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Research Article

Pain Relief Effect of Crackdol® Fast Foam in Osteoarticular Disorders

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Summary

Osteoarticular diseases affect 10% of the world's adult population and 50% of women and commonly comprise inflammatory and degenerative disorders such as joint pain (arthropathies), muscle pain (myopathies), bone pain (osteopathies) and nerve pain (tendinopathies). The target of the present observational survey was to evaluate the effect of the topical administration of a medical device (Crackdol® Fast foam) in patients with osteoarticular disorders. Twenty-six patients with osteoarticular disorders in different body areas such as upper limbs (neck, shoulder, elbow, and wrist) and lower limbs (knee, sacrum, lumbar) were included in this retrospective survey.

Results showed that Crackdol® Fast foam was very efficient in controlling the pain level with a Fast (after 0.5 hours from the administration) and a prolonged effect (after 1 month from the administration) in both upper and lower limbs application.

Crackdol® Fast foam revealed not only a good therapeutic efficacy but also no side effects, high patient compliance and adherence to the therapy representing a good candidate to be studied in more complete randomized and controlled clinical trials.

Keywords: Medical device; Natural treatment; Osteoarticular disorders; Pain

Introduction

Osteoarticular diseases affect 10% of the world's adult population and 50% of women and commonly comprise inflammatory and degenerative disorders such as joint pain (arthropathies), muscle pain (myopathies), bone pain (osteopathies) and nerve pain (tendinopathies).

The osteoarticular and muscular systems are profoundly linked to each other and to the natural aging of our body, and pain is a ubiquitous symptom of osteoarticular diseases.

Osteoarthritis is one of the most common oasteoarticular disease and its treatment represents a major health challenge [1]. It affects articular cartilage and surrounding tissues contributing greatly to functional limitations of joints and reduce patent quality of life [2].

It is possible to identify primary (idiopathic) osteoarthritis where the cause is unknown and secondary osteoarthritis where another disease or condition, such as an infection, birth abnormality, or injury is the cause [3]. Osteoarthritis can occur at all ages and may increase with advancing age because of the physiological loss of chondroitin sulfate from the collagen matrix that follows aging. The condition, if not adequately treated, could lead to a chronic course and the onset of severe, even irreversible damage to joint structures [4].

The joints most frequently affected are the knees, hips, lumbar (those in the lower back) and cervical (neck) area. Other joints, however, can also be affected, for example, osteoarthritis of the hands and that of the shoulders are common.

In the starting stage, soreness and stiffness of the joints are very common, but the symptomatology is not always proportional to the actual wear of the cartilage since some joints may be more damaged than others may and therefore they need to be treated differently depending on the severity of the damage reported.

Pain represents one of the main reasons why patients require medical consultation, moreover, pain represents a subjective phenomenon and is complicated to describe given its enormous variability in intensity among individuals.

Pain intensity refers to the severity of pain and is an extremely relevant phenomenon in clinical practice to the point that specific two-dimensional scales must be used to make a proper assessment [5].

Inflammation plays a crucial role in the pathogenesis of OA one potential explanation for this phenomenon could be that degraded cartilage induces a foreign body reaction within synovial cells. This may lead to the production of metalloproteases, synovial angiogenesis and the production of inflammatory cytokines, which leads to further cartilage destruction. Other theories propose a central role of activated synovial macrophages and the innate immune system. [6].

Temporary or permanent physical disabilities due to osteoarticular disorders significantly worsen patients' quality of life; the most frequent symptoms are frequent falls, inability to get up from the chair, difficulty walking [7].

The standard conservative treatment for osteoarticular diseases represented by nonsteroidal anti-inflammatory drugs (NSAIDs) or corticosteroids oral and/or topical administration.

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However, the use of such drugs for prolonged periods implicates various side effects that contribute to a significant reduction of the patient quality of life and often lead to therapy suspension worsening the disease status.

The target of the present observational survey was to evaluate the effect of the topical administration of a medical device (Crackdol® Fast foam) in patients with osteoarticular disorders.

The observational survey was performed under a physiatrist supervision that evaluated the effect in terms of pain reduction of the topical administration of Crackdol® Fast foam on different body areas and after various time points monitoring at the same time potential side effects.

Materials and Methods

Setting

This observational survey has been conducted by an Italian physiatrist and is based on its clinical experience in patients taking Crackdol® Fast foam.

Data were retrospectively collected in the period May 2022 to June 2022 by the physiatrist located in Campania a region in the south of Italy. Ethical approval was not necessary according to National Code on Clinical Trials declaration [8], because this observation derives from a real-life retrospective study.

The aim of the present study was to evaluate the effect of the administration Crackdol® Fast foam after 0.5 hours, 24 hours, and 1 month in patients with osteoarticular disorders.

Study Population, Treatment and Evaluated Parameters

Twenty-six patients with osteoarticular disorders in different body areas such as upper limbs (neck, shoulder, elbow, and wrist) and lower limbs (knee, sacrum, lumbar) were included in this retrospective survey.

Patients older than 18 years with acute pain or recrudescence of arthritis or osteoarthritis were included in the study. The following exclusion criteria were applied: patients with co-morbidity, cardiopathic patients, oncological patients, pregnant or breastfeeding patients.

The treatment was performed for one month with the topic application of Crackdol® Fast foam on the affected area two times a day.

At the start of the study and after 0.5 hours, 24 hours and 1 month the pain level of each patient and the area of application of Crackdol® Fast foam were recorded by the physiatrist using the VAS scale.

The doctor for each patient also collected adverse effects at the final visit.

Statistical Analysis

Data were summarized as media +/- standard deviation.

Results

Twenty-six people were included in this retrospective survey and the results were organized based on the specific area treated with Crackdol® Fast foam as reported in Table 1.

Body area	Number of people
Neck	8
Shoulder	6
Knee	3
Sacrum	3
Elbow	2
Wrist	2
Lumbar	2

Table 1: Number of people treated with Crackdol® Fast foam for each body area.

In particular, as reported in Figures 1,2, for all anatomic tested areas for upper limbs there was an important pain reduction expressed as Vas scale score after the application of Crackdol® Fast foam (0.5 h, 24 h, 1 month) with respect to the start of the study (T0).

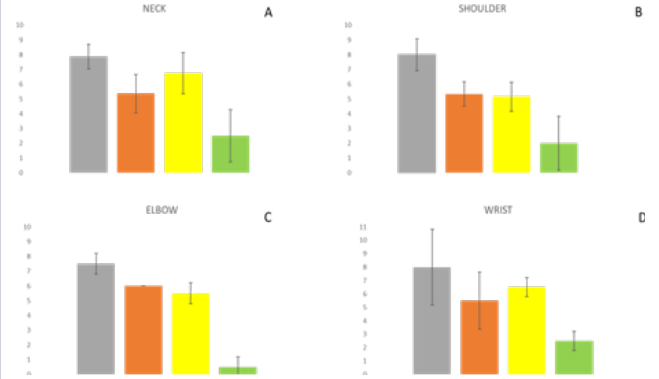

Figure 1: Vas scale score after the topical application 2 times/day of Crackdol® Fast foam at T0 (grey), after 0.5 hours (orange), after 24 hours (yellow) and after 1 month (green) on the upper limbs: Neck **(A)** Shoulder **(B)** Elbow **(C)** and Wrist **(D)**. Data are expressed as mean ± standard deviation.

At the same time, for all the tested anatomic areas referring to lower limbs there was an optimum pain control after the application of Crackdol® Fast foam for each patient.

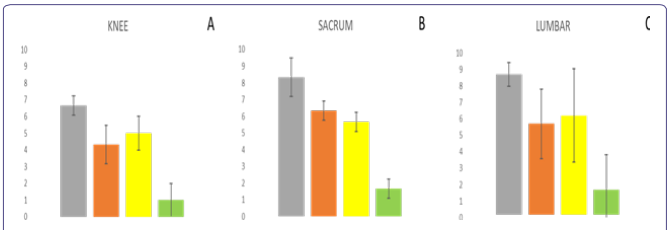

Figure 2: Vas scale score after the topical application 2 times/day of Crackdol® Fast foam at T0 (grey), after 0.5 hours (orange), after 24 hours (yellow) and after 1 month (green) on the lower limbs: Knee **(A)** Sacrum **(B)** and Lumbar **(C)** Data are expressed as mean ± standard deviation.

Discussion

OA is a well-known cause of disability around the globe [9].

Otherwise affecting people's physical health, OA may also negatively affect people's mental health. Scientific data demonstrated that people with lower limbs OA had greater chance of developing depressive symptoms than those without the disease [10]. Another study found a strong relationship between OA and perceived memory loss

that was partially related to sleep and mood impairments due to OA [11].

There is also increasing evidence that OA is a risk factor for cardiovascular diseases development. A meta-analysis found that the risk of myocardial infarction was significantly increased in OA and other types of arthritis [12]. Other studies similarly linked coronary heart disease with OA [13-15].

All these data confirm that the treatment of OA represents a great challenge for the scientific community in view of the high prevalence in the global population and because of the important implications that OA has on other body functions.

Crackdol® Fast foam is a medical device based on an innovative-patented technology containing natural substances properly combined in a high compliance formulation for topical administration.

Results showed that Crackdol® Fast foam was very efficient in controlling the pain level when applied both on upper and lower limbs zone (Figures 1,2).

Particularly, it is interesting to point out that an initial pain reduction ranging between about 20% - 35% after only 0.5 hours from the topical administration of Crackdol® Fast foam with respect to the start of the study (T0) was observed in all the patients.

This effect was probably due to the Fast effect of the medical device that provided an immediate reduction of the cutaneous temperature that stimulated the microcirculation at dermal-epidermal level, facilitating muscular and articular distension.

The ice-like effect of Crackdol® Fast foam in the acute phase (T 0.5 hours) is consistent with literature data that confirm the efficacy of cryotherapy in the management of pain [16-18].

After 24 hours from the first administration, the pain was still controlled in all treated patients and revealed lower with respect to T0.

As reported in Figures 1 and 2, after applying for one month Crackdol® Fast foam in all the observed body areas an almost complete pain reduction (up to 93% with respect to T0) was observed with VAS score between 0-3.

This prolonged effect in the time was probably related to the specific formulation of Crackdol® Fast foam that behaving as a passive micro-massage on the treated area, improved the microcirculation of the affected zone and prolongs the cryogenic action.

High patient compliance was maintained during the study and no side effect were recorded maybe because of the presence of specific emollient excipients that mitigated the possible cold irritant effect produced by Crackdol® Fast foam application.

Conclusion

On the basis of the results obtained in the present survey, Crackdol® Fast foam represents an interesting medical device able to reduce pain level in acute phase and after prolonged periods of treatment in people with osteoarticular disorders.

Crackdol® Fast foam revealed not only a good therapeutic efficacy but also no side effects, high patient compliance and adherence to the therapy.

Controlled and randomized clinical trials with a wide range of population evaluated are necessary to confirm the interesting results reported in this retrospective survey and recommend Crackdol® Fast foam as an alternative treatment in osteoarticular diseases.

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