



Topic Exploration Report

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:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	Hemosep for cell salvage during surgeries where patient is at risk of moderate to high blood loss
Topic exploration report number:	TER177

Introduction and aims

The Hemosep cell salvage system is designed to recover blood loss during cardiac and other surgical specialities, including cardiac, major (open) vascular, complex urology, obstetric, orthopaedic or trauma surgeries. It can be used in both adults and children. Unlike current cell salvage technologies that save only red blood cells, Hemosep concentrates all blood species and associated proteins for transfusion back to the patient.

Health Technology Wales researchers searched for evidence on the effectiveness of Hemosep or similar cell salvage technologies.

Summary of evidence

Secondary evidence

NICE published advice in a Medtech innovation briefing (MIB103) in May 2017 for Hemosep for cell salvage.

No systematic reviews were identified which studied Hemosep for cell salvage.

Primary evidence

NICE MIB103 identified three studies that evaluated Hemosep, two of these studies were peer-reviewed at the time (Gunaydin et al., 2013; Hogan et al., 2015), the third has since been peer-reviewed (Boyle et al., 2016;). One of the three sources had been identified by the topic proposer (Gunaydin et al., 2013). Of the three studies included in MIB103, two were RCTs in small patient populations (107 patients included in total) and were based in the UK (Boyle et al., 2016; Hogan et al., 2015) while the third, also an RCT in a small patient population (n = 102), was based in Turkey (Gunaydin et al., 2013). Two of the studies indicated that Hemosep led to better outcomes when compared with standard care (Gunaydin et al., 2013; Boyle et al., 2016) while the third study indicated that outcome measures were comparable between Hemosep and standard of care (Hogan et al., 2015).

Two additional sources of evidence were identified by the topic proposer and provided directly, an RCT and a conference poster (Gunaydin et al., 2018; Mushtaq R et al., undated). The RCT indicated that Hemosep concentrated blood species when compared with standard care (Gunaydin et al., 2018). The conference poster similarly indicated that Hemosep concentrated blood species when compared with standard care as well as shortened the length of stay of patients in ICU (Mushtaq et al., undated).

No ongoing trials were identified. The majority of identified studies had either been funded in some way by the manufacturer or authors had previously been in receipt of funding by the manufacturer.

Economic evaluations

NICE MIB103 states that the cost of the unit is £3,875 (exclusive of VAT), plus £248 in consumables per use and an additional £500 per year in maintenance costs. As three of the components are reusable, the manufacturer estimates that the average cost per treatment to be £240.

We did not identify any additional economic evaluations since publication of NICE MIB103.

Areas of uncertainty

The trials that have been performed included small numbers of patients. There does not appear to be any ongoing evidence collection. The technology could be used in a number of different clinical settings (for cardiac, major (open) vascular, complex urology, obstetric, orthopaedic or trauma surgeries; in adults and children) but the evidence to date does not reflect all of these settings.

Conclusions

Overall, the evidence indicates that Hemosep for cell salvage may lead to better outcomes, increasing blood species concentration for example, when compared with standard care. However, the evidence is limited in both quantity and in terms of the specific populations studied.

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland	We did not identify any relevant evidence from this source
Health Technology Assessment Group	We did not identify any relevant evidence from this source
Health Information and Quality Authority	We did not identify any relevant evidence from this source
UK guidelines and guidance	
SIGN	<p>Perioperative blood transfusion topic proposal Date of publication: July 2018 https://www.sign.ac.uk/assets/perioperative-blood-transfusion-proposal.pdf</p>
NICE	<p>Hemosep for cell salvage (MIB103) Medtech innovation briefing Published May 2017 https://www.nice.org.uk/advice/mib103</p> <p>Blood transfusion NICE Pathway Published November 2015 Last updated April 2019 https://pathways.nice.org.uk/pathways/blood-transfusion</p> <p>Intraoperative blood cell salvage in obstetrics (IPG144) Interventional procedures guidance Published November 2005 https://www.nice.org.uk/guidance/ipg144</p> <p>Intraoperative red blood cell salvage during radical prostatectomy or radical cystectomy (IPG258) Interventional procedures guidance Published April 2008 https://www.nice.org.uk/guidance/ipg258</p> <p>Blood transfusion (NG24) NICE guideline Published November 2015 https://www.nice.org.uk/guidance/ng24</p> <p>Caesarean section NICE Pathway Published November 2011 Last updated September 2019</p>

	<p>https://pathways.nice.org.uk/pathways/caesarean-section</p> <p>Bladder cancer NICE Pathway Published December 2015 Last updated July 2019 https://pathways.nice.org.uk/pathways/bladder-cancer</p> <p>Prostate cancer NICE Pathway Published October 2011 Last updated May 2019 https://pathways.nice.org.uk/pathways/prostate-cancer</p>
Secondary literature and economic evaluations	
ECRI	We did not identify any relevant evidence from this source
EUnetHTA	We did not identify any relevant evidence from this source
Cochrane library	We did not identify any relevant evidence from this source
Medline (Ovid) limited to publications since NICE MIB103	We did not identify any relevant systematic reviews or economic evaluations.
Primary studies	
<p>Cochrane library <i>Only include primary studies if there is insufficient secondary evidence</i></p>	<p>Haemoconcentration of cardiopulmonary bypass blood with HemoSep ISRCTN51513145 http://www.who.int/trialsearch/Trial2.aspx?TrialID=ISRCTN51513145, 2014 added to CENTRAL: 31 March 2019 2019 Issue 3</p> <p>A comparison of haemostatic biomarkers during low-risk patients undergoing cardiopulmonary bypass using either conventional centrifugal cell salvage or the HemoSep device G Boyle, A Kuffel, K Parmar, K Gibson, M Smith, A Grehan, BJ Hunt, DJ Chambers Perfusion, 2019, 34(1), 76-83 added to CENTRAL: 31 October 2018 2018 Issue 10</p> <p>Comparative evaluation of blood salvage techniques in patients undergoing cardiac surgery with cardiopulmonary bypass S Gunaydin, C Robertson, AB Budak, T Gourlay Perfusion, 2018, 33(2), 105-109 added to CENTRAL: 30 April 2018 2018 Issue 4</p>
Medline	No evidence identified in addition to the sources described above.
Ongoing primary or secondary research	
<p>PROSPERO database <i>Check for recent systematic review protocols.</i></p>	We did not identify any relevant evidence from this source

<p>Clinicaltrials.gov <i>Only include if insufficient secondary evidence and primary studies found. Check for ongoing studies that have recently closed or are due to complete in the next 6-12 months.</i></p>	<p>We did not identify any relevant evidence from this source</p>
<p>Other</p>	
<p>Evidence provided by the topic proposer</p>	<p>Comparative evaluation of blood salvage techniques in patients undergoing cardiac surgery with cardiopulmonary bypass. Gunaydin S, Robertson C, Budak AB, Gourlay T. <i>Perfusion</i>. 2018 Mar;33(2):105-109. doi: 10.1177/0267659117728328. Epub 2017 Aug 31.</p> <p>Evaluation of Hemosep® Cell Salvage Device in Cardiac Surgical Patients. Mushtaq R., Jeganath V., Levine AJ. The Heart Centre University Hospitals of North Midlands NHS Trust, United Kingdom. Conference Poster.</p> <p>Novel ultrafiltration technique for blood conservation in cardiac operations. Gunaydin S, Gourlay T. <i>Ann Thorac Surg</i>. 2013 Jun;95(6):2148-51. doi: 10.1016/j.athoracsur.2013.03.048.</p>

<p>Date of search:</p>	<p>March 2020</p>
<p>Concepts used:</p>	<p>Hemosep; cell salvage</p>