

The StethoDop: a Doppler stethoscope attachment for investigation of arterial and venous insufficiency of the lower extremities

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ABSTRACT

Background: The aim of the current study was to investigate whether the StethoDop can serve as a valid and reproducible instrument for measuring the ankle-brachial index (ABI) and assessing venous reflux, even when used by inexperienced investigators, in comparison with the classic Doppler.

Methods: I) During four weeks, four ankle-brachial index (ABI) measurements were performed on 44 patients: one measurement with the classic Doppler by an experienced investigator, one with the classic Doppler by an inexperienced investigator and two measurements with the StethoDop by the inexperienced investigator. II) 36 patients were screened for venous insufficiency by detecting venous reflux with the StethoDop and classic Doppler at the saphenofemoral and saphenopoplital junctions by an inexperienced investigator. The results were compared with the results of the duplex as gold standard and with the results of the examination by an experienced dermatologist with the classic Doppler.

Results: I) The confidence interval of ABI measurement for both the classic Doppler and the StethoDop by the inexperienced investigator was within an acceptable ± 0.21 interval of significant change. II) For venous reflux determination, the overall sensitivity and specificity of the StethoDop were comparable with the sensitivity and specificity of the classic Doppler: sensitivity 76.0 and 75.0%, specificity 94.8 and 94.2%, respectively. The positive predictive value of the StethoDop, compared with the duplex, was 87.5%; the negative predictive value was 90.0%.

Conclusion: I) For ABI measurement, the StethoDop is a valid instrument with reproducible results, even when used by inexperienced investigators. II) For venous reflux determination, the StethoDop is a valid screening instrument for venous insufficiency. However, as with determination with the classic Doppler, the reflux assessment by StethoDop gives no information about the deep veins and may miss up to 24% of apparent reflux.

INTRODUCTION

Doppler ultrasound is a simple and quick method to evaluate arterial and venous disease in a noninvasive manner. The ability of the Doppler ultrasound to study blood flow transcutaneously has been widely used. Recently a new Doppler device, called the StethoDop, became available. It is a compact 5 MHz Doppler, which can easily be attached to most standard stethoscopes. In addition to its small size, the StethoDop probe has a large surface and its crystals are placed at an optimal angle in the probe, which makes the StethoDop easy to use. The manufacturer claims that even inexperienced investigators can achieve valid and reproducible measurements. The ankle-to-brachial index (ABI), the ratio of the ankle-to-arm systolic pressure, is widely used as a simple, noninvasive and objective measure of the severity of atherosclerotic peripheral arterial disease,¹ and used as a marker of cardiovascular disease.² The ABI is a valid, reproducible measurement, when performed with a

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standard handheld Doppler device by experienced investigators;³ however, small changes in time are not always clinically relevant. Previous studies have shown that an ABI can range from at least 0.15 to 0.21⁴⁻⁷ before it should be considered as a clinically relevant and significant change. Doppler ultrasound is also a simple and quick way to noninvasively evaluate venous disease.^{8,9} The handheld Doppler is routinely used in outpatient clinics of dermatology departments to confirm the presence of reflux at both the saphenofemoral and saphenopopliteal junctions. For this, the duplex (echo Doppler) investigation is considered to be the gold standard.¹⁰ In previous studies the sensitivity of venous reflux in the saphenofemoral and saphenopopliteal veins, measured by handheld Doppler, varied between 54 and 92% and the specificity between 72 and 93%, respectively.^{8,9,11}

The aim of this study was to investigate whether the StethoDop can perform as a valid instrument with reproducible results for measuring the ABI and assessing venous reflux by inexperienced investigators, in comparison with the gold standard for these determinations.

METHODS

Ankle-to-brachial index

Forty-four patients who were referred to the vascular laboratory of the University Hospital of Nijmegen for ABI measurement during one month participated in the study. ABI measurements were performed four times in each patient on the same day. The first measurement was performed with an 8 MHz (Imexdop CT+, USA) Doppler by an inexperienced investigator. This investigator only had one week of training at the vascular laboratory, performing ten ABI measurements supervised by an experienced vascular technician. Two measurements were performed with the StethoDop by the same inexperienced investigator. Another measurement was performed with the classic 8 MHz Doppler by an experienced vascular technician.

The ABI measurements were carried out in the vascular laboratory under identical standardised circumstances with one of two identical sets of equipment. The two investigators were unaware of each other's results. The patient was positioned supine for ten minutes before testing. During this time the symptoms of intermittent claudication, cardiovascular risk factors and medical history were evaluated using a questionnaire. A physical examination was performed for peripheral oedema and palpation of the arterial pulses.

The left and right brachial systolic blood pressure and the systolic blood pressure of the posterior tibial artery and the dorsal pedal artery at the left and right ankle were

measured with a sphygmomanometer. The ABI for each limb was calculated as the higher of the two pedal artery systolic pressures divided by the higher brachial artery systolic blood pressure.

Venous reflux

Altogether, 36 patients with symptoms of venous insufficiency participated in the study. These patients were all referred to the vascular laboratory or the outpatient clinic of the dermatology department of the University Medical Centre of Nijmegen (UMCN) in an eight-week period.

The clinical symptoms (varicosis, oedema, painful or tired legs) and medical history were evaluated using a questionnaire. The Doppler assessment of venous reflux was done with the patient in standing position. Venous reflux was determined at the saphenofemoral junction in the groins, medial to the femoral artery pinching the quadriceps. In addition, venous reflux was assessed at the saphenopopliteal junction in the back of the knee, lateral to the popliteal artery pinching and releasing the calf. An audible flow signal lasting for more than one second after releasing the muscle was used as the threshold for diagnosing significant reflux.

At the outpatient clinic of the dermatology department of the UMCN three measurements were performed: one assessment of venous reflux with a classic 8 MHz Doppler (Hadeco Minidop ES-100 VX, Japan) by an inexperienced investigator, one assessment of venous reflux with the 5 MHz StethoDop by the same inexperienced investigator, and one assessment of venous reflux with the classic 8 MHz Doppler by an experienced dermatologist. The investigators were unaware of each other's results. At the vascular laboratory the reflux was assessed by the inexperienced investigator with the StethoDop and these results were compared with the duplex, which was performed by an experienced vascular technician.

Statistical methods

The mean difference and the 95% confidence interval of the difference between the ABI measurements were calculated and plotted according to the methods of Bland and Altman. With the duplex and reflux assessment performed by the experienced dermatologist with the classic Doppler as the gold standard, the sensitivity and specificity of the venous reflux assessments performed by the inexperienced investigator using the StethoDop and the classic Doppler were determined.

RESULTS

Ankle-brachial index

Of the 44 evaluated patients, 66% were male. The mean age was 61 years, range 40 to 83 years. Thirty-

three patients were referred with symptoms of intermittent claudication, eight patients were referred for postoperative control. The remaining three patients were referred for screening for atherosclerosis without symptoms. The prevalence of risk factors in the investigated population was smoking n=18 (41%), hypertension n=18 (41%), hypercholesterolaemia n=14 (32%) and diabetes mellitus n=6 (14%). For one patient, the ABI was measurable in just one leg, because the dorsal pedal artery was not compressible and the signal of the tibial posterior artery was not audible. The mean ABI measured by the vascular technicians was 0.87 (range 0.28-1.47).

The difference in ABI did not vary with mean ABI (figures 1 and 2). The mean difference between the measurements of the vascular technicians with the classic Doppler and those of the inexperienced investigator with the same classic Doppler was 0.013 with a 95% confidence interval of -0.17 to 0.20.

The mean difference between the measurements of the vascular technicians with the classic Doppler and those of the inexperienced investigator with the StethoDop was 0.020 with a 95% confidence interval of -0.16 to 0.20. The mean difference between the two measurements of the inexperienced investigator with the StethoDop was -0.0077 with a 95% confidence interval of -0.16 to 0.15.

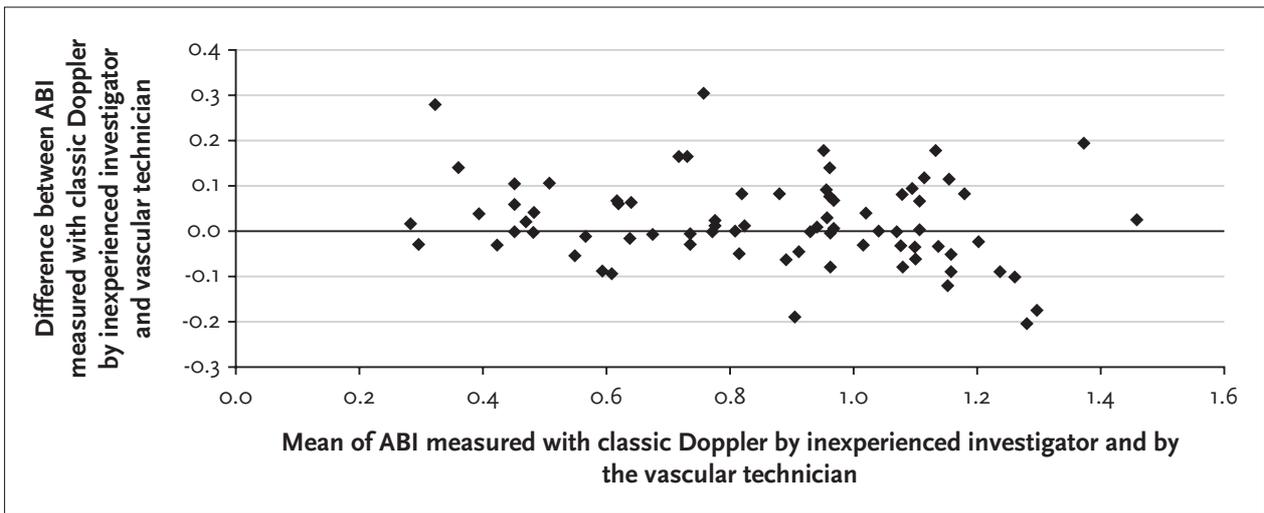


Figure 1

Mean of ABI measured with the classic Doppler by the inexperienced investigator and by the vascular technician, plotted against the difference

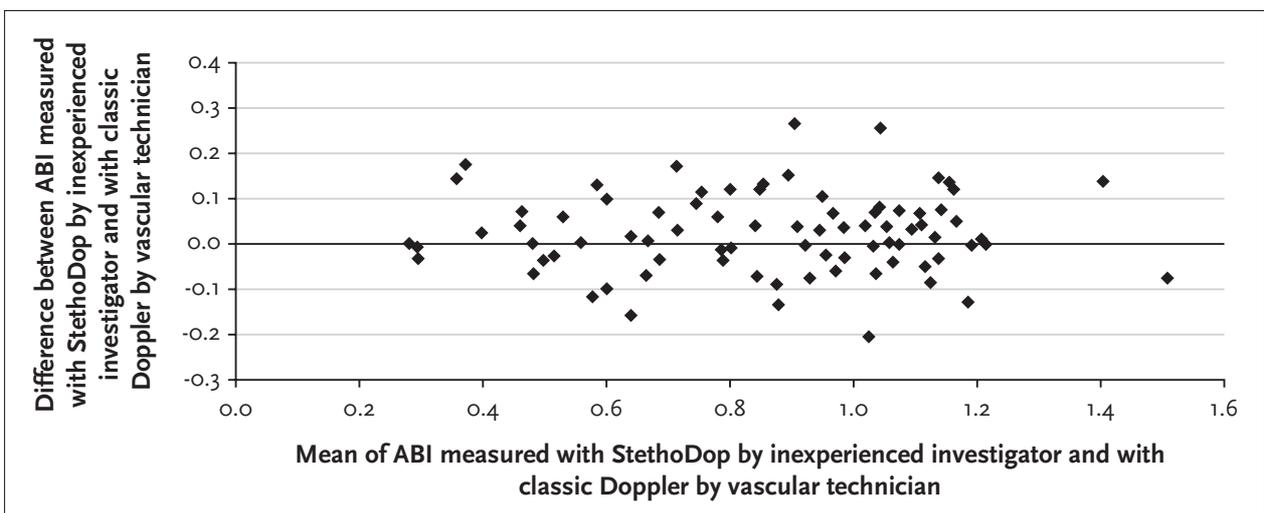


Figure 2

Mean of ABI measured with StethoDop by inexperienced investigator and with classic Doppler by vascular technicians, plotted against the difference

There was no relationship between the body mass index (BMI) and the difference in the measurements of the vascular technicians and the measurements with StethoDop or Doppler by the inexperienced investigator ($r=0.139/0.180$ right/left for StethoDop; $r=0.113/0.186$ right/left for Doppler).

Eight patients had peripheral oedema. Of these patients, in four measurements the difference between the ABI measured by vascular technicians and the ABI measured with Doppler by the inexperienced investigator was more than 0.15, where none of the StethoDop measurements differed more than 0.15.

Venous reflux

A total of 36 patients were evaluated: 27 female (75%) and 9 male (25%). The mean age was 49 years (range 23 to 82 years). Thirty-five patients had symptoms of venous insufficiency, 11 had suffered a deep venous thrombosis in the last five years. The reflux of all patients was examined with the StethoDop by the inexperienced investigator. In 18 patients the reflux was assessed with the classic Doppler by the inexperienced investigator and in 14 patients also by the dermatologist. Of 22 patients a duplex is done in one or both legs, depending on clinical presentation.

Table 1 shows the sensitivity and specificity of the measurements by the inexperienced investigator with the StethoDop and classic Doppler (the measurements of the dermatologist or the duplex as gold standard), separated in the reflux assessments of the saphenofemoral and saphenopopliteal junctions. Overall, the sensitivity of the StethoDop was 76.0%, the specificity 94.8%. The overall sensitivity of the classic Doppler was 75.0%, the specificity 94.2%. The positive predictive value of the StethoDop, compared with the duplex, was 87.5%; the negative predictive value 90.0%.

DISCUSSION

In the current study, we evaluated the clinical usability of a new Doppler instrument, the StethoDop. This study demonstrates that the StethoDop performed well for ABI measurements and for detecting venous reflux in the lower extremity and that it was easy to use.

Previous studies have shown that an ABI must change at least 0.15 to 0.21^{4,7} before this change may be considered to be significant. In our study the mean difference between the measurements of the inexperienced investigator with the StethoDop and those of the vascular technicians with the classic Doppler was 0.020 and the 95% CI was -0.16 to 0.20. This confidence interval does not exceed the +/-0.21 interval of significant change. Therefore, the ABI measurements obtained with the StethoDop are not significantly different, even when performed by inexperienced investigators. However, the measurements of the inexperienced investigator with the classic Doppler are not significantly different either, since the 95% CI was -0.17 to 0.20. These results are even better than those in the study by Ray *et al.*, showing that ABI measurements by inexperienced investigators were not comparable with those of an experienced investigator. Furthermore, the StethoDop measurements are reproducible because the 95% CI of the two measurements with the StethoDop [-0.16 to 0.15] does not exceed the +/- 0.21 interval of significant change.

Therefore, it can be concluded that the StethoDop is validated for ABI measurement with reproducible results, even when obtained by inexperienced investigators. It can be used as an initial screening instrument for atherosclerotic peripheral arterial disease, although referral to a vascular laboratory is often necessary for an additional exercise test (walking test) or for determining the localisation of the obstruction.

Table 1
Sensitivity and specificity of StethoDop and classic Doppler

LOCALISATION	DEVICE	CLASSIC DOPPLER, PERFORMED BY EXPERIENCED DERMATOLOGIST	DUPLEX, PERFORMED BY VASCULAR TECHNICIAN	OVERALL
Sapheno-femoral	StethoDop	Sensitivity: 66.7% Specificity: 91.7%	Sensitivity: 69.2% Specificity: 100%	Sensitivity: 68.8% Specificity: 95.5%
Sapheno-femoral	Doppler	Sensitivity: 50.0% Specificity: 82.4%	Sensitivity: 75.0% Specificity: 100%	Sensitivity: 70.0% Specificity: 87.5%
Sapheno-popliteal	StethoDop	Sensitivity: 100% Specificity: 96.0%	Sensitivity: 83.3% Specificity: 92.6%	Sensitivity: 88.9% Specificity: 94.2%
Sapheno-popliteal	Doppler	Sensitivity: 66.7% Specificity: 100%	Sensitivity: 100% Specificity: 100%	Sensitivity: 83.3% Specificity: 100%
Overall	StethoDop	Sensitivity: 83.3% Specificity: 93.9%	Sensitivity: 73.7% Specificity: 95.7%	Sensitivity: 76.0% Specificity: 94.8%
Overall	Doppler	Sensitivity: 60.0% Specificity: 91.2%	Sensitivity: 81.8% Specificity: 100%	Sensitivity: 75.0% Specificity: 94.2%

Previous studies have shown a sensitivity of the reflux assessment by Doppler of 54 to 92%, which is frequently higher at the saphenopopliteal junction than at the saphenofemoral junction. The specificity was 72 to 93%. The results in this study with the StethoDop are comparable, with a varying sensitivity from 69.2% at the saphenopopliteal junction to 83.3% at the saphenofemoral junction. The specificity in our study was 100% at the saphenofemoral junction and 92.6% at the saphenopopliteal junction. The overall sensitivity and specificity of the StethoDop was similar to the sensitivity and specificity of the handheld Doppler device: sensitivity 76.0 and 75.0%, specificity 94.8 and 94.2%, respectively. The positive predictive value of the StethoDop compared with the duplex as the gold standard was 100% for the saphenofemoral junction and 71.4% for the saphenopopliteal junction. These values were calculated with a small number of patients, due to the low prevalence of reflux in our group of patients. The negative predictive value is more reliable, being calculated with a higher number of patients: 83.3% for the saphenofemoral junction and 96.2% for the saphenopopliteal junction. These are acceptable results for a simple, noninvasive examination as the StethoDop reflux assessment. Moreover, the StethoDop has shown to be easy to use because of its small size, the big surface of the probe and the Doppler crystals already placed at an optimal angle. Therefore, the StethoDop seems to be suitable as a screening instrument for venous insufficiency. However, just as the classic Doppler, the reflux assessment by StethoDop gives no information about abnormalities of the deep veins. Furthermore, one may miss up to 24% of apparent reflux. Considering this, the duplex remains the reference measurement for venous reflux, although it may miss apparent refluxes. In conclusion, in this study the StethoDop appeared to be a convenient instrument with valid and reproducible results for measuring the ABI and assessing venous reflux. Further studies in larger groups may strengthen the current results.

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