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EFFECTIVENESS OF CRYOTHERAPY ON PERI-ORBITAL EDEMA AND ECCHYMOSIS AMONG PATIENTS OF SUPRA-TENTORIAL CRANIOTOMY: A RANDOMIZED CONTROL TRIAL

Nursing

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ABSTRACT

Background: Peri-orbital edema and ecchymosis are common among patients of supra-tentorial craniotomy. Due to its considerable impact on patient's discomforts, the appropriate intervention has to be provided to reduce peri-orbital edema and ecchymosis. **Objectives:** To assess the effectiveness of cryotherapy on peri-orbital edema and ecchymosis among patients of supra-tentorial craniotomy. **Methods:** A randomized control trial was conducted to assess the peri-orbital edema and ecchymosis among patients of supra-tentorial craniotomy in the Neurosurgical units of our Institute. Ethical approval was obtained from the Institute Ethics Committee. Ninety adult patients underwent supra-tentorial craniotomy for a non-traumatic lesion with peri-orbital edema or ecchymosis within 20 hours of surgery were randomized, 45 into control and experimental group each. Peri-orbital edema and ecchymosis craniotomy were assessed by using Kara and Gokalan scale. **Findings:** The baseline prevalence of peri-orbital edema and ecchymosis were comparable in both the experimental and control group. The prevalence of grade 4 periorbital-edema was significantly lesser in patients who underwent cryotherapy on 3rd (8.9% Vs. 44.4%) and 4th (0 Vs. 42.2%) postoperative days. Though the prevalence of peri-orbital ecchymosis was less in patients of the experimental group throughout cryotherapy, there was no statistically significant difference in prevalence between control and experimental group.

KEYWORDS

Cryotherapy, supra-tentorial craniotomy, peri-orbital edema, peri-orbital ecchymosis, Kara and Gokalan scale.

INTRODUCTION

A craniotomy is one of the commonest surgical approaches to access various kinds of intracranial lesions. It is the approach used for various diagnostic purposes or tumor excision, aneurysm clipping, hematoma evacuation, etc.[1]Localized complications such as periorbital edema and ecchymosis can occur for few days after craniotomy and can cause pain or discomfort to the patients. So appropriate measures can be used to reduce the severity of thesecomplications.

Craniotomy approaches may include supratentorial or infratentorial depending on the location of the intracranial location of the lesions.[2,3]Supratentorial craniotomy include various approaches like frontal, parietal, temporal, occipital, pterional, or temporoparietal.[4,5]
The possible immediate surgical complications in the patients who underwent craniotomy includecerebellar hemorrhage, cerebral edema, increased intracranial pressure and subgaleal collection. It results in increased intracranial pressure and can lead to symptoms such as headache, papilloedema, vomiting, increased blood pressure, confusion, double vision and altered level of consciousness.[1,6-10]Dawes et al. (2007) and Torres et al. (2015) reported that subgaleal collection as a complication of supratentorial craniotomy due to surgical trauma in the skull and scalp. Subgaleal collection has its significance in the postoperative period as it can result in periorbital edema, ecchymosis and related pain or discomfort to the patients.[11,12]It can be prevented to an extent by placing a suction drain on the sub-periosteum. Despite the preventive measures, the incidence of subgaleal collection can vary from 7% to 33%, and periorbital edema from 2.8% to 100%.[12,13] Periorbital edema and ecchymosis may disturb patients' vision, causes pain and eye infection, hampers eye hygiene and it also affects patient self-image. It makes neurological examination difficult such as eye response in GCS, pupillary reaction, decreases visual acuity or visual field, and also hampers the findings of the neurological examination. Periorbital edema and ecchymosis remain in patients who underwent supratentorial craniotomy for 4 to 7 days.[6,14]

Cryotherapy refers to the application of the cold gel pack over edema and ecchymosis. Cryotherapy is reported to be effective in reducing postoperative periorbital ecchymosis and nasal edema in patients undergoing rhinoplasty,[15] reductions of swelling, pain, and trismus after the third- molar extraction,[16] edema resolution following ankle fractures,[17] management of swelling in musculoskeletal as well as orthopedic injuries.[18,19]Shin (2009) has proved in a randomized control trial that cryotherapy had an effect on eyelid edema and ecchymosis aftercraniotomy.[14] But, there isa lack of adequate evidence on intervention done to reduce periorbital edema and ecchymosis in patients undergoing craniotomy. Reducing discomfort and post craniotomy is vital for improving the patient's participation in rehabilitation.[20,21,22,23]Cryotherapy is a feasible bedside intervention that can be implemented if found effective. Hence, we have undertaken this study to assess the effectiveness of cryotherapy on peri-orbital edema and ecchymosis in patients undergoing supratentorial craniotomy.

METHODS

Study design and sampling: A randomized control trial was conducted to assess the peri-orbital edema and ecchymosis among patients of supra-tentorial craniotomy in Neurosurgical units of our institute. Ethical approval was obtained from the Institute Ethics Committee with reference number NK/3265/M.Sc/105. The CTRI (Clinical Trials Registry India) registration was done under the Indian Council of Medical Research (ICMR) with registration numberCTRI/2018/02/011702. All adult patients who underwent supra-tentorial craniotomy for a non-traumatic lesion with peri-orbital edema or ecchymosis within 20 hours of surgery were screened for eligibility criteria. Patients with periorbital edema due to other reasons like pregnancy, hyperthyroidism, cardiac failure, renal failure, liver failure were excluded.Using a consecutive sampling technique, a total of 90 patients who met the inclusion criteria were enrolled in the study.Patients who met the inclusion criteria were randomly allocated into the experimental and control group using a computerized random table, 45 patients in the control and 45 patients in the experimental group. A patient information sheet was given and informed consent was taken before enrolling the patients.

Tools and techniques:Peri-orbital edema and ecchymosis among patients of supra-tentorial craniotomy wereassessed by using Kara and Gokalanscale.[24,25]It has different grading for both peri-orbital edema and ecchymosis. Peri-orbital edema is graded from 0 to 4 as none, minimal, extending onto the iris, covering the iris, and massive edema with the eyelid swollen/shut respectively.Ecchymosis is graded from 0 to 4 as none, medial, extending to the pupil, past the pupil, and to the lateral canthus respectively.

Data collection procedure:Baselineperi-orbitaledemaand ecchymosis score were assessed between 7:30am to 8:30am on 1st post-operative day. The intervention of cryotherapy was provided to the experimental group every three hourly for 10 minutes between 7:30am 4:30pm till 4th

postoperative days, and the control group received routine care. Assessment of the peri-orbital edema and ecchymosis were done in both the group at the end of every day till the 4th postoperative days from 5.00pm to5:30pm.

RESULTS

Analysis :Data was entered and coded in SPSS (Statistical Package for Social Sciences) version 20. Appropriate descriptive statistics such as percentage, mean, standard deviation, and inferential statistics were used for analysis based on the study objectives. Mann-Whitney test was used to compare the continuous variables between the two groups. Friedman test was also used to assess the comparison of effectiveness within two groups over a period of time. Chi-square was used to compare the categorical variables between two groups. Analyzed data was depicted in tables and interpreted.

Socio-demographic

Patients in both groups were comparable in terms of age, gender, diagnosis, and craniotomy approach are shown in Table 1. The mean age of patients incontrol was 43.36 ±14.11 years and 42.07±15.10 years were in the experimental group i.e. comparable (p = 0.53). Males were more in both the groups (62% in control and 67% in experimental). The purpose for which the patients underwent craniotomy was also comparable in both the groups (p = 0.50). More than half of the patientsin both the groups had undergone left side craniotomy i.e. 53% in the control group and 55.6% in the experimental group (p=0.83). Approximately half of the patients in control (40.0%) and experimental group (53.3%) had undergone pterional craniotomy (p=0.61). Mean of GCS was 12.00±2.27 in control group and 11.82 ± 2.17 in experimental group (p = 0.12).

Comparison of prevalence of peri-orbital edema:

The prevalence of peri-orbital edema in patients of the control and the experimental group which was measured by Kara and Gokalan scale on 1st, 2nd, 3rd, 4th postoperative day, is shown in table 2. The prevalence of various grades of peri-orbital edema was similar in both the groups on the 1st and 2nd postoperative days. On 2nd postoperative day, grade 4 peri-orbital edema was observed only in 15.6% of the patients in the experimental group compared to 33.3% of the patients in the control group. On the 3rd postoperative day, only 8.9% of the patients were found to have grade 4 peri-orbital edema compared to 44.4% in the control group (4.16, <0.001). On the 4th postoperative day, none of the patients in the experimental group had grade 4 peri-orbital edema, 8.9% had grade 3 peri-orbital edema and 51.1% continued to have grade 2 peri-orbital edema. While, 42.2% of the patients and 33.3% of the patients in the control group had grade 4 and grade 3 peri-orbital edema (7.43, <0.001).

Comparison of peri-orbital edema severity:

Table 3 depicts the median of peri-orbital edema score in the control and experimental group. At baseline, the median peri-orbital edemascore was comparable in both the control group and experimental group [2(1-3) Vs.2(1-2),(p=0.05)]. The median periorbital edema score was significantly lower in the experimental group thanthe control group on 3rd[2(1-2) Vs. 3(3-4), 479.00, <0.001]and 4th [2(1-2) Vs. 3(2.50-4), 785.00, <0.001] postoperative days.

Comparison of prevalence of ecchymosis:

Table 4 compares the prevalence of ecchymosis between the control and experimental group. The prevalence of periorbital ecchymosis was similar in both the control and experimental group at baseline. Though the prevalence of peri-orbital ecchymosis was less in patients of the experimental group throughout cryotherapy, there was no statistically significant difference in prevalence between the control and experimental group.

DISCUSSION

A supratentorial craniotomy is an approach in which various kinds of intracranial lesions are accessed above the tentorium including the frontal lobe, temporal lobe and occipital lobe.[1,5] During the immediate postoperative period of supra-tentorial craniotomy, patients may develop complications such as hematomas, infection, periorbital edema and ecchymosis as a result of surgical trauma.[6-10]Surgical complications may be due to increased vascular permeability and release of inflammatory markers such as histamine and histamine-like permeability factors.[6] The small arteries as surgical site undergo vasodilation and there is a change in the shape of endothelial cells which results in the crossing of macromolecules through cellular wall. This process further leads to penetrating the intercellular space. The osmotic pressure within intercellular space, in turn, elevated to a level which causes extravasation of water. Histamine reaction accelerates this process by decreasing the resistance of the vascular walls results in increased permeability for reacting proteins.[12]

The second mechanism, it is the surgical injury itself which results in increased vascular permeability. Surgical dissection and electrocoagulation lead to the extension the duration of leakage of blood and lymph from the lymphatic vessels. There will be more edema of this type if there is more tissue injury during the surgical procedure. Generally, vasodilatation remains for four days after the surgical injury. The post-traumatic edema was shown to be maximal at 72 hours after a closed soft tissue injury.[14]Periorbital edema and ecchymosis are commonly seen in patients who underwent supra-tentorial craniotomy during the post-operative period. Peri-orbital edema and ecchymosis lead to pain and discomfort in patients. It interferes with eye response of GCS, pupillary response, interference with eye instillation, and eye care. Peri-orbital edema after supratentorial craniotomy is often ignored and appropriate intervention can be taken for reducing peri-orbital edema and ecchymosis among patients of supra-tentorial craniotomy.

There is only one study conducted on the effectiveness of cryotherapy over peri-orbital and ecchymosis among patients of supra-tentorial craniotomy.[14] Therefore,we have conducted a randomized control trial to assess the effectiveness of cryotherapy on peri-orbital edema and ecchymosis among patients of supra-tentorial craniotomy.

Various methods of cryotherapy are reported in the literature. Hossein et al.(2015) had useda cold pad applied to both sides of the patient's face and around the nose, beginning one hour preoperatively.[15]Minminiet al.(2014) demonstrated cryotherapyusingan ice gel packapplied at the surgical site over the single layer of crepe bandage during the first and second postoperative days.[26]In the present study, cryotherapy was provided by a cold gel pack which was readily available. This method was used by Shin et al. (2009), where a glass-shaped cold gel pack was applied to the periorbital area with Velcro tape.[14] The cold gel pack used in the present study was of the appropriate size to be appliedtothe peri-orbital area.

Our study findings showed that the prevalence of periorbital edema was significantly lesser in patients who were provided cryotherapy. The median periorbital edema score was also significantly lesser in patients of the experimental group. There was a lesser prevalence on the 3rd, 4th day in the experimental group as compared to the control group. Similar to the previous study, in the experimental group eyelid edema increased gradually until 2ndpostoperative day and slowly diminishthereafter. Still, in the control group, the prevalence started reducing only on 4th day.[14]

The role of cryotherapy and effect on reducing the edema in patients with injuries such as reducing postoperative periorbital ecchymosis and nasal edema in patients undergoing rhinoplasty[15], reduction of swelling, pain, and trismus after the third- molar extraction[16], edema resolution following ankle fractures[17]etc.are reported in the literature. Block et al.(2010) had demonstrated cold compression therapy's effectiveness on pain relief than using the alternative interventions.[27] Though there was no significant difference in the prevalence of ecchymosis between the control group and experimental group, patients in the experimental group had less prevalence of ecchymosis in our study. But the previous study shows that there was significantly less frequency of ecchymosis after supra-tentorial in patients of a brain tumor who had undergone cryotherapy.[14]

Hossein et al. in 2015 reported the effectiveness of cryotherapy on reducing postoperative periorbital ecchymosis and nasal edema in patients undergoing rhinoplasty. This study found that using ice therapy on peri- and post-op rhinoplasty patients could significantly reduce edema and ecchymosis after the rhinoplasty surgery.[15] Cryotherapy is also proven to effectively reduce pain and hematoma after subcutaneous low molecular weight heparin injections[28] andenoxaparin.[29]On the contrary, Pool et al. in 2015 in a randomized controlled observer-blinded evaluation study, reported that eyelid cooling reduces postoperative pain in patients after upper blepharoplasty but not edema, erythema and hematoma.[30]

Though the cryotherapy induces vasoconstriction and lesser hematoma, the absorption of already developed hematoma may

influence the persistence and size of edema. Reduction in edema compared to ecchymosis promotes comforts of the patients and facilitates eye examination and eye assessment.Evidence shows that cryotherapy reduces inflammation, edema, ecchymosis, pain, burning and irritation. It also helps to anesthetize an area for a short period of time. It is also found to prevent gangrene by decreasing the tissue metabolism, inhibit bacterial growth and prevent suppuration. [18,19,20] The efficacy of cryotherapy in reducing inflammatory responses are well evident in literature.[31-35] As per the present study, cryotherapy has the main role in reducing peri-orbital edema but not in ecchymosis. Patients were monitored for side-effects of cryotherapy. None of the patients had side-effects of cryotherapy after the intervention.

In light of the findings of the present study, it can be suggested that the cryotherapy can be safely provided to the patients of supra-tentorial craniotomy with peri-orbital edema. This contributes to reducing the peri-orbital edema without causing any harm tothe patient.This is a simple, less expensive, bed-side procedure which can be provided by nursing staff among patients of supratentorial craniotomy to reduce peri-orbital edema.Similar simple nurse-led interventions are proven effective in reducing post-operative problems and improving post-operative outcome and quality of life.[36-39] However, further evidence is required with blinded studies on a large sample size.

CONCLUSION

The application of cryotherapy is found to be associated with a significantly lesser prevalence of peri-orbital edema during the postoperative period in patients who underwent supratentorial craniotomy. With further evidence, it can be used as a simple bedside intervention by the nurses to reduce the prevalence and severity of peri-orbital edema after supratentorial craniotomy.

Table 1: Sociodemographic and clinical variables of the patients: Control vs experimental group n=90

Socio-demographic/ clinical variables of thepatients	Controlgroup (n1=45) f (%) or Mean+ SD	Experiment group (n2=45) f (%) or Mean+ SD	p value
Age (years) *	43.36 ±14.11	42.07±15.10	0.53
Gender Males Females	28 (62) 17 (38)	30 (67) 15 (33)	0.56
Diagnosis Aneurysm Space occupying lesions Meningioma	19(42.2) 19(42.2) 7(15.6)	18(40) 23(51) 4(8.9)	0.50
Side of surgery Left side craniotomy Right side craniotomy	24(53.3) 21(46.7)	25(55.6) 20(44.4)	0.83
Craniotomy approach Frontal Parietal Temporal Pterional Others#	10 (22.2) 2 (4.4) 2 (4.4) 13 (28.9) 18 (40.0)	07 (15.6) 01 (2.2) 01 (2.2) 12 (26.6) 24 (53.3)	0.61
GCS on post op day 1	12.00+ 2.27	11.82 + 2.17	0.74

Table 2: Comparison of prevalence of peri-orbital edema among patients of supratentorial craniotomy: Control Vs.experimental group n=90

Day of assessment	Grade of peri-orbital edema	Control group n1=45 f (%)	Experimental group n2=45 f%	χ2 value, p-value
1st post-op day (Baseline)	1 2 3 4	13 (28.9) 18 (40) 10 (22.2) 4 (8.9)	6(13.3) 17(37.8) 17(37.8) 5(11.1)	4.53, 0.20
2nd post op day	2 3 4	11 (24.4) 19 (42.2) 15 (33.3)	14 (31.1) 24 (53.3) 7 (15.6)	3.85, 0.14
3rd post-op day	1 2 3 4	0 6 (13.3) 19 (42.2) 20 (44.4)	3 (6.7) 20 (44.4) 18 (40) 4 (8.9)	4.16, <0.001#
4th post-op day	0 1 2 3 4	1(2.2) 2 (4.4) 8 (17.8) 15 (33.3) 19 (42.2)	1 (2.2) 17 (37.8) 23 (51.1) 4 (8.9) 0	7.43, <0.001#

Table 3: Comparison of peri-orbital edema severity among patients of supratentorial craniotomy: Control Vs. experimental group n=90

Postoperative day	Periorbital edema score Median (IQR)		U value, p-value
	Control group n1=45	Experimental group n2=45	
Baseline observation	2(1-3)	2(1-2)	785.00, 0.05
1st post-up day	3(2-3)	3(1-2)	724.00, 0.01
2nd post-up day	3(2-3)	3(1-2)	831.50, 0.11
3rd post-up day	3(3-4)	2(1-2)	479.00, <0.001
4th post-up day	3(2.50-4)	2(1-2)	785.00, <0.001

Table 4: Comparison of prevalence of ecchymosis among patients of supratentorial craniotomy: Control and experimentalgroup n=90

Day of assessment	Ecchymosis Present/absent	Control group (n1=45) f%	Experimental group (n2=45) f%	χ2 value(df) p value
1st post-up day	Present Absent	8(17.8) 37(82.2)	6(13.3) 39(86.7)	0.33(1)0.56
2nd post-up day	Present Absent	18(40.0) 27(60.0)	13(28.9) 32(71.1)	1.23(1)0.26
3rd post-up day	Present Absent	18(40.0) 27(60.0)	11(24.4) 34(75.6)	2.49(1)0.11
4th post-up day	Present Absent	16(35.6) 29(64.4)	11(24.4) 34(75.6)	1.32(1)0.25

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