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ORIGINAL ARTICLE

Unsafe health and safety: sphygmomanometer cuffs are not interchangeable

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Unknown to its hypertension specialists, a major teaching hospital changed the cuffs on its sphygmomanometers from manufacturer-validated to a uniform washable alternative, in line with 'Health and Safety' concerns surrounding potential cross-contamination between patients. When clinic doctors suspected serious under-reading with the new cuffs, a systematic comparison was undertaken in 54 patients (mean ± s.d. age, 61 ± 17 years), using two UM-101 sphygmomanometers, one using the original, manufacturer-supplied cuff and the other with the washable replacement. The study confirmed an average under-reading of 8 ± 10/5 ± 5 mm Hg using the washable cuff, and a third of patients with poorly controlled hypertension were considered normotensive, after using this cuff. The UM-101 sphygmomanometers have now been re-fitted with the original cuffs. Sphygmomanometer cuffs are not interchangeable between devices and a modicum of common sense should be shown to prevent changes made in the name of Health and Safety from having the opposite effect to that intended.

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INTRODUCTION

During a specialist hypertension clinic in January 2012, three patients had substantially lower blood pressure (BP) readings than expected—in comparison either to multiple previous readings by the same doctor in the same clinic or to a combination of the referral and home BP readings, and estimates of target-organ damage on fundoscopy, electrocardiography and echocardiography. The instrument used for BP measurement in the clinic was the mercury-free 'hybrid' sphygmomanometer, the UM-101 (A&D Medical, Tokyo, Japan). This has a pressure sensor similar to automatic monitors, but relies on auscultation rather than an algorithm-based determination of systolic and diastolic pressures.[1,2] Two months earlier, the hospital Trust had changed all BP cuffs: from those individually supplied and validated for the type of monitor, to a uniform, washable, bladderless cuff. The decision to change cuffs arose from a concern about potential transmission of infection between patients while having their BP measured.[3] Documented evidence in the literature, to support or refute the interchanging of cuffs between devices, is lacking, although current CE marking regulations require that BP devices (including cuffs) are formally validated according to recognised protocols. A new UM-101 was purchased and a systematic comparison of the manufacturer-supplied versus replacement cuffs undertaken and the results of this comparison are presented here.

METHODS

Subjects

A total of 54 patients were studied. These were subjects in the British Heart Foundation PATHWAY trials, which are investigating treatment algorithms at all grades of hypertension,[4] subjects attending the Clinical Pharmacology Unit for arterial function assessments and patients attending the Trust hypertension outpatient clinic. All patients had established hypertension.[5] Those in atrial fibrillation on screening were excluded from the analyses. All patients consented to additional (comparative) BP measurements being undertaken during their study/clinic appointment.

Procedures

After a minimum of 10 min seated rest, brachial BP measurements were taken, by auscultation from the non-dominant arm on a UM-101 with the original, manufacturer-supplied cuff and bladder, and a UM-101 with replacement cuff. Systolic and diastolic pressures were identified from the first and fifth Korotkoff sounds, respectively. The sphygmomanometers were used in a random order, as determined by a pre-generated randomisation schema. A third set of readings was taken by a research nurse either immediately before or after the UM-101 readings using an oscillometric sphygmomanometer (WatchBP, Microlife, Widnau, Switzerland). Again, the order in which the oscillometric readings were taken in relation to the UM-101 readings was random. Appropriately sized cuffs were chosen based on the patient's arm circumference, measured with a tape measure. Triplicate readings were made with each device, with the last two readings used for analysis.

In an additional experiment, each cuff was applied, in turn, to an incompressible cylinder while connected both to the UM-101 and a mercury sphygmomanometer, using a three-way connector. The cuff was then inflated and deflated in 10 mm Hg increments across the physiological range of BP, with cuff pressures read simultaneously from the two sphygmomanometers. All auscultatory readings were made by the same operator, who had undertaken appropriate training in the measurement of BP using this technique.

Statistical analyses

Data were analysed using paired Student's *t*-tests to determine the significance of the differences between BP readings obtained from the two cuffs. Linear regression was used to determine the correlation coefficient (r) and Bland–Altman analyses performed to determine agreement. Data are reported as means ± s.d. and a P-value of <0.05 was considered significant.

RESULTS

The mean age of the group was 61 ± 17 years. Patient demographics are presented in Table 1. The mean BP readings on each

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device, together with cuff and bladder dimensions, are presented in Table 2. Compared with the original cuff, the replacement cuff under-read systolic and diastolic BP by 8 ± 10/5 ± 5 mm Hg ($P<0.001$ for both). The replacement cuff also under-read BP values obtained with the oscillometric device. Of the 54 patients included in the analysis, 24 patients had BP levels in the hypertensive range based on readings with the original cuff. In contrast, only 16 patients had BP levels in the hypertensive range based on readings with the replacement cuff.

Systolic and diastolic pressure values were highly correlated between the original and replacement cuffs ($r=0.79$, systolic; $r=0.93$, diastolic; $P<0.001$ for both; Figure 1a). However, the Bland–Altman analysis showed that the under-read by the replacement cuff was proportional to systolic BP, with a maximum under-read of 28/14 mm Hg (Figure 1b). Limited *post hoc* analysis showed no apparent influence of drug treatment upon the degree of under-read (data not shown).

Cuff dimensions were broadly similar across devices. However, the inflatable area (bladder) of the replacement cuff was longer and wider than the original UM-101 and oscillometric device bladders. When the original and replacement cuffs were applied, in turn, to an incompressible cylinder, cuff pressures obtained simultaneously from the UM-101 and a mercury sphygmomanometer did not differ from each other across the physiological range of BP (data not shown).

DISCUSSION

The comparison confirmed significant differences in systolic BP readings obtained by the original versus replacement cuffs for the UM-101 sphygmomanometer and provides new evidence that sphygmomanometer cuffs are not interchangeable between devices. Moreover, the average difference of 8/5 mm Hg underestimated the difference in patients with more severe hypertension. The comparison was not intended as a formal validation—or invalidation—of the UM-101 cuffs, which would require more readings across a greater range of pressures, and could not be readily undertaken during routine clinic visits.[6] It is possible that all the sphygmomanometers in the hospital have under-read BP since the cuffs were changed in November 2011. However, the most serious impact is likely to be in the clinic to which patients are referred precisely because they have uncontrolled BP. Indeed, in the current comparison, ~1/3 of patients with BP levels in the hypertensive range would have been mis-classified as normotensive on the basis of readings obtained with the replacement cuff.

Hypertension is a common condition, affecting well over half of the >60 s.[7] Every 10 mm Hg difference in systolic pressure increases stroke and myocardial infarction risk by 40% and 25%, respectively.[8] These percentages under-estimate the potential impact of the under-read because of the more serious under-read at high values, and the consequent failure to undertake appropriate escalation of treatment in the patients most in need of specialist input.

The larger inflatable area of the replacement cuff is likely to explain why the change in cuff was so damaging. A larger 'bladder' covers a greater area of the underlying artery, which is therefore likely to occlude the artery at a relatively lower cuff pressure than would be observed with a smaller bladder. Indeed, the pitfalls of selecting the wrong-sized bladder have been

Table 1. Patient demographics

Characteristic	
Age (years)	61 ± 17
Gender (*n*, M/F)	34/20
Height (m)	1.71 ± 0.11
Weight (kg)	88 ± 19
BMI (kg m^{-2})	29.7 ± 5.2
Therapy (*n*%)	50, 91

Abbreviations: BMI, body mass index; F, female; M, male. Data are means ± s.d., unless indicated.

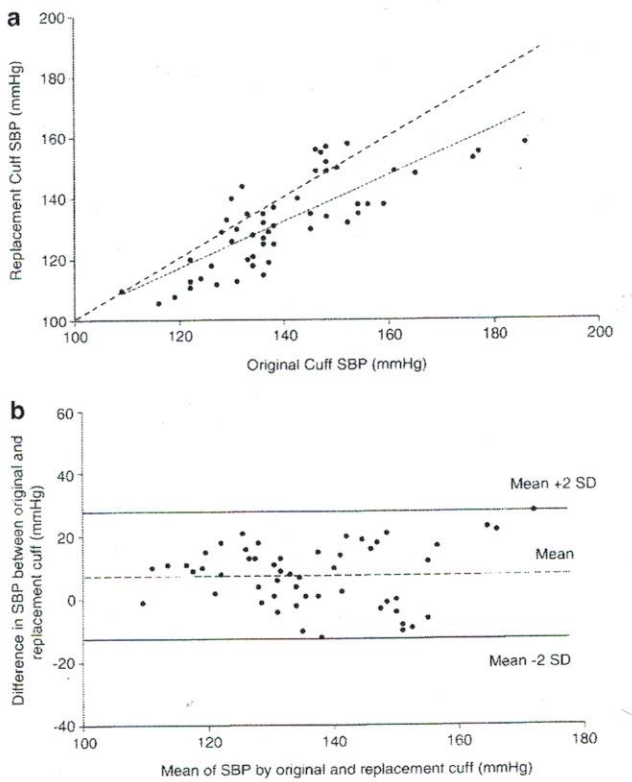

Figure 1. (**a**) Correlation between systolic blood pressure (SBP) measured with the manufacturer-supplied versus replacement cuffs. The line of identity is indicated by the dashed line. (**b**) Bland–Altman plot showing agreement in SBP measured with the manufacturer-supplied versus replacement cuffs.

Table 2. Comparison of blood pressure devices/cuffs

Device	*Systolic BP (mm Hg)*	*Diastolic BP (mm Hg)*	*Cuff dimensions*[a] *(cm)*	*Bladder dimensions*[a] *(cm)*	*Arm Circumference*[a] *(cm)*
UM-101, original cuff	140 ± 15	82 ± 12	14 × 26	12 × 24	22–32
UM-101, replacement cuff	132 ± 15*	77 ± 12*	14 × 28	14 × 28	23–33
WatchBP (automated)	139 ± 18′	83 ± 13′	14 × 34	12 × 24	22–32

Abbreviations: BP, blood pressure. Data are means ± s.d. or range. *$P<0.001$ versus original cuff. ′$P<0.001$ versus replacement cuff. [a]For adult regular cuff.

reported previously.[9,10] Moreover, it is unlikely that the pressure transducer in the UM-101 was affected since simultaneous comparisons with a mercury sphygmomanometer showed no differences across the physiological range of BP.

The importance of using the right-sized sphygmomanometer cuff is well known, as is using the correctly sized bladder. However, the lack of interchangeability of cuffs among devices is less widely appreciated. From a regulatory perspective, replacing a manufacturer-supplied cuff with an alternative cuff risks invalidating the device CE mark. Of greater concern clinically is the proven stroke risk when BP control is poor. Although articles document resident flora on BP cuffs, which provide the *potential* for infection, no infection has been documented. The risks of cross-infection in an outpatient are likely to be minute and greatly outweighed by the risks of stroke and myocardial infarction in hypertension, which have been documented in some million patients.[8] Fortunately, the UM-101 sphygmomanometers have now been re-fitted with the original cuffs. The lesson to be learned, therefore, is that health-care systems should consult with hypertension specialists when any changes in the methods or equipment surrounding BP measurement are being contemplated. Health and Safety may be an inexact science, but could still benefit from calculation, common sense and communication.

What is known about the topic

- Using a sphygmomanometer cuff or bladder, which is too large for the patient's arm, is likely to under-read BP.
- Undiagnosed hypertension or poor BP control is clinically important because every 10 mm Hg increase in systolic BP increases the risk of stroke and myocardial infarction by 40% and 25%, respectively.

What this study adds

- Changing a validated cuff to a uniform washable cuff resulted in a serious under-read of BP (8/5 mm Hg), with greater disparities between cuffs observed in individuals with poorly controlled hypertension.
- Sphygmomanometer cuffs are not interchangeable between BP measurement devices.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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