



Topic Exploration Report ¹

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

- Determine the quantity of evidence available for a technology of interest.
- Identify any gaps in the evidence.
- Inform decisions on topics that warrant fuller assessment by Health Technology Wales (HTW).

Topic exploration report number	TER550
Topic	Autologous blood microfiltration systems for peri- and post-operative cell salvage
Summary of findings	<p>In 2020, Health Technology Wales (HTW) published a topic exploration report (TER) on Hemosep and similar technologies for cell salvage (TER177). For the current TER, HTW researchers searched for evidence on the effectiveness of Hemoclear or other microfiltration cell salvage systems. Hemoclear is a single-use gravity-driven microfiltration device, requiring less training than conventional devices. It can be used where other cell salvage systems may not be available, such as in low-resource settings. Hemoclear also allows the collection of platelets in addition to red blood cells.</p> <p>No technology assessments, systematic reviews or randomised controlled trials were identified. There is limited, low quality evidence on the effectiveness of Hemoclear compared to other cell salvage systems, with a lack of evidence comparing to other filtration devices. An in vitro pilot study reported that Hemoclear was as effective as a conventional cell salvage device in concentrating erythrocytes and leucocytes. Both reduced complement C3, complement C4, and D-dimer by $\geq 90\%$. However, the conventional device reduced potentially harmful solutes more effectively than Hemoclear. A laboratory study showed that Hemoclear solute removal reached levels comparable to a conventional device.</p> <p>It is unclear whether the use of Hemoclear would result in the improvement of important clinical outcomes, such as hospitalisation and mortality. No economic evaluations of Hemoclear or other microfiltration cell salvage systems were identified. Further research and economic evaluations are required to establish the clinical and cost-effectiveness of Hemoclear and other microfiltration cell salvage systems.</p>

¹ [Cyfieithu dogfennau HTW wedi'u cyhoeddi o'r Saesneg i'r Gymraeg](#)
[Translation of published technical HTW documents from English into Welsh](#)

Introduction and aims

Allogeneic blood transfusion is the process of using a donor's blood to replace blood that was lost, for example in major surgery. Cell salvage involves a person's own blood being collected during or after surgery, for subsequent transfusion back into the same person (autologous blood transfusion). The latter aims to reduce the need for donor blood, and is routinely carried out during major surgery when a patient is at risk of moderate to high blood loss (e.g. liver, trauma, orthopaedic, vascular, obstetric and cardiothoracic surgery).

Conventional cell salvage or "cell saver" devices involve centrifugal force and only save red blood cells. These devices are often not available in low-resource settings due to the expense of consumables, the need for power supply and highly trained technical staff. More recently, cell salvage filtration devices such as Hemafuse (coarse filtration by manual force), Hemosep (ultrafiltration) and Hemoclear (gravity-driven microfiltration), have been developed.

Hemoclear is a single-use gravity-driven microfiltration device, requiring less training than conventional devices. It may be used where other cell salvage systems may not be available, such as in low-resource settings. Additionally, where conventional devices are used post-operatively in intensive care units and intensive therapy units, these could be released for use in theatre if Hemoclear was used instead. Hemoclear also allows the collection of platelets in addition to red blood cells.

For the purpose of this topic exploration report (TER), Health Technology Wales (HTW) researchers searched for evidence on the effectiveness of Hemoclear or other microfiltration cell salvage technologies. HTW previously searched for evidence on Hemosep and similar technologies, publishing TER177 in 2020.

Evidence overview

Secondary evidence

A similar topic was the subject of a previous HTW topic exploration report (TER). In 2020, HTW TER177 was published following a literature search for Hemosep and similar technologies for cell salvage. The TER only identified relevant evidence on the Hemosep cell salvage system, and largely focussed on the National Institute for Health and Care Excellence (NICE) Medtech innovation briefing (MIB103). Overall, the evidence indicated that Hemosep for cell salvage may lead to better outcomes, increasing blood species concentration for example, when compared with standard of care (SOC). However, the evidence was limited in both quantity and in terms of the specific populations studied.

In the literature search for the current TER, no technology assessments or systematic reviews were identified that specifically referred to Hemoclear or other microfiltration cell salvage systems.

Primary evidence

HTW researchers did not identify any randomised controlled trials (RCTs) on Hemoclear or other microfiltration cell salvage systems.

An in vitro pilot study (n=18) comparing the microfiltration device, Hemoclear, to the conventional centrifugal XTRA™ autotransfusion device was identified (Hoetink et al. 2020). Blood lost following cardiothoracic surgery (collected 18 hours post-surgery) was divided equally, with half processed by Hemoclear and half processed by XTRA™. The devices showed equal effectiveness in concentrating erythrocytes and leucocytes. Furthermore, both reduced complement C3, complement C4, and D-dimer by $\geq 90\%$. However, XTRA™ reduced potentially harmful solutes more significantly, by $\leq 99\%$. Free hemoglobin load was reduced 15.5% and 12.9% by Hemoclear and XTRA™, respectively.

Amenge et al. (2022) carried out a laboratory study comparing Hemoclear to the coarse filtration device, Hemafuse, and the conventional centrifugal device, autoLog, using volunteer donor blood. Hemoclear solute removal reportedly reached levels comparable to autoLog (note

Evidence overview

Hemafuse has no washing capacity). Authors highlighted the potential advantage of Hemoclear and Hemafuse over centrifugal technology in the ability to also recover platelets.

Economic evaluations

HTW researchers did not identify any economic evaluations on Hemoclear or other microfiltration cell salvage devices.

Areas of uncertainty

- There is limited, low quality evidence on the effectiveness of Hemoclear compared to other cell salvage systems, with a lack of evidence comparing to other filtration devices.
- It is unclear whether the use of Hemoclear would result in the improvement of important clinical outcomes, such as hospitalisation and mortality.
- Hemoclear could potentially be used where other cell salvage systems may not be available, such as in low-resource settings. Additionally, where conventional devices are used post-operatively in intensive care units and intensive therapy units, these could be released for use in theatre if Hemoclear was used instead. However, no data is available to show the impact of these uses.
- No economic evaluations of Hemoclear or other microfiltration cell salvage systems were identified.
- Further research and economic evaluations are required to evaluate the clinical and cost-effectiveness of Hemoclear and other microfiltration devices.

Literature search results

Health technology assessments and guidance
<p>HTW. (2020). Hemosep for cell salvage during surgery topic exploration report (TER177). Health Technology Wales. Available from: https://healthtechnology.wales/reports-guidance/hemosep-cell-salvage-technology [Accessed 11 June 2024].</p> <p>NICE. (2015). Blood transfusion NICE guideline (NG24). National Institute for Health and Care Excellence. Available from: https://www.nice.org.uk/guidance/ng24 [Accessed 11 June 2024].</p> <p>NICE. (2017). Hemosep for cell salvage. Medtech innovation briefing (MIB103). National Institute for Health and Care Excellence. Available from: https://www.nice.org.uk/guidance/mib103 [Accessed 11 June 2024].</p> <p>NICE. (2005). Intraoperative blood cell salvage in obstetrics. Interventional procedures guidance (IPG144). National Institute for Health and Care Excellence. Available from: https://www.nice.org.uk/guidance/ipg144 [Accessed 11 June 2024].</p> <p>NICE. (2008). Intraoperative red blood cell salvage during radical prostatectomy or radical cystectomy. Interventional procedures guidance (IPG258). National Institute for Health and Care Excellence. Available from: https://www.nice.org.uk/guidance/ipg258 [Accessed 11 June 2024].</p>
Evidence reviews and economic evaluations
<p>No evidence was found on Hemoclear or microfiltration.</p>
Individual studies
<p>Amenge J, Scherphof S, Osemwengie D, et al. (2022). Comparison of washing efficiency and recovery of blood cells between centrifugation, coarse filtration and microfiltration techniques to prepare autologous blood for transfusion. <i>Journal of Blood Medicine</i>. 13: 549-58. doi: https://doi.org/10.2147/jbm.s367918.</p> <p>Hoetink A, Scherphof SF, Mooi FJ, et al. (2020). An in vitro pilot study comparing the novel HemoClear gravity-driven microfiltration cell salvage system with the conventional centrifugal XTRA™ autotransfusion device. <i>Anesthesiology Research and Practice</i>. 9584186. doi: https://doi.org/10.1155/2020/9584186.</p>
Ongoing research
<p>No ongoing studies that have recently closed or are due to complete in the next 6-12 months were identified.</p>

Date of search	June 2024
Concepts used	Autologous blood transfusion; cell salvage; cell saver; Hemoclear; microfiltration system.

Proposed research question and evidence selection criteria (if selected)

Proposed Research question	Are autologous blood microfiltration systems (Hemoclear) clinically and cost-effective for peri- and post-operative cell salvage	
	Inclusion criteria	Exclusion criteria
Population	Surgical patients, specifically those undergoing cardiac, major (open) vascular, complex urology, obstetric, orthopaedic or trauma surgeries (when patient is at risk of moderate to high blood loss). Adult and paediatric populations.	
Intervention	Autologous blood microfiltration systems (Hemoclear)	
Comparison/ Comparators	<ul style="list-style-type: none"> Cell saver/salvage systems for autologous blood transfusion or as an alternative to allogeneic blood transfusion. This would include traditional centrifugal cell savers, and ultrafiltration and haemoconcentration systems (specifically, Hemosep). No autologous cell salvage 	
Outcome measures	<ul style="list-style-type: none"> Surgery risk, side effects and complications Adverse events Need for additional transfusions Blood volume saved Timeframe within which volume saved Health related QoL Resource use Economic outcomes 	
Proposed specialities	Blood and immune system; cardiovascular system; injuries, accidents and wounds	