VENTURA COUNTY HEALTH CARE PLAN

Medical Policy: Cooling Devices in the Outpatient Setting

Effective Date: 08/29/07
Revised: 08/11/11; 4/16/12
Reviewed/No Updates: 01/28/13; 02/13/14; 02/12/15; 02/11/16; 02/09/17, 02/08/18, 02/14/19, 02/13/20

Policy

VCHCP considers use of active or passive cooling devices not medically necessary in the postoperative care of patients undergoing musculoskeletal surgery.

Other applications of passive cooling devices, including but not limited to their use for non-operative musculoskeletal injuries, are considered investigational/not medically necessary.

The use of active cooling devices with additional pneumatic compression is considered investigational/not medically necessary, for all indications, including, but not limited to, the post operative care of patients.

The use of active or passive devices that combine cooling and heating is considered **investigational and not medically necessary,** for all indications, including, but not limited to the use of the VitalWrap™ system.

Definitions

Continuous cooling devices can be broadly subdivided into passive cold therapy and active cold therapy using a mechanical device.

Passive cooling device is defined as a device that provides cooling without the benefit of mechanical circulation of the cooling medium.

Active cooling device is defined as a device that provides cooling with the use of mechanical circulation of the cooling medium from a reservoir that cools the medium before returning it to the site of injury.

Examples of cooling devices include but not limited to the following: Aircast Cryo/Strap®, AutoChill® Device, Cooling Devices, Cryocuff®, Game Ready Accelerated Recovery System, Hot/Ice Thermal Blanket, Polar Care Cub Device and Polar Pack®

Background

The standard postoperative treatment of musculoskeletal surgeries consists of icepacks and various types of compressive wraps. To document the medical necessity of passive cooling devices, randomized controlled trials are required that demonstrate that passive cooling devices provide a greater likelihood of benefit compared to conventional ice packs when used in the outpatient setting.

Both the ice packs and the passive cooling devices are essentially designed to provide cold therapy, with the primary difference being that water recirculation is more convenient with passive cooling devices. To document a benefit beyond convenience, the trial design must control the number of exchanges of ice bags and episodes of water recirculation. In contrast, active cooling devices are designed to provide a steady low temperature, which might provide a unique benefit compared to the more variable temperature achieved with ice packs or passive cooling devices. Benefit is typically focused on pain control and swelling. The discussion below focuses only on randomized studies.

Passive Cooling Devices

Schroder and Passler compared the CryoCuff® device to traditional ice therapy in 44 inpatients that had undergone repair of the anterior cruciate ligament (ACL) (Schroder, 1994). Those receiving ice therapy received an ice bag three times per day postoperatively, while the CryoCuff group used the device. While those randomized to the CryoCuff group reported significant decreases in pain, swelling and analgesic use, it was not reported how frequently the cold water was recirculated in the device. Additionally, the inpatient setting is not relevant to this policy, particularly since in this German study, patients were hospitalized for 14 days. Whitelaw and colleagues reported on the results of a trial that randomized 102 patients undergoing knee arthroscopy in the outpatient setting to receive either a CryoCuff device or traditional ice therapy (Whitelaw, 1995). The number of exchanges of ice packs and water recirculation was not reported. There was no significant difference in average pain assessment, while those in the CryoCuff group reported decreased pain medication compared to the control group. Healy and colleagues reported that the CryoCuff device provided no benefit to pain control or swelling compared to ice packs in a randomized trial of 76 patients (105 knees) undergoing total knee arthroplasty (Healy, 1994). No data was provided on the number of ice pack exchanges, although the water was recirculated in the CryoCuff device every one to four hours. The duration of therapy, and whether or not it was applied in the inpatient or outpatient setting is not clear from the published article. Edwards and colleagues studied the outcomes of 71 patients undergoing ACL reconstruction who were randomized to receive either CryoCuff therapy with ice water, CryoCuff therapy with room temperature water or no cold therapy (Edwards, 1996). Therefore, this trial did not include the relevant control group of patients treated with conventional ice packs. Nevertheless, there were no significant differences in analgesic use or pain assessment among the three groups, including the group that received no cold therapy. Levy and colleagues also compared the outcomes in a trial randomizing 80 patients (100 knees) undergoing total knee arthroplasty to receive either passive cold therapy with a CryoCuff device or no cold therapy (Levy, 1993). The CryoCuff group reported a significant decrease in blood loss and mild decrease in analgesic requirements. Similar to the Edwards trial, this trial did not include the relevant control group of ice packs. Another randomized trial by Brandsson suffers from the same limitation; in this study of 50 patients undergoing ACL repair, there was no group who received standard therapy with ice packs (Brandsson, 1996).

In summary, the available scientific literature is insufficient to document that the use of passive cooling systems is associated with a greater likelihood of benefit compared to standard ice packs. Many of the published randomized studies failed to include the relevant control group of standard ice packs. Studies that did include a control group of standard ice packs reported inconsistent results (Healy, 1994), and some studies reported no significant benefit of passive cooling devices compared to no cold therapy (Edwards, 1996).

Active Cooling Devices

In contrast, a literature search identified only one randomized study that compared the outcomes of an active cooling device with traditional ice therapy. Konrath and colleagues reported on the results of a trial that randomized 103 patients undergoing ACL reconstruction to one of four different postoperative cold therapy strategies; 1&2) active cooling with a Polar Care™ pad set at a temperature of 40 to 50 degrees or 70 to 80 degrees centrigrade, respectively; 3) ice packs; and 4) no cold therapy (Konrath, 1996). Both the water in the Polar Care pad and the ice packs were changed every 4 hours. The length of hospital stay, range of motion at discharge, use of oral and intramuscular pain medicine and drain output were not significantly different between groups. These results suggest that the active cooling device is similar to ice packs, but there is inadequate evidence to demonstrate that the active cooling device is associated with a greater likelihood of benefit. Several randomized studies compared active cooling devices to no cold therapy, which are not relevant to the documentation of benefit compared to standard therapy with ice packs (Cohn, 1989; Barber, 1998; Dervin, 1998).

Other Devices and Indications

A literature search did not identify any published articles focusing on the use of active or passive cooling devices equipped with pneumatic compression. Similarly there were no published articles focusing on the role of cooling devices in non-surgical settings, i.e., for the treatment of sprains or strains, or chiropractic treatments.

E. References

1. Barber FA, McGuire DA, Click S. Continuous-flow cold therapy for outpatient anterior cruciate ligament reconstruction. J Arthroscopy Rel Surg. 1998; 14:130-135.
2. Brandsson S, Rydgren B, Hedner T, et al. Postoperative analgesic effects of an external cooling system and intra-articular bupivacaine/morphine after arthroscopic cruciate ligament surgery. Knee Surg Sports Traumatol Arthroscopy. 1996; 4:200-205.
3. Cohn BT, Draeger RI, Jackson DW. The effects of cold therapy in the postoperative management of pain in patients undergoing anterior cruciate ligament reconstruction. Am J Sports Med. 1989; 17:344-349.

4. Dervin GF, Taylor DE, Keene GCR. Effects of cold and compression dressings on early postoperative outcomes for the arthroscopic anterior cruciate ligament reconstruction patient. J Orthop Sports Phys Ther. 1998; 27:403-406.
5. Healy WL, Seidman J, Pfeifer BA, Brown DG. Cold compressive dressing after total knee arthroplasty. Clin Orthop. 1994; 299:143-149.
6. Edwards DJ, Rimmer M, Keene, GCR. The use of cold therapy in the postoperative management of patients undergoing arthroscopic anterior cruciate ligament reconstruction. Am J Sports Med. 1996; 24:193-195.
7. Konrath GA, Lock T, Goitz HT, Scheidler J. The use of cold therapy after anterior cruciate ligament reconstruction. Am J Sports Med. 1996; 24:629-633.
8. Levy AS, Marmar E. The role of cold compression dressings in the postoperative treatment of total knee arthroplasty. Clin Orthop Rel Res. 1993; 297:174-178.
9. Schroder D, Passler HH. Combination of cold and compression after knee surgery. A prospective randomized trial. Knee Surg Spports Traumatol Arthrosc. 1994; 2:158-165.
10. Whitelaw GP, DeMuth KA. Demos HA, et al. The use of the Cryo/cuff versus ice and elastic wrap in the postoperative care of knee arthroscopy patients. Am J Knee Surg. 1995; 8:28-31.

A. Attachment: None

B. History:

Author/Reviewer: Sheldon Haas, MD; Date: June 2007
Committee Review: August 09, 2007; QA: August 28, 2007
Reviewed/Updates by Albert Reeves, M.D.; Date: August 11, 2011
Committee Review: UM: August 11, 2011; QA: August 23, 2011
Reviewed/No Changes: Albert Reeves, MD; Date: April 16, 2012
Committee Reviews: UM on May 10, 2012; QA: May 22, 2012
Reviewed/No Changes: Albert Reeves, MD; Date: 1/28/13
Committee Review: UM: February 14, 2013; QA: February 26, 2013
Reviewed/ No Updates: Catherine Sanders, MD
Committee Review: UM: February 13, 2014; QA: February 25, 2014
Reviewed/No Updates by: Faustine Dela Cruz, RN & Catherine Sanders, MD
Committee Review: UM: February 12, 2015; QA: February 24, 2015
Reviewed/No Updates by: Faustine Dela Cruz, RN & Catherine Sanders, MD
Committee Review: UM: February 11, 2016; QA: February 23, 2016
Reviewed/No Updates by: Catherine Sanders, MD & Robert Sterling, MD
Committee Review: UM: February 9, 2017; QA: February 28, 2017
Reviewed/No Updates by: Catherine Sanders, MD & Robert Sterling, MD
Committee Review: UM: February 8, 2018; QA: February 27, 2018
Reviewed/No Updates by: Catherine Sanders, MD & Robert Sterling, MD
Committee Review: UM: February 14, 2019; QAC: February 26, 2019
Reviewed/No Updates by**:** Howard Taekman, MD & Robert Sterling, MD
Committee Review: UM: February 13, 2020; QAC: February 25, 2020

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes

2/9/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual Review
2/8/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual Review
2/14/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual Review
2/13/20	No	Howard Taekman, MD; Robert Sterling, MD	Annual Review