The Elag-Köln automatic blood pressure recorder

A clinical appraisal

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The performance of an Elag-Köln semiautomatic blood pressure recorder was compared with the London School of Hygiene mercury sphygmomanometer in 24 subjects providing a wide range of blood pressure measurements. Readings with the two instruments correlated highly (for systole, $r=0.99$; for diastole phase 4, $r=0.97$; for diastole phase 5, $r=0.98$), and the slopes of the regressions did not differ significantly from unity. Elag-Köln measurements were higher for systole (mean difference 3.7 mmHg, $P<0.001$) and diastole phase 5 (mean difference 7.4 mmHg, $P<0.001$), but agreed closely with diastole phase 4 readings with the London School of Hygiene instrument. The Elag-Köln recorder tested was compact, easy to use, and had acceptable accuracy. This type of instrument deserves further testing to examine its suitability for general use.

The importance of accuracy of blood pressure measurement in routine practice, in epidemiological surveys, and in clinical trials has been stressed (Rose *et al.*, 1964; King, 1969; Thulin *et al.*, 1975). Measurement errors may arise from inaccuracy of the instrument (Thulin *et al.*, 1975; Conceicao *et al.*, 1976) or from factors related to the observer (Rose *et al.*, 1964). With auscultatory methods of measurement, the principal sources of observer error are terminal digit preference, prejudice related to specific blood pressure values, and difficulty in interpretation of the Korotkoff sounds (Rose *et al.*, 1964). Several devices have been developed to avoid digit preference and prejudice (Rose *et al.*, 1964; Wright and Dore, 1970). To remove errors in the interpretation of the auscultatory phases, semiautomatic machines have been developed, but their performance has often proved unsatisfactory (Thulin *et al.*, 1975). Labarthe *et al.* (1973) evaluated 5 automatic devices and found that none of them was an adequate replacement for the mercury sphygmomanometer.

In the present study we have assessed the Elag-Köln automatic blood pressure recorder using a London School of Hygiene (LSH) sphygmomanometer as the standard for comparison.

Methods

RECORDING DEVICES

An Elag-Köln sphygmomanometer¹ (Fig. 1) without the automatic print-out recorder, and a standard

London School of Hygiene (LSH), random zero, mercury sphygmomanometer (Rose *et al.*, 1964) were compared. The Elag-Köln cuff contains a rubber air chamber which transmits pressure pulses from the brachial artery region to an amplifier and the Korotkoff phases are transformed into optical and acoustic displays. Inflation is by a high speed pump to a preselected pressure and deflation rate can be varied. As the manometer needle descends, the appearance of a flashing light and an accompanying bleep (which can be muted) indicates systolic pressure. The flash and bleep continue synchronously with the pulse beat until diastole is reached. Pulse frequency is also displayed. For this study, the rate of fall of pressure was fixed at 2 mmHg/s for the LSH machine, and as close as possible to this figure on the Elag-Köln. The pressure readings on the latter device (checked against a mercury manometer) were found to be accurate.

SUBJECTS AND PROCEDURE

Twenty hospital inpatients and 4 healthy subjects were selected to provide a wide range of blood pressures. The inpatients had hypertension or were general medical patients. One had atrial fibrillation and one pulsus paradoxus. Pressures were measured by two physicians experienced in the use of both devices. Each subject remained supine for at least 10 minutes, after which the blood pressure was recorded in either arm by both observers and with both devices (i.e. 4 pairs of simultaneous readings). The cuffs were removed and reapplied for each individual reading. The Elag-Köln scale read to the

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Fig. 1 The Elag-Köln recorder (left) shown beside the London School of Hygiene sphygmomanometer. Blood pressure is read from the right hand dial. Inflation pressure is preselected using the control knob at the centre of this dial, and automatic inflation is initiated by pressing the switch (Messen). A needle then descends the scale during deflation. Deflation rate can be varied (Regler). A flashing light (RR Optisch) and bleep appear at systole, and stop at diastole. Pulse rate is displayed on the dial on the left. The volume of the bleep is adjustable (RR Akustisch).

nearest 2 mmHg and recorded a single diastolic end-point. The LSH machine was calibrated to 1 mmHg, and both diastolic end-points (phases 4 and 5) were noted.

DESIGN AND ANALYSIS

For each subject, 4 pairs of simultaneous measurements with the 2 machines were made, and the order of observer—machine—arm was varied systematically in successive subjects. With this scheme, the mean of 4 Elag-Köln readings versus the mean of 4 LSH readings in each patient gave a comparison of the machines which was not biased by observer, by arm, or by measurement sequence. The results from the two devices were compared using Student's *t* test for paired observations. Regressions were

tested to determine whether they deviated significantly from a slope of one.

Results

For systolic blood pressure, the two machines showed a high correlation ($r=0.99$; Fig. 2) over a wide range of readings. The slope of the regression was 0.99, but the Elag-Köln values were significantly higher than those with the LSH machine (mean difference 3.7 mmHg; $t=3.97$, $P<0.001$). Elag-Köln diastolic blood pressure correlated highly with both phase 5 ($r=0.98$; slope 1.05) and phase 4 ($r=0.97$; slope 0.96) readings with the LSH machine. In absolute terms, Elag-Köln diastolic readings were closer to phase 4

Fig. 2 Correlation between readings from the London School of Hygiene sphygmomanometer and Elag-Köln machine. Each point represents the mean of 4 readings (2 observers measuring blood pressure in both arms) with each of the two measuring devices in an individual patient.

LSH pressures (mean 0.5 mmHg higher for the Elag-Köln), and were significantly higher than phase 5 (mean difference 7.4 mmHg; $t=7.15$, $P<0.001$).

The experimental design was such that 75 per cent of Elag-Köln blood pressure measurements were made with knowledge of a previous reading with either machine in the same patient. Since reading of the Elag-Köln instrument could be subject to observer bias, the correlations between blood pressure measurements with the two devices might be falsely high. We, therefore, correlated those blood pressure readings measured first with the Elag-Köln device against the subsequent blood pressure reading made in that patient by the same observer, on the same arm, but with the LSH machine. This correlation is entirely free of observer bias, but might be weakened because the measurements with the two machines were not simultaneous (LSH readings 3 to 5 minutes after Elag-Köln readings). Nevertheless the correlation between the two instruments remained high (systole, $r=0.95$, slope 0.98; diastole phase 5, $r=0.94$, slope 0.95; $n=24$).

The correlation between observers with the LSH machine was close (systole $r=0.96$; diastole, phase 5, $r=0.97$) but was even closer with the Elag-Köln machine (systole $r=0.98$; diastole $r=0.99$). Examination of the consistency of each

observer with each machine was weakened by a significant difference in systolic readings between the two arms (right arm higher by 2.7 mmHg; $t=2.75$, $P<0.02$). Within-observer correlations were similar for each machine (for LSH machine, r between 0.94 to 0.98; for Elag-Köln, r between 0.95 to 0.96). Since the Elag-Köln measurements were read visually the results were examined for evidence of terminal digit bias. The distribution of terminal digits did not differ significantly from the expected distribution for either observer ($P>0.1$).

Both observers thought the Elag-Köln device had certain advantages over the LSH machine. Measurement of blood pressure was quicker and easier particularly in noisy surroundings, and the Elag-Köln was eminently more portable (weight 3.5 kg, compared to 16.5 kg for the LSH machine). Placement of the air-chamber of the Elag-Köln cuff over the brachial artery caused no problem though we have not studied systematically the effect of inaccurate cuff placement. The rate of cuff deflation was difficult to stabilise because of the extreme sensitivity of the manual control. Further, it was noted that with deflation, the rate of fall of pressure was not uniform, being faster at high pressures and slowing as lower values were registered. The need for a source of electricity to operate the Elag-Köln could be a drawback in some situations.

Discussion

The accuracy of the Elag-Köln machine tested was acceptable, as judged by the high correlations with LSH sphygmomanometer results. Systolic blood pressure readings were on average 3.7 mmHg higher with the Elag-Köln. Since auscultatory measurements of systole are in general a few mmHg lower than direct readings (Pickering, 1968), it is likely that the Elag-Köln values were nearer true systole than LSH recordings. The Elag-Köln diastolic readings correspond to phase 4 readings by the auscultatory method, and correlated highly with phase 5 readings though measuring on average 7.4 mmHg higher. The Elag-Köln was simpler and quicker to use than the LSH sphygmomanometer, and it was considerably less cumbersome. Use of the print-out recorder (which is optional) should eliminate any risk of terminal digit preference and prejudice against certain readings.

If the performance of the machine we tested is representative and if the device proves robust in everyday use, then the Elag-Köln recorder should be of great value in ordinary hospital practice and for epidemiological surveys. The ability to repeat

blood pressure measurements simply and rapidly would be useful in intensive care units and during diagnostic or therapeutic procedures.

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