

Effectiveness of Extracorporeal Shock Wave in Patients with Musculoskeletal Injuries

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SUMMARY

The evaluation of technologies in the contemporary world has become a problem of increasing importance and urgency. Extracorporeal Shockwave therapies have been used successfully around the world for more than 20 years. It is a technology of recent incorporation in the Cuban context. An evaluative research was carried out at the International Orthopedic Scientific Complex (CCOI) "Frank País" in the period from March 2021 to July 2022. With the aim of evaluating the effectiveness of extracorporeal shock wave therapy in patients with musculoskeletal injuries. The universe was made up of all patients diagnosed with musculoskeletal injuries, who attended the hospital's outpatient clinic. Results-based effectiveness evaluation was applied. The criteria, indicators and standards that were used were validated by expert criteria. The effectiveness of shockwave therapy proved to be effective, as the defined standards achieved acceptable results in all six criteria (post-therapy pain relief, post-therapy restoration of joint mobility, independence in activities of daily living, use of the workday, patients without post-therapy complications and patients satisfied with the results of the treatment). The results achieved allowed us to verify that this technology is effective, useful and advisable in the treatment of patients with musculoskeletal injuries.

Keywords: Shock Wave; Musculoskeletal Injuries; Effectiveness

Abbreviations: SCI: Musculoskeletal Injuries; ADL: Activities of Daily Living; VAS: Visual Analogue Scale

Introduction

Medical care for musculoskeletal injuries (SCI) has increased today in Cuba, every day the number of elderly patients who need specialized medical assistance in search of a solution to their health problem is increasing, it is up to the State, to achieve the preservation of the health of its citizens [1,2]. The World Health Organization points out that SCI is a disease that affects a large number of people worldwide. According to a recent analysis, approximately 1710 million people worldwide have SCI. Although the prevalence of these disorders varies by age and diagnosis, they affect people of all ages worldwide [3]. In Cuba, SCIs are quite frequent in primary care consultations, affecting 40% of the general population, causing health

problems in the working population with the consequent disability and economic-social repercussion. It is the disability that most contributes to the need for rehabilitation services among adults globally and in Cuba [4]. It is necessary to use a new technology, which manages to improve, replace or replace some invasive procedures, old compared to new technologies. Such is the case of Extracorporeal Shockwave Therapy that has been successfully applied for more than 20 years in the world. In Cuba it began its use in the CCOI "Frank País", in 2001 obtaining satisfactory results in patients. In 2016, the Well Wave team arrived at the rehabilitation department, which allowed the application of focused piezoelectric extracorporeal shock wave therapy, a more modern modality.

It is a therapy of powerful medical technology, known as High Technology, it is important to evaluate the quality of care and to be able to determine the real value of this procedure (benefits vs. risks and costs), its safety, effectiveness and usefulness for future decision-making in Cuban public health [5]. In the author's opinion, effectiveness in very specific terms is the percentage in which the established objective is achieved (expected result). Results-based evaluation allows estimation of the preparation, collection and analysis of information based on expected outcomes. In this way, the information collected can be successfully used to guide the researcher, the patient and all research stakeholders. The model proposed by Zall and Rist was assumed [6]. In the author's opinion, we are facing a new time, proposing a new evaluative paradigm is necessary, based on the information provided by the patient in the care scenario. The more patients are linked as decision makers, the greater the likelihood of success in practice, in assessing outcome-based effectiveness, by evaluating the effectiveness of shockwave therapy in patients with musculoskeletal injuries. There is a special interest on the part of the Institution in evaluating this technology which will be part of the development plan of orthopedics and traumatology in the country, as the flagship center of Orthopedics - Traumatology and Rehabilitation of SOMA. Based on the interest of the institution, research was carried out to answer the question. What is the effectiveness of the application of the shock wave in patients with musculoskeletal injuries in the CCOI "Frank País"?

Method

An evaluative research on health policies and systems was developed in the CCOI "Frank País". In the period 2021 to 2022. Universe It was made up of all patients diagnosed with musculoskeletal injuries who attended the hospital's outpatient clinic in the period from March 2021 to July 2022, for a total of 250 patients. Upon arrival, each patient had their medical history taken, and those who met the following criteria were selected.

Inclusion Criteria

1. Patients of both sexes, aged over 18 years.
2. Patients with permanence of pain in a period of six months or more.
3. Patients who received at least three of the following treatments:
 - Drugs Infiltrations
 - Laser

- Therapeutic ultrasound
- Magnetotherapy
- Stands

Exclusion Criteria

1. Patients with chronic decompensated diseases (severe cardiovascular disorders, neurological conditions).
2. Patients with bleeding disorders.
3. Pregnant patients.
4. Patients with polyneuropathies.
5. Patients with pacemakers.
6. Patients with primary or metastatic malignancies.
7. Patients with acute or chronic tissue infections.

In the research, the clinical history of all the patients included in the study was reviewed. Visual analogue scale for pain and the Katz Index of independence in activities of daily living were performed before starting treatment and at the conclusion of the five therapy sessions in each patient. Outcome-based effectiveness assessment was selected as we aimed to assess the effectiveness of shockwave therapy in patients with musculoskeletal injuries. This model describes ten steps described below:

Estimation of Preparation

Semi-structured interviews were conducted with the board of directors, the medical research ethics commission and the Frank País Vice Directorate of Medical Assistance. A discussion group was held with the members of the scientific council of the hospital, to estimate the relevance of the evaluation. In this step, the availability of the material resources necessary to carry out the treatment was also reviewed; this was obtained by reviewing the technological cards of the equipment used. To know the status and availability of the Well Wave equipment, the quality control seal and its registration or maintenance control were reviewed.

Selection and Definition of Expected Results

The definition of the expected results with the application of the evaluated technology allowed to identify what is considered effectiveness of the actions carried out through the visual analog scale for pain, scale of independence in the activities of daily living, joint mobility, the use of the working day, complications with the use of technology and patient satisfaction.

Annex Table 2: Questionnaire for the evaluation of the effectiveness of shock waves in patients with musculoskeletal injuries.

Claims	Always	Almost always	Sometimes	Almost never	Never
After applying shockwave therapy to your damaged area relieves your pain					
After applying shockwave therapy is able to move the joint or affected area					
You are able to perform activities of daily living (bathing, feeding, dressing, toilet use)					
After applying the therapy, his stay at work improved.					
You had bruising, muscle tears, and/or redness					
Feel satisfaction after treatment ends					
Improved his health by applying shockwave therapy					

Note:

Dear Patient: We request your collaboration to study the effectiveness of shockwave therapy in musculoskeletal injuries. You only need to answer the questions below. We guarantee the greatest discretion with the data you can provide, which are of great value for this study.

At the same time, the findings of the process, the results obtained were analyzed and compared with the base data and expected standards. Positive and negative outcomes that were not foreseen before the actions were also included. It culminated with steps 7 and 8 of the model, which refer to the presentation of evaluation results by the evaluators, according to this ten-step model. The instrument to be used in the research was validated in practice by piloting 20 patients not included in the study. The satisfaction questionnaire was applied to this pilot group, with prior informed consent. This allowed to explore the level of satisfaction with respect to the treatment received, this was applied to all patients once the five sessions of therapy were finished. The questionnaire was well understood, it was not the subject of pointing out or doubts. No items needed to be changed. The relevant instrument for this type of evaluation was considered. The questionnaire was conducted to evaluate the effectiveness of shockwave therapy in patients with musculoskeletal injuries to the pilot group. It was found that the questionnaire is easy to apply, it managed to measure and collect all the steps that must be taken into account when evaluating the effectiveness of this therapy in patients. All aspects were well understood. The instrument was considered valid. The statistical information was summarized in percentages and presented in tables that allowed the analysis of the information and the arrival of the conclusions.

Ethical Considerations

The study was conducted following the ethical principles set out in the Declaration of Helsinki. The direction of the CCOI "Frank País" was formally requested authorization to carry out the investigation, after having explained the objectives of the same. Data collection began after such consent was granted in writing. Authorization was requested from the Ethics Committee for Human Research of the CCOI "Frank País", which ensured compliance with these requirements and approved the research. The information obtained was handled confidentially and was only used for investigative purposes. Each patient was asked for their consent to belong to the research and the confidential nature of the information provided and its scientific use were explained ([Annex Text](#)).

Results

As observed the predominant sex was the female represented 61.2 % of the patients included in the study, the majority age group of 51 to 60 years gathered 24.4 %. To better understand the age distribution, categories have been established, presented in Table 1 distributed by sex. The median age is 52 years, while fashion is 54 years. The musculoskeletal lesions that predominated were the heel spur and plantar fasciitis for 41.2 %. The total distribution of patients regarding the diagnosis of musculoskeletal injuries was presented in Table 2. Pain was the fundamental symptom in musculoskeletal injuries. All patients presented pain before the application of the shock wave, including the main indication for the performance of this non-invasive technique. After treatment this situation was reversed, 77.6 % of patients were pain-free after finishing the five treatment sessions. The total distribution of patients with respect to pain was presented in Table 3. 41.2% of the patients studied presented lack or absence of joint mobility before applying the treatment, after applying the therapy only 13.6% remained in that category. As relevant data of this research after applying the treatment, 62.4% of patients managed to recover joint mobility, with improvement in functional capacity. The total distribution of patients with respect to joint mobility was presented in Table 4. Patients according to the Kats Index were between category A, B and C. 68.8 % of patients had an Index A (Independent in feeding, continence, mobility, use of the toilet, dressing and bathing) after applying the therapy the situation was reversed in 82.4 %. The total distribution of patients with respect to the Kats Index was presented in Table 5. The greatest difficulty occurred in the group of patients diagnosed with calcified tendinitis of the supraspinatus who presented difficulty bathing and dressing of the upper body. The use of the working day (considering the day in 8 hours of work) before starting the treatment. Of all the patients studied, 35. 2% had a total limitation (they could not take advantage of their working day). After applying the therapy this situation was modified, only 6.8% of patients failed to complete their workday. The total distribution of patients regarding the use of the working day was presented in Table 6. In the research the complications after therapy

with shock waves were analyzed, it is important to express that of the total of cases studied, it was relevant that 100% of the patients did not present complications. In the satisfaction of patients after finishing the treatment, very satisfactory results were obtained, 98% of the patients studied were satisfied with the treatment, it should be noted that there were no dissatisfied patients. The total distribution of patients with respect to satisfaction with treatment results was presented in Table 7. The effectiveness of this technology is given in the achievement of the expected objectives that are specified in the changes that were expected, when shock wave therapy is used. The results-based evaluation was carried out, the final evaluation of the research was obtained (Table 1). The criterion of post-therapy pain relief was placed in the acceptable standard. The 77.6% of the cases studied relieved their pain after treatment. The restoration of joint mobility post-therapy was placed in the acceptable standard. 87% of the cases studied regained their mobility after treatment. The criterion of independence in activities of daily living (ADL) was placed at the acceptable standard. 82.4% of the cases studied improved their independence as a result of their problem in their shoulder, elbow or foot after the treatment. The use of the working day (considering the day in 8 hours of work) was located in the acceptable standard. The 93.2% of the cases studied improved their use as a result of their problem in their shoulder, elbow or foot after the treatment. The criterion of patients without post-therapy complications was placed in the acceptable standard. 100% of the cases studied did not suffer complications after treatment. The criterion of patients satisfied with the results of the treatment was placed in the acceptable standard. 98% of the cases studied were satisfied after treatment.

Table 1: Distribution of patients by age and sex.

Age group	Female		Male		Total	
	No.	%	No.	%	No.	%
19- 29 years	9	3.6	8	3.2	17	6.8
30-40 years	36	14.4	23	9.2	59	23.6
41-50 years	38	15.2	21	8.4	59	23.6
51-60 years	37	14.8	24	9.6	61	24.4
61-70 years	27	10.8	17	6.8	44	17.6
71-80 years	6	2.4	4	1.6	10	4
Total	153	61.2	97	38.8	250	100

Note: Source: Clinical History.

Table 2: Distribution of diagnosed patients by sex.

Diagnosis	Female		Male		Total	
	No.	%	No.	%	No.	%
Tendinitis calcificada supraespinoso	42	16.8	31	12.4	73	29.2
Epicondylitis	12	4.8	8	3.2	20	8

Tenosinovitis aquileana calcificada	38	15.2	16	6.4	54	21.6
Calcaneal Spur and Plantar Fasciitis	61	24.4	42	16.8	103	41.2
Total	153	61.2	97	38.8	250	100

Note: Source: Clinical History.

Table 3: Distribution of patients according to visual analogue scale, before and after.

Pain	Before		After	
	No	%	No	%
Painless	0	0	194	77.6
Pain in strenuous activities	106	42.2	32	12.8
Pain on the march	95	38	16	6.4
Pain at rest	49	19.6	8	3.2
Total	250	100	250	100

Note: Source: Clinical History.

Table 4: Distribution of patients according to joint mobility, before and after.

Joint mobility	Before		After	
	No	%	No	%
Lack or absence of joint mobility	103	41.2	34	13.6
Mild joint mobility <25%	54	21.6	48	19.2
Moderate joint mobility between 25 and 50%	20	8	12	4.8
Full joint mobility to functional	73	29.2	156	62.4
Total	250	100	250	100

Note: Source: Clinical History.

Table 5: Distribution of patients according to Katz Index, before and after.

Katz Index	Before		After	
	No	%	No	%
A	172	68.8	206	82.4
B	37	14.8	26	10.4
C	41	16.4	18	7.2
D	0	0	0	0
And	0	0	0	0
F	0	0	0	0
G	0	0	0	0
H	0	0	0	0
Total	250	100	250	100

Note: Source: Clinical History.

Table 6: Distribution of patients according to the use of the working day before and after treatment.

Taking advantage of the working day	Before		After	
	No	%	No	%
No limitation	63	25.2	132	52.8
Mild limitation allows you to devote 5 to 7 hours to work	47	18.8	73	29.2
Moderate limitation allows you to devote 2 to 4 hours to work	52	20.8	28	11.2
Total limitation (you cannot take advantage of your working day)	88	35.2	17	6.8
Total	250	100	250	100

Note: Source: Clinical History.

Table 7: Distribution of patients according to satisfaction with treatment results after therapy.

Satisfaction with treatment results	After	
	No	%
Satisfied	245	98
Moderately satisfied	5	2
Moderately dissatisfied	0	0
Unsatisfied	0	0
Total	250	100

Note: Source: Clinical History

Discussion

The literature agrees that age can be considered a risk factor in itself, for the suffering of musculoskeletal injuries since in the aging process itself there are changes in our body that favor the appearance of these diseases. These conditions are common in women between the ages of 40 and 60 [7]. Heel spur, plantar fasciitis, and calcified Achillean tenosynovitis are diseases that have a high prevalence that increase with age. They are of multifactorial origin, affect 10% of the population throughout their lives between the fourth and sixth decade of life also causing functional disability [8]. Plantar fasciitis is a very frequent cause of consultation in Cuba as in the world. Its prevalence is high. The picture is more common in women over 40 years of age [9]. This fact is related to the study by the author Artidiello Bustio et al., carried out at the “Abel Santamaría Cuadrado” Hospital in Pinar del Río with 60 patients, where the female sex predominated over the male sex with 43 patients and coincided with this research where the female sex turned out to be 24.4 %. Similarly, a bone spur was observed in the calcaneus, radiologically in about 50% of the patients who participated in the study [10]. At present patients suffering

from plantar fasciitis and heel spur and do not improve with conservative treatment. They require the use of shock wave therapy applied at least 3 to 5 sessions for a period of 6 months obtaining encouraging results, according to the reviewed literature [11]. The research took into account the Visual Analogue Scale (VAS). This is the most commonly used scale to measure pain.

The studies of the authors Cacchio A. et al [12], Albert J.D et al [13], Moya D and Patiño [14], and Ioppolo F. et al [15], corroborate this fact. Similar results evidenced Carmona FB, in the study “Shock-wave therapy in conditions of the osteomyoarticular system in the elderly” pain, limited movement and disability is a frequent symptom, characteristic in all these conditions and may be present in all cases [16]. Pain at rest may become nocturnal and may be severe enough to prevent sleep or wake the patient at night. This result surfaced in this research. Several authors agree that extracorporeal shock waves cross the various tissues in the body when applied, increase metabolism in the body and favor the reduction of inflammation in the area affected by the production of endorphins, causing a triggering analgesic action [17,18]. In this research, the author from her personal experience began in all patients with an energy density of 0.048 mJ/mm², increasing progressively until reaching 0.110 mJ/m² according to each patient’s tolerance, which allowed pain relief. It is described in the literature that the use of low energy levels, with an average of 0.08 - 0.11mJ/m², will determine analgesia by the so-called hyperstimulation or counterirritation effect [19,20]. Joint mobility in the literature is a variable with great recurrence. Authors such as Cacchio A. et al [12], Albert J.D et al [13], Moya D and Patiño [14], and Ioppolo F. et al [15], obtained similar data to this research.

In this sense, Akkur, conducted a comparative study between Two groups, one placebo and the other applied shockwave therapy in patients diagnosed with epicondylitis and calcified tendinitis of the supraspinatus. Similar results were observed to this investigation, a significant improvement was evidenced with a gain in mobility and functional capacity good or excellent in 56% of patients treated with extracorporeal shockwave therapy compared to 6% of the placebo group [21]. Similar results were found to this research regarding the independence of post-treatment ADLs, with three sessions at weekly intervals in the findings of Namdari S et al [22], their sample was constituted by women between 40 and 60 years of age, where shoulder movements improved after applying the therapy. Similar results to this research were evidenced in the study of Carmona FB et al, in 800 elderly patients with conditions of the osteomyoarticular system, where they were divided into three groups by the simple random method; two control groups [iontophoresis in cases of calcifications (group I)], [therapeutic ultrasound in cases of inflammation (group II)] and the study group [shock waves for both patients with calcifications and patients with inflammation (group III)]. Before treatment, pain interfered with activities of daily living in 100% of patients in all three groups. Therefore, all had Katz C index with limitations in

bathing, dressing and/or moving, mainly. After treatment there was improvement in the three groups, predominating patients with Katz Index A (independent for the development of all ADLs), being more significant in group III with 86.6 % who were treated with shock wave therapy [16].

Despite the clairvoyance provided by studies of the effectiveness of extracorporeal shockwave therapy for musculoskeletal injuries, the truth is that, in the articles reviewed [10-19], no study has given conclusive or directly revealing data on the benefit of this therapy in the use or completion of the workday. I would like to point out that there are no articles on this. In this sense, the author considers that it would be very interesting to be able to carry out other investigations where this variable is taken into account, in patients with these pathologies. Criterion that had the acceptance of the experts consulted in this research. This variable is also able to measure effectiveness when we achieve early return to work activities and there is greater permanence, safety and efficiency at work, in this way we improve the quality of life of patients. The author of this study considers from her personal experience, that the increase is due to several causes in the first place to the biological effects of shock waves. Where for the wave to have an adequate therapeutic effect, the energy must be focused on the point to be treated, in this case on the plantar fascia, epicondyle, Achilles tendon and / or supraspinatus tendon. This is what is called the primary or direct effect of the shock wave [23]. The second cause, in the author's opinion, that favored the completion of the workday of the patients studied, was the diagnosis of "plantar fasciitis", which was found in women who worked as cooks, hairdressers, cleaning assistants, among others.

The truth is that the hours of standing, favor inflammation of the plantar fascia (fibrous aponurosis) that provides fundamental support to the longitudinal arch of the foot. After applying shock wave therapy, the fibrous and poorly vascularized scar tissue was micro-ruptured, a restorative effect was obtained and improvement of pain symptoms, inflammation that resulted in a greater permanence in their job and in turn taking advantage of the workday. The specialized literature related to the effectiveness of shockwave therapy in musculoskeletal injuries [10-19] agree that it is a safe, effective and non-invasive method where a low frequency of complications are reported after the use of this technology. In the opinion of the author, the results produced in this research, after the use of shockwave therapy are factors that show patient satisfaction. Knowing the degree of satisfaction of the user or patient after using extracorporeal lithotripsy can contribute to help the professional, in the future decision making in the use of this technology. For the purposes of this research, the author assumes, considering it related to the proposed objectives, the definition issued by Revicki D.A, the term satisfaction with the treatment which is defined as: an evaluation by the patient about the process of administration of the treatment and its related results [24]. Finally, a new evaluative paradigm is necessary, it is the patient-cen-

tered care approach, which is becoming increasingly important in clinical practice since, among others, it could affect compliance with therapeutic regimens and, therefore, their effectiveness [25].

In the daily care work of the Frank Pais Hospital, the author has insisted that the patient must be at the center of everyone's attention, in order to solve their needs, putting this fact into practice in this research. The results of this research coincide with a previous study conducted by the author at the CCOI "Frank País", in 107 patients where the effectiveness of shockwave therapy in tendon and ligament injuries of the osteomyoarticular system was evaluated. According to the criteria for evaluating the response to treatment, the results were satisfactory in 56% of the patients studied [18]. The main weakness of this study was the small sample size, but with results similar to those found in other studies reviewed in the specialized literature on this topic [16-25]. More than 8000 cases treated in scientific papers have now been documented, generally highlighting the effectiveness of therapy in musculoskeletal injuries [10-19]. The results expected in this research confirmed the effectiveness of this technology. This makes it necessary to consider it as an alternative in the treatment of patients with musculoskeletal conditions. It is a novel, non-invasive and risk-free technology.

Conclusion

The study of patients with musculoskeletal injuries identified that the predominant sex was female, from 51 to 60 years of age. The musculoskeletal injury detected in most patients was heel spur and plantar fasciitis. Shockwave therapy in the Cuban context proved to be effective insofar as once applied, the expected results were achieved and the selected criteria reached the defined standards, with the six criteria defined in the research being acceptable. This research has made visible that the expected results measure specific aspects of the effectiveness of shock wave therapy, which confirms that knowledge about it allows the development of research in the evaluation of this health technology.

Conflict of Interest

The authors declare that there is no conflict of interest.

Authors' Contribution

Marisel Ibarbia Carreras: General conception of research design. Correction and drafting of the document. Analysis and interpretation of data. Dr. C Nelcy Martínez Trujillo: Correction and writing of the document.

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