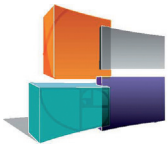
Anaesth Crit Care Pain Med 36 (2017) 109–114



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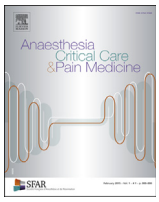

Original Article

The efficacy of intra-articular lidocaine administration in chronic knee pain due to osteoarthritis: A randomized, double-blind, controlled study☆

H. Evren Eker*, Oya Yalcin Cok, Anis Aribogan, Gulnaz Arslan

Baskent university, faculty of medicine, department of anaesthesiology and reanimation, discipline of pain medicine, Adana teaching and medical research centre, Dadaloglu Mahallesi, no. 4/A, Serinevler 2591 sk., 01250 Yuregir/Adana, Turkey

ARTICLE INFO

Article history:
Available online 30 July 2016

Keywords:
Osteoarthritis
Chronic pain
Lidocaine
Intra-articular injection

ABSTRACT

Background: Intra-articular injections for the treatment of knee pain due to osteoarthritis are performed when conservative therapies have failed. The intra-articular injection of lidocaine may be an effective treatment modality due to its neuronal membrane-stabilizing effect and long-lasting anti-inflammatory action. In this study, we compared the efficacy of intra-articular 0.5% lidocaine versus saline injection on pain, stiffness and physical function in patients with osteoarthritis.

Methods: Patients with osteoarthritis were randomly allocated to two groups. Group I ($n = 26$) received 7 mL 0.5% lidocaine and group II ($n = 26$) received 7 mL saline into the painful knee for a series of three injections spaced by 1 week intervals under ultrasound guidance. Knee pain was measured with a numeric rating score (NRS) at baseline and 3 months after the 3rd injection. WOMAC scales, including pain (WOMAC-P), stiffness (WOMAC-S) and physical function (WOMAC-F), were assessed and recorded at baseline, 30 minutes after the 1st injection, immediately prior to the 2nd and 3rd injections and 3 months after the 3rd injection.

Results: Demographic data were comparable between groups. The NRS after 3 months was significantly lower in group I ($P = 0.001$). The WOMAC-P, immediately prior to the 3rd injection and 3 months afterwards, was significantly lower in group I ($P = 0.006$, $P = 0.001$, respectively). The WOMAC-S was improved prior to the 3rd injection and sustained until 3 months in group I ($P = 0.035$, $P = 0.004$, respectively). The WOMAC-F was improved after the 1st injection and sustained until 3 months in group I ($P = 0.002$, $P < 0.0001$ and $P < 0.0001$, respectively).

Conclusions: Intra-articular 0.5% lidocaine injection under ultrasound guidance has a potential role in the management of chronic knee pain due to osteoarthritis for a 3-month period.

1. Introduction

Osteoarthritis causes knee joint pain and dysfunction due to joint degeneration, a process that involves progressive loss of articular cartilage, sclerosis of subchondral bone and osteophyte formation. The incidence of knee osteoarthritis increases rapidly after the age of 40 and oxidative damage is responsible for the age related loss of chondrocyte function. The increased loading of the knees also accelerates degeneration with the presence of inflammation [1].

The key objective for the treatment of osteoarthritis is to suppress pain and improve function. The patients unresponsive to conservative management to achieve these goals are usually offered intra-articular injections. The goal of intra-articular injections is in general to delay the timing for knee arthroplasty for younger patients or to avoid such surgery in older patients. Considering current techniques, intra-articular corticosteroid therapy is effective for pain reduction but provides only short-term benefits (< 3 weeks) and there is a lack of evidence for efficacy in functional improvement [2]. Viscosupplementation provides viscosity and elasticity of the synovial fluid and hyaluronic acid delays the development of osteoarthritis at early stages through a chondroprotective effect. In the synovial fluid, the latter supplements endogenous hyaluronan, which serves as a lubricant and shock absorber. However, hyaluronic acid protects

☆ Clinical trial registration number: NCT02632565.

* Corresponding author.
E-mail address: evreneker@yahoo.com (H.E. Eker).

http://dx.doi.org/10.1016/j.accpm.2016.05.003

against osteoarthritis in the long-term and requires recurrent injections [2,3].

The search for an efficient treatment can be oriented towards potent, long lasting anti-inflammatory agents due to the inflammatory mechanism of osteoarthritis. Lidocaine has been studied for its ability to inhibit both components of C fibres and sympathetic postganglionic neuron (SPGN) mediated inflammation in the rat knee joint [4]. Its anti-inflammatory effects were demonstrated at subclinical concentrations, although lidocaine is often used at higher concentrations (with possible neurotoxic and myotoxic effects) for acute pain treatment [4]. It is also known that amide local anaesthetic agents provide long-lasting anti-nociceptive effects by inhibition of induction of peripheral and central sensitization. Therefore, the intra-articular injection of lidocaine can be considered as a valuable treatment modality due to its neuronal membrane-stabilizing effect and long-lasting anti-inflammatory action.

This is the first clinical, randomized, controlled study which evaluates the benefit of intra-articular injections of lidocaine in osteoarthritis. In this study, we compared the efficacy of intra-articular 0.5% lidocaine versus saline injection on pain, stiffness and physical function in patients with osteoarthritis according to a NRS and WOMAC scales and performed injections under ultrasound guidance to identify the correct trajectory for needle placement and increase accuracy.

2. Materials and methods

This study was approved by the Baskent university Institutional review board and ethics committee (project no.: KA08/83) and supported by the Baskent university research fund. The patients with chronic knee pain due to osteoarthritis received written information about the study and any patient who accepted to participate provided written informed consent. The trial was designed as a prospective, double-blind, randomized, controlled study. A random allocation sequence was consecutively numbered for the participants and opaque, sealed envelopes determining control or treatment group was generated with a computer.

The patients with knee pain due to osteoarthritis who had only temporary relief with medical and/or physiotherapy were referred to the pain clinic. Knee pain, morning stiffness, crepitation and osteophytes on x-ray examination indicating knee osteoarthritis were examined at the initial visit [5]. Kellgren-Lawrence grades 2 to 4 were assigned for the radiologic criteria of osteoarthritis and obtained with an anteroposterior radiography of the patient in the upright standing position with the knee fully extended [6]. The validated Turkish version of the Western Ontario and McMaster universities (WOMAC) scale, in which high scores indicate more and worse symptoms, was used to determine the severity of osteoarthritis and to assess patients at each visit [7,8].

The inclusion criteria were:

- one-sided chronic knee pain due to osteoarthritis with morning stiffness, crepitation and osteophytes on x-ray examination;
- confirmation of osteoarthritis according to the WOMAC scale;
- refractory pain despite medical pain therapies and/or physiotherapy or patients who were unable to complete the therapies;
- average daily pain intensity ≥ 5 on an 11-point Numerical rating scale (NRS).

The exclusion criteria were:

- chronic pain in both knees;
- accompanying symptoms in one or both knees for tendinitis, bursitis, chondromalacia patella and rheumatoid arthritis;
- the possibility of an accompanying diagnosis of fibromyalgia and radiating pain due to spinal stenosis without back pain;
- skin lesions and other risk factors for infection;
- history of mechanical derangement, trauma (dislocation, meniscus tear, torn ligament) or surgery;
- anticoagulant therapy.

Group I ($n = 26$) received intra-articular injections of 7 mL 0.5% lidocaine and group II ($n = 26$) received intra-articular injections of 7 mL saline into the painful knee for a series of three injections spaced over one week intervals. Ultrasound guidance was used for all injections. At the initial visit, all patients were evaluated with a baseline data survey including age, sex, weight, height, body mass index (BMI), osteoarthritis classification, affected knee, intensity and duration of pain, previous pharmacotherapy and physiotherapy.

The primary outcome measure of the study was based on pain and knee pain was measured with an 11-point Numerical rating scale (NRS) at baseline and 3 months after injections. The secondary outcome measures were based on the determination of stiffness and physical function in addition to pain. The WOMAC scale consists of 24 questions grouped into 3 subscales including pain (WOMAC-P), stiffness (WOMAC-S) and physical function (WOMAC-F). The latter were performed for assessment and recorded at baseline, 30 minutes after the 1st injection, immediately prior to the 2nd and 3rd injections and 3 months after the 3rd injection. There are five alternative answers to every question (0 = none, 1 = slight, 2 = moderate, 3 = very, 4 = extremely) and the maximum score is 20 points for pain, 8 points for stiffness and 68 points for physical function. The patients were offered tramadol 50 mg with a maximum dose of 4 times per day when required during the 3 month period and analgesic consumption was recorded. Initial assessments and examinations were performed by a senior pain physician. All records at each visit were collected by the same-blinded pain practitioner.

2.1. Ultrasound guided injection technique

The procedure was performed through the infrapatellar region with the patient placed in a sitting position with the knee flexed at a 90° degree angle to maximally stretch the patellar tendon, widen the entrance and abduct the Hoffa fat pad. An ultrasound machine with a 6 to 13 MHz linear array probe was used (Fujifilm Sonosite, Inc. Bothell, WA 98021, USA). Ultrasound was performed primarily to identify findings in the injection site and to estimate the approach route to the target point before performance of intra-articular injection. The patella, femur and tibia/fibula, patellar ligament, patellar fat pads and joint space (which is the target site) were identified. The entrance route of the needle was estimated through the midpoint of the patellar ligament and just over the upper part of the patellar fat tissue. The inverted triangular image visualised as a hypo-echoic space was encircled by the patellar ligament as well as the femoral and tibia bones. Following sterile preparation, the transducer was placed over the patella tendon perpendicularly and aligned on the axial plane to both sides until achieving the widest, simultaneous image of the intra-articular space, femur and tibia on the ultrasound screen. The needle is then introduced with an out-of plane technique (Fig. 1).

2.2. Intra-articular injection procedure

The solution for intra-articular injection was prepared by a technician with 2.5 mL 2% lidocaine and 7.5 mL saline for the study group and 10 mL saline for the control group. A total of 7 mL was injected for each procedure. Twenty-three gauge 1.5-inch syringe needles were used. All injections were carried out by the same pain