

Thienpont E. Does advanced cryotherapy reduce pain and narcotic consumption after knee arthroplasty? Clin Orthop Relat Res. 2014;472(11):3417-23.

Design: Randomized clinical trial

Purpose of study: to compare the effectiveness of advanced cryotherapy devices with that of cold pack in alleviating pain and decreasing narcotic use in patients undergoing knee arthroplasty

Population/sample size/setting:

- 100 patients (25 men, 75 women, mean age 68) undergoing knee arthroplasty at a University orthopedics department in Brussels
- Patients were eligible if they were undergoing primary knee arthroplasty for osteoarthritis between January 2012 and October 2012 and had not had previous surgery apart from meniscectomy in the affected knee
- Exclusion criteria were inflammatory disease, infection, neurologic problems, coagulopathy, preoperative anticoagulation, or a history of deep vein thrombosis or pulmonary emboli

Interventions:

- All patients were operated on by the same surgeon with a minimally invasive procedure with a subvastus approach and all received a cemented implant under general anesthesia; no lateral releases were done and no drains were used, and continuous passive motion was also not used, but enoxaparin was used in all patients after surgery
- All patients had the same multimodal preventive and postoperative pain treatment with acetaminophen, celecoxib, and local infiltration analgesia with adrenaline, with morphine or tramadol postoperatively for breakthrough pain as needed
- All patients had the same rehabilitation program beginning with full weightbearing the day after surgery and active ROM exercises
- Patients were allocated to two treatments with a quasi-randomized schedule in which the operating room (OR) management decided the ordering in which patients would be operated on and the patients were alternated between the two groups; at least four operations were done each day that the OR was used for the knee replacements
- Allocation was to cryotherapy (n=50) or conventional cold packs with ordinary ice and water (n=50)
 - o Cryotherapy was done with a computer-assisted system with continuous controlled cold therapy maintaining a steady temperature of 11° C for a prolonged time
 - The device was begun in the recovery room for 4 hours and continued in the patient's room

- On the morning after surgery the device was used for two hours, then the patients had scheduled physical therapy, then the device was used again for two hours; this sequence was repeated in the afternoon, after which the patients could use it during the evening and night as they felt the need
- The control group had conventional cold packs (2 packs anterior and 1 pack posterior to the knee), applied for 15 minutes at a time in the recovery room and again on arrival back at the ward; it was repeated 2 hours and 4 hours after surgery
 - On the following days the patients used the cold back for 15 minutes after their PT sessions in the morning and again in the afternoon, with the option of using it during the evening and night as they felt the need

Outcomes:

- The primary outcomes were (1) scores of postoperative pain (VAS at rest and during active deep knee flexion) and (2) analgesic use measured as morphine and tramadol consumption
- The length of hospital stay was five days for both groups
- No differences were observed on postoperative pain scores or on analgesic use
 - On day 2, when postoperative pain tends to be the worst, the mean VAS on movement was 5.5 in both groups, and the mean VAS for pain at rest was 4 in the cryotherapy group and 3.5 in the cold pack group; the mean VAS for pain on walking on day 2 was 5.5 in the cryotherapy group and 4.5 in the cold pack group
 - The groups consumed nearly identical amounts of morphine (38 for cryotherapy and 38.5 mg for cold packs), and similar amounts of tramadol (282 mg for cryotherapy and 317 mg for cold packs)
- Several secondary measures, such as range of motion, swelling, hematoma, and walking without aid, were equal between groups; the cold pack group slightly outperformed the cryotherapy group on active flexion at 6 weeks postop (120° vs 114°)

Authors' conclusions:

- Advanced cryotherapy devices do not offer any advantages over conventional cold packs in the setting of knee replacement for OA
- The cryotherapy device did keep some patients awake at night because of the noise the device makes
- A possible weakness was that the treatment with cryotherapy was not continued at home, where it could have been beneficial; however, that was not possible in the study setting

Comments:

- There was some compromise of the allocation concealment and the blinding due to the allocation of patients
- However, these features of the study are not flaws, because the lack of blinding (in a study partly supported by the device maker) would tend to produce spurious advantages for the cryotherapy device rather than erase any advantages of the product
- There is a misprint in the description of the cold pack, which was set at -17°C in the text; the actual temperature was not described, but could have been close to 0°C ; the fact that the pack was applied for only 15 minutes rather than 2 hours suggests that it could have been colder than the cryotherapy device
- The fact that the cold pack was applied for a shorter time than the cryotherapy device also would tend to favor the cryotherapy device rather than the cold pack
- The sample size was sufficient to detect any clinically important differences in the main outcomes

Assessment: high quality study which supports good evidence that a conventional cold pack is as effective as an advanced computer-controlled cryotherapy device in relieving pain after knee arthroplasty for osteoarthritis