



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:	HemaClear exsanguination tourniquet to provide a bloodless surgical field during limb surgery
Topic exploration report number:	TER176

Introduction and aims

HemaClear, previously known as S-MART, is a single-use sterile elastic exsanguination tourniquet. It is used to facilitate bloodless surgical field for limb operations, including knee arthroplasty and arthroscopy, foot and ankle surgery, upper extremity and hand surgery, paediatric orthopaedics, vascular surgery and trauma. HemaClear could be used as an alternative to the pneumatic tourniquet in people needing limb surgery.

Summary of evidence

Secondary research

NICE published a Medtech innovation briefing (MIB187) in July 2019 for HemaClear for bloodless surgical field during limb surgery.

No systematic reviews were identified which studied HemaClear for bloodless surgical field during limb surgery.

Primary research

NICE MIB187 identified over 20 peer-reviewed studies evaluation HemaClear. Of these, the NICE MIB included six main studies investigating the clinical effectiveness of HemaClear compared with pneumatic tourniquets for bloodless surgical field during limb surgery, one of which was in the UK setting. Three of these are prospective randomised comparative studies, two are retrospective comparative studies and one is a mixed retrospective/prospective comparative study. Out of a total of 539 patients, 61% used HemaClear. Overall, the results suggest that HemaClear is as effective as a pneumatic tourniquet at achieving a bloodless field, and that HemaClear may reduce the amount of post-operative blood collected and reduce the haemoglobin drop compared with pneumatic tourniquets. However, two of the studies identified noted that HemaClear did not reduce the number of blood transfusions needed. Only one of the

studies included in NICE MIB187 suggested that HemaClear is less painful than pneumatic tourniquets. The studies suggest that caution is needed in using HemaClear with people at risk of developing a venous thromboembolism. HemaClear is contraindicated in people with a known deep vein thrombosis.

We did not identify any additional evidence since publication of NICE MIB187 and no ongoing trials were identified.

Economic evaluations

NICE MIB187 states that HemaClear costs between £15.95 and £41.80 (excluding VAT) depending on the model (see table 1). Each model is sold in boxes of 10 to 12. One of the studies identified in NICE MIB187 estimated the cost per patient of using HemaClear as 30 Euros more than the pneumatic tourniquet, although this study and another study in the NICE MIB noted substantial reductions in operative time with HemaClear compared with the pneumatic tourniquet.

We did not identify any additional economic evaluations since publication of NICE MIB187.

Areas of uncertainty

The NICE MIB identified uncertainty surrounding some outcomes such as pain and complications, and a lack of medium- to long-term follow up. The NICE MIB states that there is limited evidence in different specialities other than limb surgery, such as haemodialysis access surgery and plastic surgery. All of the evidence identified in the NICE MIB investigated bloodless surgical field in adults and not children.

Conclusions

NICE MIB187 provides advice on the use of HemaClear for bloodless surgical field during limb surgery. Overall, studies show that HemaClear may be as effective as pneumatic tourniquets in providing a bloodless field in the adult population. Although HemaClear costs more than pneumatic tourniquets, HemaClear has been shown to reduce operative time and result in fewer complications. However, there is uncertainty surrounding some outcomes such as pain and complications and a lack of medium- to long-term follow up.

We did not identify any additional evidence since publication of NICE MIB187.

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	We did not identify any relevant evidence from this source
NICE	<p>NICE Pathway. Rheumatoid arthritis. Managing rheumatoid arthritis. Surgical treatment. April 2013. Updated January 2020: https://pathways.nice.org.uk/pathways/rheumatoid-arthritis</p> <p>NICE Pathway. Osteoarthritis. Management of osteoarthritis. Surgical options. February 2014. Updated October 2019: https://pathways.nice.org.uk/pathways/osteoarthritis</p> <p>NICE Pathway. Trauma. Limb and joint fractures in hospital. Person aged 16 or over. February 2016. Updated August 2019: https://pathways.nice.org.uk/pathways/trauma</p> <p>NICE Medtech Innovation Briefing (MIB) 187: HemaClear for bloodloss surgical field during limb surgery. July 2019: https://www.nice.org.uk/advice/mib187</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 since publication of NICE MIB187
Medline (Ovid)	We did not identify any relevant evidence from this source since publication of NICE MIB187
Primary studies	
Cochrane library	We did not identify any relevant evidence from this source since publication of NICE MIB187
Medline	We did not identify any relevant evidence from this source since publication of NICE MIB187
Ongoing primary or secondary research	
PROSPERO database	We did not identify any relevant evidence from this source

Clinicaltrials.gov	We did not identify any relevant evidence from this source
Other	
Evidence provided by Topic Proposer	The Topic Proposer did not provide any evidence published since availability of the NICE MIB187 in July 2019

Date of search:	March 2020
Concepts used:	HemaClear; S-MART; sterile exsanguination tourniquet; bloodless surgical field; surgery; pneumatic tourniquet