


Clinimetrics of the Lanarkshire Oximetry Index for patients with leg ulcers: A systematic review and meta-analysis

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Abstract

Ankle Brachial Pressure Index (ABPI) measurement has long been considered the gold standard of vascular assessment for people with lower limb ulceration. Despite this, only around 15% of patients in the United Kingdom who require an ABPI measurement undergo the assessment. The Lanarkshire Oximetry Index (LOI) is a cheaper and arguably more accessible approach to vascular assessment and was initially proposed as an alternative to the ABPI in 2000. No synthesis of evidence related to the LOI has been performed since its introduction into the literature. Primary studies were sought to determine the clinimetric properties of the LOI and its level of agreement with ABPI assessments. Systematic searches of MEDLINE, CINAHL, Cochrane Central Register of Controlled Trials, BNI, ProQuest Health and Medicine, Science Direct, Google Scholar and the British Library (online search) were conducted. Reference lists of identified studies were also reviewed to identify additional studies. Three primary studies met the inclusion criteria, reporting data from 307 patients and 584 limbs assessed using both the LOI and ABPI. All three studies reported fair to moderate kappa values for interrater reliability ($\kappa = 0.290\text{--}0.747$) and statistically significant positive correlation coefficients ($r = 0.37$, $p < 0.001$ in two studies) between the LOI and ABPI. The combined data from the three studies indicated a sensitivity of 52% (41.78–62.1, 95% confidence interval [CI]) and specificity of 96.08% (93.4–97.9, 95% CI) for the LOI using the ABPI as a reference. Additional data are required to indicate the safety of the LOI in practice. Data are also required to determine if the LOI is more acceptable to clinicians compared to the ABPI and whether there are any barriers/enablers to its implementation in practice. Given the relatively low specificity of the LOI, it may be beneficial to combine measurement of the LOI with a subjective clinical risk assessment tool to improve the sensitivity of this alternative approach to vascular assessment.

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KEYWORDS

ABPI, diagnostics, Lanarkshire Oximetry Index, LOI, reliability

Key Messages

- **Comprehensive evaluation:** This systematic review and meta-analysis represents the first synthesis of evidence related to the Lanarkshire Oximetry Index (LOI) as an alternative to the gold standard Ankle Brachial Pressure Index (ABPI) for vascular assessment in patients with leg ulcers.
- **Promising findings:** The study reveals fair to moderate interrater reliability and a statistically significant positive correlation between the LOI and ABPI, with a sensitivity of 52% and specificity of 96.08% for the LOI, suggesting its potential as a viable alternative for vascular assessment.
- **Future research implications:** The study identifies the need for additional data to confirm the safety and acceptability of the LOI in clinical practice and proposes the combination of LOI measurement with a subjective clinical risk assessment tool to improve sensitivity and enhance patient care.

1 | INTRODUCTION

The Ankle Brachial Pressure Index (ABPI) has been the established standard for vascular assessment in individuals with lower limb ulceration.¹ While alternative methods, such as duplex ultrasound² and artificial intelligence-powered analysis of arterial doppler waveforms,³ have been explored, recent epidemiological data show limited adoption of these advanced diagnostic tools in the United Kingdom.⁴ Guest et al.⁴ found that around 25% of wounds in the United Kingdom lack a proper diagnosis, and only about 15% of patients with lower limb ulcers have documented ABPI assessments. Given that wound care is predominantly managed by nurses in the United Kingdom, they play a crucial role in improving outcomes.⁴

In 2000, Bianchi et al.⁵ proposed an alternative assessment approach, the Lanarkshire Oximetry Index (LOI), which is procedurally similar to the ABPI but utilises a pulse oximeter instead of a doppler. LOI does not require identification of specific vascular anatomy or the same level of dexterity as ABPI. This simplicity of its use has been appreciated in recent studies, as it avoids causing distress to patients and negative attitudes among nurses.⁶ Moreover, general practitioners have cited time constraints and lack of staff training as barriers to performing ABPI assessments,⁷ as reiterated in a systematic review by Cain et al.⁸

The LOI offers a cheaper and more straightforward alternative to ABPI.⁵ Additionally, with the growing trend of patients owning pulse oximeters for self-monitoring respiratory diseases,⁹ it appears to be an easy and patient-friendly approach to clinical assessment. Despite these advantages, the LOI is not currently

featured in contemporary best-practice documents or included in National Institute for Health and Care Excellence (NICE) quality standards.^{10,11}

This systematic review aims to establish whether current evidence investigating the clinimetric properties of the LOI supports its use as an alternative to the ABPI. The LOI offers a potentially cheaper, easier and more readily available approach to vascular assessment. If the LOI is a viable alternative to the ABPI assessment, it may enable nurses to provide basic vascular assessment to a larger number of patients with lower limb wounds without requiring additional equipment or skills. This has implications for treatment and healing outcomes. The LOI also represents an opportunity for improvements in vascular assessment within low-resource settings where access to more complex technologies is limited.

2 | PHYSIOLOGY OF THE LOI ASSESSMENT COMPARED TO THE ABPI

The ABPI involves measurement of the blood pressure at the upper arm and the lower limb, by auscultating the dorsalis pedis and posterior tibial artery using a doppler probe and compression of the vessel using a sphygmomanometer. The pressure measured at the ankle is then divided by the pressure at the arm to produce the ABPI value.¹² The ratio calculated as part of the ABPI assessment therefore determines if there is arterial stenosis within the arterial system between the aorta and the ankle. Crucially the ABPI uses larger arterial vessels, which may be rendered incompressible due to calcification secondary to diabetes, old age or renal disease. The

ABPI may also fail to identify patients who have developed rich collateral vascular networks.¹²

Pulse oximeters determine the oxygenation of the blood beneath their sensors. This is achieved by photodetectors that calculate the proportion of infrared light absorbed by the haemoglobin content of the blood¹³ (Bianchi, 2005). The LOI therefore relies on the occlusion of arterial vessels during compression of the vessels using a sphygmomanometer, leading to signal loss caused by hypoxemia rather than a cessation of Korotkoff sounds noted by auscultation using a doppler probe. The LOI, like the ABPI, is also susceptible to misdiagnosis due to the development of collateral vessels and calcification; however, it offers numerous benefits that are listed in Table 1. The figures generated from the LOI assessment are interpreted in the same way that ABPI values are interpreted. For example, an LOI value of 0.8 is equivalent to an ABPI value of 0.8. A full description of the LOI procedure is provided by Sardina.¹⁶

2.1 | Research question

How effective is the LOI as an alternative noninvasive test for lower limb arterial disease?

2.2 | Objectives

1. To determine the clinimetric properties (sensitivity and specificity) of the LOI compared to the current gold standard ABPI assessment.
2. To identify any barriers and enablers to the implementation of the LOI reported within existing literature.

3 | METHODS

3.1 | Eligibility criteria and screening

Literature included in the review had to be primary studies, which provided original data comparing the LOI to ABPI assessments. Studies without comparisons between these assessment methods were not included. No restrictions were included in relation to country of origin. Only English language articles that were accessible digitally were included. Duplicates were screened using EndNote Online and then the retrieved reports were manually screened using Microsoft Excel by a team of three reviewers. A date restriction was used as the LOI was initially proposed only in 2000. The search strategy was reviewed by an academic librarian prior to its implementation. The full eligibility criteria can be seen in Table 2.

All screening decisions were made via consensus of the three reviewers (MW, MS, SP). Details of the search terms using the PICO (Population, Intervention, Comparison, Outcome) model¹⁸ can be seen in Table 3. Where possible, filters were used to screen out non-primary studies, for example, by filtering out book chapters or review articles. The search was conducted in September 2022: the details of the search can be seen in the PRISMA flowchart in Figure 1.

3.2 | Information sources

MEDLINE, CINAHL, Cochrane Central Register of Controlled Trials, BNI, ProQuest Health and Medicine, Science Direct, first 10 pages of Google Scholar (the term 'Lanarkshire Oximetry Index' was searched in all fields) and the British Library (online search). Reference lists of identified studies were also reviewed to identify additional studies.

4 | SEARCH RESULTS

4.1 | Data items

Data indicating the numbers of true positives, true negatives, false positives and false negatives of the LOI were extracted from the published studies to calculate an estimate of sensitivity and specificity using a combined sample. We used 2*2 contingency tables to calculate sensitivity and specificity for each study. The calculations were performed using MedCalc Software (Version 20.218¹⁹). We used an ABPI of 0.8 as the threshold indication for peripheral arterial disease (PAD) as this is currently accepted in clinical practice.²⁰ Our estimates of sensitivity and specificity were derived directly from that threshold for each included study, and pooled estimates of sensitivity and specificity were also calculated.²¹

4.2 | Results

Three studies meeting the review criteria were identified: Bianchi et al.,⁵ Bianchi et al.¹⁷ and Papanas et al.²² Of these, one study was conducted in Greece,²² while the other two were carried out in the United Kingdom (Scotland). All three studies were quantitative in design. Two studies mentioned seeking ethical approval, and one study declared adherence to the Helsinki Declaration of Human Rights (2008) and obtaining informed consent.²²

The study characteristics are summarised in Table 4. The studies involved a total of 307 patients and 584 limbs, all assessed using LOI within clinic settings (two in leg

TABLE 1 Potential benefits and limitations of the Lanarkshire Oximetry Index.

| Benefits | Limitations |
|---|---|
| Pulse oximeters are cheaper than doppler probes required for the ABPI ^{14,15} | May have lower diagnostic accuracy in patients with calcified arteries or well-developed collateral circulation (as per ABPI) ¹⁶ |
| Requires less manual dexterity to perform ⁵ | May not work in patients with grossly dystrophic toenails or peripheral vasoconstriction (e.g., Raynaud's disease) ¹⁶ |
| Requires no knowledge of peripheral vascular anatomy to perform (i.e., identification of the posterior tibial or dorsalis pedis vessels) as this is not required knowledge to perform the procedure ¹⁶ | |
| May be faster to perform ¹⁴ | |
| Can be used in patients with gross oedema where ABPI is not possible ¹⁷ | |

Abbreviation: ABPI, Ankle Brachial Pressure Index.

ulcer/dermatology clinics and one in a diabetic foot clinic). However, only one study clearly described the inclusion criteria for participants.¹⁷ The participants in the studies had conditions such as open ulcers, venous dermatitis and type 2 diabetes. The age of participants ranged from 32 to 94, and the majority were female ($n = 76$, 71%, and $n = 90$, 56%, respectively) in the studies reporting demographic data.^{17,22}

In all three studies, Nellcor Puritan Bennett pulse oximetry devices were used. The positioning of participants on couches in preparation for ABPI and LOI varied across the studies. One study reported positioning the upper body at 40° to the horizontal,⁵ another used a semi-recumbent position¹⁷ and one did not specify positioning.²² Acclimatisation to room temperature (25°C) and a 10-min rest period were reported in the Papanas et al.²² study only. Waiting time between conducting the two tests was not described, but all studies reported on the study procedures. The ABPI was conducted following standard procedure, and instances where LOI or ABPI measurements could not be recorded were noted across the studies. Two studies also monitored the change in ulcerated areas (rate of healing) and time to healing within subjects.^{5,17}

4.3 | Study risk of bias assessment

A risk of bias assessment was conducted using the Quality Assessment of Diagnostic Accuracy Studies

TABLE 2 Eligibility criteria.

| Inclusion | Exclusion |
|---|--|
| Studies providing comparative data showing the sensitivity and specificity of the Lanarkshire Oximetry Index (LOI) compared to the Ankle Brachial Pressure Index (ABPI) | Articles which do not provide original data on the diagnostic performance of the LOI |
| Primary studies | Secondary studies |
| Published in English | Not published in English |
| Peer reviewed | Non-peer reviewed reports |
| Articles published between 2000 and 2022 (LOI first proposed in 2000) | Articles published before 2000 |

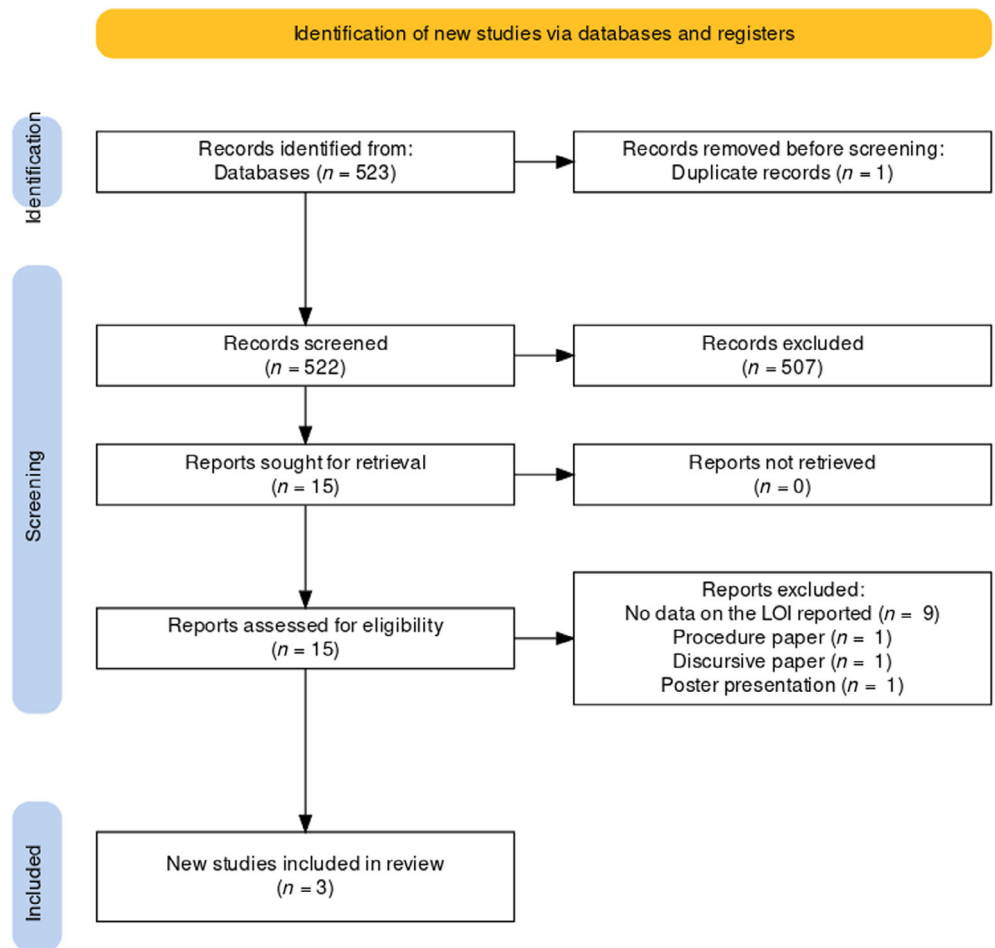
TABLE 3 Search strategy.

| | |
|--|---|
| Population—patients with leg ulcers/requiring assessment for peripheral arterial disease (PAD) | Ulcer OR vascular OR wound OR VLU OR MeSH descriptor [Leg ulcer] |
| Intervention—Lanarkshire Oximetry Index | Lanarkshire Oximetry Index OR LOI OR pulse oximetry index |
| Comparison—Ankle brachial pressure index | Ankle brachial pressure index OR ABPI |
| Outcome—Sensitivity/specificity/agreement | Sensitivity OR specificity OR reliab* OR accuracy OR validity OR precision OR agreement |
| Combined search statement (searched in all fields) | (Ulcer OR vascular OR wound OR VLU) AND (Lanarkshire Oximetry Index OR LOI OR pulse oximetry index) AND (Ankle brachial pressure index OR ABPI) AND (Sensitivity OR specificity OR reliab* OR accuracy OR validity OR precision OR agreement) |

2 (QUADAS-2) tool described by Whiting et al.²³ The tool was designed for the evaluation of diagnostic accuracy studies and is therefore appropriate for this review. It is currently used by the Cochrane Collaboration for reviews of diagnostic accuracy studies. QUADAS considers four domains: patient selection, index test, reference standard and flow and timing. Each domain is assessed for any risks of bias introduced by the methodology and for the studies applicability to the review question.

Within this review, all studies were reviewed by two reviewers (MW and SP) and any disagreements were

FIGURE 1 PRISMA flowchart.



discussed with a third reviewer (MS) to reach consensus. A summary of the risk of bias assessment can be seen in Table 5. The table shows the application of the QUADAS-2 tool to analyse the risk of bias within the studies included in the review. Four domains (patient selection, index test, reference standard and flow and timing) are assessed to determine the overall risk of bias with three additional domains (patient selection, index test and reference standard) considered to determine the applicability of results to the target population of our review, in this case, patients requiring screening for PAD prior to compression therapy.

Patient selection is reviewed to ensure that there is no systematic selection bias. Within our included studies we considered there to be a low risk of bias within the Bianchi et al.¹⁷ study. However, the Bianchi et al.⁵ study was considered to have a high risk of bias due to it being unclear whether consecutive or random sampling had been undertaken. It was also unclear if there were inappropriate exclusions within the sample. The risk of bias in relation to patient selection within the Papanas et al.²² study was considered unclear as it was not reported within this study if exclusions had occurred and whether these were appropriate.

The risk of bias introduced by the index test was considered low in all included studies. All studies utilised the ABPI as a reference standard. Although this is not considered an absolute gold standard for the assessment of vascular disease, it is currently the gold standard for clinical assessment of patients with leg ulcer to screen for PAD,¹² and features in the National Wound Care Strategies essential assessment criteria for lower limb assessment.²⁴

The risk of bias introduced by the reference standard was considered low in the Bianchi et al.¹⁷ study and the Papanas et al.²² study but unclear in the Bianchi et al.⁵ study. This was due to the time between assessments using the LOI/ABPI not being reported within the study. The Bianchi et al.⁵ study also had an unclear risk of bias in relation to flow and timing due to it being unclear whether all patients were included in the final analysis.

There were no applicability concerns (i.e., do the included patients match the review question) identified within the studies included in the review. All studies were conducted within leg ulcer clinic settings and are likely demographically consistent with the target population who would require an ABPI/LOI assessment.

TABLE 4 Summary of studies.

| Study | Number of participants | Participant demographics | Setting | Pulse oximetry device used | Correlation of LOI with ABPI |
|------------------------------|--------------------------|---|----------------------|-------------------------------------|---|
| Bianchi et al. ⁵ | 39 patients 77 legs | Not described | Leg ulcer clinic | Nellcor Puritan Bennet NPD-95 | Fair agreement; (weighted $\kappa = 0.39$) No correlation co-efficient reported |
| Bianchi et al. ¹⁷ | 107 patients 195 legs | 76 (71%) female Mean age 72 (range 32–94) 73 (68%) had open ulcers Venous dermatitis—34 Diabetic patients—22 | Leg ulcer clinic | Nellcor Puritan Bennett, NPB-295 | Fair agreement ($\kappa = 0.303$) Significant positive correlation between LOI and ABPI ($r = 0.37$, $p < 0.001$) |
| Papanas et al. ²² | 161 patients 322 legs | 90 (56%) female Mean age 63 (range 53–73) Diabetic patients—161 | Diabetic foot clinic | Nellcor Puritan Bennett, NPB-295 | Moderate agreement ($\kappa = 0.569$) with medial arterial calcification defined as ABPI > 1.2 ($\kappa = 0.747$) Significant positive correlation between LOI and ABPI ($r = 0.37$, $p < 0.001$) |

Abbreviations: ABPI, Ankle Brachial Pressure Index; LOI, Lanarkshire Oximetry Index.

4.4 | Limitations of the included studies

Despite all three studies reporting that the LOI is a viable and cheaper alternative to the ABPI for assessing patients for PAD, the data collected were limited. The researchers did not examine costs between the two methods, which could have included cost of equipment, cost of training staff to become competent in the skill of ABPI and LOI and the time it takes to conduct each test. These outcomes should be examined in future studies. The researchers also did not collect feedback from nursing staff who conducted the ABPI and LOI, nor the participants tested on, to compare ease of use, acceptability and usability of the two methods. Two of the manuscripts were pilot studies and were not powered, which limits the assessment of treatment effect.²⁵ The third study was conducted to provide additional safety data and as an open prospective trial: bias may have been introduced by conducting measurement of ABPI and LOI on each participant by the same person prior to diagnosis and treatment selection.

4.5 | Agreement between ABPI and LOI

All the included studies reported Kappa statistics to determine interrater reliability between the LOI and the ABPI. Two studies, Bianchi et al.¹⁷ and Papanas et al.,²² also included simple correlation statistics that both showed significant positive correlation between the LOI and ABPI ($r = 0.37$, $p < 0.001$ in both studies). Calculation of Kappa statistics is a widely used approach to

determine agreement between measures.²⁶ However, due to the limitations of Kappa, particularly its sensitivity to distribution of marginal totals, it is important to note that the Kappa statistic should not be relied upon independently of both interpretation of the specific context, and ideally, other forms of correlation analysis.²⁷ Within the included studies the Kappa statistics reported varied from 0.29⁵ to 0.747.²² Typically, $\kappa < 0.2$ is considered poor agreement and $\kappa > 0.61$ is considered to show good agreement.²⁷ This indicates that the studies in this review showed a spread of fair to good agreement based on reported Kappa values and significant positive correlation based on the correlation coefficients.

4.6 | Sensitivity and specificity

The ability of a tool to identify true positive assessments is known as sensitivity, and the consistency with which it identifies true negatives is its specificity.²⁸ Determining the sensitivity and specificity of a tool depends on a definitive clinical outcome to determine whether the assessment outcome was correct.²⁹ For example, in this case it would require data to indicate whether PAD was or was not present within the leg (e.g., via angiography or using an ABPI ratio). This would need to be compared to whether the LOI identified PAD as being present or absent, which would allow the sensitivity and specificity of the LOI to be determined.

Data were extracted from each study to generate 2*2 contingency tables to calculate sensitivity and specificity

TABLE 5 Quality Assessment of Diagnostic Accuracy Studies-2 analysis indicating risk of bias.

| Study | Risk of bias | | | | Applicability concerns | | |
|------------------------------|-------------------|------------|--------------------|-----------------|------------------------|------------|--------------------|
| | Patient Selection | Index test | Reference Standard | Flow and Timing | Patient Selection | Index test | Reference Standard |
| Papanas et al. ²¹ | ? | ☺ | ☺ | ☺ | ☺ | ☺ | ☺ |
| Bianchi et al. ¹⁶ | ☺ | ☺ | ☺ | ☺ | ☺ | ☺ | ☺ |
| Bianchi et al. ⁸ | ☹ | ☺ | ? | ? | ☺ | ☺ | ☺ |

☺ Low risk ☹ High risk ? Unclear risk

estimates from each of the three studies. The individual and pooled sensitivity and specificity results of these calculations can be seen in Figures 2 and 3.

Figures 2 and 3 indicate that while the specificity of the LOI is good, the sensitivity shows wide variation, and the estimates calculated using combined data from the three studies included in the review shows a relatively poor sensitivity of 52%. This indicates that that LOI is more likely to miss a case of PAD than to incorrectly identify a patient as having PAD.

4.7 | Barriers and enablers to implementation

No barriers or enablers to the implementation of the LOI were reported within the retrieved studies. The studies also did not assess ease of use of the LOI. There is currently no evidence that the LOI has been successfully implemented or that it is being used routinely in clinical practice based on the studies included in this review.

5 | DISCUSSION

This study represents the first synthesis of evidence concerning the use of pulse oximeters as an alternative to doppler-based pressure ratios for screening patients for PAD.

The current evidence demonstrates that the ABPI can be safely and effectively replaced by the LOI as a screening tool for PAD. Crucially, the data indicates a significant agreement between ABPI and LOI methods for PAD screening. In the studies analysed, no adverse events were reported in association with the use of LOI to assess patients. While one study reported a single case of

misdiagnosis,²² it is important to note that ABPI, despite being the recommended first-line assessment modality for PAD, is not infallible.¹⁷

Although angiography is considered the ideal standard for assessing vascular disease, it is not practical as a routine screening modality for patients with leg ulcers and PAD. The ongoing lack of timely assessment using ABPI for patients who require it highlights the need for alternative approaches to PAD screening. Further research, ideally using angiography as a comparison, is required to explore alternative assessment methods such as LOI. It is plausible that LOI could outperform ABPI in sensitivity and specificity for PAD screening if a more invasive reference like angiography were employed.

The evidence from this review suggests that the application of compression therapy based on LOI values did not result in ischemia.^{5,17} In cases where an ABPI measurement was unattainable due to gross edema, LOI values were still obtainable, making LOI more clinically pragmatic.¹⁷ Additionally, clinical outcomes reported in the studies do not support the idea that LOI increases risks to patients receiving inappropriate compression therapy or that severe cases of PAD may be missed, despite lower sensitivity estimates compared to ABPI. It is vital to consider a holistic assessment of patients with leg ulcers, using ratios such as ABPI/LOI as just one component.⁸ LOI findings should be interpreted in conjunction with other clinical vascular assessment methods.

The benefits of timely access to compression therapy, which promotes wound healing,³⁰ outweigh the potential risks of misdiagnosis of PAD when using LOI, especially considering the current low rate of ABPI assessments in the United Kingdom.⁴ Integrating a subjective clinical risk assessment tool that combines risk scores with LOI measurements might enhance the overall sensitivity of LOI and obviate the need for the costly and complex

Sensitivity of the LOI with 95% upper and lower confidence intervals

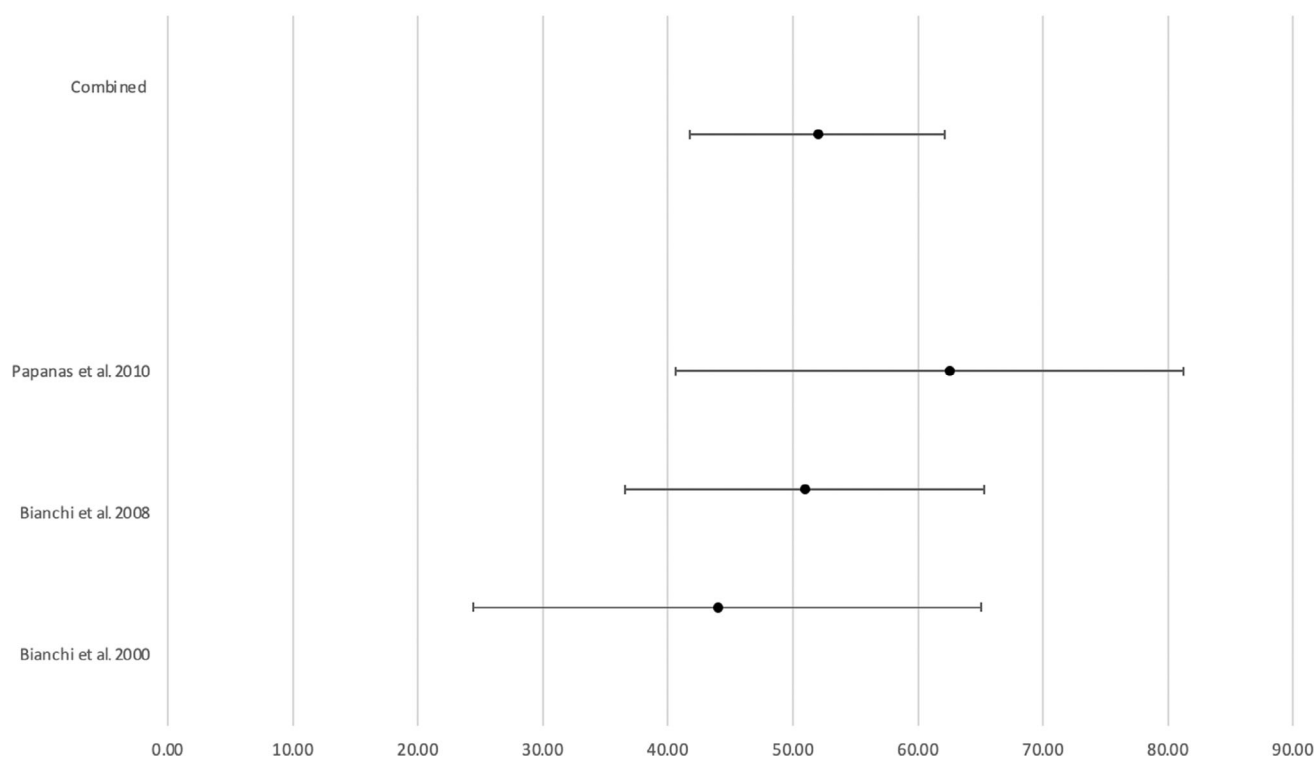


FIGURE 2 Sensitivity of the Lanarkshire Oximetry Index with 95% upper and lower confidence intervals.

ABPI assessment. However, such a risk assessment tool would require development and validation in combination with LOI to assess its feasibility.

For clinicians working with patients with leg ulcers, LOI can serve as a safe and accessible assessment tool when doppler equipment or ABPI expertise is lacking. The evidence supports the use of LOI to improve access to compression therapy for patients who would benefit from it. However, given the limitations of current research, clinicians should collect additional data to augment our understanding of LOI's efficacy and safety in identifying patients with PAD. Clinimetric studies aimed at establishing the sensitivity and specificity of LOI using the established cutoff value of 0.9 should be conducted. Moreover, the development of a clinical risk assessment tool to be used alongside LOI could potentially enhance its sensitivity and reduce the risk of missed PAD cases.

According to a study by Blanchfield¹⁴ involving a survey of 80 nurses who look after patients with leg ulcers. The LOI offers improved perceptions of accessibility and ease of use compared to the ABPI. Being a noninvasive procedure using a pulse oximeter, the LOI eliminated the need for the client to lay flat for an extended period, making it more convenient for patients with mobility issues. Additionally, the LOI provides a quick and

straightforward assessment of blood flow, with simple interpretation through pulse waveforms or light indicators. Its applicability during compression bandaging ensures continuous monitoring of arterial blood flow, and its lower cost and reduced need for specialised skills make it an accessible option for a broader range of healthcare practitioners.¹⁴

To move the field forward, future research should include cost-effectiveness analyses (CEA) comparing the costs and effects of these alternative interventions and investigating the barriers and enablers to their implementation. While studies employing angiography as a reference would be desirable, the practicality of such an approach may be challenging. Therefore, clinicians and researchers should prioritise conducting thorough clinimetric studies to further validate LOI's potential as a reliable screening tool for PAD.

5.1 | Limitations

Due to the ABPI not being a gold standard assessment method for vascular disease, agreement between the ABPI and LOI has been considered as a proxy to determine the diagnostic value of the LOI. Only studies

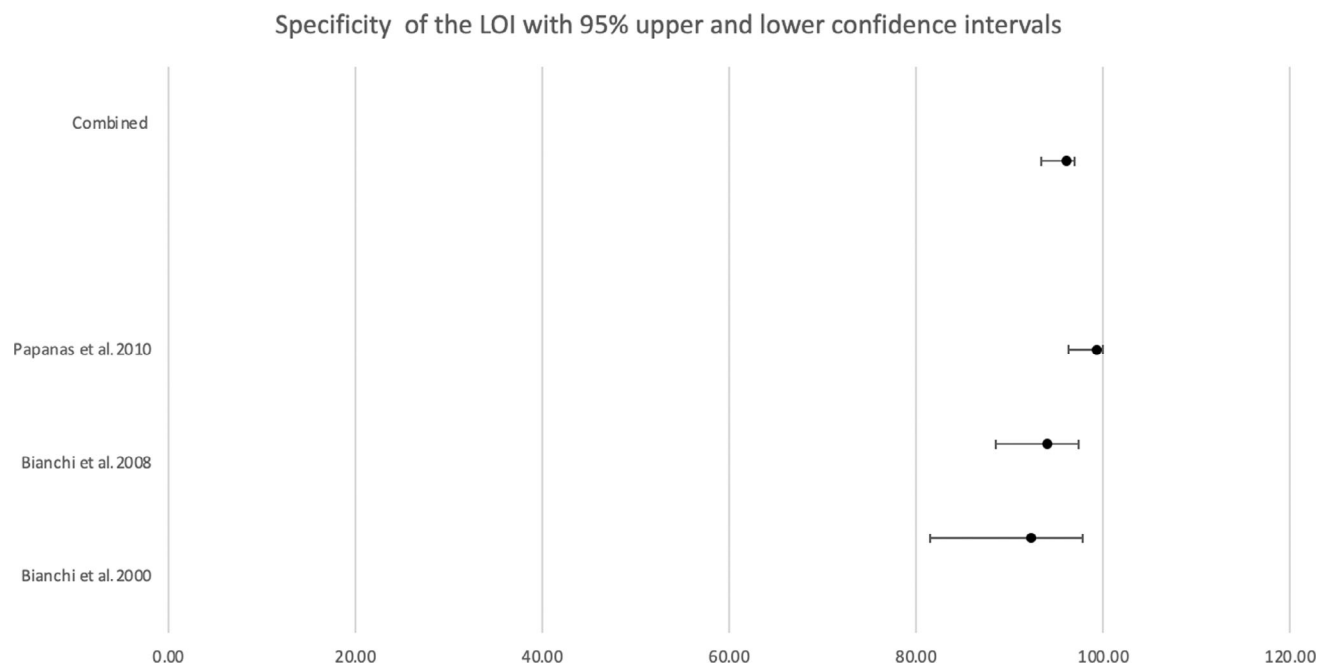


FIGURE 3 Specificity of the Lanarkshire Oximetry Index with 95% upper and lower confidence intervals.

conducted in clinic settings are currently available; as such, it is not clear if the findings of this study are generalisable to the patient/clinician population outside of this context.

Separate pooled estimates of sensitivity and specificity were calculated: this is recommended as part of a meta-analysis of diagnostic accuracy studies.^{21,31} Simple pooled analyses for both sensitivity and specificity do not take into account the potential threshold effect or heterogeneity of the included studies; however, the three studies included in this review all used the same threshold indication for PAD. Bivariate models and hierarchical summary receiver operator characteristic models, which take account for heterogeneity and correlation between sensitivity and specificity within each of the included studies, could not be carried out as part of this review as only three studies were included: a minimum of four studies is recommended to carry out these analyses.³²

5.2 | Conclusion

The purpose of this systematic review was to examine how effective the LOI is as an alternative noninvasive test for lower limb arterial disease. Three studies were found, reporting data from 307 patients and 584 limbs assessed using the LOI and ABPI. The findings indicated that the LOI shows fair to high levels of agreement with the ABPI (κ 0.29–0.747) and showed a statistically significant, positive correlation coefficient ($r = 0.37$, $p < 0.001$ in two

studies). The combined data from the three studies indicated a sensitivity of 52% (41.78–62.1, 95% confidence interval [CI]) and specificity of 96.08% (93.4–97.9, 95% CI) for the LOI using the ABPI as a reference. No adverse clinical outcomes were reported as a result of the use of the LOI. The LOI was reportedly usable in cases where ABPI assessments were not possible due to gross oedema making assessment with a doppler impossible.

The evidence indicates that the LOI is a viable alternative to the ABPI. However, additional data are required to indicate its sensitivity and specificity, ideally using angiography as an index although the ABPI may be a more pragmatic index. Data are also required to determine if the LOI is more acceptable to clinicians and patients compared to the ABPI and if there are any barriers/enablers to its implementation in practice. Improvements in the sensitivity of the LOI may be achieved via the use of a clinical risk assessment tool used alongside the LOI measurement to ensure that cases of PAD are not missed.

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CONFLICT OF INTEREST STATEMENT

One member of the research team JB was an investigator in two of the reviewed papers. However, this individual

did not participate in quality appraisal of the included studies so the risk of bias was mitigated.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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