The Hawksley random zero sphygmomanometer

Should be abandoned

EDITOR,—The two most common sources of interobserver variation in the measurement of blood pressure are measurement bias and digit preference. It is to reduce these errors that use of the Hawksley random zero sphygmomanometer is advocated. Once again, however, the accuracy of this instrument has been questioned, and it seems that, rather than reducing bias, this sphygmomanometer underestimates the true blood pressure.[1]

The manufacturer claims that "operator bias is eliminated from the measurement" (manufacturer's promotional literature), but even this has been questioned by the results of a small, informal study.[2] In a much larger study we have confirmed that observer bias and digit preference are not eliminated by use of the Hawksley sphygmomanometer.[3]

During a multicentre, double blind trial of a new antihypertensive agent 3621 measurements of blood pressure were made. Hawksley random zero sphygmomanometers that either were new or had been serviced immediately before the study were used. The investigators were asked to round up their measurements to the nearest 2 mm Hg, use Korotkoff phase V to estimate diastolic pressure, and use a large cuff where appropriate. The study was carried out in 20 centres (seven hospitals and 13 general practices); a total of 173 patients attended a clinic on up to seven occasions. Each centre's preference for the terminal digit was examined for the three measurements random zero, systolic blood pressure, and diastolic blood pressure with the χ^2 test.

In only three centres was no preference for the terminal digit detected. In the remaining centres five showed a preference in all three measurements, eight showed a preference in two measurements, and four centres showed a preference in one measurement. Zero was the digit chosen most commonly. These data reinforce the view of Conroy and colleagues that use of the Hawksley random zero sphygmomanometer should be abandoned.

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Repeat experiment exonerates instrument

EDITOR,—Rónán M Conroy and colleagues correctly say that the zero muddler was designed to reduce observer bias in the measurement of blood pressure.[1] In a previous report on the Hawksley instrument the same group of researchers described an experiment in which two observers were separated from each other in booths, one with a mercury sphygmomanometer and the other with a Hawksley sphygmomanometer: the two instruments were connected by a T tube to a third booth, where there was a "controller" and a patient with a cuff on his arm.[2] The controller inflated the cuff, auscultated the arm, and gave "auditory clues" to the observers when the systolic and diastolic pressures were reached. The observers wrote down the mercury levels on their respective sphygmomanometers. After five measurements on each of 10 patients the Hawksley results were lower than those for the standard instrument by a mean (SD) of 5·1 (3·5) mm Hg for systolic and 3·9 (3·0) mm Hg for diastolic blood pressure. The researchers concluded that it verges on the scandalous that vast sums have been spent gathering data with an inaccurate instrument.

Rose *et al* classified observer error in sphygmomanometry into three categories: systematic error, terminal digit preference, and observer prejudice.[3] We have repeated the experiment described above in a format which enables us to distinguish between inaccuracy in the instrument and observer error. The two sphygmomanometers, connected to the same cuff on a subject's arm, were placed side by side, and the movement of the mercury columns as the cuff was deflated was recorded by a video camera. The video tape was then viewed by observers who repeatedly used the pause facility on the video recorder to compare the readings on the two instruments at exactly the same instant. Within the limits of the resolution of the video tape the two instruments gave exactly the same reading, at every time interval, when the zero error was allowed for.

We must therefore ask why Conroy and colleagues are so convinced that the Hawksley instrument underestimates blood pressure. Could it be observer prejudice?

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Advice to authors

Priority will be given to letters that are less than 400 words long and are typed with double spacing. All authors should sign the letter. Please enclose a stamped addressed envelope for acknowledgment.

Manufacturer fights back

EDITOR,—Nowhere in their article on measurement error associated with the Hawksley random zero sphygmomanometer do Rónán M Conroy and colleagues give any theoretical explanation of why they think that there is a variance and on what grounds they make their allegations.[1] In their second paragraph the authors mention their previous report entitled "Inaccuracy of the random zero sphygmomanometer."[2] After that report's publication staff from Hawksley and Sons visited the blood pressure unit of Beaumont Hospital to discuss with Professor Eoin O'Brien and his colleagues the issues raised and the test methods used, and we explained why we thought that the discrepancies had arisen. We also emphasised the need for people using the random zero sphygmomanometer to be correctly trained. It was suggested that we should resubmit instruments for validation studies, but we had to decline this because of the costs.

I would like to point out that previously O'Brien and O'Malley said: "The random-zero sphygmomanometer is an accurate instrument that eliminates a major source of error—namely, observer bias—and the principle might be developed further and incorporated in many standard sphygmomanometers."[3]

The random zero sphygmomanometer has been subject to over 20 years of constant evolution and improvement. To make it work in a similar fashion to a standard sphygmomanometer we have produced a mark II model with a smaller capacity and a variance of 0-20 mm. This has a lower reservoir, which shortens the inflation time, and the operator needs to wait only long enough for the column to stabilise, not for five seconds. This new model is quicker to operate because the chamber is filled at a lower inflation level; this results in less discomfort for the patient and less venous congestion. This is important when working with children or elderly people.

As Hense has pointed out, there could well have been a "methods" problem with the use of the previous models.[4-6]

I was disappointed to read such a biased article.

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Don't condemn it without proper evidence

EDITOR,—We believe that Rónán M Conroy and colleagues' article on the Hawksley random zero sphygmomanometer presents a less than balanced view.[1] The authors quote other workers who have tested the accuracy of the instrument but do not quote their figures. We have tabulated them and present them with the findings of the Dublin group (table).[2-6]

It becomes evident that there is, indeed, a

Results of different studies examining accuracy of Hawksley random zero sphygmomanometer compared with standard mercury sphygmomanometer. Three groups presented results as the mean differences between the two instruments; the two others reported the range of difference

Study	Measurement given	Systolic pressure (mm Hg)	Diastolic pressure (mm Hg)		No of subjects
			Phase IV	Phase V	
Evans and Prior[2]	Mean difference	−1·2	−2·2		906
Labarthe *et al*[3]	Mean difference	−1·6	−2·6	−2·7	24 subjects, multiple readings
Gaudemaris *et al*[4]	Range of difference	−0·77 to −3·06		−1·04 to 2·7	40-500 readings, six protocols
Parker *et al*[5]	Range of difference	−2·5 to −3·3		−1·9 to −2·7	66
O'Brien *et al*[6]	Mean difference	−3·5		−7·5	86

systematic tendency to underread both systolic and diastolic pressures with the Hawksley random zero sphygmomanometer compared with the conventional mercury manometer. Only O'Brien *et al*,[6] however, have found large differences in the measurement of diastolic pressure. Labarthe *et al* commented that a modified type of mercury sphygmomanometer (the Hawksley random zero sphygmomanometer) "compared well" with the standard device,[3] and after their examination Parker *et al* commented that the data did not indicate that one instrument was clearly superior to the other and, in fact, the Hawksley random zero sphygmomanometer may be more appropriate where appreciable observer bias might invalidate clinical findings.[5]

All instruments, including the Hawksley random zero sphygmomanometer, require correct use; for the Hawksley random zero sphygmomanometer this means pumping the mercury column to over 240 mm Hg and waiting for five seconds to allow the reservoir to fill with mercury before deflating the cuff with the special control valve, which regulates this to 2 mm Hg/s. The Hawksley instrument, like all other machinery, requires careful maintenance to retain its accuracy. Conroy and colleagues rightly draw attention to the need for accuracy in medical instruments, particularly when the results obtained with a particular instrument are widely applied. The findings of O'Brien *et al*[6] are indeed worrying, but in the light of the evidence from other workers we would like to see further studies of the Hawksley random zero sphygmomanometer before it is consigned to the dustbin. It has several advantages over the standard mercury sphygmomanometer, although we recognise that it has problems—for example, we have found that its zero is not truly random, but this problem does not invalidate its use.

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Measuring instruments are never perfect

EDITOR,—We welcome the recognition that measurement errors occur when the Hawksley random zero sphygmomanometer is used.[1] We question, however, whether a comparison with a mercury sphygmomanometer is valid as any machine will have systematic errors. Should methods of estimating blood pressure be evaluated against intra-arterial measurement or will such measurements themselves accurately reflect true blood pressure? Surely such purist aspirations will be thwarted by the medical equivalent of the uncertainty principle.

As has been recognised,[1] comparison studies are not compromised by measurement bias as long as the same machine is used, so that relatively true readings are given. Far more important, however, are the effects of the different circumstances in trials and in clinical practice. Measurements in trials are usually preceded by 10 minutes' rest and are taken by a research nurse. A pressor effect resulting from the presence of a doctor is well documented.[2] For laborious and expensive trials to provide clinically useful data some scientific accuracy has to be sacrificed in an attempt to retain clinical relevance.[3] This imperative of retaining a link with the real world of clinical practice is the principle of ecological validity.

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Instrument is accurate if used properly

EDITOR,—Rónán M Conroy and colleagues cast doubt on the validity of a large number of blood pressure studies and therapeutic trials by questioning the accuracy of the Hawksley random zero sphygmomanometer.[1] They report that in their hands the Hawksley instrument gave readings that on average were 3·5 mm Hg lower for systolic pressure and 7·5 mm lower for diastolic pressure than readings given by a standard orthodox mercury manometer. These discrepancies between the instruments differ (by a factor of about three for diastolic pressure) from those reported previously.

Under static conditions the random zero sphygmomanometer gives readings identical with those of the orthodox manometer, as can be shown by linking both instruments to a single cuff and comparing measurements after correcting for the zero error in the research instrument. In clinical use the observer can influence the zero error mechanism in two ways: if insufficient time is allowed for the reserve mercury chamber to fill before deflation is started the range of observed zero errors will be restricted; and if insufficient care is taken to ensure that complete deflation has occurred the zero error to be subtracted will be falsely high. This is the only known mechanism that can account for falsely low readings.

The main virtue of the Hawksley instrument, which was developed by Wright and Dore[2] from Garrow's "zero-muddler for unprejudiced sphygmomanometry,"[3] is that it allows multiple consecutive but independent measurements to be made without bias. This gives it great advantages over the standard manometer and made it the instrument of choice for use in epidemiological and therapeutic trials. There was no commercially available alternative at the time of the large national and international trials.

Unless it is possible to show a convincing alternative explanation of the mechanism of their findings the authors should not be allowed to undermine the authority of the many important cardiovascular studies that have used a random zero sphygmomanometer. Adequate training and testing of observers, as occurred in the Medical Research Council's trials,[4,5] for example, are critical to the use of either instrument.

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Used in epidemiology, not individual people

EDITOR,—Rónán M Conroy and colleagues comment that the Hawksley random zero sphygmomanometer underestimates both systolic and diastolic blood pressures when compared with the standard mercury sphygmomanometer.[1]

Other studies have shown that on average both systolic and diastolic blood pressures are higher when they are measured directly than when they are measured by the cuff method.[2,3] The two methods, however, have a high correlation. The mean difference between intra-arterial and cuff blood pressures was 24·6 mm Hg for systolic pressure, 5·3 mm Hg for diastolic pressure (muffling), and 13·1 mm Hg for diastolic pressure (disappearance).[3] The difference between the two methods could not be explained by the intra-arterial pressure or age. Thus the differences that Conroy and colleagues found were relatively small compared with the differences between cuff and intra-arterial pressures.

Both the London School of Hygiene sphygmomanometer[4] and the "zero muddler" were designed for epidemiological use and were subsequently adopted for use in trials of treatment of blood pressure. The originators of the instruments never suggested that they should be used to measure blood pressure in individual patients.

Criteria for treatment are based on various premises—for example, the results of randomised controlled trials of treatment in patients with a given blood pressure. The fact that the Hawksley sphygmomanometer underestimates blood pressure would be of consequence if the criteria for treatment were based on results obtained, for example, by intra-arterial measurement of blood pressure.

In view of the known sources of variation of blood pressure the criteria for treatment must be clearly defined and these definitions must be adhered to. Thus criteria based on measurements made with a standard sphygmomanometer must be appropriately corrected if a random zero instrument is used.

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