

Efficacy of laser + cryo-thermal therapy in rehabilitation following total knee replacement surgery: a randomized controlled trial

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ABSTRACT

BACKGROUND: In the post-operative period after total knee replacement, the main problems are: inflammation, edema and pain. Among the use of instrumental methods to stimulate the healing processes we recognize the application of cold (cryotherapy) or heat (thermotherapy) or both together (contrast therapy) and laser therapy to produce an anti-inflammatory effect. An innovative device that combines the therapeutic advantages of these different forms of physical therapy is QMD Helios.

AIM: Evaluate the effectiveness of the use of the QMD Helios laser device in association with standard rehabilitation therapy in reducing inflammatory symptoms in patients following total knee replacement.

DESIGN: Randomized controlled trial.

SETTING: Rehabilitation structure, inpatient

POPULATION: 64 patients whit total knee replacement surgery were randomly assigned to the experimental group (cryothermal laser+ standard physiotherapy n=32) or control (standard physiotherapy n=32).

METHODS: Both groups underwent treatment 5 days a week for 3 weeks. For the patients enrolled in the experimental group, each session included laser therapy+ cryo-thermal followed the standard rehabilitation program. Patients assigned to control underwent only the standard rehabilitation program. All patients were assessed before (T0) and after (T1) the treatment. With four outcome measures : pain subscale of the WOMAC and Lequesne's Algo-Functional Index (LIKERT scale), knee circumference (measured at the middle line of the knee joint space) and knee flexion /extension range of motion by goniometer.

RESULTS: The experimental group showed a greater improvement at T1 in pain (WOMAC pain subscale $p=0.017$) and edema reduction (knee circumference $p=0.0001$) than the control group, as well as a more rapid recovery in management of ADLs (Lequesne's Algo-Functional

Index $p=0.045$). No significant difference was found between groups in the ROM flexion ($p=0.17$) and ROM extension ($p=0.11$).

CONCLUSIONS: Cryo-thermal laser therapy represents a good therapeutic option in association with standard physiotherapy for use in patients following total knee replacement surgery.

CLINICAL REHABILITATION IMPACT: Cryo-thermal + laser therapy can be considered a valid form of therapy, non-invasive and without significant side effects, able to improve the pain and edema typical of patients in the early phase following knee replacement surgery and allow a faster return to ADLs.

Key words: Total Knee Replacement – Laser Therapy – Cryotherapy- Thermotherapy- Rehabilitation Protocol

INTRODUCTION

As life expectancy increases, more and more people are afflicted with degenerative joint diseases. Knee osteoarthritis is a pathology typical of old age (over 60 years), but it can also occur in younger people (aged 40-50 years) and is more prevalent in women (11%) than men (7%).^{1,2} Total knee replacement surgery is becoming increasingly frequent.³⁻⁵ In the immediate post-operative period, the main problems encountered by patients are: inflammation, edema and, above all, pain. These can strongly influence the restoring of a correct muscle-joint function and hence the time needed for a return to normal activities of daily living (ADLs).⁶⁻⁹ Post-operative rehabilitation is now a fundamental part of the functional recovery of patients after knee replacement surgery.¹⁰ Traditional rehabilitation programs are mainly focused on improving joint mobility, reducing musculotendinous retractions, increasing muscle strength and establishing a correct gait pattern.¹⁰⁻¹³ Over the years, in addition to the manual rehabilitative techniques, the use of instrumental methods to stimulate the healing processes and speed up recovery times has become a frequent practice, especially for the management of post-operative pain and inflammation. One of these methods is laser therapy, which consists of light radiation composed of a beam of photons with specific physical characteristics that interacts with living tissue to produce an anti-inflammatory, analgesic and biostimulation effect.¹⁴⁻¹⁷ Another form of instrumental therapy used in rehabilitation for the management of pain/edema resulting from an inflammatory process is the application of cold (cryotherapy) or heat (thermotherapy) or both together in combination (contrast therapy).¹⁸⁻²⁰ Cryotherapy is a type of physical therapy that produces temporary anesthesia of the part undergoing treatment.²¹⁻²⁴ Thermotherapy consists of the application of heat to stimulate a biological process inducing the release of chemotactic substances and growth factors, which have a powerful regenerative and reparative action.²⁵⁻²⁷ An innovative device that combines the therapeutic advantages of these different forms of physical therapy is QMD Helios (Hakomed, Egna, BZ, Italy)., designed to provide cryo-thermal and laser treatment. The device is equipped with a high-power diode laser. This therapeutic laser can work at 3 different wavelengths (808 nm, 1064 nm, 1120 nm). The wavelengths are each individually controlled and can be delivered in various modes: continuous wave, pulsed mode, super pulse, and Harmonic pulsation (laser wave emission with a variable frequency -

determined by means of a scan performed by the device - suited to the tissue to be treated). This innovative triple-wavelength emission represents the most versatile solution when one wishes to obtain different therapeutic effects at the same time. In addition to the use of laser, the device allows the application of cryo-thermal therapy, simultaneously or separately. Simultaneous administration promotes thermal shock, a basic principle of contrast therapy characterized by a marked variation of temperature (30-40 degrees) within a short space of time (30-60 seconds) inducing vasodilation through the heat and vasoconstriction through the cold. Thermal shock is effective in the early stages of rehabilitation for a rapid resolution of pain and swelling.²⁸ Although in recent years instrumental therapy has come to play a very important role in rehabilitation medicine in the management of pain/inflammation in the acute patient, there is lack of reported evidence in the literature on the use of laser therapy in patients after knee replacement surgery. We thus aimed in this study to evaluate the effectiveness of the use of the QMD Helios laser device in association with standard rehabilitation therapy in reducing edema and pain symptoms in patients following total knee replacement.

METHODS

SUBJECTS

The study was carried out on patients admitted consecutively to the Department of Neuromotor Rehabilitation of the Scientific Institute of Montescano, Istituti Clinici Scientifici Maugeri, Italy, between July and December 2018. Inclusion criteria were age between 50 and 85 years, first total knee replacement surgery, and a good general physical condition permitting performance of the daily rehabilitation program. Patients affected with diabetic neuropathy, renal heart disease, hypersensitivity or allergic reactions, Raynaud's disease, lupus, rheumatoid arthritis, scleroderma, Buerger's disease, peripheral vascular disease, or impaired circulation were excluded. The study design and protocol were approved by the institutional Review Board and Ethics Committee (approval # CE 2200, 03/05/2018, chair: Marcello Imbriani) and the study was carried out in accordance with the World Medical Association's code of Ethics (Declaration of Helsinki, 1967). Written informed consent was obtained from all patients before their participation in the study.

PROTOCOL

This was a parallel-group, 1:1 allocation ratio, single-center, randomized, superiority trial. Enrolled patients were randomly assigned to the experimental group (cryo-thermal-laser + standard physiotherapy) or control (standard physiotherapy) group on a 1:1 allocation basis using a computer-generated list of random numbers. The sequence was concealed until assignment, and the healthcare personnel enrolling participants did not know in advance which treatment the patient was assigned.

Both groups underwent treatment 5 days a week for 3 weeks. For the patients enrolled in the experimental group, each session included cryo-thermal + laser therapy followed by the exercises prescribed in the standard rehabilitation program. Patients assigned to control underwent only the standard rehabilitation program of exercises, conducted in the same way as in the experimental group.

All patients were assessed before (T0) and after (T1) the treatment.

For each patient, four outcome measures were assessed: pain subscale of the Western Ontario and McMaster Universities Arthritis Index (WOMAC), knee circumference (measured at the middle line of the knee joint space), knee flexion and extension range of motion (ROM) by goniometer, and Lequesne's Algo-Functional Index. Womac and Lequesne indexes were scored on a five point (0-4) LIKERT scale. In addition, any side effects, complications and adverse reactions were recorded.

Standard rehabilitation treatment

The standard rehabilitation treatment consisted of 30 min/day of passive mobilization with cpm (continuous passive mobilization device) in order to restore normal joint function (at least 90° of flexion and full extension). This was followed by passive and active assisted mobilization exercises for joint recovery (flexion-extension), strengthening of the quadriceps and pelvic girdle muscles

(isometric followed by isotonic contractions), lengthening of the retracted muscles, proprioceptive exercises and gait training. The duration was 70 min.

Therapeutic treatment with the cryo-thermal laser device

Cryotherapy

The device used was the QMD Helios cryo-thermal device. Each session involved, first, a cycle of cold (temperature -1 °C) for 5 min with the patient in supine position with a support placed under the popliteal fossa of the knee.

Laser therapy

The laser therapy was carried out employing two different modes: first in harmonic pulsation and after with fixed pulsed mode. The parameters (wavelength, watt, and time) are pre-set by the device's program (wavelengths of 808nm, 1064nm, 1120 nm and 24 W). The first application of laser therapy consisted of harmonic pulsation using a medium-sized pointer placed on the most superficial points of the knee joint capsule. In the second cycle of laser, a fixed pulsed mode was used. The medium-sized pointer was moved slowly along the anterior knee compartment, for a length of time proportional to the extent of the skin surface area to be treated.

Contrast therapy

Finally, to finish the treatment, there were two cycles of contrast therapy, consisting in the alternation of cold and heat, guiding the handpiece in an upwards sense in the first case and downwards in the second in association with active movements of knee flexion-extension to promote the draining effect. The contrast therapy always started with a cold cycle. The duration of the latter was 2 min and the initial temperature was 5 °C, which decreased by 1 °C at subsequent cycle; heat therapy, on the other hand, lasted 1 min and the starting temperature was 40 °C, which increased by 1 °C at subsequent cycle (for two cycles each treatment).

Sample size estimation

A difference in effect between cryo-thermal/ laser therapy + standard rehabilitation and standard rehabilitation alone of at least 2 on the WOMAC pain subscale (scale range:0-20) was considered as clinically significant. To detect this difference with a type I error of 5% and a statistical power of 95%, assuming from a previous study²⁹ a SD of the difference between the two measurements of 2.4, the estimated sample size was 32 subjects per group.

Statistical analysis

Descriptive statistics are expressed as mean \pm standard deviation (SD) for normally distributed data, or as median (lower and upper quartiles) for non-normally distributed data. Data were analyzed by two-way ANOVA (factors: treatment and time), with repeated measures on the factor time. All tests were two-sided and a $p < 0.05$ was considered statistically significant. All analyses were performed using the SAS/STAT statistical package, release 9.2 (SAS Institute Inc., Cary, NC, USA).

RESULTS

A total of 108 patients admitted for rehabilitation following first total knee replacement surgery were screened for inclusion in the study. Of these, 40 patients were excluded according to the selection criteria, leaving 68 patients who were randomly subdivided into two groups via a computer-generated list. Four patients were not included in the final analysis as they did not complete the treatment protocol. Therefore, 32 patients (16 males and 16 females) were analyzed in the experimental group and 32 (12 males and 20 females) in the control group, for a total of 64 patients. The mean age was 68.1 years in Group 1 and 69.9 years in Group 2.

Outcome measures

Results for the four outcome measures evaluated at T0 and T1 in the two groups are presented in the table I.

Baseline values were not significantly different between group for all measurement. As the table shows, the experimental group showed a greater improvement at T1 both in perceived pain (WOMAC pain subscale $p=0.017$) and edema reduction (average knee circumference $p=0.0001$) than the control group, as well as a more rapid recovery in management of ADLs in the acute phase (Lequesne's Algo-Functional Index $p=0.045$). No significant difference was found between groups in the recovery of joint function (ROM flexion $p=0.17$, ROM extension $p=0.11$).

DISCUSSION

The aim of this study was to investigate if, in patients undergoing primary total knee replacement, the use of cryo-thermal+laser treatment in addition to standard rehabilitation exercises could reduce pain and edema better than the standard exercise program alone, and hence favor a more rapid return to daily living activities. The results obtained showed a better performance in the cryo-thermal+laser group both in terms of greater improvement in perceived pain (WOMAC pain subscale) and in edema reduction (average knee circumference), and a faster recovery in management of ADLs in the acute phase (Lequesne index). On the other hand, there was no significant difference between groups in the recovery of joint function (ROM flexion, ROM extension). From a clinical point of view, the greater decrease in the experimental group vs. controls both in pain perception (-10 vs. -8.1 points) and in edema (-2.6 vs. -1.4 cm) demonstrates that the cryo-thermal device is effective in controlling the inflammatory component in patients in the early post-operative period. Cryo-thermal + laser treatment, in fact, made it possible in the early post-operative phase to reduce the sensation of motor difficulty linked to edema, to inhibit the conduction of painful afferents, and so improved patients' capacity to perform the prescribed exercises. According to our study data, this combined form of therapy (cryo-thermal+laser) can be considered a valid tool enabling a more rapid functional use of the neo-articulation in both simple actions (isometric muscular contractions thanks to a decrease in muscle inhibition and post-operative stiffness) and complex actions (walking

with progressive loading and climbing stairs). In the literature it is amply demonstrated that the use of direct techniques of mobilization and muscle strengthening starting in the first days post-surgery favors an early recovery of the osteo-muscular function of the knee in patients who have undergone a knee replacement.³⁰⁻³² The use of instrumental physical therapy can have a primary effect on reducing the inflammation (pain, edema and functional loss) and only secondarily produces a greater increase of the ROM linked to a "mechanical" problem and to the patient's difficulty in integrating the operated limb into the body schema. The main factor that limits these recovery processes is, on the one hand, the inflammatory process consequent on surgery and, on the other hand, the pain, causing difficulty in returning to daily life activities and a consequent increase in the length of hospital stay. The use of laser radiation, alone, in inflammatory diseases of the knee has been reported in previous studies^{14-17,33-35} showing a reduction of pain and inflammatory symptoms (e.g. vascular and thermal alterations and edema formation with consequent pain).³⁶⁻³⁷ A reduction of the inflammatory factors may be enhanced by treating the inflamed tissue, through a decrease in the phenomenon of exudation and proliferation, stimulating the adaptive responses of the organism. In cellular biostimulation, the metabolism is increased so augmenting the cells' mitotic index which activates the repair process. At the vascular level, there is an increase in the microcirculation.³⁸ In particular, studies in the biomedical field have shown that the 808 nm wavelength of laser therapy appears to have a mainly biostimulant property and it has a high affinity for cytochrome-c oxidase.³⁸⁻³⁹ The 1064 nm wavelength has mainly an antalgic and decontracting effect.³⁹ The 1120 nm wavelength acts mainly on serotonin, dopamine (pain neurotransmitter) and on substance P of the muscles, obtaining a better effect on muscle tissue and a regression of the pain stimulus of inflammatory origin, with a relative anti-edema role.³⁹ In addition to laser therapy, cryotherapy and contrast . Cryotherapy allows to achieve a metabolic effect with a decrease in blood flow, venous pressure, saturation, hemoglobin level and nerve conduction.⁴⁰⁻⁴² In addition, according to some preliminary studies, cryotherapy prior to rehabilitative activity could have a beneficial effect on a decrease in the stasis of inflammatory substances and could promote muscle activation with better motor performance in the immediate, required by the exercises provided by physiotherapy.⁴³ In fact, the decrease in the algic stimulus with the subsequent physical activity of therapeutic exercise could decrease muscle inhibition and

increase the patient's ability to return to a correct motor pattern early. A further anti-edema effect is linked to contrast therapy (alternation of cryotherapy and thermotherapy) promoting a phase of vasodilation / vasoconstriction with a decrease in the natural stasis process following post-operative inflammation.⁴⁴ During the administration of this form of thermal energy, while the operator moves the handpiece, the patient performs flexion-extension movements of the joint in order to favor an active process of mechanical pump to drain and wash-out the catabolites induced by the movement.

The specific mechanisms underlying the reduction in inflammation induced by cryo-thermal laser radiation, however, have not yet been established, due mainly to the biological variability of the inflammatory response, the presence of comorbidities and to the acute conditions "induced" by surgery in which the organism puts into action a series of adaptations to the inflammation. According to our initial preliminary results, cryo-thermal + laser therapy can be considered a valid form of therapy, non-invasive and without significant side effects, able to improve the pain and edema typical of patients in the early phase following knee replacement surgery and allow a faster return to ADLs.

Study limitations

The main limitations of the study are: the absence of a 6-month and 1-year follow-up to evaluate the long-term benefits of use of cryo-thermo laser therapy as an adjunct to physiotherapy, and the lack of instrumental examinations (ultrasound, CT, MRI) for a more precise measurement of edema and of use of blood chemistry tests with markers to evaluate the inflammatory component.

CONCLUSIONS

Cryo-thermal+laser therapy represents a good therapeutic option in association with standard physiotherapy for use in patients following total knee replacement surgery. It has no significant contraindications and is well tolerated by the patient.

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there are no conflicts of interest of the authors

the Consort Checklist has been attached to the cover letter