Accuracy of automated auscultatory blood pressure measurement during supine exercise and treadmill stress ECG-testing

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Objectives Monitoring of brachial blood pressure during exercise-ECG testing is mandatory and changes in blood pressure (BP) can provide critical management evidence. Patient movement, mechanical vibration, artifactual sounds and observer variability make standard manual techniques problematic. This was an investigator-initiated study to assess an automated auscultatory technique of BP assessment (Tango® exercise blood pressure monitor [SunTech Medical Instruments, NC, USA]) to adequately measure BP during stress-ECG testing.

Methods Initially five fit young male volunteers underwent invasive right brachial artery BP recording using a low-compliance fluid-filled catheter with simultaneous manual and automated assessment. Secondarily, during exercise-ECG testing, the system was assessed against beat-to-beat brachial blood pressures obtained from a catheter-tip solid-state pressure manometer positioned in the ipsilateral brachial artery.

Results In the supine study overall mean difference (± SEM) between invasive and manual blood pressures were 3.26 (1.53) mmHg and 3.89 (1.90) mmHg for diastolic BP (DBP) and systolic BP (SBP) respectively. Corresponding differences between invasive and automated results, and manual and automated were 3.68 (0.84) mmHg and – 7.31 (1.83) mmHg and – 0.64 (± 1.43) and – 11.42 (± 1.59) mmHg. During treadmill exercise-ECG testing the combined mean difference (± SEM) between invasive and automated SBP and DBP was 4.79 (± 0.14) mmHg and 6.33 (± 0.10) mmHg respectively.

Conclusion Automated BP assessment during exercise-ECG testing is feasible with the use of appropriate automatic devices likely to be at least as accurate as manual BP registration. The Tango device is tolerant to exercise and provides reliable automatic BP assessment with absolute differences within an acceptable clinical range. Blood Press Monit 9:000–000 © 2004 Lippincott Williams & Wilkins.

Blood Pressure Monitoring 2004, 9:000–000

Key words: Tango exercise blood pressure monitor, automated blood pressure measurement, exercise-ECG testing, invasive comparison

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Introduction

Accurate registration of brachial blood pressure (BP) during exercise is an important component of diagnostic cardiological stress ECG-testing. Patient movement, mechanical vibration, artifactual sounds and observer variability make observation using standard manual techniques problematic. The SunTech Tango® exercise blood pressure monitor (SunTech Medical Instruments, NC, USA) aims to overcome these issues by performing R-wave gated brachial sphygmomanometry incorporating noise-reducing signal processing specifically implemented to allow extraction and identification of Korotkoff (K)-sounds and thus systolic and diastolic blood pressures during exercise.

This was an investigator-initiated study with a view to implementing a non-manual system into standard exercise-ECG protocols. If an acceptable automated method of BP recording during stress-ECG testing were available, accuracy of monitoring during the procedure may be greatly improved. The objective therefore was to assess the ability of an automated auscultatory technique of BP assessment (the Tango device) to adequately measure BP during stress-ECG testing. The study was in two parts; initially we performed a comparison of the Tango device with manual and invasive BP recording during supine exercise in normal healthy volunteers. Secondarily, to investigate the accuracy and usefulness of automated testing in clinical practice we performed a comparison in sequential subjects referred to our stress-ECG service against the ‘gold-standard’ of brachial artery pressure measured using an indwelling solid-state catheter-tip manometer during standard treadmill (Bruce) protocol testing.
Methods
Two related studies were performed. All subjects gave informed written consent and the study was performed in accordance with institutional ethics committee requirements and the principles of the Declaration of Helsinki.

Supine exercise (study 1)
Initially five fit young male volunteers (23–34 years) underwent invasive right brachial artery BP recording using a low-compliance fluid-filled catheter (3.0 French, natural frequency > 200 Hz) connected to a disposable pressure transducer (Biosensors International) positioned at the height of the left atrium while performing graded supine bicycle exercise (30 Watt increase per three minutes of exercise, referred to as study 1). Simultaneously manual and automated sphygmomanometric assessment by two trained observers and the Tango system was undertaken. Automated and manual sphygmomanometry was performed on the contralateral arm to the catheterization using a T-connector to a mercury sphygmomanometer connected in series with the automated pneumatic cuff of the Tango device. The diaphragm of a teaching stethoscope was secured with tape over the contralateral brachial artery at the same height as the catheter tip. The two observers using the stethoscope were blinded from each other. Manual systolic blood pressure (SBP) was assessed as the commencement of Korotkoff sounds and diastolic blood pressure (DBP) taken at the complete cessation of sounds (K5). Heart rate and invasive BP waveforms were continuously recorded using the CVMS cardiovascular monitoring system (McPherson Scientific, Melbourne, Australia). This system allows continuous recording of the intra-brachial pressure waveform sampled at 200 samples/second as well as the facility to mark relevant time points during recording.

Treadmill exercise (study 2)
In a second study in 10 sequential consenting patients (nine male, one female; age 37–63 years) presenting by referral to our cardiology outpatients service for clinically indicated treadmill exercise-ECG, we performed comparison of invasive brachial blood pressure measured by catheter-tip manometer (Millar Instruments Inc, USA) and simultaneous non-invasive assessment by the Tango exercise blood pressure monitor (no manual assessment).

A modified Bruce protocol exercise-ECG testing as per our standard clinical practice was employed. Calibrated invasive brachial artery blood pressure waveform measurements were continually recorded using a high-fidelity Millar MicroTip® solid-state pressure transducer (Millar Instrument, Houston Tx USA).

In both studies invasive BP was recorded throughout the procedure and during recovery. Brachial cannulation and catheter insertion was performed by an experienced physician under strict sterile conditions.

During exercise-ECG testing, the Tango system was manually triggered to automatically acquire blood pressure readings at two-minute intervals during the procedure and through the recovery period. As each automatic acquisition cycle commenced and ended time markers were manually stamped on the CVMS data acquisition system to allow subsequent off-line time-registration of invasive mean beat-to-beat blood pressure data corresponding with non-invasive estimates of systolic and diastolic BP.

The Tango system takes a finite time to inflate and deflate the cuff to determine non-invasive BP and therefore for comparison purposes as reported here the mean of all cyclical systolic and diastolic BP values determined automatically from the invasive waveform data between the annotated start and finish points of inflation were calculated using built in peak and trough detection and averaging routines available in the CVMS system.

Statistics

![Blood Pressure Monitoring](image-url)
Tango and (time averaged) invasive estimates of SBP and DBP were compared by reproducibility co-efficient and the results presented as correlations and Bland–Altman plots as recommended for the comparison of two measures of clinical indices [1].

Results
Supine exercise (study 1)
Results for each individual were analysed as represented graphically in Figure 1. Figure 2 shows a graphical comparison of DBP and SBP results for manual versus invasive, and automatic versus invasive assessment for the group combined with summary statistics for all comparisons shown in Table 1. Overall for all assessments combined the mean difference (± standard error) between invasive and manual blood pressures were 3.26 (1.53) mmHg and 3.89 (1.90) mmHg for DBP and SBP respectively. Corresponding differences between invasive and automated results and manual and automated were 3.68 (0.84) mmHg and −7.31 (1.83) mmHg and −0.64 (± 1.43) and −11.42 (± 1.59) respectively for DBP and SBP. We further calculated the percentage of results that varied by more than ±5 mmHg for the three comparisons. The absolute difference between invasive and Tango assessment of SBP and DBP was greater than 5 mmHg for 48% and 56% of estimates respectively; for manual versus Tango and manual versus invasive assessment the corresponding results (DBP, SBP) were 51%, 52%, 49% and 57% respectively.

Results from study 1. Left hand panels: scattergrams showing difference versus mean of non-invasive and invasive blood pressures. Filled circle and solid line shows manual versus invasive BP, open circles and dotted line indicates automatic (Tango) versus invasive blood pressures. Right panels: linear regression of invasive on automatic SBP and DBP.
Treadmill exercise (study 2)

During the 10 exercise tests performed (average duration 10 min, 3–5 stages of Bruce Protocol) 120 assessments of non-invasive brachial BP were performed. For all measurements combined the mean difference (± standard error) between invasive and automated Tango SBP and DBP was 4.79 (± 0.14) mmHg and 6.33 (± 0.10) mmHg respectively. Results for all 10 subjects individually are summarised in Table 2 and Figure 3 shows the individual regression lines of automated blood pressure assessment against invasive blood pressure for both SBP and DBP. A wide range of offset and more variation in slope is evident in DBP results compared to the more closely aligned SBP comparisons. Figure 4 shows the frequency distribution and cumulative distributions for both the systolic and diastolic comparisons during treadmill testing. For systolic BP measurement the Tango device was between −7 mmHg and 16 mmHg of the invasive SBP in 80% of the cases. A similar comparison for DBP showed 80% of comparisons between −4 mmHg and 17 mmHg. Figure 5 shows the Bland–Altman plot for all 120 blood pressure comparisons. Confidence limits for the difference included 0 mmHg in both systolic and diastolic cases and there was no trend to larger variation at either end of the invasive BP range.

Also indicated in Tables 1 and 2 are those comparisons that fall outside the range defined as acceptable (mean difference < 5 mmHg) by the American Association for the Advancement of Medical Instrumentation criteria for sphygmomanometers [2].

Discussion

Monitoring of brachial blood pressure during exercise-ECG testing is mandatory and changes in blood pressure can provide critical management evidence. It is, however, well known that manual registration of blood pressure
during exercise, although assumed to be the gold standard, is in practice often difficult to record and its validity, even in trained hands, questionable. If an automated technique at least as reliable as manual registration could be demonstrated this would potentially improve patient monitoring and diagnostic information in the context of routine stress-ECG testing. In this context of a practical need we undertook testing of a commercial system designed for automated blood pressure assessment during treadmill exercise. Although in standard practice manual BP is used, this, as discussed above, is not necessarily accurate and hence we employed invasive assessment of brachial artery pressure as the comparator ‘gold-standard’.

Consideration of the results of the supine bicycle exercise study highlights the technical difficulty in manual BP assessment during even relatively immobile exercise. There is no standard recommendation for assessment of automated (or manual) blood pressure registration against invasive techniques or for acceptability during exercise. Standard criteria such as the 1987 American Association for the Advancement of Medical Instrumentation (AAMI) standard for sphygmomanometers [2] or the British Hypertension Society (BHS) protocols for evaluating the accuracy of BP devices [3,4] deal with validation against a non-invasive standard. In the supine component of our study there was no apparent difference on AAMI criteria between manual and automated BP when compared to invasive brachial BP as a gold standard. The two manual operators were an experienced physician and an experienced cardiac technologist; even so mean manual readings differed by greater than the AAMI criteria of 5 mmHg in approximately 50% of registrations. An unknown proportion of this variation may have been due to the finite time required for manual registration of BP and potential changes in beat-by-beat BP recorded invasively and subsequently averaged. In every case the systolic sound assessed by the manual assessors would be...
from a different cycle to that from which DBP was taken with the averaging of intervening sequential invasive peak and trough pressures having an indeterminate effect.

In the upright treadmill studies the mean difference criteria was in general exceeded, more so when considering DBP (8/10) than SBP (6/10), with the standard deviation usually within the specified acceptable range of 8 mmHg. The AAMI criteria is not specified for use during potentially varying BP (i.e., during exercise) so comparison with this standard, for either the usually accepted manual or other automated methods, may not necessarily represent appropriate assessment. In view of the discrepancies shown between manual and invasive pressures in the supine study the true relevance of mean pressure differences exceeding AAMI limits by the range shown in the treadmill study is not clear but does not seem worse than for manual techniques.

Other studies have investigated the consistency of automated BP registration with manual auscultation during exercise in adults [5,6] and in children [7] undergoing stress testing. Good correlation has generally been reported between these automatic and manual assessments [6,8]. To our knowledge our study is the first to assess automated assessment of BP during exercise against direct high-fidelity invasive measurement.

Although we have referred to both AAMI and BHS guidelines regarding device accuracy these were designed for evaluating aneroid or electronic sphygmomanometers for standard clinical use and not for specialized applications such as blood pressure monitoring during exercise. We referenced these standards as providing a reasonable basis of initial comparison with which users are familiar, it should be remembered however that required accuracy depends on application and on the likely consequences of any error on clinical outcome. In usual practice devices that differ from a reference device by 0–5 mmHg are considered accurate with no clinically relevant error while those with errors greater than 15 mmHg are considered very inaccurate [9]. Blood pressure monitoring during exercise stress testing is not used to diagnose hypertension or determine need for blood pressure therapy but rather to assess adequacy of acute haemodynamic response, and therefore wider margins of error seem reasonable and the ability to track BP change might be considered more important than the absolute error at any blood pressure level.

Specific issues and applications require specific protocols and testing. Based on this study we suggest that assessment against invasive measures in small numbers of individuals (rather than introducing further error by manual assessment) is appropriate for this type of blood pressure assessment device. Presentation of results by difference versus reference scatter plot and cumulative frequency of error magnitude are useful as they allow users to assess the likely range of errors and allow assessment on a case-by-case basis depending on the perceived accuracy required of a particular application. In cardiological exercise-ECG testing we have found accuracy of the order demonstrated in the current study to be adequate.

Although manual comparison was not attempted in study 2, the differences demonstrated between manual and invasive studies in study 1 suggest that manual assessment as usually practiced during treadmill exercise may be no better than automated assessment. In presenting our results as difference versus reference scattergrams (Figure 5) we have used the measured invasive pressures as the abscissa rather than the mean of the two assessments as is often presented when, for example, interest is in two non-invasive assessments of the same parameter when neither assessment can be taken as absolutely correct.

As mentioned above, a possible limitation of these studies was the averaging of systolic and diastolic blood pressures over the period of the Tango automated inflation/deflation cycle, the finite length of which extends over a number of cardiac cycles. Potential errors therefore occur related to accuracy of annotating the start and finish of the Tango cycle on the invasive recording and through the Tango identifying systolic and diastolic pressures on cardiac cycles that may not be representative of these mean values. Such effects are unlikely to have practical impact but will tend to increase apparent differences in non-invasive to invasive results.

**Conclusion**

The Tango device is tolerant to exercise and appears to provide reliable automatic BP assessment. In our supine study discrepancies between invasive, manual and automatic measurements were within a useful clinical range. The Tango device also appears tolerant to treadmill exercise and during diagnostic stress-ECG testing the SBP and DBP obtained using automatic assessment tracked intra-brachial BP. Absolute differences were again within an acceptable range.

Automated BP assessment during standard exercise-ECG testing is feasible. Our results suggest that in practice the use of appropriate automatic devices is likely to be at least as accurate as manual BP registration during routine stress-ECG testing.

**Acknowledgement**

SunTech Medical Instruments (NC, USA) supplied the Tango® automated sphygmomanometer devices and Millar MikroTip® catheters used in this study.
References
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