TITLE: Intravascular Cooling Devices to Induce Therapeutic Hypothermia: Clinical Effectiveness and Safety

DATE: 12 June 2012

RESEARCH QUESTIONS

1. What is the clinical effectiveness of intravascular cooling devices for the induction of therapeutic hypothermia following cardiovascular or cerebrovascular events?

2. What is the clinical evidence regarding the safety of intravascular cooling devices for the induction of therapeutic hypothermia following cardiovascular or cerebrovascular events?

KEY MESSAGE

Two randomized controlled trials and nine non-randomized studies regarding the clinical effectiveness and safety of intravascular cooling devices for the induction of therapeutic hypothermia following cardiovascular or cerebrovascular events were identified.

METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2012, Issue 5), 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 June 1, 2012. Internet links were provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.
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 and non-randomized studies.

Two randomized controlled trials (RCTs) and nine non-randomized studies regarding the clinical effectiveness and safety of intravascular cooling devices for the induction of therapeutic hypothermia following cardiovascular or cerebrovascular events were identified. No health technology assessments, systematic reviews, or meta-analyses were identified. Additional references of potential interest are provided in the appendix.

OVERALL SUMMARY OF FINDINGS

Two small RCTs\(^1\,\!^2\) studied the safety and feasibility of endovascular cooling. One study\(^1\) (20 patients) found that endovascular cooling as an adjunct therapy in patients with acute myocardial infarction might reduce the infarct size at three days. The second study\(^2\) (58 patients) determined that endovascular cooling as an adjunct to thrombolysis therapy in patients with acute ischemic stroke was feasible and safe.

Nine non-randomized studies were identified regarding endovascular cooling; one in patients with acute hemorrhagic stroke\(^3\), one in patients with neurological injuries\(^11\), and seven in patients with cardiac arrest\(^4\,\!^9\,\!^10\). Evidence from these studies suggests that endovascular cooling provides better temperature control than other cooling methods, with few differences in patient outcomes. Few adverse events were reported. Table 1 summarizes the non-randomized study results.

<table>
<thead>
<tr>
<th>First author, date</th>
<th>Objective</th>
<th>No. of patients</th>
<th>Results/Author conclusions</th>
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<tbody>
<tr>
<td>Abdullah, 2011(^3)</td>
<td>To compare the use of mild hypothermia (using intravascular catheter) versus standard stroke management, in patients with hemorrhagic stroke.</td>
<td>Intervention=6 Control=18</td>
<td>The hypothermia group showed a statistically significant improvement at 6 months and 1 year (using the modified Rankin scale). Therapeutic hypothermia may be beneficial.</td>
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<td>Finley, 2011(^4)</td>
<td>To compare endovascular cooling with conventional surface cooling following cardiac arrest.</td>
<td>No. of patients not reported</td>
<td>&quot;Endovascular cooling maintains target temperatures better than conventional surface cooling.&quot; Adverse events were reported to be similar between groups.</td>
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<td>Knapik, 2011(^5)</td>
<td>To compare endovascular cooling with traditional methods of cooling in patients with acute coronary syndrome.</td>
<td>Intervention=20 Control=21</td>
<td>Endovascular cooling maintains more precise temperature control compared with traditional methods of cooling.</td>
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<td>Tomte, 2011(^6)</td>
<td>To compare core cooling with surface cooling in comatose cardiac arrest survivors.</td>
<td>Total no. of patients=167</td>
<td>The two methods of cooling resulted in similar survival and neurological function. Surface cooled patients had significantly more episodes of sustained hyperglycemia and core cooled patients had significantly more</td>
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<tr>
<td>First author, date</td>
<td>Objective</td>
<td>No. of patients</td>
<td>Results/Author conclusions</td>
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<td>Gillies, 2010&lt;sup&gt;7&lt;/sup&gt;</td>
<td>To compare endovascular cooling with surface cooling in comatose survivors of cardiac arrest.</td>
<td>Intervention=42, Control=41</td>
<td>Endovascular cooling resulted in better temperature control and fewer adverse events than surface cooling.</td>
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<td>Kulstad, 2010&lt;sup&gt;8&lt;/sup&gt;</td>
<td>To compare endovascular cooling with no cooling in patients with neurological impairment following cardiac arrest from ventricular fibrillation/tachycardia.</td>
<td>No. of patients not reported</td>
<td>Endovascular cooling appeared to improve neurological outcome in patients with cardiac arrest (not statistically significant), and was most beneficial in patients with ventricular fibrillation.</td>
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<td>Ferreira, 2009&lt;sup&gt;9&lt;/sup&gt;</td>
<td>To compare therapeutic mild hypothermia using various methods with no cooling in comatose survivors of cardiac arrest.</td>
<td>Endovascular cooling=24, External cooling=25, No cooling=26</td>
<td>Therapeutic mild hypothermia improved survival and neurological outcomes. Outcomes did not differ between the two cooling methods.</td>
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<tr>
<td>Flint, 2007&lt;sup&gt;10&lt;/sup&gt;</td>
<td>To compare endovascular cooling with surface cooling in comatose survivors of cardiac arrest.</td>
<td>No. of patients not reported</td>
<td>Endovascular cooling provided better control of hypothermia maintenance.</td>
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<td>Hoedemaekers, 2007&lt;sup&gt;11&lt;/sup&gt;</td>
<td>To compare five cooling devices in patients with various neurological injuries.</td>
<td>Total=50 (10 patients per group)</td>
<td>Intravascular cooling was more reliable for maintaining a stable temperature.</td>
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REFERENCES SUMMARIZED

Health Technology Assessments
No literature identified.

Systematic Reviews and Meta-analyses
No literature identified.

Randomized Controlled Trials


Non-Randomized Studies


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APPENDIX – FURTHER INFORMATION:

Case series


PubMed: PM20817376

PubMed: PM17922082

PubMed: PM17598898

Review Articles

PubMed: PM20621922

Additional References

PubMed: PM22264371