Araştırma makalesi
Research article

The Effect of Cold Application on Drain-Related Pain Control After Thyroidectomy

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ABSTRACT

Aim: To determine the effect of cold application on pain experienced and analgesic requirement frequency in patients with post-thyroidectomy drains.

Material and Methods: This randomized controlled trial was carried out in a Training and Research Hospital General Surgery Department in Istanbul between 15 May and 20 November, 2016. Fifty-nine patients with drains inserted post-thyroidectomy were randomly divided into two groups. Cold application was performed on the experimental group three times, 3 hours after analgesic administration on post-operative day 0, and immediately before drain removal on post-operative day 1. A cold gel pad was placed on the neck area for 20 minutes. Pain severity was measured 15 minutes after the cold application. The control group did not receive cold therapy, but pain severity was also measured.

Results: The patients in the experimental group had less pain on post-operative day 0, although the difference was not statistically significant ($p>0.001$). The severity of pain experienced after the removal of the drain on post-operative day 1 was significantly lower in the experimental group ($p<0.001$). Analgesic requirement frequencies among patients in the experimental group were significantly lower on post-operative days 0 and 1 ($p\leq0.001$).

Conclusion: Cold application reduced drain-related pain along with analgesic requirements. It can contribute to the healing process by reducing pain.

Keywords: Cold application, drain, pain, thyroidectomy

ÖZ

Tiroidektomi Sonrası Drenle İlişkili Ağrı Kontrolü Üzerine Soğuk Uygulamanın Etkisi

Amaç: Çalışmanın amacı, tiroidektomi sonrası dreni olan hastaların yaşadığı ağrı ve analjezik gereksinim sıklığı üzerine soğuk uygulamanın etkisini belirlemektir.

Gereç ve Yöntem: Randomize kontrollü deneysel bir tasarım olan bu çalışma, Mayıs-Kasım 2016 tarihinde, İstanbulda bir Eğitim Araştırma Hastanesinin genel cerrahi servisinde yürütüldü. Tiroidektomi sonrası dren takılan 59 hasta ile yapıldı. Hastalar randomize bir şekilde iki gruba ayrıldı. Soğuk uygulama, ameliyat sonrası 0. gün analjezik uygulamalarından 3 saat sonra toplam 3 kere uygulandı. Ameliyat sonrası 1. gün ise dren çıkartılmadan hemen önce uygulama yapıldı. Soğuk jel ped boyun bölgesinde drenin üzerine yerleştirilerek, 20 dakika boyunca soğuk uygulama yapıldı. Ağrı şiddeti soğuk uygulamadan 15 dakika sonra ölçüldü. Kontrol grubuna herhangi bir girişim uygulanmadı, sadece ağrı şiddeti ölçüldü.

Bulgular: Deney grubundaki hastaların ağrı şiddeti, ameliyat sonrası 0. gün daha azdı ancak, istatistiksel bir fark bulunmadı ($p>0.001$); ameliyat sonrası 1. günde dren çıkarıldıktan sonraki ağrının şiddeti deney grubunda anlamlı derecede düşük bulundu ($p<0.001$). Deney grubundaki hastaların analjezik gereksinim sıklığı ameliyat sonrası 0. ve 1. günlerde anlamlı olarak düşük bulundu ($p\leq0.001$).

Sonuç: Soğuk uygulamanın, drenle ilişkili ağrı ile beraber analjezik gereksinimini azalttığı bulundu. Soğuk uygulama ağrıyı azaltarak iyileşme sürecine katkıda bulunabilir.

Anahtar kelimeler: Ağrı, dren, soğuk uygulama, tiroidektomi

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INTRODUCTION

Although numerous clinical studies have reported that there is no need for routine drain use after thyroid surgery[1-4], drains are commonly used for the early detection of postoperative bleeding[5,6]. However, drain use is a controversial subject[5]. The presence of a drain is also painful and frustrating for patients[6-8], and 90% require analgesics in the first 24 hours after thyroidectomy[9]. Duman, Cetin, Yigit, & Erem (2014) reported usually administering pain relief medication twice a day to patients with drains[10]. Colak et al. (2008) reported high postoperative first day VAS values in a group using drains, and that analgesic requirements were higher in the postoperative period[7].

Alleviation of pain caused by painful interventions is usually required administration of opioids and nonsteroidal anti-inflammatory drugs[11]. However, these drugs are also reported to suppress cyclooxygenase inhibition and platelet aggregation, thereby creating a tendency to bleed risk, and they should therefore be used with caution for providing analgesia[12].

Much research is taking place aimed at reducing pain severity and dosages of analgesic drugs, using non-pharmacological methods[11,13,14]. Non-pharmacological methods are relatively inexpensive and safe[15]. These may be classified as (i) psychological interventions (including distraction, stress management, hypnosis, and other cognitive behavioral interventions), (ii) acupuncture and acupressure, (iii) transcutaneous electrical nerve stimulation, and (iv) physical therapies (including massage, heat/cold, physiotherapy, osteopathy, and chiropractic)[16]. Cold application, one of these methods, is frequently employed for reasons such as simplicity, low cost, and ease of implementation. Cold application slows down tissue metabolism and local nerve conduction rates, and exhibits vasoconstrictive, anti-inflammatory and analgesic effects[17,18]. Cold application increases the pain threshold and reduces the use of analgesic[19]. Post-traumatic cold application reduces permeability at the microvasculature level by affecting the vascular endothelium adhesion of leukocytes in tissue, lowers edema by reducing the extracellular release of macromolecules, and consequently reduces hemorrhage and hematoma formation. In addition, it reduces the severity of local tissue damage by lowering the metabolic activity of the tissue, provides analgesia by slowing the pain transmission rate in post-traumatic efferent nerves, and also reduces analgesic requirements. Cold has also been reported to play a role in suppressing the tension reflex at the spinal level and in reducing muscle spasm[20].

Previous studies have investigated the effect of cold application on reducing pain caused by painful interventions[11,21,22]. Drain-related pain has been reported after thyroidectomy[5,6,23], but no studies have investigated the effect of non-pharmacological methods on reducing pain. However, it has been suggested that cold application may be useful in reducing drain-related pain. Cold application, an inexpensive and simple method for relieving pain, one of the drain-related problems after thyroidectomy, was therefore selected in the present study. The quality of nursing care can be improved if nurses monitor the advances in cold application methods.

Study Aim

In this study, we aimed to determine the efficacy of cold gel pad application in relieving drain-related pain and possibly reducing the frequency of requests for analgesia in the postoperative period.

Research Hypotheses

H0: Cold application has no effect on pain severity or frequency of requests for analgesia.

H1: Patients in the cold application group will have significantly lower drain-related pain severity than those in the control group.

H2: Patients in the cold application group will make significantly fewer requests for analgesia than those in the control group.

MATERIAL and METHODS

Study Design

This study was conducted as a prospective, single-center, parallel, two arm (1:1), randomized controlled trial.

Study Sample

The study population consisted of 72 patients who underwent total thyroidectomy at a Training and Research Hospital General Surgery Department between May 15 and November 20, 2016. This hospital is one of the largest and oldest in Istanbul.

The inclusion criteria were as follows:

-Absence of cold allergy (the patient being asked),
-Age 18 or above,
-Absence of peripheral vascular disease,
-Absence of swelling in the neck region,
-Ability to understand and speak Turkish and willing to participate in the study,
- Minivac drain is placed for all patients, and
-Being on postoperative days 0 and 1

All patients were evaluated by the researchers before and after thyroidectomy in terms of the inclusion criteria.

G*Power 3.1 software was used to calculate the sample size. The severity of drain-related pain was considered the main parameter. In Deveci et al. (2013) study, mean pain severity was 4.95 ± 1.05 among patients with drains and 3.64 ± 1.06 in the group without drains[24]. When the alpha level was set at 0.05 and the expected power of the study was 80%, the minimum size calculated based on the mean pain severity was 30 patients for both the experimental group and the control group. Simple randomization was used. In order to ensure randomization, patients were included in the study via the closed envelope method and a table of random numbers. White envelopes were used for intervention and black envelopes for control. Randomization was performed using computer software (https://www.randomizer.org/). After baseline assessment, participants were randomly allocated into one of two groups, Group 1 being the control group participants who received no intervention for pain relief (n=33), while Group 2 received cold therapy (n=33). However, four patients in the experimental group wished to leave the study, and three patients in the control group dropped out because of

hemodynamic instability. Figure 1 depicts the flowchart of the study participants. The data analyst and outcome assessor were blinded to the study groups.

Data Collection Tools

A patient evaluation form, cold gel pad and Thermoflash were used for data collection.

Patient evaluation form was consisting of two parts. The first part of the form included questions concerning descriptive characteristics such as patient's age, sex, diagnosis, type of surgery, duration of the surgery and requests for analgesia on postoperative days 0 and 1. The second part of the form included the chart on which control and experimental group pain severity data were recorded using a Visual Analog Scale (VAS). The VAS used to assess pain levels consisted of a 10-cm vertical line, one end of which represented 0, no pain, while the other end represented 10, signifying the worst possible pain[25].

The cold gel pack was 13x13 cm in size. The cold gel packs cooled to -14 ºC. It is kept in the deep freeze for approximately 2 hours before use. The cold gel packs used immediately after removing from deep freeze and wrapped in sterile gauze before use. Separate gel packs were used for each patient.

A Thermoflash LX-26 thermometer was used to measure skin temperature. The ThermoFlash had a 5-second measurement time and was capable of measuring temperatures of 0-60 °C with an accuracy of ± 0.2°C. The device was calibrated, and temperature was measured with the thermometer at a distance of 5-15 cm from the skin.

Data Collection

The researchers used the patient evaluation form and the face-to-face interview method. The entire study process was conducted in cooperation with the nurses in the clinic. The patients in both groups were asked to use the VAS to measure the severity of drain-related pain on postoperative day 0 (three times) and day 1 (once). The patient's analgesic requirement status was recorded (Figure 1).

A: Cold application group: All the patients in the experimental group were interviewed before the first cold application, at which the first part of the patient evaluation form was completed. Patients received dexketoprofen 50 mg three times per day on postoperative day 0 within the unit routine. Since the elimination half-life ranges between 1 and 2.7 hours, cold application was administered 3 hours after each analgesic administration (day 0, three cold applications). In order for the application to be effective, the cold gel pad was applied to the neck area (the cold gel pack being placed over the drain) for 20 minutes and wrapped with a sterile gauze. Following the cold application, the skin surface temperature around the drain was measured by the researcher using a digital thermometer was assessed and recorded. On the first postoperative day, cold application was administered to the neck area for 20 minutes immediately before the drain was removed, the physician removing the drain once the application had finished. Pain severity in the experimental group was measured with the VAS 15 minutes after drain removal (Figure 1).

B: Control group: The first part of the patient evaluation form was completed using the control group data. Patients received analgesics three times per day on day 0 within the normal unit routine. Pain severity was measured with the VAS 3 hours after each analgesic administration. On the first postoperative day, pain severity was assessed and recorded approximately 15 minutes after drain removal (Figure 1).

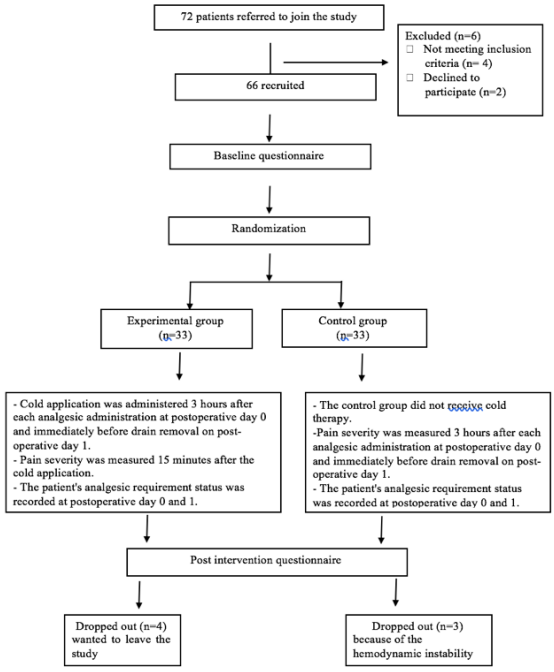

Fig.1. Recruitment Flow

Data Analysis

Statistical analysis performed on Statistical Package for the Social Sciences for Windows 16 software (SPSS, Chicago, IL, USA). Number, percentage, median, mean and standard deviation were used for descriptive statistics, and chi-square analysis (Pearson) was employed to compare the similarity / homogeneity of groups in terms of their descriptive characteristics. The difference between the groups' mean pain scores and frequency of requests for analgesia on postoperative days 0 and 1 were evaluated using the Mann Whitney-U test. The results were evaluated at a confidence interval of 95% and a significance level of $p < 0.001$.

Ethical Consideration

Before the study commenced, permission was granted by the Training and Research Hospital General Surgery Department, and ethical approval was obtained from the Training and Research Hospital Local Ethics Committee (Decision No. 2016/03/08, Dated 11.04.2015). Informed consent was obtained from patients once they had been explained about the study purpose and content.

Limitations

This study has several limitations. Since pain and the patient's desire for analgesia are subjective phenomena, their assessment was based on participant statements.

Since we encountered no previous studies investigating the efficacy of any method for reducing draining-related pain after thyroidectomy, the cold application was examined in the light of studies investigating similar situations.

RESULTS

Baseline comparisons

The study was completed with 59 patients (Figure 1). Demographic data were compared between the experimental and control groups using the Pearson chi-square test. No significant statistical difference was observed between the groups in terms of demographic characteristics. The mean age of the patients was 50.07 ± 1.55 years, and 54.2% were female. Papillary-anaplastic thyroid carcinoma was diagnosed in 55.9% of patients, and total thyroidectomy intervention was performed on 79.6% of these. The mean operative time was 113.2 min. The groups were similar in terms of descriptive characteristics (p> 0.001).

Primary Outcome-Pain severity

Median pain severity scores in the experimental and control groups were similar at postoperative day 0, but the patients in the experimental group experienced lower drain-related pain severity than the control group at postoperative day 1. Analysis of the distribution of changes in the experimental and control groups in terms of pain scores by evaluation times revealed no statistically significant difference between the groups on postoperative day 0 (p >0.001, Table 1). However, a statistically significant difference was observed between the groups on postoperative day 1 (fourth measurement) ($p \leq 0.001$, Table 1).

Table 1. Comparison of Mean Scores of Pain According to Measurement Times of Patients in the Experimental and Control Groups

Groups	Control (n=30)	Experimental (n=29)	Test value *p*
1st measurement M±SD Median (Min-Max)	6.03±2.51 5 (1-10)	6.55±1.86 7 (2-10)	MW-U:356.00 p>0.001
2nd measurement M±SD Median (Min-Max)	5.20±2.00 5 (2-10)	4.41±1.42 5 (1-7)	MW-U:352.00 p>0.001
3rd measurement M±SD Median (Min-Max)	4.50±1.81 4 (2-8)	3.86±1.66 4 (1-8)	MW-U:365.50 p>0.001
4th measurement (Postoperative 1st day) M±SD Median (Min-Max)	3.00±1.46 3 (0-6)	1.62±1.17 2 (0-4)	MWU: 285.50 p≤0.001

M:Mean, SD: Standard deviation, MW-U: Mann Whitney U test. The Mann Whitney-U test was used for assessment.

Secondary Outcome-Analgesia requests

The median frequency of requests for analgesia was lower in the cold application group than in the control group. In terms of time points, a statistically significant difference was determined between the groups on postoperative days 0 and 1 (p≤0.001, Table 2).

Table 2. Comparison of Analgesic Request Frequency Averages on Day 0th and Day 1st of Patients in the Experimental and Control Groups

Analgesic request	Control (n=30)	Experimental (n=29)	Test value *p*
0th day analgesic request M±SD Median (Min-Max)	2.69±0.71 3 (2-4)	2.03±0.18 2 (2-3)	MW-U: 207.500 p≤0.001
1st day analgesic request M±SD Median (Min-Max)	1.83±1.00 2 (1-4)	0.67±0.47 1 (1-2)	MW-U: 140.000 p≤0.001

M:Mean, SD: Standard deviation, MW-U: Mann Whitney U test. The Mann Whitney-U test was used for assessment

DISCUSSION

The key finding of this study, that cold application reduced pain on day 1 postoperatively, will contribute to the literature by providing evidence-based information concerning the effect of the cold application on pain and frequency of analgesic requirements in patients with post-thyroidectomy drains. The study findings sufficiently show that cold application reduced drain-related pain along with the specific need for analgesics.

In the present study, it was found that pain severity was similar in the experimental and control groups on the postoperative day 0 and that cold application decreased pain severity in the experimental group on the postoperative day 1. Kalemera Ssenyondo et al.'s (2013) from an East African hospital titled "Whether the drain should be used after thyroid surgery or not" determined that patients with drain in the post-operative period mostly experienced pain and infection[26]. Numerous studies from Turkey have also reported that patients with drains have higher VAS scores on postoperative day 0[8,24]. Another studies reported that patients undergoing thyroidectomy experienced drain related pain after 12 h, 24 h and 48 h.[27,28]. Finding of this study confirmed that drain is still a frustrating procedure for patients. Perception of pain is a complex phenomenon that is affected by emotional conditions[29]. Knowing that patients are in the experimental group can cause anxiety, and this situation may have affected their pain severity. Anxiety may be the reason for the groups' similar intensity of pain on postoperative day 0. Although numerous studies have demonstrated the efficacy of cold application methods in reducing pain associated with surgical incision and chest tube removal[11,21], to the best of the present authors' knowledge, this is the first study on the effects of cold application in reducing drain-related pain after thyroidectomy. Our results support the findings of previous studies and suggests that the local effect of the

cold application on the nerves increases over time, resulting in a significant decrease in VAS values.

In the present study, cold application in pain control reduced the need for analgesia at postoperative days 0 and 1. Previous studies reported an increased need for analgesic drugs on the day of surgery and postoperative day 1 after drain insertion following thyroid surgery[7,30]. The pain experienced after thyroidectomy can be controlled by nonsteroidal anti-inflammatory agents or opioids. The importance of pain management after traumatic procedures and of a multimodal approach involving analgesic, pharmacological and non-pharmacological techniques applied by nurses after surgery has also been emphasized in the literature[31]. Also, the literature states that a combination of pharmacological and non-pharmacological methods has a 23% success rate in pain management[32]. The American Academy of Healthcare Policy and Research Agents' Acute Pain Management Guidelines suggest that non-pharmacological methods should be used in order to reduce the rate of analgesic use, together with analgesic combinations for pain experienced in the post-operative period, and to improve quality of life by reducing pain as much as possible following surgical interventions[33]. Non-pharmacological pain relief methods have become increasingly popular because of their lower side-effects[34]. Haynes[35] reported that cold application, a non-pharmacological method for use in painful situations, reduce pain levels determined using VAS, and increases tolerance as a result. Colak et al. (2008) reported that patients with drains had higher VAS values on postoperative days 0 and day 1, and that analgesic requirements were also higher in the postoperative period in this group of patients[7]. The finding of this study suggested that cold application increased pain tolerance, thus significantly reducing the demand for analgesia. This result confirms the H2 hypothesis and supports the findings of previous studies.

CONCLUSIONS

Cold application was not effective on day 0 after surgery, but was effective on day 1. Since the severity of pain experienced decreased, analgesic requirements also decreased.

Cold application in patients without cold allergy may be appropriate for reducing pain associated with the drain and removal procedure. We, therefore, think that further studies with larger numbers of patients are now needed.

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Yazar katkıları:

Çalışma tasarımı: ZT, AAS, CA
Veri toplama: AAS, CA
Veri Analizi: ZT, YK
Literatür Araştırması: ZT, YK, AAS
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Ethics Committee Approval: Bakırköy Dr. Sadi Konuk Training and Research Hospital Clinical Research Ethics Committee (Decision No: 2016/03/08, Date:11.04.2015)

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Author contributions

Study design: ZT, AAS, CA
Data collection: AAS, CA
Data analysis: ZT, YK
Literature search: ZT, YK, AAS
Drafting manuscript: ZT, AAS, YK

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