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What evidence exists that describes whether the use of cryotherapy (cold therapy) is effective for improving adult patient outcomes following total knee arthroplasty?

This report aims to summarize the best available evidence describing whether cryotherapy is effective in improving patient outcomes following knee replacement surgery and if so, what modality of cryotherapy is best. Evidence related to the impact of cryotherapy application on nursing practice or health-care related costs is also presented when available.

Key Messages:

- Total Knee Arthroplasty (TKA) is performed in adults frequently suffering from end-stage osteoarthritis to improve pain, mobility function and quality of life. However, the early postoperative period challenges patients with significant pain, stiffness and blood loss.
- Cryotherapy involves the application of cold to the skin at an injury or incision site through various modalities, including ice/gel packs, cold compression devices and computer-assisted continuous cold therapy.
- Cryotherapy is currently being used in some health centres following TKA as part of a multimodal pain management strategy, to decrease blood loss and to reduce stiffness and improve range of motion (ROM) in the early postoperative period.
- In this review, 3 good to poor quality systematic reviews with meta-analysis of randomized controlled trials (RCTs) determined whether cryotherapy was effective on patient outcomes in the early postoperative period following TKA. The systematic reviews reported low to medium quality of the RCTs reviewed:
  - 2 of the 3 reviews found a small effect of cryotherapy in reducing reported pain on postoperative day 2. One study did not find any effect on pain, or difference between groups on the consumption of analgesics. One review reported a small decrease in the use of NSAIDs when cryotherapy was used.
  - 2 reviews found a small decrease in blood loss with cryotherapy.
  - One review found a small increase in range of motion.
  - 2 of the 3 reviews stated that despite small significant differences found within groups, it may be clinically insignificant.
  - There was no difference in reported adverse events in groups receiving cryotherapy.
- In this review, 6 RCTs compared different modalities of cryotherapy following TKA. 4 studies compared advanced cryotherapy devices (cold flow device) with ice, and 1 study compared ice to usual care.
  - There were no differences found in any of the studies for self-reported pain, use of analgesics, blood loss, transfusion requirements, edema, range of motion, nausea and vomiting, length of stay and adverse events.
  - Patient satisfaction varied, with some studies reporting patients found the advanced cryotherapy devices to be comfortable and others complaining of noise.
- One RCT and 1 literature review provided some insight on the impact on nursing practice and cost associated with cryotherapy.
  - In one study, nurses perceived less time to apply and manage ice/gel packs than the cryotherapy devices. Nurses also perceived safety concerns with the devices due to the tubes and wiring.
  - Ice bags were reported as less costly than advanced cryotherapy devices.
- All the studies varied considerably in the protocol for cryotherapy application, even within groups of studies. The start of cryotherapy, frequency, length of administration, temperature of ice or cooling device was inconsistent across studies and within intervention and control groups. Similarly, most of the RCTs had very limited number of participants and blinding was not possible due to the nature of the intervention. In addition, potential participants were excluded from studies due to co-morbidities. This may not represent a realistic patient population in practice.
- The American Association of Orthopedic Surgeons (AAOS) moderately recommended that cryotherapy devices do not improve patient outcomes following TKA.

Who is this summary for?
This summary was requested by Debbie Watson, ERAS Surgical Pathway Coordinator.

Information about this summary:
This report covers a broad collection of literature and evidence sources with a search emphasis on systematic reviews.

This summary includes:
Key findings from a broad collection of recently published literature (from 2012-2017) and other evidence sources.

This summary does not include:
Recommendations, additional information, or detailed description of the interventions in the studies.

1. Background:

Contents:

1. Background
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Cryotherapy involves the application of cold or low temperature to the skin around an injury or incision to reduce the metabolic rate of the surrounding soft tissue. Local cold application can induce vasoconstriction and decreased circulation leading to less inflammation and edema. It is also thought to reduce sensory nerve conduction which contributes to pain relief [1]. It is currently available in a number of modalities including first generation cryotherapy which includes ice or cold gel packs; second generation cryotherapy that include circulating ice water through a padded device and third generation computer assisted devices that provide continuous cold therapy. Cryotherapy is commonly used for many surgical procedures and is being evaluated to improve outcomes in Total Knee Arthroplasty (TKA) or total knee replacement surgeries. TKA is performed to treat end-stage knee arthritis (osteoarthritis) to improve pain, mobility, function and quality of life. However, the immediate and early post-surgical experience for patients can be challenging, where patients are faced with pain, stiffness with reduced range of motion (ROM) and significant blood loss. In order to improve the early post-operative experience, and to intervene with a multimodal pain relief approach, cryotherapy is used in many clinical areas to address and improve these significant patient outcomes.

This rapid review will present summaries of the best available evidence that describe whether cryotherapy is effective in improving patient outcomes following TKA. A secondary question is whether there are superior cryotherapy modalities for TKA, and the impact of cryotherapy on nursing practice and health-related costs. A detailed search strategy was developed by the medical librarian (T. Landry). Search concepts included Subject Headings and text words (specific search terms are available upon request). Sources included Medline via Ovid (including the Cochrane Database of Systematic Reviews), Ovid EMBASE and CINAHL via EBSCO. . The search date was November 16, 2017, and was not limited to year of publication. Duplicates and out of scope articles were discarded by the librarian. The EIDM-A (S. Castiglione) also searched the Joanna Briggs Library, UpToDate database, and relevant association websites, which produced 1 relevant source [2]. The EIDM-A reviewed all titles and abstracts and included only those that met the research question (21 articles). After reading the full text, 10 articles were retained and included in the review. Studies that were of very low quality were discarded. Reports that did not present high levels of evidence (systematic reviews or Randomized controlled trials (RCTs)) were not included as the methodology did not address the question of this review. The analysis of studies, including appraisal and summary, and the final report were prepared by the EIDM-A and reviewed by the librarian, Chair of the Clinical Practice Review Committee of the MUHC (D. Gaumond) and the nurse surgical pathway coordinator for the ERAS program (D. Watson).

Three systematic reviews on the effectiveness of cryotherapy in adult patients with TKA published between 2012-2017 were included in this rapid review [3-5]. They were considered good to poor quality. Five RCTs were found (2012-2017) that were not previously reviewed by the systematic reviews evaluating cryotherapy compared to control or different cryotherapy modalities [6-10]. Other articles (observational studies, opinions, case studies) were not included in determining whether cryotherapy was effective, except when there was a discussion on the impact of cryotherapy on nursing practice or healthcare related costs [11]. One guideline summary from the American Association of Orthopedic Surgeons was included in this report since they made a statement on the use of cryotherapy following TKA [2]. A table of all the articles found and reviewed is available upon request (sonia.castiglione@muhc.mcgill.ca).

Levels of Evidence (adapted from OHRI KTA Evidence Summary document)

Each piece of evidence presented in this summary is assigned a level.

This assignment is based on the evidence being presented and not on the claim made by the authors.

- **Platinum:** systematic reviews and meta-analysis
- **Gold:** Randomized controlled trials (RCTs)
- **Silver:** Observational studies (non-randomized trials, case-control, time-series, cohort studies, case series, literature reviews, qualitative studies.)
- **Bronze:** Expert committee guidelines, reports or opinions, commentary or editorials.
- **Level of evidence** cannot be determined.

2. Summary of Findings:

a. Systematic Reviews and meta-analysis of the effect of cryotherapy for TKA

A systematic review, published in 2017, evaluated the effectiveness of commonly used drug-free interventions for pain management after TKA, including cryotherapy. A systematic search of medical databases and grey literature (unpublished or non-peer reviewed documents) was conducted. Studies were selected for adult patients who underwent TKA (all forms of fixation, surgical approaches and types of prostheses). 8 RCTs that evaluated cryotherapy after TKA were combined in a meta-analysis for a total of 1383 patients. No statistically significant difference was found in reported pain with cryotherapy compared to routine pharmacological methods. Also, no difference was found in the consumption of analgesics with cryotherapy. A statistically significant reduction in NSAID consumption was found with cryotherapy compared to no intervention or to compression. The studies combined in the meta-analysis varied greatly in terms of method, dose and frequency of cryotherapy intervention, and types of surgical procedure used. The studies included were appraised by the authors to be of low to very low quality. The authors concluded that "this study demonstrated very low certainty evidence for the use of cryotherapy for postoperative analgesia after TKA." Further studies were recommended. No comment on the practicality or cost effectiveness of cryotherapy in practice was made. [5]

In 2015, a systematic review and meta-analysis of 12 studies was conducted to evaluate the effectiveness of cryotherapy in patients after joint arthroplasty. A limited but systematic search of only 3 databases was carried out. The studies included in the meta-analysis were RCTs that compared cryotherapy (any method) to a control group in either TKA or THA (only TKA results are reported here.) The authors used an evaluation tool and appraised the RCTs to have a medium level of quality. A high level of heterogeneity were found in the studies relative to the method, frequency and dose of cryotherapy, and some combined cryotherapy with other interventions such as compression when compared to a control. The authors did not present any demographic data on the patients included in this study, and poorly addressed how the outcomes were measured in the initial studies. Overall, cryotherapy showed a small reduction in blood loss in patients following a TKA. Cryotherapy also showed a small decrease in reported pain on postoperative day 2, but not on day 1. Cryotherapy did not report any more adverse effects compared with control, but a reporting bias was found. This means that studies that did not report adverse effects with cryotherapy were more likely to be published. The authors concluded that cryotherapy is safe, and that there was a small reduction in blood loss, and pain on postoperative day 2 compared with controls. [3]

A 2012 Cochrane Systematic Review and Meta-analysis was conducted to evaluate the effect of cryotherapy after TKA in the acute phase. A systematic search of multiple medical, nursing and physiotherapy databases for peer reviewed RCTs and controlled trials, as well as grey literature was carried out. Studies conducted with adults who underwent TKA for osteoarthritis, and received cryotherapy (any means) within 48 hrs after surgery were included in the meta-analysis. 12

studies met these criteria. The authors found significant clinical heterogeneity between the intervention and controls, where a number of studies combined cryotherapy with compression and where the frequency and method of administration varied from study to study. The studies were graded low for quality. Cryotherapy showed a small but statistically significant reduction in blood loss, as well as small decrease in reported pain at postoperative day 2, but not at any time point. Patients with cryotherapy did not report any more adverse events compared to controls. Patients who received cryotherapy demonstrated a small increase in range of motion of the affected joint compared to controls. There was no impact on transfusion rate, analgesic use or hospital length of stay. Overall, the authors remark that any impact of cryotherapy is small and may be clinically insignificant. They caution the decision to use cryotherapy by taking into account the practical aspects and potential inconveniences of this intervention in practice. [4]

b. RCTs comparing the cryotherapy devices

✳ *In 2017, a study was conducted to determine whether temperature controlled cold flow device was superior to ice bags administered in homogenous participants in the post-operative period following TKA for end-stage knee arthritis only. Participants were randomized into two groups (24 in cold flow group and 26 in ice bag group) and received identical treatment other than the cooling device. The treatments provided to both groups were described but not validated as being equal. Participants were assessed preoperatively and at three postoperative time points (day 1, day 3 and day 7). The results found no difference in the two groups with respect to sex, weight, height, total blood volume and preoperative hematocrit. No adverse effects were recorded in either group. No statistically significant differences found in knee circumference variation (edema), blood loss, transfusion requirement, pain (numeric pain rating scale) and analgesic requirement, or in active range of motion evaluation. Participants in the study group only were asked whether they were comfortable with the cooling device, and most indicated there were comfortable. The authors concluded that continuous cold flow device in the acute postoperative setting after TKA showed no superiority compared to traditional icing methods in patient outcomes. The sample size was small and the patients were not representative of a realistic sample, as multiple exclusions were applied. As well, comfort was not evaluated in the control group. Similarly, there was no description of the icing regiment used in the control group. [10]*

✳ *An RCT was published in 2016 to determine whether an icy/gel cryotherapy pack was non-inferior (the same) as a more elaborate circulating cold water therapy device on patient outcomes (pain, swelling, blood loss, range of motion, satisfaction, length of stay, adverse effects) following a KTA. They also evaluated the nursing satisfaction and economic impact of each intervention. Participants were randomized into 2 groups, the intervention group which received circulating cold water therapy with static compression or the control group receiving the gel/ice packs with static compression postoperatively. Participants in both groups were being treated for end stage osteoarthritis and received the same care protocol regardless of the study group. The cryotherapy in both groups was administered continuously and then intermittently up to day 11 after surgery and beyond. Follow up occurred in the postoperative period to discharge and then at 3 weeks and at 6 weeks. Both groups were similar in age and gender proportion. There was no significant difference found between groups in length of stay, blood loss, or ROM at discharge. There was no difference between groups in the change of thigh/knee circumference at the first hospital dressing change, then at 3 and 6 week follow up. Similarly, there were no differences in how often each device was used, how long the cooling effect lasted, how often pain medication was used in the past 24 hours, ease of use, equipment failures or patient overall rating of satisfaction. The only significant difference found was a lower pain level in the ice/gel pack group at 6 weeks. Staff reported less time applying and replenishing the ice/gel versus the cooling device, and reported more safety concerns with the cooling device. Almost 75% of staff recommended the ice/gel pack over the cooling device. Lastly, the ice/gel cryotherapy was less costly than the circulating cool water device. The authors conclude that this study "demonstrat[ed] the noninferiority of an ice/gel pack cryotherapy compression wrap compared to a circulating cold water cryotherapy device" and recommended that institutions can switch to ice/gel packs that have a lower cost and staff satisfaction and not compromise patient outcomes. The study was unable to blind participants or staff, but described clear methods to achieve at these conclusions. [6]*

✳ *In 2015, a non-blinded randomized controlled trial was conducted to compare the effects of cryotherapy with a cooling device vs ice on pain, range of motion, nausea and vomiting, opioid consumption, hemoglobin levels, length of hospital stay, patient satisfaction and overall function of the knee following a total replacement surgery. 37 participants were placed in the study group and received a cooling device for 48 hrs, while 34 participants received intermittent cooling with ice as needed both post operatively. Both groups were similar in demographics but no tests of significance were reported.*

Also, the study authors did not describe the protocol for intermittent ice application. In addition, the control group was underpowered by one participant. The results indicated that there were no significant differences between groups in all the variables studied. The patients in the intervention group were more satisfied with the cooling device. The authors concluded that the additional costs of the cooling device may not be warranted. [7]

✳ *A paper in 2015 described a study using an RCT crossover to study whether a 30 minute application of cryotherapy (ice packs) at the time of pain medication administration following TKA provided pain relief compared to usual care (none). Participants were randomized into two groups receiving either no cryotherapy or cryotherapy with their first pain episode with medication administration and then the opposite treatment for their second medication administration. Pain levels were measured just prior to, then 30 min and 60 min after medication administration, and satisfaction with pain management measured only after 60 min. The medication received by each participant was similar at their first and second medication treatment. 29 participants were randomized, 15 in group one and 14 in the other group. The total sample size met statistical power requirements and the two groups were deemed to be similar. Baseline scores were similar for pain in the two treatment groups. Pain decreased in both groups following administration of medication with or without treatment and was lower at 60 min than at 30 min. There was no statistically significant difference in the change of pain scores in both groups. Similarly, there was also no change in the satisfaction scores with each group. However, those receiving cryotherapy for their second pain episode with analgesic medication had higher satisfaction scores than those who received cryotherapy for their first pain episode. The authors concluded that "the 30 minute application of cryotherapy is unlikely to significantly improve pain management." The authors conceded that a longer application of cryotherapy may have shown further results. Also, the authors did not describe how satisfaction was evaluated and may be due to the perception that the nurse was exhausting all possibilities to manage pain. [9]*

✳ *In 2014, a quasi-randomized controlled trial was conducted that tested the hypothesis that advanced cryotherapy devices (cool flow bands) compared to first generation cryotherapy (cold packs) resulted in better post-operative pain control with lower consumption of narcotics, better early ROM, and less postoperative bleeding and swelling following primary TKA. The author also measured length of stay and reported adverse events with the treatment. Patients with osteoarthritis were sorted into both treatment groups based on order of the day (participant 1-advanced cryotherapy, participant 2-cold pack, 3-advanced etc…). 50 participants were in each group which met power requirements. The differences in the groups were reported. The advanced cryotherapy group received 4 hours of continuous cooling at 11^{o}C immediately after surgery. The day after surgery, 2 hrs of treatment was followed by physiotherapy with 2 hours of treatment again, and repeated in the afternoon. The participants were allowed to use the treatment overnight if they wished (where most did). The participants in the ice pack group received 15 min of the cold packs (conserved at -17^{o}C) immediately following surgery and then again on the ward. This was repeated at 2 hrs and then 4 hrs after surgery. Following this, patients received the same cold pack for 15 min following physiotherapy 2x per day and could use the cold pack during the night if they wished. There was no mention of how many participants in this group used the cold pack at night. No differences were found between the groups for pain scores at rest, movement and walking at day 1 and day 2, and no differences in the equidoses of morphine and tramadol were observed. No differences were also found up to 6 weeks after surgery in ROM, straight leg raising, walking without an aid, swelling and hematoma. No differences in length of stay were found, and neither in blood loss or in inflammatory tests. In the advanced cryotherapy group, some patients, 30% of participants complained of too much noise when using the treatment overnight. No serious adverse effects were found in either group. The author concludes that "advanced cryotherapy devices, representing prolonged continuous cooling do not offer any clinical advantage for patients undergoing knee arthroplasty." The author mentioned that the increase in cost associated with advanced cryotherapy devices cannot be supported. [8]*

c. Other studies/reports

✸ *A literature review published in 2011 reported on the effects of cryotherapy after TKA. 11 articles were retained after a search of a limited number of databases. Some studies reviewed noted complications with the use of the Cryo/cuff but were not discussed in detail. Other studies reported some malfunctioning equipment which was a hindrance to adherence. Similarly, participants in some studies were reportedly tired of having to attach and reattach the cryo/cuff equipment when going to physiotherapy or for ambulation. None of the studies reviewed provided a financial implication to the use of cryotherapy. The authors state that most of the studies showed no difference in ROM of the operative knee, a decrease in swelling and a decrease in blood loss with cold compression. However, these studies were deemed as poor quality. Further*

research needed to be conducted specifically around issues related to use of the equipment and their financial implications. [11]

- *The American Academy of Orthopedic Surgeons (AAOS) published a guideline in 2016 on the surgical management of osteoarthritis of the knee. Cryotherapy devices were addressed. The guideline makes a moderate recommendation that cryotherapy devices do not improve outcomes following knee arthroplasty. [2]*

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