Clinical Practice Guideline: **Superficial Heat and Cold**

Date of Implementation: **June 16, 2016**

Product: **Specialty**

Related Policies:
CPG 121: Passive Physiotherapy (Therapeutic) Modalities
CPG 135: Physical Therapy Medical Policy/Guidelines
CPG 155: Occupational Therapy Medical Policy/Guidelines
CPG 264: Acupuncture Services Medical Policy/Guidelines
CPG 278: Chiropractic Services Medical Policy/Guidelines

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GUIDELINES

A. American Specialty Health – Specialty (ASH) considers the proper application of hot or cold packs performed with other therapeutic procedures to be clinically appropriate for many patients with musculoskeletal disorders who have reported pain, edema, inflammation, or documented loss of mobility. The use of hot or cold packs as stand-alone treatments is rarely therapeutic, and thus not required or indicated as the sole treatment approach to a patient's condition.

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Circulating and noncirculating cooling devices, with or without compression, used in the outpatient setting are considered not medically necessary.

Notes Related to the Above Guideline

- The stand-alone application of hot or cold packs does not typically require the skills of a licensed health care professional and can be safely self-administered in accordance with provider instructions.
    - Services which do not require the skills of a licensed health care professional are considered not medically necessary.
- Cold and heat are believed to have therapeutic benefits to modify the disease processes (e.g., cold to reduce acute inflammation and swelling, and heat to speed healing through increased blood supply).
- Typical use involves application of cold for the first few days after onset of symptoms and thereafter application of heat.
- Use of ice packs and various bandages and wraps following surgery or musculoskeletal and soft tissue injury is common. It is medically reasonable to use hot/cold therapy for any musculoskeletal disorder, in which there may be inflammation (e.g., strains, sprains, tendinitis, tenosynovitis, contusions, fractures, epicondylitis, carpal tunnel syndrome, and osteoarthritis), or post-surgery.
    - The standard postoperative treatment for musculoskeletal surgeries consists of cryotherapy (cold therapy) and various types of compressive wraps. Both ice packs (with or without additives to maintain temperature) and cooling devices can provide cryotherapy. Circulating cooling devices are designed to provide a constant low temperature, which might provide additional benefit compared with the more variable temperature achieved with the intermittent replacement of ice packs. Noncirculating cooling devices might also allow less variable cooling due to the larger volume of ice stored in the insulated tank and the use of circulated ice water.

C. ASH considers use of paraffin baths as medically necessary when ALL of the following criteria are met:

- Treatment of pain and/or limited mobility of the distal extremities (hands and feet) (e.g., non-acute, chronic, or post-traumatic inflammatory conditions such as arthritis); and
- Applied prior to performance of a primary therapeutic procedure designed to increase mobility which enhances the ability to perform usual activities of daily living (e.g., combined with therapeutic exercise or manual therapy for a patient who has reported pain and/or documented limited mobility); and
- Patient is free of contraindications; and

- Documentation of a reduction in the patient’s pain and/or an improved mobility and ability to perform age-appropriate usual activities of daily living within the initial stages of treatment (i.e., 3 weeks).

Notes Related to this Entire Guideline:

- General Medical Necessity Criteria from CPGs 135, 155, 264, and 278 must also be met. See policy *Physical Therapy Medical Policy/Guidelines (CPG 135 – S), Occupational Therapy Medical Policy/Guidelines (CPG 155– S), Acupuncture Services Medical Policy/Guidelines (CPG 264– S), Chiropractic Services Medical Policy/Guidelines (CPG 278– S)* for information.
- Modalities should be selected based on the most effective and efficient means of achieving the patient’s functional goals. Seldom should a patient require more than one (1) or two (2) passive therapeutic modalities to the same body part during the therapy session. Use of more than two (2) passive therapeutic modalities on a single visit date and for a prolonged period is unusual and should be justified in the documentation for consideration of medical necessity.
- The use of modalities as stand-alone treatment is rarely therapeutic, and thus not required or indicated as the sole treatment approach to a patient’s condition. Therefore, a treatment plan should not consist solely of passive therapeutic modalities but should also include skilled therapeutic procedures [for example, chiropractic manipulation, manual therapy {CPT 97140}, therapeutic exercise, acupuncture, etc.].
- Multiple heating modalities should not be used on the same day. Exceptions are rare and usually involve musculoskeletal pathology/injuries in which both superficial and deep structures are impaired. Documentation must support the use of multiple modalities as contributing to the patient’s progress and restoration of function.
- When the symptoms that required the use of passive modalities begin to subside and function improves, the medical record should reflect the discontinuation of those modalities, so as to determine the patient’s ability to self-manage any residual symptoms. As the patient improves, the medical record should reflect a progression of the other procedures of the treatment program (therapeutic exercise, therapeutic activities, etc.). In all cases, the patient and/or caregiver should be taught aspects of self-management of his/her condition from the start of therapy.

CPT® Codes and Descriptions
(HCPCS codes for DME are not relevant to this CPG)*

CPT® Code	CPT® Code Description
97010	Application of a modality to 1 or more areas; hot or cold packs
97018	Application of a modality to 1 or more areas; paraffin bath

*Fluidized Therapy does not have a specific CPT® code

NOTE: It is not appropriate to bill for vasopneumatic device CPT® code 97016 for use of any circulating and noncirculating cooling devices with compression for purposes of superficial cold application.

DESCRIPTION/BACKGROUND

Cryotherapy

Cryotherapy is the therapeutic use of cold in a superficial manner. In rehabilitation settings, it is used to control pain and inflammation, edema, reduce spasticity and to facilitate movement (Cameron, 2022). Cryotherapy influences hemodynamic, neuromuscular, and metabolic systems. Initially vasoconstriction occurs (first 15-20 minutes) followed by vasodilation if the cold is applied for longer periods of time or when the tissue temperature reaches less than 10° C. Cold application also decreases nerve conduction velocity, increases pain threshold, and may also alter muscle strength. Cryotherapy has also been shown to reduce spasticity temporarily (Cameron, 2022). Both conventional cryotherapy 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. Examples of passive cold therapy units are those devices in which fluid flows through a blanket or cuff, providing immediate cooling to an affected area. The CryoCuff® uses an insulated jug filled with cold water attached to a cuff. Elevating the jug fills and pressurizes the cuff. Compression is controlled by gravity and is proportional to the elevation of the cooler. When body heat warms the water, it is re-chilled simply by lowering the cooler. Another passive cold compression therapy unit is the Polar Care Cub unit. 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. These more complicated cold therapy units may employ mechanical pumps and refrigerators that are powered by battery or electricity. The Game Ready™ Accelerated Recovery System is an example of an active cooling device that combines cold and intermittent pneumatic compression therapies. The system consists of a wrap, a connector hose, and a control unit. The wrap contains two internal chambers, one for air and the other for cooling water. The microprocessor control unit features various adjustable compression cycles and temperature controls. Another active system is the AutoChill® device, which may be used with a CryoCuff®, consists of a pump that automatically exchanges water from the cuff to the cooler, eliminating the need for manual water recycling. The Hot/Ice Thermal Blanket is another circulating cooling device. It consists of 2 rubber pads connected by a rubber hose to the main cooling unit. Fluid is circulated via the hose through the thermal blankets. The temperature of the fluid is controlled by the main unit and can be either hot or cold. The Hilotherm® Clinic circulates cooled water through preshaped thermoplastic polyurethane facial masks for use after different types of facial surgery. ThermaZone® provides thermal therapy with pads specific to various joints as well as different areas of the head (front, sides, back, eyes). CTM™ 5000 and cTreatment are computer-controlled devices that provide cooling at a specific (11°C, or 52ºF) and continuous temperature. However, there is no evidence that these more complicated cold therapy units provide any additional benefit over the CryoCuff or conventional ice bags or packs.

Cryotherapy Contraindications and Precautions

The use of cryotherapy is contraindicated for the following:

- Cold hypersensitivity
- Cold intolerance
- Cryoglobulinemia
- Paroxysmal cold hemoglobinuria
- Raynaud disease or phenomenon
- Over regenerating peripheral nerves
- Over an area with circulatory compromise or peripheral vascular disease

Precautions for cryotherapy include:

- Over the superficial branch of a nerve
- Over an open wound
- Hypertension
- Impaired or insufficient sensation or mentation or for pediatric patients unable to provide proper feedback for safe application.

Thermotherapy

Thermotherapy is the application of superficial heat. Within the rehabilitation environment, superficial heat is used to control pain, increase soft tissue extensibility and circulation, and accelerate healing. It also has hemodynamic, neuromuscular, and metabolic effects. Heat causes vasodilation with resultant increases in blood flow. Superficial heat agents do not heat to the level of most muscle tissue. Deep heating modalities such as ultrasound or diathermy are used for that purpose. Increased tissue temperature increases nerve conduction velocity and firing rates. Some studies have also found that heat will increase pain thresholds and reduce muscle strength (initial 30 minutes following heat application). Heat will also increase the metabolic rate, thus any heating agents should be avoided or used with caution in patients with acute inflammation (Cameron, 2022).

Hot packs, also known as hydrocollator packs, warm tissue by conduction. They typically consist of canvas bags filled with silicon dioxide that absorbs many times its own weight in water. Hot packs are immersed in a hot water bath, and are removed from the bath when needed, wrapped in 6 to 8 layers of toweling or an insulating cover, and applied to the patient. They are often used to heat the body part prior to rehabilitation/therapy. To avoid scalding, excess water should be drained from the pack and the covering towels or pad should be checked for excessive dampness. The packs cool slowly and can remain warm for 30 or more minutes. Medicare considers hydrocollator units as non-covered institutional equipment. Air-activated wearable heat wraps are another form of superficial heat that are commercially available and can be worn for up to 8 hours. They are made of cloth embedded with multiple discs made of iron powder, activated charcoal, sodium chloride and water. When the wrap is removed from the plastic and exposed to oxygen, the discs oxidize producing an exothermic reaction and thus heat. General indications for therapeutic heat include pain, muscle spasm, contracture, tension myalgia, hematoma resolution, bursitis, tenosynovitis, fibrositis, fibromyalgia, superficial thrombophlebitis, and collagen vascular diseases.

A paraffin bath is a modality designed to apply heat to the hands or feet through the use of paraffin wax. Paraffin baths are a device that delivers heat to a distal extremity by the use of melted paraffin and mineral oil, for the purpose of treating the extremity by creating a transient tissue temperature rise through heat conduction. Paraffin baths are primarily used to treat contractures or loss of mobility, particularly for patients with osteoarthritis, rheumatoid arthritis, hand contractures, or scleroderma. It can be used post surgically as well once surgical incisions are healed. It is applied prior to performing other therapeutic procedures designed to increase mobility which enhances the ability to perform usual activities of daily living. The typical paraffin bath consists of a container filled with approximately a 1:7 mixture of mineral oil and paraffin maintained at 52°C to 54°C. The patient may either continuously immerse the treated part for 20 to 30 mins or may repetitively dip and remove the treated area from the paraffin.

Fluidized therapy (fluidotherapy) is a high intensity heat modality consisting of a dry whirlpool of finely divided solid particles suspended in a heated air stream, the mixture having the properties of a liquid. It heats via convection. Warm air is circulated through the bottom of a bed of finely divided cellulose particles in a container. The combination of air flowing around the high surface area of the finely divided particles and the bulk movements of solids produces high heat fluxes and uniform temperatures throughout thus providing a strong massaging action, sensory stimulation, and levitation. Both temperature and amount of agitation can be adjusted. Temperatures for intervention typically range from 102° F to 118° F. The lower ranges are recommended for patients with edema formation and are used in the initial treatments. Patients can also do exercises while they are using fluidized therapy. The indications for fluidized therapy are similar to paraffin baths and whirlpool. Use of fluidized therapy dry heat is an acceptable alternative to other heat therapy modalities in reducing pain, edema, and muscle spasm from acute or subacute traumatic or non-traumatic musculoskeletal disorders of the extremities.

Thermotherapy Contraindications and Precautions

The use of thermotherapy is contraindicated for the following:

- Recent or potential hemorrhage
- Thrombophlebitis
- Impaired sensation
- Impaired mentation or for pediatric patients unable to provide proper feedback for safe application. Malignant tumor
- IR irradiation of the eyes

Precautions for use of thermotherapy include:

- Acute injury or inflammation
- Pregnancy
- Impaired circulation
- Poor thermal regulation
- Edema
- Cardiac insufficiency
- Metal in the area
- Over an open wound
- Over areas where topical counterirritants have recently been applied
- Demyelinated nerve

EVIDENCE REVIEW

Cryotherapy and Hydrocollator Packs

The Philadelphia Panel Practice Guidelines did not support the use of thermotherapy for knee pain (Philadelphia Panel Practice Guidelines, 2001). Brosseau et al. (2003) sought to determine the effectiveness of thermotherapy in the treatment of OA of the knee. The outcomes of interest were relief of pain, reduction of edema, and improvement of flexion or range of motion (ROM) and function. Randomized and controlled clinical trials including participants with clinical or radiographical confirmation of OA of the knee; and interventions using heat or cold compared to standard treatment or placebo were considered for inclusion. Three randomized controlled trials, involving 179 patients, were included in this review. The included trials varied in terms of design, outcomes measured, cryotherapy or thermotherapy treatments and overall methodological quality. In one trial, administration of 20 minutes of ice massage, 5 days per week, for 3 weeks, compared to control demonstrated a clinically important benefit for knee OA on increasing quadriceps strength. There was also a statistically significant improvement, but no clinical benefit in improving knee flexion ROM and functional status. Another trial showed that cold packs decreased knee edema. Authors concluded that ice massage compared to control had a statistically beneficial effect on ROM, function and knee strength. Cold packs decreased swelling. Hot packs had no beneficial effect on edema compared with placebo or cold application. Ice packs did not affect pain significantly compared to control in patients with OA. More well designed studies with a standardized protocol and adequate number of subjects are needed to evaluate the effect of thermotherapy in the treatment of OA of the knee.

A Cochrane review by Robinson et al. (2002) evaluated the effectiveness of different thermotherapy applications on objective and subjective measures of disease activity in patients with rheumatoid arthritis (RA). Comparative controlled studies, such as randomized controlled trials, controlled clinical trials, cohort studies or case/control studies, of thermotherapy compared to control or active interventions in patients with RA were eligible. No language restrictions were applied. Abstracts were accepted. Seven studies (n=328 subjects) met the inclusion criteria. The results of this systematic review of thermotherapy for RA found that there was no significant effect of hot and ice packs applications, cryotherapy and faradic baths on objective measures of disease activity including joint swelling, pain, medication intake, range of motion (ROM), grip strength, hand function compared to a control (no treatment) or active therapy. There is no significant difference between paraffin wax and therapeutic ultrasound as well as between paraffin wax and faradic bath combined to ultrasound for all the outcomes measured after 1, 2 or 3 week(s) of treatment. There was no difference in patient preference for all types of thermotherapy. No harmful effects of thermotherapy were reported. Authors concluded that superficial moist heat and cryotherapy can be used as a palliative therapy. Paraffin wax baths combined with exercises can be recommended for beneficial short-term effects for arthritic hands. These conclusions are limited by methodological considerations such as the poor quality of trials. The Ottawa Panel Evidence-Based Clinical Practice Guidelines (2004) reviewed the available literature for the effectiveness of thermotherapy for rheumatoid arthritis and concluded that hot paraffin wax plus exercise was more effective than a control treatment for increasing finger mobility. There were also “clinically important” improvements in pain and stiffness that did not reach statistical significance, suggesting the study was underpowered (*n*=13 per group).

In a review of the evidence for the treatment of low back pain (LBP), Chou and Huffman (2007) found that superficial heat was effective in the treatment of acute LBP (good evidence with moderate benefit). No evidence supported its use for chronic LBP. In another Cochrane Collaboration systematic review (French et al., 2006), superficial heat or cold was assessed for its effectiveness in treating LBP. Nine trials were included in this review. Authors concluded that the available evidence is limited to support the use of ice or heat for LBP. Some studies did report that over-the-counter heat wraps significantly reduced pain over the short-term. In a review by Poitras and Brosseau (2008), no studies were found eligible to support or refute the use of hot, cold, or ice packs for chronic LBP.

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Graham et al. (2013) completed a systematic review on physical modalities for acute to chronic neck pain. Of 103 reviews eligible, 20 were included and 83 were excluded. No benefit was noted for infrared light over placebo for whiplash associated disorder (WAD), Moderate evidence of no benefit: infrared light was no better than placebo for acute whiplash associated disorder, chronic myofascial neck pain or subacute to chronic neck pain. No added benefit was noted when hot packs were combined with mobilization, manipulation, or electrical muscle stimulation for chronic neck pain. Improved design and long term follow up were suggested for future research.

Raynor et al. (2005) conducted a meta-analysis of studies investigating the use of cryotherapy following anterior cruciate ligament (ACL) reconstruction. The authors identified six studies that met criteria and that were included in the analysis. They concluded that, while some individual studies did find significant impact on pain, drainage, or range of motion (ROM), the pooled analysis did not when controlling for data quality. In addition, the studies included in the analysis involved mostly small study populations and multiple groups, diluting the power of the findings. A study addressing the use of a passive cooling device was published in 2015 by Yu and colleagues investigated the effect of cryotherapy after elbow arthrolysis on elbow pain, blood loss, analgesic consumption, range of motion, and long-term elbow function. Patients were randomly assigned into a cryotherapy group (n=31, cryotherapy plus standard care) or a control group (n=28, standard care). For postoperative days 1 through 7, visual analog scale scores of pain both at rest and in motion indicated significantly better pain control in the cryotherapy group ($p<0.05$). There were no significant differences between the 2 groups in VAS scores at 2 weeks and 3 months after surgery. Less medication was consumed by the cryotherapy group than the control group for pain relief ($P<.01$). Authors concluded that cryotherapy was effective in relieving pain and reducing analgesic consumption for patients received elbow arthrolysis and that the application of cryotherapy will not affect blood loss, ROM, or elbow function.

Ruffilli et al. (2015) compared two homogeneous groups of patients, one receiving traditional icing regimen and the other a temperature-controlled continuous cold flow device, in post-operative setting after ACL reconstruction. The Hilotherm group resulted in lower pain perception (NRS), blood loss, knee volume increase at the patellar apex and 10 cm proximal to the superior patellar pole, and higher range of motion ($p < 0.05$) in the first post-operative day. No difference in pain killers’ consumption was noted. Authors concluded that the Hilotherm group showed significant better results in first post-operative day. Further studies with higher number of patients and longer follow-up are required to assess the beneficial effects on rehabilitation and the cost-effectiveness of the routinely use of this device. Kraeutler et al. (2015) compared the effect of compressive cryotherapy (CC) vs. ice on postoperative pain in patients undergoing shoulder arthroscopy for rotator cuff repair or subacromial decompression. A commercial device was used for postoperative CC. A standard ice wrap (IW) was used for postoperative cryotherapy alone. Forty-six patients completed the study and were available for analysis; 25 patients were randomized to CC and 21 patients were randomized to standard IW. No significant differences were found in average pain, worst pain, or morphine equivalent dosage on any day. Authors concluded that there does not appear to be a significant benefit to use of CC over standard IW in patients undergoing shoulder arthroscopy for rotator cuff repair or subacromial decompression. Further study is needed to determine if CC devices are a cost-effective option for postoperative pain management in this population of patients.

Ruffilli et al. (2017) completed a similar study on patients with total knee arthroplasty (TKA). The study was a prospective randomized controlled study, involving 50 patients after primary TKA. The two groups were homogenous for preoperative and intraoperative features. The groups showed no statistically significant differences in all the evaluated parameters. Results demonstrated that continuous cold flow device in the acute postoperative setting after TKA did not show superiority in reducing edema, pain, and blood loss, compared with traditional icing regimen. Thus, due to the costs, it should be reserved to selected cases. Gatewood et al. (2017) investigated the efficacy of device modalities used following arthroscopic knee surgery. Twenty-five studies were included in this systematic review, nineteen of which found a significant difference in outcomes. For alleviating pain and decreasing narcotic consumption following arthroscopic knee surgery, cryocompression devices are more effective than traditional icing alone, though not more than compression alone. CPM does not affect post-operative outcomes. Authors concluded that cryotherapy is recommended for inclusion into rehabilitation protocols following arthroscopic knee surgery to assist with pain relief, recovery of muscle strength and knee function, which are all essential to accelerate recovery.

Despite limited understanding of the response to heat, cold, or contrast modalities in the management of knee OA, the application of superficial heat or cold is very common, often self-initiated, and is considered a component of a “first-line” intervention in the management of knee pain in older adults. Porcheret et al. (2007) reported that of 201 older patients with knee pain surveyed, 84% reported applying superficial heat or cold, and most reported this treatment as a self-initiated intervention. Additionally, Cetin et al. (2008) reported that the use of superficial heat or cold in conjunction with diathermy, TENS or ultrasound led to varying levels of symptom relief and functional improvements in patients with knee OA. Denegar et al. (2010) assessed preferences for, and effects of, 5 days of twice daily superficial heat, cold, or contrast therapy applied with a commercially available system permitting the circulation of water through a wrap-around garment, use of an electric heating pad, or rest for patients with level II-IV osteoarthritis (OA) of the knee. Treatment with the device set to warm was preferred by 48% of subjects. Near equal preferences were observed for cold (24%) and contrast (24%). Pain reduction and improvements in KOOS subscale measures were demonstrated for each treatment but responses were ($P < 0.05$) greater with preferred treatments. Most patients preferred treatment with the water circulating garment system over a heating pad. Authors recommend that when superficial heat or cold is considered in the management of knee OA that patients experiment to identify the intervention that offers them the greatest relief and that contrast is a treatment option. In summary, the available scientific literature is insufficient to document that the use of passive cooling systems is associated with a greater likelihood of incremental 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 et al., 1994), and some studies reported no significant benefit of passive cooling devices compared to no cold therapy (Edwards et al., 1996). Several studies support the use of heat wraps for improvement of mobility and pain (Bellew et al., 2016).

Essentially, the evidence does not support the isolated use of hot packs, infrared light, for non-specific neck pain. There is moderate evidence to support the use of superficial heat for temporary reduction of pain and disability in the treatment of acute and sub-acute LBP. Although there were some adverse events reported, the literature precludes reliable and valid estimates of the risk of major and minor harm associated with these modalities. According to the AHRQ Comparative Effectiveness publication on Non-Invasive Treatments for Low Back Pain (2016), the following key points were reported for superficial heat and cold:

- For acute or subacute low back pain, a systematic review found a heat wrap more effective than placebo for pain relief at 5 days. Two subsequent trials also found a heat wrap associated with decreased pain intensity at 3 to 4 days or increased pain relief at 8 hours. Another trial found a heat wrap during emergency transport associated with substantially lower pain intensity versus an unheated blanket upon arrival to the hospital.
- For acute low back pain, one higher-quality trial found heat plus exercise associated with greater pain relief at day seven and on the RDQ versus exercise without heat.
- One fair-quality trial found heat plus an NSAID associated with better pain scores versus an NSAID without heat at day 15, based on the McGill Pain Questionnaire.
- For acute or subacute low back pain, a systematic review included one trial that found heat more effective for pain relief than acetaminophen or ibuprofen after 1 to 2 days of treatment; the heat wrap was also associated with greater improvement on the RDQ respectively.
- For acute low back pain, a systematic review included one trial that found no clear differences between heat versus exercise in pain relief or function.
- No study compared superficial cold versus placebo or no cold treatment.
- For acute low back pain, one small trial with methodological shortcomings found cold plus naproxen associated with better pain scores versus naproxen alone, based on the McGill Pain Questionnaire.
- There was insufficient evidence from three trials to determine effects of heat versus cold, due to methodological limitations and imprecision.

- Heat was not associated with increased risk of skin flushing versus no heat or placebo in two trials; no serious adverse events were reported with use of heat.

According to the 2017 American College of Physicians (ACP) clinical practice guideline on noninvasive treatments for acute, subacute, and chronic low back pain, Moderate-quality evidence showed that a heat wrap moderately improved pain relief (at 5 days) and disability (at 4 days) compared with placebo. Low quality evidence showed that a combination of heat plus exercise provided greater pain relief and improved Roland Morris Disability Questionnaire (RDQ) scores at 7 days compared with exercise alone in patients with acute pain. Low-quality evidence showed that a heat wrap provided more effective pain relief and improved RDQ scores compared with acetaminophen or ibuprofen after 1 to 2 days. Low-quality evidence showed no clear differences between a heat wrap and exercise in pain relief or function. Superficial heat is supported as a second-line or adjunctive treatment option for acute low back pain of less than 6 weeks in duration (Foster et al., 2018).

Szekeres et al. (2018) investigated the immediate effects of using a moist hot pack (MHP) vs therapeutic whirlpool bath (WB) for improving wrist ROM during a therapy session for patients with distal radius fracture. About 60 adult patients, with a mean age of 54 years in the MHP group and 53 years in the WB group, with healed distal radius fracture were randomized into 2 groups of 30. Patients in group 1 were placed in an MHP for 15 minutes during therapy. Patients in group 2 had their arm placed in a WB and were asked to perform active wrist ROM exercises for the same period. This occurred for 3 consecutive therapy visits, with wrist and forearm ROM being measured before and after heat during each visit. Both WB and MHP improved wrist ROM during therapy sessions in this study, making both these acceptable options for clinical use when the goal is to precondition a patient for other treatments. Authors concluded that individuals who received WB showed a statistically greater increase in wrist ROM than those receiving MHP during a therapy session, although the difference between groups may or may not be clinically important considering the small changes in ROM observed in this study.

Freiwald et al. (2018) studied the effects of supplemental heat therapy in multimodal treated chronic low back pain patients on strength and flexibility. Within a multimodal treatment concept, 176 patients with chronic low back pain were treated either with or without supplemental heat wrap therapy. The range of movement and strength parameters of the trunk in flexion, extension, lateral flexion and rotation were measured before and after 12 weeks of treatment. The range of movement as well as strength parameters of the trunk improved on average within the multimodal treatment. Patients receiving additional thermotherapy supplemental to basic multimodal treatment showed a further improvement of strength parameters regarding extension, rotation to the right and rotation to the left in comparison to those conducting only the multimodal treatment. No group differences were detected in flexibility. Authors concluded that the implementation of thermotherapy for

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several hours a day (heat wrap therapy) in daily clinical practice in addition to an individualized, evidence-based multimodal treatment concept can be recommended to enhance strength parameters.

Kwiecien and McHugh (2021) authored a paper on cryotherapy. Traditionally, ice is used in the treatment of musculoskeletal injury while cold water immersion or whole-body cryotherapy is used for recovery from exercise. In humans, the primary benefit of traditional cryotherapy is reduced pain following injury or soreness following exercise. Cryotherapy-induced reductions in metabolism, inflammation, and tissue damage have been demonstrated in animal models of muscle injury; however, comparable evidence in humans is lacking. This absence is likely due to the inadequate duration of application of traditional cryotherapy modalities. Traditional cryotherapy application must be repeated to overcome this limitation. Recently, the novel application of cooling with 15° C phase change material (PCM), has been administered for 3-6 h with success following exercise. Although evidence suggests that chronic use of cryotherapy during resistance training blunts the anabolic training effect, recovery using PCM does not compromise acute adaptation. Therefore, following exercise, cryotherapy is indicated when rapid recovery is required between exercise bouts, as opposed to after routine training. Ultimately, the effectiveness of cryotherapy as a recovery modality is dependent upon its ability to maintain a reduction in muscle temperature and on the timing of treatment with respect to when the injury occurred, or the exercise ceased. Therefore, according to authors, to limit the proliferation of secondary tissue damage that occurs in the hours after an injury or a strenuous exercise bout, it is imperative that cryotherapy be applied in abundance within the first few hours of structural damage.

Miranda et al. (2021) investigated the effectiveness of cryotherapy on pain intensity, swelling, range of motion, function, and recurrence in acute ankle sprain. Only 2 RCTs with high risk of bias were included. Both evaluated the additional effects of cryotherapy, comparing cryotherapy combined with other intervention versus other intervention stand-alone. Uncertain evidence shows that cryotherapy does not enhance effects of other intervention on swelling, pain intensity and range of motion. Authors concluded that current literature lacks evidence supporting the use of cryotherapy on management of acute ankle sprain. There is an urgent call for larger high-quality randomized controlled trials.

Klintberg and Larsson (2021) evaluated the certainty of evidence for the use of cryotherapy in patients with musculoskeletal disorders. Eight SRs and 50 RCTs from a total of 6,027 (+839) were included. In total 34 studies evaluated cryotherapy in surgical procedures, 12 evaluated cryotherapy use in acute pain or injury and twelve studies evaluated cryotherapy in long-term pain and dysfunction. The certainty of evidence is moderate (GRADE III) after surgical procedures to reduce pain, improve ROM, for patient satisfaction and few adverse events are reported. Cryotherapy in acute pain and injury or long-term pain and dysfunction show positive effects but have a higher number of outcomes with low certainty of evidence (GRADE II). Authors concluded that cryotherapy may safely be used in musculoskeletal injuries and dysfunctions. It is well tolerated by patients. More advanced forms of cryotherapy may accentuate the effect. Future research is needed where timing, temperature for cooling, dose (time) and frequency are evaluated.

Mendes et al. (2022) analyzed the effect of cryotherapy on pain intensity in the immediate post-operative period of ACL reconstruction. Fifteen studies were included in this review. Authors concluded that cryotherapy is effective in reducing pain intensity because there were reductions in the scores of subjective pain scales in the immediate post-operative period of ACL reconstruction. Cryo-compression was shown to be superior to conventional cryotherapy. Glattke et al. (2022) evaluated the efficacy of various rehabilitative modalities for ACL reconstruction. A total of 824 articles from 2012 to 2020 were identified using multiple search engines. Fifty Level-I or II studies met inclusion criteria and were evaluated. Authors note that cryotherapy is an effective analgesic when used perioperatively. Ruiz-Sánchez et al. (2022) reviewed the current clinical practice guidelines on management and treatment of ankle sprains, assess their quality, analyze the levels of evidence, and summarize the grades of recommendation. Seven clinical practice guides were included in this review. Seventeen recommendations were extracted and summarized. Six of the recommendations analyzed present enough evidence to be applied in clinical practice and are highly recommended for ankle sprain management: Ottawa rules, manual therapy, cryotherapy, functional supports, early ambulation, short term NSAIDs and rehabilitation.

Aggarwal et al. (2023) evaluated the effect of cryotherapy in the acute phase after total knee replacement (TKR) (within 48 hours after surgery) on blood loss, pain, transfusion rate, range of motion, knee function, adverse events, and withdrawals due to adverse events. Randomized controlled trials or controlled clinical trials comparing cryotherapy with or without other treatments (such as compression, regional nerve block or continuous passive motion) to no treatment, or the other treatment alone, following TKR for osteoarthritis were included. Major outcomes were blood loss, pain, transfusion rate, knee range of motion, knee function, total adverse events, and withdrawals from adverse events. Minor outcomes were analgesia use, knee swelling, length of stay, quality of life, activity level and participant-reported global assessment of success. Twenty-two (20 randomized trials and 2 controlled clinical trials) trials met inclusion criteria, with 1,839 total participants. The mean ages reflected the TKR population, ranging from 64 to 74 years. Cryotherapy with compression was compared to no treatment in 4 studies, and to compression alone in 9 studies. Cryotherapy without compression was compared to no treatment in eight studies. One study compared cryotherapy without compression to control with compression alone. All control interventions in the primary analysis were combined. Certainty of evidence was low for blood loss (downgraded for bias and inconsistency), pain (downgraded twice for bias) and range of motion (downgraded for bias and indirectness). It was very low for transfusion rate (downgraded for bias, inconsistency, and imprecision), function (downgraded twice for bias and once for inconsistency), total adverse events (downgraded for bias, indirectness, and imprecision) and withdrawals from adverse events (downgraded for bias, indirectness, and imprecision). The nature of cryotherapy made blinding difficult, and most studies had a high risk of performance and detection bias. Low-certainty evidence from 12 trials (956 participants) shows that cryotherapy may reduce blood loss at one to 13 days after surgery. Blood loss was 825 mL with no cryotherapy and 561 mL with cryotherapy: mean difference (MD) 264 mL less. Low-certainty evidence from six trials (530 participants) shows that cryotherapy may slightly improve pain at 48 hours on a 0- to 10-point visual analogue scale (lower scores indicate less pain). Pain was 4.8 points with no cryotherapy and 3.16 points with cryotherapy: MD 1.6 points lower. Authors were uncertain whether cryotherapy improves transfusion rate at zero to 13 days after surgery. The transfusion rate was 37% with no cryotherapy and 79% with cryotherapy (risk ratio (RR) 2.13; 2 trials, 91 participants; very low-certainty evidence). Low-certainty evidence from three trials (174 participants) indicates cryotherapy may improve range of motion at discharge: it was 62.9 degrees with no cryotherapy and 71.2 degrees with cryotherapy: MD 8.3 degrees greater. Authors were uncertain whether cryotherapy improves function two weeks after surgery. Function was 75.4 points on the 0- to 100-point Dutch Western Ontario and McMaster Universities Arthritis Index (WOMAC) scale (lower score indicates worse function) in the control group and 88.6 points with cryotherapy (MD 13.2 points better; 4 trials, 296 participants; very low-certainty evidence). Authors were uncertain whether cryotherapy reduces total adverse events: the risk ratio was 1.30 (16 trials, 1,199 participants; very low-certainty evidence). Adverse events included discomfort, local skin reactions, superficial infections, cold-induced injuries, and thrombolytic events. They were also uncertain whether cryotherapy reduces withdrawals from adverse events (RR 2.71; 19 trials, 1347 participants; very low-certainty evidence). No significant benefit was found for secondary outcomes of analgesia use, length of stay, activity level or quality of life. Evidence from seven studies (403 participants) showed improved mid-patella swelling between two and six days after surgery (MD 7.32 mm less), though not at six weeks and three months after surgery. The included studies did not assess participant-reported global assessment of success. Authors concluded that the certainty of evidence was low for blood loss, pain, and range of motion, and very low for transfusion rate, function, total adverse events, and withdrawals from adverse events. Uncertainty existed whether cryotherapy improves transfusion rate, function, total adverse events or withdrawals from adverse events. They downgraded evidence for bias, indirectness, imprecision and inconsistency. Hence, the potential benefits of cryotherapy on blood loss, pain and range of motion may be too small to justify its use. More well-designed randomized controlled trials focusing especially on clinically meaningful outcomes, such as blood transfusion, and patient-reported outcomes, such as knee function, quality of life, activity level and participant-reported global assessment of success, are required.

Wyatt et al. (2023) investigated the effect of various methods of cryotherapy on the following: (1) pain; (2) swelling; (3) postoperative opioid use; and (4) range of motion

(ROM) after TKR in a systematic review. The studied outcomes included pain ratings, knee/limb swelling, opioid use, and ROM. Six studies were selected for inclusion in this review. Results noted that opioid use was significantly decreased in cryotherapy groups compared to non-cryotherapy groups within the first postoperative week only ($P < .05$). This effect may be augmented by the use of computer-assisted (temperature regulated) cryotherapy devices, compared to other modalities including ice packs. Pain ratings also decrease, but this decrease may not be clinically relevant. Cryotherapy appears to confer no consistent benefit to ROM and swelling at any time point. Computer-assisted cryotherapy may be associated with decreased opioid consumption after TKA compared to traditional ice packs. Authors concluded that cryotherapy's role after TKA appears to be in decreasing opioid consumption primarily in the first postoperative week. Pain ratings also decrease consistently with cryotherapy use, but this decrease may not be clinically relevant. Study heterogeneity requires further research focusing on optimizing cryotherapy modalities within the first postoperative week, and analyzing cost associated with modern outpatient postoperative TKA protocols.

Paraffin Bath

Chang et al. (2014) compared the efficacy of combining a wrist orthosis with either US therapy or paraffin bath therapy in treating CTS patients. Twice per week, one group underwent paraffin therapy, and the other group underwent ultrasound therapy. Statistical analysis revealed significant improvements in symptom severity scores in both groups. After adjusting for age, gender and baseline data, the analysis of covariance revealed a significant difference in the functional status score between two groups. Authors concluded that the combination of ultrasound therapy with a wrist orthosis may be more effective than paraffin therapy with a wrist orthosis. Rashid et al. (2013) explored differences in the efficacy of mobilization techniques in post-traumatic stiff ankle with and without paraffin wax bath. The inclusion criteria were age range from 20-60 years, pain, loss of ROM, with history of trauma and fracture of ankle. The patients with similar complaints but with surgical treatment were excluded. Group A was given mobilization techniques with paraffin wax bath while group B was treated without paraffin wax bath. Authors concluded that joint mobilization and wax bath therapy is an effective and beneficial tool to improve the symptoms and quality of life in post-traumatic stiff ankle patients. They also noted that joint mobilization techniques combined with wax bath were more effective in the management of post-traumatic stiff ankle as compared to wax therapy alone. Sibtain sought to determine the efficacy of paraffin wax bath with mobilization techniques compared with joint mobilization alone. Authors concluded paraffin wax bath with joint mobilization techniques were more effective than mobilization techniques without paraffin wax bath in the rehabilitation of post traumatic stiff hand. Ordahan and Karahan (2017) investigated the effectiveness of paraffin therapy in patients with CTS. Seventy patients diagnosed with mild or moderate CTS were randomly divided into two groups as splint treatment (during the night and daytime as much as possible for 3 weeks) alone and splint (during the night and day time as much as possible for 3 weeks) + paraffin treatment (five consecutive days a week for 3 weeks). Clinical and electrophysiological assessments were performed before and 3 weeks after treatment. The patients were assessed by using visual analog scale (VAS) for pain, electroneuromyography (ENMG), and Boston Carpal Tunnel Syndrome Questionnaire (BCTSQ). The significant improvement was found in VAS scores in both groups when compared with pretreatment values ($p < 0.05$). There was no significant improvement in functional capacity score ($p > 0.05$), whereas a significant improvement was noted in the BCTQ symptom severity scale score in the splint group ($p < 0.05$). Significant improvements were demonstrated in both scorers in the combined treatment group. Similarly, significant improvements were found in the combined treatment group in terms of motor and sensory distal latency, sensory amplitude, and median sensory nerve velocity ($p < 0.05$). There was no significant change in electrophysiologic parameters in the splint group ($p > 0.05$), and the difference in these parameters between the groups was statistically significant ($p < 0.05$). In conclusion, using splinting alone in patients with CTS is an effective treatment for reducing symptoms in the early stages. Paraffin treatment with splint increases the recovery in functional and electrophysiological parameters.

Dellhag et al. (1992) evaluated the effects of active hand exercise and paraffin bath treatment in 52 subjects with RA. Authors reported that paraffin bath treatment followed by active hand exercise resulted in significant improvements of range of motion (ROM) and grip function. Active hand exercise alone reduced stiffness and pain with non-resisted motion and increased ROM. Paraffin bath alone had no significant effect. Robinson et al. (2002) evaluated the effectiveness of different thermotherapy applications on objective and subjective measures of disease activity in patients with RA. Seven studies (*n*=328 subjects) met the inclusion criteria. The results of this systematic review of thermotherapy for RA found that there was no significant effect of hot and ice packs applications and cryotherapy on objective measures of disease activity including joint swelling, pain, medication intake, range of motion (ROM), grip strength, hand function compared to a control (no treatment) or active therapy. There is no significant difference between wax and therapeutic ultrasound for all the outcomes measured after 1, 2 or 3 week(s) of treatment No harmful effects of thermotherapy were reported. Authors conclude that superficial moist heat and cryotherapy can be used as a palliative therapy. Paraffin wax baths combined with exercises can be recommended for beneficial short-term effects for arthritic hands. They noted that these conclusions were limited by methodological considerations such as the poor quality of trials.

Dilek et al. (2013) evaluated the efficacy of paraffin bath therapy on pain, function, and muscle strength in patients with hand osteoarthritis. At baseline, there were no significant differences between groups in any of the parameters ($P>.05$). After treatment, the paraffin group exhibited significant improvement in pain at rest and during ADL, ROM of the right hand, and pain and stiffness dimensions of the outcome measures used. The control group showed a significant deterioration in right hand grip and bilateral lateral pinch and right chuck pinch strength, but there was no significant change in the other outcome measures.

When the 2 groups were compared, pain at rest, both at 3 and 12 weeks, and the number of painful and tender joints at 12 weeks significantly decreased in the paraffin group. Bilateral hand-grip strength and the left lateral and chuck pinch strength of the paraffin group were significantly higher than the control group at 12 weeks. Authors conclude that paraffin bath therapy seemed to be effective both in reducing pain and tenderness and maintaining muscle strength in hand osteoarthritis and may be regarded as a beneficial short-term therapy option, which is effective for a 12-week period.

Sandqvist et al. (2004) investigated the effects of treatment with paraffin bath in patients with systemic sclerosis (scleroderma). In 17 patients with scleroderma one hand was treated daily with paraffin bath in combination with hand exercise. The other hand was treated with exercise only and was considered a control. Hand function was estimated before treatment and after 1 month of treatment, concerning hand mobility and grip force, and perceived pain, stiffness, and skin elasticity. At the follow-up, finger flexion and extension, thumb abduction, volar flexion in the wrist, and perceived stiffness and skin elasticity had improved significantly in the paraffin-treated hand compared with the baseline values. In this pilot study, hand exercise in combination with paraffin bath seemed to improve mobility, perceived stiffness, and skin elasticity. Mancuso and Poole (2009) investigated whether the use of paraffin and active hand exercises would improve activity and participation in persons with scleroderma. In this series of 3 single case studies, participants used paraffin and performed active hand exercises daily for 8 weeks. All participants experienced clinically significant improvements in both body function/structure measurements of hand function and in their ability to participate in activities. Significant improvements were found more frequently on body function/structure measures than activity/participation measures. Authors reported that this preliminary study lends support in favor of using paraffin and hand exercises as a treatment to improve hand function related to participation in daily activities in persons with scleroderma. Further research with a larger sample and increased variable control should be performed.

Fluidized Therapy (Fluidotherapy)

Kelly et al. (2005) examined the effects of the superficial heating modality, fluidotherapy, on skin temperature and on sensory nerve action potential (SNAP) conduction latency and amplitude of the superficial radial nerve in healthy individuals. Results demonstrated a significantly elevated superficial skin temperature, while tactile stimulation alone and no treatment (control group) did not bring about a temperature change. As the superficial skin temperature increased, there was an associated decrease in the distal sensory latency of the superficial radial sensory nerve action potential. Authors concluded that these results should be an important consideration for the clinician using superficial heating modalities. Studies comparing its effective heating with that of a paraffin bath and whirlpool have found them to be similar (Borrell et al., 1980). Han and Lee (2017) investigated the effect of fluidotherapy on hand's dexterity and activities of daily living for stroke patients with upper limb edema. The objective of the present study was to treat 30 stroke patients with a three-week course of fluidotherapy to investigate the efficacy of such therapy for reduction of edema. Authors conclude that findings suggest that using fluidotherapy can reduce edema, and such a reduction can have a positive effect on activities of daily living.

Sezgin Ozcan et al. (2019) evaluated whether combining fluidotherapy to conventional rehabilitation program provides additional improvements on pain severity, upper extremity functions, and edema volume in patients with poststroke complex regional pain syndrome (CRPS). Thirty hemiplegic patients with subacute stage CRPS type-1 of the upper extremity were randomly divided into 2 groups. Both groups received a 3-week conventional rehabilitation program (5 days/week, 2-4 hours/day). The experimental group received 15 sessions additional fluidotherapy application to the affected upper extremity (40° C, 20 minutes in continuous mode, 5 sessions/week). At the post-treatment evaluation, significant improvements were revealed regarding to the edema volume, pain visual analog scale, painDETECT and functional independence measure scores, and the Brunnstrom stages of upper extremity and hand in both groups ($P < .05$). But among the parameters mentioned above, only the decrease in edema volume and the painDETECT scores were greater in fluidotherapy group than the control group ($P < .05$). Authors concluded that the addition of the fluidotherapy to the conventional rehabilitation program provides better improvements on neuropathic pain and edema volume in subacute stage poststroke CRPS. Erdinc Gündüz et al. (2019) evaluated the efficacy of dry heat treatment (fluidotherapy) in improving hand function in patients with rheumatoid arthritis. All patients were randomly divided into two groups. Group 1 underwent dry heat treatment (fluidotherapy) and Group 2 was a control group. Patients in both groups participated in a joint protection and exercise program. A total of 93 participants were allocated to Group 1 ($n = 47$) and Group 2 ($n = 46$). At baseline, there were no significant differences between the groups in any parameter except significantly poorer Health Assessment Questionnaire score in Group 1 ($P = 0.007$). At week 3, there were no significant differences between the groups in any of the parameters ($P > 0.005$). At week 12, Duruoz Hand Index scores were significantly better in Group 2 ($P = 0.039$). Authors concluded that dry heat treatment (fluidotherapy) was not effective in improving hand function in patients with rheumatoid arthritis. Moreover, no positive effect on any other clinical parameters was observed.

Kanika et al. (2023) reviewed the available literature of physiotherapy treatment for CRPS following a stroke. Out of all 389 studies, only 4 RCT's were included for systematic review and meta-analysis. Mirror therapy, Laser therapy and Fluidotherapy was found to be effective than control in improving pain intensity and functional independence in patients with CRPS following stroke. This review concluded that physiotherapy interventions in the form of exercise therapy and electrotherapy has proven to be effective in treating the symptoms of CRPS following stroke.

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education, training, and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a member only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the member to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2017).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See policy *Managing Medical Emergencies (CPG 159 – S)* for information.

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