Effect of sodium hyaluronate on recovery after arthroscopic knee surgery: a randomised controlled trial

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Introduction
Arthroscopic knee surgery is a commonly performed day case procedure, associated with rapid recovery. Though the incidence of complications is low, patients may experience side-effects such as pain, swelling and loss of joint mobility in the early postoperative period. Although these side-effects may be attributed to a large extent to the surgical trauma, various reports have commented on the negative influence of irrigating fluid (saline) used in arthroscopy. Sodium hyaluronate (HA) is a viscous fluid substitute widely used in the treatment of osteoarthritic joints. Intrarticular injection of exogenous HA can help to relieve pain and improve function in osteoarthritic knees. Although, reports have shown that exogenous HA produces tissue healing and protects articular cartilage and synovial membrane from damage following the experimental insult to joint tissues,1 intrarticular injection of HA has been shown to augment the flow of synovial fluid, normalise its synthesises and inhibit the degradation of endogenous HA.2

Methodology
This study was conducted at Royal Oldham Hospital, Oldham, UK, between 2002 and 2004. It was approved by the local ethics and research committee.

Study design
A single centre, randomised, blind prospective clinical trial.

Inclusion criteria: Patients aged older than 18 years, who had a clinical indication for knee arthroscopy (OA) were included in the study. Patients with osteoarthritis (OA) were selected from rheumatology outpatients. Informed consent was provided.

Exclusion criteria: Patients excluded if they had anterior knee pain; severe OA, as shown by radiographs of tibial osteoarthritis; crystalline arthritis or inflammatory arthritis or malignancy or any clinical examination; local infections; known hypersensitivity to nonsteroidal anti-inflammatory drugs or exogenous hyaluronate or other components of Viscoseal®. Pregnant or lactating patients were also excluded.

Study procedure
Following arthroscopic knee surgery, patients were randomised to one of two groups. The control group had 10 ml of 0.9% bupivacaine injected into the joint after the procedure. Following evacuation of saline (as is the current practice in our centre), while the group had 10 ml of Viscoseal® injected to the joint. Randomisation was achieved by the use of a computerised random number algorithm to create 50 cards that were placed in sealed opaque envelopes. Following arthroscopy, envelopes were opened in theatre by a theatre practitioner who was not connected with the trial. Opening of the envelope was determined at the point of intervention. The allocated group, whether blinded or not revealed in the case notes and patients were kept blinded to their ultimate allocation.

Each injection of fluid was given via a suprapatellar approach, under arthroscopic visualisation. All patients had arthroscopic diagnostic follow-up by the treating consultant to their pathology. Similar arthroscopic portals were used in all cases. Minimal manipulation were tried to a visible rim. Loose debris and articular cartilage flaps were removed. No chondroplasty, abrasion or partial meniscectomy was performed. Patients were given clobidronate (Phosphate of orally, 10 mg, once a day), paracetamol (300 mg), 3 times a day for pain control and were asked to record the number of tablets used.

End points
Outcome measures were recorded by patients who were given questionnaires to assess their pain and function at the time of admission and at various times during treatment. The surgical intervention was followed by all patients. No walking aids were used and a graduated exercise programme was followed by all patients. No walking aids were used and a graduated exercise programme was followed by all patients. Pain was assessed using the visual analogue scale.

Statistical analysis
Purposive analysis had suggested that, assuming a difference in pain between groups of 1 cm on the VAS, and a standard deviation of 1 cm in each group, at least 22 patients would be required at each time point (12 patients in the control group and 10 in the study group). The sample size was calculated using the difference of means test (expanded twofailed test, significance p < 0.05).

Results
A total of 72 patients were invited to participate, of whom 49 agreed to participate in the study. Among the arthroscopy, 24 patients were assigned to each group. Follow-up was available for 45 patients (21 in the study group and 22 in the control group). Baseline demographic data are shown in Table 1. There were no differences in age, sex, their preoperative pain and function levels (as seen by VAS scores and weight bearing on implant). Differences of 12.13 patients among the two groups had similar distribution of pathology and treatment procedures (Table 1). Patients were considered to be in the OA group if radiographic evidence of a loss of more than 75% of articular cartilage was noted or if, during arthroscopy, grade 3 OA changes were noted in more than one compartment.

Discussion
Arthroscopic knee surgery is a safe procedure with a low incidence of complications,1,2 but it is often associated with pain and swelling and loss of joint mobility in the early postoperative period. This not only has an important bearing on patient comfort but may determine the speed of recovery after surgery. A low level of pain has a very positive effect on the patient’s mood, which in turn aids rehabilitation. This study was designed to determine whether a postoperative injection of sodium HA would aid the rehabilitation of a patient by reducing pain and improving function.

HA is an uncharged, high molecular weight polysaccharide belonging to the family of glycosaminoglycans and is a normal vital constituent of both articular cartilage and synovial fluid. The principal role of HA is to maintain the structural and functional characteristics of the extracellular matrix of the cartilage and the biological fluids. HA provides synovial fluid with its remarkable physical properties, allowing it to act as a lubricant, a shock absorber and a substrate for SAAG. By enhancing the movement of potentially damaging cells and molecules through the joint space.4 Viscoseal® with HA is proposed to protect matrix components and decrease local effects of osteoarthritis and ochronous tissue from mechanical stress and to give synovial joint relief by covering the nociceptors in the joint capsule.1 Exogenous HA has been used in various orthopaedic joints in addition to other products and has been shown to have a significant effect on the pain and function.5 In the immediate postoperative period while less analgesic was consumed in the study group at 3 and 6 weeks, there was also a significant difference in pain and swelling at 6 weeks between the two groups, according to assessment by the independent physiotherapist (Figure 2).

Conclusion
Vaccinoptheorists after arthroscopic knee surgery offers significantly improved function and outcomes over the contemporary period. Further larger studies would help to identify differences of effect in different subgroups of patients population.

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References