The influence of cryotherapy (Cryotron®) on pain and inflammation following arthroscopy of the shoulder

Prof Dr Romain Meeusen

Dr Frank Handelberg, Laurence Framhout,

Stéphanie Daems

Vrije Universiteit Brussel

Belgium

Abstract

Objective: To examine the influence of cryotherapy on subacromial temperature, pain and inflammation in the postoperative shoulder

Participants: Twenty patients undergoing diagnostic shoulder arthroscopy

Intervention: Cold was administered via a *Cryotron*® , a second group received a 'placebo' treatment, while a third group served as control.

Visual analogue scores (VAS) were used to obtain pain scores and a patient-controlled analgesia system (PCA) was applied to standardize post operative medication. C-reactive proteins (CRP) were measured to get an idea of the inflammatory reaction.

Results: Skin temperatures differed significantly after post operative cryotherapy. *Cryotron*® treatment resulted in a very steep temperature drop during the first minute of application. Subacromial temperature was significantly lower for the *Cryotron*® group during the night (when no cold was applied).
According to the results of this study, cryotherapy has a positive effect on reducing post operative pain. Both VAS values and medication use were lower in the experimental groups. CRP measurements did not reduce significantly due to cryotherapy, but it seems that cryotherapy used suppresses the inflammatory reaction, as shown by one case with acute gout.

Conclusion: These results indicate that postoperative pain is influenced significantly when cryotherapy is applied.

Keywords: Cryotherapy, Inflammation, C-reactive proteins, Cold therapy, Pain

Introduction

The use of cryotherapy dates back to the time of the Acient Romans and Greeks. The only cooling modalities in those times were ice and snow. Today, advances in the delivery of cryotherapy have resulted in greater postoperative use (Swenson et al., 1996; Levy et al., 1997). The use of cold for the treatment of musculoskeletal injuries, whether caused by athletic injuries or by surgery, is generally accepted but largely based on empirical evidence. Unfortunately, this unanimity in the use of cold treatment has somewhat masked the physiological fundamentals and the mechanism by which it is effective in controlling pain and enhancing comfort is not fully understood. (Meeusen et al., 1998; Meeusen and De Meirleir, 1991; Swenson et al., 1996; Meeusen and Lievens, 1986; Scheffler et al., 1992; Levy et al., 1997; Speer et al., 1996; Fedorczyk, 1997).

Besides the analgesic effect, cryotherapy is also believed to decrease inflammatory reaction, edema and haematoma formation. Physiological reactions such as vasoconstriction and decrease in blood flow, nerve conduction velocity and muscle spasm have also been attributed to the therapy (Meeusen et al., 1998; Meeusen and De Meirleir, 1991; Swenson et al., 1996; Ivey et al., 1994; Levy et al., 1997). Cold application obviously influences tissue temperature, and this temperature reduction depends on the application method, it's temperature, and the application time (Meeusen and Lievens, 1986; Speer et al., 1996; Meeusen and De Meirleir, 1991; Swenson et al., 1996).

Several studies have examined the effects of cryotherapy on rehabilitation following knee surgery, but only few investigated the efficacy of cold application in the postoperative shoulder.

Until now no study examined the effects of different cryotherapy applications on both skin and intra-articular temperature in combination with pain measures and inflammatory parameters.

Therefore the purpose of this study, is to examine the effect of cryotherapy on skin temperature, subacromial temperature, pain and inflammation in the postoperative shoulder.

Materials and Methods

Subjects

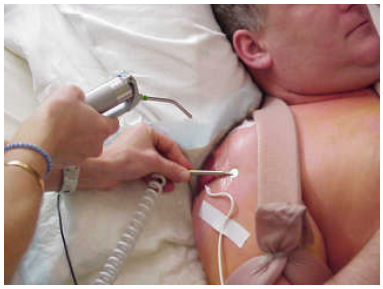
In this randomized, prospective study twenty patients (6 men and 14 women) underwent diagnostic shoulder arthroscopy, if necessary preceded by mobilisation under narcosis. The mean age of the participants was 49,6 ± 7,2years. The procedures included shaving of the acromion and acromioclavicular resection. Patients clinically diagnosed with instability problems or those needing an open cuff repair were excluded. All operations were performed under general anaesthesia and by the same surgeon (F.H.) to ensure standardized procedures. At the end of surgery, a temperature probe type 400 (Smiths Industries, Irvine, CA, U.S.A.) with an accuracy of 0,2°C was placed under direct arthroscopic vision into the subacromial space.

Procedure

The study protocol and design and the Informed Consent form were approved by the ethical commission of the Vrije Universiteit Brussel.

In a randomized fashion, cold was administered by *Cryotron*® (Cryonic Médical France). This methods uses a brief application (45 sec) of high pressure (50 Bar), cold air (-78°C) with a specific "pistol" to the area of interest (45 cm^2). The pistol was held at a distance of 10 cm from the skin. Two areas of the shoulder were treated i.e. the "acromion" surface and the "deltoid" region.

This treatment cycle was repeated every 3 hours.



We used a placebo group. In the placebo group a "spraying of the shoulder region" with the same pistol was used. No cold air, nor pressure was used.

For reasons of comparison (CRP measures) a control group with no treatment was included.
Cryotherapy was stopped during the night to assure the patient a good night's rest.

Measurements

The patients were informed of the study design and each of them signed an informed consent form. A clinical and therapeutical examination followed.
Since cold penetration depends on the depth of the target tissue (Meeusen and De Meirleir, 1991), we found it necessary to measure the tissue surrounding the shoulder. Therefore an echography was taken to determine the thickness of the subcutane fat layer and the M. deltoideus.
Skin temperature was measured using an adhesive temperature sensor type STS-400 (Smiths Industries, Irvine, CA, U.S.A.) on the lateral part of the shoulder. Temperature was measured every hour, T_0 representing the start of the measurements.
For the *Cryotron*® patients temperature was registered immediately after application during the first 60 sec with time intervals of 5 seconds. This procedure was followed because the temperature drop was the steepest in the first 60 secs after application. The next measurement was 30 min later and 1 and 2 hours after the cold application.
Intra-articular temperatures were recorded immediately after application at 30 and 60 seconds, and at the same time as skin temperatures. During the night temperature was registered every 2 hours until the next morning.

Painscores were obtained by a visual analog scale (VAS). The first VAS was taken the day before the operation. Postoperative we started at the recovery room. Registration took place together with temperature measurements.
To standardize analgesia, a patient-controlled analgesia system with Dipidolor® was used. This way the patient provides his own intravenous medication supply by pushing a button. A lock-out interval of 10 minutes was imposed to avoid overdosis. Per dosis the patient received 2mg or 1ml Dipidolor®. The maximum amount in 4 hrs was 30mg. The total amount of dipidolor (mg), the number of PCA requests (= demand) and the number of successful administrations (= delivery) were stored by

the PCA device. The morning after surgery the system was removed. Our patients were not allowed to receive any other medication for the duration of the study.

C-reactive proteins (CRP) in blood plasma were measured as an indication of inflammation. In our study 3 blood samples were collected. The first one was taken 1 day pre-operative, the second one 6 hours after starting the measurements and the last one the first day postoperative. The detection limit was <5mg/l.

At the end of the study period the morning after the operation, the last temperature and VAS measurements were done and the temperature probe and PCA-system were removed.

Data were statistically analyzed by a t-test, ANOVA or the Kruskal-Wallis 1-way ANOVA. Statistical significance was assigned at $p \leq 0.05$. When necessary, a Bonferroni adjustment was applied.

Table 1: Patient Profile (n = 20)

Group	Age (yrs) (mean + SD)	BW (kg) (mean + SD)	Thickness subcut. fat (mm) (mean + SD)	Thickness M. delt. (mm) (mean + SD)
Cryotron® (n = 10)	49,5 ± 7,4	66,3 ± 6,0	3,4 ± 1,4	5,1 ± 2,6
Placebo (n = 5)	55,8 ± 9,7	75,9 ± 10,7	3,7 ± 1,6	6,3 ± 2,6
Control (n = 5)	46,0 ± 2,5	74,0 ± 5,5	5,9 ± 2,6	5,3 ± 1,0

Results

Temperature

On arrival in the recovery room both skin temperature and subacromial temperature for the 3 groups had decreased. This is attributed to the low temperature in the operation room, irrigation of the shoulder during arthroscopy and lowering of the metabolism due to narcosis. Skin temperature one minute after application averaged

at the “clavicula zone” 16,45°C (± 3,3°C) in the *Cryotron*® group, and 28,6°C (± 2,6°C) in the control group. These differences were statistically significant. For the “biceps zone” skin temperature after one minute was 16,0°C (± 2,4°C) in the *Cryotron*® group, and 27,6°C (± 3,6°C) in the control group. Again there was a statistically significant difference between both groups.

The subacromial temperature averaged 33,3°C (± 1,3°C), and 32,7°C (± 1,3°C) for the *Cryotron*®, and control group respectively. At this point no significant differences for the subacromial nor skin temperatures between the control group and the test group were found.

Surprisingly, the subacromial temperature for the *Cryotron*® group, during the night (2,4,6 and 8 hours after stopping therapy) were significantly lower than for the control group.

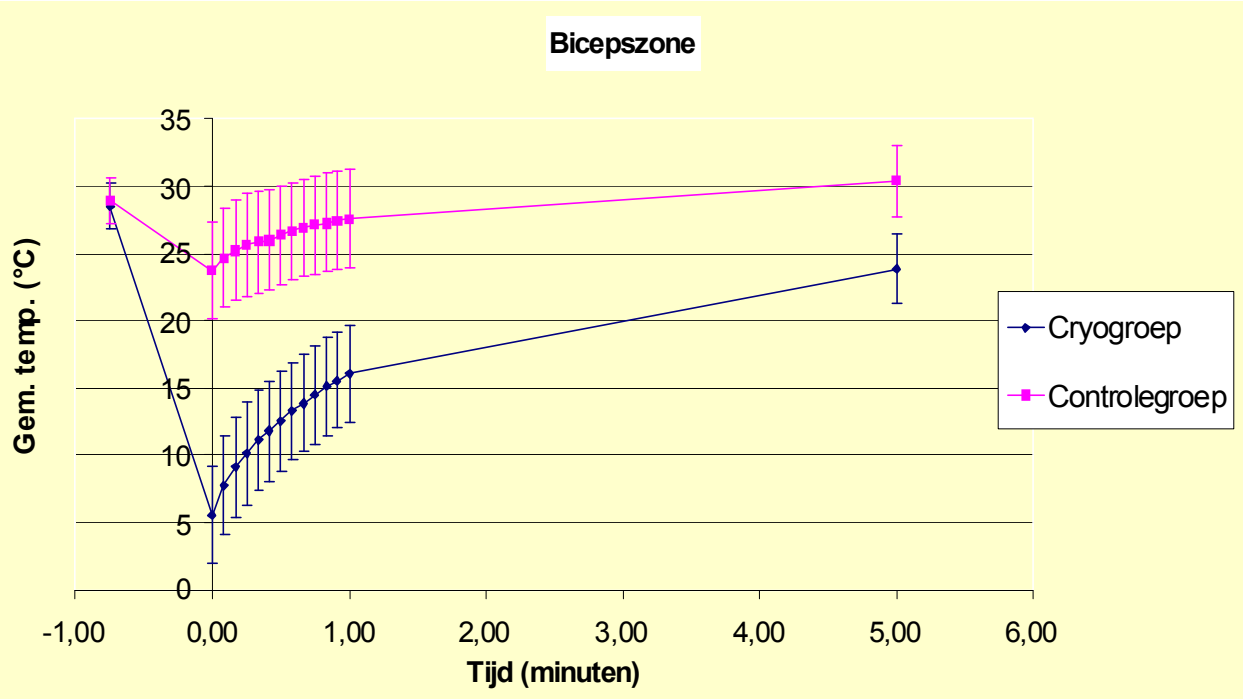


Fig. 1. Mean skin temperatures for the 2 groups (bicepszone), during the application and the first minutes of recovery

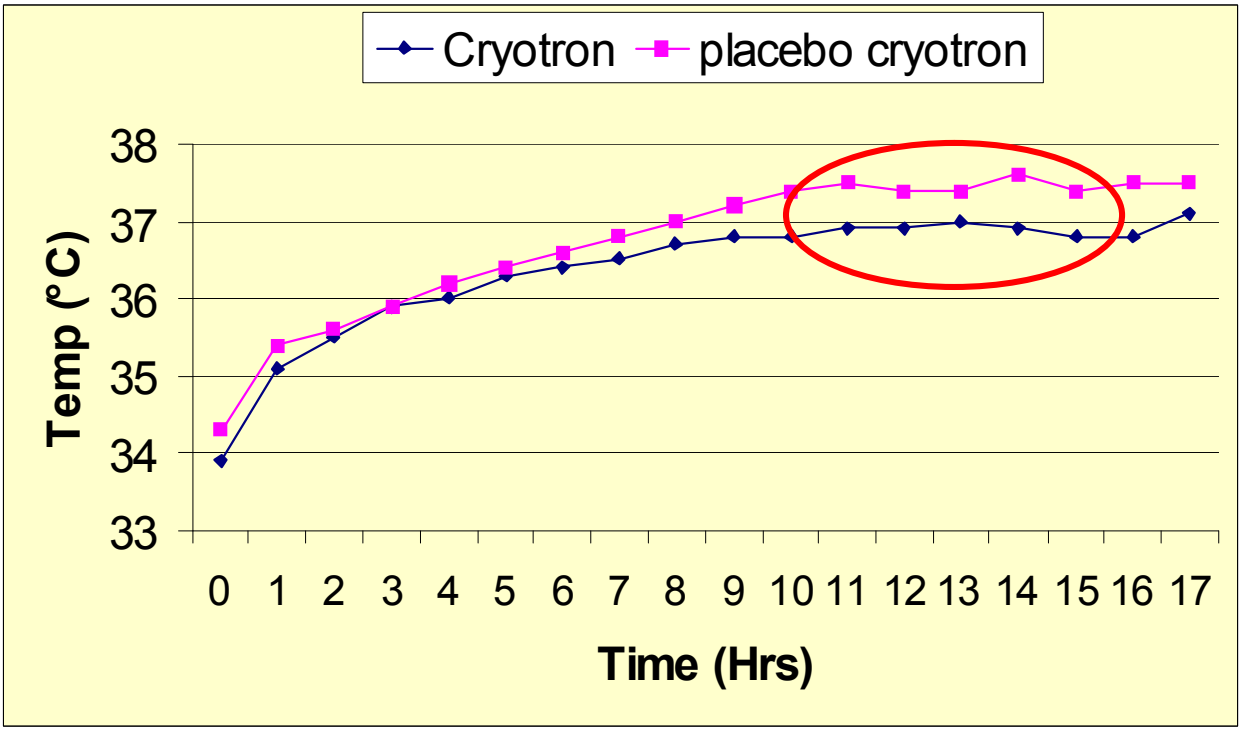


Figure 2. Mean subacromial temperatures. The circle indicates significant difference between both groups.

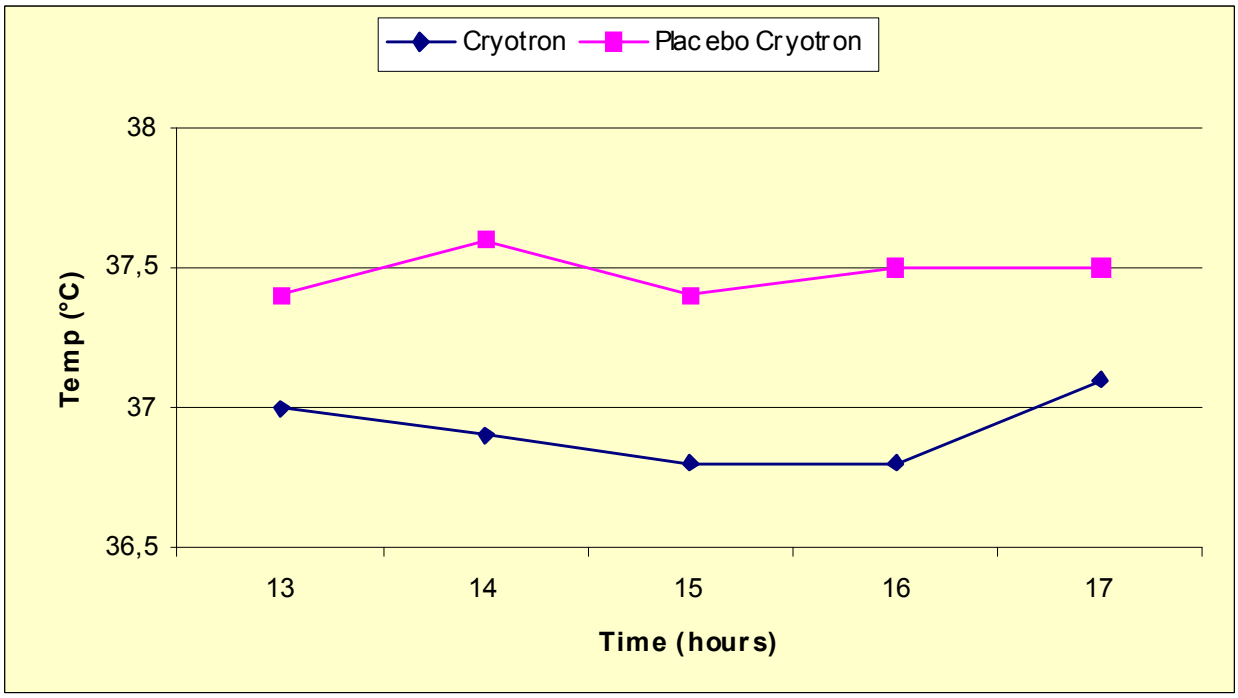


Figure 3. Illustration of the difference between the *Cryotron*® group and the control group during the night. Intra-articular temperature for the *Cryotron*® group was significantly lower.

Pain

Visual analog scores were analysed by the Kruskal-Wallis one way ANOVA. Figure 4 illustrates the VAS curves. For the control group an irregular course is seen. Pain increases immediately after the operation, while for the *Cryotron*® group there is a decrease in the same period. Over the total measuring period VAS scores for the *Cryotron*® group are significantly lower.

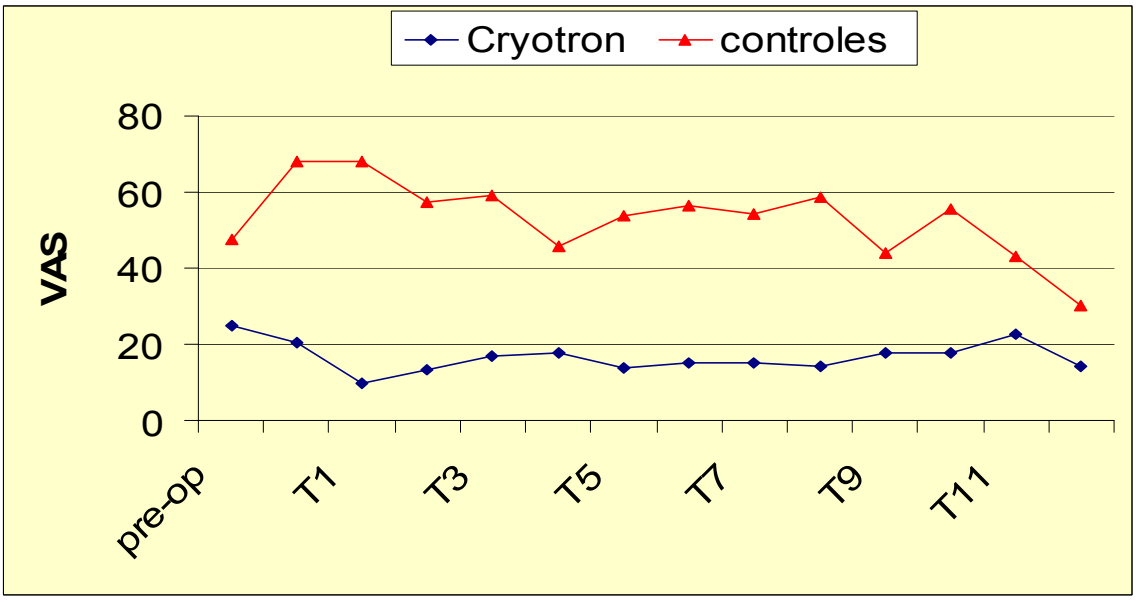


Fig. 4. Mean VAS values for the *Cryotron*® and control group

Figure 5 shows the results as monitored by the PCA-system. Patients in the *Cryotron*® group perceived the need to use analgetics less often than those in the control group. A lock-out interval of 10 minutes was imposed to avoid overdosis. Per dosis the patient received 2mg or 1ml Dipidolor®. The maximum amount in 4 hrs was 30mg. The total amount of dipidolor (mg), the number of PCA requests (= demand) and the number of successful administrations (= delivery) were stored by the PCA device.

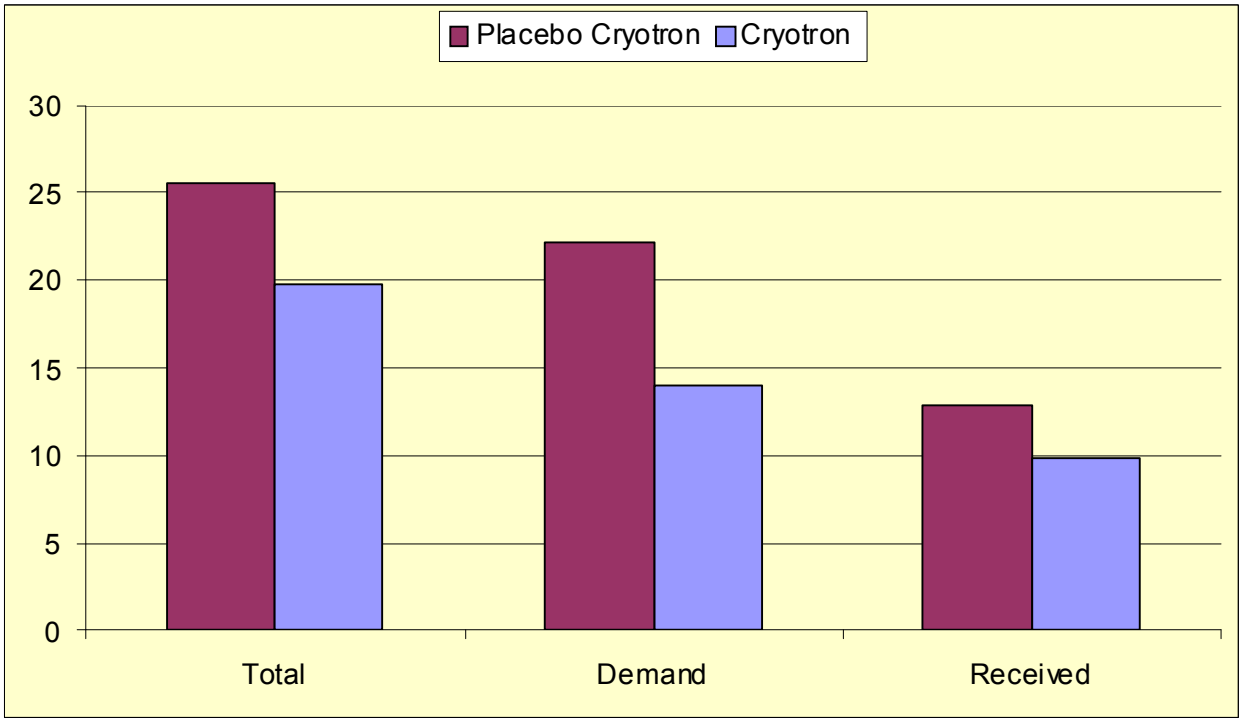


Figure 5. The total amount of analgetics (PCA pump), the number of demands, and the number of painkiller received was significantly lower for the *Cryotron*® group compared to the placebo group.

Inflammation

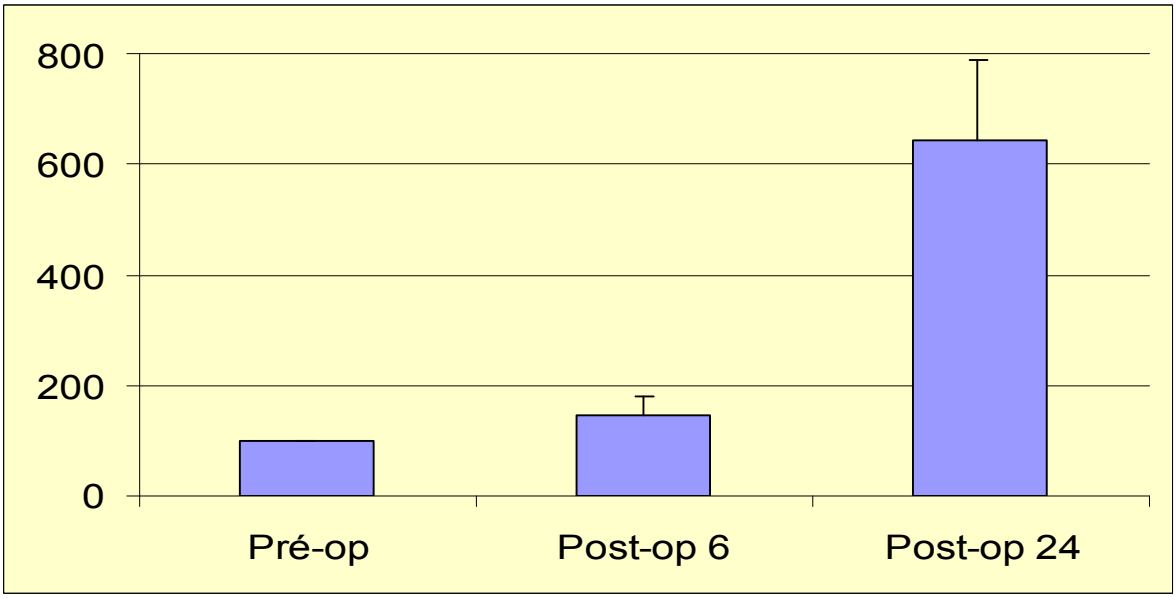


Figure 6. 'normal' increase in inflammation (CRP) due to artroscopy.

The "normal" reaction after arthroscopy is an increase in inflammatory parameters. This was also seen our study, however this increase was lower in the *Cryotron*® group compared to placebo *Cryotron*®, or no application at all. As shown in figure 7, this inflammatory reaction is lower in the *Cryotron*® group.

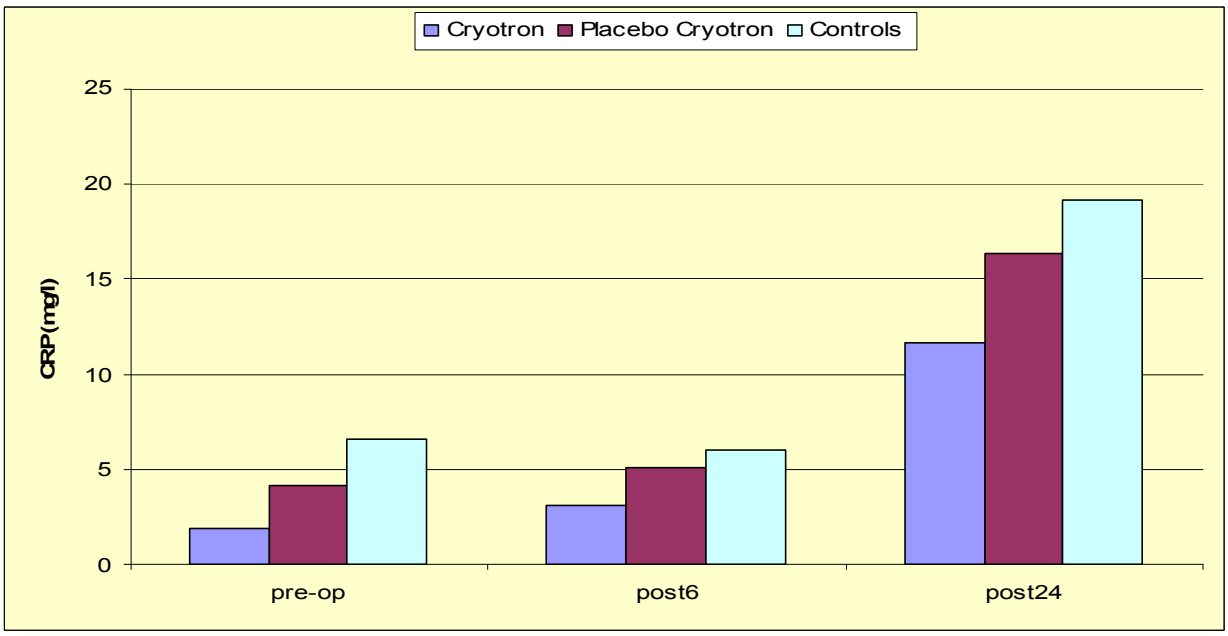


Figure 7. Comparison of the increase in inflammation between treatments. Note that the *Cryotron*® group has lower inflammatory reaction than the placebo or control group.

Surprising are the results of the effect of *Cryotron*® on an acute inflammatory reaction. One subject which was not included in the group results, but the data are shown as case presentation, developed an acute gout attack. This resulted in an extreme inflammatory reaction. Figure 8 shows the absolute values for the group and the individual with the gout attack. In figure 9 we see that *Cryotron*® created a suppression of the inflammatory reaction (% increase).

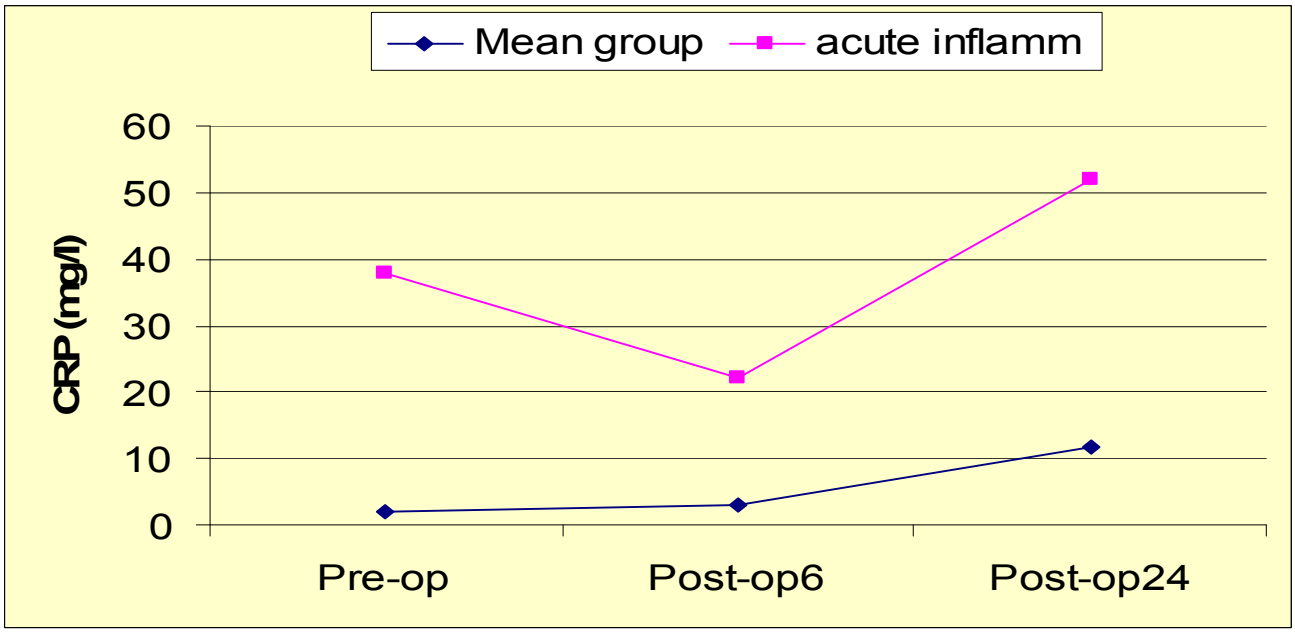


Figure 8. CRP measures between the group and the individual with an acute inflammatory crisis (gout).

The percent increase of CRP's due to inflammation (compared in time) is much suppressed by the application of *Cryotron*® on the individual with an acute inflammatory response. This means that once a large inflammatory reaction is established this is suppressed by *Cryotron*® as seen in figure 9.

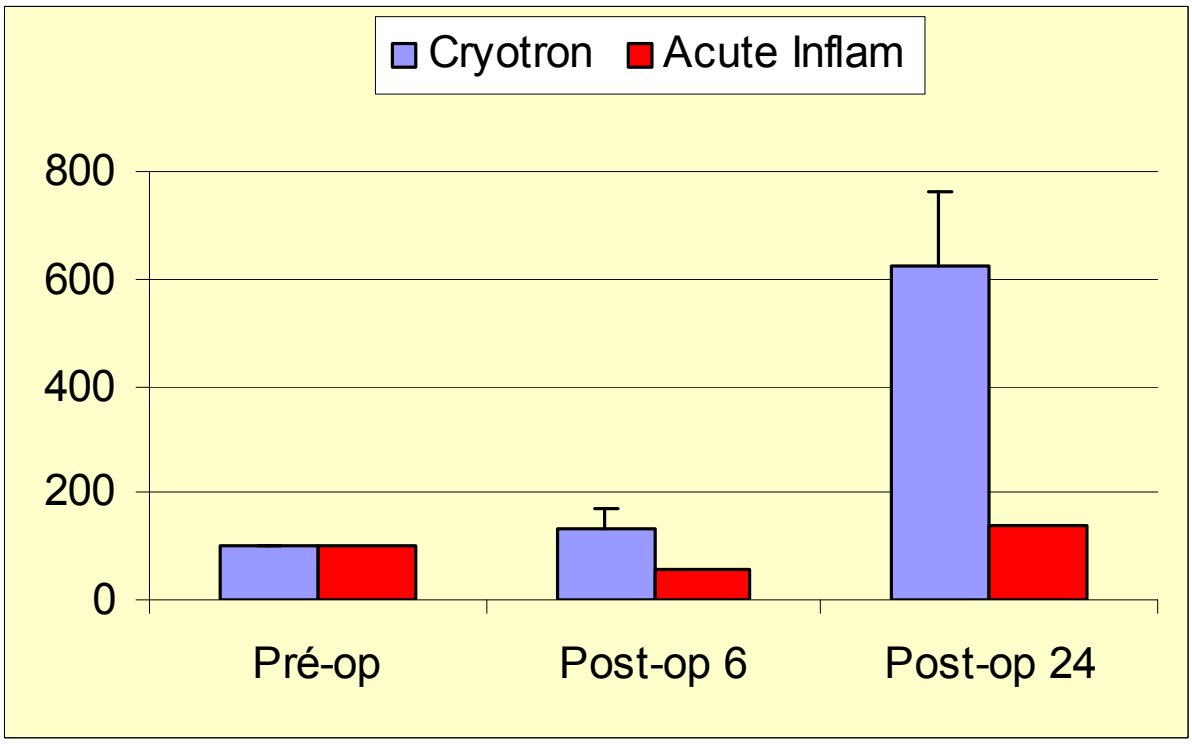


Figure 9. Percent increase comparison

Discussion

In the present study we measured the influence of cryotherapy on the postoperative skin temperature, subacromial temperature, pain and inflammation in the shoulder. We did use a placebo *Cryotron*®, in order to avoid the psychological effect of "treating" one group of patients and giving no attention to the controls.

As expected skin temperatures decreased following cryotherapy. At night when cold application is stopped, a gradual increase in temperature is seen until a plateau is formed. This confirms the observations of Meeusen and De Meirleir (1991) and Kowal (1983). When comparing the temperature measures from the night we saw that temperatures in the experimental group were significantly lower compared to control. Meaning that there has to be an "after effect" created by the brief cold application we used.

The response of deep tissues to cooling depends on the depth of the tissue and the temperature of the applied cold modality (Levy et al., 1997; Meeusen and De Meirleir, 1991). Most researchers also report a delayed drop (Meeusen and De Meirleir, 1991). According to Dahlstedt et al. (1996) skin temperature should be lower then 20°C to achieve a persistent intra-articular temperature drop. In the present study mean skin temperatures dropped very fast due to *Cryotron*®, but also increase quickly thereafter. There are several individual factors that could have influenced these results (large error bars). The interindividual factors that play a role are the thickness of the fatlayer and of the M. Deltoideus. We assume that differences in subacromial temperatures between different persons is caused by this factor.

To objective pain we used visual analog scales, which are considered to be the best method for measuring personal sensations (Speer et al., 1996). Speer et al. (1996) used VAS the first and the tenth day postoperative to evaluate pain, comfort, sleep, use of analgetics and overall satisfaction. After cryotherapy, severity as well as frequency of pain decreased.

Meeusen and Lievens (1986) indicated that pain relief occurs when target tissues are cooled to temperatures around 10°C to 15°C. We agree with Speer et al. (1996) by speculating that the effectiveness of cryotherapy was mainly due to cutaneous and subcutaneous analgesia. For both experimental groups VAS scores are lower than the values in the control group and diminish in the course of the study. One day

postoperative VAS values are still lower in both test groups. The large standard deviations point to the interindividual differences in pain sensation. The VAS curve for the control group has an irregular course. Two hours post operative pain reduces slightly, probably due to medication use. Post operative medication use is also lower in the *Cryotron*® group. Based on these results we state that cryotherapy has a positive effect on reducing post operative pain.

The severity of inflammation was evaluated by measuring the amount of C-reactive proteins in blood plasma. CRP levels 6h and 24h postoperative were lower in the experimental group. Post operative standard deviations in the control group were rather high.

Surprising are the results of the effect of *Cryotron*® on an acute inflammatory reaction. One subject which was not included in the group results, but the data are shown as case presentation, developed an acute gout attack. This resulted in an extreme inflammatory reaction. The percent increase of CRP's due to inflammation (compared in time) is much suppressed by the application of *Cryotron*® on the individual with an acute inflammatory response. This means that once a large inflammatory reaction is established this is suppressed by *Cryotron*®.

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