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Original Article

Effectiveness of cold therapy in reducing acute pain among persons with cardiac surgery: A randomized control trial

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Abstract

The aim of this randomized control trial, repeated-measure design was to investigate the effects of cold therapy in reducing pain after cardiac surgery during the first 72 postoperative hours. Seventy participants were matched and were randomly assigned to the intervention (n=35) or control group (n=35). The experimental group received a sterile cold gel pack to maintain the skin temperature at 10-15 °C for 20 min. The control group received the routine care. Acute pain was measured using a Thai version of the modified Brief Pain Inventory. The data were analyzed with repeated measures MANOVA. The results showed that the experimental group had significantly lower mean pain than the control group (P<0.001). In addition, pain scores in the experimental group were significantly decreased during the first 72 postoperative hours (P<0.001). Thus, the cold therapy was effective in reducing pain after cardiac surgery during the acute phase.

Keywords: acute pain, cardiac surgery, cold therapy, pain management

1. Introduction

Acute pain is the most common symptom that occurs after cardiac surgery (Forster, 2003; Utriyaprasit & Moore, 2005). Cardiac surgical patients experience pain due to the surgical incision made during the course of the surgery, and they experience irritation and inflammation of the pleura from thoracic catheters. Despite the existing available knowledge, patients still report poorly controlled pain in the acute postoperative phase following cardiac surgery (Koranyi, Barth, Trelle, Strauss, & Rosendahl, 2014). Patients perceived pain scores at high levels during the first 24-72 hours (Aragon, Farris & Byers, 2002; Milogrom *et al.*, 2004; Toleb, 2001; Yorke, Wallis, & McLean, 2004). Yorke *et al.* (2004) also revealed that a majority of patients (51%) experienced bad pain sensation in the chest wound area. Furthermore, responses of the patients in regards to their sensory effects included reports of tender (70.6%), sharp (58.8%) and aching (56.9%) pain, and the feeling of tiredness and exhaustion (86.7%). Cardiac surgery patients also expressed the interference of pain on their daily functions. Intensive pain from coughing was reported in 78% of patients and 62% experienced severe pain while moving, while 49% complained of intensive pain even while resting (Lahtinen, Kokki, & Hynynen, 2006). In the Thai context, during the first 72 postoperative hours, two-thirds of cardiac surgery patients reported moderate to severe interference of pain from deep breathing and coughing, followed by general activity and walking (Keawnantawat, Thanasilp, & Preechawong, 2016).

Uncontrolled acute pain after cardiac surgery has a major impact leading to prolonged ICU hours, extended cost and length of stay, increased morbidity and mortality rates, and poor recovery outcomes (Fortner, Okon, & Portenoy, 2002; Scott *et al.*, 2001). Especially in the first few days after an operation, uncontrolled acute pain during weaning from a ventilator can delay tracheal extubation (Renaud, 2002). After extubation, the feeling of pain limits patients while per-

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forming rehabilitation activities which resulted in inadequate lung expansion (Milogramet *et al.,* 2004). Reluctance to participate in daily activities because of pain, limits patients from performing early mobilization and increases the risks for deep vein thrombosis (Margereson & Riley, 2003). Moreover, acute postoperative pain predicted both the presence and severity of persistent postoperative pain up to two years later in follow-ups. The more intense the pain during the first week after surgery and the more it interfered with functioning, the more likely the patients reported persistent postoperative pain (Choinière *et al.,* 2014).

Standard care to manage acute pain following cardiac surgery is to follow the World Health Organization 3-step pain ladder, and strong opioids are most commonly prescribed. However, patients who have undergone cardiac surgery reported receiving insufficient doses of analgesic drugs, and that the dose of pain killer prescribed by the doctor and administered by nurses was lower than they actually required (Parizad, Abdolahzadeh, & Mousavi-Shabestari, 2014). Although these medications can lessen pain to a certain level, increasing dosages for greater pain relief can have negative adverse effects that are problematic. The side effects may be grouped according to the organ system that is affected; for example, neurologic, and gastrointestinal (Harris, 2008). A number of sources indicated that non-pharmacological interventions combined with pharmacological interventions may provide the most effective pain management (Banks, 2007). Pain that occurs during movement cannot be managed by medications only. Hence, this considerably reflects the need of further strategies that properly control pain.

Cold therapy is an effective, inexpensive, and simple intervention for pain management which is well documented in sport injuries, post-surgery, and medically associated pain. The mechanism of action for cold therapy includes altering nerve conduction velocity, inhibiting nociceptors that results in a reduction of muscle spasms or a reduction in metabolic enzyme activity levels or both (Airaksinen *et al.,* 2003). However, the use of cold therapy in cardiac surgery was reported in relatively few studies. Chailler, Ellis, Stolarik, and Woodend (2010) demonstrated that frozen gel pack application was effective on a sternal incision dressing before performing deep breathing and coughing exercises in coronary artery bypass graft (CABG) patients. Kol, Erdogan, Karsl, and Erbil (2013) found that the application of ice for 20 min to the chest tube insertion site could reduce pain associated with irritation in patients who underwent thoracotomy with chest tube placement. Another study from Khalkhali, Tanha, Feizi, and Ardabili (2014) also reported that the application of a cold gel pack at the pain site was associated with the benefit of deep breathing and coughing during the first day of post-heart surgery. Similarly, Zencir and Eser (2016) showed the positive effects of cold therapy on pain with breathing exercise and coughing during the first two postoperative days.

In this current study, the aim was to determine the effect of cold therapy on pain intensity and its interference in persons following cardiac surgery during the first 72 postoperative hours. Hence, this is one of a small number of studies that highlights the effectiveness of cold therapy as an easy and effective pain relief intervention for this posto-perative phenomenon.

2. Materials and Methods

2.1 Study design

A two-group randomized controlled trial with a repeated-measure design was conducted to determine acute pain in Thai patients who underwent an elective cardiac surgery. Pain was composed of intensity and interference dimensions. Eligible patients participated in a cold therapy program during the first 72 postoperative hours. Data were collected daily during this period.

2.2 Participants

The samples were patients who underwent an elective cardiac surgery at a cardiac surgery center in Bangkok, Thailand from November 2016 to February 2017. Eligibility criteria included age above 18 years at the time of the initial screening, good consciousness with high levels of cooperation, the ability to read, write, and understand the Thai language, no history of alcoholism, no use of hypnotic/ tranquilizer/sedative drugs, no neurological pathology/deficit, never diagnosed with Raynaud's disease, cryoglobulinemia, cold hemoglobinuria, and the willingness to participate fully in all aspects of the intervention. Participants were excluded if they had to undergo an urgent re-operation, had cognitive impairments or had severe postoperative complications.

Power analysis and effect size determination were conducted using G*Power version 3.1.9.2. Since most nursing studies cannot expect effect sizes in excess of 0.50 (Polit & Beck, 2006), this study aimed to detect differences in pain intensity and pain interference between two groups. A total of 62 participants (31 per group) were required for the study to yield 80% power with a .05 level of significance. The actual power was 0.807. Given a typical 10% attrition rate, at least 68 patients were required for the total sample.

2.3 Ethical considerations

Permission for the research was granted by the ethics committee on human rights at the research setting (Approval NO. MURA 2015/60). Cardiac surgery patients who met the inclusion criteria were informed about the study and a consent form was given to those who agreed to participate in the program. This study followed the provisions of the 1995 Declaration of Helsinki (as revised in Brazil 2013).

2.4 Randomization and blinding

Pair matching was performed to reduce bias by creating two comparable groups with similar baseline factors. Demographic factors that can cause variations in pain level reports are age, gender, and type of operation (Eisenberg, Pultorak, Pud, & Bar-El, 2001; Yorke *et al.,* 2004). Thus, these three variables were used to form matched subject pairs. First, based on the inclusion criteria, patients who met the eligible requirements were matched 1:1 based on the following factors: age (within 5 years), same gender, and similar type of surgery. Next, a computer-generated binary random number was then established by an individual who

was not involved in this study to randomly assign one member of each pair to treatment and one to control. After being assigned to the intervention, the participants in the control group were blinded to usual care, while the participants in the experimental group were blinded to the cold therapy group.

2.5 Intervention group

The cold therapy consisted of two sessions (10:00 am and 2:00 pm) per day during the first 72 postoperative hours. It was provided to participants in the experimental group before they had to perform daily activities. Participants were elevated to stay in the upright position and skin sensitivity was tested at the sternotomy wound area. A reusable gel pack, size 10.0x26.5 cm was used as the cold source. It is manufactured of a soft, naturally drug-free, non-toxic, biodegradable gel held in a flexible plastic contour. The gel packs were kept in the freezer before application over the surgical dressing covering the sternal incision to yield the therapeutic level between 10-15 ℃ for 20 min (Bleakley, McDonoughv, & MacAuley, 2004; MacAuley, 2001). The temperature of the gel pack was tested using the same digital thermometer each time before the cold therapy session started. The target skin was re-evaluated every 10 min to maintain the analgesic range, to detect frostbite early, and to assess the participant's satisfaction. After 20 min, the gel pack was removed and the participants performed deep breathing exercises and coughing (Figure 1).

Figure 1. Cold therapy program.

2.6 Usual care group

The participants received offers of pain management information, body position changing, pain evaluation, administration of prescribed pain medication, and evaluation of pain management outcome or side effects.

2.7 Measurements

2.7.1 Demographic data sheet

The demographic data sheet consisted of two parts: the demographic data section and the pain management section. The demographic data section included age, gender, marital status, level of education, income, current occupation, types of the payment, and medical data, i.e. type of cardiac surgery, length of stay in the ICU, duration of endotracheal tube intubation, duration of intercostal chest drainage (ICD), duration of hospital stay, number of ICDs, and the number and locations of surgery wounds. The pain management section recorded the use of analgesic drug or drugs prior to admission and current postoperative analgesia.

2.7.2 The Thai version of a modified version of Brief Pain Inventory (BPI-T)

The acute pain level of cardiac surgery patients was measured using the Thai version of a modified version of Brief Pain Inventory (BPI-T). It is a self-report questionnaire which consists of 2 subscales covering 10 items, including 4 items of intensity subscale and 6 items of interference subscale. The intensity subscale asked participants to rate their pain 4 times during the last 24 hours as (1) pain at least, (2) pain at worst, (3) average pain, and (4) pain right now. Scores were presented using a numerical rating scale with 0 = no pain and 10 = pain as bad as you can imagine. A pain intensity index was calculated by adding the scores on the pain intensity items. The interference subscale were examined by participants rating "How pain had interfered with your life in the past 24 hours?" with (1) general activities, (2) sleep, (3) mood, (4) walking, (5) deep breathing and coughing, and (6) relations with others. Scores were bounded by 0 = does not interfere and 10 = completely interferes. A pain interference index was calculated by the mean score of the 6 pain interference items.

This instrument was originally developed by Cleeland and colleagues in 1991 (Cleeland, 2009) and was later modified for use in the immediate cardiac surgery context by Watt-Watson and colleagues (Watt-Watson, Stevens, Streiner, Garfinkel, & Gallop, 2001). The modified version of BPI was translated into Thai by Keawnantawat *et al.* (2016). Confirmatory factor analysis and convergent validity have been reported. Cronbach's alpha coefficients were 0.76 and 0.85 for the intensity and interference subscale, respectively.

2.8 Data collection

The participants were given a clear explanation and were informed regarding the aims of the study, protocols, measurements, benefits and risks, and the right to withdraw from the study. After receiving permission with written informed consent, clinical data were collected from their medical records. The researcher asked eligible participants to complete the questionnaire on acute pain assessment throughout the period of the study. The questionnaires took 5-10 minutes to complete.

2.9 Statistical analysis

SPSS version 21 with a significance level <0.05 was used. Descriptive statistics were performed to describe the characteristics of the participants and the dependent variables. Independent t-test and Chi-square test were done to compare the characteristics of the participants and dependent variables between the two groups. The repeated measures of multi-variate analysis of variance (RM-MANOVA) was applied to determine the significant difference of mean score of pain intensity and pain interferences between the two groups.

3. Results

A total of 124 patients who underwent cardiac surgery were initially screened and 91 patients were potentially eligible (88.62%) (Figure 2). Eighty patients were finally eligible and consented to participate (87.91%). Forty participants were randomly assigned to the experimental group and another 40 to the control group. During the study period, five participants who had been assigned to the experimental group could not finish the study. Two participants had delayed extubation, one developed unstable hemodynamics, one developed delirium, and another participant died. In the control group, three participants had delayed extubation, one had unstable hemodynamics, and another participant went for reoperation. Therefore, there were finally 35 participants in each group.

3.1 Participants and baseline characteristics

In the control group, the mean (SD) age was 54.89 (13.67) years (Table 1). They were mostly male (60%), married (51%), and Buddhists (83%). More than half of them had no surgical experience (57%). The majority of the participants (94%) currently used the analgesia. One-third of the participants underwent isolated CABG-surgery (34%) and 29% had isolated vulvular surgery (Table 2). More than half of the participants had a single surgical wound (54%) and two ICDs (77%) that were retained 1-3 days (71%). Analgesic prescriptions were categorized according to the WHO 3-step ladder. The results showed that strong opioids were most often prescribed (71%) combined with multimodal analgesia. Equianalgesic conversion was used to transform between prescribed opioids to be the comparable unit based on the

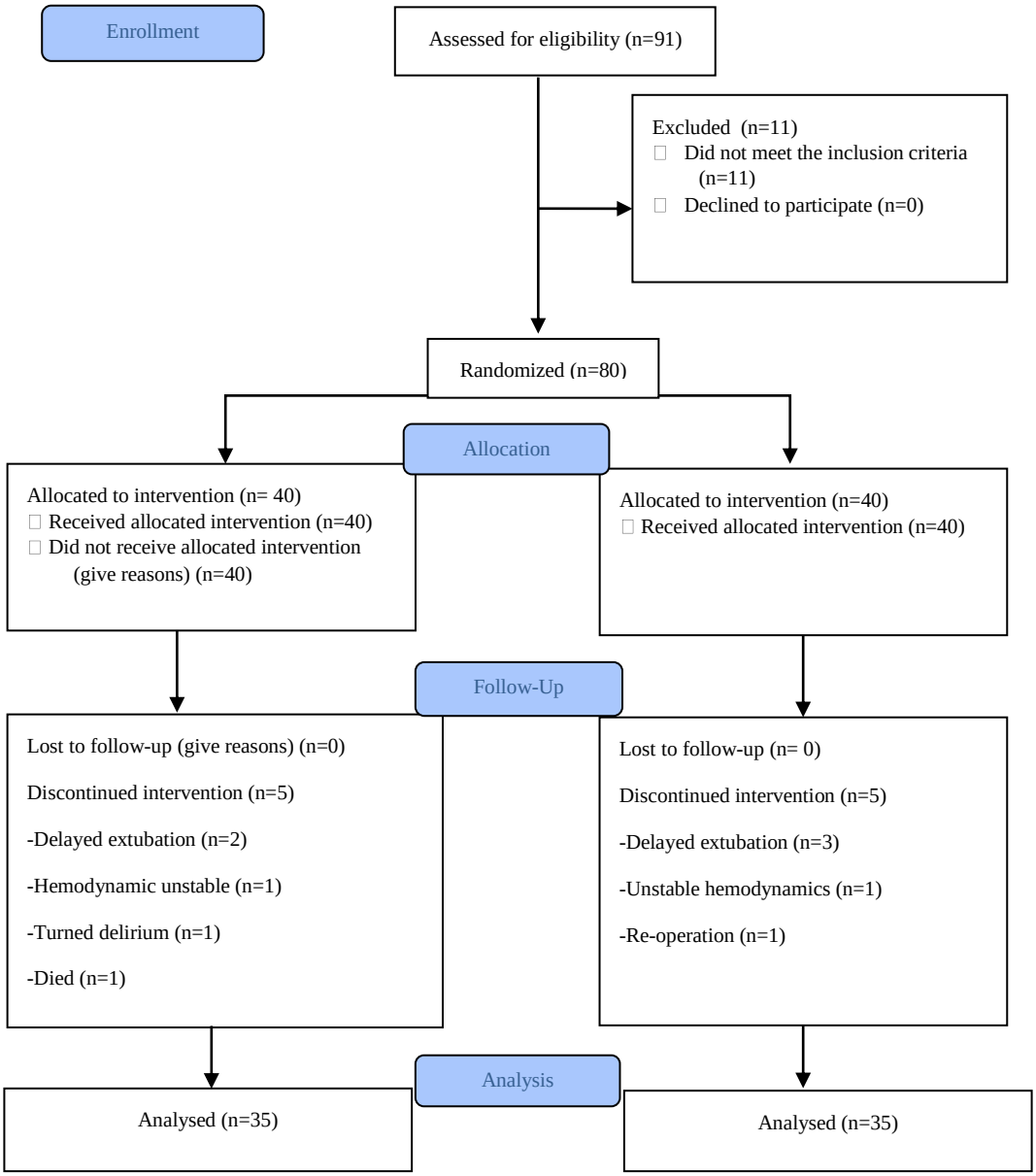

Figure 2. CONSORT 2010 flow diagram.

Table 1. Participant characteristics at baseline (n=35/each group)

Characteristics	Control N=35		Experimental N=35		$\chi 2$	*df*	P-value
	n	%	n	%			
Gender					.00	1	1.000
Male	21	60	21	60			
Female	14	40	14	40			
Status					7.43	3	0.067
Married	18	51	21	60			
Single	14	40	8	23			
Widowed	1	3	6	17			
Divorced	2	6	0	0			
Religion					.00	2	1.000
Buddhism	29	83	29	83			
Muslim	4	11	4	11			
Christian	2	6	2	6			
Previous surgery					.51	1	0.477
Never	20	57	17	49			
Experienced	15	43	18	51			
Current analgesia usage					.22	1	0.642
No	33	94	32	91			
Yes	2	6	3	9			

Table 2. Physiological status among participants.

Characteristics	Control		Experimental		$\chi 2$	*df*	P-value
	n	%	n	%			
Type of surgery					1.46	5	0.924
CABG	12	34	12	34			
Valve	10	29	10	29			
Aneurysm	6	17	6	17			
Combined	4	11	4	11			
Congenital	2	6	2	6			
Miscellaneous	1	3	1	3			
Analgesia (Type)					.07	1	0.792
Opioid	25	71	26	74			
Multimodal	10	29	9	26			
Analgesia dose (mg/day), mean (SD)							
Day 1	4.96	±3.65	4.7	±4.08	19.85	15	0.183
Day 2	10.63	±4.93	9.33	±5.87	15.70	18	0.611
Day 3	6.87	±5.02	5.94	±4.91	10.56	13	0.653
Total	22.46	±10.39	19.97	±10.92	25.50	31	0.751
Number of wounds					10.3	2	0.586
1 area	19	54	19	54			
2 areas	15	43	16	46			
3 areas	1	3	0	0			
Number of ICDs					1.12	2	0.574
1 tube	6	17	9	26			
2 tubes	27	77	23	66			
3 tubes	2	6	3	8			
Duration of ICD (days)					2.97	2	0.236
1-3	25	71	18	51			
4-6	9	26	15	43			
>6	1	3	2	6			

American Pain Society guideline and critical review papers. The results showed that participants were prescribed opioids at 4.96-10.63 mg/day.

The participants in the experimental group had a mean (SD) age of 54.74 (14.20) years. More than half (60%) were males and married. The majority of the participants (83%) were Buddhists. About half of the participants had surgical experience (51%) and 9% were using analgesia before the period of study. About one-third (34%) of the participants underwent isolated CABG-surgery, whereas 29% had isolated vulvular surgery. About half of the participants had one surgical wound (54%) with two ICDs (66%) that were retained 1-3 days (51%). Strong opioids were most often prescribed (74%) with the daily dose of 4.7-9.33 mg/day and combined with multimodal analgesia.

Overall, descriptive data analysis did not show any significant differences between the groups for the characteristics at baseline or physiological status.

3.2 Effects of cold therapy

The mean (SD) pain intensities of the control group were 2.79 (1.74) (mild) to 3.59 (1.10) (moderate) (Figure 3). In the experimental group, the mean (SD) pain intensities were 1.08 (0.64) (mild) to 2.94 (1.33). The mean (SD) pain interference in the control group ranged from 2.65 (1.54) to 2.85 (1.53), whereas the mean (SD) pain interference in the experimental group ranged from 0.91 (0.59) to 2.21 (1.31) (Figure 4). From the RM-MANOVA analysis, the interaction effect of time and group on pain is presented (F (1.50, 101.96)=133.83, P=0.000) (Table 3). This means that the difference between the groups varied depending on the level of another effect (Portenoy & Kanner, 1996). Regarding the main effect of time, it was found a difference of at least one pair at the three time points as within subject factor, F (1.50, 101.96)=39.77, P=0.000). Pairwise comparison was further performed (Table 4). Pain intensity was significantly different between any time point for the experiment group (P=0.000) but was only significantly different between day 1 and day 2 to day 3 for those in the control group (P=0.000).

Similar to pain interference, the participants in the experimental group also had significantly different pain interference at any time point (P=0.000). For the pain interference of those in the control group, only one time was significantly different between day 1 and day 2 (P=0.024). The main effects of the group was also revealed, F (1, 68) =22.24, P=0.000 (Table 5). Post hoc comparisons confirmed that participants in the experimental group had significantly lower pain intensity and pain interference than those in the control group from day 2 to day 3 (P=0.000).

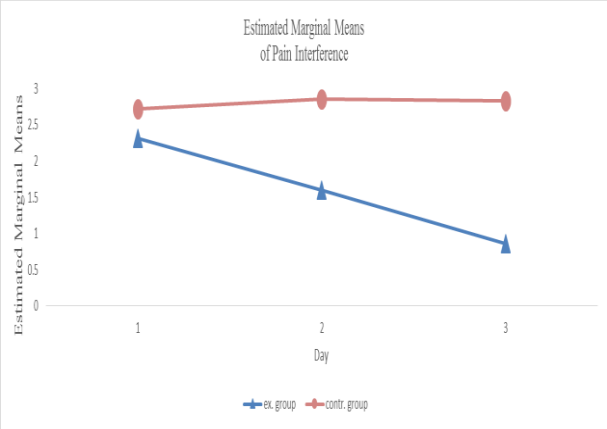

Figure 3. Mean pain intensity between the control and experimental group.

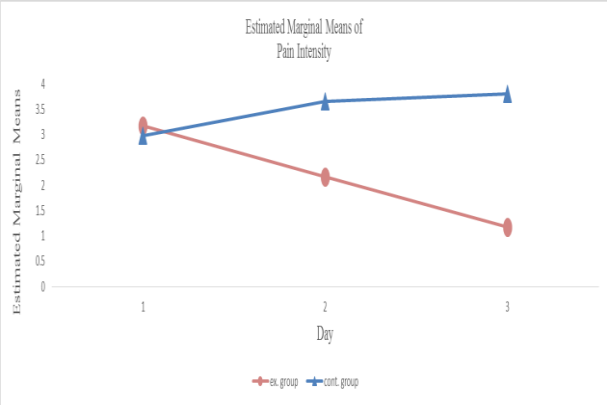

Figure 4. Mean pain interference between the control and experimental group.

Table 3. Repeated measures MANOVA of pain.

Source of Variation	SS	df	MS	F	P-value
Between subjects					
Group	85.03	1	85.03	22.24	0.000
Within group (error)	238.50	68	3.51		
Total	323.53	69	88.54		
Within group					
Time	22.52	1.50	15.02	39.77	0.000
Group * Time	75.80	1.50	50.55	133.83	0.000
Time x within group (error)	38.51	101.96	0.38		
Total	136.83	104.96	65.95		
Total	460.36	173.96	154.49		

4. Discussion

The results from this study indicated the effectiveness of implementing the cold therapy on acute pain in patients with cardiac surgery. However, interaction effects of time and group were found. It could be explained according to the theoretical concept of pain that classifies acute pain as pain of recent onset that ends or is anticipated to end during a period of days to weeks or less than 3 months (Conn, 2005). In this case, it could mean that acute pain after cardiac surgery would gradually reduce from day by day. The effectiveness of cold therapy was shown. The explanation could be that cold therapy manipulates the natural mechanism of pain. According to the gate control theory, cutting the sternal bone is a physical factor causing acute pain after cardiac surgery so that cold therapy manipulates this natural mechanism. Applying frozen gel pack for 20 min on the periphery path-

Table 5. Between group-Post Hoc comparisons of pain

Time points	Dependent Variable									
	Pain Intensity					Pain Interference				
	Con.	Exp.	x̄ dif	SE	P-value	Con.	Exp.	x̄ dif	SE	P-value
Day 1	2.79	2.94	0.15	0.371	0.687	2.65	2.21	0.43	0.341	0.204
Day 2	3.57	1.97	1.60	0.307	0.000	2.85	1.50	1.35	0.306	0.000
Day 3	3.58	1.07	2.51	0.215	0.000	2.80	0.91	1.89	0.256	0.000

ways will stimulate large pain fiber nerve conduction so that the transmission of small pain fibers is reduced and the gate will close resulting in decreased pain (Conn, 2005).

Correspondingly, the participants stated that cold therapy made them feel more comfortable and relaxed with decreased pain. Furthermore, the cold therapy made their chest feel more comfortable and they could take a deep breath more smoothly. This finding is similar to the previous studies using cold modality to relieve pain after cardiac surgery (Chailler *et al.*, 2010; Khalkhali *et al.*, 2014; Zencir & Eser, 2016). Findings from previous evidence indicated the effectiveness of applying a cold gel pack on a sternotomy wound to eliminate pain during the episodes of deep breathing and coughing exercise.

However, this study also differs from others by allocating a cold gel pack to the experimental group, whereas the control group received routine care. This hereby hypothesized that measuring the effect of treatments in the same subject could account for carryover effects resulting in a biased interpretation (Li, 2014). The application of cold gel pack for 20 min in the participants in the experimental group performed better pain control then those who received routine care. Moreover, the measurement used in this study was also dissimilar to others. Recognizing that diagnosis of insufficient functions is crucial in complete pain assessment (American Pain Society Quality of Care Committee, 1995). Thus this study employed a comprehensive scale measuring both pain intensity and pain interference aspects. Consequently, finding also indicated that pain interferes differently for the type of activity during the first 72 postoperative hours.

4.1 Implications, limitations, and recommendations

Although cold therapy is not the principle pain management, it is proposed as an integrative therapeutic intervention. The nurses then can enhance the interpersonal relationship while providing the program. Moreover, cold therapy implementation can also help promote patient comfort. This study encourages implementation; however, there is the limitation of generalizability. Furthermore, the effects of the intervention were possibly affected by time changes. Another consideration is the duration of the intervention. A longer duration might have improved pain control. Further research should be replicated among patients with poorly controlled pain to prevent the development of chronic post-operative pain.

5. Conclusions

Cold therapy appears to be a useful intervention to decrease acute pain among Thai cardiac surgery patients and would be a useful supplement to surgical care.

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