated blood pressure recordings are due to the way the automated machine works. However, it is possible that these differences depend on precisely how the manual blood pressure is detected and on differences in the group of people in whom the machines are being tested. The aim of this study is to to see if understanding some of these factors may improve the accuracy of blood pressure machine validation. This includes looking at whether a microphone would be better than using humans to listen to blood pressure sounds, and whether the intervals between readings or the cuff used in the comparison makes a difference. The researchers will also look at whether the squeezability of a person's arm and the speed of the pulse flowing down the arm could also affect the readings.

Who can participate?
Healthy volunteers aged between 18 and 85

What does the study involve?
The researchers measure specific physical characteristics which may influence blood pressure measurement such as weight, height, arm size and pulse velocity. They then assess blood pressure derived from the monitor and by manual readings using two trained independent observers using a double-headed stethoscope. Sounds from the stethoscopes are also measured as well as the point at which the arterial pulse returns below the cuff as the cuff is deflated. Nine alternating manual and automated readings are made at either 30- or 60-second intervals before a 10-minute rest. A second set of nine alternating manual and automated readings are made at the alternative time interval (30 or 60 seconds) and then the arm size and blood flow measurements are repeated before a further 10-minute rest. The researchers then measure nine alternating manual and automated blood pressure readings with either an automated cuff or a cuff of similar design made with the same materials as the cuff used for manual readings in the first part of the validation, and repeat using the alternative cuff for a further nine readings followed by arm size and blood flow measurements at the end of the experiment. Differences in automated and manual readings are analysed with respect to the way in which the manual readings were detected and the physical characteristics of the participants.

What are the possible benefits and risks of participating?
Potential benefits of participating include the possibility of having an unexpected high or low blood pressure or an irregular pulse recognised. Whilst this means that the person cannot continue in the study it may lead to earlier awareness of a possible health problem. Taking part in a study which may help others in the future can be satisfying. A pleasant experience in this study may encourage people to take part in other research and to volunteer in other ways in the health community. For some volunteers who are working within healthcare, experiencing first-hand what research is like can arouse a possible interest in asking research questions of their own. People who have taken part in similar studies have found it a positive experience and have found hospitals and research less frightening than anticipated. Potential risks include some mild discomfort and slight bruising after repeated blood pressure measurements, although there have been no significant complaints from over 300 people who have taken part in similar studies. Breach of confidentiality is very unlikely to be significant since all individual data is de-identified at the time of recording. No personal facts of any potentially embarrassing nature are sought and no personal details are recorded apart from age, sex, ethnicity, height, weight, arm dimensions and blood pressure.

Where is the study run from?
Stepping Hill Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2016 to March 2019

Who is funding the study?
Omron Healthcare UK

Who is the main contact?
Dr Philip Lewis
philip.lewis@stockport.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Philip Lewis

ORCID ID
http://orcid.org/0000-0002-7903-390X

Contact details
Department of Cardiology
Stepping Hill Hospital
Stockport
United Kingdom
SK2 7JE
+44 (0)1614195478
philip.lewis@stockport.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
197681

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 197681

Study information

Scientific Title
Analysis of physical and human factors affecting blood pressure measurement with especial relevance to validations of blood pressure monitors in man

Acronym
FABPMV

Study objectives
Using a standard international protocol for comparing machine blood pressures with those obtained manually, an unpublished UK study in 2015 showed less favourable comparability than a study using the same machine in France published in the previous year. Based on their previous and current research, the researchers believe that a variety of factors might lead to such a disparity including differences in 1) the accuracy of the observers' assessment of the blood pressure sounds, 2) physical characteristics of the subjects used, 3) the effect of exchanging the cuffs between readings and 4) differences in the recovery of blood flow in the arm dependent on variations in the time between readings allowed within the protocol. The researchers wish to investigate whether such variations can be circumvented in order to produce a better validation protocol.

Research questions:
1. Do differences between manual and automated blood pressures result from differences in the intervals between readings and do changes of cuffs between each reading increase the variability of blood pressure measurements?
2. Are sequential changes in blood pressure related to the number of measurements made, to changes in arm circumference or skinfold thickness, changes in pulse wave velocity or other factors related to the subject of the measurement or the cuff used in measurement? If there are local factors affecting blood pressure changes related to the cuff-inflation-deflation cycles, does the contralateral blood pressure measured without cuff compression remain relatively unaltered or mirror the pressure changes in the arm in which cuff measurements are taken?
3. Can automated detection of blood pressure by acoustic or Doppler wave analysis be used instead of auscultation (listening to the blood pressure sounds) thus making blood pressure measurement standards more objective and reproducible?

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 14/08/2017, North of Scotland REC 1 (North of Scotland Research Ethics Service, Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; Tel: +44 (0)1224 558458; Email: nosres@nhs.net), ref: 17/NS/0075

Study design
Within-subject cross over randomized observational single centre study

Primary study design
Observational

Secondary study design
Case crossover study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Blood pressure measurement

Interventions
The researchers will recruit 80 volunteers and measure specific physical characteristics which may influence blood pressure measurement e.g. weight, height, arm size and pulse velocity. Then they will assess blood pressure derived from the monitor and by manual readings using two trained independent observers using a double-headed stethoscope. Sounds from the stethoscopes will also be measured as well as measuring the point at which the arterial pulse returns below the cuff as the cuff is deflated. Nine alternating manual and automated readings will be made at either 30- or 60-second intervals prior to a 10-minute rest. A second set of nine alternating manual and automated readings will be made at the alternative time interval (30 or 60 seconds) and then the arm size and blood flow measurements will be repeated prior to a further 10-minute rest. The researchers will then measure nine alternating manual and automated blood pressure readings with either an automated cuff or a cuff of similar design made with the same materials as the cuff used for manual readings in the first part of the validation, and repeat using the alternative cuff for a further nine readings followed by arm size and blood flow measurements at the end of the experiment. Differences in automated and manual readings will be analysed with respect to the way in which the manual readings were detected and physical characteristics of the participants.

Intervention Type
Other

Primary outcome measure

Systolic and diastolic blood pressure measured manually by two observers using standard auscultation and a mercury-containing sphygmomanometer, by an automated blood pressure recorder (Omron M6), by microphone, Doppler waveform and continuous sphygmomanometer cuff pressure waveform and video-recording of the mercury column in two sequences of nine blood pressure readings made alternately manually (with an appropriately sized Accoson cuff) or by the Omron M6 (using an Omron cuff) at 30 or 60 second intervals

Secondary outcome measures
1. Systolic and diastolic blood pressure measured manually by two observers using standard auscultation and a mercury-containing sphygmomanometer, by an automated blood pressure recorder (Omron M6), by microphone, Doppler waveform and continuous sphygmomanometer cuff pressure waveform and video-recording of the mercury column made alternately manually or by the Omron M6 in two sequences of nine blood pressure readings at 60-second intervals. One sequence will use the Omron cuff and the other will use a specially constructed cuff which resembles the Omron cuff in size and shape but differs in using the same materials as the previously-used Accoson cuffs.
2. Continuous finger blood pressure measured using a Portapres recorder on the contralateral side during all four sequences
3. Upper arm circumference measured with a spring-loaded tape measure and triceps skin-fold thickness measured using callipers before and after each sequence of nine blood pressure measurements
4. Bilateral pulse wave velocity (carotid-radial) measured using a Complior device before and after each sequence of nine blood pressure measurements

Overall study start date
31/01/2016

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Healthy volunteers aged between 18 and 85 years of age
2. Willing to have repeated blood pressure measured whilst sitting silently in four sequences of 9 readings in any one sequence
3. Resting heart rate between 50-110 bpm
4. Upper arm circumference ≥ 22 cm and ≤ 42 cm
5. Resting systolic blood pressure ≥ 90 and ≤ 180 mm Hg

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
80

Key exclusion criteria
Participants who:
1. Take anticoagulants
2. Bruise easily
3. Have circulatory problems (e.g. have an arterial shunt or arterial narrowing)
4. Have a pacemaker
5. Have atrial fibrillation
6. Have any other marked pulse irregularity
7. Have a resting heart rate < 50 or > 110 bpm
8. Have systolic and/or diastolic blood pressure sounds in either arm which are not easily heard by the observers
9. Have initial systolic and/or diastolic blood pressures in either arm which differ by > 4 mmHg
10. Have systolic blood pressure at rest < 90 or > 180 mmHg
11. Have blood pressure differences between arms at rest of ≥ 20 mmHg systolic and/or ≥ 10 mmHg diastolic
12. Have disorders of upper arm anatomy, muscle tone, tremor or power
13. Take medications or substances likely to cause short term changes in blood flow or pressure
14. Those who have had caffeine-containing drinks, alcohol or nicotine within 4 hours of the beginning of the study
15. Those lacking capacity to provide informed consent

Date of first enrolment
06/08/2018

Date of final enrolment
01/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Stepping Hill Hospital
Research & Innovation Centre
Stepping Hill Hospital
Stockport
United Kingdom
SK2 7JE

Sponsor information

Organisation
Omron Healthcare UK

Sponsor details
Opal Drive
Fox Milne
Milton Keynes
United Kingdom
MK15 0DG

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Omron Healthcare UK

Results and Publications

Publication and dissemination plan
After analysis of the results the researchers will present the findings at specialist conferences and in peer-reviewed journals concerned with blood pressure measurement.

Intention to publish date
01/05/2020

Individual participant data (IPD) sharing plan
Individual de-identified participant datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No