

EFFICACY OF CRYOTHERAPY ON PAIN, EYELID OEDEMA AND FACIAL ECCHYMOSIS AFTER CRANIOTOMY AMONG NEUROSURGICAL PATIENTS

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Abstract: Cryotherapy is a method of pain treatment which uses a method of localized low temperatures to decrease nerve irritation, injures and swelling in both soft tissue injury and postoperative swelling and controlling edema. This study aimed to determine the impact of cryotherapy on pain, eyelid oedema and facial ecchymosis after craniotomy among neurosurgical patients. Design: a quasi-experimental research design was used. Setting; the current study was conducted in inpatient neurological Department of Menoufia University Hospital. Subjects included 160 patients from the above mentioned setting, they divided into two equal groups; the study group (I) had received cryotherapy management, and the control group (II) received routine hospital care. Tools: 3 tools were used for data collection. Tool I: included two parts: Demographic characteristics and medical data. Tool II: Visual Analogue Pain Scale. Tool III: Five point rating scale to assess eye lid oedema and facial ecchymosis. Results: There was highly statistically significant difference in pain level between the study group and the control group. Also, there was statistically significant decrease in eyelid oedema and facial ecchymosis in the study group than the control group. Conclusion: The study concluded that Pain score, degree of eyelid oedema and ecchymosis were significantly decreased among the study group than the control group so the study recommended that cryotherapy should be done for all patients after craniotomy to reduce pain, eyelid oedema and facial ecchymosis.

Keywords: Cryotherapy, Craniotomy, Eyelid oedema, Facial ecchymosis, Pain.

1. INTRODUCTION

Craniotomy is "a surgery to cut a bony opening in the skull in which a section of the skull, called a bone flap, is removed to access the brain underneath" and craniotomy may be small or large depending on the problem ⁽¹⁾. There are many purposes for craniotomy as diagnosing, removing, or treating brain tumors, cutting or fixing of an aneurysm, removing blood or blood clots from blood vessels, remove an abnormal mass of blood vessels, e a brain abscess and infected pus-filled pocket, repairing skull fractures, repairing a tear in the membrane lining the brain (dura mater) and relieving pressure within the brain (intracranial pressure) by removing damaged or swollen areas of the brain that may be caused by traumatic injury or stroke. The craniotomy also was done for treating epilepsy, neurological condition involving the brain that makes people more susceptible to seizures, and implanting stimulator devices to treat movement disorders such as Parkinson's disease or dystonia ⁽²⁾.

Post craniotomy patients are expected to suffer various degree of pain suggested to reasons as include lesser number of pain receptors in dura, pain insensitivity of the brain, reduced pain fiber density along the incision lines or development of auto analgesia. Pain after craniotomy has reported that 60–90% of patients experience pain, with 64–84% having moderate to severe pain ⁽³⁾.

The edema and ecchymosis after craniotomy are common discomforts to patients and may affect patient self-image and occur at almost the same time after surgery, they have to be simultaneously managed ⁽⁴⁾.

Patients continue to suffer pain due to insufficient use analgesic therapies particularly in the first hour after surgery that might continue until first or second day after surgery. The patients may have inadequate pain; various postoperative complications and prolonged hospital stay which might be distressing for the patients ^(5,6).

The cryotherapy goal is to reduce inflammation, control pain and spasm, stimulate the vasoconstriction of blood vessels, increase capillary constriction and reduce the temperature of the damaged area, it is also utilized as a way of managing localized areas of some cancers (called cryosurgery) such as prostate cancer, decrease cell growth and reproduction (cellular metabolism), increase cellular survival and to treat abnormal skin tissue. It also is widely used to relieve muscle pain, hemorrhage and breakdown, as well as changing pain transmission from injured tissues ^(7,8).

Significance of the Study

Cryotherapy is the local or general use of cooling methods in medical therapy. It could be used to manage a various types of tissue lesion and is used in an effort to relieve muscle ache, twists and swelling after soft tissue damage or surgery. It can be carried out through different methods as application of ice packs, immersion in ice baths or use of cold chambers. Therefore, this study was conducted to evaluate the efficacy of cryotherapy on pain, eyelid oedema and facial ecchymosis after craniotomy among neurosurgical patients.

Aim of Study

This study aimed to determine the impact of cryotherapy on pain, eyelid oedema and facial ecchymosis after craniotomy among neurosurgical patients.

Research Hypotheses

The following research hypotheses are framed in an attempt to accomplish the aim of the study:

The subject who receive cryotherapy (study group I) will show decrease in pain level, eyelid oedema and facial ecchymosis compared to subjects who do not receive it (control group II).

II. METHODOLOGY

Research design

Quasi-experimental research design was utilized to achieve the aim of the study.

Research setting

The current study was conducted at Neurological Department of Menoufia University Hospital, Shebin El-Kom district, Menoufia Governorate, Egypt.

Sample:

A purposive sample of 160 persons who were admitted to the Neurological Department for undergoing craniotomy, agreed to take part in the study and fulfill the inclusions criteria. The study subjects were divided randomly and alternatively into two equal groups 80 patients in each as follow:

- **The study group (I):** received cryotherapy management.
- **The control group (II):** received routine hospital care.

Inclusion criteria: a) Patients over 18 years of age, b) Patients have ability to communicate verbally or nonverbally, c) Patients able to give written consent.

Exclusion criteria: a) Patients with a score of Glasgow Coma Scale < 15, b) Patients with neurological instability or deterioration, c) Patients with fluctuated vital signs and d) Patients have allergy from cold.

Sample size:

The ideal sample size was calculated by **Slovin's Formula** ⁽⁹⁾ which offers sample size calculator through these values: level of confidence, population size and margin of error (confidence interval).

$$n = \frac{N}{1 + N(e)^2}$$

Where; n= sample size; N= total population number (266); e= margin error(0.05).

Tools: three tools were utilized by the researchers to achieve the aim of the study and to collect the needed data. These tools were as follow:

Tool (I): Structural interview questionnaire:-

This tool was established by the researchers and included two parts:

Part 1: Demographic data:

Such as age, gender, educational level, marital status, occupation, economic status, etc.....

Part 2: Medical data:

It included information about diagnosis, location, duration and Reoperation within 3 hours.

Tool (II): Visual analogue scale (VAS)

It is an adopted scale by **Smeltzer, & Bare (2014)** ⁽¹⁰⁾ which provides easy Method to determine pain intensity. The measurements are from 0 to 10 to rate the pain degree. The scoring system was interpreted as follows; A score of 0 means no pain while a score of 1-3 denotes mild pain, a score of 4-6 indicates moderate pain, a score of 7-9 illustrates severe pain, while 10 means excruciating pain.

(Alghadir, Anwer, & Iqbal A. 2018) ⁽¹¹⁾ tested the reliability of the scale and found that the retest reliability was $r = 0.84$ and reported that the visual analogue pain scale had high test–retest reliability and it was the most reliable, with the minimum errors in measuring of acute pain.

Tool (III): five point rating scale

It was adopted by **Kara & Gokalan (1999)** ⁽¹²⁾ and was used to measure eyelid oedema and facial ecchymosis. This scale is rating from 0 to 4.

For eyelid edema: 0 means no edema and 4 indicate massive edema and for facial ecchymosis: 0 means no ecchymosis and 4 means ecchymosis $\geq 6 \text{ cm}^2$

Scoring system for eyelid oedema: 0 means no oedema, 1 means minimal oedema, 2 means oedema outspreading on the iris, 3 means oedema cover the iris and 4 means huge oedema with a swollen locked eyelid. The facial ecchymosis scoring system is: 0 means no ecchymosis, 1 means ecchymosis less than 2 cm^2 , 2 means that the ecchymosis less than 4 cm^2 , 3 means ecchymosis blew 6 cm^2 and 4 means ecchymosis equal or more 6 cm^2 .

Reliability: **Kara & Gokalan (1999)** ⁽¹²⁾ tested the reliability of the scale and reported that the questionnaire of the scale had high internal constancy with $\alpha = 0.94$ with high test re-test reliability.

Validity: All tools will be tested for content validity by five experts in the field including (Nurse Educators and neurological specialist to ascertain relevance and completeness).

Reliability: Each question in each study tool will be tested for reliability. This will be done by asking each question twice so as to compare the consistency of answers produced for the same questions by the same respondent. Accordingly, the necessary adjustment will be carried out.

Formal approval: An approved permission was obtained from the administrative authorities of Menoufia university hospital to conduct the study in the Neurosurgical Department after clarification of the study aim.

Ethical consideration

Written consent was obtained from the patient after clarification of the study aim for participants before the start of the study. Privacy and confidentiality were assured through coding the data.

Pilot study: A pilot study was initially done prior to data collection on 10% of the subjects (18 patients) to assess the developed tools for testing feasibility and applicability of the tools. The required changes were done accordingly; however, the data obtained from the pilot study were not included in the current study.

2.5. Data collection procedure:

- The data collected over a period of 8 months from 1 November 2017 to 30 June 2018.
- The participants of the study were selected and divided randomly and alternatively into two equal groups; the **study group (I)**: received cryotherapy management while **the control group (II)**: received routine hospital care.
- All the participants were interviewed individually in the neurosurgical unit of Menoufia University Hospital. An interview was implemented by the researchers for all participants of both study and control groups for collecting baseline socio-demographic data and medical data, by using the tools I. It took about 20 minutes.
- Subjects of all groups were assessed immediately postoperatively for pain level, eyelid edema and facial ecchymosis using tool (II) and tool (III)
- The researcher went through extensive literature to design (develop) cryotherapy. Individualized plan for patients in group I was developed based on the finding of the assessment. Goals, priority of care and expected outcomes criteria were formulated and taken to consideration first.
- Study group was received the cryotherapy by using two dry cold methods, 9-inch ice bags with round-shaped and cold gel packs. Each ice bag was filled with ice chips and was emptied from air then the ice bag was put on the surgical wound with the patient in the flat position on his back and head was elevated 30 °. Simultaneously a glasses-shaped cold gel pack was applied to the periorbital area with Velcro tape. The period of cryotherapy application was twenty minutes per hour; it started three hours after surgery every hour, except from 10 pm–7 am and for three days after surgery. Cryotherapy was done by patients, nurses and or caregivers after education about the technique.
- Pain level was measured every day for the first three days post-operative using tool II.
- Eyelid edema and facial ecchymosis were measured the first three days post-operative using tool III.
- Control group received the standard routine hospital care and were also evaluated for pain level, eyelid edema and facial ecchymosis immediately post-operative and first, second, and third day post-operative using tool II and III.
- Evaluation was done using all tools at three time intervals before and after the intervention.
- A comparison between both groups (study and control) was done to determine the effect of cryotherapy on pain, eyelid oedema and facial ecchymosis after craniotomy among neurosurgical patients.

III. STATISTICAL ANALYSIS

Data were gathered and analyzed statistically by Statistical Package of Social Science (SPSS) version 20 in the form of mean and standard deviation for quantitative data, and frequency and percent for qualitative data. The tests which were used for significance involved chi-square test (χ^2) to determine the relationship between two qualitative variables and t-test which was utilized for comparison between two groups having quantitative variables. P value ≤ 0.05 was significant; P value of < 0.001 is highly significant.

IV. RESULTS

Table (1): The distribution of socio-demographic characteristics for both the study and control groups.

	Study group N=80	Control group N=80	P value
Age	48.9 ± 7.43	49.03 ± 8.21	0.920
Gender			
Male	29 (36.25%)	31 (38.75%)	0.744
Female	51(63.75%)	49 (61.25%)	
Education			
Illiterate	22(27.5%)	17(21.25%)	0.133
Read and write	2(2.5%)	8 (10%)	
Secondary	45(56.25%)	39 (48.75%)	
universal	11(13.75%)	16 (20%)	
Social status			
married	40(50%)	45 (56.25%)	0.864
single	10 (12.5%)	9(11.25%)	
divorced	14(17.5%)	11(13.75%)	
widow	16(20%)	15(15.75%)	
Occupation			
Worker	44 (55%)	47(58.75%)	0.773
Not work	17 (21.25%)	12(15%)	
Employee	12(15%)	14(17.5%)	
other	7(8.75%)	7(8.75%)	

Table (1) showed that the mean age of both study and control groups were 48.9 ± 7.43 and 49.03 ± 8.21, respectively, and most of the studied subjects in both groups were females. About more than half of the patients (56.25% and 48.75%) had secondary education for study and control respectively Moreover, 50% of the study group and 56.25% of the control group were married and most of the studied subjects in both groups were workers (55% and 58.75% for study and control, respectively).

Table (2): Frequency and percentage distribution for the patients according to medical history for both the study and control group.

	Study group N=80	Control group N=80	P value
Diagnosis			
Tumor	68(85%)	63 (78.75%)	.053
Non-tumor	12(15%)	17(21.25%)	
Location			
Frontal	28(35%)	21(26.25%)	.653
Bifrontal	10(12.5%)	14(17.5%)	
Temporal	12(15%)	11(13.75%)	
Fronto-temporal	28(35%)	33(41.25%)	
Orbital	2(2.5%)	1(1.25%)	
Duration/ hours	2.453 ± 0.329	2.734 ± 0.312	0.817
Reoperation within 3 hours			
Yes	14(17.5%)	16(20%)	.685
No	66(82.5%)	64(80%)	

Table (2) showed that the majority of both study and control groups were diagnosed with tumor (85% and 78.75%, respectively). Location of operation of both study and control groups were fronto-temporal (35% and 41.25%, respectively).

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Table (3): The difference between studied subjects in the both groups (study and control) regarding to postoperative pain immediately, and every day at three day interval after surgery.

Pain score	Study group N=80	Control group N=80	P-value
Immediate postoperative	8.4250 ± 1.32908	8.2500 ± 1.45399	0.428
First day	7.6250±.97273	8.4125±1.24975	000**
Second day	6.4875±.71146	7.6875±1.84592	000**
Third day	4.4500±1.24168	7.5250±0.98051	000**

*Statistically significant at $P \leq 0.05$

Table (3) revealed that there was a statistically decrease in pain level the study and the control groups after first, second and third day post-operative in relation to the mean of both study and control groups (4.4500 ± 1.24168 and 7.5250 ± 0.98051 , respectively) and P value = 000.

Table (4): The difference between the study and the control groups concerning postoperative eyelid oedema, immediately, in the first, second and third days.

Eyelid oedema	Study group N=80	Control group N=80	P value
Immediate postoperative	4.4250 ± 0.6319	4.4375± 0.5920	0.897
First day	3.8750±.66323	4.5250± 0.5025	0.000*
Second day	3.2250 ± 0.4202	4.1625 ± 0.5142	0.000*
Third day	2.6750 ± 0.5905	3.8500 ± 0.5056	000*

*Statistically significant at $P \leq 0.05$

Table (4): Showed that there was a highly statistical significant improvement of the mean score of eyelid edema, 2.6750 ± 0.59054 in the study group compared to 3.8500 ± 0.50566 in the control group at third day after surgery. Statistical significant differences existed at first, second and third day post-operative with P value. 000.

Table (5): The difference between the study and control groups regarding to postoperative facial ecchymosis, immediately and every day at three day interval.

Facial ecchymosis	Study group N=80	Control group N=80	P-value
Immediate postoperative	3.0625 ± 0.6626	3.0500±.65410	.905
First day	2.7625 ± 0.55675	3.000±.61624	.011*
Second day	2.4750±0.61572	2.8625±.52153	.000*
Third day	1.7125 ± 0.65976	27625 ± 0.5335	.000

Table (5) showed that there was a statistical significant improvement of facial ecchymosis 1.7125 ± 0.65976 of the study group compared to 27625 ± 0.53353 of the control group at third day post-operative intervention. Highly statistical significant differences existed at second and third day post-operative with P value .000

V. DISCUSSION

Craniotomy is a surgery to make a bony opening in the skull, a section of the skull, called a bone flap is removed to access the brain underneath. After craniotomy, a lot of patients suffer from discomforts as pain, eyelid oedema and ecchymosis (13, 14, 15). In the current study a clinical trial to control these effects. The aim of the study was to evaluate the effectiveness of cryotherapy on pain, eyelid oedema and facial ecchymosis following craniotomy among neurosurgical patients. The findings of this study will be discussed as follows:

Demographic characteristics and medical data for patients: the result of the present study shown that there was no statistical significant difference between the patients in both groups concerning their demographic characteristics and

medical data at the baseline and this was consistent with Gottschalk et al ⁽¹⁶⁾ who reported that the studied groups didn't differ significantly at baseline

Regarding to demographic characteristics; the present study conducted that the mean, age for the study and control groups were forty-eight and forty --nine years old, respectively with no significant difference between the two groups. This finding was consistent with the study done by Algar et al ⁽¹⁷⁾ who mentioned that the age of the craniotomy was around 40-50 years old. Moreover, the findings of the study done by Baker et al ⁽¹⁸⁾ illustrated that the age of the majority of patients involved in his study was less than 55 years old and it increased most commonly in people aged over 40years old and also younger people may also be affected.

In relation to the sex, the current study revealed that, more than half of subjects in the study and control groups were females this agreed with Roberts ⁽¹⁹⁾ who reported that the majority of the subjects were females. This result disagreed with the study done by Tuffaha, et al & Philadelphia et al ^(20, 21) they reported that the majority of studied patients were males.

With regards to level of education, the results of the present study revealed that majority of both study and control group had secondary education. These results were supported by Kanlayanaphotporn & Janwantanakul ⁽²²⁾ who reported that the secondary education people are more at risk than higher education.

In reference to marital status, the present study revealed that about half of the studied subjects were married. This finding was matched with their age group and was supported by Kargi et al ⁽²³⁾ who told that the majority of their studied subjects were married.

In relation to occupation, our study demonstrated that, more than half of the studied subjects were workers with no significant difference between two groups; these findings were in congruence with Kim & Bang ⁽²⁴⁾ who stated that workers had a high risk than others.

Regarding to diagnosis, it was apparent in the present study that the most subjects in both groups were diagnosed with tumor. This result was in line with **Donough et al & Levy & Marmar** ^(25, 26) who mentioned that the majority of their studied subjects brain tumor.

Regarding to location of surgery, this study revealed that the location of surgery was fronto-temporal & frontal in the majority of both study and control groups .This similar to **Suzanne et al** ⁽²⁷⁾ who reported that the majority of their studied location of surgery

Regarding to duration of surgery, the present study showed that, the majority of study and control groups duration of surgery was less than three hours. These findings were consistent with Stoneham et al & Lim et al ^(28, 29) who stated that the duration of surgery of studied patients were 2-2.5 hours.

Regarding to postoperative pain, the present study emphasized that there was a decrease in postoperative pain level in the study group than control group because study group used cryotherapy intervention. This result was in agreement with Dunbar et al ⁽³⁰⁾ who mentioned that the patients suffered the greatest pain in the first hour after surgery and the cryotherapy group felt less pain than the control group at the 3rd day postoperatively. This result was supported by Donnelly et al & Woodrow et al ^(31, 32) that told that the pain reduced more quickly in the cryotherapy group than in the control group. Moreover, this result was consistent with Nadler et al & Finan et al

^(33, 34) that reported on their studies; participants were experiencing a reduction in pain in intervention group which received cryotherapy compared with the other group.

Regarding to eyelid oedema, the results of the present study showed that there was statistical significant differences between the cryotherapy group and control group regarding to eyelid oedema. This finding was supported by Mordhorst et al ⁽³⁵⁾ who stated that cryotherapy has reduced oedema through decreasing the permeability and contraction of peripheral circulation and help in alleviating eyelid swelling after craniotomy Klimek et al & Quist et al ^(36, 37) reported that cryotherapy decreased eyelid oedema and the effects of cryotherapy continued from nine hours to seven days after craniotomy and cryotherapy group had less eyelid oedema than the control group. Moreover, this result was consonant with Coldsack et al & Saam et al ^(16, 38) who mentioned that the pulsatile cold compression through application of

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cryotherapy /Cuff with 30–35 mm Hg decreased the area of swelling in ankle fractures by 2.9%, 4.4% and 4.9%, compared with healthy ankles at 24- 48 and 72 hours after-treatment respectively.

Regarding facial ecchymosis, the result of the present study revealed that there was an improvement in the study group than the control group regarding facial ecchymosis. These findings were consistent with Miroslav et al ⁽³⁹⁾ who stated that early application of cryotherapy was more effective in reducing bleeding and edema when applied during the acute period of inflammation. Also Cormack and Costello & Bieuzan et al ^(40, 41) stated that immediately application of cryotherapy post-craniotomy and maintained it during periods of eyelid oedema and ecchymosis was effective. These findings support the benefits of cryotherapy in effective control of pain, oedema and ecchymosis more than any other techniques, as medication or patch.

VI. CONCLUSION

Based on the results of the present study, it can be concluded that Pain score was significantly decreased in the cryotherapy group than the control group where the cryotherapy group had a lower degree of eyelid oedema and facial ecchymosis after craniotomy.

RECOMMENDATIONS

Use of cryotherapy after craniotomy to reduce pain score, degree of eyelid oedema and ecchymosis among neurosurgical Patients. Repeat the study with a larger sample for generalization of results.

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