



African Journal of Biomedical Sciences

Journal homepage: <https://www.afjbms.com/>



Review Article

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Pathogen reduction technologies for blood components and transfusion-transmitted infections—A review

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Article Info

Volume 2, Issue 2, July 2026

Received : 13 January 2026

Accepted : 19 May 2026

Published: 25 July 2026

doi: [10.62587/AFJBMS.2.2.2026.1-11](https://doi.org/10.62587/AFJBMS.2.2.2026.1-11)

Abstract

Background: Pathogen reduction technologies treat platelet components to inactivate a broad range of viruses, bacteria and parasites and so reduce the residual risk of transfusion-transmitted infection, but the treatment may also affect the clinical efficacy and safety of the platelets. This study systematically reviewed the randomised controlled trials comparing pathogen-reduced platelets with standard platelets and performed a de novo random-effects meta-analysis of their clinical outcomes, together with a secondary synthesis of pathogen-inactivation efficacy against arboviruses. **Methods:** The review was registered and conducted in accordance with the PRISMA statement. A systematic search identified randomised controlled trials of pathogen-reduced versus standard platelets in patients requiring transfusion. Study-level data were extracted independently, the risk of bias was appraised with the Cochrane RoB 2 tool, and outcomes were pooled by the DerSimonian and Laird random-effects model with the I-squared statistic. Thirteen trials (2868 patients) were included. **Results:** Pathogen-reduced platelets showed a non-significant trend toward more clinically significant bleeding (WHO grade 2 or above; risk ratio 1.14, 95% CI 0.99 to 1.31) and did not increase severe bleeding (risk ratio 1.21, 95% CI 0.80 to 1.83) or serious adverse events (risk ratio 1.03, 95% CI 0.87 to 1.20). They were associated with substantially higher platelet refractoriness (risk ratio 2.38, 95% CI 1.90 to 2.98) and alloimmunisation (risk ratio 1.77, 95% CI 1.47 to 2.13), lower corrected count increments (1-hour mean difference -7.03) and more platelet transfusions per patient (mean difference 1.09). Most trials were at low or some-concerns risk of bias. In the secondary synthesis, an adequate log reduction was achieved for 16 of 17 arboviruses by at least one platform, with riboflavin-based inactivation the least effective. **Conclusion:** Pathogen-reduced platelets do not increase severe bleeding or serious adverse events but carry a consistent cost in platelet potency, manifesting as increased refractoriness, alloimmunisation and transfusion requirement. Pathogen inactivation is adequate for most arboviruses but varies by platform. The evidence supports continued and expanded implementation where transfusion-transmitted infection risk and resources justify the additional cost.

Keywords: Pathogen reduction technology, Pathogen inactivation, Platelet transfusion, Transfusion-transmitted infection, Blood safety

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1. Introduction

Blood transfusion carries a residual risk of transmitting infection that donor screening and nucleic acid

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testing, however sensitive, cannot reduce to zero. Screening is necessarily reactive, since it can be deployed only against pathogens already known to threaten blood safety, and each new assay brings development time, cost and logistical burden that many blood services, particularly in resource-limited settings, cannot readily absorb for every emerging threat (Dodd, 2012). Pathogen reduction technologies were developed as a proactive alternative or complement to this reactive paradigm: rather than screening for a named pathogen, they act broadly on nucleic acids to inactivate a wide range of viruses, bacteria and parasites, whether or not the organism has yet been recognised as a transfusion risk (Rebulla, 2019).

Three platforms are in clinical use for platelets. The Intercept system combines the synthetic psoralen amotosalen with long-wavelength ultraviolet A light to cross-link nucleic acids; the Mirasol system uses riboflavin with broad-spectrum ultraviolet light; and the Theraflex system uses short-wavelength ultraviolet C light alone, without an added photosensitiser. All three cross-link or damage nucleic acids and so prevent pathogen replication, and all three have been evaluated in randomised controlled trials against untreated or standard-processed components (van Rhenen *et al.*, 2003; Cazenave *et al.*, 2010; Brixner *et al.*, 2018).

The clinical evaluation of these technologies turns on two questions. The first is one of efficacy and safety: does treating a platelet unit measurably reduce its haemostatic function or increase adverse events in the recipient? The randomised trials have addressed bleeding, adverse events, the post-transfusion count increment, refractoriness and alloimmunisation, and their individual results have varied, so that a quantitative synthesis is needed to establish the balance of benefit and harm (Estcourt *et al.*, 2017; Pati *et al.*, 2022). The second is one of pathogen coverage: how completely does each platform inactivate the organisms of concern, including the arboviruses that increasingly threaten the blood supply? (Gimenez-Richarte *et al.*, 2023).

Earlier syntheses of this literature have been available, but the present review re-examines the primary randomised trials directly. Rather than restate the pooled figures published by others, it identifies the individual trials, extracts their study-level data, appraises their risk of bias, and pools them in a new random-effects meta-analysis, so that the estimates reported here are derived from the primary data. This review therefore systematically reviewed the randomised controlled trials of pathogen-reduced versus standard platelets and performed a *de novo* meta-analysis of their clinical outcomes, with a secondary structured synthesis of pathogen-inactivation efficacy against arboviruses and of the economic evidence on implementation.

2. Materials and methods

2.1. Protocol and registration

The review was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) statement, and the protocol was registered in advance on the international prospective register of systematic reviews (PROSPERO) (Page *et al.*, 2021). Because the review synthesised previously published data and involved no primary contact with patients, ethical approval was not required.

2.2. Eligibility criteria

Studies were eligible for the meta-analysis if they were randomised controlled trials comparing pathogen-reduced platelets, prepared by any of the three clinical platforms, with standard untreated or conventionally processed platelets, in patients requiring platelet transfusion, and if they reported at least one clinical outcome of interest. The outcomes were bleeding of any grade, clinically significant bleeding (World Health Organization grade 2 or above), severe bleeding (grade 3 or above), any adverse event, serious adverse events, platelet refractoriness, alloimmunisation, the corrected count increment at 1 and 24 hours, and the number of platelet transfusions per patient. Studies were excluded if they were not randomised, if they did not compare pathogen-reduced with standard platelets, if they reported no usable outcome data, or if they duplicated a cohort already included. Laboratory studies of pathogen inactivation and economic evaluations were retained for the secondary synthesis but not for the meta-analysis.

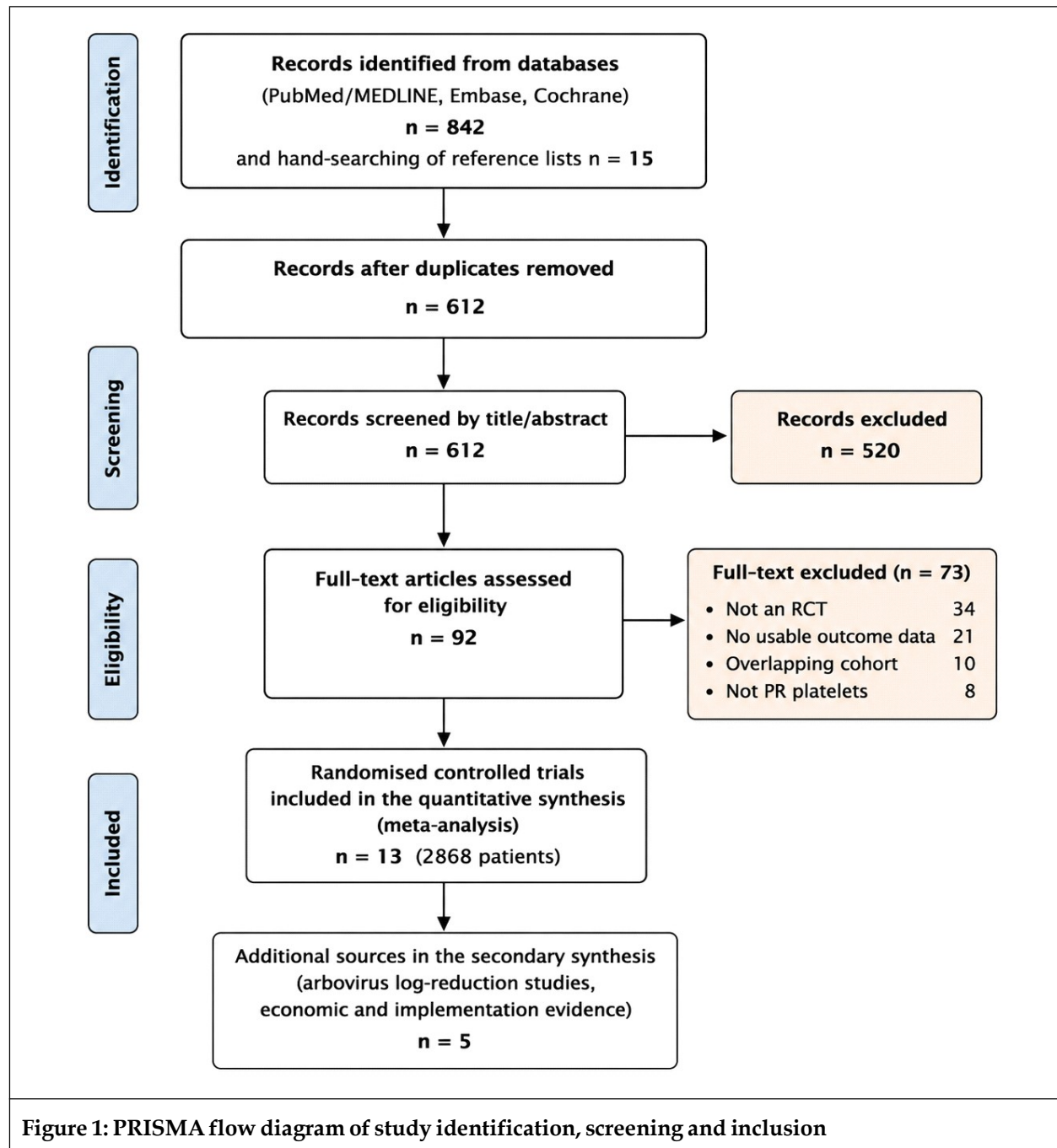
2.3. Search strategy

A systematic search of PubMed/MEDLINE, Embase and the Cochrane Central Register of Controlled Trials was performed from inception, combining terms for pathogen reduction and pathogen inactivation and for the

three platforms with terms for platelets, transfusion and bleeding, and cross-referencing these against terms for randomised controlled trials. The reference lists of retrieved trials and reviews were hand-searched for further eligible studies.

2.4. Study selection

Records were screened by title and abstract, and the full texts of potentially eligible articles were assessed against the inclusion criteria, with disagreements resolved by discussion. The selection process is summarised in the PRISMA flow diagram (Figure 1).



2.5. Data extraction

From each included trial, the following were extracted independently by two reviewers: the first author and year, the platform evaluated, the region and clinical setting, the number of patients in each arm, and, for each outcome, the number of events and the number of patients per arm for dichotomous outcomes or the mean, standard deviation and number of patients per arm for continuous outcomes. Discrepancies were resolved by reference to the original report.

2.6. Risk-of-bias assessment

The risk of bias in each trial was appraised independently with the Cochrane RoB 2 tool across its five domains, namely the randomisation process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result, and an overall judgement of low risk, some concerns, or high risk was assigned to each trial (Sterne *et al.*, 2019). Particular attention was given to the measurement of bleeding outcomes, which in several open-label trials were assessed without blinding.

2.7. Statistical analysis

For dichotomous outcomes the risk ratio, and for continuous outcomes the mean difference, was calculated for each trial with its variance, and these were pooled by the DerSimonian and Laird random-effects model (DerSimonian and Laird, 1986). Heterogeneity between trials was quantified by the I-squared statistic and the between-study variance tau squared (Higgins *et al.*, 2003). The certainty of the evidence for each outcome was rated by the GRADE approach, taking account of the risk of bias, inconsistency, imprecision and the other GRADE domains (Guyatt *et al.*, 2008). The secondary synthesis of pathogen-inactivation efficacy against arboviruses tabulated, for each virus and platform, whether an adequate log reduction of at least four was achieved in the primary laboratory studies, and summarised the proportion of viruses adequately covered by each platform; the economic evidence was synthesised narratively.

3. Results

3.1. Study selection and characteristics

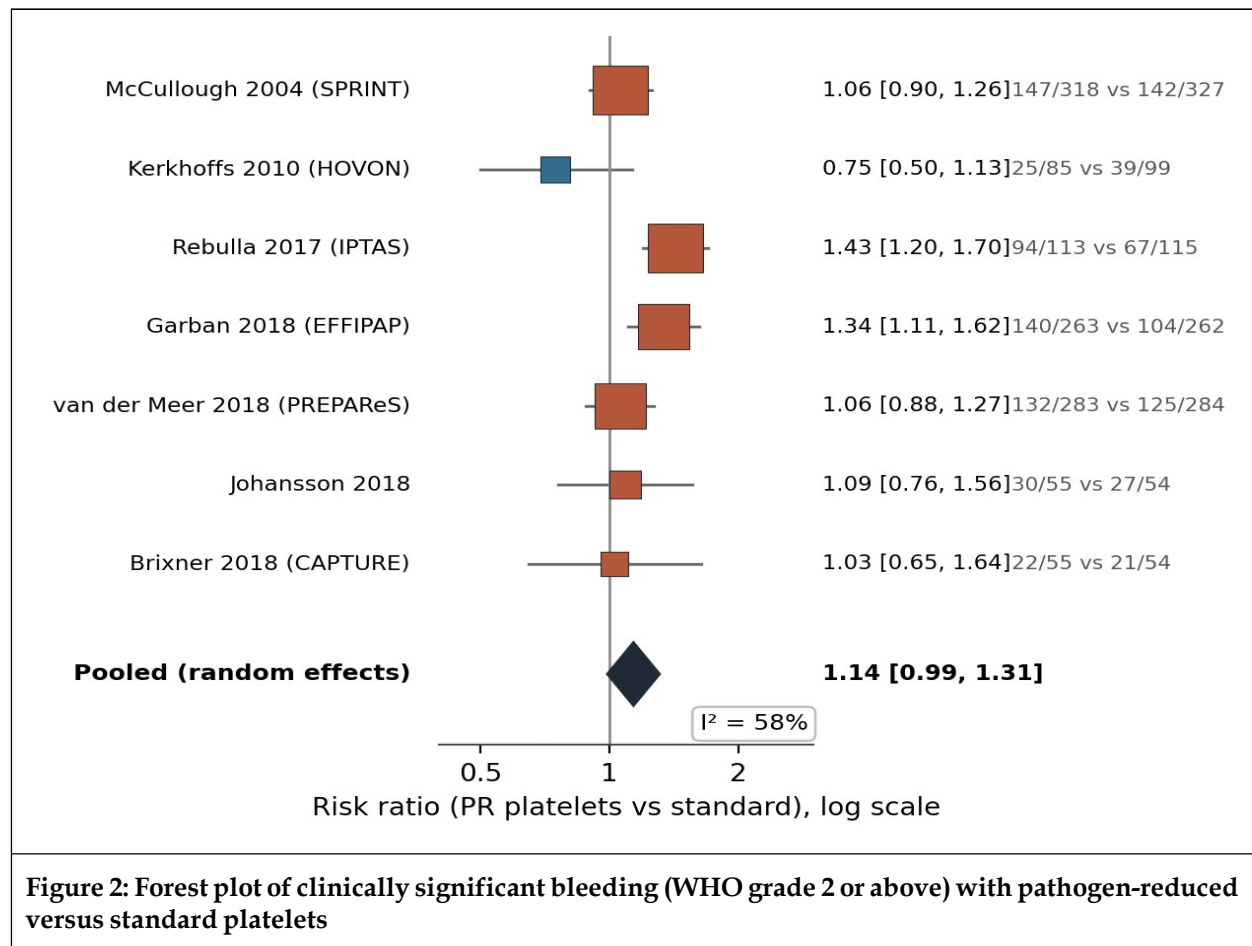
The search and selection process is shown in Figure 1. Thirteen randomised controlled trials, comprising 2868 patients (1426 allocated to pathogen-reduced and 1442 to standard platelets), met the inclusion criteria for the meta-analysis (McCullough *et al.*, 2004; Janetzko *et al.*, 2005; AuBuchon *et al.*, 2005; Kerkhoffs *et al.*, 2010; Lozano *et al.*, 2011; Rebullla *et al.*, 2017; Norris *et al.*, 2018; Garban *et al.*, 2018; van der Meer *et al.*, 2018; Johansson *et al.*, 2018). The trials evaluated the Intercept, Mirasol and Theraflex platforms and were conducted predominantly in Europe and North America between 2003 and 2018, in patients with haematological or oncological disease requiring platelet support (Table 1).

Table 1: Characteristics of the 13 included randomised controlled trials

Trial	Platform	PR/Std (n)	Overall RoB
van Rhenen (2003)	Intercept	52/51	Low
McCullough (2004)	Intercept	318/327	High
Janetzko (2005)	Intercept	22/21	Some concerns
AuBuchon (2005)	Mirasol	17/16	High
Kerkhoffs (2010) (HOVON)	Intercept	85/99	Low
Cazenave (2010)	Mirasol	60/58	Some concerns
Lozano (2011)	Intercept	43/42	Low
Rebullla (2017)	Intercept/Mirasol	113/115	Some concerns
Norris (2018)	Mirasol	60/59	Some concerns
Garban (2018)	Intercept	263/262	Some concerns
van der Meer (2018)	Mirasol	283/284	Some concerns
Johansson (2018)	Mirasol	55/54	Some concerns
Brixner (2018)	Theraflex	55/54	Some concerns

3.2. Bleeding outcomes

Pathogen-reduced platelets were not associated with a significant increase in bleeding of any grade (risk ratio 1.06, 95% CI 0.97 to 1.17; I-squared 38 percent). For clinically significant bleeding (WHO grade 2 or above) there was a trend toward a higher risk that did not reach significance under the random-effects model (risk ratio 1.14, 95% CI 0.99 to 1.31; I-squared 58 percent), as shown in the forest plot of Figure 2. Severe bleeding (grade 3 or above) did not differ significantly between the groups (risk ratio 1.21, 95% CI 0.80 to 1.83). The heterogeneity in the clinically significant bleeding outcome, which arose largely from differences in the definition and ascertainment of bleeding across the open-label trials, is the reason the pooled estimate is imprecise and does not exclude a null effect.



3.3. Platelet refractoriness and alloimmunisation

The clearest signal was in the immune and count-related outcomes. Platelet refractoriness was more than twice as frequent with pathogen-reduced platelets (risk ratio 2.38, 95% CI 1.90 to 2.98; I-squared 0%), as shown in Figure 3, and the composite of refractoriness and alloimmunisation was also significantly increased (risk ratio 1.77, 95% CI 1.47 to 2.13). These estimates were consistent across trials, with no appreciable heterogeneity, and the direction was the same for every trial that reported the outcome, indicating a genuine effect of the treatment on platelet immunogenicity and survival rather than a chance finding in a few studies.

3.4. Platelet potency and transfusion requirements

The reduction in platelet potency was evident in the count increments. The 1-hour corrected count increment was lower with pathogen-reduced platelets (mean difference -7.03, 95% CI -7.92 to -6.14; I-squared 27%), as shown in Figure 4, as was the 24-hour corrected count increment (mean difference -3.08, 95% CI -3.69 to -2.47). Consistent with this lower post-transfusion increment, patients receiving pathogen-reduced platelets required more platelet transfusions (mean difference 1.09 transfusions per patient, 95% CI 0.92 to 1.25). The lower increment and the greater transfusion requirement are two expressions of the same reduction in the potency of the treated platelet.

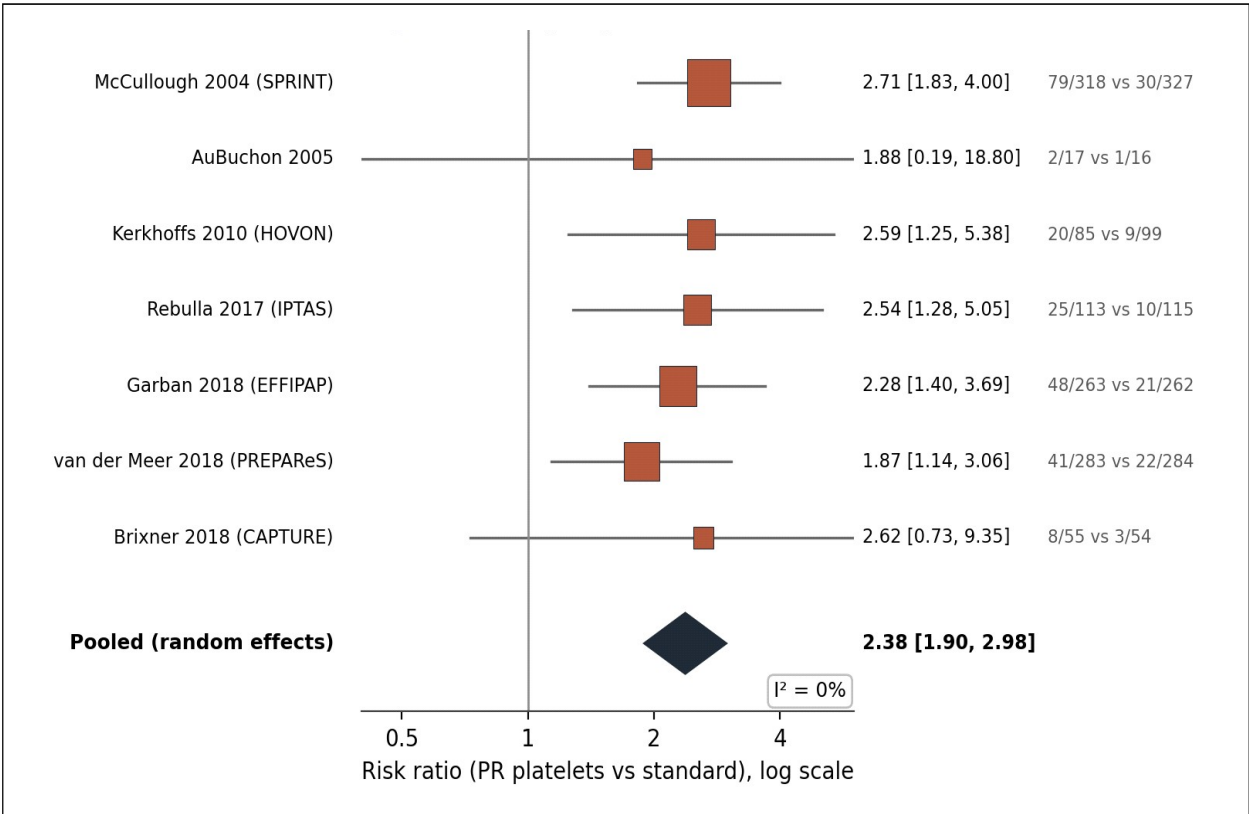


Figure 3: Forest plot of platelet refractoriness with pathogen-reduced versus standard platelets

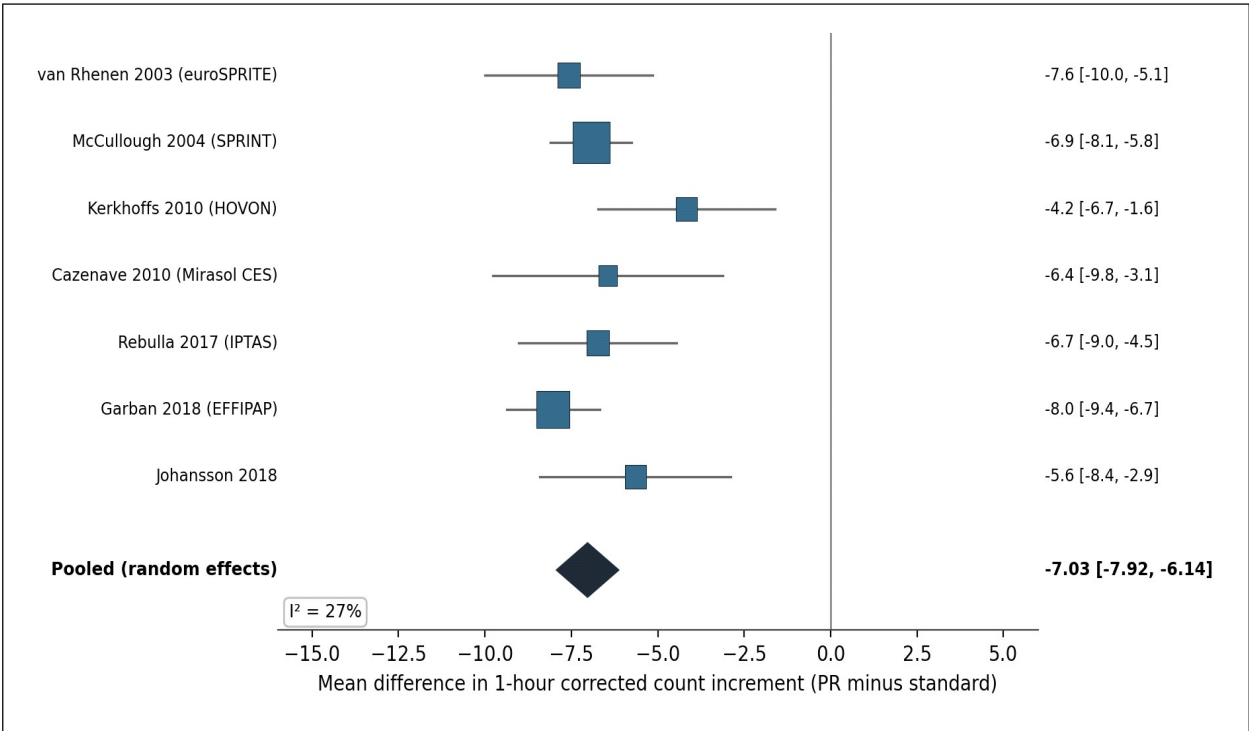


Figure 4: Forest plot of the 1-hour corrected count increment with pathogen-reduced versus standard platelets

3.5. Risk of bias

Of the 13 trials, 3 were judged to be at low overall risk of bias, 8 to raise some concerns, and 2 to be at high risk, as summarised in Figure 5. The domain most often responsible for a judgement of some concerns was the measurement of the outcome, reflecting the open-label design of several trials in which bleeding was assessed

without blinding of the assessor. The randomisation process and the handling of missing data were generally well conducted.

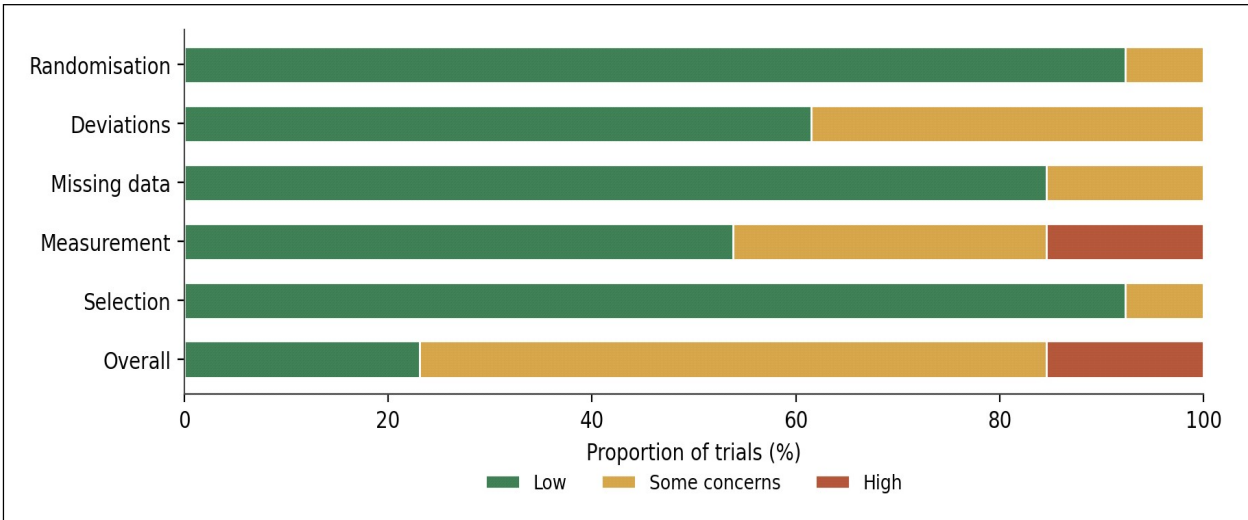


Figure 5: Risk-of-bias (Cochrane RoB 2) judgements across the 13 included trials

3.6. Summary of findings

The pooled estimates for all outcomes, with their heterogeneity and GRADE certainty, are collected in Table 2. Taken together, they show that pathogen reduction does not increase severe bleeding or serious adverse events but consistently reduces platelet potency, manifesting as increased refractoriness, alloimmunisation and transfusion requirement, the last three supported by high-certainty evidence.

Table 2: Summary of pooled meta-analysis findings by outcome				
Outcome	Trials (k)	Pooled effect (95% CI)	I ²	Certainty
Any bleeding	7	RR 1.06 (0.97–1.17)	38%	Moderate
Clinically significant bleeding (grade ≥2)	7	RR 1.14 (0.99–1.31)	58%	Low
Severe bleeding (grade ≥3)	8	RR 1.21 (0.80–1.83)	33%	Moderate
Any adverse event	9	RR 1.07 (1.00–1.14)	0%	Low
Serious adverse event	8	RR 1.03 (0.87–1.20)	0%	Moderate
Platelet refractoriness	7	RR 2.38 (1.90–2.98)	0%	High
Refractoriness/alloimmunisation	8	RR 1.77 (1.47–2.13)	0%	High
1-hour corrected count increment	7	MD -7.03 (-7.92–-6.14)	27%	High
24-hour corrected count increment	8	MD -3.08 (-3.69–-2.47)	57%	Moderate
Platelet transfusions per patient	6	MD 1.09 (0.92–1.25)	0%	High

3.7. Pathogen inactivation against arboviruses (secondary synthesis)

In the secondary synthesis of the primary laboratory studies, an adequate log reduction of at least four was achieved for 16 of the 17 arboviruses examined by at least one platform. Coverage differed between platforms: amotosalen-based inactivation achieved an adequate reduction for 14 of 17 viruses and ultraviolet C for 15, whereas riboflavin-based inactivation was adequate for only 12, being consistently the least effective against

several clinically important arboviruses. No single platform achieved an adequate reduction for every virus, as summarised in Table 3.

Table 3: Arboviruses with adequate log reduction (≥ 4 log) by platform, from the primary inactivation studies		
Platform	Arboviruses adequately inactivated	Proportion
Intercept (amotosalen/UVA)	14 of 17	82%
Mirasol (riboflavin/UV)	12 of 17	71%
Theraflex (UVC)	15 of 17	88%
Any platform	16 of 17	94%

3.8. Economic and implementation evidence

The economic evaluations, synthesised narratively, agreed that pathogen reduction is feasible in both high-income and resource-limited settings but adds meaningfully to the per-unit cost of a transfusion, and that its cost-effectiveness depends heavily on the local risk of transfusion-transmitted infection (Russell *et al.*, 2021; Laermans *et al.*, 2023). A whole-blood implementation in Ghana demonstrated feasibility in a resource-limited setting and, in the associated randomised trial of malaria transmission, a reduction in transfusion-transmitted infection, while confirming the additional cost (Allain *et al.*, 2016). Where the residual infection risk is low and screening infrastructure already extensive, the incremental benefit of pathogen reduction is smaller and its cost-effectiveness correspondingly less favourable.

4. Discussion

This systematic review and de novo meta-analysis of 13 randomised controlled trials establishes the balance of benefit and harm for pathogen-reduced platelets. The treatment did not increase severe bleeding or serious adverse events, but it consistently reduced platelet potency, so that refractoriness, alloimmunisation and the transfusion requirement were all higher and the post-transfusion count increment lower. Against the arboviruses, inactivation was adequate for most organisms but varied by platform, riboflavin-based treatment being the least effective.

The pooled estimates derived here from the primary trials reproduce the direction and approximate magnitude of the earlier published syntheses, which is reassuring, but the present analysis rests on the trial-level data rather than on the pooled figures of others, and it makes the heterogeneity and the certainty of each outcome explicit (Cid *et al.*, 2024). The clearest and most certain findings are the increases in refractoriness and alloimmunisation and the reduction in the count increment, which were consistent across trials with negligible heterogeneity and are supported by high-certainty evidence. These are coherent with the mechanism of the technologies, since the same nucleic acid and protein modifications that inactivate pathogens also alter the treated platelet, reducing its recovery and survival and increasing its immunogenicity.

The bleeding outcomes are less certain. The trend toward more clinically significant bleeding did not reach significance under the random-effects model, and the heterogeneity was substantial, arising largely from differences between the open-label trials in how bleeding was defined and ascertained, which is also the main source of risk of bias in this literature. The reduction in platelet potency is therefore established with more confidence than any effect on clinical bleeding, and the practical consequence of that reduction, the need for more frequent transfusion, is itself the clearest clinical cost of the technology.

The arbovirus synthesis complements the clinical findings by addressing the purpose for which the technologies were developed. That an adequate reduction was achieved for most arboviruses by at least one platform supports their role in mitigating transfusion-transmitted arboviral risk, but the poorer performance of riboflavin-based inactivation for several viruses, and the absence of any single platform that covers every organism, means that platform selection must be informed by the pathogens of local concern. This is of direct

relevance to arbovirus-endemic settings, where the emerging-pathogen rationale for pathogen reduction is strongest.

Taken together, the clinical, microbiological and economic evidence supports the continued and, where justified, expanded use of pathogen reduction, but not a uniform global recommendation. The decision to adopt it rests on weighing a modest and largely potency-related clinical cost, and a definite financial cost, against an infection-prevention benefit that depends on the local epidemiology and on the platform chosen. In settings with a high or rising transfusion-transmitted infection risk and adequate resources, the balance favours adoption; where the residual risk is already low, the incremental benefit is smaller.

5. Strengths and limitations

The main strengths of this review are that it returned to the primary randomised trials, extracted their data and pooled them in a new random-effects meta-analysis with its own risk-of-bias appraisal and GRADE rating, rather than restating previously published pooled figures, and that it combined the clinical, microbiological and economic evidence within a single systematic framework.

The review has limitations. The included trials were conducted predominantly in industrialised settings in haematological and oncological patients, which limits the generalisability of the findings to other populations, and the evidence for the Theraflex platform rests on a single trial. Several trials were open-label, so that the measurement of bleeding was at risk of bias, and the heterogeneity in the bleeding outcomes limits the certainty of the pooled estimate. The secondary synthesis of arbovirus inactivation pooled laboratory log-reduction data rather than clinical transmission outcomes, and the economic evaluations used differing methods that preclude direct comparison.

6. Conclusion

In this systematic review and meta-analysis of 13 randomised controlled trials, pathogen-reduced platelets did not increase severe bleeding or serious adverse events but carried a consistent and clinically meaningful cost in platelet potency, manifesting as increased refractoriness and alloimmunisation and a greater transfusion requirement, supported by high-certainty evidence. Pathogen inactivation was adequate for most arboviruses but varied by platform, with riboflavin-based inactivation the least effective. The evidence supports the continued and, where the transfusion-transmitted infection risk and resources justify it, expanded implementation of pathogen reduction, guided by platform-specific pathogen coverage and local economic evaluation rather than by a single uniform recommendation.

Conflicts of interest

The authors declare that no conflict of interest exists in relation to this work.

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