NICE National Institute for Health and Care Excellence

NICE guidance

Automated ankle brachial pressure index measurement devices to detect peripheral arterial disease in people with leg ulcers

Diagnostics guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

1.1 There is not enough evidence to recommend routine adoption of automated ankle brachial pressure index (ABPI) measurement devices to detect peripheral arterial disease in people with leg ulcers. They should only be used in the context of research for these people.

1.2 Centres already using automated ABPI measurement devices to detect peripheral arterial disease in people with leg ulcers can continue to use them, only if:

- they collect data or do research to assess their value and how well they identify people with peripheral arterial disease (see the section on further research)
- people using the devices have experience assessing peripheral arterial disease
- people using the devices are aware of their limitations, particularly diagnostic accuracy and the risk of missing peripheral arterial disease, and that there are differences between devices
- further assessment using other methods, including manual doppler, is available.

1.3 Further research is recommended on automated ABPI measurement devices (see the section on further research) to:

- assess their ability to detect peripheral arterial disease in people with leg ulcers
- assess how they affect time to treatment for venous leg ulcers
- assess clinical outcomes for treatments started after ABPI assessment
- explore the most appropriate user (specialist and non-specialist in assessing peripheral arterial disease) and the most appropriate healthcare setting for their use
- explore whether different ABPI thresholds can improve their sensitivity for

detecting peripheral arterial disease.

Why the committee made these recommendations

Treatment for leg ulcers caused by a problem with blood flow in the veins (venous) involves compression therapy with bandages or stockings. Compression therapy is not suitable for some people with peripheral arterial disease because it could disrupt blood flow to the leg. Measuring ABPI as part of a clinical assessment can help detect if someone has peripheral arterial disease and therefore should not have compression therapy.

Currently, ABPI is measured and calculated manually. The assessment takes up to 1 hour and can be uncomfortable for people with leg ulcers. Automated ABPI measurement devices may potentially be easier and faster to use than manual doppler measurement, and more comfortable for people with leg ulcers. But there is limited evidence on whether automated devices can reduce the length of time an ABPI assessment takes.

There is a lack of clinical evidence on automated ABPI measurement devices and most studies were done in people without leg ulcers. So, it is unclear how well automated devices detect peripheral arterial disease in people with leg ulcers. There is also uncertainty about which healthcare setting the devices should be used in (for example, hospital or community) and who should use them (specialist or non-specialist in assessing peripheral arterial disease). It is therefore unclear:

- whether automated devices reduce the length of time before starting treatment for venous leg ulcers
- how inaccurate test results impact clinical decision making and health outcomes.

Economic modelling shows that automated ABPI devices are unlikely to be cost effective compared with manual doppler measurement unless they reduce the length of time before treatment starts, which is uncertain. The results of the economic model are also uncertain because there is no evidence on how results from automated ABPI measurement devices affect clinical decision making or clinical outcomes. So, automated ABPI measurement devices are only recommended in the context of research. Centres already using the devices can continue to use them if they do research and ensure safety.

2 The diagnostic tests

Clinical need and practice

The condition

2.1 Leg ulcers are slow-healing wounds that usually develop on the inside of the leg, just above the ankle. It is estimated that about 1 million or 2% of adults in the UK have a leg ulcer (Guest et al. 2020). Around 65% of leg ulcers are venous, meaning they are caused by a problem in the blood flow in the veins. Treatment involves using compression such as bandages or stockings. Strong compression therapy can disturb the arterial blood supply in the leg, so it should not be offered to people with peripheral arterial disease.

2.2 People with peripheral arterial disease may not have any symptoms, but it can lead to serious complications such as chronic limb-threatening ischaemia. In this condition, loss of blood supply to the leg causes tissue to die and there is a significant risk of losing a limb and premature death.

Care pathway

2.3 The National Wound Care Strategy Programme (NWCSP) recommendations for lower limb ulcers advise using the ankle brachial pressure index (ABPI) to screen for peripheral arterial disease in people with leg ulcers alongside a full clinical assessment. This is currently measured manually using a handheld doppler ultrasound probe.

2.4 People with leg ulcers may present in primary care. NWCSP guidance recommends that immediate care for ulcers should include cleaning, application of emollient and a simple low-adherent dressing. In the absence of any 'red flag symptoms' (such as infection, symptoms of sepsis, ischaemia, suspected deep vein thrombosis or skin cancer), mild graduated compression should be applied until full clinical assessment and ABPI measurement can take place. However, if there are not enough

staff able to do manual doppler assessment, delayed assessment may lead to longer periods without compression or sub-optimal compression. Clinical experts noted that in practice some practitioners are uncomfortable applying even mild compression without ABPI measurement. People should be offered a full clinical assessment within 14 days of initial presentation, but clinical experts noted this is a challenge and it can take substantially longer in some areas.

Potential value of the technologies

2.5 Automated ABPI measurement devices may be easier to use than manual devices. This may reduce the time needed to complete the assessment and make ABPI measurement more comfortable for people with leg ulcers. A further potential benefit could be a reduction in the time to assessment and, consequently, treatment for people with venous ulcers when there are not enough staff able to do manual doppler assessment.

The interventions

2.6 Automated ABPI devices include doppler-based, oscillometry-based and plethysmography-based devices. Doppler-based devices use a doppler probe and provide doppler waveform signals as an output. Oscillometry-based devices assess oscillations in the vessel wall, and plethysmography-based devices assess blood volume changes. These devices either estimate blood pressure directly or use a pressure cuff to help with the measurement. Diabetes, rheumatoid arthritis, systemic vasculitis, atherosclerotic disease and advanced chronic renal failure can cause calcium build-up and hardening of the arteries, which can make ABPI measurements appear misleadingly normal. Clinical experts highlighted the value of information provided by doppler waveform signals in these situations. Devices that do not provide doppler waveform signals may provide information about the quality of arterial circulation in the ankles, but there is uncertainty about whether these alternative outputs are comparable with doppler waveform signals.

2.7 This evaluation considers 7 automated devices for measuring ABPI and assessing arterial circulation (see table 1). Costs shown in table 1 exclude VAT and include the cost of the equipment and other fixed costs such as

purchase of additional cuffs to complete the set, and software when applicable.

Table 1 Characteristics and features of the automated ABPI measurement devices

Automated device	Technology	Component	Resting period needed	Cost (£ per unit)
BlueDop Vascular Expert	Doppler	Handheld doppler device	No rest	4,995
boso ABI-system 100	Oscillometry	2 arm cuffs 2 ankle cuffs	5 minutes	3,187
Dopplex Ability	Plethysmography	4 dual-chamber cuffs	No rest	3,937
MESI ABPI MD	Plethysmography Oscillometry	3 cuffs	No rest	2,499
MESI mTABLET ABI	Plethysmography Oscillometry	4 wireless cuffs	5 minutes	2,874
WatchBP Office ABI	Oscillometry	2 cuffs	5 minutes	2,145
WatchBP Office Vascular	Oscillometry	2 cuffs	5 minutes	2,445

The comparators

2.8 Currently, ABPI is measured in people with leg ulcers during initial clinical assessment. Blood pressure is measured using a handheld doppler ultrasound probe and a sphygmomanometer with a manually inflated cuff. The ABPI is calculated manually. People with leg ulcers need to lie down before and throughout the test. The test takes up to 1 hour and may be painful and uncomfortable for people with leg ulcers.

2.9 ABPI measurement is typically done by district or community nurses at a person's home, care home or a leg ulcer clinic, or by practice nurses at GP practices. This is when they are trained in doing both the full clinical

assessment and ABPI measurement. In some parts of the country, leg ulcer clinics are in use, or are being implemented. Some clinics may already do, or increasingly do in the future, initial ABPI assessment. In areas without enough practitioners trained to do manual doppler measurements, people may have initial ulcer care and then be referred to specialist vascular services for the full clinical assessment.

2.10 The reference standard for detecting peripheral arterial disease is imaging such as duplex ultrasound, magnetic resonance angiography or CT angiography. However, these would not be used as part of the initial clinical assessment in practice.

3 Committee discussion

The diagnostics advisory committee considered evidence on automated devices for measuring ankle brachial pressure index (ABPI) and assessing arterial circulation using one of the following:

- BlueDop Vascular Expert (BlueDop Medical)
- boso ABI-system 100 (BOSCH + SOHN)
- Dopplex Ability Automatic ABI System (Huntleigh Healthcare)
- MESI ABPI MD (MESI)
- MESI mTABLET ABI (MESI)
- WatchBP Office ABI (Microlife)
- WatchBP Office Vascular (Microlife).

Evidence was considered from several sources, including a diagnostics assessment report and an overview of that report. Full details are in the project documents for this guidance.

Benefits of the technology

Leg ulcers can be painful and ABPI assessment can be uncomfortable

3.1 A patient expert explained that leg ulcers are unpleasant and painful. There is anxiety and shame about their appearance, which can lead to depression. Manual assessment for ABPI can cause pain and discomfort. People with leg ulcers often have mobility issues, making it difficult to travel to appointments, particularly if they are in a specialist setting. They noted a potential benefit of the automated devices is a shorter ABPI assessment, which may reduce discomfort for the person being assessed. A company also noted that their product was cuffless, which may increase comfort for people having ABPI assessment. The committee acknowledged that this was plausible but noted that there is

no data available to demonstrate this. The patient expert also noted that automated devices may increase ease of carrying out the assessment in a home setting if they can be used more widely in primary and community care by staff less experienced in assessing peripheral arterial disease. This would improve access to the assessment for those less able to travel.

Waiting times for ABPI assessment can be long, which may delay appropriate treatment

3.2 A patient expert explained that it can take a long time between referral and ABPI assessment for peripheral arterial disease, which can cause anxiety, and that waiting times vary geographically. Clinical experts agreed that access to ABPI assessment varies across the UK, with people waiting between 2 weeks and 12 weeks for an appointment. The National Wound Care Strategy Programme (NWCSP) recommendations for lower limb ulcers advise applying mild compression while waiting for the full clinical assessment (including ABPI assessment) if peripheral arterial disease is not initially suspected. However, a clinical expert noted that this often does not happen in practice and that only about 25% of people with leg ulcers have mild compression before full clinical assessment. The NWCSP preventing and improving care of chronic lower limb wounds: implementation case reports that most people with leg ulcers have venous leg ulcers (about 65%). So, delays in ABPI assessment can delay starting treatment. The committee heard that one of the claimed benefits of the automated devices is improved access to ABPI assessment. This could lead to quicker treatment and healing of the leg ulcer for people without peripheral arterial disease. Clinical experts noted that the devices may be of more benefit in areas with limited availability of healthcare professionals able to do manual doppler assessment. The committee concluded that if evidence shows the automated devices lead to earlier access to treatment, then this could improve healing time and would be of substantial benefit.

Clinical effectiveness

How the automated devices fit into the care pathway is unclear

3.3 The committee discussed how the automated devices might be used in different settings or by staff with less expertise in ABPI measurement, including in primary care and the community. Clinical experts advised that if the devices could be safely used by staff with less expertise then this could improve time to assessment and therefore treatment and healing. It was noted that care pathways are evolving and that, in some parts of the country, tissue viability-led, dermatology-led or vascular service-led leg ulcer clinics are in use or are being implemented. These may increasingly do initial ABPI assessment. Clinical experts questioned whether treatment for venous leg ulcers could still be started alongside ABPI assessment if the automated devices are used in settings or by people with less expertise in ABPI measurement. The clinical experts highlighted that some treatments such as compression stockings needed less expertise but that others such as bandaging may still require a specialist to apply them. Therefore, in these cases, there may be no improvement in time to treatment even if the ABPI measurement could be done earlier. Most of the studies on using the automated devices were done in specialist settings. Clinical experts advised that this could impact the generalisability of the results to other, less-specialist settings. The committee noted that one of the studies (Green et al. 2020) identified by the external assessment group (EAG) was done in GP practices. The study reported that GPs thought that using the automated device improved clinical management of leg ulcers. However, it also reported that the GPs had concerns about whether they had time available and whether it was within their remit to assess wounds. Clinical experts commented that the number of ABPI assessments done in GP practices may vary widely and some may not do enough ABPI assessments to justify purchasing an automated device. The committee concluded that it is unclear where in the care pathway it is best to use the devices. It agreed that automated devices could have substantial benefits for people with leg ulcers. This is if they could be safely used in a wider range of settings or by a greater number of healthcare professionals, and if they lead to earlier access to treatment.

The diagnostic accuracy evidence available for automated ABPI devices is not generalisable to people with leg ulcers

3.4 The committee noted that only 2 observational studies from the 24 studies identified were in people with leg ulcers (1 study excluded marked oedema) and these did not report diagnostic accuracy data (sensitivity or specificity). The EAG extracted diagnostic accuracy data from 22 studies in people without leg ulcers, 6 of which reported results for people with diabetes. Clinical experts were concerned about the generalisability of these studies to the leg ulcer population because taking measurements in people with leg ulcers may be more difficult, particularly when they have oedema or swollen limbs. People with leg ulcers are more likely to have these complications and clinical experts advised that, in their experience, technical failure (failure of the device to produce a result) is more likely in people with oedema. They also commented that in their experience, technical failure is more likely in people with peripheral arterial disease, and this was seen in some of the studies. The committee noted that prevalence of peripheral arterial disease in the studies varied widely. Because of this, it is likely that the accuracy data in the available studies is not applicable to people with leg ulcers. There was also limited evidence of use of the devices in people with diabetes or other conditions associated with an increased risk of leg ulcers. These conditions can cause hardening of the arteries, which can make the ABPI result appear misleadingly normal. Consequently, there is considerable uncertainty about the accuracy of the test in these populations. The committee concluded that the diagnostic accuracy data on the automated devices could not be generalised to a leg ulcer population, so there is considerable uncertainty about the diagnostic accuracy of the devices in this population.

Automated devices may increase risk of inappropriate treatment in people with peripheral arterial disease

3.5 The committee discussed the accuracy of the automated devices. It commented that data suggested automated devices generally had good specificity but only moderate sensitivity for detecting peripheral arterial disease. The EAG report suggested that the automated devices tend to overestimate ABPI, which could lead to cases of peripheral arterial

disease being missed. This could mean some people have inappropriate compression, causing harm. It noted, however, that some of the differences seen between the results from the automated devices and from manual doppler may not have been clinically significant. Clinical experts further noted that NWCSP guidance states that ABPI assessment should be done by someone with expertise to recognise symptoms of and red flags for peripheral arterial disease. There was concern that these red flags could be missed if automated devices were used in settings or by staff with less expertise in assessing peripheral arterial disease. This, combined with the suggested lower sensitivity of the automated devices, could cause cases of peripheral arterial disease to be missed, leading to inappropriate treatment and harm for people with arterial leg ulcers. Clinical experts also highlighted that ABPI results may be unreliable in people with certain comorbidities, such as diabetes. It is important that other outputs such as doppler waveform are used to validate the ABPI result in these cases. Some automated devices provide additional outputs such as doppler waveforms or similar, but interpreting doppler waveforms is a specialist skill, so staff with less experience in assessing peripheral arterial disease may still misinterpret it. The EAG confirmed that accuracy data reported in the studies was based on ABPI result alone and that no studies reporting on the use of other outputs of the devices or the impact of test results on clinical decision making were identified. Therefore, no conclusions could be drawn on the impact of the use of the devices on clinical decision making, but there was concern that cases of peripheral arterial disease would be missed because of an inaccurate result. The committee concluded that future studies should look at how the test result is used to direct treatment so that the impact of false results on clinical decisions can be fully understood.

Impact of the automated devices on health outcomes is uncertain

3.6 The committee heard that no evidence looking at the impact of inaccurate test results on clinical outcomes was found. Therefore, the impact of inaccurate test results on health outcomes is uncertain. Clinical experts discussed that inappropriate compression treatment of leg ulcers in people with peripheral arterial disease could risk harm. They also noted that misdiagnosing people with peripheral arterial disease could cause unnecessary delays to the treatment of venous leg ulcers. The

committee concluded that the impact of misdiagnosis is uncertain but that consequences could be more severe for people with peripheral arterial disease. However, people with peripheral arterial disease would represent a smaller proportion of the population with leg ulcers (see section 3.2). The committee noted that it would be helpful to have further information on how incorrect results impact health outcomes, to inform decision making in the future.

Impact of the automated devices on time to treatment is uncertain

3.7 The committee discussed whether the use of automated devices in alternative settings or by staff with less specialist expertise could improve access to ABPI assessment and therefore reduce time to treatment and improve ulcer healing for some people (see section 3.2). It heard that there were no studies looking at the effect of automated devices on time to assessment or time to treatment. One study in people with leg ulcers reported that GPs felt that using the MESI ABPI MD automated device improved clinical management (Green et al. 2020). However, other studies were done in specialist settings. Clinical experts advised that the impact of the devices on time to treatment would depend on the setting and availability of expertise and that this varies widely across the country. They also noted it would depend on whether there was enough expertise in these settings to start treatment of leg ulcers in people without peripheral arterial disease more quickly (see section 3.3). The committee concluded that the devices may improve access to ABPI assessment and may therefore improve time to ulcer treatment and healing. However, no evidence was identified.

The impact of automated devices on the time taken for ABPI assessment is uncertain

3.8 The committee discussed how long the ABPI assessment takes and noted that evidence suggests automated devices can reduce the duration of the assessment. Patient experts explained that this may make assessments more comfortable for people with leg ulcers and could increase access to ABPI assessment by increasing the number of people who can be assessed. The committee heard that studies reported

that most people with leg ulcers found the automated devices acceptable, but some felt discomfort when the cuff was fully inflated. It also heard that time taken for assessments was not consistently reported across studies and generally assessments with automated devices were only a few minutes faster than manual assessments. Clinical experts questioned whether the amount of time saved was enough to have a meaningful impact. They also noted that technical failure of the automated devices could mean manual doppler would then need to be done, increasing the length of the overall assessment. One clinical expert who had used an automated device as part of an evaluation confirmed that technical failure resulted in a longer assessment time in their experience. This could occur more often in people with peripheral arterial disease, oedema, diabetes or other conditions that cause calciphylaxis in tissues (see section 3.4). However, consultation comments submitted by a large community service provider that uses automated devices suggested that they could halve the assessment time compared with manual doppler. The committee concluded that evidence suggests automated devices reduce the time taken for ABPI assessment but that the amount of time saved and the impact of this are uncertain.

Cost effectiveness

Automated devices are unlikely to be cost effective unless they reduce time to treatment

3.9 The committee noted that the economic model results suggested that automated devices were unlikely to be cost effective unless improved access to ABPI assessment and treatment could be shown (see section 3.3). No evidence was identified to suggest that automated devices may speed up access to treatment (see section 3.7). The committee concluded that there is potential for the devices to be cost effective. However, there is currently not enough evidence on whether they improve time to treatment or ulcer healing.

Economic model results are very uncertain

3.10 The committee noted that there were substantial uncertainties in the economic model because of a lack of data to inform key model inputs. The model results appeared highly sensitive to improvements in ulcer healing time for venous ulcers (because of quicker access to treatment). The impact of inaccurate test results on clinical decision making and clinical outcomes was highly uncertain because no evidence was identified to inform these inputs in the model (see section 3.6). Clinical expert opinion was used to inform these inputs in the model. The committee further noted that diagnostic accuracy estimates in the model were based on single studies for each of the devices and these studies were done in people without leg ulcers (see section 3.4). The EAG advised that it pooled data on the devices when possible but that it did not consider the results to be robust because of the differences between studies. Only 2 devices had enough studies to allow for pooling of data and this reduced the sensitivity of both devices (MESI ABPI MD and WatchBP Office ABI). It therefore opted to use single estimates in the model. The committee concluded that evidence on the impact of the automated devices on clinical decision making or clinical outcomes would improve the robustness of the economic model results. Therefore, the devices can only be recommended for use in the context of research. Consultation comments submitted by a large community service provider highlighted that automated devices are already used in practice. Clinical experts commented that they were also aware that automated devices are used in some local areas and specialist services. The committee agreed that automated devices already purchased by the NHS and implemented within a care pathway can continue to be used, only if centres using them collect data to show their impact on people with leg ulcers. This is provided that people using the automated devices are aware of the:

- limitations of the devices
- lack of evidence showing the accuracy of the devices for detecting peripheral arterial disease in people with leg ulcers
- risk of missing peripheral arterial disease if devices are not used alongside a full clinical assessment by someone with experience assessing peripheral

arterial disease.

Research considerations

Consideration of the most appropriate care pathway is needed

3.11 The committee considered that a key benefit of the automated devices could be improvements in time to treatment and healing of venous ulcers (see section 3.2). However, this could depend on how and where the devices are used in the care pathway and the availability of expertise. Clinical experts questioned whether staff with less expertise would be able to start some of the treatments such as compression bandaging for people identified as having venous leg ulcers (see section 3.3). They also raised concerns about whether less-experienced healthcare professionals would be able to perform a holistic assessment of the ulcer and recognise red flags for peripheral arterial disease (see section 3.5). The committee concluded that consideration of the most appropriate place for the automated devices in the care pathway was needed and that studies should be done in these settings.

Consideration of alternative thresholds may be helpful

3.12 The committee acknowledged that the EAG's report extracted data from some studies that looked at the optimal threshold for the automated devices. These studies reported that using an ABPI threshold higher than the commonly used value of 0.9 could improve sensitivity and therefore reduce the risk of missing peripheral arterial disease. The committee noted that it is possible that an alternative threshold may help prevent inappropriate treatment and associated consequences in some cases (see section 3.5). However, clinical experts advised that higher thresholds are not currently used in practice and they would therefore need validating in independent studies in people with leg ulcers.

4 Recommendations for further research

Diagnostic accuracy

4.1 The committee recommends more research on diagnostic accuracy in people with leg ulcers. The following considerations should be made when doing this research:

- where the devices would be used in clinical practice and by who (specialist and non-specialist users; see section 3.11)
- the most appropriate threshold for the automated measurement (see section 3.12); if an alternative threshold to the currently established threshold is being researched, then a prespecified threshold should be used and research should be done in a population not used to derive this threshold (external validation)
- whether using additional outputs from other devices such as doppler waveform and pulse volume waveform impacts clinical decision making (see section 3.5).

Time to treatment

4.2 The committee recommends collecting further data on the impact of the automated devices on time to treatment for people with leg ulcers to reduce uncertainty in the economic modelling.

Clinical outcomes

4.3 The committee recommends collecting further data on clinical outcomes such as time to healing, and incorrect use of compression and its associated adverse consequences when possible.

5 Implementation

NICE intends to develop tools, in association with relevant stakeholders, to help organisations put this guidance into practice.

In addition, NICE will support this guidance through a range of activities to promote the recommendations for further research. The research proposed will be considered for developing specific research study protocols as appropriate. NICE will also incorporate the research recommendations in section 4 into its guidance research recommendations database and highlight these recommendations to public research bodies.

6 Diagnostics advisory committee members and NICE project team

Committee members

This topic was considered by the diagnostics advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the test to be assessed. If it is considered there is a conflict of interest, the member is excluded from participating further in that assessment.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Additional specialist committee members took part in the discussions for this topic:

Specialist committee members

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Joanna Atkin
Lay specialist committee member

NICE project team

Each diagnostics assessment is assigned to a team consisting of a technical analyst (who acts as the topic lead), a technical adviser and a project manager.

Jean Isaac, YingYing Wang, Suvi Härmälä
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