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Review Article

The effectiveness of NIRS technology to the early diagnosis of lower limb ischemia in patients on peripheral VA ECMO: A systematic review and *meta*-analysis

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ABSTRACT

Background: Acute lower limb ischemia is a major complication of peripheral venoarterial ECMO, significantly impacting patient outcomes and survival rates. Traditional methods for assessing limb perfusion, such as physical exams and Doppler ultrasound, are often unreliable and do not provide continuous monitoring. Near-infrared spectroscopy (NIRS), a non-invasive technique, shows promise for perfusion monitoring in venoarterial ECMO patients, but its effectiveness in the early detection of limb hypoperfusion remains unreviewed.
Aim: Evaluate the effectiveness of NIRS technology in the early diagnosis of lower limb ischemia in patients undergoing peripheral VA ECMO.
Methods: The search strategy covered five databases. Inclusion criteria included studies in Portuguese, English, Spanish, or German involving participants aged 18 or older dependent on peripheral VA ECMO. The intervention assessed was limb perfusion monitoring using NIRS in VA ECMO patients. The primary outcome was the effectiveness of NIRS in the early diagnosis of limb ischemia. Exclusion criteria included review articles, book chapters, books, editorials, conference papers, and studies on pediatric patients, central VA ECMO, or venovenous ECMO. Study quality was evaluated using the ROBINS-I tool. Meta-analysis was performed using R package meta. Narrative synthesis was applied when *meta*-analysis was unfeasible.
Results: Of 180 studies, 164 were excluded after initial screening. Of the remaining 16 studies, eight were removed for irrelevance, high bias risk, or pediatric focus, leaving eight studies. The results revealed a pooled sensitivity of the diagnostic method of 0.71 (95% CI: [0.67, 0.74]) and a pooled specificity of 0.68 (95% CI: [0.61, 0.74]).
Conclusions: NIRS technology is an effective diagnostic tool for reliably detecting true positive cases of limb ischemia.
Implications for Clinical Practice: The decrease in NIRS values and the difference between limbs may indicate hypoperfusion, requiring further investigation. NIRS also helps assess distal perfusion catheter functionality, enhancing our ability to provide safe, high-quality care.

Introduction

Extracorporeal membrane oxygenation (ECMO) in the venoarterial modality (VA) provides critical support to patients for periods ranging from days to weeks. It is often described as a “bridge to decision,” encompassing various clinical scenarios. These include facilitating

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weaning after myocardial function recovery, preparing for heart transplantation, enabling long-term mechanical circulatory support, or, in cases deemed futile, respectfully withdrawing support [1].

To maximize its benefits, VA ECMO is recommended for consideration within six hours of cardiogenic shock onset, particularly when conventional pharmacological treatments and fluid therapy fail to restore stability. It is also indicated for patients experiencing reversible cardiocirculatory collapse or those eligible for alternative forms of support, such as ventricular assist devices or heart transplantation [2]. Additionally, extracorporeal cardiopulmonary resuscitation (ECPR) is increasingly used as a rescue strategy for patients with refractory cardiac arrest and is also considered an indication for VA ECMO [3].

Among the different VA ECMO approaches, peripheral VA ECMO is widely used due to its rapid deployment and accessibility. In adults, femoral artery cannulation is often preferred. However, despite its life-saving potential, peripheral VA ECMO is associated with significant vascular complications, particularly acute lower limb ischemia, which occurs in over 16 % of patients, substantially increases morbidity and mortality [4]. A 2023 study by Krasivskyi reported limb ischemia in 18,3 % of cases, reinforcing the importance of addressing this complication [5].

Acute lower limb ischemia remains one of the most serious complications of peripheral VA ECMO, with severe consequences for patient outcomes and survival rates [6]. It is associated with prolonged length of stay, increased morbidity, and higher in-hospital mortality [7]. Beyond these risks, limb ischemia can escalate to critical complications, such as fasciotomy or compartment syndrome (10.3 % of cases), limb amputation (4.7 %) and even death [4], further underscoring the need for early recognition and intervention.

The pathophysiology of limb ischemia in peripheral VA ECMO is multifactorial. The most common cause is insufficient blood flow to the cannulated limb, often resulting from partial or complete occlusion of the femoral artery by the arterial cannula. Other contributing factors include high doses of vasoactive drugs, pre-existing peripheral vascular disease, and activation of the coagulation cascade, all of which increase the risk of ischemic complications [8]. If not promptly addressed, these factors can lead to limb amputation and, in the most severe cases, patient mortality. Consequently, early diagnosis and intervention are critical to improving outcomes and remains a key focus within the scientific community [9].

To mitigate the risk of ischemic complications, the insertion of a distal perfusion cannula (DPC) is a widely recommended strategy. Distal perfusion cannulas restore blood flow beyond the cannulated femoral artery, reducing the risk of ipsilateral limb ischemia [10]. A systematic review and *meta*-analysis by Juo et al. found that patients with DPC experienced an absolute reduction in ischemic limb complications of more than 15 % [11], highlighting the effectiveness of this approach in preventing lower limb ischemia.

Despite preventive measures, effective monitoring of lower limb perfusion remains essential. The traditional methods, such as physical examination and Doppler ultrasound, have significant limitations. Peripheral pulses may be difficult to palpate due to non-pulsatile blood flow from the extracorporeal circuit or vasoconstriction induced by vasopressor therapy. Moreover, neither method allows for continuous perfusion monitoring, increasing the risk of underdiagnosing limb hypoperfusion. Nevertheless, frequent limb assessment remains critical, with clinicians looking for early signs of ischemia, such as pallor, skin color changes, temperature alterations, and mottling [12].

Given the severe consequences of undetected ischemia, early and accurate monitoring of limb perfusion is paramount. Delayed recognition can lead to compartment syndrome, requiring fasciotomy and, in severe cases, limb amputation. These complications not only impact functional outcomes but also significantly affect patient survival [9]. Therefore, improving monitoring strategies and ensuring timely intervention remains essential priorities in ECMO management.

Near-infrared spectroscopy (NIRS) is a non-invasive technology that enables continuous monitoring of regional tissue oxygenation. Similar to pulse oximetry, NIRS operates based on the principle of light absorption and scattering within the near-infrared range (600–1000 nm). Initially developed for cerebral oxygenation monitoring—particularly in congenital cardiac surgery due to its proven accuracy—NIRS has since expanded its applications across multiple medical fields. These include non-cardiac surgeries, electrophysiological procedures, and intensive care settings, where it has demonstrated significant clinical utility [13,14]. Beyond its original role in brain oxygenation assessment, NIRS has evolved into a valuable tool for evaluating systemic and cerebral microcirculation. It is now widely employed to monitor local tissue and muscle oxygenation, as well as perfusion, providing clinicians with critical insights into patients with circulatory impairment [15]. Given its ability to detect real-time changes in tissue oxygenation, NIRS has gained interest as a potential tool for monitoring lower limb perfusion in patients undergoing peripheral VA ECMO.

Despite promising preliminary data, research on the use of NIRS for lower limb perfusion monitoring in peripheral VA ECMO remains limited. While some studies have explored its potential, no systematic review has yet been conducted to evaluate its effectiveness in the early detection of limb hypoperfusion – a crucial factor in preventing lower limb ischemia. Thus, the objective of this review was to evaluate the effectiveness of NIRS technology in the early diagnosis of lower limb ischemia in patients undergoing peripheral VA ECMO. Specifically, this review seeks to address the following research question: How effective is NIRS technology in the early detection of lower limb ischemia in patients on peripheral VA ECMO?

Methods

This Systematic Review was developed according to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) checklist [16]**.** The search strategy was conducted on February, 18, 2024, with no timeframe restrictions to ensure the comprehensive identification of all potentially relevant studies. Imposing temporal limitations could have inadvertently excluded important research, particularly since NIRS applications in VA ECMO constitute a relatively recent and emerging field. Moreover, at the time of the search, no systematic review on the topic had been conducted, and restricting the search to a specific period could have further hindered the identification of relevant studies. The protocol was registered on PROSPERO on March 27, 2024 (PROSPERO: CRD42024529475).

Search strategy

To ensure inclusion of all appropriate studies we used a combination of Medical Subject Heading (MeSH) and free text words. Search terms are listed in a supplementary material Table 1. Searches were performed in five databases, CINAHL via EBSCO, MEDLINE via PubMed, Scopus, Web of Science and Cochrane library.

Selection of studies

In order to conduct the research process, the PRISMA diagram was designed. Inclusion criteria were based on the PICO mnemonic (Population, Intervention, Comparator and Outcome). Published studies in Portuguese, English, Spanish and German were considered in the review process. We included studies involving participants aged 18 years or older, regardless the sex, race, social and/or clinical status and participants dependent on peripheral VA ECMO. The intervention in study was monitoring limb perfusion with near-infrared spectroscopy in patients on VA ECMO with or without comparator. The outcome of interest involved the effectiveness of near-infrared spectroscopy (NIRS) technology in the early diagnosis of limb ischemia. Either observational or experimental studies were eligible for inclusion, but review articles, book chapters, books, editorial articles and conference papers were

Table 1
Study characteristics.

Study Reference	Country	Clinical Setting	Aim	Ascertainment dates	Study			Population	NIRS target values	Outcomes
					Design	Comparator	Sample size, n			
Kim et al., 2017 (20)	South Korea	No information	Investigate the effectiveness of NIRS monitoring for the early detection of limb ischemia in patients who were placed on VA-ECMO via femoral artery.	July 2012 – July 2013 (control group) August 2013 – August 2014 (NIRS group)	Retrospective cohort Prospective Single Center	Yes: No NIRS monitoring	64 Comparator = 36 NIRS = 28	Comparator: Mean age:59,5 ± 17,1 Female: 9 Male: 27 ECMO duration (hours): 124,6 ± 90,7 NIRS Mean age: 56,3 ± 19,2 Female: 16 Male: 12 ECMO duration (hours): 113,7 ± 70.6	Absolute NIRS value < 40 %	No patient in the NIRS group underwent fasciotomy because of the development of compartment syndrome, while 13.9 % did in the control group, and the difference was statistically significant. Without NIRS monitoring, it may be difficult to make sure that reperfusion is successful even after prophylactic distal perfusion. NIRS monitoring is a useful and reliable method for the early detection of lower limb ischemia in patients undergoing peripheral VA-ECMO
Patton-Riviera et al., 2018 (24)	USA	Intensive care Unit	Evaluate the usefulness of non-invasive lower-limb oximetry, using NIRS to detect limb ischemia.	June 2016 – January 2017	Retrospective cohort Single Center	No	25	Mean age: 55 ± 13 (22–78) Female: 12 Male: 13 Days on ECMO: 9 ± 13 Primary indication: cardiogenic shock	Less than 50 % for more than 4 min; Difference between the two limbs > 15 %	Continuous NIRS monitoring can increase the confidence of bedside support staff to care for ECMO patients and identify distal-limb hypoperfusion. Advancements in NIRS technology seem to have improved its accuracy for continuous, non-invasive monitoring of regional tissue and may provide clinicians with an additional metric to protect the distal portion of the cannulated leg
Vinogradsky et al., 2023 (21)	USA	Cannulation was performed by the cardiothoracic surgery team	Evaluate the effect of using continuous noninvasive lower limb oximetry with NIRS to detect tissue hypoxia and guide distal perfusion catheter (DPC) placement on the rates of leg ischemia requiring surgical intervention	January 2010 – December 2021: January 2013——2014 pre NIRS era 2017——2021 NIRS era	Retrospective cohort Single Center	Yes: No NIRS monitoring	490 Comparator = 141 NIRS = 349	Comparator: Mean age: 60 (47–66) Male: 100 Female: 41 Days on ECMO: 3,25 Primary indication: acute myocardial infarction NIRS: Mean age: 60 (49–68) Male: 241 Female: 108 Days on ECMO:	Absolute NIRS value < 50 %; Difference between the two limbs > 15 %	The patients in the NIRS cohort had a significantly lower incidence of surgical intervention for limb ischemia. No patient has required amputation since the introduction of NIRS monitoring. The use of NIRS to guide DPC placement in patients receiving femoral VA-ECLS was associated with a significant, threefold reduction in the incidence of leg ischemia requiring surgical intervention compared with selective DPC insertion based on clinical

(*continued on next page*)

Table 1 (*continued*)

Study Reference	Country	Clinical Setting	Aim	Ascertainment dates	Study			Population	NIRS target values	Outcomes
					Design	Comparator	Sample size, n			
								5 Primary indication: acute myocardial infarction		signs. Application of continuous NIRS monitoring for patients receiving femoral VA-ECLS might help increase the detection of limb hypoperfusion events and allow for the timely initiation of salvage therapies.
Vranken et al., 2020 (25)	Netherlands	Intensive care unit	Assess the efficacy of cerebral and limb tissue oximetry during VA ECLS	No information	Retrospective cohort Single Center	No	23	Mean age: 59 ± 13 Female: 18 Male: 5 Days on ECMO (median duration): 5 Primary indication: ECPR	No information	Tissue oximetry aids in early recognition of compromised limb perfusion and contributes to timely intervention by identifying the need for an additional distal cannula. Non-invasive tissue oximetry is a viable monitoring method for assessing distal limb tissue perfusion in patients assisted by ECLS and should therefore be part of routine monitoring.
Son et al., 2021 (22)	USA	Patients were cared for by ECMO-specialized nursing staff, an-esthesia intensive care, and cardiac surgery.	Report the institutional experience about monitoring femoral VA-ECMO patients with serial ankle-brachial-index (ABI) and the relationships between ABI and NIRS.	January 2019 – October 2019	Retrospective cohort. Single center	Yes: ankle-brachial index monitoring	22	Mean age: 56.5 ± 14.0 Male: 16 Female: 6 Hours on ECMO: 128,8 ± 78,3 Primary indication: cardiac arrest or cardiogenic shock	They do not provide information about target values.	Four patients had clinically significant events identified by clinical exam and ABI without correlated changes in NIRS. Absolute oximetry StO2 values can be falsely reassuring and not sensitive enough to ischemic events with one group raising caution on the overreliance on NIRS oximetry.
Fisser et al., 2022 (23)	Germany	No information	Investigate the prevalence of arterial and venous complications in patients requiring peripheral VA ECMO and its risk factors at the time of cannulation and during ECMO support and to assess vascular complications in association with decannulation.	January 2010 – January 2020	Retrospective cohort Single Center	No	427	Median age: 59 (50–68) Male: 73 %; Female: 27 %; SOFA score: 14 Days on ECMO in ischemia group (median): 4 Days on ECMO in no ischemia (median): 4 Primary indication: ECPR	Absolute NIRS value < 40 %; Difference between the two limbs > 25 %;	Vascular surgery was performed in 19 % (82/427) of patients, of whom 1 % (4/427) required major amputation. Limb ischemia occurred in 25 % of the patients and was associated with mortality.
Wong et al., 2012 (26)	USA	Surgical Cardiac care Unit	Prove that the use of NIRS with ECMO is important in detecting ischemic cerebral	July 2010 – June 2011	Retrospective cohort. Single Center	No	20 VA: 17	Median age: 48 (17 – 74) Female: 9 Male: 11	Absolute NIRS value < 40 %; Drop in NIRS value more	Six patients (35 %) had a clinically significant drop in unilateral lower limb tracings. Four of this patients (67 %)

(*continued on next page*)

Table 1 (*continued*)

Study Reference	Country	Clinical Setting	Aim	Ascertainment dates	Study			Population	NIRS target values	Outcomes
					Design	Comparator	Sample size, n			
			and peripheral vascular events.					Days on ECMO (median): 7 Primary indication: cardiac arrest or cardiogenic shock	than 25 % from baseline;	required lower limb two-compartment fasciotomies for prophylaxis against compartment syndrome. Near-infrared spectroscopy technology is a useful and highly applicable monitoring parameter that not only provides us with important bedside "point of care" information, but also serves as a new "vital sign" that has improved the quality of care and outcomes of critically ill ECMO patients.
Lamb et al., 2017 (27)	USA	No information	Evaluates a protocol (that includes placement of DPC) designed to address the problem of limb ischemia in patients placed on ECMO	July 2010 – January 2015	Retrospective cohort. Single center	No	91	Mean age: 50 (21—–78) Male: 62 Female: 29 Days on ECMO: 10 Primary indication: cardiogenic shock	Absolute NIRS value < 40 %; Drop in NIRS value 25 % or more than baseline;	Of the 91 patients, 12 developed limb ischemia. Treatment options included replacing the DPC and/or fasciotomies. All seven patients with emergent DPC placement after acute ischemia had resolution of symptoms after DPC placement, NIRS tracings that returned to preischemic. Using continuous NIRS monitoring of limb perfusion, along with physical examination, a trained intensive care staff, placement of a DPC at the time of cannulation, and open vessel repair at decannulation seems to limit vascular complications of the cannulated limb.

DPC: distal perfusion cannula; VA: venoarterial; ECPR: extracorporeal cardiopulmonary resuscitation.

excluded, as were studies involving pediatric patients, central VA ECMO, and venovenous ECMO.

Data extraction and risk of bias assessment

Following the full-text review, data extraction and bias assessment were conducted by two study authors using a predefined data extraction form, with the following data (supplementary material table 2 and 3): study year; country; study design; study objective; ascertainment dates; sample size; comparator; population; inclusion criteria; exclusion criteria; method of evaluation (placement procedures; monitored parameters; record documentation; diagnostic accuracy measures; intervention for hypoperfusion signs); target values; impact of monitoring NIRS on outcome; improvement NIRS with intervention; diagnostic criteria for limb ischemia; NIRS efficacy/NIRS contribute and positive aspects of NIRS. Disagreements were solved by consensus or, if required, with the involvement of a third author. If necessary, reviewers reached out to the authors of the studies to clarify existing data, request missing data, or obtain additional information.

The risk of bias was assessed using the ROBINS-I tool [17]. Each study was evaluated for bias across all seven domains, with risk categorized as low, moderate, serious, critical, or no information. For serial cases, the risk of bias was assessed using The Joanna Briggs Institute Critical Appraisal tools for use in JBI systematic reviews [18].

Data synthesis and analysis

A narrative synthesis was employed to summarize the characteristics of the studies, including their design, settings, participant characteristics, the placement and monitoring of NIRS, and NIRS-based interventions. Participant age and the duration of ECMO support were presented as medians. A narrative synthesis was employed for outcomes where *meta*-analysis was not feasible. For outcomes reported in at least two studies, *meta*-analyses were conducted. To evaluate the primary outcome, two independent reviewers meticulously extracted relevant data for sensitivity and specificity analyses, ensuring alignment with the *meta*-analysis objectives. These metrics were then plotted to visually represent individual study outcomes. All *meta*-analyses were performed using *R*, employing the packages *meta* [19], *gridGraphics*, and *gridExtra*. A random-effects model was applied, justified by the observed heterogeneity in intervention effects across studies. This heterogeneity arises from differences in intervention content, measurement instruments, and study designs, making the random-effects model suitable for accounting for both within-study and between-study variability.

Results

Fig. 1 depicts the study selection process. 180 studies were identified using the search query in the aforementioned databases after duplication removal. But 164 were removed after scan read. Of the remaining 16 references that underwent full-text assessment, five were removed because they did not answer the research question, two were removed

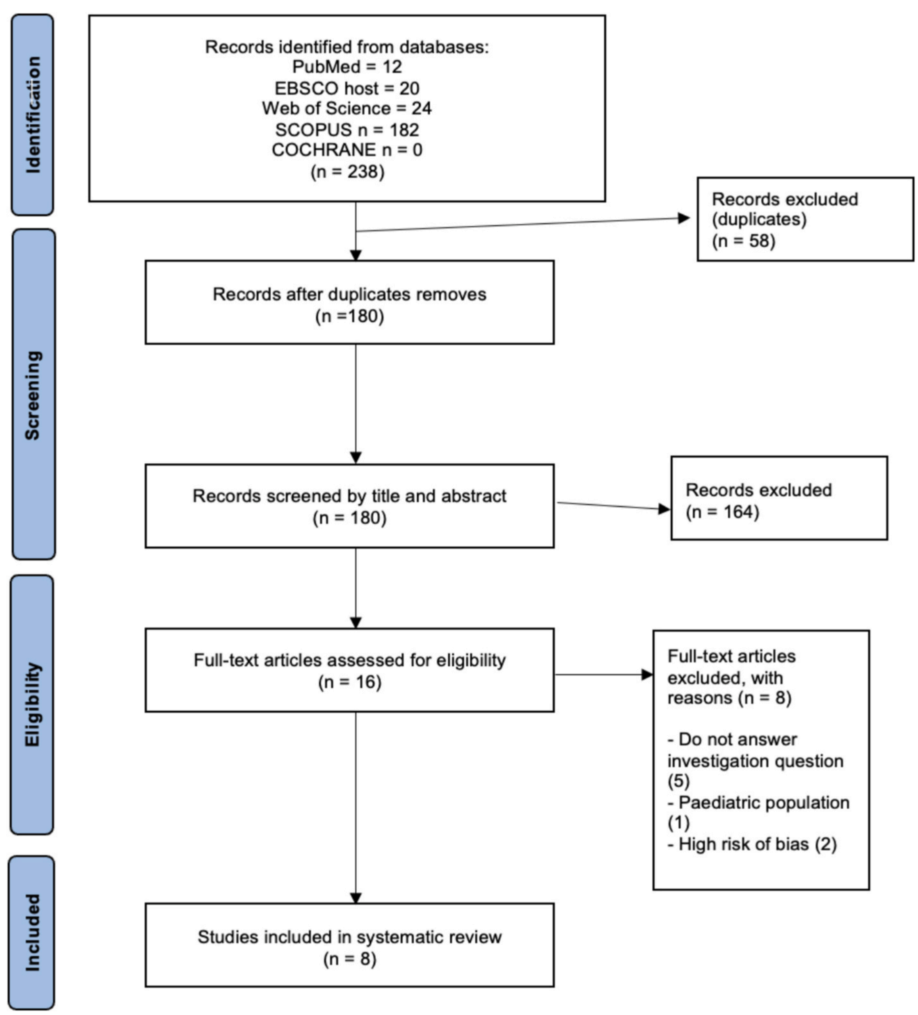

Fig. 1. Prisma flow diagram.

because they were judged to be at high risk of bias and one was removed because it focused on pediatric patients (supplementary material). The final number of studies included in this review was therefore 8, and these studies are summarized in Table 1.

Study design and settings

All studies included in this review were observational and conducted at a single center. Three studies included a comparator group: two compared outcomes without NIRS monitoring [20,21], while another used ankle-brachial index monitoring [22]. The remaining articles were single-arm studies. The sample sizes ranged from 20 to 490 patients, with median ages ranging between 17 and 78 years, but only one study reported the median SOFA score, which was 14 [23] (Table 1.).

Regarding the setting, two of the studies were performed in general intensive care units [24,25], one was performed in a surgical cardiac care unit [26] and one study mentioned that the cannulation procedure was performed by the cardiothoracic surgery team but did not specify the type of ICU where data was collected [21]. The median number of days on ECMO ranged from 3.25 to 10 days [20–27]. The primary indication that prompted extracorporeal support in the venoarterial configuration was cardiogenic shock in two studies identified [24,27], either cardiac arrest or cardiogenic shock in two studies [22,26], and ECPR also in two [23,25]. One study did not mention the clinical condition that led to the initiation of extracorporeal support [20] (Table 1.).

NIRS placement and monitoring

Sensor placements included near the tibia or medial calf, midway between the knee and ankle, on the medial gastrocnemius, or the calf, with timing varying from cannulation to ECMO weaning [20–22,24–26]. Two studies did not specify placement [23,27]. Three authors described sensor replacement protocols: pads were replaced for mispositioning, looseness, or suspected ambient light interference [24]; every 72 h or sooner if needed [26]; and once every seven days during the ECLS period [25].

The monitored parameters included: absolute NIRS values with differential monitoring between cannulated and non-cannulated limbs [21–24]; absolute values and reductions from baseline [26,27]; and absolute values alone [20,25]. NIRS target values ranged from readings below 40 % [20,23,26,27] to below 50 % for hypoperfusion [21,24]. One study [25] did not specify reference values. Thresholds for limb differentials included > 15 % [21,22,24] and > 25 % for significant issues [23]. Notably, only one study [22] relied exclusively on limb differentials for diagnosis, providing a target value specifically for this parameter despite also monitoring absolute NIRS values. Regarding the frequency of documentation, two studies reported continuous NIRS monitoring [21,26], whereas three others described hourly recording [20,22,24] and two did not specify the frequency. One of these noted that regional oxygen saturation in both legs was continuously measured using NIRS [23], while the other stated that continuous limb perfusion monitoring was initiated immediately after ECMO commencement and measured bilaterally with NIRS [27].

Interventions based on NIRS

Interventions used to improve lower limb perfusion, once device functionality was confirmed, included: increasing tissue oxygenation by enhancing ECMO flow, mean arterial pressure, and hemoglobin levels [20]; reducing vasopressors, infusing vasodilators, or using inotropes [23]; placing a distal perfusion cannula (DPC) [21,23,24,26,27]; optimizing the DPC via aspiration, flushing, or replacement [22]; performing prophylactic fasciotomy for compartment syndrome or ischemia over 4 h [26]; and consulting vascular surgery in emergencies [27]. The following interventions were shown to improve NIRS parameters: increasing oxygen supply to tissues, which resulted in higher NIRS absolute values [20], and rising rSO_2 values in patients treated with a distal perfusion cannula (DPC) [20–22,24–27]. The following findings were reported in the included studies: all patients showed rSO_2 values exceeding 40 [20]; absolute StO_2 levels normalized above 60 % post-DPC insertion [24]; NIRS values returned to pre-ischemiclevels after DPC insertion [27]; and rSO_2 absolute values increased from 29.3 $\pm$ 2.7 to 64.0 $\pm$ 5.1 [25]. Optimization of the reperfusion cannula (e.g., clot removal via syringe aspiration) resulted in an increase in rSO_2 from 31.3 $\pm$ 0.8 to 79.5 $\pm$ 9.0 [25].

Clinical benefits

Five studies were single-arm. The main clinical outcomes associated with NIRS monitoring were as follows: vascular surgery was required in 19 % (82/427) of patients, with 1 % (4/427) undergoing major amputation [23]; four patients (67 %) had two-compartment lower limb fasciotomies as a prophylactic measure, with no limb loss reported among those with femoral peripheral cannulation [26]; of the 12 patients with ischemia who did not have DPC, 2 underwent DPC insertion, 5 required both DPC insertion and fasciotomy, and 4 required fasciotomy alone [27]. Complications from distal femoral artery cannulation (bleeding, thrombus) occurred in 17.4 % of patients [25].

Three studies included a comparator arm [20–22]. The following associations were identified: in the NIRS group, no patients required fasciotomy for compartment syndrome, compared to 13.9 % in the control group ($p = 0.04$) [20]. In the same study, among patients in the NIRS group who developed ischemia, survival to discharge was 42.9 %, compared to 61.9 % in those without ischemia ($p = 0.418$). In Vinogradsky's study, 9 patients in the NIRS group underwent surgery for limb ischemia (4 thrombectomies, 6 fasciotomies, no amputations), while in the control group, 12 patients required interventions (2 thrombectomies, 6 fasciotomies, 2 amputations) [21]. The author reported that NIRS-guided DPC placement reduced the incidence of limb ischemia requiring surgery by threefold compared to selective DPC insertion based on clinical signs alone [21]. One study did not provide data on the impact of NIRS monitoring on clinical outcomes [22].

The contributions of NIRS technology to the early identification of signs of hypoperfusion were described by all authors and included the following:

- NIRS helped confirm successful reperfusion, identifying thrombotic occlusion of the reperfusion cannula through sudden rSO_2 drops [20].
- NIRS provided real-time monitoring of lower limb perfusion, while its absence may delay detection by hours, risking hypoperfusion [20].
- StO_2 values below 50 % for more than four minutes showed comparable specificity to Doppler ultrasound in detecting adequate perfusion [24].
- NIRS enhanced the detection of limb hypoperfusion, enabling timely salvage therapy [21].
- NIRS was superior for monitoring compartment tissue ischemia due to its noninvasive nature and direct measurement of tissue ischemia [26].
- Combined with physical examination, trained staff, DPC placement at cannulation, and open vessel repair, NIRS helped reduce vascular complications in the cannulated limb [27].
- NIRS enabled early recognition of compromised limb perfusion and supported timely interventions, such as additional distal cannula placement, as a potential early marker for distal ischemia [25].

One author presented a negative perspective on NIRS, reporting that in their study, four patients with clinically significant ischemic events, identified through clinical examination and ABI, showed no correlation with NIRS value variations [22].

The positive aspects of NIRS technology described by the authors included: being a noninvasive, continuous real-time method for monitoring of tissue oxygen saturation, which correlated with higher survival rates to hospital discharge [20]; increasing the confidence of ECMO bedside staff in detecting distal-limb hypoperfusion by providing an additional protective metric [24]; enabling early detection of limb ischemia and immediate action to prevent severe complications [23]; offering crucial bedside 'point-of-care' information, acting as a new 'vital sign' that improves care quality and outcomes for critically ill ECMO patients [26]; and aiding in the early recognition of compromised limb perfusion, facilitating timely intervention such as distal cannula placement [25].

Risk of bias assessment

The risk of bias assessment of the included studies, based on ROBINS-I tool, indicated an overall moderate risk in most cases. The primary reason for the risk of bias in the included studies was the retrospective nature of the study design. The primary concern was bias due to confounding (D1), which was rated as moderate in all studies, suggesting that uncontrolled variables may have influenced the results. Additionally, there were uncertainties regarding bias in classification of interventions (D3), with some studies lacking sufficient information for a complete assessment. On the other hand, the domains related to outcome measurement (D6) and the selection of reported outcomes (D7) predominantly showed low risk, enhancing the reliability of the findings. The studies also demonstrated good quality in managing missing data (D5) and in implementing the planned interventions (D4), with most articles presenting a low risk of bias in these aspects.

However, the presence of some domains with insufficient information indicates that the bias assessment may have been limited in certain studies. Overall, despite the moderate risk in some areas, the results suggests that the analyzed studies have reasonable methodological quality, with some limitations that should be considered when interpreting the findings (supplementary material Figs. 1 and 2).

Meta-analysis

Two studies reported sensitivity and specificity values for diagnosing critical limb ischemia using NIRS monitoring [23,24]. The cutoffs used in these studies were an StO_2 differential ≥ 15 % and $StO_2 < 50$ % for more than four minutes [24] and a differential between legs ≥ 25 % and absolute NIRS values below 40 %, whereas ischemia was defined as a combination of the following findings: cold limb, mottled skin, and pulseless Doppler ultrasound [24], as well as pallor, hypothermia, or pulselessness and sonographic evidence of absent perfusion [23].

Sensitivity. The pooled sensitivity of the diagnostic method across the two studies was 0.71 (95 % CI: [0.67, 0.74]), with individual study estimates ranging between with individual study sensitivity estimates of 0.73 (95 % CI: [0.63, 0.73]) (24) and 0.70 (95 % CI: [0.68, 0.71]) [23] (Fig. 2). Heterogeneity was moderate (I2 = 50.8 %I2 = 50.8 %, p = 0.153), suggesting variability between the studies that was not statistically significant.

Specificity. The pooled specificity was 0.68 (95 % CI: [0.61, 0.74]), with individual specificity estimates ranging between 0.71 (95 % CI: [0.66, 0.73]) (24) and 0.65 (95 % CI: [0.63, 0.66]) (23) (Fig. 3). Heterogeneity was high (I2 = 91.6 %I2 = 91.6 %, p < 0.001), reflecting substantial variability between the two studies.

Risk of bias

All of the studies were found to have an overall moderate risk of bias (Appendix Fig. 1). The primary reason for the risk of bias in the included studies was the observational nature of the study design.

Discussion

In this systematic review and *meta*-analysis of eight studies assessing the effectiveness of NIRS technology in the early diagnosis of lower limb ischemia in patients undergoing peripheral VA-ECMO, we found that NIRS has high sensitivity but moderate specificity, with significant heterogeneity. Given the exponentially increasing use of VA-ECMO, growing expertise in percutaneous cannulation, and the strong association between limb ischemia and in-hospital morbidity, mortality, and length of stay, these findings underscore the need for further research to evaluate the effectiveness of NIRS in diagnosing acute lower limb ischemia.

This need becomes even more pressing with the expanding use of ECMO for treating cardiogenic shock and extracorporeal cardiopulmonary resuscitation (ECPR) in adults which highlights the importance of a targeted approach to the detecting, preventing, and managing acute lower limb ischemia [12]. The etiology of this condition in peripheral VA ECMO is multifactorial, often resulting from insufficient blood flow to the cannulated limb, typically due to partial or complete occlusion by the arterial cannula. Additional contributing factors include high doses of vasoactive drugs, pre-existing peripheral vascular disease, and activation of the coagulation cascade [8]. Given its significant impact on patient outcomes – affecting approximately one-third of patients undergoing peripheral VA ECMO [8] – early identification and intervention is critical. To address this challenge, NIRS technology is increasingly used to monitor tissue oxygenation in the lower limbs of peripheral VA-ECMO patients, enabling early detection of hypoperfusion [20]. Recognizing its potential benefits, the Extracorporeal Life Support Organization (ELSO) recommends NIRS for VA ECMO patients, particularly those with peripheral cannulation [2]. However, optimizing patients' outcomes requires not only advanced technology but also a well-coordinated multidisciplinary team. In this context, nurse play a crucial role, as they are instrumental in the early detection of lower limb ischemia through comprehensive physical assessments, continuous monitoring, and interpretation of NIRS value. Their vigilance and expertise are essential in facilitating timely intervention and ensuring safe, high-quality care for ECMO patients [28,29].

The studies in this review were conducted in intensive care units [24,25] and cardiology intensive care units [26]. However, only three authors mentioned the data collection context, which may limit the interpretation and generalization of the results. Cardiogenic shock and ECPR were the main indications for peripheral VA-ECMO cannulation, consistent with the primary clinical indications outlined by Richardson et al [30].

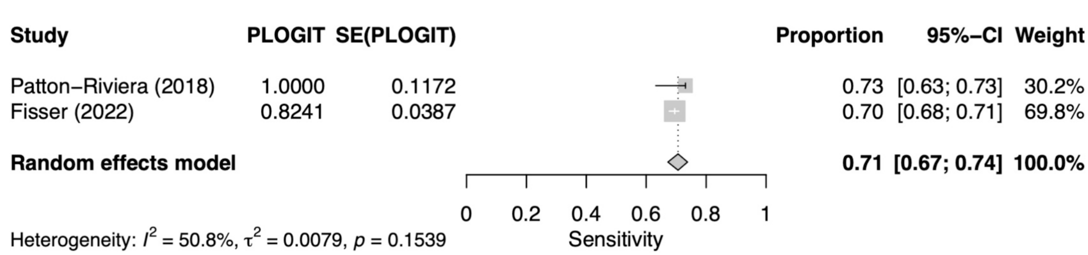

Fig. 2. Pooled sensitivity of diagnostic of NIRS technology.

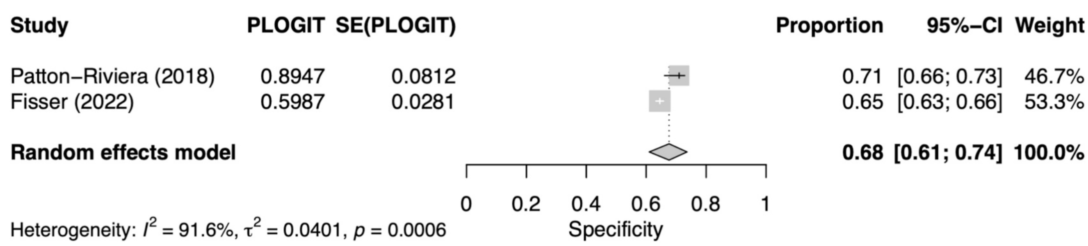

Fig. 3. Pooled specificity of diagnostic of NIRS technology.

The authors describe various methods for monitoring regional oxygen saturation in the lower limbs, including sensor placement and recording frequency. Evidence recommends placing NIRS sensors on the gastrocnemius muscles of both limbs before, during, and after ECMO support [2,12]. Most studies place the sensor medially on the lower limbs, midway between the knee and ankle. Positioning the sensor over the gastrocnemius muscle for reliable signal tracking is suggested, as it is well-perfused and contrasts with bony structures like the tibia [31].

The lack of standardization in monitoring methods compromises result comparability and data reliability, as factors like sensor condition, placement, and replacement frequency can affect NIRS values. NIRS only measures regional oxygen saturation to a depth of 4 cm, and the results depend on sensor placement [32]. NIRS utility is further limited to the sensor's attachment point [31]. Standardizing the monitoring method is crucial to improving clinical practice, enabling timely hypoperfusion identification, and facilitating result comparison in research. This requires developing protocols based on high-evidence studies that define sensor location and recording frequency to maximize NIRS efficacy.

No standardized cutoff values for NIRS tissue oxygen saturation indicating limb ischemia were identified in the studies [12]. ELSO recommends NIRS values above 50 %, ideally 60 % [2], which aligns with the target values presented by Vinogradsky and Patton-Riviera. Regarding the diagnostic criterion based on the StO_2 difference between the cannulated and non-cannulated limbs, no standardized reference values exist. ELSO recommends that the NIRS differential should not exceed 20 % [2], but the authors reviewed present different target values [21–24]. The NIRS differential can help diagnose cannula-related obstruction, as a thrombotic occlusion can be identified by a sudden drop in rSO_2 values [9,20].

Several interventions to improve lower limb perfusion have been described, including addressing mechanical causes and inserting a distal perfusion cannula (DPC) [20–27]. DPC placement is essential to ensure antegrade perfusion, particularly due to the near-total femoral artery occlusion caused by the ECMO cannula [33]. The placement of a DPC reduces the incidence of limb ischemia by at least 15.7 % [11] and is effective in managing reversible acute ischemia [34].

A 2022 *meta*-analysis highlighted interventions, including smaller-caliber arterial cannulas (less than 17 Fr) and prophylactic DPC insertion, as effective in reducing acute lower limb ischemia [8]. Prophylactic DPC placement was found to lower 30-day mortality in VA-ECMO patients with cardiogenic shock (from 53.2 % to 33.1 %) [35]. However, a selective DPC strategy, when paired with a strict limb ischemia monitoring protocol, may be safe and avoid the risks of additional arterial catheters [10]. These findings highlight the need for further research to clarify the best approach for DPC placement. Prophylactic fasciotomy in cases of suspected compartment syndrome was mentioned in the protocol "Decreased Lower Limb Tracing Protocol" by Wong et al. (2012). However, selective fasciotomy was shown to prevent nearly half of fasciotomies without increasing complication rates, supporting a selective approach over prophylactic fasciotomy for treating lower limb vascular injuries [36]. This may explain why only one article in this review referenced prophylactic fasciotomy.

The data reviewed suggests that when hypoperfusion management interventions are effective, NIRS values increase, demonstrating the technology's sensitivity [20–22,24–27]. For example, in Patton-Riviera's study, StO_2 rose above 60 % after distal perfusion cannula insertion, while in Wong's study, low rSO_2 readings resolved in all six patients (35 %) after interventions from the "Decreased Lower Limb Tracing Protocol." These findings align with Su et al. (2020) who identified that lower $rStO_2$ in the cannulated leg may indicate ischemia [37].

NIRS monitoring impacts clinical outcomes in patients on peripheral VA-ECMO. For instance, in Kim's study, none of the NIRS group patients required fasciotomy due to compartment syndrome, compared to 13.9 % in the control group. In Vinogradsky's study, NIRS-guided DPC placement reduced leg ischemia requiring surgery by threefold, with no amputations in the intervention group, compared to two amputations in the control group. NIRS can also expedite surgical correction of perfusion deficits, preventing complications like compartment syndrome and limb loss in these patients [38].

Data on the sensitivity and specificity of NIRS technology for diagnosing acute lower limb ischemia in patients on peripheral VA-ECMO are presented by Fisser et al. (2022) and Patton-Rivera et al, (2018). Both studies evaluate the diagnostic accuracy of the differential between the cannulated and non-cannulated limbs. Our pooled analysis shows that NIRS technology has high sensitivity across the studies, similar to findings by Su et al. (2020) who noted that large differences in $rStO_2$ between limbs may indicate ischemia [37]. However, the pooled specificity showed moderate performance with high heterogeneity ($I2 = 91.6$ %), reflecting substantial variability between the two studies. This significant heterogeneity suggests that differences in study design, population characteristics, or diagnostic thresholds may contribute to the variability observed.

The use of NIRS technology enhances the monitoring of lower limb perfusion by enabling early detection of hypoperfusion and facilitating timely intervention to prevent complications. Recognized as an early marker of ischemia by several authors (20,21,25), NIRS plays a key role in clinical decision-making. For instance, Vranken et al. (2020) underline its effectiveness in identifying compromised perfusion and the need for additional distal cannulas, while Vinogradsky et al. (2023) emphasize its utility in detecting hypoperfusion events and guiding salvage therapies. Kim et al. (2017) point out that, in the absence of NIRS, detection of hypoperfusion might be delayed, resulting in severe complications. Similarly, Feng et al. (2021) highlights NIRS as a more objective tool for assessing perfusion compared to bedside evaluations, enabling earlier interventions [39].

Another significant advantage of NIRS technology is its ability to provide non-invasive, continuous real-time monitoring of tissues oxygen saturation in patients on peripheral VA-ECMO [20]. This capability supports the early identification of distal limb hypoperfusion [24] and allows for timely measures to prevent serious complications [23]. Additionally, NIRS has demonstrated potential in the early diagnosis of acute compartment syndrome, which is particularly critical in non-pulsatile states such as ECMO, where conventional diagnosis can be challenging [40]. By offering the possibility of earlier ischemia correction in viable limbs [12], NIRS serves as an invaluable method for continuous perfusion monitoring in cannulated limbs [31].

Son, Karin et al. [22] found that a decreasing Ankle-Brachial Index (ABI) may precede a drop in StO2 detected by NIRS oximetry, likely due to vascular collateralization and compensatory mechanisms. Their findings suggest that NIRS may not be as sensitive to ischemic events as ABI. In their study, two patients exhibited a decline in ABI and ultimately lost Doppler tones without any changes in NIRS oximetry readings, both requiring leg revascularization. Additionally, two other patients were diagnosed with DPC thrombosis only after a decrease in ABI, again without alterations in NIRS oximetry. These findings suggest that NIRS should not be used as a standalone method for monitoring hypoperfusion [22].

Chanan et al. (2020) further highlight that combining multiple monitoring strategies – such as physical examination, Doppler ultrasound, limb circumference measurements, and biomarkers – allows for earlier detection of limb hypoperfusion [12]. Notably, even with high NIRS sensitivity, further treatment should not be delayed when clinical suspicion of limb ischemia is present. However, physical examination can be particularly challenging in peripheral VA-ECMO patients due to non-pulsatile blood flow or the use of vasopressors. These limitations further underscore the need for complementary diagnostic tools to ensure timely recognition and management of limb ischemia.

Doppler ultrasound remains one of the most widely used methods for assessing lower limb perfusion and was employed in the majority of the studies analyzed. When comparing the sensitivity of NIRS technology to that of Doppler ultrasound, Steffen et al. Found, in their study that both patients who developed lower limb ischemia had NIRS values below 40 % and an absence of pulses on Doppler ultrasound [7]. However, performing Doppler ultrasound in peripheral VA-ECMO patients presents significant challenges, as these individuals often exhibit minimal or no arterial pulsatility. In such cases, blood flow pattern are primarily influenced by the centrifugal ECMO pump, in combination with the patient's hemodynamic profile, making Doppler assessment more complex. Consequently, the clinical utility of Doppler-derived flow velocities in this population remains difficult to determine. Moreover, these evaluations are technically demanding and require a high level of expertise, ideally performed by highly trained specialists, who may not always be readily available [41].

The lack of standardization in intervention protocols across the studies reviewed limits the comparability of results and the development of robust clinical evidence. As a result, there is a pressing need for standardized protocols based on high-quality evidence that balance scientific rigor and ethical considerations. In light of recent evidence, we propose a flowchart for monitoring regional oxygen saturation in lower limbs of peripheral VA-ECMO patients, which we believe could be implemented effectively in clinical practice (Fig. 4).

The selection of the target values described in the flowchart was based on the robustness of the data presented in Vinogradsky's study, a retrospective cohort study including 490 patients monitored with NIRS. Notably, among the studies included in the review, this study had the largest sample size, further strengthening its reliability. Additionally, findings from Patton-Rivera's study further supported the selection of these target values. In this study, an StO_2 below 50 % for more than four minutes had a positive predictive value (PPV) of 86 % and a negative predictive value (NPV) of 100 % for detecting distal limb hypoperfusion. Moreover, when an StO_2 differential of 15 % or greater was observed, and the cannulated limb had an StO_2 below 50 % for over four minutes, sensitivity, specificity, PPV, and NPV all reached 100 % for diagnosing cannula-related obstruction. The strength of these findings provided a

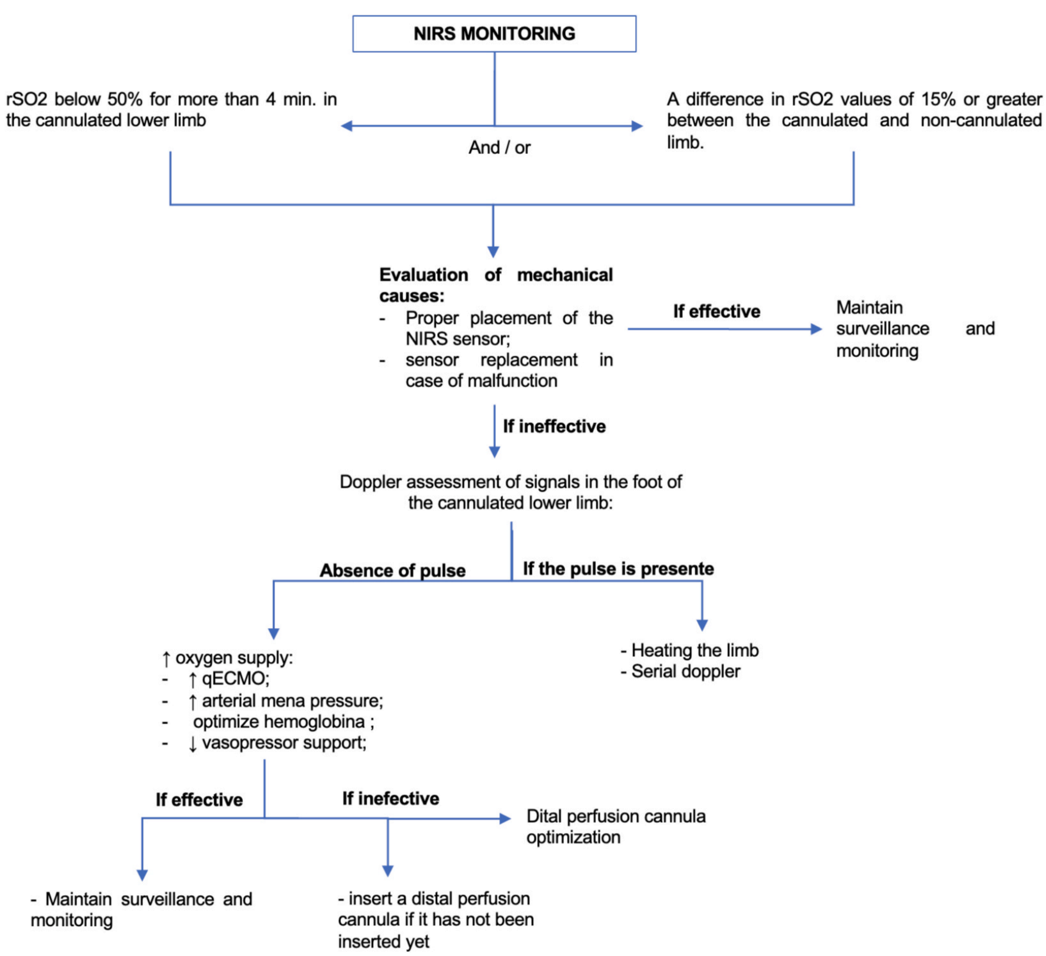

Fig. 4. Intervention flowchart when reducing the NIRS value.

solid rationale for incorporating these target values into the development of the flowchart.

Limitations

Our study has limitations that should be mentioned. First, it included a limited number of articles, all of which were observational in nature, impacting the overall methodological quality of the review. Second, most of the studies included exhibit a moderate risk of bias, also related to the observational nature of the included studies. Comparing results across studies was challenging due to several factors, such as the lack of standardization in reference values and the diagnostic criteria for ischemia used by the different authors.

The heterogeneity observed ($I^2 = 91.6$ %) must be cautiously interpreted, given that this calculation is based on only two studies; thus, the high heterogeneity likely reflects differences in measurement protocols, clinical populations, or practices, as well as the limited available evidence.

Another limitation is the scarcity of direct comparative data between NIRS and other diagnostic methods, such as Doppler ultrasound and ABI, which restricts a more comprehensive evaluation of sensitivity and specificity across techniques.

Conclusion

NIRS technology plays a significant role in diagnosing lower limb ischemia in patients on VA ECMO. Our findings suggest that NIRS technology is a highly effective diagnostic method for consistently detecting true positives cases of limb ischemia. However, the pooled specificity showed moderate performance with substantial variability, indicating the need for further standardization of diagnostic criteria or study methodologies to improve the consistency of specificity results. Given these limitations, the NIRS technology should not replace clinical evaluation nor be used as a standalone monitoring tool. Instead, it should be integrated with other diagnostic modalities to ensure a comprehensive and accurate assessment of lower limb ischemia.

The decrease in NIRS value relative to baseline, as well as the difference in NIRS value between the two lower limbs, appear to be indicators of limb hypoperfusion that warrant further investigation using additional methods. Additionally, this technology allows for the assessment of distal perfusion catheter functionality.

Our results suggest that NIRS should be incorporated into the continuous monitoring of lower limb perfusion in patients undergoing peripheral VA ECMO, in combination with other tools such as clinical evaluation and Doppler ultrasound. The proposed flowchart outlines the integration of these modalities into clinical decision-making strategies, with the primary goal of early detection of hypoperfusion signs and the prevention of acute limb ischemia.

This systematic review provided valuable insights into the effectiveness of NIRS technology for early diagnosis of lower limb ischemia in patients undergoing peripheral VA ECMO. These findings have enhanced our capacity to deliver safe and high-quality care. Therefore, critically analyzing these results will help disseminate the best available evidence, provide essential data for addressing the research question, and inform the development of future research endeavors.

The authors recommend that more experimental studies be conducted in future investigations to elevate the level of scientific evidence on this topic. This would guide the multidisciplinary teaḿs intervention toward evidence-based practice, contributing to safer and high-quality patient care.

Review registration

PROSPERO: (Registration Number: CRD42024529475; Registration date: March 27, 2024; Registration name: The effectiveness of NIRS technology to the early diagnosis of lower limb ischemia in patients on peripheral VA ECMO).

Ethics statement

Not applicable.

Funding source information

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CRediT authorship contribution statement

Raquel Coelho: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Resources, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Joana Tavares:** Writing – original draft, Visualization, Methodology, Investigation, Data curation. **Catarina Marinheiro:** Writing – original draft, Validation, Supervision, Methodology, Investigation, Formal analysis. **Carina Costa:** Writing – original draft, Methodology, Investigation, Conceptualization. **Simão Ferreira:** Software, Funding acquisition, Formal analysis, Data curation. **Tiago Gregório:** Supervision, Project administration.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Data statement

The data that our review is based on is available in the manuscripts of the included articles.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.iccn.2025.104039.

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