

## Using Hawksley Random Zero Sphygmomanometer as a Gold Standard May Result in Misleading Conclusions\*

RÓNÁN M. CONROY,<sup>1</sup> NEIL ATKINS,<sup>2</sup> FÁINSÍA MEE,<sup>2</sup> EOIN O'BRIEN<sup>2</sup> and KEVIN O'MALLEY<sup>2</sup>

From the <sup>1</sup>Department of Epidemiology & Preventive Medicine, Royal College of Surgeons in Ireland, Dublin 2, and <sup>2</sup>Blood Pressure Unit, Beaumont Hospital, Dublin 7, Ireland

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We combined a database of paired blood pressure measurements taken using the Hawksley random-zero sphygmomanometer and a standard mercury sphygmomanometer and a database of paired measurements made on a SpaceLabs 90202 ambulatory blood pressure recorder and standard sphygmomanometer to determine how the SpaceLabs 90202 would have fared if it had been assessed against the Hawksley random-zero sphygmomanometer instead of a standard sphygmomanometer. The pooled database contained 255 triplicate readings. Using the standard sphygmomanometer as gold standard, the Spacelabs had a median error of 2 mm/Hg for both systolic and diastolic. Against the Hawksley random-zero sphygmomanometer, median error was –3 mm systolic and –6 mm diastolic. The proportion of errors >10 mm rose from 11% (systolic) and 9% (diastolic) with the standard sphygmomanometer to 16% and 29% with the Hawksley random-zero sphygmomanometer. Because it underestimates systolic and diastolic pressures, the use of the Hawksley random-zero sphygmomanometer as a gold standard may have resulted in misleading conclusions about performance of some automated BP recorders. *Key words: hypertension, measurement, Hawksley random-zero sphygmomanometer.*

### INTRODUCTION

A controlled comparison of the Hawksley random zero sphygmomanometer and the standard mercury sphygmomanometer revealed a substantial lack of agreement between the two instruments [1]. Using the assessment protocol of the British Hypertension Society [2], the Hawksley under-read both systolic and diastolic pressures, by an average of 3.5 mm and 7.5 mm Hg, respectively. At the time of publication, we concluded that this finding might have serious implications for the interpretation of studies which had been carried out using the Hawksley instrument.

There are four main areas in which the Hawksley instrument had been used: the collection of population data, the evaluation of treatment trials, the selection of patients for studies—importantly, for studies of anti-hypertensive treatment—and the evaluation of automated blood pressure recording devices. It is the last application that this study addresses: what are the consequences of using a Hawksley rather than a mercury sphygmomanometer in evaluating an automated blood pressure recorder?

### MATERIALS AND METHODS

Two sets of data were pooled to conduct the analysis.

The first database was gathered during the evaluation of a SpaceLabs 90202 automated blood pressure measuring instrument against a mercury sphygmomanometer [3]. It consisted of paired measurements, one taken with each instrument. The 85 subjects in this study were aged between 22 and 79 years, and were recruited from patients attending a blood pressure clinic, other hospital inpatients, and healthy hospital staff. This selection of subjects allowed the inclusion of a wide range of blood pressures. All subjects were in sinus rhythm and had an arm circumference of <35 cm.

The second database contained the data upon which the original report comparing the Hawksley and standard mercury instruments was based. Both sets of data were collected using the British Hypertension Society protocol [2] and described in detail in the original report [1]. A total of 258 readings were made using 86 subjects, aged 15–80 years. A pooled database was compiled from these two by adding matched Hawksley sphygmomanometer readings to the mercury/SpaceLabs database. For each systolic and diastolic reading made with the mercury sphygmomanometer in the mercury/SpaceLabs database, a mercury sphygmomanometer reading within 1 millimetre of mercury was identified in the mercury/Hawksley database, and the corresponding Hawksley reading added to the mercury/SpaceLabs database. Where readings could not be matched exactly, they

\* A copy of the data set upon which this report is based is available from the authors.

Table I. Evaluation of the SpaceLabs 90202 blood pressure recorder against a mercury sphygmomanometer and against a Hawksley random zero sphygmomanometer

	Mercury (mm)		Hawksley (mm)	
	SBP	DBP	SBP	DBP
Mean error	1.9	1.9	-3.0	-6.2
Standard deviation	6.2	5.6	7.6	7.1
25th/75th percentiles	-2 to +6	-1 to +5	-8 to +2	-11 to -2
Percent of errors in the interval:				
<5 mm	57.3%	64.7%	43.3%	35.0%
<10 mm	83.9%	89.0%	78.3%	69.6%
<15 mm	97.6%	97.3%	92.1%	10.2%
over 15 mm	2.3%	2.7%	7.9%	10.2%
BHS Grade*	C	B	D	D
Number of paired measurements used in comparison	255	255	254	246

\* BHS Grade: A, when cumulative % of readings <5, <10 and <15 mm/Hg are 80, 90 and 95 respectively; B when 65, 85 and 95; C when 45, 75 and 90; and D when worse than C.

were matched to the first reading 1 mm above or below, and 1 mm added or subtracted from the corresponding Hawksley reading to adjust. (The decision as to whether to match upward or downward was based on the observation number: odd-numbered observations were downward-matched, even ones upward). Readings which could not be matched to within a millimetre were excluded from the study.

The resulting database contained triplicate readings: a reading made on the SpaceLabs 90202, one made simultaneously on a mercury sphygmomanometer, and one made with a Hawksley sphygmomanometer when a mercury sphygmomanometer, read simultaneously, showed the same pressure as that recorded by the mercury sphygmomanometer in the SpaceLabs validation study. The use of random matching from an experimentally-derived dataset preserves the empirical pattern of discrepancy between the Hawksley and mercury instruments.

## RESULTS

Table I shows the performance of the SpaceLabs 90202 assessed against the mercury sphygmomanometer and the Hawksley. There were 255 paired readings available upon which to base the comparison of the mercury and SpaceLabs instruments, and 254 systolic and 246 diastolic paired Hawksley/SpaceLabs readings. The loss of ten readings was because no matching mercury reading existed within 1 mm of the reference reading. The readings which could not be paired were mainly in the lower end of the blood pressure range—of the ten, six had systolic pressures in the range

90–101 and diastolic pressures between 49 and 61 mmHg. One unmatched reading was of 190/143 mmHg.

The SpaceLabs instrument, as previously reported [3], had a slight tendency to underestimate both systolic and diastolic blood pressures. Its mean error (mercury minus SpaceLabs) was about +2 mmHg for both readings. The mean error changed direction and rose in size to -3 mmHg systolic and -6.2 mmHg diastolic when the Hawksley was substituted as a reference instrument. Using the standard sphygmomanometer, 57% of systolic errors, and 65% of diastolic errors were of less than 5 mmHg. When the Hawksley was used as a reference instrument, this fell to 43% and 35%. Likewise, the percentage of errors of more than 15 mmHg rose from 2% (systolic) and 3% (diastolic), when the mercury instrument was used as a reference, to 8% (systolic) and 10% (diastolic) when the Hawksley was substituted. The two reference instruments differed significantly in the distribution of errors in each category— $\chi^2 = 10.3$ ,  $df = 3$ ,  $p = 0.016$  for systolic pressure and  $\chi^2 = 55.3$ ,  $df = 3$ ,  $p < 0.001$  for diastolic pressure. The net effect of changing from the mercury to the Hawksley as a reference instrument is a negative shift in the error distribution.

The British Hypertension Society grading system was used to rate the performance of the SpaceLabs 90202. When rated against the mercury sphygmomanometer, it achieved a rating of B for diastolic accuracy and C for systolic. This dropped to a D grade in both cases when the Hawksley was used as a reference instrument.

We also examined the relationship between the

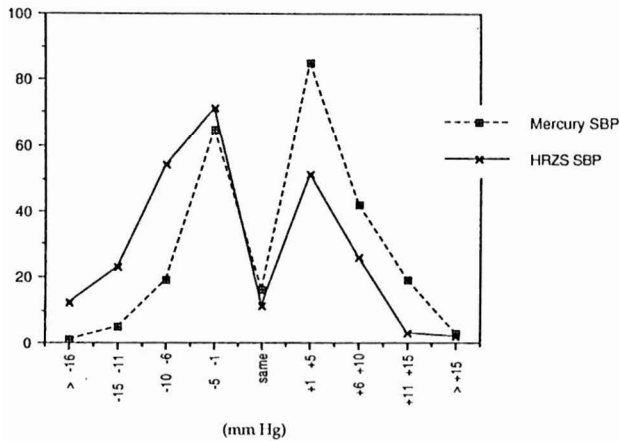


Fig. 1. Systolic pressure errors comparing SpaceLabs 90202 with HRZS or mercury sphygmomanometer.

size of the difference between the SpaceLabs machine and reference instrument as a function of the blood pressure, as measured by the reference instrument. When the mercury sphygmomanometer was used as a reference instrument, systolic errors increased by an average of 0.8 mmHg with every 10 mm increase in systolic pressure, and diastolic errors by 0.7 mmHg. With the Hawksley as reference instrument, systolic pressure errors increased by 0.8 for a 10-mm increase in pressure and diastolic pressure errors by 1.4 mmHg.

## DISCUSSION

In a recent review of the consequences of the inaccuracy of the Hawksley sphygmomanometer, we speculated that the use of the instrument as a reference in the validation of automated blood pressure recording devices might result in a misleadingly unfavourable evaluation [4]. The present study design, by pooling data from two studies, each of which used a Hawksley sphygmomanometer in comparison with another instrument, simulates an experiment in which triplicate blood pressure readings are taken simultaneously using a mercury sphygmomanometer, a Hawksley Random-zero sphygmomanometer and a SpaceLabs 90202 automated blood pressure recorder. The technique used, that of pooling two databases based on random matching, has the advantage that it incorporates no prior assumptions about the pattern of error of any of the instruments being compared, which would have been the case, for example, if we had substituted for each mercury reading the mean of all Hawksley readings taken at that pressure.

As reported previously, the SpaceLabs 90202 blood pressure recording instrument has a reasonable level of

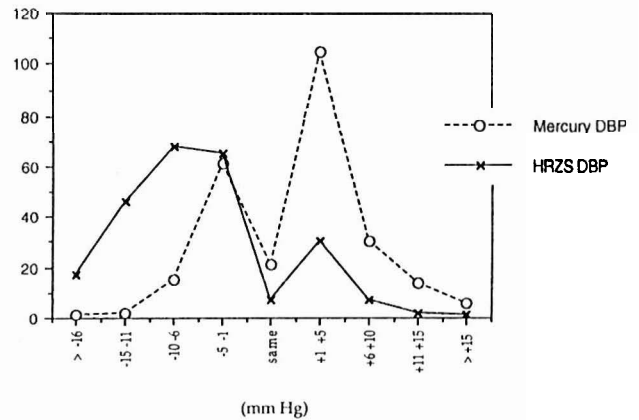


Fig. 2. Diastolic pressure errors comparing SpaceLabs 90202 with HRZS or mercury sphygmomanometer.

agreement with a standard sphygmomanometer. The effect of replacing the standard instrument with a Hawksley sphygmomanometer was to reverse the direction of the average measurement error found, and to demote the machine from BHS grades C and B, for systolic and diastolic accuracy respectively, to grade D overall—the lowest rating of accuracy in the BHS grading system. Such a report, had it been published, might have been commercially damaging. Furthermore, the manufacturers might have been impelled to recalibrate their instrument so that it agreed as closely as possible with the Hawksley, thereby enshrining the measurement errors of the latter instrument in their own. This would have been ironic, because the SpaceLabs instrument, according to the data presented, is more accurate an instrument than the Hawksley.

The results presented highlight the consequences of the continuing use of the Hawksley. We have reviewed these extensively in a recent publication [4], and we can here only reiterate our recommendations that any blood pressure measuring instruments which have been assessed only against the Hawksley instrument should be reassessed against a mercury sphygmomanometer, and that the use of the Hawksley as a reference instrument for such assessments be discontinued.

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*Address for correspondence:*

Rónán Conroy  
Department of Epidemiology  
Royal College of Surgeons  
Mercer Building  
Lower Mercer Street  
Dublin 2  
Ireland