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ORIGINAL STUDY

Cryotherapy after Total Knee Arthroplasty provides faster recovery and better ranges of motion in short term follow up. Results of a prospective comparative study

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Cryotherapy is applied in Total Knee Arthroplasty (TKA) to improve functional outcome. The aim of this study is to investigate whether an advanced cryotherapy device does not increase the risk of complications and improves knee function or decreases swelling.

A prospective cohort of TKA patients was formed by a cryotherapy group and a control group. The primary outcome was complication ratio. Our secondary outcomes were functional results and swelling.

No significant differences were found in complication ratio between 31 patients in the cryotherapy group and 31 patients in the control group. The cryotherapy group showed a significant better knee flexion and less swelling in the early rehabilitation phase. No differences were found at the other follow-up moments or in the other outcomes.

This advanced cryotherapy device is safe in respect of postoperative complications, improves knee function and decreases swelling in the early rehabilitation phase. However, it is questionable if an advanced cryotherapy device with its additional costs is necessary to provide the desired effects of cryotherapy.

Keywords : cryotherapy ; total knee arthroplasty ; rehabilitation ; complications.

Cryotherapy is generally agreed to be an effective treatment in (sports) injuries and anterior cruciate ligament reconstruction *(6,15,18)*. The cold application enhances vasoconstriction and affects enzyme function by decreasing tissue metabolism. The reduction of blood flow contributes to a decreased inflammatory response and less edema formation *(14)*. By delaying or elimination of the pain signal transmission, the analgesic effect of local cooling is realized *(2)*.

Cryotherapy in Total Knee Arthroplasty (TKA) revealed different results but limited studies have been published *(8,10-13,16,19,24)*. Kullenberg et al. used cold compression for three days after TKA ;

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All cryotherapy pads were delivered by Biomet, Inc., Warsaw, Ind. No fee was charged for this service. The study was conducted independently.

the treatment group of 43 patients demonstrated a better range of motion at discharge and three weeks follow-up. Furthermore, the mean time of hospital stay was less in the treatment group than in the control group *(12)*. Other studies have shown less pain *(16,24)*, improved range of motion *(13,16)* or less blood loss after cryotherapy *(8,24)*. On the other hand, other researchers found no significant difference between cold compression and normal compression *(10,11,19)*. The authors of the most recent Cochrane review, published in 2012, concluded that cryotherapy is generally safe. It may improve the knee range of motion in the first weeks after surgery and it could slightly reduce the amount of blood loss. They discussed that the aim of any cryotherapy device is to reduce intra-articular and deep tissue temperature. Therefore, possible new cryotherapy devices could be adopted to provide an optimum cooling dose *(3)*.

In previous studies, the Cryocuff device (Aircast, Summit, New Jersey) was the most common used device to apply cold compression *(8,10,12,13,24)*. In a postal survey among inpatient orthopedic physiotherapists, the Cryocuff device was the main method of cryotherapeutic application as well (59%), followed by crushed ice (30%) *(5)*. The Cryocuff device covers the entire knee but leaves the popliteal space and patella free of pressure. The cuff is connected to a cooling container and provides 30 mm Hg cold compression *(12)*. Other reported devices are a cooling flow device (wrapped with a final layer of compressive crepe bandage, also called "continuous-flow cold therapy") *(16)* and normal cold packs anterior and posterior to the knee *(11)*.Another relatively new device is the GameReady device (Coolsystems, Inc.), a "cryopneumatic" device which combines compression and cryotherapy. In a randomized controlled trial, it showed a significant decrease in opioid consumption till two weeks after TKA *(21)*.

Recently, a relatively new device has been developed : the Cryoceutical Treatment Server 100 (Waegener Research & Development, Beerse, Belgium). This advanced device consists of a "cTreatment Server" (CTS) and a "cTreatment Pad" (CTP). The CTS is a system that exchanges thermo energy with the human body by circulation of a specially developed fluid through the CTP. The CTS runs software which controls the amount of energy to be exchanged and it can execute several protocols for different treatment applications (e.g. TKA, arthroscopy and anterior cruciate ligament reconstruction) *(1)*. The benefits of the system could be a reduction of postoperative swelling, postoperative pain, and perioperative blood loss, a lower risk of postoperative complications and an improved mobility and shorter hospitalization. The possible benefits of Cryoceutical Treatment (CT) has only been investigated in one study as far as we know. Thienpont performed an RCT in which CT was compared with regular cold packs *(22)*. He found no advantages of CT over regular cold packs. However, no comparison was made with a control group without the use of cryotherapy.

The aim of this study is to investigate whether CT is a safe device regarding postoperative complications and if CT is an effective treatment after TKA regarding knee function, swelling and patients outcomes in the early rehabilitation phase.

PATIENTS AND METHODS

All patients diagnosed with osteoarthritis or rheumatoid arthritis of the knee requiring primary TKA were included in a prospective cohort. The intervention group (the cryotherapy group) was included in a period of four months. The control group was included prior and after inclusion of the intervention group. These patients did not receive any cryotherapy. Patients in the cryotherapy group had to sign informed consent. Patients with cold allergy, intolerance or urticarial signs or requiring revision arthroplasty were excluded. No patients were included in the control group during the intervention period to prevent performance bias.

The pre-treatment evaluation was performed according to our institute's protocol in both groups and consisted of clinical assessment, clinical scores and radiographic evaluation. The surgical procedure was identical. TKA was performed using the Vanguard Complete Knee System (Biomet, Inc, Warsaw, Ind). The tibial component was cemented and the femoral component either cemented or uncemented. Postoperative treatment was conducted

using a standard "rapid recovery" protocol with early mobilization from the first postoperative day till readiness for discharge on the fourth postoperative day. Follow-up was planned postoperatively within one week, at two and six weeks and three months.

Our primary outcome was the number of post-operative complications consisting of superficial surgical site infections, local hematoma, allergic reactions or blisters of the CT, wound leakage more than 4 days, wound dehiscence and bleeding and deep venous thrombosis. Our secondary outcomes were functional results (knee flexion and extension), postoperative swelling, clinical scores and blood loss (difference in hemoglobin levels) and patient satisfaction. Swelling was measured by the circumference of the knee using a tapeline at the middle part of the patella ; the postoperative difference in circumference was calculated for analyses. We used the Knee injury and Osteoarthritis Outcome Score (KOOS) and Oxford Knee Score (OKS) as clinical scores. KOOS is a patient-reported subjective outcome scale, with different subscales : pain, symptoms, function in daily living (ADL), function in sport and recreation (Sport\Rec) and knee-related quality of life (QOL) *(7)*. For this study, we excluded Sport/Rec, because we did not expect any sports activity by TKA patients during study follow up. The OKS is a validated knee-specific outcome measure designed to minimize the influence of comorbidities *(9)*. Hemoglobin levels were measured preoperative and on the first and third postoperative days.

Patients in the cryotherapy group were asked if they would like to use the system again if they could choose again, on a scale of 0-10 (0 certainly not, 10 certainly), presented as "cryotherapy satisfaction". Body temperature was measured 1, 2 and 3 hours after surgery (during cryotherapy in the intervention group) and 2 times/day at the postoperative days. All outcomes were recorded on an assessment form.

CT was available for 32 patients. This number of patients was based on previous research *(8,10,17)*. The treatment server consisted of a standard cryotherapy protocol. The protocol of the CTS included pre- and postoperative periods of cryotherapy with a CTP (size S, M or L) (figures 1 and 2). The center of the cuff was positioned on the postoperative Robert-Jones bandage of the knee without covering the patella. Two days after surgery, the bandage was removed and cryotherapy was continued directly on the knee. The cryotherapy protocol consisted of a preoperative period of 1 hour at 8-10 °C, at least 1 hour before surgery ; a postoperative period of 3 hours at 8-10 °C, immediately after surgery ; 2 times of 2 hours at 13-15 °C on day 1 and 3 times of 1

Figure 1. — Cryoceutical Treatment Server 100 consists of a "cTreatment Server" and a "cTreatment Pad".

Figure 2. — The "cTreatment Pad" of the knee.

hour at 13-15°C on the following days till discharge. The treatment was finished after discharge. For the whole CT treatment, 350 euro is charged per patient in daily practice.

Cryotherapy was discontinued if patients had an allergic reaction or blisters at the knee, if they experienced chills, or if informed consent was withdrawn.

After the study period, patients from the intervention group were matched to the control group. Matching of the groups was performed by an independent researcher. The matching was based on sex, age (in groups of 5 years difference, e.g. 60-65 years old) and Body Mass Index (BMI, in groups of 5 kg/m^2 difference, e.g. 20-25 kg/m^2) and was performed randomly ; the researcher who analyzed the data was blinded for the results. Data were analyzed according to the intention-to-treat principle. The data of the patients in the intervention group were analyzed in this group, regardless of a possible discontinuation of cryotherapy. We expected that all outcomes were normally distributed. Therefore, repeated measures ANOVA and independent t-tests were used for statistical evaluation. Statistic difference was defined by a p-value of <0.05. We used IBM-SPSS 21.0 for statistical testing.

RESULTS

In our prospective cohort of 70 TKA patients, 32 patients received cryotherapy. The matching strategy resulted in 31 matched couples : 31 patients in the intervention group and 31 patients in the control group. One cryotherapy patient could not be matched as no appropriate match was available. Demographic data are shown in table I. No significant differences were found in these preoperative data.

In the intervention group, 29 patients finished the entire standard cryotherapy protocol. One patient received only preoperative cryotherapy because the orthopedic surgeon excluded her from postoperative cryotherapy. She was known with multiple comorbidities (diabetes, COPD, obesity). One other patient received only two times 1 hour of cryotherapy at the second and third postoperative day, because she felt uncomfortable and experienced chills. Complications are shown in table II. There were 5 hematomas (16.1%) in the cryotherapy group and 3 hematomas (9.7%) in the control group. This difference was not significant. The patient with a superficial infection in the intervention group recovered completely after rest and antibiotics. One allergic reaction was noted, but most likely due to NSAID's, because it did not worsen during cryotherapy and recovered after discontinuation

Table I. — Comparison of preoperative demographic data, presented as mean ± Standard Deviation

	Cryotherapy group, N=31	Control group, N=31	p-value
Sex: M/V	11/20	11/20	-
Age in years	64.3 ±8.2	64.3 ±7.5	n.s.*[2]
BMI in kg/m^2	30.1 ±5.5	30.0 ±5.8	n.s.
Knee flexion in degrees	113 ±10.5	112 ±14.7	n.s.
Hemoglobin level in mmol/l	8.6 ±0.86	8.4 ±0.94	n.s.
Knee circumference in cm at midpatella	42.1 ±3.5	41.4 ±3.7	n.s.
Oxford Knee Score (12-60)*	43.5± 7.3	39.4± 9.4	n.s.
KOOS (0-100) *[1] :			
– Pain	29.7 ±18.1	36.1 ±20.3	n.s.
– Symptoms	41.3 ±17.5	42.1 ±18.8	n.s.
– ADL	33.2 ±20.0	39.5 ±22.3	n.s.
– QOL	13.6 ±11.4	20.5 ±18.7	n.s.

*12 represents the best score and 60 the worst. *[1] Knee injury and Osteoarthritis Outcome Score : 100 represents the best score and 0 the worst. *[2] n.s. : not significant (p>0.05).

Table II. — Comparison of postoperative complications

	Cryotherapy group, N=31	Control group, N=31
Superficial Infection	1	0
Hematoma	5	3
Allergic reaction	1	0
Wound leakage >4 days	0	1
Wound dehiscence/bleeding	0	1
Deep Venous Thrombosis	0	1

Table III. — Comparison of postoperative results after the fourth day (/discharge) and 2 weeks, presented as mean ± Standard Deviation

	4th day, group 1*	4th day, group 2*	p-value	2 weeks, group 1	2 weeks, group 2	p-value
Knee flexion in degrees	86.1 ± 12.2	77.1 ±14.3	0.01	98.6±11.5	87.1±17.5	0.04
Extension deficit in degrees	2.90 ±4.04	2.93 ±4.54	>0.05	2.42 ±4.45	3.10 ±3.64	n.s. *2
Swelling in cm*1	3.55 ±1.38	4.52 ±2.06	0.04	2.76 ±1.29	3.61 ±1.80	0.04

* Group 1= intervention (cryotherapy) group, group 2 = control group. *1 Swelling was measured using a tapeline at the middle part of the patella ; the postoperative difference in circumference was calculated for analyses. *2 n.s. : not significant (p>0.05).

Table IV. — Comparison of postoperative results after 6 weeks and 3 months, presented as mean ± Standard Deviation

	6 weeks, group 1*	6 weeks, group 2*	p-value	3 months, group 1	3 months, group 2	p-value
Knee flexion in degrees	112.6 ±10.2	106.9 ±11.7	0.047	118.2 ±9.4	114.5 ±11.0	n.s.*2
Extension deficit in degrees	2.74 ±4.25	2.68 ±3.59	>0.05	1.61 ±3.26	2.58 ±3.62	n.s.
Swelling in cm*1	1.79 ±1.50	2.58 ±2.00	>0.05	1.63 ± 1.50	2.07 ±1.70	n.s.
Oxford Knee Score (12-60)	29.0 ±8.4	27.7 ±10.9	>0.05	24.7 ±8.5	24.1 ±9.9	n.s.
KOOS (0-100) :						
– Pain	68.8± 21.4	66.6 ±23.9	>0.05	76.0 ±20.6	73.2 ±26.2	n.s.
– Symptoms	63.8±13.2	64.2 ±16.2	>0.05	71.4 ±14.7	66.0 ±18.6	n.s.
– ADL	71.2±18.2	70.7 ±21.3	>0.05	75.4 ±18.5	76.4 ±22.1	n.s.
– QOL	42.5±17.3	50.4 ±23.5	>0.05	53.6 ±21.1	58.1 ±25.9	n.s.

* Group 1= intervention (cryotherapy) group, group 2 = control group. *1 Swelling was measured using a tapeline at the middle part of the patella ; the postoperative difference in circumference was calculated for analyses. *2 n.s.: not significant (p>0.05).

of NSAID's. No re-interventions were needed in the intervention group. In the control group, one patient had bloody wound leakage from the second till fourteenth postoperative day ; a re-intervention was needed to evacuate the hematoma and to stop the bleeding. This patient developed a wound dehiscence after the re-intervention, six weeks after the primary operation. Seven patients had a complication in the cryotherapy group, six patients in the control group. No patients in both groups needed a manipulation under anesthetics.

Postoperative results are shown in table III and IV. The cryotherapy group showed a significant better knee flexion at the fourth postoperative day and after two and six weeks. After three months, knee flexion was comparable in both groups. The cryotherapy group had significant less swelling at the fourth postoperative day and after two weeks. After six weeks and three months the difference was no longer present. No differences were found at the other follow-up moments or in the other outcomes.

Hemoglobin levels were 7.2 and 6.7 mmol/l at the first and third postoperative day in the cryotherapy group, compared to 6.7 and 6.5 mmol/l in the control group (p>0.05). Of 30 cryotherapy patients,

"cryotherapy satisfaction" was asked. Median score was 7.5, with a range of 0-10. Comparison of body temperature didn't show any statistical differences at either follow up moment.

DISCUSSION

Our study was designed to investigate if this relatively new cryotherapy device is a safe device. Based on the complications, we can conclude that CT is safe to provide cryotherapy after TKA. One superficial infection was found in the intervention group, which is acceptable in comparison with the normal TKA population. These results are in accordance with the Cochrane review, in which 707 TKA patients were included for occurrence of adverse events *(3)*.

The pooled data in the same review regarding knee range of motion showed the same difference as in our study : a significant better flexion in the cryotherapy group at discharge (4th day) and after two weeks. These results are also in accordance with the other study in which CT was used *(22)*. Furthermore, our study showed a better flexion at six weeks after surgery and no difference after three months. This indicates that cryotherapy is only favorable in the early rehabilitation phase and could be part of a standard rapid recovery protocol after TKA. On the other hand, in the study of Thienpont a lower active flexion at 6 weeks was noticed in the CT group, indicating that a longer time of immobilizing could also worsen the range of movement *(22)*. Few studies measured knee swelling after cryotherapy, but no significant differences were found in these studies. Furthermore, swelling was only measured in the first week after surgery *(10,13,20,24)*. In our study, significant less swelling was measured at discharge and after two weeks, another indication that cryotherapy would be favorable in the early phase. After six weeks and three months, no differences in knee circumference was found, nor in the clinical scores (KOOS and Oxford knee score).

Preceding work showed significant better pain scores in cryotherapy groups, especially on the second day after TKA *(4,8,12,13,16,17,20)*. Less analgesics were consumed by cryotherapy patients in the first two weeks in one study *(21)*. It is however not clear in some of these studies, if a standard pain management protocol was used for both study groups. For example, in the randomized trial by Su et al, no standard pain protocol is described. It is known that different pain management protocols can influence the postoperative pain scores *(25)*. We did not include VAS pain scores and analgesic consumption for analyses, because the methods of anesthesia differed too much in our cohort. In future studies, a standard pain management protocol should be used to compare pain scores in the most reliable way.

In previous studies, hospitalization time (or length of stay) could be an important outcome. Five studies measured the length of stay *(8,12,19,20,23)*, but no significant differences were found. In our hospital, we already perform a "rapid recovery" protocol in TKA patients. Most patients are admitted to our hospital for four days. Because of this protocol, we did not expect any differences in hospitalization time and therefore didn't use this outcome in our study. Future studies could use discharge criteria (e.g. VAS pain score <4, 90 degrees knee flexion) as an outcome if a standard rehabilitation protocol exist.

In addition to the complication rate, few negative effects were noted in the cryotherapy group. One patient felt uncomfortable during a few hours of cryotherapy. Patient satisfactory score was high. However, the costs of the treatment are relatively high compared the described effects.

A limitation of this study is that we did not compare this score with satisfaction in the control group. Another negative effect could be a lower body temperature in the cryotherapy group, but we did not found any difference in core temperature.

Our study has several other limitations. First of all, the number of patients (62) is low, but as mentioned, our goal was to investigate if this device does not increase the risk of postoperative complications. We based our number of patients on previous research. Secondly, we did not perform a randomized trial, which would require a larger population. As this cryotherapy system was relatively new, a pilot study was performed initially for safety reasons ; we expanded the pilot numbers to create a prospective cohort study, with a matched control

group. Furthermore, we couldn't use any blinding strategy ; in an ideal situation, the researcher is blinded if patients received cryotherapy or not.

We conclude that CT does not increase the risk of postoperative complications after TKA whereas it induces improved flexion and less swelling in the early rehabilitation phase. However, it is questionable if an advanced cryotherapy device with its additional costs is necessary to provide the desired effects of cryotherapy.

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