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A Sub-study of the ASCOT Trial

The suitability of an automated blood pressure measuring device—the Omron HEM-705CP—in a large multicentre study: the ASCOT study

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Introduction

In most large clinical trials blood pressure is usually measured by the traditional auscultatory technique of Riva-Rocci/Korotkoff using a stethoscope and mercury sphygmomanometer. However it is well recognised that such measurements are subject to inaccuracy from systematic errors, principally due to terminal digit preference and observer prejudice or bias. Attempts to address these sources of error in clinical trials have included observer training,[1] and modifying the mercury sphygmomanometer.[2] The London School of Hygiene sphygmomanometer and the Hawksley random zero sphygmomanometers were designed to minimise digit preference and observer bias but both devices have been shown to be inaccurate.[3–5] Another issue, which influenced the choice of blood pressure measuring device for the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT), was the increasing move to prohibit mercury from use in clinical practice.[6,7] Aneroid devices were rejected for the study because they become inaccurate with use, and are just as prone as the standard mercury sphygmomanometer to the errors described above.[2] The only remaining option was to select an automated device, and at the time of commencing the ASCOT study, the only automated device to have fulfilled the requirements of the protocols of the British Hypertension Society (BHS)[8] and the Association for the Advancement of Medical Instrumentation (AAMI)[9] was the OMRON HEM-705CP.[10] This device provides a hard copy of the blood pressure measurements and pulse rate together with the time and date of recording. However, it was designed for self-measurement of blood pressure, and prior to being approved as the device for use in ASCOT, the tubing of the cuff had to be lengthened, and a calibrating methodology was devised.

There are now more than 1000 OMRON-705CP devices in use in ASCOT centres in Scandinavia and approximately 150 between the UK/Ireland ASCOT study centres. This provides a unique opportunity to audit the performance of an automated device in a large multi-centre study. The information from such a survey could have implications both for the design of automated devices in the future and the use of such devices in other large clinical trials.

Objectives

The objectives of this study are:

- to determine what proportion of devices fail to function or become inaccurate,
- to determine the reasons for failure,
- to assess the acceptability of the devices and finally
- to assess if any further modifications would be advantageous.

Study design

This will be a descriptive survey, and the results will be presented in the form of summary statistics. Data will be collected from all ASCOT centres using a questionnaire, which will be circulated to each user and regional coordinating centre, seeking infor-

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mation on the numbers of devices in circulation, and the number that had to be repaired or replaced, and the reasons for repair or replacement (see Appendix). This information will be collected at yearly intervals for the duration of the study.

Discussion

The measurement of blood pressure in clinical practice by the century-old technique of Riva Rocci/Korotkoff is dependent on the accurate transmission and interpretation of a signal (Korotkoff sound or pulse wave) from a *subject* via a device (the *sphygmomanometer*) to an *observer*. Errors in measurement can occur at each of these interactionary points of the technique, but by far the most fallible component is the observer. In 1964, Geoffrey Rose and his colleagues classified observer error into three categories.[11] Systematic error, which leads to both intraobserver and interobserver error, may be caused by lack of concentration, poor hearing, confusion of auditory and visual cues etc; terminal digit preference refers to the phenomenon whereby the observer rounds off the pressure reading to a digit of his or her choosing, most often to zero,[12] and observer prejudice or bias, the practice whereby the observer simply adjusts the pressure to meet his or her preconceived notion of what the pressure should be.[13] Training of observers to overcome these deficiencies has been attempted using direct instruction with a binaural stethoscope, manuals, booklets and published recommendations, audiotape training methods, video-film methods and most recently CD-ROMs.[14] However, training is time-consuming and does not guarantee accurate measurement.[1]

Efforts have been made to devise devices that would minimise or abolish observer error. Two devices, based on the conventional technique, were designed specifically for research use—the London School of Hygiene sphygmomanometer and the random zero sphygmomanometer.[2] The first device, though popular in epidemiological studies for many years, had been accepted without validation as the 'gold standard'; however since 1982, when a calibration error was demonstrated, the device has not been in use.[3] The Hawksley or 'zero-muddler' sphygmomanometer has been availabe commercially for nearly 30 years, and had been generally accepted as the instrument of choice for epidemiological and research studies because it reduced observer bias and obscured digit preference. However, the accuracy of the random-zero sphygmomanometer had been accepted rather uncritically, as it is basically a mercury sphygmomanometer, and it had replaced the London School of Hygiene Sphygmomanometer as the 'gold standard'. A number of recent studies, however, have demonstrated that the instrument systematically gives lower readings than the standard mercury sphygmomanometer,[4] and that it is subject to inaccuracy if not used carefully.[5,15] Because of these concerns, its use in research is now debatable and, like the mercury sphygmomanometer, it may soon be banned from clinical use.

An accurate automated sphygmomanometer capable of providing print-outs of systolic, diastolic, and mean blood pressure together with heart rate and the time and date of measurement would eliminate errors of interpretation and abolish observer bias and terminal digit preference. Moreover, the need for elaborate training as described above would no longer be necessary, though a period of instruction and assessment of proficiency in using the automated device will always be necessary. Another advantage of automated measurement is the ability of such devices to store data for later analysis. This development is in fact occurring and a number of large research studies are employing automated technology to measure blood pressure instead of the traditional mercury 'gold standard'.

If the OMRON device is found to be reliable, robust and acceptable in the measurement of blood pressure it may be recommended for use in many future clinical trials. The proposed sub-study will identify possible flaws of the OMRON device, which will subsequently be helpful in the design of future blood pressure monitoring instruments.

None of the investigators of this study have an interest, financial or otherwise, in the company that manufactures the OMRON device.

References

1 O'Brien E *et al.* Training and assessment of observers for blood pressure measurement in hypertension research. *J Hum Hypertens* 1991; **5**: 7–10.
2 O'Brien E, Beevers G, Marshall D. *ABC of Hypertension.* Third Edition. BMJ Publications: London, 1995.
3 Fitzgerald D, O'Callaghan W, O'Malley K, O'Brien E. Inaccuracy of the London School of Hygiene Sphygmomanometer. *Br Med J* 1982; **284**: 18–19.
4 O'Brien E, Mee F, Atkins N, O'Malley K. Inaccuracy of the Hawksley random-zero sphygmomanometer. *Lancet* 1990; **336**: 1465–1468.
5 Conroy R, O'Brien E, O'Malley K, Atkins N. Measurement error in the Hawksley random zero sphygmomanometer: what damage has been done and what can we learn? *BMJ* 1993; **306**: 1319–1322.
6 O'Brien E. Will mercury manometers soon be obsolete? *J Hum Hypertens* 1995; **9**: 933–934.
7 O'Brien E. Replacing the mercury sphygmomanometer. *BMJ* 2000; **320**: 815–816.
8 O'Brien E *et al.* The British Hypertension Society protocol for the evaluation of blood pressure measuring devices. *J Hypertens* 1993; **11** (Suppl 2): S43–S63.
9 American National Standard for Electronic or Automated Sphygmomanometers: ANSI/AAMI SP10–1987. Arlington, VA: Association For The Advancement Of Medical Instrumentation (3330 Washington Boulevard, Suite 400, Arlington, VA 22201–4598); 1993, p 40.
10 O'Brien E, Mee F, Atkins N, Thomas M. Evaluation of three devices for self-measurement of blood pressure: according to the revised British Hypertension Society

Protocol: the Omron HEM-705CP, Phillips HP5332, and Nissei DS-175. *Blood Press Monit* 1996; **1**: 55–61.
11 Rose G. Standardisation of observers in blood pressure measurement. *Lancet* 1965; **1**: 673–674.
12 Keary L *et al.* Terminal digit preference and heaping in blood pressure measurement. *J Hum Hypertens* 1998; **12**: 787–788.
13 O'Brien E. Chapter 1B. Conventional blood pressure measurement. In: Birkenhager W (ed). *Practical Management of Hypertension.* Kluwer Academic Publishers: Dordrecht, Boston, London, 1996, p 13–22.
14 *Blood Pressure Measurement.* CD ROM The British Hypertension Society. BMJ Books: BMA House, Tavistock Square, London WC1H 9JR, 1998.
15 Brown WCB *et al.* Mechanisms by which the Hawksley random zero sphygmomanometer underestimates blood pressure and produces a non-random distribution of RZ values. *J Hum Hypertens* 1997; **11**: 75–93.

Appendix: OMRON questionnaire

A. General information

Site number: .....
Site Name: .....
How many Omrons are currently at your site: 1..., 2..., 3..., 4..., 5..., 6..., >6...
How many patients have been randomised at your site .....

B. Problems you have had at your site with the OMRON device

In the last 12 months approximately how many devices have been returned for repair from your site .....
Reasons for return of OMRON Devices
(please tick the appropriate answer(s))

Failure

1. Non-function from first day	yes...	no...
2. Subsequent failure to function	yes...	no...

Inaccuracy

1. Calibration errors	yes...	no...
2. Inconsistent readings	yes...	no...
3. Readings very high	yes...	no...
4. Readings very low	yes...	no...
5. Unable to read B/P	yes...	no...

Practical problems

1. Pumping up too much	yes...	no...
2. Printer/paper feed jam	yes...	no...
3. Printer slow to print out	yes...	no...
4. Printer stopped working	yes...	no...
5. Intermittent printer problems	yes...	no...
6. Printing lines not printing clearly	yes...	no...
7. Paper not feeding through	yes...	no...

Other problems
(please specify) .....

C. What aspects of the OMRON do you like

(Please tick)

Having a print out of the readings	.....
Having the date and time on the print out	.....
That it automatically inflates to 240 mm Hg if needed	.....
It can be used by battery or electric current	.....
Easy to use	.....

Other *(please specify)* .....

D. What modifications do you think should be made to the device

(please specify)
.....
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