

Major Device-Dependence of Measured Hypertensive Status From 24-Hour Ambulatory Blood Pressure Monitoring After Aortic Coarctation Repair



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Received 3 February 2018; received in revised form 10 April 2018; accepted 6 May 2018; online published-ahead-of-print 6 June 2018

Background

Twenty-four-hour (24-hr) ambulatory blood pressure monitoring (ABPM) is often considered the gold standard to detect hypertension. We aimed to determine the short-term progression of 24-hour blood pressure after coarctation repair and to compare ABPM between two different devices.

Methods

We performed a cross-sectional study using 24-hour ABPM (Oscar 2) in 47 patients aged 16–48 years with previous paediatric coarctation repair and not on antihypertensive medication. Results were compared to a previous ABPM using paired analyses. A subset (10/47, 21%) had an additional previous ABPM performed using a Spacelabs device.

Results

After a mean follow-up of 27 ± 6 years after repair, hypertension and prehypertension on Oscar 2 ABPM was present in 57% (27/47) and 11% (5/47), respectively. Mean follow-up time between Oscar 2 ABPMs was 3.9 ± 1.4 years, and between first Oscar 2 and Spacelabs and between Spacelabs and second Oscar 2 ABPM was 1.4 ± 0.8 and 1.8 ± 0.3 years, respectively. There was no difference in the proportion of hypertensive patients between Oscar 2 ABPMs (55% [26/47] vs. 57% [27/47], $p = 1.0$) but 17 patients (17/47, 36%) had a reclassification of 24-hour ABPM status. Mean 24-hour systolic blood pressure was higher in both Oscar 2 ABPMs compared to Spacelabs (142.4 ± 11.7 vs. 120.4 ± 11.8 mmHg, $p = 0.0001$; and 137.4 ± 12.2 vs. 120.4 ± 11.8 mmHg, $p = 0.0001$; respectively).

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Conclusion

There was high intra-device reproducibility of 24-hour ABPM results using an Oscar 2 device but poor inter-device reproducibility in patients with repaired coarctation. Device-specific reference values may be required to ensure reliable 24-hour ABPM interpretation.

Keywords

24-hour ambulatory blood pressure monitoring • Coarctation of the aorta • Hypertension • Prehypertension • Reproducibility

Introduction

Late hypertension may be a major determinant of mortality following coarctation repair [1]. Late hypertension has been reported in up to 75% of patients after coarctation repair using office-measured blood pressure [2–7], but few studies have been performed using 24-hour ambulatory blood pressure monitoring (ABPM), now considered the gold standard to detect hypertension [8,9]. Studies that have employed 24-hour ABPM in this setting have reported a hypertension prevalence of between 15% and 61% [2–6,10]. Although a number of factors may contribute to this large range, such as differences in age, follow-up time, surgical factors, and intrinsic vascular and neural abnormalities [1,4,7,10–12], the potential influence of measurement-related issues (such as device-dependence) on hypertension prevalence has not been addressed in this patient group.

We previously investigated the prevalence of late hypertension after coarctation repair using 24-hour ABPM in two published studies of 62 patients with hypoplastic arches [5] and 80 patients with normal sized arches [6] and observed a prevalence of 60% and 61%, respectively. However, in a recently published, unrelated study of 20 of these same patients using a different 24-hour ABPM device, we found a hypertension prevalence of only 15% [10]. We were intrigued by the significant difference in the prevalence of hypertension despite a difference of only 1.5 years between the two 24-hour ABPM readings. In this study, we aimed to determine the short-term serial progression of 24-hour blood pressure in this young repaired coarctation population by repeating the 24-hour ABPM using the original device, and to compare 24-hour ABPM measurements between two different devices.

Methods

Study Population

The study protocol was approved by the Human Research and Ethics Committee of The Royal Children's Hospital, Melbourne. Written informed consent was obtained from each patient or their parents if ≤ 18 years of age. All patients from our original published cohorts who had previously undergone 24-hour ABPM after coarctation repair at the Royal Children's Hospital, Melbourne, who were living in the state of Victoria, were not on any antihypertensive medication, and did not have univentricular physiology or intellectual disability, were contacted [5,6,12].

Study Protocol

Twenty-four-hour ambulatory blood pressure monitoring

A correctly-calibrated oscillometric device (Oscar 2; SunTech Medical, Oxfordshire, UK) was used on the right arm of all patients using an appropriately-sized cuff as per the manufacturer's guidelines. Patients were advised to avoid participation in sport. Blood pressure measurements were performed automatically every 30 minutes during the day and every 60 minutes during night-time sleep. The device was checked and calibrated against a mercury manometer as per the manufacturer's guidelines prior to use.

Hypertension on 24-hour ABPM was defined in children as mean 24-hour systolic or diastolic blood pressure ≥ 95 th percentile for a separate reference population, and prehypertension as mean 24-hour systolic or diastolic blood pressure between the 90–95th percentile [8]. In adults, hypertension was defined as mean 24-hour systolic blood pressure ≥ 135 mmHg or diastolic blood pressure ≥ 85 mmHg, and prehypertension as mean 24-hour systolic blood pressure between 130–135 mmHg or diastolic blood pressure between 80–85 mmHg [9]. If the systolic and diastolic blood pressure readings belonged to different categories, the higher of the two readings was used to assign the blood pressure category.

Serial evaluation of 24-hour blood pressure and between ABPM devices

Patients' 24-hour ABPM results were compared to their previous 24-hour ABPM results. All patients had a previous 24-hour ABPM performed using the Oscar 2 device [5,6]. A subset of patients (10/55, 18%) had an additional previous 24-hour ABPM performed using a correctly-calibrated Spacelabs 90217A device using the above protocol (oscillometric device, Model 90217A Ambulatory Blood Pressure Monitor, Spacelabs Healthcare Limited, UK) [10]. The Spacelabs device was checked and calibrated against a mercury manometer as per the manufacturer's guidelines prior to use.

Statistical Analysis

Data were analysed using STATA version 13.1 (Stata Corporation, College Station, TX, USA). Data are summarised as counts and percentages for categorical variables and either mean \pm standard deviation or median (interquartile range) for continuous variables. Paired student t-test and McNemar's test were used to analyse paired 24-hour blood pressure measurements and the proportions of hypertensive patients between the first and second Oscar 2 ABPM for all 55 patients. Mean change in 24-hour systolic and diastolic blood pressures

between 24-hour ABPMs were calculated as: $[\sum(\text{second 24-hour ABPM} - \text{first 24-hour ABPM})]/\text{number of patients}$. Bland-Altman plots and calculation of 95% limits of agreement were performed to analyse the difference in 24-hour systolic and diastolic blood pressure between the Oscar 2 and Spacelabs device for the subset of 10 patients with both readings. A p -value ≤ 0.05 was considered statistically significant.

Results

Patient Characteristics

Of the 133 potential patients, 47 (35%) (28 males, 19 females) agreed to participate and were comparable to those who did not participate in terms of age, gender ratio, and surgical age. Patient demographics at the time of this study (second Oscar 2 ABPM), associated cardiac anomalies, and operative characteristics of the patients are displayed in Table 1.

The mean age of the patients was 29 ± 8 years (range: 16–48 years). Mean follow-up time since coarctation repair was 27 ± 6 years. Coarctation repair was performed during the first year in 68% (32/47).

The mean follow-up time between the first and second Oscar 2 ABPM was 3.9 ± 1.4 years, and there were no aortic arch reinterventions during this time. There was no difference in body mass index between the first and second Oscar 2 ABPMs ($23.4 \pm 0.6 \text{ kg/m}^2$ vs. $24.2 \pm 0.6 \text{ kg/m}^2$, $p = 0.07$).

Comparison Between First and Second Oscar 2 ABPM

A comparison of 24-hour ABPM results between the first and second Oscar 2 ABPMs is shown in Figure 1 (green lines). Mean change in systolic and diastolic 24-hour blood pressure between second and first Oscar 2 ABPM was $1.2 \pm 9.9 \text{ mmHg}$ and $2.7 \pm 6.9 \text{ mmHg}$, respectively (Figure 2A, D). Mean 24-hour diastolic blood pressure was higher but below prehypertension threshold on the second 24-hour ABPM compared with the first ABPM (73.1 ± 8.2 vs. $70.3 \pm 7.0 \text{ mmHg}$, $p = 0.01$), but there was no difference in mean 24-hour systolic blood pressure (136.6 ± 10.9 vs. $135.2 \pm 11.5 \text{ mmHg}$, $p = 0.4$).

When analysed by day-time and night-time 24-hour blood pressure, mean day-time diastolic blood pressure was higher but below prehypertension threshold on the second 24-hour ABPM compared with the first ABPM (76.6 ± 9.2 vs.

Table 1 Patients' demographics, associated cardiac anomalies, and surgical characteristics.

	Total ($n = 47$)
Demographics	
Male	28 (60%)
Median age at surgery, <i>days</i>	39 (6 days-2 years)
Median age at first Oscar 2 ABPM, <i>years</i>	24 (IQR: 19–30)
Median age at Spacelabs ABPM ($n = 10$), <i>years</i>	28 (IQR: 25–34)
Median age at second Oscar 2 ABPM, <i>years</i>	29 (IQR: 22–33)
Mean time between first and second Oscar 2 ABPMs, <i>years</i>	3.9 ± 1.4
Mean time between first Oscar 2 and Spacelabs ABPMs, <i>years</i>	1.4 ± 0.8
Mean time between first Spacelabs and second Oscar 2 ABPMs, <i>years</i>	1.8 ± 0.3
Associated cardiac anomalies	
Ventricular septal defect	22/42 (52%)
Bicuspid aortic valve	23/44 (52%)
Atrial septal defect/patent foramen ovale	15/42 (36%)
Transposition of the great arteries	5/42 (12%)
Left ventricular outflow tract obstruction	2/42 (5%)
Double outlet right ventricle	2/42 (5%)
Partial anomalous pulmonary venous drainage	2/42 (5%)
Left superior vena cava	1/42 (2%)
Surgical approach	
Thoracotomy: Sternotomy	43 (91%): 4 (9%)
Surgical technique	
Subclavian flap repair	22 (47%)
End-to-end anastomosis	13 (28%)
Patch repair	5 (11%)
End-to-side anastomosis	4 (9%)
Extended end-to-end anastomosis	3 (6%)

Abbreviations: ABPM, ambulatory blood pressure monitoring; IQR, interquartile range.

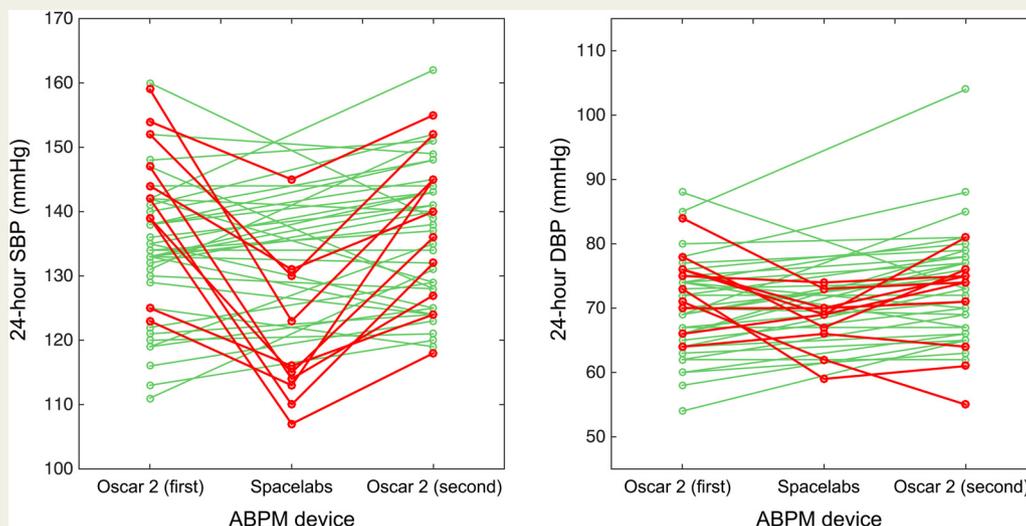


Figure 1 Change in 24-hour systolic blood pressure (SBP, left) and diastolic blood pressure (DBP, right) between the Oscar 2 (first and second measurements) and Spacelabs devices. Patients with all three measurements are shown in red, while patients with only Oscar 2 measurements are shown in green.

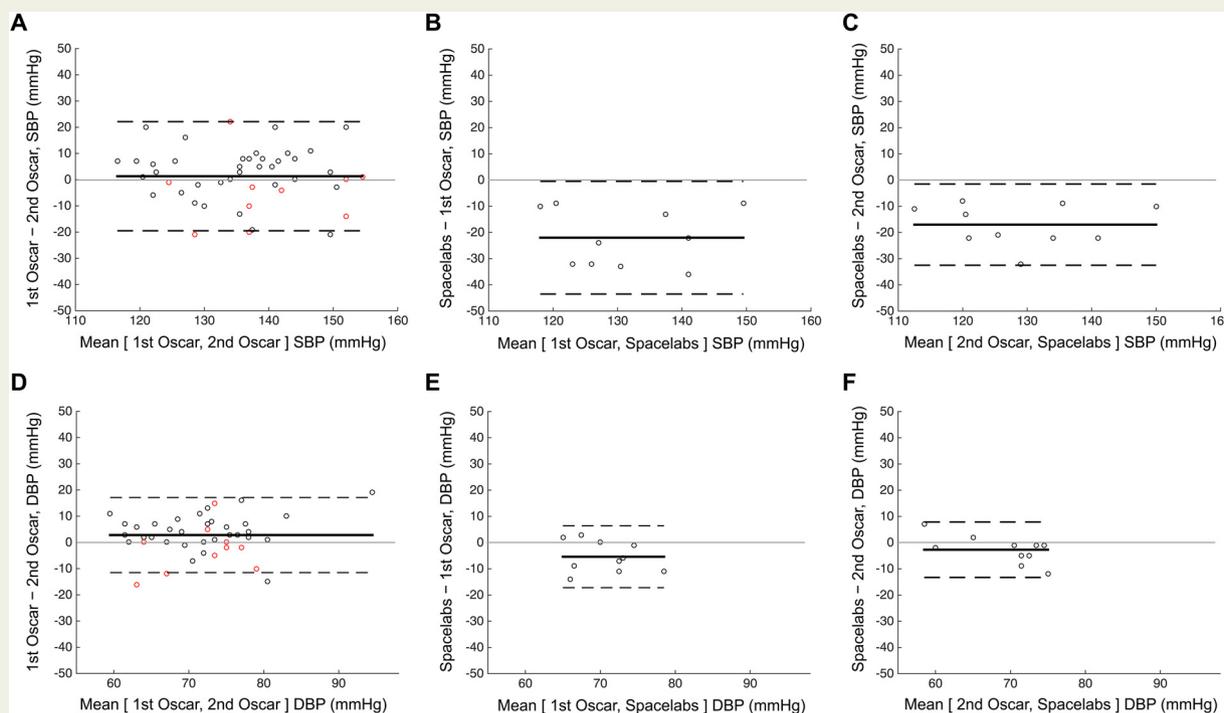


Figure 2 Bland-Altman plots for 24-hour systolic (SBP, A–C) and diastolic blood pressures (DBP, D–F) between the first and second Oscar 2 measurements (A,D), between Spacelabs and the first Oscar 2 measurements (B,E) and between Spacelabs and the second Oscar 2 measurements (C,F). In panels A and D, red markers indicate individuals in whom Spacelabs measurements were also performed.

73.7 ± 7.4 mmHg, *p* = 0.02), but there was no difference in mean day-time systolic blood pressure (141.2 ± 12.0 vs. 139.0 ± 12.5 mmHg, *p* = 0.2). There was no difference in mean night-time systolic or diastolic blood pressure between the second 24-hour ABPM compared with the first ABPM

(120.8 ± 10.9 vs. 122.9 ± 12.0 mmHg, *p* = 0.2; and 61.2 ± 6.2 vs. 60.7 ± 7.3 mmHg, *p* = 0.6); respectively).

There was no difference in the proportion of patients with hypertension between the second ABPM and the first ABPM (55% [26/47] vs. 57% [27/47], *p* = 1.0).

Table 2 Comparison of 24-hour blood pressure between the first and second Oscar 2 ABPMs.

	Second Oscar 2 ABPM (n, %)			Total (n = 47)
	Normotensive	Prehypertensive	Hypertensive	
First Oscar 2 ABPM				
Normotensive	7	1	1	9
Prehypertensive	3	3	6	12
Hypertensive	5	1	20	26
<i>Total</i>	15 (32%)	5 (11%)	27 (57%)	47 (100%)

Abbreviation: ABPM, ambulatory blood pressure monitoring.

Thirty (30/47, 64%) patients retained the same 24-hour blood pressure status between the two blood pressure measurements (Table 2). There was a higher reclassification of 24-hour blood pressure status in eight patients (8/47, 17%): one normotensive patient became prehypertensive, one normotensive patient became hypertensive, and six prehypertensive patients became hypertensive. There was a lower reclassification of 24-hour blood pressure status in nine patients (9/47, 19%): four prehypertensive patients became normotensive; and six hypertensive patients became normotensive, and one hypertensive patient became prehypertensive.

Comparison Between Oscar 2 and Spacelabs ABPM Devices

For the 10 patients who had an additional ABPM with the Spacelabs device, the mean follow-up time between the first Oscar 2 and the Spacelabs ABPM was 1.4 ± 0.8 years, and between the Spacelabs and second Oscar 2 ABPM was 1.8 ± 0.3 years.

A comparison of all three 24-hour blood pressure measurements for the 10 patients who underwent an additional previous Spacelabs measurement is shown in Figure 1 (red lines). Mean difference in systolic and diastolic 24-hour blood pressure between the Spacelabs and first Oscar 2 ABPMs was -22.0 ± 11.0 mmHg and -5.4 ± 6.0 mmHg, respectively. Corresponding differences between the Spacelabs and second Oscar 2 ABPMs were -17.0 ± 7.9 mmHg and -2.7 ± 5.4 mmHg, respectively.

Mean 24-hour systolic blood pressure was higher in both Oscar 2 ABPMs compared to the Spacelabs ABPM (142.4 ± 11.7 mmHg vs. 120.4 ± 11.8 mmHg, $p = 0.0001$; and 137.4 ± 12.2 mmHg vs. 120.4 ± 11.8 mmHg, $p = 0.0001$; respectively). Mean 24-hour diastolic blood pressure was higher in the first Oscar 2 ABPM compared to the Spacelabs ABPM (73.3 ± 5.9 mmHg vs. 67.9 ± 4.6 mmHg, $p = 0.02$) but not between the Spacelabs ABPM and second Oscar 2 ABPM (67.9 ± 4.6 mmHg vs. 70.6 ± 8.0 mmHg, $p = 0.1$).

When analysed by day-time and night-time 24-hour blood pressure, mean day-time systolic blood pressure was higher in both Oscar 2 ABPMs compared to the Spacelabs ABPM (145.4 ± 15.6 vs. 126.2 ± 13.8 mmHg, $p = 0.002$; and 142.3 ± 13.3 vs. 126.2 ± 13.8 mmHg, $p = 0.0003$; respectively).

There was no difference in mean day-time diastolic blood pressure between the Spacelabs ABPM and first or second Oscar 2 ABPMs (70.8 ± 4.6 vs. 76.6 ± 7.2 mmHg, $p = 0.06$; and 70.8 ± 4.6 vs. 73.8 ± 8.9 , $p = 0.2$; respectively). Mean night-time systolic blood pressure was higher in both Oscar 2 ABPMs compared to the Spacelabs ABPM (130.2 ± 13.0 vs. 110.8 ± 12.0 mmHg, $p > 0.00001$; and 121.4 ± 10.6 vs. 110.8 ± 12.0 mmHg, $p = 0.004$; respectively). Mean night-time diastolic blood pressure was higher in the first Oscar 2 ABPM compared to the Spacelabs ABPM (63.5 ± 6.2 mmHg vs. 58.4 ± 4.6 mmHg, $p = 0.03$) but not between the Spacelabs ABPM and second Oscar 2 ABPM (58.4 ± 4.6 mmHg vs. 59.8 ± 5.2 mmHg, $p = 0.3$).

The proportion of patients with hypertension on 24-hour ABPM was higher in both Oscar 2 ABPMs compared to the Spacelabs ABPM (80% [8/10] vs. 10% [1/10], $p = 0.02$; and 60% [6/10] vs. 10% [1/10], $p = 0.06$; respectively).

Bland-Altman plots for 24-hour systolic and diastolic blood pressures between the first and second Oscar 2 ABPMs, between the Spacelabs and first Oscar 2 ABPMs, and between the Spacelabs and second Oscar 2 ABPMs are provided in Figure 2, and the mean difference and 95% limits of agreement for these comparisons provided in Table 3.

Discussion

There is a large variation in the reported prevalence of late hypertension after coarctation repair. This is the first study to investigate the possibility that some of this variation may be due to differences in the measurement devices employed. We previously reported nearly 60% of patients with previous coarctation repair to be hypertensive on 24-hour ABPM using the Oscar 2 device [5,6], a higher prevalence than reported O'Sullivan *et al.* (30%) and de Divitiis *et al.* (54%) using two other ambulatory blood pressure devices [2,3]. Even lower prevalence was reported in two studies using the Spacelabs device in patients who were not on antihypertensive therapy, with 23% reported by Hager *et al.* [4] and 15% in our recent study [10]. The large variation in the reported prevalence of late hypertension after coarctation repair may be due in part to well-known risk factors for its development including patient factors such as older age at follow-up and longer length of follow-up, surgical factors such as older age at

Table 3 Limits of agreement for 24-hour systolic and 24-hour diastolic blood pressure between the two Oscar 2 ABPMs, and between Spacelabs and the two Oscar 2 ABPMs.

	Mean difference \pm standard deviation	95% limits of agreement
First vs. second Oscar 2		
24-hour SBP, mmHg	-1.3 ± 10.6	(-22.6, 19.9)
24-hour DBP, mmHg	-2.8 ± 7.3	(-17.4, 11.8)
Spacelabs vs. first Oscar 2		
24-hour SBP, mmHg	-22.0 ± 11.0	(0.05, 44)
24-hour DBP, mmHg	-5.4 ± 6.0	(-6.6, 17.4)
Spacelabs vs. second Oscar 2		
24-hour SBP, mmHg	-17.0 ± 7.9	(1.2, 32.8)
24-hour DBP, mmHg	-2.7 ± 5.4	(-8.1, 13.5)

Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure

coarctation repair, mechanical factors such as the presence of arch re-obstruction, and intrinsic vascular and neural abnormalities such as increased sympathetic activity [1,4,7,10–12]. However, a possible role of device-dependency as a confounder has not received adequate attention.

We examined the natural serial progression of 24-hour blood pressure in our young repaired coarctation population. The prevalence of hypertension was very similar between the two Oscar 2 ABPMs. Nevertheless, despite a mean time difference of only 4 years between the first and second ABPMs using the Oscar 2 device, blood pressure status was reclassified in more than a third of patients. Although half of previously prehypertensive patients in our study were reclassified as hypertensive, a quarter of previously hypertensive patients were reclassified to normotensive or prehypertensive status despite not being on any antihypertensive medications. While the serial change in blood pressure may not be reflected across the entire spectrum of coarctation patients, including those repaired at an older age or on antihypertensive medications, our proportion of reclassified patients is similar to the findings of de la Sierra et al. in the general population, although in their study most cases of status change were an increase to sustained hypertension [13]. It is difficult to determine whether these blood pressure reclassifications are reliable without multiple repeated 24-hour blood pressure measurements, which is unlikely to be tolerated by patients. However, we were able to reproduce the same blood pressure status in almost two-thirds of patients using the same device.

The same could not be said when we compared 24-hour blood pressure results between two different 24-hour ABPM devices. The mean difference of blood pressure measurements recorded between the Oscar 2 and Spacelabs devices was large, approximately 20 mmHg for 24-hour systolic blood pressure despite both devices being properly calibrated and fitted by experienced operators in all our studies. These differences were seen when 24-hour blood pressure was analysed separately by day-time or night-time. As a consequence of this wide systolic blood pressure variation, the proportion of patients classified as hypertensive in our

studies was vastly different, depending on whether an Oscar 2 or Spacelabs device was used. Interestingly, Kallem et al. reported a difference of 8–10 mmHg in mean systolic blood pressure between two different, simultaneously worn ABPM devices and concluded that device-specific normative values may be required [14].

There is currently no consensus on the reproducibility and re-test reliability of 24-hour blood pressure monitoring using the same device in the general population, with some studies reporting moderate to high reproducibility [13,15], while others reporting poor reproducibility [16,17]. Both the Oscar 2 and Spacelabs ABPM devices have been validated in prior studies [18–21] using multiple protocols including the standard set by the Association for the Advancement of Medical Instrumentation (mean difference of >5 mmHg or a standard deviation of >8 mmHg compared with manual auscultation [22]). Importantly, however, the validation of these devices has only been performed in a ‘static’ office setting despite its intended use in a 24-hour ambulatory setting.

The severe lack of reproducibility between different devices is concerning and warrants caution in the use of 24-hour blood pressure monitoring as the gold standard for the detection and diagnosis of hypertension [23]. While one should not extrapolate our findings and conclude that all ABPM devices are unreliable, similar to Kallem et al. [14], based on the findings of our study, we support the notion that ABPM device manufacturers should consider developing age- and gender-matched normative reference guides for their devices. This will allow more accurate diagnosis of hypertensive and prehypertensive status of patients regardless of the device used.

Limitations

The sample size of patients who underwent 24-hour blood pressure measurements with both devices was small and a larger sample size may have reduced the variation seen between the two devices. Similarly, the Spacelabs device was only used in one time-point and multiple time points may allow us to determine its reproducibility. However, there was a clear bias in 24-hour systolic blood pressure

between devices that were present in every patient, suggesting a reproducible bias in these two 'validated' and widely used devices. How such differences could be possible when both devices are 'validated' requires further investigation. We did not perform 24-hour ABPM using the two devices simultaneously but this would have been difficult in our coarctation population as many had previously undergone a subclavian flap repair, precluding the use of blood pressure monitoring on the left arm. Differences in cuff sizes and design between devices may potentially impact on blood pressure readings despite following manufacturers' guidelines. Although we observed a difference in blood pressure measurements between the two 24-hour blood pressure monitoring devices, we were unable to ascertain which device is more accurate as we did not have direct intra-arterial blood pressure measurements. Further work is required to determine if the differences in 24-hour blood pressure measurements between the two devices is specific to the repaired coarctation population.

Conclusions

With serial 24-hour ABPM in a cohort of patients with repaired coarctation, there was a reclassification of 36% (approximately half of which were reclassified higher) within a relatively short timeframe. There was high intra-device reproducibility of 24-hour ABPM results using an Oscar 2 device but poor inter-device reproducibility in patients with repaired coarctation. Device-specific reference values may be required to ensure reliable 24-hour ABPM interpretation.

Funding

This project was supported by the Victorian Government's Operational Infrastructure Support Program and a Heart-Kids Grant-in-Aid research grant. Melissa Lee was supported by a NHMRC Medical Research Postgraduate Scholarship (1134274), a National Heart Foundation Health Professional Scholarship supported by The Noel and Imelda Foster Research Award (100681), an Avant Doctors-in-Training research scholarship, and an Australian Government Research Training Program Scholarship. Jonathan Mynard is a NHMRC R.D. Wright Career Development Fellow and National Heart Foundation Future Leader Fellow. Gavin Lambert is a NHMRC Senior Research Fellow. Yves d'Udekem is a NHMRC Clinician Practitioner Fellow (1082186).

Disclosures

Christian Brizard is a consultant for Admedus. Gavin Lambert has received honoraria or travel support for presentations from Pfizer, Wyeth Pharmaceuticals, Servier and Medtronic, and was a consultant for Medtronic. Yves d'Udekem is a consultant for Actelion and MSD.

Acknowledgements

We would like to acknowledge Janina Chapman and the ongoing support of Heart Research at the Murdoch Children's Research Institute.

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