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Establishing a Treatment Flow in Patients with Knee Osteoarthritis

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Abstract

It is a common clinical experience that core therapies are usually insufficient to fully control symptoms after diagnosis has been made and with disease progression. In agreement with the basic principle of treatment recommendation, which requires combination of treatment modalities, parallel addition of sequential non-pharmacological and pharmacological therapies should be established.

Keywords: Disease progression; Pharmacological therapy; Re-alignment treatment; Lateral osteoarthritis; Patellar taping; Placebo effect

Introduction

The consequent treatment algorithm that was derived from the present effort is depicted. Background treatment, which follows the core set, further background physical remedies should be established as needed. In parallel, and if the patient is still symptomatic, background pharmacological therapy should be started and progressively moved toward combination treatment as soon as the clinical response is not satisfactory [1]. During Background treatment, the patient should be referred to a physical therapist for assessment to determine whether physical treatments should be introduced. In particular, the physical therapist should first evaluate whether correction for mal-alignment is necessary. Moreover, he/she should also assess, during treatment and throughout steps thereafter at any time, whether other physical measures may be useful for additional symptom relief in parallel to the pharmacological interventions established by the physician [2].

Methodology

Varus or valgus malalignment is a risk factor for knee osteoartritis and its progression. Therefore, there is a theoretical rationale for using biomechanical interventions such as braces or insoles in patients with uni-compartmental tibiofemoral osteoartritis to reduce malalignment, to reduce the consequent articular stress, and thus to improve pain and function, or even retard disease progression [3]. Despite significant heterogeneity and poor trial quality, there is reasonable evidence to suggest that knee braces actually improve biomechanical imbalance and may improve knee osteoartritis symptoms. The same may apply with multi-modal re-alignment treatment that includes braces, foot orthoses, and appropriate footwear [4]. Among foot orthoses, there are many studies on laterally wedged insoles in medial compartment knee osteoartritis aimed to increase foot pronation, thereby reducing medial compartment loading. Their biomechanical effects are more inconsistent and the clinical efficacy is controversial; in particular, a recent high-quality meta-analysis found a significant effect on pain in all randomized controlled studies combined, but no effect when the more reliable higher quality trials were considered [5]. There are fewer studies on laterally wedged insoles with sub-talar strapping and on medially wedged insoles for uni-compartmental lateral osteoartritis, although they tend to show efficacy. There is insufficient evidence to determine whether braces or insoles affect the progression of knee osteoartritis. European Alliance of Associations for Rheumatology did not recommend the use of insoles among non-pharmacological treatments for knee osteoartritis, also in view of an increased risk of adverse effects. On the other hand, appropriate footwear should be recommended [6]. Ideal patients for bracing are younger individuals, more physically active, not severely obese, with uni-compartmental symptomatic tibiofemoral osteoartritis and malalignment that is reducible by valgus or varus stress maneuvers on physical examination. For laterally wedged insoles, patients should also probably have early and mild disease [7].

Discussion

Among additional physical remedies, access to walking aids is an important help in providing security to patients: although appropriate clinical studies are scarce, a recent randomized trial confirmed that use of a cane improves symptoms in knee osteoarthritis [8]. Referral to a physical therapist may also include assessment for the use of thermal therapies, such as ultrasound, for which there is some evidence of efficacy, albeit in low-quality studies. Indeed, more recent randomized trials failed to show additional improvement of ultrasound over a sham procedure, or for manual therapy in combination with exercise, or patellar taping where needed [9]. Balneotherapy and, especially, acupuncture ranked high in a recent network meta-analysis of all physical treatments for knee osteoarthritis as shown in (Figure 1). On

Figure 1: Physical treatments for knee osteoarthritis.

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the other hand, other studies suggest that the benefit of acupuncture is small, especially compared with sham acupuncture, and possibly due to expectation or placebo effect [10]. Finally, Transcutaneous Electric Nerve Stimulation is also a possible physical intervention; the evidence is scarce, especially because of the availability of mainly small and low-quality studies. However, a recent larger randomized trial suggested that Transcutaneous Electric Nerve Stimulation may reduce the need for analgesic medications [11]. Interestingly, the recent ACR guidelines suggested an approach that would advise reserving acupuncture and Transcutaneous Electric Nerve Stimulation as a non-pharmacological alternative to surgery when this is contraindicated or the patient is unwilling to undergo surgery. There are no specific studies in this respect and thus it is correct that both acupuncture and Transcutaneous Electric Nerve Stimulation are listed here and considered throughout the algorithm flow including, but not necessarily, as an alternative to surgery [12]. The aim of pharmacological treatment is to establish a first chronic therapy that may improve or control symptoms or at least provide rescue analgesia. Paracetamol at doses no greater than per day on a regular basis is recommended as an initial pharmacological approach in most clinical guidelines, despite its minimal effects on symptoms but in the presumption of acceptable safety and affordable price. However, a recent meta-analysis outlined that the vast majority of clinical trials were performed over durations of less than 6 months, thus questioning paracetamol chronic treatment role; indeed, the only placebo-controlled study of 6-month duration found a significant effect on function but not on pain [13]. This meta-analysis also confirmed the small effect size, less than 0.20, detected in a previous Osteoarthritis Research Society International guideline update and confirmed in large trials or those analyzed by intention-to-treat as shown in (Figure 2). In addition, there is accumulating evidence for an increased risk of gastrointestinal adverse events with paracetamol use, with significant elevation in liver enzymes. Indeed, paracetamol is the most frequent cause of drug-induced liver injury in the United States and over half of such cases are due to unintentional ingestion. A safer and more sensible approach would be to use as a background therapy, chronic Symptomatic Slow-Acting Drugs for Osteoarthritis, with as needed paracetamol for short-term, rescue analgesia [14]. Among Symptomatic Slow-Acting Drugs for Osteoarthritis, prescription glucosamine sulphate should be differentiated from other glucosamine preparations. The latest update of a specific Cochrane Review clearly showed that while the overall pain benefit of all glucosamine formulations together is jeopardized by high heterogeneity, subgroup analysis of non-prescription glucosamine high quality trials showed no benefit versus placebo. Conversely, high-quality trials of the patented prescription formulation approved in Europe and elsewhere showed that it was superior to placebo in the treatment of pain and functional impairment, all three pivotal trials are long-term studies of 6 months to 3 years treatment in patients with mild-to-moderate pain and the calculated global effect size, without heterogeneity, is on pain and on function i.e., in about the same range of short-term trials of oral non-steroidal anti-inflammatory drugs [15]. A recent network meta-analysis, again mixing all formulations, was criticized for severe methodological flaws and the journal editor withdrew the article's negative conclusions. The Appropriateness Criteria guidelines did not recommend glucosamine because they noted that glucosamine is not a prescription drug in the USA, but only dietary supplements exist whose quality has not been evaluated by the Food and Drug Administration. In addition, such dietary supplements often contain glucosamine hydrochloride and a large, NIH-sponsored trial showed no benefit of this preparation, similar to other studies of glucosamine hydrochloride, indeed, these formulations have a different pharmacokinetic profile than prescription glucosamine sulphate once daily approved in Europe, and appropriate bioequivalence studies should be conducted before recommending glucosamine generic or Over-the-counter products. Long-term prescription glucosamine sulphate may delay joint structure changes, suggesting potential benefit beyond symptom control when used early in the management of knee osteoarthritis as recommended here. Chondroitin sulphate may offer similar benefits on joint structure changes in patients with mild-to-moderate disease using prescription chondroitin sulphate. It should, however, be acknowledged that joint structure modification is not an approved indication for either prescription chondroitin or glucosamine sulphate but a potential benefit when they are used for long-term symptom control. In this respect, the data on chondroitin sulphate have been reported as conflicting. On the other hand, full data of one pivotal trial on chondroitin 4&6 sulphate have been published more recently and show chondroitin sulphate to reduce joint structural changes with a symptomatic effect that could be clinically relevant, as confirmed in another recent study. The prescription drug used in this study should be distinguished from low-quality Over-the-counter products available outside of Europe. As for glucosamine sulphate, the negative conclusions of a recent network meta-analysis were withdrawn by the editor. Beside their efficacy record, both glucosamine sulphate and chondroitin are safe medications, with no difference in adverse effects compared with placebo, which would also strengthen their role as chronic background treatments. Glucosamine and chondroitin sulphate are often used in combination as dietary supplements. Unfortunately, there are no published trials of the two pharmaceutical-grade prescription preparations combined. On the other hand, the previously mentioned NIH-sponsored trial, while finding no overall benefit, described a significant symptomatic effect in an exploratory analysis of patients with moderate-to-severe pain receiving a glucosamine hydrochloride and chondroitin sulphate combination. Indeed, a similar combination has been shown to have comparable efficacy to celecoxib after few months in knee osteoarthritis patients with moderate-to-severe pain. More interestingly, and following preliminary data from the Osteoarthritis Initiative database, a recently published trial from Australia found significant and clinically relevant joint structure modification after few years with a non-prescription or pharmaceutical grade chondroitin sulphate combination, with apparently no effects on symptoms given the very mild and placebo responsive population studied. The evidence for efficacy of other Symptomatic Slow Acting Drugs for Osteoarthritis, such as avocado soybean un-saponifiables and diacerein, is scarcer.

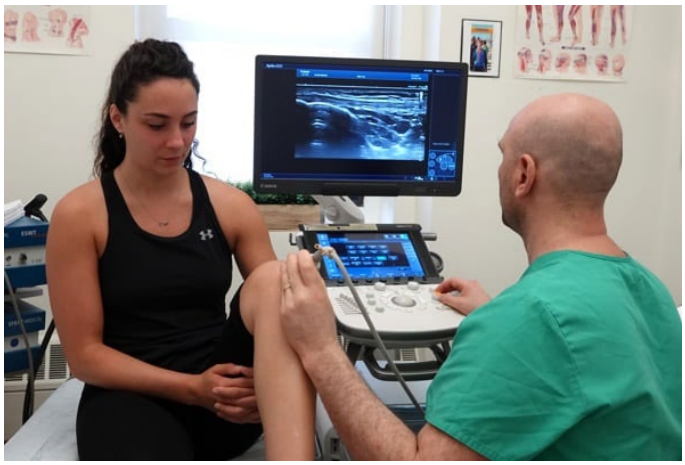

Figure 2: Treatment is to establish chronic therapy.

Conclusion

With respect to diacerein, the European Medicines Agency recently informed that despite the most recent meta-analysis showing some degree of efficacy without heterogeneity, safety issues may outline a negative benefit/risk ratio and a re-assessment was recommended. Furthermore, newer drugs are gaining credit for their possible role as disease-modifying agents in osteoarthritis, e.g., strontium ranelate, a chemical entity currently marketed for the treatment of post-menopausal osteoporosis and osteoporosis in males. Scavenger receptor exhibited effects on sub-chondral bone and cartilage, which may be suggestive of a beneficial effect on osteoarthritis progression.

Acknowledgement

None

Conflict of Interest

None

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