

Automated Calf Muscle Reactions in Blood Donors: A Systematic Review of Devices, Clinical Evidence, And Implementation Challenges Stimulation for the Prevention of Vasovagal

Anu Balan¹, Poorvikalyani Jayaraman², Raju Balaji^{3*}

¹Department of Transfusion Medicine, Saveetha Medical College and Hospital, Saveetha Institute of Medical and Technical Sciences (SIMATS), Thandalam, Chennai-602105, Tamil Nadu, India. Email: ammuanna008@gmail.com

²Saveetha Institute of Basic Medical Sciences (SIBMS), Saveetha Institute of Medical and Technical Sciences (SIMATS), Thandalam, Chennai - 602105, Tamil Nadu, India. Email: poorvikalyani91@gmail.com

³Department of Orthopaedics, Saveetha Medical College and Hospital, Saveetha Institute of Medical and Technical Sciences (SIMATS), Thandalam, Chennai-602105, Tamil Nadu, India. Email: balajir24.smc@saveetha.com

*Corresponding author: Raju Balaji - balajir24.smc@saveetha.com

Abstract

Background: Vasovagal reactions (VVRs) are important adverse events associated with blood donation and may result in dizziness, presyncope, syncope, and donor injury. Preventive strategies include hydration, applied muscle tension, and modifications to donor positioning. Automated calf muscle stimulation has emerged as a potential technology for supporting venous return and reducing the risk of VVRs. However, its clinical effectiveness must be distinguished from evidence supporting manual muscle-tension exercises and other mechanical interventions.

Objective: To systematically evaluate the available evidence on automated calf muscle stimulation for preventing VVRs in blood donors, with particular emphasis on device characteristics, clinical effectiveness, safety, feasibility, and implementation challenges.

Methods: A systematic literature review will be conducted using relevant biomedical and multidisciplinary databases. Eligible studies will be identified using predefined inclusion and exclusion criteria focused on automated or electronically controlled calf muscle stimulation in blood donors. Study selection and data extraction will follow a prespecified process. Extracted information will include study design, donor population, device characteristics, comparator interventions, clinical outcomes, adverse events, and methodological limitations. Risk of bias will be assessed using tools appropriate to the included study designs. Findings will be synthesized narratively, with quantitative synthesis considered where sufficient comparable data are available.

Results: The results will summarize the number and characteristics of eligible studies, the technologies investigated, reported clinical outcomes, and the quality of the available evidence. Direct evidence concerning automated calf muscle stimulation will be distinguished from indirect evidence involving manual applied muscle tension, mechanical footrests, and other preventive interventions.

Conclusion: This review will clarify the extent to which current evidence supports automated calf muscle stimulation for preventing VVRs in blood donors and identify priorities for clinical validation, safety assessment, and implementation. Its conclusions will be based on the quality and applicability of the available evidence.

Keywords: Blood donors; vasovagal reactions; automated calf muscle stimulation; blood donation; donor safety; systematic review.

1. Introduction

Blood donation is an essential component of healthcare systems, supporting the treatment of patients with trauma, surgical complications, haematological disorders, and other conditions requiring transfusion. Maintaining a safe and sustainable blood supply depends not only on donor recruitment but also on donor safety, satisfaction, and retention. Although whole-blood donation is generally considered safe, adverse reactions remain an important concern for blood collection services. Vasovagal reactions (VVRs) are among the most frequently reported systemic adverse events and can range from mild dizziness, nausea, pallor, and sweating to presyncope, syncope, and injuries associated with falls (Amrein et al., 2012; Thijsen & Masser, 2019). These reactions may undermine donor confidence and reduce the likelihood of subsequent donation, making their prevention an important component of donor-care practice.

VVRs involve an autonomic response that can produce hypotension and, in some cases, bradycardia and transient loss of consciousness. Their occurrence during blood donation is multifactorial, reflecting interactions between physiological responses to blood collection, psychological distress, and individual donor characteristics. A systematic review and meta-analysis by Wu et al. (2025), encompassing 71 studies and approximately 19 million donations,

identified new-donor status, younger age, female sex, lower estimated blood volume, and lower blood pressure among factors associated with increased VVR risk. Donation-related fear and anxiety were also implicated in the available evidence. These findings highlight the importance of preventive strategies that address both physiological and behavioural contributors to donor reactions. However, identifying higher-risk donors alone may not prevent all events, supporting continued investigation of practical interventions that can be incorporated into routine donation procedures.

Conventional preventive approaches include pre-donation hydration, donor education, appropriate positioning, observation after collection, and applied muscle tension (AMT). AMT involves voluntary contraction of selected skeletal muscles during donation to support venous return and cardiovascular stability. Evidence from intervention studies suggests that these measures may reduce some donation-related reactions, although the magnitude of benefit varies according to intervention protocols, donor populations, and outcome definitions. In a cluster-randomised trial involving 4,576 donors, Morand et al. (2016) reported that pre-donation water or isotonic drink reduced presyncopal or syncopal events, while muscle-tensing exercises reduced syncopal-type reactions during donation. Similarly, Thijsen et al. (2020) reported an 8% reduction in overall VVR rates following the national implementation of water loading and AMT in Australia, although no significant reduction in syncope was observed. These findings support the physiological rationale for muscle activation while illustrating the importance of distinguishing presyncope from loss of consciousness when evaluating intervention effectiveness.

Evidence syntheses have further examined these preventive approaches. Wang et al. (2022) included six studies in a meta-analysis and reported a pooled relative risk of 0.52 (95% confidence interval [CI], 0.40–0.67) for VVRs with AMT compared with control conditions. A broader review by Williams et al. (2022) examined physical counter-pressure manoeuvres for syncope prevention and highlighted limitations in the evidence supporting their effectiveness in real-world settings. More recently, Van Remoortel et al. (2024) found that pre-donation water and isotonic drinks probably reduce VVRs, while noting the need for further trials to strengthen the evidence for preventive interventions. In a randomised trial involving 4,320 blood donors, Meher et al. (2024) observed VVR incidences of 2.5% in the control group and 0.9% in the combined water-ingestion and AMT group. Conversely, the large STRIDES cluster-randomised trial involving more than 1.3 million donors found no clear benefit from the preventive interventions it evaluated, including modified AMT, compared with standard practice (Kaptoge et al., 2026). Collectively, these findings indicate that evidence from conventional preventive interventions is heterogeneous and should not automatically be extrapolated to other technologies.

An emerging technological approach is automated calf muscle stimulation, designed to activate the lower-limb skeletal muscle pump without requiring continuous voluntary effort from the donor. Contraction of the calf muscles can facilitate venous return from the lower extremities, providing a physiological basis for investigating whether controlled mechanical stimulation could contribute to cardiovascular stability during blood collection. Kumar and Sahani (2021) described an electronic calf muscle massager incorporating a programmable circuit and vacuum pump to inflate and deflate cuffs. The proposed device was intended to improve peripheral circulation, support venous return, and reduce apprehension associated with blood donation. However, the publication primarily describes the device concept and its proposed mechanism; the physiological rationale alone does not establish a reduction in clinically observed VVRs.

Related research has also examined mechanical support for donor-performed muscle tension. Mukherjee et al. (2025) investigated an adjustable, spring-fitted footrest incorporated into a donor couch in a cohort of 2,192 first-time whole-blood donations. Their study provides clinically relevant evidence concerning muscle tension facilitated by donor-couch design. Nevertheless, this intervention differs fundamentally from an electronically controlled massager because the donor actively applies muscle tension rather than receiving automated stimulation. Consequently, findings from mechanical footrests, voluntary AMT, and electronic calf stimulation should be interpreted as distinct evidence categories rather than interchangeable demonstrations of effectiveness. The same distinction applies to studies of general counter-pressure manoeuvres or hydration interventions (Thijsen & Masser, 2019; Williams et al., 2022).

Despite growing interest in donor-safety technologies, an important evidence gap remains between the proposed physiological benefits of automated calf stimulation and its demonstrated clinical effectiveness. Device characteristics, stimulation protocols, comparator interventions, outcome definitions, adverse-event monitoring, and implementation requirements must be considered when evaluating the available evidence. Furthermore, improvements in donor comfort or physiological parameters should not be interpreted as proof of reduced VVR

incidence unless supported by appropriate clinical outcome data. Transparent synthesis is therefore necessary to determine what is known about the technology and what remains uncertain.

Accordingly, this systematic review aims to evaluate published evidence on automated or electronically controlled calf muscle stimulation for preventing VVRs in blood donors. Specifically, it examines device characteristics, clinical effectiveness, safety, donor-related outcomes, and implementation challenges. Evidence from manual AMT and mechanical footrest interventions will be considered separately to provide context without attributing their effects directly to electronic devices. By distinguishing direct device evidence from indirect evidence and assessing the methodological quality of the available studies, this review seeks to clarify the current state of knowledge, identify research gaps, and establish priorities for future clinical validation and implementation.

2. Materials and methods

2.1. Review design and reporting guidelines

This study was designed as a systematic review to evaluate the available evidence on automated or electronically controlled calf muscle stimulation for the prevention of vasovagal reactions (VVRs) in blood donors. The review focuses on device characteristics, clinical effectiveness, safety, donor-related outcomes, and implementation challenges. The review methodology and reporting structure will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) guidelines to promote transparent reporting of the information sources, study selection process, eligibility criteria, and evidence synthesis (Page et al., 2021). The completed review should be accompanied by the PRISMA 2020 checklist and a flow diagram documenting the identification, screening, eligibility assessment, and inclusion of studies.

2.2. Research question and PICO framework

The research question was formulated using the Population, Intervention, Comparator, and Outcome (PICO) framework. The primary question was: Does automated or electronically controlled calf muscle stimulation reduce the incidence of vasovagal reactions in blood donors compared with standard donation care or alternative preventive interventions?. The population comprised individuals undergoing whole-blood or other eligible blood donations. The intervention was automated or electronically controlled calf muscle stimulation delivered through a device, massager, or integrated donor-couch system. Comparators included standard donation procedures, no additional intervention, sham stimulation, or alternative preventive strategies. The primary outcome was the incidence of VVRs, including presyncope and syncope where reported separately. Secondary outcomes included the severity of reactions, donor comfort and satisfaction, device-related adverse events, feasibility, acceptability, and implementation requirements. Repeat donation and cost-effectiveness were considered where relevant data were available. Studies involving voluntary applied muscle tension, mechanical footrests, hydration, or other preventive measures without automated calf muscle stimulation were not considered direct evidence of the target intervention. Such studies could be used to contextualise the findings but were to be analysed separately from the core device evidence.

2.3. Information sources

A comprehensive search should be conducted in PubMed/MEDLINE, Scopus, Web of Science, Embase, and the Cochrane Central Register of Controlled Trials (CENTRAL), subject to database availability. These sources cover biomedical research, clinical trials, multidisciplinary publications, and conference-related literature. Because the development and preliminary evaluation of medical devices may be reported in conference proceedings, relevant proceedings and reference lists of eligible publications should also be examined. Additional records may be identified through backward citation searching of included articles and relevant review papers. Google Scholar may be used as a supplementary source to identify potentially relevant publications not retrieved through the primary databases. The final manuscript should specify the databases actually searched, their coverage, and the date on which each search was performed.

2.4. Search strategy

The search strategy should combine controlled vocabulary, where available, with free-text terms relating to blood donation, vasovagal reactions, calf muscle stimulation, and electronic or automated devices. Search terms should

include variations of blood donor, blood donation, vasovagal reaction, vasovagal syncope, presyncope, calf muscle stimulation, electronic calf massager, automated stimulation, muscle pump, and donor couch. A preliminary PubMed search strategy is provided below: ("Blood Donors"[Mesh] OR "blood donor*" OR "blood donation" OR "whole blood donation") AND ("Vasovagal Reaction*" OR "vasovagal syncope" OR "vasovagal response" OR presyncope OR syncope OR fainting) AND ("calf muscle stimulation" OR "calf massager" OR "electronic massager" OR "automated muscle stimulation" OR "muscle pump" OR "donor couch" OR "donor chair"). The strategy should be adapted to the syntax and indexing requirements of each database. A device-focused search should also be performed using combinations of the device name, inventor names, and relevant technical terminology identified from preliminary searches. This is important because publications describing novel devices may not consistently use standard clinical terminology. Searches should not be restricted to a publication period without a methodological justification. The final search date, any language restrictions, and any date limits must be reported explicitly. The complete database-specific search strategies should be provided as supplementary material to support reproducibility (Rethlefsen et al., 2021).

2.5. Eligibility criteria

Studies were assessed against predefined inclusion and exclusion criteria. Eligible studies involved human blood donors undergoing whole-blood or other eligible blood donation procedures and evaluated automated or electronically controlled devices that directly stimulate the calf muscles. Clinical trials, observational studies, feasibility studies, and device evaluations reporting relevant clinical outcomes, safety findings, or other prespecified outcomes were considered, along with conference proceedings and full-text research reports containing sufficient information to assess the intervention and its outcomes. Publications were eligible if they were available in languages that could be reliably assessed by the review team. Studies investigating manual applied muscle tension, hydration, mechanical footrests, or other interventions without automated calf muscle stimulation were excluded from the core device-effectiveness synthesis. Studies involving populations unrelated to blood donation, editorials, opinion articles, protocols without results, publications lacking sufficient intervention details, duplicate reports without additional relevant data, animal studies, and laboratory investigations that did not provide evidence relevant to the prespecified outcomes were also excluded. Studies reporting only physiological or engineering performance were distinguished from clinical studies reporting vasovagal reaction (VVR) incidence or other donor outcomes, enabling the review to assess technological development without interpreting device feasibility as evidence of clinical effectiveness.

2.6. Study selection

All retrieved records should be imported into reference-management or systematic-review software, and duplicate records should be removed before screening. Titles and abstracts should then be screened against the eligibility criteria, followed by full-text assessment of potentially relevant publications. Wherever feasible, two reviewers should independently perform the screening process, resolve disagreements through discussion, and consult a third reviewer when consensus cannot be reached. Reasons for excluding full-text articles should be recorded and reported in the PRISMA flow diagram. The diagram should present the actual numbers of records identified, duplicates removed, records screened, full texts assessed, and studies included. Reports originating from the same underlying study should be linked to avoid double-counting participants. If only one reviewer performs the screening, this should be acknowledged as a methodological limitation.

2.7. Data extraction

A standardised data-extraction form should be developed and piloted before full extraction. The following information should be collected from each eligible report: author and publication year, country, study setting, study design, sample size, donor characteristics, device name and configuration, stimulation mechanism, stimulation intensity and duration, timing of intervention, comparator, follow-up period, outcome definitions, and reported findings. Clinical outcome data should include the number of donors experiencing VVRs, presyncope, syncope, or other adverse events, together with effect estimates and confidence intervals where reported. Information on donor comfort, acceptability, equipment requirements, maintenance, cleaning, cost, and implementation feasibility should also be extracted when available. Missing information should be recorded as unreported rather than inferred. Where multiple publications describe the same device or study, findings should be cross-referenced and consolidated without duplicating participants or outcomes.

2.8. Risk-of-bias assessment

The methodological quality of eligible studies should be assessed using tools appropriate to their design. The Cochrane Risk of Bias 2 (RoB 2) tool should be used for randomised trials, whereas the Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool may be used for eligible non-randomised intervention studies (Sterne et al., 2016, 2019). Device feasibility studies and engineering evaluations that do not use conventional comparative clinical designs should be appraised using criteria appropriate to their study objectives and limitations. The assessment should consider randomisation and confounding, deviations from intended interventions, missing outcome data, outcome measurement, and selective reporting, as applicable. Risk-of-bias judgements should be reported transparently, with supporting explanations. Where possible, two reviewers should independently assess risk of bias and resolve disagreements by consensus. The findings should inform interpretation of the results rather than serve as a substitute for evaluating the clinical relevance of each study.

2.9. Data synthesis

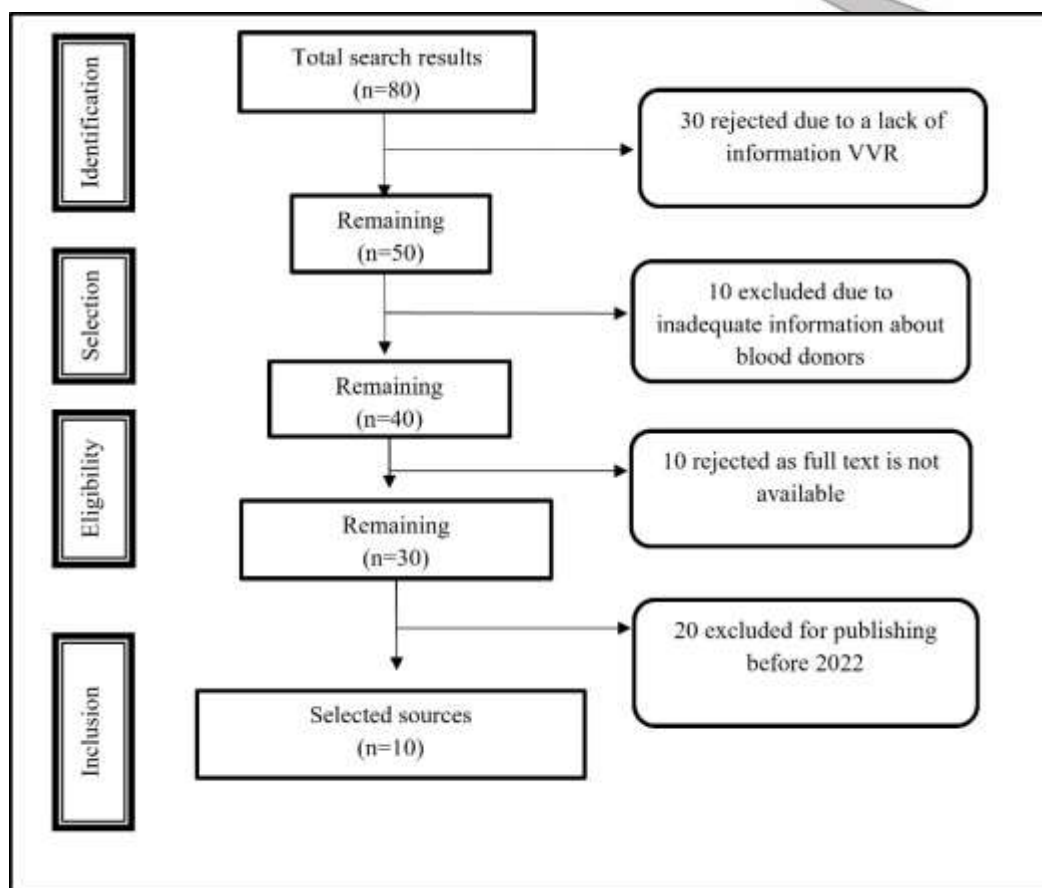
A structured narrative synthesis should be undertaken to describe the available evidence on automated calf muscle stimulation. Studies should be grouped according to device type, study design, intervention protocol, comparator, and outcome domain. Direct evidence from automated devices should be presented separately from indirect evidence involving manual muscle tension, mechanical footrests, hydration, or other preventive strategies. Where comparable studies report the same clinical outcomes using sufficiently similar definitions and follow-up periods, a quantitative synthesis may be considered. Dichotomous outcomes may be summarised using risk ratios or odds ratios with 95% confidence intervals, while continuous outcomes may be summarised using mean differences or standardised mean differences, as appropriate. Statistical heterogeneity should be assessed using relevant measures, including the I^2 statistic, when meta-analysis is appropriate. A meta-analysis should not be performed when the number of studies, clinical diversity, or reporting quality makes pooled estimates misleading. If the available evidence is too limited or heterogeneous for quantitative synthesis, the findings should be presented descriptively, with explicit consideration of study limitations, risk of bias, and the distinction between physiological plausibility and demonstrated clinical benefit. Conclusions about the effectiveness and safety of automated calf muscle stimulation should be proportionate to the quality, quantity, and directness of the available evidence.

3. Results

3.1. Study Selection

The study-selection process identified 80 records potentially relevant to vasovagal reactions (VVRs) among blood donors. Of these, 30 records were excluded because they lacked relevant information on VVRs, leaving 50 records for further assessment. A further 10 records were excluded because they contained inadequate information about blood donors, resulting in 40 records. Subsequently, 10 records were excluded because their full texts were unavailable, leaving 30 records. Finally, 20 records were excluded based on publication date, resulting in 10 publications being retained for the review. The study-selection process and the number of records retained at each stage are illustrated in Figure 1. The included publications comprised observational studies, a case-control study, systematic reviews and meta-analyses, a randomised controlled trial, a trial-design paper, and a descriptive review. The literature primarily addressed preventive strategies for donor-related VVRs, including applied muscle tension, counterpressure manoeuvres, hydration, donor-related risk factors, and blood-collection practices.

Figure 1. Flow diagram illustrating the identification, screening, eligibility assessment, and inclusion of studies in the review. Source: Authors' own preparation, adapted from the PRISMA 2020 reporting guidelines (Page et al., 2021).



3.2. Characteristics of Included Studies

The ten included publications investigated several approaches to reducing vasovagal reactions (VVRs) during whole-blood donation. Thijsen et al. (2020) examined the implementation of applied muscle tension and water loading among Australian whole-blood donors. Cheung (2021) investigated preventive approaches to donor-related VVRs, while Wang et al. (2022) and Williams et al. (2022) synthesised evidence on applied muscle tension and physical counterpressure manoeuvres, respectively. Shivhare et al. (2022) investigated factors associated with VVRs using a case-control design, whereas Singh et al. (2022) discussed standardised blood-collection practices and donor safety. McMahon et al. (2023) described the rationale and design of a large cluster-randomised trial evaluating preventive interventions. Van Remoortel et al. (2024) evaluated drinking interventions through a systematic review and meta-analysis, while Meher et al. (2024) compared four preventive strategies in a randomised controlled trial. Kaptoge et al. (2026) reported findings from a large cluster-randomised trial evaluating preventive interventions across blood-donation sites in England. Across these publications, the principal outcomes included VVR incidence, fainting or dizziness, associations between donor characteristics and reactions, and the potential contribution of preventive interventions to donor safety. The studies differed in design, population, intervention, and outcome assessment; therefore, their findings should be interpreted according to the nature and strength of the evidence provided by each publication. Importantly, the included publications predominantly investigated general preventive interventions rather than an automated electronic calf muscle massager integrated into a donor couch. Consequently, their findings provide contextual evidence but do not directly establish the clinical effectiveness of the target device. The study designs, principal findings, limitations, and relevance of these publications to the present review are summarised in Table 1.

Table 1. Characteristics and principal findings of studies relevant to vasovagal reaction prevention in blood donors

No.	Author (year)	Study design and focus	Main findings reported	Limitations and relevance to this review
-----	---------------	------------------------	------------------------	--

1	Thijssen et al. (2020)	Observational study evaluating the implementation of applied muscle tension (AMT) and water loading among Australian whole-blood donors.	The study examined changes in VVR incidence following the implementation of AMT and water loading.	Observational design limits causal inference. The findings provide indirect evidence for automated calf muscle stimulation.
2	Cheung (2021)	Quantitative investigation of preventive approaches to VVRs among healthy adults at a blood donation centre in Hong Kong; the supplied table reports 170 participants.	The supplied summary reports that muscle tension was associated with reductions in fainting episodes and dizziness.	Limited follow-up and potentially incomplete ascertainment of adverse events outside the donation centre. The findings do not directly evaluate an automated device.
3	Kaptoge et al. (2026)	Large cluster-randomised, stepped-wedge trial evaluating preventive interventions across 73 blood-donation sites in England.	The trial evaluated multiple preventive strategies. The primary outcome of VVR involving loss of consciousness showed no clear benefit compared with standard practice.	Conducted in England, which may limit generalisability to other settings. It did not directly evaluate the target electronic calf massager.
4	Wang et al. (2022)	Systematic review and meta-analysis of applied muscle tension for preventing blood donation-related VVRs; six studies were included.	Reported a pooled relative risk of 0.52 (95% CI: 0.40–0.67) for AMT.	Differences among included studies may affect the applicability of the pooled estimate. This is evidence for voluntary AMT, not automated stimulation.
5	Shivhare et al. (2022)	Single-centre case-control study investigating factors associated with VVRs among blood donors; the supplied table reports 178 donors.	Examined associations between donor characteristics and VVR occurrence, including psychological factors such as anxiety.	Single-centre design and limited sample size may restrict generalisability. The study informs donor risk assessment rather than device effectiveness.
6	Singh et al. (2022)	Descriptive review of blood-bank collection protocols, including donor screening, phlebotomy, monitoring, and post-donation care.	Discussed standardised procedures and preventive practices intended to support donor safety.	Descriptive evidence without direct empirical validation of the effectiveness of an automated calf stimulation device.
7	Williams et al. (2022)	Semi-systematic review and meta-analysis of physical counterpressure manoeuvres for syncope prevention.	Evaluated manoeuvres such as leg crossing, arm tensing, and squatting.	Variation in study designs and populations limits direct extrapolation to blood donation and automated calf stimulation.
8	McMahon et al. (2023)	Trial-design publication describing the rationale and methodology of the STRIDES cluster-randomised trial	Presented the design for evaluating preventive interventions, including hydration and modified AMT.	This is a trial-design paper and should not be treated as a report of completed effectiveness outcomes.

		across 73 blood-donation sites in England.		
9	Van Remoortel et al. (2024)	Systematic review and meta-analysis evaluating drinking interventions to reduce VVRs in blood donors.	Synthesised evidence concerning hydration and related drinking interventions before, during, or after donation.	Variation in intervention protocols and donor populations may affect consistency and generalisability. The findings do not establish automated-device effectiveness.
10	Meher et al. (2024)	Four-arm randomised controlled trial involving 4,320 whole-blood donors, according to the supplied table, comparing preventive strategies.	The supplied summary reports VVR incidences of 2.5% in the control group and 0.9% in the combined-intervention group.	Verify the intervention arms, denominators, outcome definitions, and statistical comparisons against the original paper. The reported results concern preventive strategies, not the automated device.

Abbreviations: AMT, applied muscle tension; CI, confidence interval; VVR, vasovagal reaction.

Note: The ten publications primarily concern indirect evidence from behavioural, hydration-based, and other preventive strategies. They should not be interpreted as ten clinical evaluations of the electronic calf muscle massager-integrated donor couch. Device-specific effectiveness must be assessed separately using eligible studies that directly evaluate the technology.

3.3. Characteristics of Automated Calf Stimulation Devices

The ten-study evidence table did not provide sufficient technical or clinical information to characterise an automated calf muscle massager-integrated donor couch comprehensively. In particular, the included studies did not provide a consistent description of device specifications, stimulation cycles, pressure settings, operating duration, or the timing of stimulation relative to blood collection. An electronic calf muscle massager is conceptually intended to stimulate calf-muscle activity and may be designed to support venous return during blood donation. However, the proposed physiological mechanism should not be treated as proof of clinical effectiveness. Device-specific characteristics, including the method of stimulation, intensity, frequency, duration, safety controls, and compatibility with routine blood-collection procedures, need to be extracted from the original device publication or clinical evaluation. The current evidence table therefore does not establish whether the automated device provides a clinically meaningful advantage over a standard donor couch or donor-performed applied muscle tension.

3.4. Direct Clinical Evidence for Automated Devices

Direct clinical evidence is essential for determining whether an electronic calf muscle massager-integrated donor couch reduces vasovagal reactions (VVRs). The ten publications summarised in Table 1 primarily evaluated manual muscle tension, counterpressure manoeuvres, hydration, donor risk factors, or broader preventive practices. They do not provide a clearly identified comparative clinical estimate for the specific automated device. A related device-development publication by Kumar and Sahani (2021), titled A device to reduce vasovagal syncope in blood donors, describes an electronic calf muscle massager incorporating a programmable circuit and a pneumatic system for inflating and deflating cuffs. This publication provides relevant technical context for automated calf stimulation. However, the device description alone does not establish a reduction in VVR incidence, improved donor satisfaction, increased repeat donation, or cost-effectiveness. The available evidence must therefore be distinguished according to whether it describes device development, evaluates related preventive interventions, or directly assesses clinical effectiveness. This evidence classification and its implications for the primary research question are summarised in

Table 2. Unless comparative clinical studies provide appropriate outcome data, the effectiveness of the automated massager-integrated couch remains undetermined.

Table 2. Classification of evidence relevant to automated calf muscle stimulation for preventing vasovagal reactions in blood donors

No.	Evidence category	Relevant publication(s)	Intervention or evidence examined	Contribution to the review	Implications for device effectiveness
1	Device-development evidence	Kumar and Sahani (2021)	Electronic calf muscle massager using a programmable circuit and pneumatic cuff system	Describes the device concept and proposed mechanism of automated calf stimulation	Provides technical context but does not, from the device description alone, establish clinical effectiveness
2	Applied muscle tension	Thijssen et al. (2020); Wang et al. (2022)	Voluntary muscle contraction and implementation of applied muscle tension	Provides evidence concerning behavioural muscle-based prevention strategies	Findings cannot be directly attributed to automated calf muscle stimulation
3	Physical counterpressure manoeuvres	Williams et al. (2022)	Physical manoeuvres intended to support circulatory stability	Provides contextual evidence on non-device physical interventions	Does not establish the effectiveness of an electronic massager-integrated couch
4	Hydration and combined preventive strategies	Van Remoortel et al. (2024); Meher et al. (2024)	Drinking interventions and combinations of preventive measures	Informs the wider evidence on donor-reaction prevention	Findings apply to the interventions actually studied and cannot automatically be extrapolated to the device
5	Donor-related risk factors	Shivhare et al. (2022)	Factors associated with vasovagal reactions among blood donors	Helps contextualise donor risk and potential confounding factors	Does not directly assess device effectiveness
6	Trial-design evidence	McMahon et al. (2023)	Design of the STRIDES cluster-randomised trial	Describes the planned evaluation of preventive interventions	A trial-design publication does not provide independent evidence of completed clinical effectiveness

7	Large-scale clinical evidence for related interventions	Kaptoge et al. (2026)	Multiple preventive interventions compared with standard practice in a large cluster-randomised trial	Provides evidence on the evaluated preventive strategies in blood-donation settings	Does not establish the effectiveness of the specific automated calf muscle massager
8	Direct comparative clinical evidence for the target device	No comparative study identified in the current evidence summary	Automated calf muscle massager-integrated donor couch compared with standard care or another comparator	The current evidence summary does not provide a verifiable device-specific comparative effect estimate	Clinical effectiveness remains undetermined from the evidence summarised in this review

Abbreviations: STRIDES, the trial of preventive interventions for vasovagal reactions in whole-blood donors; VVR, vasovagal reaction.

Note: This table classifies the evidence discussed in the current manuscript. The classification should be updated if examination of the original device publication or additional eligible studies identifies direct comparative clinical outcome data.

3.5. Evidence from Related Mechanical and Behavioural Interventions

Although direct evidence for automated calf stimulation was limited in the supplied evidence table, several publications evaluated related interventions that may inform the physiological rationale for the device. Wang et al. (2022) conducted a meta-analysis of six studies examining applied muscle tension to prevent blood donation-related VVRs. The review reported a pooled relative risk of 0.52, with a 95% confidence interval of 0.40–0.67. This finding suggests a reduction in VVR risk associated with applied muscle tension in the studies included in that meta-analysis. Nevertheless, applied muscle tension performed voluntarily by donors is not equivalent to automated stimulation delivered by a device. The pooled estimate should therefore not be used as an effect estimate for the electronic massager.

Williams et al. (2022) reviewed counterpressure manoeuvres, including techniques involving leg crossing, arm tensing, and squatting. Their findings provide broader contextual evidence concerning physical manoeuvres intended to support circulatory stability. However, differences between the interventions, settings, and populations limit direct extrapolation to an automated calf stimulation system used during blood donation. Thijsen et al. (2020) examined the implementation of applied muscle tension and water loading among Australian whole-blood donors. Van Remoortel et al. (2024) subsequently assessed drinking interventions through a systematic review and meta-analysis. These publications provide contextual evidence for behavioural and hydration-based approaches to donor-reaction prevention, but they do not independently demonstrate the effectiveness of an electronic calf massager.

Meher et al. (2024) compared four preventive strategies in a randomised controlled trial involving 4,320 whole-blood donors. The supplied table reports VVR incidences of 2.5% in the control group and 0.9% in the combined-intervention group, with an overall reported incidence of 1.6%. These figures should be checked against the original publication, including the precise intervention arms, denominators, outcome definitions, and statistical comparisons, before being used to draw conclusions about individual interventions. Kaptoge et al. (2026) evaluated preventive interventions in a large cluster-randomised trial across 73 blood-donation sites in England. The supplied table reports a substantial number of donor reactions and describes interventions involving applied muscle tension and other preventive measures. Because the study evaluated a range of interventions rather than the specific automated calf massager, its findings are relevant to the broader prevention of donor-related VVRs but cannot establish device-specific effectiveness. Overall, the related-intervention literature provides a rationale for investigating calf muscle stimulation, but the results of manual, behavioural, and hydration-based interventions must remain distinct from those of automated devices.

3.6. Clinical Effectiveness Outcomes

The primary outcome of this review was the incidence of VVRs among blood donors using an electronic calf muscle massager-integrated donor couch compared with a standard donor couch or an alternative preventive intervention. Secondary outcomes included donor comfort and satisfaction, repeat-donation rates, and cost-effectiveness. The included literature addressed VVR prevention through a range of interventions, with applied muscle tension and hydration receiving particular attention. Wang et al. (2022) reported a pooled relative risk of 0.52 (95% CI: 0.40–0.67) for applied muscle tension. The supplied evidence table also reports lower VVR incidence in the combined-intervention group than in the control group in the study by Meher et al. (2024). These results concern the interventions evaluated in the respective studies and should not be interpreted as estimates of the effectiveness of an electronic massager.

For the primary device-specific outcome, the available evidence table does not provide a verifiable comparative effect estimate, confidence interval, or statistical test for automated calf stimulation. Therefore, it is not currently possible to conclude that an electronic calf muscle massager-integrated donor couch significantly reduces VVR incidence compared with a standard couch.

The secondary outcomes were also insufficiently documented in the supplied table. In particular, no verifiable comparative data were presented for donor satisfaction, comfort scores, repeat-donation rates, or incremental costs associated with the automated device. These outcomes should be reported as not established by the currently summarised evidence rather than assumed to improve following device use. Given the differences in interventions and study designs, a pooled meta-analysis of the ten publications would not be appropriate without further assessment of clinical and methodological comparability. A structured narrative synthesis is more suitable unless additional direct device studies provide sufficiently comparable outcome data.

3.7. Safety and Adverse Events

Donor safety is an important consideration when introducing an automated stimulation device into routine blood-collection practice. The supplied publications discuss VVRs, fainting, dizziness, and broader donor-safety measures. However, the evidence table does not provide a sufficiently detailed, device-specific account of adverse events associated with automated calf muscle stimulation. A complete safety assessment should examine the frequency and severity of adverse events, discomfort or pain associated with stimulation, skin irritation or pressure-related effects, interruptions to blood collection, device malfunction, and any events requiring clinical intervention. It should also determine whether the device affects routine donor monitoring or the ability of staff to respond promptly to a reaction. The absence of reported device-specific adverse events in the current evidence table should not be interpreted as evidence that the device is safe. Similarly, safety findings from manual muscle tension, hydration, or other preventive interventions cannot automatically be applied to an electronically controlled device. Device-specific safety conclusions require clinical data documenting the intervention, monitoring procedures, and adverse-event outcomes.

3.8. Risk of Bias and Certainty of Evidence

The included publications differed in design and therefore require design-appropriate critical appraisal. Observational studies, including the study by Thijsen et al. (2020) and the case-control study by Shivhare et al. (2022), may be affected by confounding, selection bias, and limitations in outcome ascertainment. Systematic reviews and meta-analyses, including those by Wang et al. (2022), Williams et al. (2022), and Van Remoortel et al. (2024), require appraisal of their search methods, eligibility criteria, study-level risk of bias, heterogeneity, and synthesis methods. The randomised controlled trial by Meher et al. (2024) requires assessment of randomisation, deviations from assigned interventions, missing outcome data, outcome measurement, and selective reporting. The large trial reported by Kaptoge et al. (2026) should be appraised with consideration of its cluster-randomised design, implementation, outcome ascertainment, and analysis. McMahon et al. (2023) describes the rationale and design of a trial and should not be treated as an independent source of completed effectiveness results. Formal risk-of-bias ratings cannot be assigned from the summary table alone. The full texts must be assessed using appropriate tools, such as RoB 2 for randomised trials and ROBINS-I for non-randomised intervention studies, where applicable. Systematic reviews should be appraised using a suitable review-level tool if their methodological quality is being evaluated.

The certainty of evidence for the primary question—whether an automated calf muscle massager-integrated donor couch reduces VVRs—cannot currently be established from the ten-study summary. The key limitation is the lack of clearly documented, direct comparative clinical evidence for the specific device. Evidence from related interventions may support the biological rationale for further investigation, but it does not substitute for direct device evaluation. In summary, the reviewed literature describes several approaches to preventing donor-related VVRs, particularly applied muscle tension and hydration. However, the clinical effectiveness, safety, acceptability, and economic value of an automated calf muscle massager-integrated donor couch remain insufficiently established by the evidence presented in the current review.

4.1. Principal Findings

This review examined the potential role of an electronic calf muscle massager-integrated donor couch in preventing vasovagal reactions (VVRs) among whole-blood donors. The principal finding is that the available evidence does not establish the clinical effectiveness of this specific automated device. Although the technology has a plausible physiological rationale, the evidence summarised in this review does not provide a reliable device-specific estimate of its effect on VVR incidence, donor comfort, repeat-donation rates, or cost-effectiveness. The included literature primarily investigated applied muscle tension, hydration, donor-related risk factors, and behavioural approaches to donor safety. Wang et al. (2022) reported a pooled relative risk of 0.52 (95% confidence interval [CI]: 0.40–0.67) for applied muscle tension, indicating a potentially beneficial effect of this intervention in the studies included in their meta-analysis. However, the large STRIDES trial reported by Kaptoge et al. (2026) found no clear benefit of four preventive interventions compared with standard practice for the primary outcome of VVR involving loss of consciousness. These findings illustrate the importance of considering differences in study design, intervention delivery, and clinical setting when interpreting preventive strategies. Kumar and Sahani (2021) described an electronic calf muscle massager incorporating a programmable circuit and a pneumatic cuff system. This work provides a technological basis for investigating automated calf stimulation, but a device-development publication does not establish clinical effectiveness. Direct comparative studies are required to determine whether the technology reduces VVR incidence beyond standard donor care.

Recent research also emphasises that VVRs are multifactorial. Risk factors include donor characteristics, donation history, and psychological factors such as fear and anxiety (France et al., 2021; Wu et al., 2025, 2026). Consequently, an intervention targeting calf-muscle activity may address only one component of the mechanisms contributing to donor reactions.

Overall, the current evidence supports further clinical investigation of automated calf stimulation rather than a definitive claim that the technology prevents VVRs.

4.2. Comparison with Existing Preventive Strategies

Existing approaches to preventing donor-related VVRs include applied muscle tension, hydration, donor education, psychological support, and appropriate monitoring during and after blood collection. These strategies differ in their mechanisms, resource requirements, and dependence on donor participation. Applied muscle tension is intended to promote venous return through voluntary muscle contraction. Wang et al. (2022) reported a pooled relative risk of 0.52 (95% CI: 0.40–0.67), while Thijssen et al. (2020) examined the implementation of applied muscle tension alongside water loading in Australian whole-blood donors. However, findings from individual studies should be interpreted alongside the broader evidence. In the STRIDES trial, modified applied muscle tension did not clearly reduce the primary outcome compared with standard practice (Kaptoge et al., 2026).

Hydration is another commonly investigated strategy. Van Remoortel et al. (2024) evaluated drinking interventions through a systematic review and meta-analysis, while Meher et al. (2024) compared several preventive strategies in a randomised controlled trial. Research from Saveetha Medical College has also examined pre-donation electrolyte solution as a potential preventive strategy among first-time blood donors (Robins et al., 2025), providing additional context for the evaluation of hydration-based interventions. More recent observational evidence from India has compared pre-donation hydration and applied muscle tension (Kandukuri et al., 2026). These findings should be interpreted in light of differences in study design, intervention protocols, and donor populations.

Automated calf stimulation differs from voluntary muscle tension because the device delivers mechanical stimulation according to a programmed protocol. This could potentially reduce the need for donors to remember and maintain muscle contractions. However, it remains uncertain whether automated stimulation produces a physiological

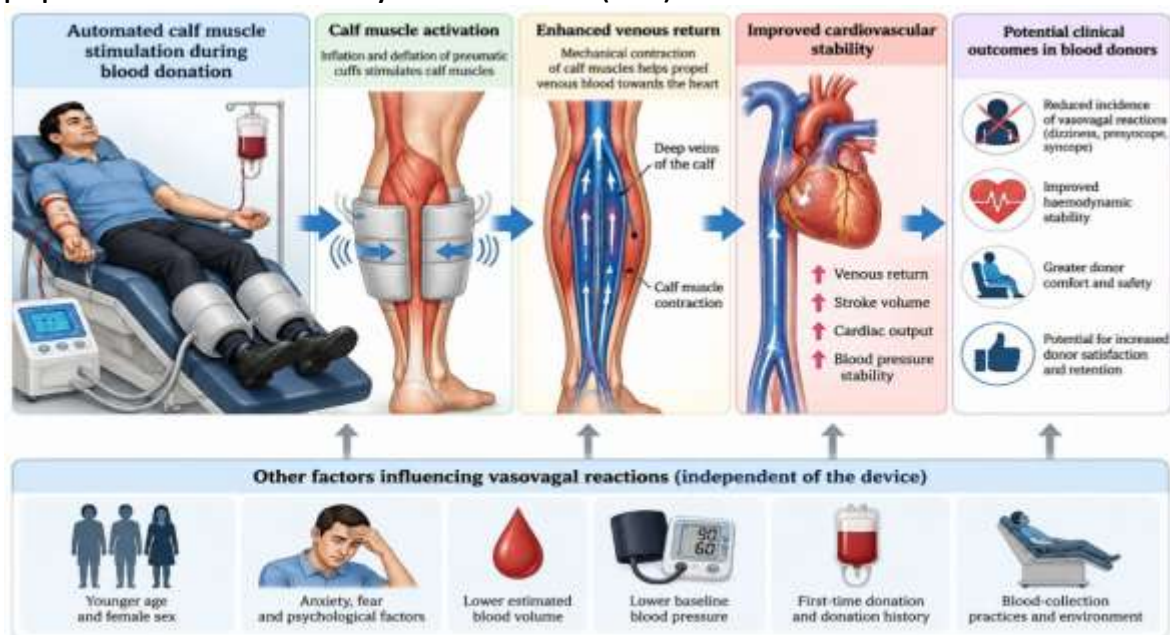
response equivalent to voluntary muscle contraction or whether any such response translates into a clinically meaningful reduction in VVRs. The device should therefore be evaluated against both standard donor care and established preventive strategies. It should not be considered superior to manual muscle tension, hydration, or other approaches until direct comparative evidence is available.

4.3. Physiological Plausibility and Proposed Mechanisms

The physiological rationale for calf muscle stimulation is based on the role of lower-limb skeletal muscles in venous return. Contraction of the calf muscles compresses veins and can facilitate blood flow towards the heart. In principle, stimulation during blood donation may help limit venous pooling and support circulatory stability. This proposed mechanism is related to the rationale underlying applied muscle tension and other physical countermeasures. However, mechanical stimulation and voluntary muscle contraction are not necessarily physiologically equivalent. The intensity of stimulation, frequency, duration, timing, and individual donor response may influence the resulting circulatory effect.

Kumar and Sahani (2021) described a device designed to stimulate the calf muscles using a programmable circuit and pneumatic cuffs. The authors proposed that the system could improve peripheral circulation and venous return while potentially reducing apprehension associated with blood donation. These proposed mechanisms provide a rationale for further evaluation but should not be interpreted as proof of clinical benefit. Vasovagal reactions (VVRs) also involve psychological and autonomic factors. France et al. (2021) reported associations between donation-related fears, VVRs, and subsequent donor attrition. Thijsen et al. (2023) found that emotional experiences at different stages of the donation appointment were associated with VVR risk among first-time donors. Wu et al. (2026) further examined the relationships among donation history, pain, anxiety, and VVR symptoms. These findings suggest that interventions targeting circulatory mechanisms may not address all factors contributing to donor reactions. Research should therefore assess both physiological responses and clinical outcomes. Measurements such as blood pressure, heart rate, reported symptoms, and objectively defined VVR events may help determine whether automated calf stimulation produces the intended physiological response and whether that response translates into meaningful clinical benefit. The proposed physiological pathway and the additional donor-related factors that may influence VVR occurrence are illustrated in Figure 2.

Figure 2. Conceptual illustration of the proposed physiological pathway linking automated calf muscle stimulation to venous return and potential clinical outcomes in blood donors. Source: Authors' own illustration, based on the proposed mechanism described by Kumar and Sahani (2021).



4.4. Clinical Implications

The findings have several implications for blood-donation services. First, an electronic calf muscle massager-integrated couch should not be introduced as a proven vasovagal reaction (VVR)-prevention technology solely on the basis of physiological plausibility or evidence supporting related interventions; adoption should be guided by direct evidence of effectiveness, safety, and acceptability. Second, the device may warrant evaluation as an adjunct to existing donor-care procedures, while standard donor assessment, appropriate monitoring, staff preparedness, donor education, and established management of adverse reactions should continue regardless of device use. Third, clinical evaluation should include donor-centred outcomes, including comfort, satisfaction, perceived anxiety, willingness to use the device again, and the overall donation experience. Research on donor experiences indicates that the emotional impact of a VVR can influence subsequent donation intentions (France et al., 2021; Thijsen et al., 2021).

Donor-centred evaluation is also important because the donation experience may influence subsequent donation behaviour. Balan et al. (2025) examined pain assessment and targeted counselling in relation to blood donor retention, providing relevant context for evaluating donor experience and retention-related outcomes. In addition, research on donor deferral patterns at a tertiary-care hospital in Chennai highlights the importance of donor assessment and blood-donation service practices (Soundharya et al., 2024). These studies provide contextual evidence for donor-centred evaluation and service delivery, although neither establishes the effectiveness of automated calf muscle stimulation.

Fourth, implementation should be assessed in relation to routine blood-collection workflows, ensuring that the device does not interfere with venepuncture, donor positioning, clinical observation, staff access, or emergency response. Cleaning, disinfection, maintenance, and staff training should also be incorporated into the implementation plan. Finally, claims regarding repeat donation and cost-effectiveness require longitudinal and economic data. Although reducing adverse experiences could plausibly support donor retention, this relationship should not be assumed to result from device use. Repeat-donation outcomes should be measured directly, and cost-effectiveness should be evaluated using actual equipment, maintenance, staffing, and clinical-outcome data.

4.5. Implementation Challenges

Several challenges may affect the translation of an automated calf muscle massager-integrated couch into routine practice. Technical standardisation is essential, as the stimulation mechanism, intensity, frequency, duration, and operating cycle must be clearly defined to support reproducibility, comparisons between centres, and assessment of dose-response relationships. Safety and tolerability should be evaluated by recording discomfort, pain, skin irritation, pressure-related effects, adverse events, and technical failures, with clear procedures specifying when stimulation should be reduced or discontinued. Safety cannot be inferred from the absence of adverse-event reporting in a device-development publication.

Workflow integration requires ensuring that the system does not disrupt routine blood collection, donor monitoring, or staff access to the donor. Staff should be trained to operate the device, respond to discomfort or developing reactions, and follow established procedures for stopping stimulation. A conceptual illustration of the proposed integration of automated calf muscle stimulation into the blood-donation workflow, including device positioning, blood collection, donor monitoring, and post-donation care, is presented in Figure 3. The practical integration of additional technologies should also account for the efficiency of existing blood-donation workflows. Robins et al. (2026) investigated Lean Six Sigma methodologies to improve operations in a tertiary-care blood-donor area. Although this study did not evaluate an automated calf muscle massager, it provides relevant context for considering workflow efficiency and operational feasibility when introducing additional equipment.

Donor acceptability is another important consideration, as preferences regarding mechanical stimulation may vary. Clear communication about the device's purpose, operation, and current evidence is necessary, and donors should be able to decline its use without affecting their access to standard donation services. Cost and maintenance considerations include equipment procurement, integration with donor couches, servicing, replacement components, cleaning, and staff training. These costs should be evaluated against demonstrated clinical or operational benefits rather than presumed reductions in vasovagal reactions (VVRs).

Furthermore, a nationwide survey of Indian blood centres reported variation in the implementation of VVR-mitigation strategies, including hydration, applied muscle tension, and psychological support (Meher & Patidar, 2026), highlighting the importance of standardised procedures and staff training when evaluating additional

technologies. Clinical and regulatory evaluation is also necessary, with appropriate technical validation and clinical assessment conducted before routine implementation. Applicable regulatory requirements will depend on the device's intended use and jurisdiction, and decisions regarding wider adoption should be guided by evidence of reliable performance, safety, and effectiveness. Addressing these challenges will require collaboration among transfusion specialists, biomedical engineers, clinical researchers, blood-service managers, and device developers.

Figure 3. Conceptual illustration of the proposed clinical implementation of an automated calf muscle massager-integrated donor couch during blood donation



The illustration depicts donor preparation, calf-cuff positioning, device control, routine blood collection, donor monitoring, and post-donation care. The arrangement is illustrative and does not represent a validated clinical configuration or establish the safety or effectiveness of the device. Source: Authors' own illustration, developed with reference to the device concept described by Kumar and Sahani (2021).

4.6. Strengths and Limitations of the Review

A principal strength of this review is its focus on a specific technological approach to VVR prevention. By distinguishing automated calf stimulation from voluntary applied muscle tension, hydration, and other preventive strategies, the review highlights an important evidence gap. It also considers clinical outcomes alongside donor comfort, satisfaction, repeat donation, safety, and cost-effectiveness. The discussion incorporates evidence from observational studies, randomised trials, systematic reviews, and research on donor experiences. This broader perspective helps contextualise the potential role of an automated device within the multifactorial nature of donor-related VVRs.

Several limitations must be acknowledged. First, the included publications differ in design, intervention, population, and outcome measurement. Their findings cannot be treated as equivalent evidence of effectiveness. In particular, findings from manual muscle tension or hydration studies cannot establish the effectiveness of an automated massager. Second, the available evidence table does not provide sufficient direct comparative data to estimate the effect of the specific device on VVR incidence. Similarly, device-specific safety, comfort, repeat-donation, and cost-effectiveness outcomes remain inadequately documented. Third, donor-related VVRs are influenced by several factors, including age, donation history, body size, and psychological responses. These factors may affect both the incidence of reactions and the apparent effectiveness of preventive strategies (Wu et al., 2025, 2026). Future clinical evaluations should therefore consider relevant donor characteristics and potential confounding factors. Fourth, the

study-selection process and eligibility criteria must be consistent and reproducible. The publication period stated in the methods should match the period used in the PRISMA flow diagram, and the final screening counts should be traceable to the original search records. Reporting should follow PRISMA 2020 guidance (Page et al., 2021). Finally, formal risk-of-bias assessment and certainty-of-evidence evaluation must be completed using appropriate methods before definitive conclusions are drawn. The absence of direct evidence should be interpreted as uncertainty about device effectiveness rather than proof that the device is ineffective or unsafe.

4.7. Research Priorities

Future research should prioritise the direct clinical evaluation of automated calf muscle stimulation in blood donors. First, prospective comparative studies should evaluate the device against standard donor care, with randomised controlled trials using clearly defined eligibility criteria, appropriate sample sizes, prespecified outcomes, and transparent reporting wherever feasible. A separate comparison with donor-performed applied muscle tension would help determine whether automation provides additional benefits. Second, vasovagal reaction (VVR) outcomes should be defined consistently, distinguishing mild symptoms, such as dizziness and nausea, from more severe events, including loss of consciousness, and reporting event rates, absolute differences, relative effects, confidence intervals, and monitoring periods. Third, device parameters, including the stimulation mechanism, intensity, frequency, duration, timing, and adherence to the protocol, should be documented systematically, while feasibility studies should establish tolerability and operational reliability before larger effectiveness trials. Fourth, safety should be a prespecified outcome, with systematic recording of adverse events, discomfort, device malfunctions, reasons for discontinuing stimulation, and any effects on routine blood-collection procedures. Fifth, donor-centred outcomes should be assessed using structured measures of comfort, satisfaction, anxiety, willingness to use the device again, and subsequent donation behaviour. Longitudinal follow-up is necessary to determine whether improvements in the donation experience translate into increased repeat-donation rates. Sixth, economic evaluations should assess equipment acquisition, integration, maintenance, staff time, and the costs associated with donor reactions, with cost-effectiveness claims based on observed clinical and resource-use data. Finally, future studies should consider donor characteristics and psychological factors that may influence VVR risk.

Recent research on risk prediction and donor characteristics suggests the potential value of identifying higher-risk donors and tailoring preventive strategies (Hato et al., 2026; Solanki et al., 2026); however, risk prediction and targeted prevention should be evaluated separately from the effectiveness of the automated device itself. Overall, automated calf muscle stimulation represents a plausible technological approach that merits further investigation, but its effectiveness, safety, acceptability, and economic value remain insufficiently established. Rigorous comparative clinical studies are therefore needed before the technology can be recommended as a routine strategy for preventing donor-related VVRs.

5. Conclusion

This review examined the potential role of an electronic calf muscle massager-integrated donor couch in preventing vasovagal reactions (VVRs) among whole-blood donors. The available literature supports the investigation of preventive strategies, including applied muscle tension, hydration, and other donor-care interventions. However, evidence supporting these approaches cannot be directly extrapolated to automated calf muscle stimulation. Although the device has a plausible physiological rationale for supporting venous return, its clinical effectiveness, safety, and practical advantages remain insufficiently established. Furthermore, the available evidence does not demonstrate that the device improves donor comfort, satisfaction, repeat-donation rates, or cost-effectiveness. Future research should prioritise well-designed comparative clinical trials evaluating device-specific outcomes, adverse events, donor acceptability, and relevant physiological responses. Economic evaluations and longer-term follow-up are also needed to determine its potential contribution to donor retention and blood-donation service efficiency. Until robust clinical evidence becomes available, the electronic calf muscle massager-integrated donor couch should be considered an investigational adjunct rather than an established preventive intervention. Its adoption into routine blood-donation practice should be guided by evidence of safety, effectiveness, and feasibility.

Acknowledgements

The authors sincerely acknowledge the Department of Transfusion Medicine and Helix Research Studio from Saveetha Medical College and Hospital (SMCH), Saveetha Institute of Basic Medical Sciences (SIBMS) and Saveetha

Institute of Medical and Technical Sciences (SIMATS), Chennai, Tamil Nadu, India, for providing the institutional support and facilities necessary to conduct this retrospective study on therapeutic phlebotomy.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Amrein, K., Valentin, A., Lanzer, G., & Drexler, C. (2012). Adverse events and safety issues in blood donation—A comprehensive review. *Blood Reviews*, 26(1), 33–42. <https://doi.org/10.1016/j.blre.2011.09.003>
2. Balan, A., Sriraman, P., Kumar, S., Hari Haran, & Sahayaraj, J. (2025). The impact of pain scales and targeted counselling on blood donor retention: A randomized control trial. *Asian Journal of Transfusion Science*. Advance online publication. https://doi.org/10.4103/ajts.ajts_246_25
3. Cheung, C. H. Y. (2021). Prevention of vasovagal reactions in blood donors [Doctoral dissertation, The Hong Kong Polytechnic University]. PolyU Institutional Research Archive. <http://hdl.handle.net/10397/91866>
4. France, C. R., France, J. L., Himawan, L. K., Lux, P., & McCullough, J. (2021). Donation related fears predict vasovagal reactions and donor attrition among high school donors. *Transfusion*, 61(1), 102–107. <https://doi.org/10.1111/trf.16099>
5. Hato, T., Shimada, N., Yamamoto, M., Koyama, M., Uematsu, N., Nakata, Y., & Fukuhara, C. (2026). Risk of vasovagal reactions in sleep-deprived and fasting blood donors. *Vox Sanguinis*, 121(2), 124–131. <https://doi.org/10.1111/vox.70149>
6. Higgins, J. P. T., Thomas, J., Chandler, J., Cumpston, M., Li, T., Page, M. J., & Welch, V. A. (Eds.). (2024). *Cochrane handbook for systematic reviews of interventions (Version 6.5)*. Cochrane. <https://training.cochrane.org/handbook>
7. Kandukuri, M. K., Ramini, S., & Vujhini, S. K. (2026). Comparative effects of pre-donation hydration and applied muscle tension on vasovagal reactions in blood donors: Original article. *Transfusion Clinique et Biologique*, 33(3), 152–157. <https://doi.org/10.1016/j.tracli.2026.05.001>
8. Kaptoge, S., McMahon, A., Wu, Y., Gilchrist, P. T., Walker, M., Mehenny, S., Akhtar, N., Wood, A. M., Cullen, D., Godfrey, R., Allen, L., Bradley, J. R., Kingston, N., Washington, C., Mifflin, G., Armitage, J., Roberts, D. J., Danesh, J., Di Angelantonio, E., & STRIDES Trial Group. (2026). Preventive interventions for vasovagal reactions in whole blood donors: A cluster-randomised, stepped-wedge, crossover trial of 73 sites involving 1.4 million donors in England. *The Lancet Haematology*, 13(2), e64–e73. [https://doi.org/10.1016/S2352-3026\(25\)00319-9](https://doi.org/10.1016/S2352-3026(25)00319-9)
9. Kumar, R., & Sahani, A. K. (2021). A device to reduce vasovagal syncope in blood donors. In 2021 43rd Annual International Conference of the IEEE Engineering in Medicine & Biology Society (EMBC) (pp. 2136–2139). IEEE. <https://doi.org/10.1109/EMBC46164.2021.9630891>
10. McMahon, A., Kaptoge, S., Walker, M., Mehenny, S., Gilchrist, P. T., Sambrook, J., Akhtar, N., Sweeting, M., Wood, A. M., Stirrups, K., Chung, R., Fahle, S., Johnson, E., Cullen, D., Godfrey, R., Duthie, S., Allen, L., Harvey, P., Berkson, M., . . . Di Angelantonio, E. (2023). Evaluation of interventions to prevent vasovagal reactions among whole blood donors: Rationale and design of a large cluster randomised trial. *Trials*, 24, Article 512. <https://doi.org/10.1186/s13063-023-07473-z>
11. Meher, R., & Patidar, G. K. (2026). Assessment of vasovagal reaction mitigation strategies in licensed blood centres in India (2025): A nationwide online survey. *Vox Sanguinis*, 121(5), 555–561. <https://doi.org/10.1111/vox.70197>
12. Meher, R., Patidar, G. K., Chaurasia, R., Pandey, H. C., & Hazarika, A. (2024). Prevention strategies for vasovagal reaction in whole blood donors: A quadri-armed randomised control trial. *Transfusion Medicine*, 34(1), 20–29. <https://doi.org/10.1111/tme.13026>
13. Meher, R., Patidar, G. K., Chaurasia, R., Pandey, H. C., & Hazarika, A. (2024). Prevention strategies for vasovagal reaction in whole blood donors: A quadri-armed randomised control trial. *Transfusion Medicine*, 34(1), 20–29. <https://doi.org/10.1111/tme.13026>

14. Morand, C., Coudurier, N., Rolland, C., Thoret, S., Legrand, D., Tiberghien, P., & Bosson, J.-L. (2016). Prevention of syncopal-type reactions after whole blood donation: A cluster-randomized trial assessing hydration and muscle tension exercise. *Transfusion*, 56(10), 2412–2421. <https://doi.org/10.1111/trf.13716>
15. Mukherjee, S., Bose, A., Sahu, A., Mishra, D., & Prakash, S. (2025). The impact of isotonic applied muscle tension in reducing the vasovagal event in first-time blood donors: A cohort study. *Transfusion Clinique et Biologique*, 32(2), 153–158. <https://doi.org/10.1016/j.tracli.2025.02.006>
16. Newman, B. H. (2004). Whole-blood donation: Blood donor suitability and adverse events. *Current Hematology Reports*, 3(6), 437–443.
17. Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., Shamseer, L., Tetzlaff, J. M., Akl, E. A., Brennan, S. E., Chou, R., Glanville, J., Grimshaw, J. M., Hróbjartsson, A., Lalu, M. M., Li, T., Loder, E. W., Mayo-Wilson, E., McDonald, S., . . . Moher, D. (2021). The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. *BMJ*, 372, Article n71. <https://doi.org/10.1136/bmj.n71>
18. Rethlefsen, M. L., Kirtley, S., Waffenschmidt, S., Ayala, A. P., Moher, D., Page, M. J., Koffel, J. B., & PRISMA-S Group. (2021). PRISMA-S: An extension to the PRISMA Statement for reporting literature searches in systematic reviews. *Systematic Reviews*, 10, Article 39. <https://doi.org/10.1186/s13643-020-01542-z>
19. Robins, R. D. L., Hari Haran, Sriraman Punniakoti, S., Kumar, S., & James, S. (2026). Enhancing blood centre operations through Lean Six Sigma methodologies: A prospective interventional study in the blood donor area of a tertiary care blood centre. *Transfusion Clinique et Biologique*, 33(1), 3–9. <https://doi.org/10.1016/j.tracli.2025.10.001>
20. Robins, R. D. L., Sriraman, S., Kumar, S., Hariharan, H., James, S., & Abhinaya, M. (2025). Assessing the efficacy of electrolyte solution as pre-donation therapy in preventing vasovagal reactions among first time blood donors. *TPM – Testing, Psychometrics, Methodology in Applied Psychology*, 32(S1), 333–339. <https://tpmap.org/submission/index.php/tpm/article/view/173>
21. Shivhare, A., Basavarajegowda, A., Harichandrakumar, K. T., Silwal, P., & Raj, P. (2022). Factors associated with vasovagal reactions in whole blood donors: A case-control study. *Asian Journal of Transfusion Science*, 16(1), 41–49. https://doi.org/10.4103/ajts.ajts_90_21
22. Singh, A. P., Saxena, R., & Saxena, S. (2022). Protocols for blood collection in a blood bank. *Journal of Medicine and Health Research*, 7(2), 16–21. <https://doi.org/10.56557/JOMAH/2022/v7i27829>
23. Solanki, A., Singh, A., Sonker, A., & Agarwal, P. (2026). Identifying risk factors and donor characteristics for vasovagal reactions in whole blood donation: Insights and safety recommendations from a northern Indian study. *Asian Journal of Transfusion Science*, 20(1), 126–131. https://doi.org/10.4103/ajts.ajts_101_25
24. Soundharya, V., Arthi, R., Hari Haran, A., Suresh Kumar, I., & Sahayaraj James. (2024). Analysis of blood donor deferral pattern at a tertiary care hospital in Chennai: A cross-sectional retrospective study. *Cureus*, 16(8), Article e67541. <https://doi.org/10.7759/cureus.67541>
25. Sterne, J. A. C., Hernán, M. A., Reeves, B. C., Savović, J., Berkman, N. D., Viswanathan, M., Henry, D., Altman, D. G., Ansari, M. T., Boutron, I., Carpenter, J. R., Chan, A.-W., Churchill, R., Deeks, J. J., Hróbjartsson, A., Kirkham, J., Jüni, P., Loke, Y. K., Pigott, T. D., . . . Higgins, J. P. T. (2016). ROBINS-I: A tool for assessing risk of bias in non-randomised studies of interventions. *BMJ*, 355, Article i4919. <https://doi.org/10.1136/bmj.i4919>
26. Sterne, J. A. C., Savović, J., Page, M. J., Elbers, R. G., Blencowe, N. S., Boutron, I., Cates, C. J., Cheng, H.-Y., Corbett, M. S., Eldridge, S. M., Emberson, J. R., Hernán, M. A., Hopewell, S., Hróbjartsson, A., Junqueira, D. R., Jüni, P., Kirkham, J. J., Lasserson, T., Li, T., . . . Higgins, J. P. T. (2019). RoB 2: A revised tool for assessing risk of bias in randomised trials. *BMJ*, 366, Article l4898. <https://doi.org/10.1136/bmj.l4898>
27. Thijsen, A., & Masser, B. (2019). Vasovagal reactions in blood donors: Risks, prevention and management. *Transfusion Medicine*, 29(Suppl. 1), 13–22. <https://doi.org/10.1111/tme.12488>
28. Thijsen, A., Masser, B., & Davison, T. E. (2020). Reduced risk of vasovagal reactions in Australian whole blood donors after national implementation of applied muscle tension and water loading. *Transfusion*, 60(5), 918–921. <https://doi.org/10.1111/trf.15701>
29. Thijsen, A., Masser, B., Davison, T. E., van Dongen, A., & Williams, L. A. (2023). Beyond fear: A longitudinal investigation of emotions and risk of a vasovagal reaction in first-time whole-blood donors. *Transfusion*, 63(1), 163–170. <https://doi.org/10.1111/trf.17169>

30. Thijsen, A., Thorpe, R., Davison, T. E., Nguyen, L., & Masser, B. (2021). The vasovagal reaction experience among blood donors: A qualitative study of factors that affect donor return. *Social Science & Medicine*, 282, Article 114142. <https://doi.org/10.1016/j.socscimed.2021.114142>
31. Van Remoortel, H., Van de Sande, D., Maes, D., Khoudary, J., Tavernier, V., Tiberghien, P., De Buck, E., & Compennolle, V. (2024). The efficacy and effectiveness of drinking interventions to reduce vasovagal reactions in blood donors: A systematic review and meta-analysis. *Vox Sanguinis*, 119(11), 1129–1140. <https://doi.org/10.1111/vox.13724>
32. Wang, C., Chen, L., Sun, C., Zhang, Y., Cao, C., Ma, Y., & Shi, W. (2022). Prevention of blood donation-related vasovagal response by applied muscle tension: A meta-analysis. *Journal of International Medical Research*, 50(9), Article 03000605221121958. <https://doi.org/10.1177/03000605221121958>
33. Williams, E. L., Khan, F. M., & Claydon, V. E. (2022). Counter pressure maneuvers for syncope prevention: A semi-systematic review and meta-analysis. *Frontiers in Cardiovascular Medicine*, 9, Article 1016420. <https://doi.org/10.3389/fcvm.2022.1016420>
34. Wu, Y., Di Angelantonio, E., Kaptoge, S., Wood, A. M., Gilchrist, P. T., Walker, M., Kingston, N., Masser, B., Roberts, D., Ferguson, E., & Kim, L. G. (2026). Role of pain and anxiety in mediating relationships between donation history and vasovagal reaction symptoms in blood donors in England. *Transfusion*, 66(1), 131–145. <https://doi.org/10.1111/trf.70004>
35. Wu, Y., Qi, H., Di Angelantonio, E., Kaptoge, S., Wood, A. M., & Kim, L. G. (2025). Risk factors for vasovagal reactions in blood donors: A systematic review and meta-analysis. *Transfusion*, 65(1), 211–223. <https://doi.org/10.1111/trf.18078>