Pentosan Polysulfate Sodium in the Perioperative Period: Safety and Guidelines
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Acknowledgments:

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada’s health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.
Research Questions
1. What evidence is available regarding any safety issues associated with patients on pentosan polysulfate sodium in the perioperative period?
2. What are the evidence-based guidelines associated with the management of pentosan polysulfate sodium in the perioperative period?

Key Findings
One evidence-based guideline was identified regarding the management of pentosan polysulfate sodium in the perioperative period.

Methods
A limited literature search was conducted on key resources including PubMed, Embase (Ovid), Medline (Ovid), The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2007 and November 28, 2017. Internet links were provided, where available.

Selection Criteria
One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria
<table>
<thead>
<tr>
<th>Population</th>
<th>Patients (any age) taking pentosan polysulfate sodium in the perioperative period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention Comparators</td>
<td>Pentosan polysulfate sodium (Elmiron)</td>
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<tr>
<td>Q1:</td>
<td>Standard of care; Placebo; No treatment</td>
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<tr>
<td>Q2:</td>
<td>No comparator</td>
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<tr>
<td>Outcomes</td>
<td>Q1: Safety issues, risks, and harms (e.g., bleeding risk, hematomas associated with the insertion and removal of epidurals in the perioperative period)</td>
</tr>
<tr>
<td>Q2:</td>
<td>Guidelines (e.g., stopping and starting of pentosan polysulfate sodium in the perioperative period, what types of anesthesia is best used in these patients)</td>
</tr>
<tr>
<td>Study Designs</td>
<td>Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, evidence-based guidelines</td>
</tr>
</tbody>
</table>
Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, and evidence-based guidelines.

One evidence-based guideline was identified regarding the management of pentosan polysulfate sodium in the perioperative period. No relevant health technologies, systematic reviews, meta-analyses, randomized controlled trials, or non-randomized studies were identified.

Additional references of potential interest are provided in the appendix.

Overall Summary of Findings

One evidence-based guideline by the National Institute for Health and Care Excellence (NICE) was identified regarding the management of pentosan polysulfate sodium in the perioperative period. In terms of safety, NICE highlighted the United States Food and Drug Administration (FDA) label that specified that patients undergoing invasive procedures should be evaluated for hemorrhage.

References Summarized

Health Technology Assessments
No literature identified.

Systematic Reviews and Meta-analyses
No literature identified.

Randomized Controlled Trials
No literature identified.

Non-Randomized Studies
No literature identified.

Guidelines and Recommendations

See: Safety, second bullet, page 2
Appendix — Further Information

Clinical Practice Guidelines – Unspecified Methodology

   See: Bladder medications in table, page 11


Additional References

   See: Section on How should I take pentosan polysulfate sodium?, fourth paragraph