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ORIGINAL STUDY

A prospective comparative study between a cooling device and manual cooling after total knee arthroplasty

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Studies have shown that the use of cryotherapy after a total knee arthroplasty can have beneficial effect on blood loss, pain and medication usage. In this study, the effect of the applied cryotherapy procedure is investigated.

52 patients underwent a total knee arthroplasty. The test group received continuous cooling, whereas the control group received manual conventional cooling with ice dressing. The knee circumference and range of motion, medication use, satisfaction and pain were investigated.

There is no statistical significant difference in pain and medication usage. A significant difference is observed in the swelling of the knee on the first postoperative day, the range of motion on the 7th, 10th, 11th and 12th postoperative day, and the satisfaction rate.

This study shows that continuous cooling has a positive effect on the swelling and range of motion of the knee, and on the satisfaction of the treatment.

Clinical trial registration number : Clinical trial number : EudraCT2015-000259-26.

Keywords : total knee arthroplasty ; cryotherapy ; Vascutherm ; cold pack ; continuous cooling.

INTRODUCTION

The effect of applying cold after trauma or surgery has been extensively studied over the past decades. The scientific basis of the beneficial effect of cooling on the posttraumatic or postsurgical inflammatory response has been well established. Cold induces vasoconstriction decreasing interstitial oedema formation *(4)*. Low temperatures lead to a decrease in the synthesis of pro-inflammatory cytokines *(8)*. Pain sensation is diminished due to slowing of nerve conduction velocity *(1)*.

Postoperative swelling of the knee after total knee arthroplasty due to hemartrosis and interstitial oedema of the surrounding tissues may hamper the recovery and early rehabilitation in patients undergoing total knee arthroplasty (TKA). Especially pain and swelling of the knee can delay or inhibit range of motion exercises. This can affect the final result, a stable yet mobile and pain-free joint.

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Studies comparing cooling versus no cooling have shown a reduction in blood loss, less postoperative pain and an improved range of motion *(3,6,10)*.

A literature search concerning the best or most efficient method of cooling shows either conflicting evidence or no significant difference *(2,7,9)*.

Given the fact that cooling has a beneficial effect, we hypothesized that more continuous cooling is better and hasten early rehabilitation and improve patient satisfaction. Therefore we compared two cooling methods: standard static compressive ice dressing (coldpack) versus a continuous cooling device (VascuTherm 4, ThermoTek Inc. USA). Different manufacturers have developed continuous cooling devices, with optional static or cyclic compression. We chose not to use a cryopneumatic cuff, giving additional cyclic compression, to minimize bias and focus specifically on the continuous cooling effect.

We hypothesized that using a continuous cooling device in comparison to static ice dressings would;

1. reduce postoperative pain,
2. lead to less analgesics consumption,
3. reduce knee girth (less swelling),
4. improve range of motion,
5. improve patient satisfaction due to ease of use.

Figure 1. – VascuTherm 4 (ThermoTek Inc. USA) continuous cooling device.

MATERIALS AND METHODS

All patients in this study needed to undergo a total knee replacement caused by primary osteoarthritis. The patients were randomly divided in two separate groups: the experimental group received continuous cooling using a device (Vascutherm 4, ThermoTek inc. USA) shown in Figure 1, whereas the control group received the standard procedure that involves the use of ice dressing that is applied to the patients manually.

The patients that underwent the surgery alternately received a different postoperative cooling. One week, all patients received continuous cooling, and the other week the next group of patients received the ice dressing therapy. This way, there was no interference between the two different patient groups.

In total, 26 patients were included in the test group (continuous cooling), and 26 patients were included in the control group (manual cooling). The control group included 9 male and 17 female patients, with an age of 69.15 ± 9.71 years. The test group included 7 male and 19 female patients with an age of 69.12 ± 9.00 years.

The ASA-scores of the patients varied between 1 (healthy patient) and 4 (severe systemic disease that is a constant threat to life). More than 90% of the patients were assigned with a score of 2 or 3 (1: 1.92%; 2: 63.46%; 3: 28.85%; 4: 3.85%; unknown: 1.92%). The ASA-scores of both groups are not significantly different (with $\alpha = 0.05$).

This study is a single center, single surgeon study. The subvastus approach was applied to both groups of patients. The experimental procedures involving human subjects described in this paper were approved by the medical ethical committee of the AZ Turnhout Hospital. All subjects provided written informed consent.

The cooling starts when the patient is discharged from the recovery room. A nurse applies the selected cooling method.

The test group received continuous cooling using the Vascutherm 4 (ThermoTek Inc.). The

temperature is set to 10 degrees Celsius. The patient always wears the cooling sleeve, except when standing up or walking. A maximum of 6 cooling cycles is applied per day.

The control group received manual conventional cooling with ice dressing (cold pack), with a size of 30 cm by 30 cm. Each patient gets 2 cold packs and a sleeve to prevent frost injury. One cold pack is applied on 4 fixed moments during the day, during 20 to 30 minutes.

The patients were monitored during 16 days: the day of the operation and 15 postoperative days. The first 4 days, the patients stayed in the hospital, and afterwards they were monitored at home by filling out a diary, assisted by a physiotherapist.

For all consecutive days, the questionnaire inquired on the number and times of cooling, the pain in rest (Numeric Rating Scale (NRS), 0 to 10), the administration of medication, rate of satisfaction (6 points scale with verbal description), mobility of the knee (range of motion: flexion / extension) and the circumference of the knee (midpatellary).

Furthermore, the preoperative pain, mobility and knee circumference were inquired, as well as the timing, complications, cooling, pain, medication and mobility at the day of the operation itself. Afterwards, possible side effects of cooling, postoperative complications and general patient information were acquired.

Not all patients filled in the questionnaire at home all days. Therefore, there is a decrease in available information towards the last days of the monitoring.

Mann-Whitney U-tests were applied to the pain scale data (ordinal data), to investigate if there is a statistical significant difference in both groups (test group versus control group). The medication data, the knee circumference and knee range of motion (ROM) data were tested for normality using the Kolmogorov-Smirnov test. As the medication data seemed not to be normally distributed, the Mann-Whitney U-tests were also applied to this data *(5)*. To the knee circumference and ROM data, independent samples t-tests were applied. In all tests, a significance level of $\alpha = 0.05$ was used.

Where appropriate, bar plots of the data are shown, to give an indication of the distribution of the data. Other data is given in an overview table (Table 1).

RESULTS

The circumference of the knee was measured to have an indication of the swelling over time. In Figure 2 and the third section of Table I, we compare the circumference of the knee with the preoperative circumference. The values express the percentual increases in circumference. A value of zero indicates an equal value, and a positive and negative value indicate a larger and smaller circumference, respectively. Furthermore, Table I shows an indication of the p-values of the independent samples t-test, and the number of patients that filled in the knee circumference in the questionnaire on a certain day. If we only take into account the values that were filled in by at least 50% of the patients, we can see there are significant differences between both groups.

The first four postoperative days the relative knee circumference seems smaller in the test group compared to the control group. However, only the difference at the first postoperative day is statistically significant ($p = 0.03$).

After 5 days and beyond, the evolution of the knee circumference stays the same for both groups. The last 3 days, less than 50% of the patients filled in the questionnaire, so these values are more prone to differences of individual patients.

Figure 2 and the fourth section of Table I gives an indication of the median ROMs per day. In both groups, we can observe an increase in ROM the first 5 days after operation, after which the values stay more or less stable.

The general trend indicates a higher ROM when using continuous cooling, with a significant difference on days 7, 10, 11 and 12. It has to be said that the number of registrations at home (after day 4) is low. Therefore the results might be more prone to the variation of some individuals.

To compare the medication use, first we investigate the total dosages given during the 16 days of monitoring of the three types of medication that were included in the therapy : Paracetamol

Table 1. – Evolution of monitored parameters. This table gives an overview of the different parameters that were monitored during the study, for each day starting at the operation day until 15 days after operation. For each patient, the median and maximum pain value per day was calculated, together with the knee circumference and knee range of motion. For each patient group (continuous cooling and manual cooling) the median value was taken over all patients in the group for each day. These values are shown in 4 sections. Also the p-values are given when applying the Mann-Whitney U-tests (median and maximum pain), and the independent samples t-tests (knee circumference and ROM). In the last rows of each section, the number of registrations in each group of the specific parameter is given.

Day	Oper.	Post-operative														
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Pain values																
Median pain per day per subject																
median vascutherm	3,00	2,50	2,00	1,00	2,00	2,25	2,00	2,50	2,00	3,00	2,50	3,00	2,50	2,50	3,25	3,00
median manual	5,00	4,00	3,00	2,00	2,75	2,00	3,00	2,75	2,50	2,50	2,00	2,50	1,50	2,50	2,50	3,00
p-value	0,29	0,15	0,26	0,15	0,83	0,93	0,61	0,92	0,53	0,79	0,59	0,93	0,33	0,90	0,97	0,99
# Vascutherm	7	19	21	19	20	18	19	18	17	17	17	17	16	17	4	4
# manual	5	20	21	22	22	22	21	20	19	18	18	20	18	14	8	9
Maximum pain per day per subject																
median vascutherm	6,00	5,00	3,00	3,00	4,00	3,00	3,00	3,00	3,00	3,00	4,00	3,00	3,00	3,00	3,50	3,50
median manual	6,00	5,00	4,00	3,00	4,00	4,00	3,00	4,00	4,00	3,00	3,50	3,00	3,00	3,00	3,50	3,00
p-value	1,00	0,65	0,10	0,30	0,42	0,62	0,90	0,78	0,89	0,79	0,74	0,77	0,71	0,95	0,82	1,00
# Vascutherm	7	19	21	19	20	18	19	18	17	17	17	17	16	17	4	4
# manual	5	20	21	22	22	22	21	20	19	18	18	20	18	14	8	9
Knee circumference (%)																
median norm. vascu	0,00	6,12	5,41	5,93	5,00	6,37	6,33	6,29	4,88	6,25	6,25	5,00	6,30	3,80	5,00	5,00
median norm. manu.	0,00	10,00	9,10	8,54	9,30	8,33	7,69	6,98	7,80	6,25	7,39	4,05	6,25	2,50	1,22	1,89
p-value ttest	0,15	0,03	0,08	0,15	0,06	0,49	0,43	0,73	0,40	0,71	0,94	0,67	0,25	0,96	0,56	0,61
# Vascutherm	6	15	21	24	23	20	19	16	15	15	17	17	18	13	3	3
# manual	10	24	24	23	21	19	19	19	17	15	20	18	17	12	9	8
ROM knee (°)																
median vacutherm		63,00	75,00	85,00	90,00	92,00	98,00	98,00	105,00	100,00	100,00	102,50	105,00	102,50	92,00	/
median manual		50,00	75,00	82,50	87,50	88,50	90,00	90,00	86,50	83,00	85,00	90,00	91,50	92,50	95,00	99,00
p-value ttest		0,24	0,65	0,71	0,06	0,24	0,08	0,02	0,10	0,27	0,01	0,01	0,01	0,16	0,80	/
# Vascutherm		19	23	24	12	10	9	9	3	2	9	8	8	8	1	0
# manual		21	25	20	10	10	9	9	4	3	9	9	8	4	3	2

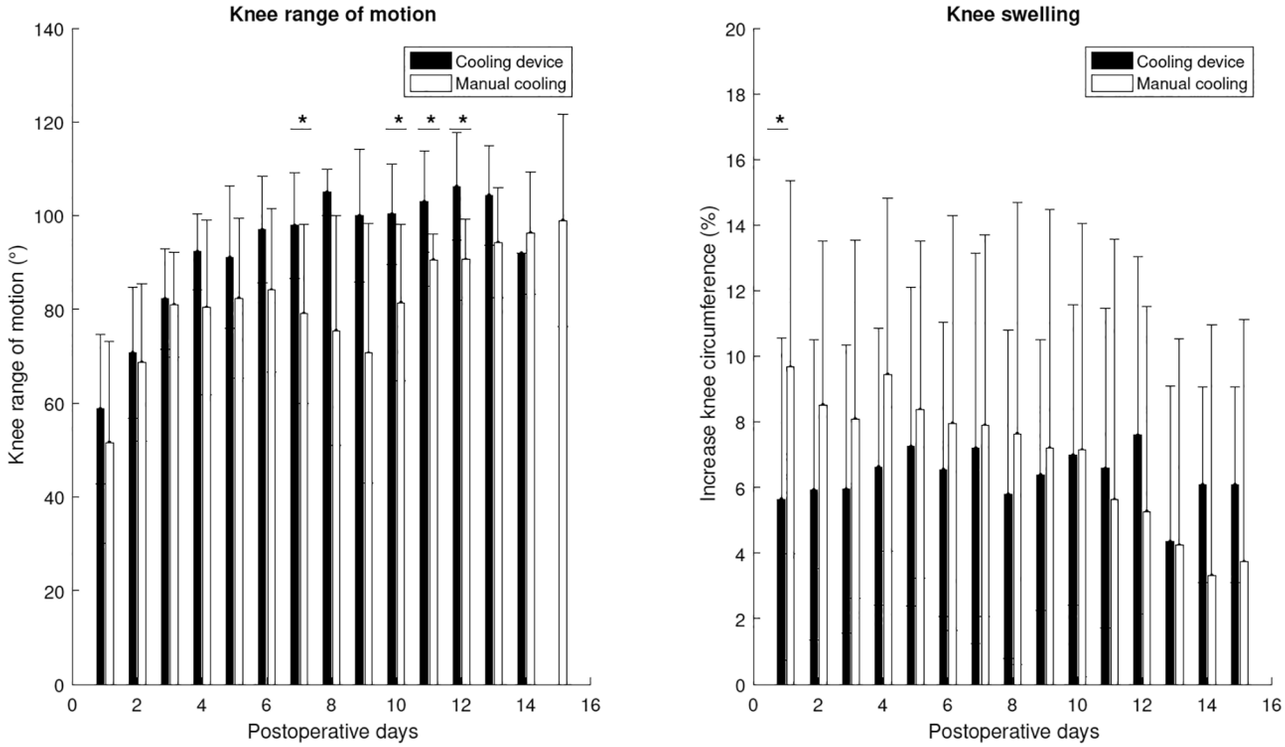

Figure 2. – Knee range of motion and swelling. This figure shows the postoperative evolution of the knee range of motion of the test and control group on the left, and the knee circumference on the right. The circumference is expressed as the percentual increase on the current day compared to the preoperative situation. A value of zero means that the circumference is exactly the same as before the operation, a positive value means a larger circumference. The asterisks shown above the bar plot indicate a significant difference on a certain day between the test and control group.

1g, Diclofenac 75 mg and Tramadol 50 mg. These results are shown in Figure 3.

Inspecting this figure, there seems to be a lower usage of medication when applying continuous cooling. However, these differences are not statistically significant as the p-values of the Mann-Whitney U-test are $p = 0.21$, $p = 0.90$ and $p = 0.36$ for Paracetamol, Diclofenac and Tramadol, respectively.

The patients could fill in a satisfaction score every day, on a 6 point verbal scale. In general we can observe that the satisfaction of both groups is good, with only few dissatisfied patients during few days. The indication normal occurs more in the manual cooling group compared to the continuous cooling group. In the latter group the percentage of very good ratings is higher. More than 95% of the ratings in both groups has an indication of normal or higher.

Comparing both groups with the Mann-Whitney U-test, there is a significant difference in satisfaction between both groups, with a p-value of 0.01, with a higher satisfaction for the continuous cooling group.

Figure 4 gives the percentual occurrence of each pain level in both groups. There seems to be a tendency towards higher pain levels using the manual cooling compared to continuous cooling, although they are not significantly different.

Table I shows the evolution of the pain in the test group and control group, starting on the day of the operation, and ending 15 days after the operation. The first section in this table shows the median values over all patients in one group of the median

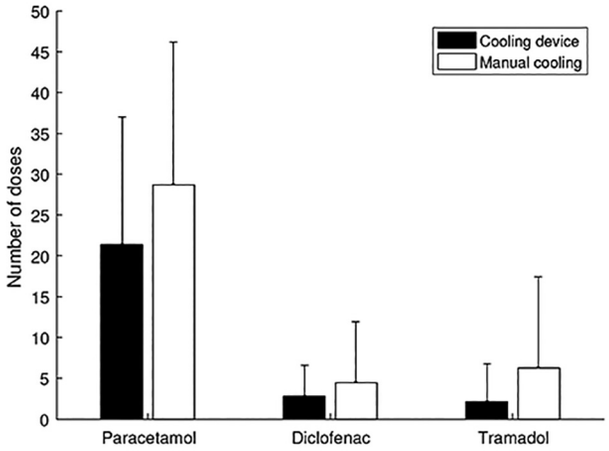

Figure 3. – Medication usage per group. The plot shows the mean and standard deviation of the total medication usage per patient during the 16 days of monitoring. The total number of doses is given for the test and control group. No difference was statistically significant with $\alpha = 0.05$.

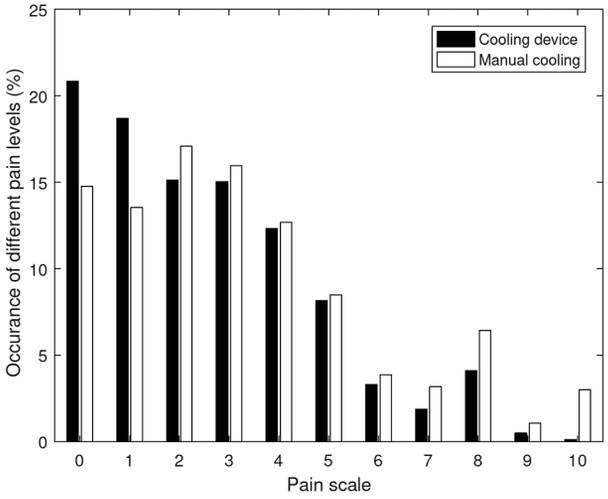

Figure 4. – Pain level per group. The percentage of occurrence of each pain level for the whole monitoring period is given for test and control group. Before calculating the percentages, the weight of the scores of each patient was normalized to give every patient the same influence. The difference in both ratings was not statistically significant with $\alpha = 0.05$.

pain value per patient per day (hence one pain score for the patients per day). Below, the number of registered patient pain values for each group is given, together with the p-value resulting from the Mann-Whitney U-test. Not all patients had filled in a pain score every day, therefore, the number of registered pain values per group per day can differ. Especially for day 0 (operation day) and day 14 and 15 the number of scores is low.

The next section of Table I shows the median values over all patients in one group of the maximum pain value per patient per day. As with the previous section, the p-values from the Mann-Whitney U-test and the number of registered scores per patient group are given per day.

The differences we observe in the pain levels, a lower value during the first four days after operation in the test group, are not statistically significant with an α of 0.05.

DISCUSSION

It has to be noted that the usage of medication in general is low, both in the continuous cooling and in the manual cooling. This might be due to the fact that all patients received cryotherapy, in whatever form, which reduces the pain *(9)*.

When we do a first inspection of the differences between the monitored parameters of both groups, the patients seem to benefit from the automated continuous cooling. The knee circumference is lower during the first four days, the ROM of the knee is larger when the patients are at home (at day 7, 10, 11 and 12), the average usage of Paracetamol and Tramadol is lower, in general the patients are more satisfied and the median of the median and maximum pain is lower during the first four days after operation. However, only some of these visual trends can be confirmed when applying the test statistics.

The differences that are statistically significant with a significance level of 0.05 are:

- a lower knee circumference for the test group the first postoperative day;
- a higher satisfaction rate for the test group at the 7th; 10th; 11th and 12th postoperative day.

The vast majority of both groups are satisfied with their treatment, regardless of the applied therapy. More than 95% of the ratings in both groups has an indication of normal, good, very

good or perfect. More than 80% of the ratings in the manual cooling group and more than 90% of the ratings in the cryotherapy group were good or better. But next to these good ratings, a few patients complained about the sound of Vascutherm and quit the study early. Also, some patients that recovered in the same room as the patients in this study, without using the device, complained about the sound of the system. In total, 5 patients using the Vascutherm quit the study before the end of the monitoring period, compared to one subject using the manual cooling.

There is a statistical difference between both groups for the ROM when the patients have left the hospital. But it should be noted that the number of recordings is lower compared to other parameters and compared to the first days in the hospital. The results should therefore be interpreted with care. A possible explanation of these results is that in the home situation, patients are more motivated to apply the Vascutherm compared to the manual cooling.

The first postoperative day, the circumference of the knee is lower in the continuous cooling group. As a larger circumference is linked to the swelling of the knee, we can say that automated continuous cooling has a positive effect on the swelling of the knee.

Ni et al. *(7)* found in their study a significant reduction in pain, the second day after operation. In our study, the observed differences in pain are not statistically significant. The study of Ni et al. discusses studies that compared cryotherapy against not using cryotherapy, whereas in our study we compare two different procedures of applying cryotherapy. This illustrates that the method of cooling is not as determining in pain reduction.

To conclude, this study shows that the main advantages of using continuous cooling over manual cooling are the reduction in the knee circumference and hence the swelling of the knee at the first postoperative day. Secondly we demonstrated an increased ROM during the second week of recovery. Furthermore, the continuous cooling device had a positive effect on patient satisfaction thanks to the ease of use compared to ice dressings. To some patients these advantages did not compensate for the burden of the sound of the automated cooling system.

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