Thai Journal of Obstetrics and Gynaecology
January 2018, Vol. 26, pp. 52-58

GYNECOLOGY

Gel Pack Reduced Postoperative Pain in Benign Gynecologic Surgery: A randomized controlled trial

Wanlayanee Nuangpho, M.D.*,
Sukanya Srinil, M.D.*,
Thumwadee Tangsiriwatthana, M.D.*,
Maleechat Sripipattanakul, M.D.*.

** Department of Obstetrics and Gynecology, Khon Kaen Hospital, Khon Kaen 40000, Thailand*

ABSTRACT

Objectives: To examine the effectiveness of gel pack for reducing postoperative pain in patient who undergoes exploratory laparotomy for benign gynecologic surgery.

Materials and Methods: Twenty eight participants who underwent benign gynecological surgery under general anesthesia at Khon Kaen Hospital in March 2016 were randomized by computer generated into two groups: gel pack group (N=14) and control group (N=14). Gel pack was applied at 2 hours after operation for 20 minutes and pain score was measured using visual analog scale (VAS) at 2 (baseline), 6 and 24 hours, respectively. The VAS was divided into two grades by pain-intensity; mild (VAS < 4), and moderate to severe (VAS ≥ 4). The comparison of pain-intensity was analyzed by Fisher exact test ($p < 0.05$).

Results: Gel pack was statistically significant reduced postoperative pain from moderate-severe pain to mild pain intensity at 6 hours compared with control group (11 to 8 cases versus 14 to 14 case, $p = 0.01$, 95%CI 0.03-0.89). There was no statistically significant difference in opioid consumption, hospital stay and wound infection between two groups.

Conclusion: Gel pack can reduce postoperative pain at 6 hour in benign gynecological operation without complication.

Keywords: Gel pack, exploratory laparotomy, benign gynecologic surgery, postoperative pain.

Correspondence to: *Wanlayanee Nuangpho, M.D., Department of Obstetrics and Gynecology, Khon Kaen Hospital, Khon Kaen, 40000, Thailand, Phone: (043) 336789, E-mail: wnuangpho@gmail.com*

การศึกษาทดลองแบบสุ่มเรื่องการใช้ถุงเจลเย็นเพื่อลดระดับความเจ็บปวดหลังผ่าตัดในผู้ป่วยนรีเวชที่ไม่ใช่มะเร็ง

วัลยาณี เนื่องโพธิ์, สุกัญญา ศรีนิล, ทุมวดี ตั้งศิริวัฒนา, มาลีชาติ ศรีพิพัฒนกุล

บทคัดย่อ

วัตถุประสงค์: *เพื่อศึกษาประสิทธิภาพของการใช้ถุงเจลเย็นในการลดระดับความเจ็บปวดหลังผ่าตัด ในผู้ป่วยที่ได้รับการผ่าตัดทางนรีเวชที่ไม่ใช่มะเร็ง*

วิธีการศึกษา: *ผู้ป่วยนรีเวชที่ไม่ใช่มะเร็ง จำนวน 28 ราย ที่นัดมาผ่าตัดทางหน้าท้อง ในเดือนมีนาคม พ.ศ. 2559 ที่โรงพยาบาลขอนแก่น ได้รับการสุ่มแบ่งเป็น 2 กลุ่มๆ ละ 14 คน โดยกลุ่มทดลองจะได้รับถุงเจลเย็นวางบนแผลผ่าตัดที่ 2 ชั่วโมงหลังการผ่าตัด เป็นเวลานาน 20 นาที และผู้ป่วยทุกคนจะได้รับการดูแลอื่นๆ หลังผ่าตัดตามปกติ รวมถึงการประเมินความเจ็บปวดหลังการผ่าตัด โดยใช้ visual analog scale (VAS) โดยจะประเมินความเจ็บปวดที่ 2, 6 และ 24 ชั่วโมงหลังการผ่าตัด ตามลำดับ ซึ่งคะแนนความเจ็บปวดจะแบ่งเป็นระดับความเจ็บปวด 2 ระดับ คือ ระดับเจ็บปวดเล็กน้อย (mild; VAS < 4) และ ระดับเจ็บปวดปานกลางถึงรุนแรง (moderate to severe; VAS ≥ 4) เปรียบเทียบสัดส่วนของความแตกต่างของระดับความเจ็บปวดระหว่างสองกลุ่มทดลอง โดยใช้ Fisher's exact test (กำหนดค่า $p < 0.05$)*

ผลการศึกษา: *พบว่าระดับความเจ็บปวดที่ 6 ชั่วโมงหลังการผ่าตัด ในผู้ป่วยกลุ่มที่ได้รับถุงเจลเย็นที่มีความเจ็บปวดอยู่ในระดับเจ็บปวดปานกลางถึงรุนแรง มีจำนวนลดลงอย่างมีนัยสำคัญทางสถิติ จาก 11 ราย เป็น 8 ราย ส่วนกลุ่มที่ได้รับการดูแลตามปกติ มีจำนวนผู้ป่วยที่มีความเจ็บปวดอยู่ในระดับเจ็บปวดปานกลางถึงรุนแรงไม่เปลี่ยนแปลง มีจำนวน 14 ราย ตั้งแต่เริ่มการวิจัย และที่ 6 ชั่วโมงหลังการผ่าตัด ($p = 0.01$, 95%CI 0.03-0.89) นอกจากนี้ปริมาณการใช้ยาแก้ปวดมอร์ฟีน ระยะเวลาพักรักษาในโรงพยาบาล ตลอดจนการติดเชื้อบริเวณแผลผ่าตัดพบว่า ไม่แตกต่างกันในผู้ป่วยทั้งสองกลุ่ม*

สรุป: *ถุงเจลเย็นสามารถลดระดับความเจ็บปวดที่ 6 ชั่วโมงหลังการผ่าตัด ในผู้ป่วยนรีเวชที่ไม่ใช่มะเร็งได้ อย่างมีนัยสำคัญทางสถิติ และการใช้ถุงเจลเย็นไม่ก่อให้เกิดภาวะแทรกซ้อนเพิ่มเมื่อเปรียบเทียบกับผู้ป่วยที่ได้รับการดูแลตามปกติ*

คำสำคัญ: *เจลเย็น, ถุงเจลเย็น, ผ่าตัดนรีเวชทางหน้าท้อง, ลดปวดหลังผ่าตัด, นรีเวชทั่วไป*

Introduction

Postoperative pain in trans-abdominal surgery patients are mostly found within 24 hours after surgery, this is mainly due to soft tissue injury that leads to local inflammation and stimulation of surrounding nociceptors. Pharmacologic therapies are used to relieve this pain, in exchange of their side effects[1,2]. Alternatively, there are many non-pharmacological treatments which could ease the pain, with much lesser side effects such as acupuncture, massage, repositioning, breathing exercises, physical modalities and we were interested in heat and cold application within 24 hour of tissue injury[3]. Cryotherapy induced lowering the temperature of skin, which helps to decrease inflammatory process by reducing blood flow, slowing down nerve conduction velocity, inhibiting edema formation and reducing muscle spasm. Thus, lowering cellular metabolism and also lessen secondary injury by decreasing cellular metabolism[4]. Optimum temperature of cryotherapy is 10-15°C. It can be applied to the skin at surgery site for 20-30 minutes per session as immediately or within 12-72 hours after surgery[5]. This modality is used in many fields of surgery such as general surgery, ophthalmology, orthopedics, plastic, otolaryngeal surgery and some obstetrics and gynecologic surgery[6-10]. There are many types of cryotherapy, of these, ice pack is the most common used. However, cold gel pack (CGP) is also an interesting alternative as it could provide the optimum temperature of cryotherapy.

In an experiment, skin was applied for 20 minutes with ice pack, gel pack, frozen peas, and mixture of water and alcohol, and skin temperature was recorded; the result were 10.2 ± 3.5°C, 13.9 ± 4.1°C, 14.4 ± 3.0°C, and 10.0 ± 4.5°C, respectively[11]. Therefore, cold gel pack gives optimum temperature, its flexibility provides proper skin contact, convenient since its reusable, accessible, and low cost.

Nowadays, there is no study about CGP in patient who underwent benign gynecologic operation. The aim of our study was to examine the effectiveness of CGP for reducing postoperative pain in patient who underwent exploratory laparotomy for benign gynecologic surgery.

Materials and Methods

Twenty eights participants were enrolled to the study in March 2016. Inclusion criteria were a Thai woman who underwent benign gynecological surgery, under general anesthesia, and received postoperative morphine (body weight (BW) > 50 kg; Morphine 3 mg, BW < 50 kg; morphine 2 mg) every 4 hour as needed in the first 24 hours as pain controller. Participants who used narcotic drugs within 24 hours prior to operation, used of local anesthesia at surgical wound, had underlying diseases which take medicine that effected pain perception, ice hypersensitivity, hypothermia (body temperature below 35°C), history of Raynaud phenomenon and active skin lesion at surgical site were excluded.

The participants were randomly assigned into two groups (14 each) by computer generated using block of four. The random numbers were put into sequentially sealed opaque envelops. Randomization was performed after wound closing. The envelope which contained random number was picked up by scrub nurses. The skin suture methods included subcuticular and interrupted stitches (by nylon 4/0 or staples). Intervention group, cold gel pack (3M NexcareR size10cm x 25cm), frozen at (-10)-0°C for 1-2 hours and wrapped by 2-mm thick towel, was placed onto the surgical wound and covered by waterproof dressing (tegadermR without pad) at 2 hours after the procedure for 20 minutes. After removed CGP, the tegadermR without pad was checked that it was not detached and CGP was cleaned before reused. Control group received standard routine postoperative care. Individual informed consent was obtained before operation. Before using CGP, it was tested its sustain efficacy by left it at room temperature (30-35°C) and wrapped by 2-mm thick towel. We found that it could preserve the optimal temperature at 10-15°C for 3 hours. Postoperative pain scores were measured by visual analog scale (VAS) at 2 (before placed CGP), 6 and 24 hours after operation. Participants were asked to mark the vertical line on the 10-cm line and pain score was measured in centimeter by ruler. The participants were informed that "0" represented no pain, and "10" was the

worst pain. Outcome assessors were nurses at gynecologic ward who did not involve in the preceded processes. Both groups equally received standard postoperative care. Vital signs were recorded before placing CGP then recorded every 4 hours. The primary outcome was postoperative pain at 6 hours. Pain score was classified into two categories according to pain intensity, mild pain (VAS < 4) and moderate to severe pain (VAS 4-6 and 7-10, respectively)[12]. The secondary outcomes included opioid consumption, length of hospital stay, wound complication. Wound complication was observed after placed CGP and via telephone interview at 1 month after the procedure.

Sample size was calculated by using data from pilot study. We used formula for test of difference in two independence proportions with alpha of 0.05, power of 90% and 10% dropouts. The sample size was 14 participants per group.

Fisher's exact and Pearson Chi square test was used for categorical variables and for continuous variables student t-test or Mann-Whitney-U test were used depended on data distribution. The primary outcome was presented as percentage, relative risk with 95% confidence interval. Other outcomes were presented as mean and standard deviation and median with interquartile range. P value < 0.05 is considered statistically significant. Statistical analysis was performed by SPSS version 17 software.

Results

Twenty eight eligible participants were enrolled into the study. Fourteen received cold gel pack at two hours after operation and the other fourteen receive routine post-operative care (Fig. 1.).

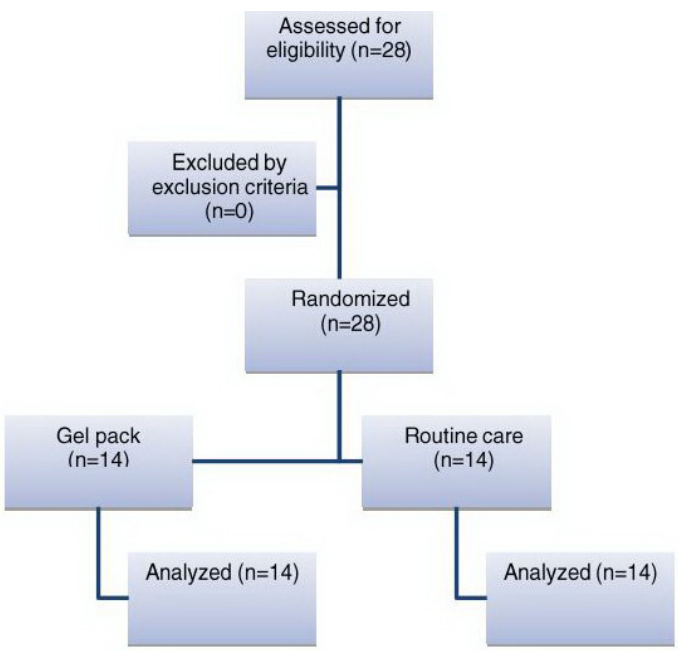

Fig. 1. Flow chart of participants' progress through the study.

Baseline characteristics including age, body mass index (BMI), operation, surgeon, type of incision, incision length, operative times, underlying diseases (hypertension, migraine and thalassemia) and base line postoperative pain at 2 hours were similar in both groups as presented in Table 1. The operations were classified into four groups which were total abdominal hysterectomy (TAH), TAH with adnexal surgery, adnexal surgery alone and other (adnexal surgery with repaired small bowel). There

was significant different in postoperative pain intensity at 6 hours between groups (RR 0.57, p = 0.01, 95%CI 0.03-0.89). At 6 hours after operation, in CGP group, the number of participants who rated their pain as moderate and severe pain decreased from 11 to 8 participants, while all of the participants in routine group, pain persisted in moderate to severe intensity as at baseline (Table 2).

Table 1. Baseline characteristics.

	Control (n=14)	CGP (n=14)	p value
Age, year, mean (SD)	43 (5.14)	42.78 (9.04)	0.76
BMI, kg/m^2, mean (SD)	23.42 (3.01)	24.07 (3.07)	0.62
Operation, n			0.62
TAH	3	2	
TAH with adnexal surgery	9	9	
Adnexal surgery	1	3	
Adnexal surgery with repaired small bowel	1	0	
Surgeon, n			0.43
Staff	10	8	
Resident	4	6	
Incision, n			0.25
Low midline	6	9	
Pfannenstiel	8	5	
Incision length, cm, mean (SD)	12.57 (2.20)	12.07 (1.59)	0.33
Operative times, minutes, mean (SD)	77.14 (23.43)	75.21 (26.66)	0.64
Underlying disease, n	2	5	0.38
Hypertension	2	3	
Migraine	0	1	
Thalassemia	0	1	
Postoperative pain at 2 hours, n			0.22
Mild	0	3	
Moderate to severe	14	11	

CGP; cold gel pack, BMI; body mass index, cm; centimeter

Table 2. Comparison of postoperative pain between two groups measured by VAS at 6 hours.

Postoperative time	Pain scale				
	Control (n=14)	CGP (n=14)	p value	RR	95%CI
6 hours, n			0.01	0.57	0.03-0.89
Mild	0	6			
Moderate to severe	14	8			

CGP; cold gel pack

Every participant in CGP group could tolerate to the intervention, no one asked to remove CGP before 20 minutes. When we recorded VAS, we asked every participant about the comfortable of placing CGP. There was no reported of shivering, sub-temperature or frost bite. There was no significant difference in opioid consumption, wound infection rate, length of hospital stay and postoperative pain at 24 hours as presented in Table 3.

Table 3. Comparison of secondary outcome between two groups.

Postoperative time	Control (n=14)	CGP (n=14)	p value	RR	95%CI
Morphine accumulated dose, mg (median (IQR))	15 (12-15)	12 (9-15)	0.09		
Postoperative hospital stay, day	3	3	1.00		
Wound complication	0	0	NA		
Postoperative pain at 24 hours, n			1.00	1	0.06-14.45
Mild	13	13			
Moderate to severe	1	1			

CGP; cold gel pack, mg; milligram

Discussion

In this study, we found that CGP effectively reduced postoperative pain intensity in patients who underwent benign gynecologic surgery under general anesthesia at 6 hours after surgery compare to pain intensity at 2 hours (baseline).

These result explained that CPG applied only one time at 2 hours after the procedure for 20 minutes were sufficiency to continue the mechanism of cryotherapy for reduce postoperative pain for 6 hours. Type of incisions did not influent postoperative pain, according to Habib et al[13], compared between vertical and Pfennenstiel incision in gynecologic surgery, there was no significant difference in postoperative pain and amount of opioid consumption. Their findings were comparable with ours. Koç et al[14], studied about the effectiveness of ice pack in patient who underwent inguinal hernia operation and found that ice pack could reduce postoperative pain at 2, 6 and 24 hours. This finding differed from ours by postoperative pain score at 2 and 24 hours, this might be due to different intervention, surgical incision. They also found no side effects of ice pack as in the present study.

In bigger incision and operation, Amari et al[15] studied efficacy of ice packs in reducing postoperative midline incision pain and narcotic usage. The result showed significant reduction in postoperative pain and narcotic used only in the first day after surgery, at 8.00 am and 4.00 pm. This finding was consistent with present study in the effectiveness of cryotherapy in reducing postoperative pain in first 24 hours as well as rate of wound infection and length of hospital stay. However, mode of pain measurement, duration of pain recorded and types of operations and intervention were different.

Michael et al[16] studied in patients who underwent exploratory laparotomy, who received postoperative pain relief using intravenous self-administered morphine sulfate infusion pump, they found that patients who received cryotherapy (ice thermal blanket) used more morphine sulfate on the first postoperative day than control group, which was inconsistent with our study. This might be due to different kind of cryotherapy and methods of pain management.

The morphine consumption in CGP group was lesser than control group by mean of 12 versus 15 milligrams, respectively. However there was no statistical significant difference (p = 0.09) probably due to the

sample size of this study calculated for the primary outcome (VAS) so it was insufficient to evaluate the morphine consumption.

The strength of our study was a randomized controlled trial. Our limitation was un-blinded intervention, and assessments of pain after discharge from hospital were done via phone interview.

Further study, the impact of the environment such as temperature, multiple or continuous place of CGP should be considered. Patient's satisfaction should be taken into account for further study.

Conclution

In conclusion, cold gel pack could effectively reduce postoperative pain at 6 hours in benign gynecological operation without complication.

Acknowledgements

We would like to show our sense of appreciation to the participants, the nurses of the operating room and the gynecologic ward for their assistance in data collection and the staffs of Department of Obstetrics and Gynecology, Khon Kaen Hospital for their assistance and support.

Potential conflicts of interest

The authors declare no conflict of interest.

References

1. Ramsay MA. Acute postoperative pain management. Proc (Bayl Univ Med Cent) 2000;13:244-7.
2. Hamitouche Y, Benhamou D. Postoperative pain relief after gynecologic surgery. J Gynecol Obstet Biol Reprod (Paris) 2004;33(1Pt1):7–13.
3. Elsa W, Maureen FC. Acute Pain: Assessment and Treatment. Advances practice nursing eJournal. Available from: http://www.medscape.com/viewarticle/735034
4. Chanliongco PM. Cold (Cryo) Therapy. In: Walkowski S, Singla AK, Vivian DG, Lennard TA, editors. Pain Procedures in Clinical Practice. 3rd ed. Saint Louis: Hanley & Belfus; 2011. p 555.
5. Cryotherapy: A Review of the Literature. Chiroaccess article 2008. Available from: http://www.chiroaccess.com/articles/cryotherapy-a-review-of-the-literature.aspx?id=0000070
6. Akan M, Misirlioğlu A, Yildirim S, Cakir B, Taylan G, Aköz T. Ice application to minimize pain in the split-thickness skin graft donor site. Aesthetic Plast Surg 2003;27:305–7.
7. Waterman B, Walker JJ, Swaims C, Shortt M, Todd MS, Machen SM, et al. The efficacy of combined cryotherapy and compression compared with cryotherapy alone following anterior cruciate ligament reconstruction. J Knee Surg 2012;25:155–60.
8. Rotenberg BW, Wickens B, Parnes J. Intraoperative ice pack application for uvulopalatoplasty pain reduction: a randomized controlled trial. Laryngoscope 2013;123:533–6.
9. Forouzanfar T, Sabelis A, Ausems S, Baart JA, van der Waal I. Effect of ice compression on pain after mandibular third molar surgery: a single-blind, randomized controlled trial. Int J Oral Maxillofac Surg 2008;37:824–30.
10. East CE, Begg L, Henshall NE, Marchant P, Wallace K. Local cooling for relieving pain from perineal trauma sustained during childbirth. Cochrane Database Syst Rev 2007;(4):CD006304.
11. Kanlayanaphotporn R, Janwantanakul P. Comparison of skin surface temperature during the application of various cryotherapy modalities. Arch Phys Med Rehabil 2005;86:1411–5.
12. Jones KR, Vojir CP, Hutt E, Fink R. Determining mild, moderate, and severe pain equivalency across pain-intensity tools in nursing home residents. J Rehabil Res Dev 2007;44:305–14.
13. Habib AS, Wahl K, Gu J, Gan TJ, Adenosine Study Group. Comparison of postoperative pain outcomes after vertical or Pfannenstiel incision for major gynecologic surgery. Curr Med Res Opin 2009;25:1529–34.
14. Koç M, Tez M, Yoldaş O, Dizen H, Göçmen E. Cooling for the reduction of postoperative pain: prospective randomized study. Hernia 2006;10:184–6.
15. Watkins AA, Johnson TV, Shrewsberry AB, Nourparvar P, Madni T, Watkins CJ, et al. Ice packs reduce postoperative midline incision pain and narcotic use: a randomized controlled trial. J Am Coll Surg 2014;219:511–7.
16. Finan MA, Roberts WS, Hoffman MS, Fiorica JV, Cavanagh D, Dudney BJ. The effects of cold therapy on postoperative pain in gynecologic patients: a prospective, randomized study. Am J Obstet Gynecol 1993;168:542–4.