



Multifaceted Comparison of Two Cryotherapy Devices Used After Total Knee Arthroplasty



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Cryotherapy Device Comparison

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BACKGROUND: Some form of cryotherapy used after total knee arthroplasty is commonplace. However, various factors determine the specific device deployed.

PURPOSE: This study aimed to answer the following questions:

- Is an ice/gel pack cryotherapy wrap noninferior to a more elaborate circulating cold water therapy device in terms of patient outcomes, patient satisfaction, and hospital staff satisfaction?
- What is the projected economic impact of using an ice/gel pack cryotherapy wrap versus a circulating cold water cryotherapy device?

METHODS: A group of 100 patients undergoing primary total knee arthroplasty by a single surgeon were enrolled in an institutional review board–approved, prospective study and randomized to receive either a circulating cold water or ice/gel pack cryotherapy device postoperatively. Demographic, pain, swelling, blood loss, range of motion, compliance, satisfaction, and adverse event outcomes were recorded until 6 weeks after surgery. Hospital staff satisfaction and economic variables were examined.

RESULTS: The ice/gel pack cryotherapy wrap was noninferior to the cold water cryotherapy device for any patient outcome measured. Average pain level at 6 weeks postoperative was significantly less in the ice/gel pack cryotherapy wrap group. Hospital staff satisfaction was higher with the ice/gel pack cryotherapy wrap.

Substantial economic savings can be realized at our institution by switching to the lower cost cryotherapy device.

CONCLUSION: In this study, the lower cost ice/gel pack cryotherapy wrap was noninferior to the circulating ice water cryotherapy device with respect to objective patient outcomes and subjective patient satisfaction after total knee arthroplasty. Hospital staff satisfaction and economic considerations also favor the ice/gel pack compression cryotherapy wraps.

Total knee arthroplasty (TKA) is utilized for the treatment of end-stage knee arthritis in many countries around the world. In the United States, the projected growth in demand for joint arthroplasty is dramatic (Kurtz, Ong, Lau, Mowat, & Halpern, 2007). Knee arthroplasty can provide significant improvements in pain, mobility, function, and health-related quality of life (Adie, Naylor, & Harris, 2010). However, these benefits come at the expense of early postoperative pain, swelling/edema, stiffness with reduced range of motion (ROM), and blood loss (Thienpont, 2014; Webb, Williams, Ivory, Day, & Williamson, 1998). Using cold and compression for soft tissue injury has been well-documented and described since several hundred years BC. (Drez & Committee, 1989; Kullenberg, Ylipää, Söderlund, & Resch, 2006; Webb et al., 1998). Several forms of cryotherapy are available including applying crushed ice in bags, cold/gel packs, circulating ice water, or computer-assisted continuous controlled cold therapy to the skin surrounding an area of trauma or surgery (Adie et al., 2010; Thienpont, 2014). The combination of cold and compression limits capillary ooze and development of hematoma, promotes vasoconstriction reducing the local inflammatory response, swelling, and heat due to the trauma/surgery, and slows the conduction of nerve fibers producing a reduction in pain transmission and improved anesthetic effect that may last long after the cooling is stopped (Algaflly & George, 2007; Farry,

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Prentice, Hunter, & Wakelin, 1980; Khoshnevis, Craik, & Diller, 2014; Kullenberg et al., 2006; Levy & Marmar, 1993; Martin, Spindler, Tarter, & Detwiler, 2002; McMaster & Liddle, 1980; Nielsen, 1983; Thienpont, 2014; Webb et al., 1998).

A main goal of multimodal pain management after knee arthroplasty is to minimize the use of opioids and their related adverse effects (Baratta, Gandhi, & Viscusi, 2014). Cryotherapy may have a role in multimodal pain management after knee surgery with its possible benefits and minimal side effects (Koyonos, Owsley, Vollmer, Limpisvasti, & Gambardella, 2014). Cryotherapy has long been a standard of care at our institution while its standard use varies greatly among and between countries (Barry, Wallace, & Lamb, 2003; Thienpont, 2014).

However, several recent systematic reviews and meta-analyses, including a review of the Cochrane Database, have yielded mixed results ranging from some reviews finding a lack of support for cryotherapy after TKA with the potential benefits being too small to justify its routine use to others observing the benefits were obvious regarding minimizing blood loss with cryotherapy decreasing pain and positively impacting quadriceps activation (Adie, Kwan, Naylor, Harris, & Mittal, 2012; Adie et al., 2010; Ewell, Griffin, & Hull, 2014; Markert, 2011; Ni et al., 2014). It is our duty as healthcare providers to appropriately allocate finite resources to evidence-based approaches shown to be efficacious in an era of increasing expenses, decreasing reimbursement, and escalating national and international healthcare expenditures. To that end, our study aimed to answer the following questions: Is an ice/gel pack cryotherapy wrap noninferior to a more elaborate circulating cold water therapy device in terms of patient outcomes, patient satisfaction, and hospital staff satisfaction?

What is the projected economic impact of using an ice/gel pack cryotherapy wrap versus a circulating cold water cryotherapy device?

Methods

STUDY DESIGN

Our hospital's institutional review board approved this prospective, randomized controlled study. One hundred patients were consented and prospectively enrolled from June 2012 to September 2013 after meeting our inclusion criteria. All patients subsequently underwent an elective, primary TKA by a single surgeon at a single institution and were randomized into one of two groups to receive postoperatively either the circulating cold water with static compression device (Polar Care Glacier; Breg, Inc.) or the ice/gel pack cryotherapy static compression wrap (Knee Compression Wrap; Solution Matrix, Inc.).

Patients with a primary diagnosis of osteoarthritis scheduled to undergo a primary, unilateral TKA by one surgeon were enrolled and consented by a nurse in our preoperative, day surgery area. Patients had to be at least 18 years of age, anticipated to be discharged to home rather than a skilled nursing or rehabilitation facility, able to read and understand English, and be willing and able to return for follow-up visits and meet with

the research team (if necessary). Patients could not have physical or cognitive limitations that would contraindicate the application and use of each device or to answer study questions. Patient could have no previous experience with either device. Patients with any known coagulopathies were also excluded.

Nurses and certified nurse assistants on the hospital inpatient orthopaedic floor responsible for taking care of study patients postoperatively were thoroughly educated on the appropriate application, use, and adverse effects of each device (according to the manufacturers' instructions) by our hospital's joint care coordinator.

Randomization was performed by a computerized random number generator (Microsoft Excel, 2013) and patients who met criteria were placed sequentially into either the circulating cold water device or ice/gel pack cryotherapy groups.

Demographic data including age and gender were collected on each patient. On the morning of surgery in the preoperative holding area, each patient's thigh/knee circumference 3 cm above the midpatella on the operative extremity was measured and recorded. A preoperative multimodal regimen of extended release oxycodone, celecoxib, and scopolamine was given. An epidural with intravenous sedation or general anesthesia without femoral or adductor canal block was performed by a trained anesthesiologist. A single surgeon then performed a primary, unilateral TKA using a mini-midvastus approach under tourniquet with a cemented, cruciate-retaining implant. Bupivacaine with epinephrine was injected periarticularly prior to final component implantation in all patients. No lateral patellar releases were performed. An autoreinfusion drain was used and output recorded for each patient. An immediate postoperative dressing consisting of three 4 × 8 pieces of sterile gauze, two ABD dressings, and a toe-to-groin ACE wrap was applied to each patient in the operating room. In the recovery room, either the circulating cold water device or the ice/gel cryotherapy wrap was applied per the randomization schedule. The postoperative cryotherapy usage protocol is summarized in Table 1. For the circulating cold water device, the temperature dial was set at its coolest setting. For the ice/gel pack compression cryotherapy wraps, patients and staff were instructed to replace the gel packs with fresh, frozen packs every 3–4 hours.

Postoperative multimodal pain management included long- and short-acting oral narcotics, celecoxib, and intravenous narcotics for breakthrough pain after removal of the epidural. The amount of in-hospital narcotic administration was recorded and converted into an equianalgesic morphine dose for analysis. All patients followed the same postoperative rehabilitation program. Patients ambulated a minimum of 15 ft on the day of surgery and progressed per their therapists' direction. No continuous passive motion machines were utilized. All patients received pharmacologic anticoagulation and sequential compression devices. The immediate postoperative dressing was changed to a single island dressing, and knee-high compression stockings were applied immediately prior to discharge or on postoperative day 2, whichever came later. The thigh/knee circumference was measured and recorded again

TABLE 1. POSTOPERATIVE CRYOTHERAPY USAGE PROTOCOL

Treatment Period	Frequency/Duration	Skin Inspection
Days 1–3 after surgery	While awake: Continuous	Inspect skin under pad every 1–2 hours
	While asleep: Continuous	Inspect skin upon waking
Days 4–10 after surgery	While awake: 1 hour on and 1 hour off	Inspect skin under pad every 1–2 hours
	While asleep: Continuous	Inspect skin upon waking
Day 11 after surgery and beyond	While awake: As needed for pain control: Continuous for 1-hour intervals; not to exceed 12 hours/day	Inspect skin under pad every 1–2 hours
	While asleep: May be used continuously as needed for pain control	Inspect skin upon waking

at the time of the first dressing change. Operative knee ROM was recorded at hospital discharge. Hospital length of stay, number of blood transfusions, change in hematocrit (HCT)/hemoglobin (HGB), and presence of complications were all recorded.

Study patients were followed postoperatively at 3 weeks and 6 weeks. At discharge and at each follow-up visit, patients were asked to complete a questionnaire specifically designed for this study (see Figure 1). Patients' thigh/knee circumference was also measured and recorded at each visit along with the presence of any adverse events or equipment failures.

OUTCOME MEASURES

Any narcotic pain medication provided to a patient during his or her hospitalization was recorded by the hospital nursing and pharmacy personnel. The total amount of narcotic medication utilized by each study patient was calculated and then converted into an equiesic morphine equivalent dose for comparison. Preoperative HGB and HCT were recorded as Gm/dL and percentage, respectively. The preoperative HGB and HCT were then compared with the final postoperative HGB and HCT drawn on the day of discharge and the changes in values were calculated. The total amount of output from the surgical drain was recorded as cubic centimeters. Drains were routinely discontinued when output fell below 50 cc/8 hours. The number of units of allogeneic blood transfusions required for each patient was recorded. Range of motion of the operative knee on the day of discharge was measured and recorded by physical therapists trained in postoperative joint arthroplasty rehabilitation. Thigh/knee circumference was measured at a point 3 cm proximal to the midpatella using the same flexible ruler at each time point. Length of stay was measured in days. Equipment failures were defined as any event necessitating a change or replacement of a part or the entire device. For data analysis, the response choices to the first patient study questionnaire question (On average, how often have you used the cooling device in the past 3 weeks?) were converted to a 0 to 5 numerical scale as follows: Did not use = 0, Once a day = 1, 2 Times a day = 2, 3 Times a day = 3, Greater than 3 times a day = 4, and Nonstop = 5. Similarly, the response choices to the third patient study questionnaire question (On average, how often have you needed to use pain medication in the past 24

hours?) were converted to a 0 to 5 numerical scale as follows: Not at all = 0, Less than every 3–4 hours = 1, Every 3–4 hours = 2, Every 6–8 hours = 3, Every 12 hours = 4, and Greater than every 12 hours = 5. For the study questionnaire question regarding the duration the cooling device provided a cooling effect, nonsensical (>360 minutes) and nonnumerical (continuous, always, constant, etc.) answers were eliminated from analysis. Ease of use and patient overall satisfaction were scored by the study patients on a 1–5 scale ranging from very difficult to very easy for ease of use and very dissatisfied to very satisfied for overall satisfaction.

At the end of the study, nurses and certified nurse assistants engaged in an online, web-based survey (see Table 2) to poll hospital staff regarding their experience with each device (SurveyMonkey, www.surveymonkey.com). Hospital cost data were obtained from current market price of each device and extrapolated for current and projected TKA volume at our institution.

DATA ANALYSIS

The study data were tested for noninferiority using χ^2 , Wilcoxon rank sum, and *t* tests (Walker & Nowacki, 2011). Chi-square tests were used for ratings data and Wilcoxon rank sum and *t* tests were used for measurement data. A 95% confidence interval was used for all tests. To resolve situations with missing data, only available data from a follow-up measurement or rating were included in the statistical analysis. Power analysis demonstrated that this study contained a sufficient sample size to prove noninferiority for each of the power analysis parameters analyzed with an appropriate equivalence margin, 80% power, and a significance level of 0.05. Statistical analysis was performed with Excel 2013 (Microsoft, Redmond, WA).

Results

One hundred patients were deemed eligible, consented, and enrolled in the study. Of these 100 patients, 49 were randomized into the circulating cold water device group and 51 into the ice/gel pack group. After initial enrollment, three patients declined further participation in the study. All three patients were in the ice/gel pack group leaving 49 patients in the circulating cold water group and 48 patients in the ice/gel pack group. Statistical analysis was performed on a per-protocol basis.

Patient Identification #: _____

An investigation comparing the use of the Breg "Polar Care" Cold Therapy System versus the Solution Matrix, Inc. Cold Therapy wrap for patients undergoing Total Knee Replacement.

Please complete the following questions as they relate to your experience with the cooling device used following your total knee replacement surgery.

1. On average, how often have you used the cooling device in the past three weeks?	Did not use	Once a day	2 Times a Day	3 Times a Day	Greater than 3 Times a Day	Nonstop

2. On average, how long did the cooling device provide a cooling effect?	Number of Minutes			Did Not Feel Cool		

3. On average, how often have you needed to use pain medication in the past 24 hours?	Not at all	Less than Every 3-4 hours	Every 3-4 hours	Every 6-8 hours	Every 12 hours	Greater than every 12 hours

4. Please rate the ease of use of the cooling device.	1 Very Difficult	2 Difficult	3 Neither Easy nor Difficult	4 Easy	5 Very Easy

5. Please rate your overall satisfaction with the cooling device.	1 Very Unsatisfied	2 Unsatisfied	3 Neutral	4 Satisfied	5 Very Satisfied

6. Circle your average pain level over the last 24 hours in the scale to the right?

Pain Scale

0 1 2 3 4 5 6 7 8 9 10
0 No Pain 5 Moderate Pain 10 Worst Pain

7. Did you experience any equipment failure while using the cooling device?	Yes	No

If yes, please describe: _____

Thank you for completing the questionnaire and being part of the research study.

FIGURE 1. Study questionnaire administered to patients at discharge, 3 weeks, and 6 weeks postoperatively.

There was no significant difference in average age or gender between the ice/gel pack cryotherapy wrap group and the circulating cold water therapy device group (64.65 vs. 65.33; $p = .1492$ and 60% female vs. 53% female; $p = .2282$, respectively). Similarly, there were no differences found for in-hospital outcomes of length of stay, total drain output, change in HGB or HCT, number of blood transfusions, or day of discharge ROM–flexion or ROM–extension (see Table 3).

At discharge, 3-week follow-up visit, and at the 6-week follow-up visit, 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, number of equipment failures, or patient overall rating of satisfaction with each device (see Table 4). Overall, there were eight reports of a cooling device not feeling cool; however, there was no consistency in this perception between device used or study interval.

There were no significant differences in the thigh/knee circumference measurements preoperatively, nor were there significant differences in the change in thigh/knee measurement at the first in-hospital dressing change, 3-week follow-up visit, or the 6-week follow-up visit as compared to the preoperative measurement for either group (see Table 5).

TABLE 2. HOSPITAL STAFF SATISFACTION/EXPERIENCE SURVEY QUESTIONS

Question	Response Type
Have you used a cooling device when caring for your patient?	Yes/No
How many minutes during your shift did you spend applying or replenishing the "Polar Care" cold therapy device?	Number of minutes
How many minutes during your shift did you spend applying or replenishing the "Solution Matrix" cold therapy wrap?	Number of minutes
Did you observe any patient safety concerns? ^a	Yes/No
Were patients compliant with the recommended use of the cold therapy?	Yes/No
Which product would you recommend for your patients to apply cold therapy?	Polar Care/Solution Matrix Wrap

^aStaff were allowed to write in comments to this question.

There were no significant differences in average pain level at discharge or the 3-week follow-up visit; however, there was a significant difference in average pain level at 6 weeks with a lower pain rating in the ice/gel pack cryotherapy group (see Table 4).

The results of hospital staff survey comparing the ice/gel pack cryotherapy wrap and the circulating cold water device demonstrated a fewer average number of minutes applying/replenishing the gel pack wrap (8.75 minutes) versus the circulating cold water device (15.72 minutes), 54.5% of respondents observed a safety concern (all related to the circulating cold water device's cords/tubing and none to the gel pack wraps), 90.9% overall patient compliance with each device, and 72.7% of hospital staff respondents recommend the ice/gel pack cryotherapy wrap over the circulating cold water device.

At our institution, the ice/gel pack cryotherapy wrap costs \$97.34 less than the circulating cold water device. Therefore, for every 100 TKAs performed, our institution would see cost savings of \$9,734 if the ice/gel pack cryotherapy wrap was used rather than the circulating cold water device.

Discussion

Cryotherapy and compression devices have long been used after TKA in an attempt to reduce pain, edema, inflammation, and swelling (Su et al., 2012). Some currently available cryotherapy/compression devices have multiple tubes and/or cords that can present a fall risk hazard to patients and caregivers. Compression wraps

without tubing/cords also allow patients to ambulate without necessitating device removal/disconnection, providing greater flexibility and potentially improving safety. Different devices require various amounts of time and effort to safely and effectively apply, replenish, and maintain. In addition, there is a broad range of costs associated with each device. We sought to evaluate whether a lower-cost, easier to use, cryotherapy/compression ice/gel pack wrap was noninferior to our currently used circulating cold water static compression device.

Several studies have compared various cryotherapy dressings with or without compression with standard, noncryotherapy dressings, resulting in a broad spectrum of results. Levy and Marmar (1993) and Morsi (2002) found significant benefits with cold compression in patients undergoing TKA compared with standard compression dressings in blood loss, pain scores, and ROM. Kullenberg et al. (2006) and Holmström and Härdin (2005) both found that cryotherapy was an acceptable alternative to epidural anesthesia for total and unicompartmental knee arthroplasty, respectively. Webb et al. (1998) also found a reduction in blood loss and pain when a cold compression device was used compared with a wool and crepe dressing in TKA. Gibbons, Solan, Ricketts, and Patterson (2001) found no difference in pain scores, ROM, or need for analgesia but a reduction in surgical drain blood loss comparing a cold compression dressing with a modified Robert Jones bandage. Scarcella and Cohn (1995) also found no significant differences in narcotic usage or ROM during the TKA postoperative course while using a cold

TABLE 3. COMPARISON OF IN-HOSPITAL OUTCOMES

Parameter	Circulating Cold Water ^a	Gel Pack Wrap ^a	<i>p</i>
Length of stay (days)	2.27 (0.81)	2.35 (0.91)	.98
Total drain output (cc)	442.04 (516.64)	590.00 (438.36)	.06
Change in hemoglobin (Gm/dL)	2.00 (1.23)	1.81 (1.09)	.25
Change in hematocrit (percentage)	6.11 (4.05)	5.36 (3.34)	.18
Allogeneic blood transfusions (number of units)	0.143 (0.500)	0.042 (0.289)	.89
ROM on discharge—flexion (degrees)	75.92 (15.71)	79.48 (11.69)	.18
ROM on discharge—extension (degrees)	8.32 (6.95)	6.00 (7.94)	.86

Note. ROM = range of motion.

^aValues represent mean (standard deviation).

TABLE 4. COMPARISON OF PATIENT QUESTIONNAIRE RESULTS

Parameter	Circulating Cold Water ^a	Gel Pack Wrap ^a	<i>p</i>
How often cooling device used—discharge	3.72 (1.92)	3.92 (1.75)	.72
How often cooling device used—3 weeks	3.27 (1.10)	3.22 (0.88)	.69
How often cooling device used—6 weeks	1.57 (1.38)	1.90 (1.08)	.98
Length of cooling effect (minutes)—discharge	135.77 (111.28)	155.79 (77.33)	.21
Length of cooling effect (minutes)—3 weeks	83.93 (71.87)	92.30 (69.42)	.71
Length of cooling effect (minutes)—6 weeks	65.63 (50.74)	57.50 (52.09)	.13
How often used pain medication—discharge	2.54 (1.17)	2.38 (1.03)	.63
How often used pain medication—3 weeks	2.23 (1.51)	2.50 (1.54)	.83
How often used pain medication—6 weeks	2.21 (1.91)	2.23 (2.06)	.94
Ease of use rating—discharge	4.13 (0.86)	4.17 (0.83)	.63
Ease of use rating—3 weeks	4.27 (0.90)	4.40 (0.74)	.67
Ease of use rating—6 weeks	4.37 (1.02)	4.23 (0.72)	.98
Overall satisfaction rating—discharge	4.26 (0.88)	4.24 (0.86)	.65
Overall satisfaction rating—3 weeks	4.46 (0.90)	4.29 (0.93)	.85
Overall satisfaction rating—6 weeks	4.41 (1.14)	4.29 (0.97)	.92
Pain rating—discharge	4.82 (2.10)	4.85 (2.14)	.97
Pain rating—3 weeks	2.68 (1.68)	2.96 (2.20)	.82
Pain rating—6 weeks	2.36 (2.03)	2.26 (2.44)	.01
Number of equipment failures—Overall	0.034 (0.18)	0.055 (0.23)	.22

^aValues represent mean (standard deviations).

therapy device. Multiple review articles have also been published on cryotherapy after TKA, producing conflicting results ranging from positive improvement in quadriceps activation, torque, and force production (Ewell et al., 2014), and obvious benefits on blood loss (Ni et al., 2014) to purporting the evidence available does not justify the routine use of cryotherapy after TKA (Adie et al., 2010, 2012).

Thienpont (2014) recently found in a similarly powered study comparing a computer-assisted continuous controlled cold therapy device (cTreatment) to ice packs without compression after TKA no significant differences in pain scores, need for analgesics, or secondary outcomes other than knee flexion at 6 weeks. These results compare favorably with the results found in the present study. He went on to suggest that advanced cryotherapy should not be used in fast track TKA if it cannot provide other concomitant advantages or the economic cost is higher (Thienpont, 2014). The present study also does not support the increased cost associated

with a continuous cold water therapy device compared to ice/gel pack compression cryotherapy wrap.

Su et al. (2012) also compared a cryopneumatic device (GameReady) to ice with static compression. In their study, they also found no significant difference in knee ROM, pain rating by Visual Analogue Scale (VAS), several functional measures, or knee girth. While they did find a difference at 2 weeks in consumption of morphine equivalents with a lower amount in the cryopneumatic group, this did not correlate to a difference in pain rating by VAS or knee function, nor did this difference in narcotic consumption persist past 2 weeks (Su et al., 2012). Although these results are similar, the present study actually found a significantly decreased average pain level at 6 weeks in the ice/gel pack compression cryotherapy wrap group compared with the circulating cold water cryotherapy device. The improved patient satisfaction ratings for the cryopneumatic device found by Su et al. (2012) could not be replicated by the circulating cold water cryotherapy device used in the present study as

TABLE 5. COMPARISON OF THIGH/KNEE CIRCUMFERENCE MEASUREMENTS

Parameter	Circulating Cold Water ^a	Gel Pack Wrap ^a	<i>p</i>
Preoperative measurement	45.80 (8.76)	46.11 (6.78)	.43
Measurement difference first dressing change less preoperative	2.56 (5.37)	2.83 (5.28)	.41
Measurement difference 3-week follow-up less preoperative	1.83 (4.70)	2.69 (5.25)	.22
Measurement difference 6-week follow-up less preoperative	0.94 (4.56)	1.56 (4.32)	.28

^aValues represent mean (standard deviations).

there were no significant differences found in ease of use, equipment failure, or overall patient satisfaction at any time point.

In a short follow-up study, Smith, Stevens, Taylor, and Tibbey (2002) compared cold therapy after TKA via a noncompressive cryopad machine to ice in plastic bags with a compression bandage applied to the wound. Comparable to the present study, they found no significant differences in length of stay, blood loss, need for transfusion, swelling, ROM, pain, or narcotic use (Smith et al., 2002).

In their cost-benefit analysis, Smith et al. (2002) showed the cryopad technology cost far more than the ice bag compression bandage, with no significant improvement in outcomes measured. This finding corresponds with the findings of the present study.

Markert (2011) reiterated that financial cost is always a major element in patient care and cost-effectiveness must be considered. Given the noninferiority of the ice/gel pack cryotherapy compression wrap, the per case cost savings of \$97.34 is an important factor for our institution in selecting which cryotherapy device is to be used during the rehabilitation process for our TKA population.

Involving staff and patients in the decision to change a long-standing process for postoperative cooling of the surgical site revealed that patient, family, and staff preferences contributed to easy adoption of the ice/gel pack cryotherapy wrap. As less time was required for applying/replenishing the ice/gel cryotherapy wraps compared to the circulating cold water devices, staff productivity improved resulting in time-savings. Staff also perceived enhanced patient safety with the elimination of cords and the ability to maintain the cooling effect during ambulation.

This study is important to orthopaedic nursing teams as it includes a review of the research related to cryotherapy in the postoperative patient undergoing TKA. Integrating evidence-based practices that include patient preference; patient, family, and staff satisfaction; pain control; patient safety; and cost into our care plans supports improved outcomes for both patient recovery and hospital expenses in the current healthcare climate of declining reimbursements and emphasis on patient experience.

LIMITATIONS

One potential limitation of this study was the lack of blinding. This could not be accomplished because of the nature and differences of the devices used as well as the requirement for the patient and his or her caregiver(s) to operate each device. However, each patient was randomly assigned to each group and had no prior experience with either device. Objective patient data obtained (drain output, change in HGB/HCT, thigh/knee circumference, etc.) would not be influenced by patient or caregiver knowledge of which device was used.

Another potential weakness of this study involved not having included a third, control group of patients that did not receive any form of compression/cryotherapy. Including this group was considered at study inception but rejected as cryotherapy was valued as a standard of care at our institution, and withholding this form

of therapy that has only a modest adverse event profile would not aid in accomplishing the study objectives (Adie et al., 2010; Ni et al., 2014).

This study also did not evaluate the actual temperature changes around the knee. It is understood that the intra-articular temperature changes with cryotherapy are limited and the local effects of various temperature differentials and duration of treatment are somewhat unknown and can vary with the particular device utilized, application technique, and patient compliance (Ohkoshi et al., 1999; Scharf, 2014). It was not the objective of this study to evaluate those parameters but rather to attempt to determine whether a lower cost ice/gel pack cryotherapy wrap was noninferior to a more elaborate and expensive circulating cold water therapy device in terms of patient outcomes, patient satisfaction, and hospital staff satisfaction. According to Scharf (2014), we must have a better understanding of the physiology of cooling and its effects on wound healing before adopting new and expensive cooling systems.

Conclusion

This study demonstrates the noninferiority of an ice/gel pack cryotherapy compression wrap compared to a circulating cold water cryotherapy device. Average pain level at 6 weeks postoperative was significantly less in the ice/gel pack cryotherapy wrap group. This study also demonstrates that an institution can switch from the more expensive circulating cold water therapy device to a less expensive ice/gel pack cryotherapy compression wrap at a substantial institutional savings without compromising patient satisfaction or outcomes. Such a switch can likewise result in improved hospital staff satisfaction with less staff concern for patient safety.

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