

Study on Role of Viscosupplementation in Primary Osteoarthritis of Knee in Elderly Population

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ABSTRACT

Introduction: Knee osteoarthritis is a common and progressive joint disease. With an estimated incidence rate of 240 per 100,000 populations per year, it is a major public health problem in the US and often results in early retirement and joint replacement.

Methodology: This study was conducted among 30 elderly (60 years & above) patients attending out-patient department of Orthopaedics of Medical College & Hospital, Kolkata with primary osteoarthritis of knee.

Result: By age-> Although not an inevitable consequence of ageing, OA is strongly age related; this may reflect the cumulative effect of insults to the joint, aggravated by decline in neuromuscular function or senescence of homeostatic repair mechanisms.

By gender-> Women have a higher prevalence and radiographic severity of OA knee. Women are also more likely to have symptoms if radiographic OA is present.

By occupation-> Labors and weight bearers are mostly affected, of which again homemakers (women) are involved in this study.

Conclusion: This study was conducted to establish the effective implementation of intra-articular hyaluronic acid injection therapy in osteoarthritis of knee in comparison with the results of conservative therapy and intra-articular steroids injection therapy. We come into conclusion that injection Hylan G-F 20, if its cost is reduced, might be at least used for the treatment of primary OA knee very early to better avoid the costly surgical intervention like prosthesis or total joint replacement.

Key words: Viscosupplementation, Primary Osteoarthritis, Knee, Elderly Population.

INTRODUCTION

Knee osteoarthritis is a common and progressive joint disease. With an estimated incidence rate of 240 per 100,000 population per year, it is a major public health problem in the US and often results in early retirement and joint replacement. In the absence of effective disease modifying medical interventions for knee osteoarthritis, treatments are primarily symptomatic in nature, often including intraarticular

injections of a corticosteroid or hyaluronic acid. Corticosteroids have been employed for years in treatment of osteoarthritis, and as a result, rheumatologists have substantial clinical experience of their utility and effectiveness. Consensus statements widely recommend corticosteroids as useful adjunctive treatment in the management of knee osteoarthritis. Clinical trials and meta-analyses have demonstrated their efficacy. Hyaluronic acid, a large viscoelastic

glycosaminoglycan that is naturally present in healthy joint fluid is a relatively new intervention that is now widely used. It confers to joint fluid a number of protective properties, including shock absorption, traumatic energy dissipation, protective coating of the articular cartilage surface and lubrication. The original biologic rationale for the therapeutic use of synthetic hyaluronic acid in knee osteoarthritis was its potential to increase the viscosity of synovial fluid. Therefore, the basis for the Food and Drug Administration's approval for hyaluronic acid was a medical device rather than a pharmaceutical, and despite many placebo-controlled trials of hyaluronic acid products, contention remains regarding their effectiveness. Although numerous clinical trials reported durable benefits on knee Osteoarthritis, others failed to show benefits compared with placebo.

This raised the question about the magnitude of therapeutic effects of hyaluronic acid products and stimulated a number of meta-analyses. However the conclusions of meta-analyses were also inconsistent: 2 analyses drew strongly positive conclusions but had potential conflicts of interest; 2 reported a small effect; and 2 others inferred that hyaluronic acid is not more effective than saline as a placebo. In the trace of this controversy, we aim to re-examine the clinical usefulness of hyaluronic acid products from the perspective of their relative efficacy when compared with intraarticular corticosteroids conservative treatment.

Aims and Objectives

Purpose of our study is to compare the results of conservative therapy, intra-articular corticosteroids injection therapy and intra-articular hyaluronic acid injection therapy in primary osteoarthritis of knee.

Specific Objectives of This Study

1. To compare the results between conservative, intra-articular corticosteroids and intra-articular hyaluronic acid injection in primary osteoarthritis of knee.
2. To evaluate the functional outcomes of the three modes of treatment in primary osteoarthritis of knee.

METHODOLOGY

Study area: Medical College, Kolkata

Study period: Six months

Sample size: 30 patients total:- 10-conservative treatment; 10-i.a. steroids injection; 10-i.a. hyaluronic acid injections.

Sample design

1. Patient selection:

This study was conducted among the elderly (60 years & above) patients attending outpatient department of Orthopaedics of Medical College & Hospital, Kolkata with primary osteoarthritis of knee.

2. Inclusion criteria:

Patients above 60 years with knee joint pain including both male and female.

3. Exclusion criteria:

- Age below 60 years
- Pain in knee after trauma
- Local infections in and around knee joint
- Uncontrolled diabetes mellitus
- Severe joint deformity
- Patient on anticoagulant therapy
- Patient with history of surgery in and around the knee

Study design:

Institutional based prospective study.

Study tools:

- 20-ml, 10-ml and 3-ml disposable syringes
- 20-gauge 1 ½-inch needles
- 22-gauge 1-inch or 1 ½-inch needles
- Paper towels or drapes, disposable gloves
- Forceps, alcohol sponges

- Povidone-iodine solution (or equivalent) or other antimicrobial solution
- Lidocaine 1% (without epinephrine)
- Adhesive bandages
 - Corticosteroids injections (methyl prednisolone)
 - Hyaluronic acid injections

Parameters to be studied:

Core outcomes to be identified in accordance with the recommendations of the Outcome Measures in Arthritis Clinical Trials (OMERACT) III consensus conference.

1. Pain
2. Physical function
3. Patient global assessment

Plan for data analysis:

Details of demographic features, occupation and outcome measures of different treatment options from the schedules were verified, sorted and tabulated in appropriate tables. Relevant findings of different treatment types implemented in causation of alleviation of symptoms and their clinical variables were discussed.

RESULTS AND DISCUSSIONS

Overview:

- i) Osteoarthritis (OA) is the most common form of arthritis
- ii) Symptoms of OA are often episodic
- iii) The goals of treatment are to relieve pain, minimize disability and improve quality of life
- iv) Non-pharmacologic treatments are as important as pharmacologic treatment for OA

v) The effect of corticosteroids is largely absent by the 26-week time point, but the absolute effect of hyaluronic acid at this time point is modest

vi) Criteria of joint replacement include uncontrolled pain and severe impairment of function despite conservative treatment

1. Guidelines for management of OA:

i) Conservative treatment [education, exercise programme, advice to reduce adverse mechanical factors, thermo therapy, weight loss of obese, acupuncture, electrotherapy, paracetamol, topical NSAIDs, topical capsaicin, oral NSAIDs, opioids, chondroitin-glucosamine preparations, walking aids, braces, assistive devices etc.]

ii) Intra articular corticosteroid injection [methyl prednisolone]

iii) Intra articular hyaluronic acid injection

TABLE-1: Distribution of types of treatment options

Type of treatment	No. of patient	Percentage (%)
CONSERVATIVE	10	33.33
I-A CORTICOSTEROIDS	10	33.33
I-A HYALURONAN	10	33.33

2. Demographic Profile

By age-> Although not an inevitable consequence of ageing, OA is strongly age related; this may reflect the cumulative effect of insults to the joint, aggravated by decline in neuromuscular function or senescence of homeostatic repair mechanisms.

By gender-> Women have a higher prevalence and radiographic severity of OA knee. Women are also more likely to have symptoms if radiographic OA is present.

TABLE-2: Age-wise distribution of respondents

Age group	Conservative	I-A corticosteroids	I-A hyaluronan	Total
60-64 years	03	03	03	09
65-74 years	03	06	06	15
75 years+	04	01	01	06
Total	10	10	10	30

By occupation-> Labors and weight bearers are mostly affected, of which again homemakers (women) are involved in this study.

Table-3: Distribution according to occupation

Occupation	Conservative	I-A corticosteroid	I-A hyaluronan	Total
Labour	02	03	01	06
Athelets	01	0	0	01
Retired	05	0	01	06
Homemakers	02	07	08	17
Total	10	10	10	30

3. Outcome measures in arthritis clinical trials

By subsidence of pain and swelling->

Table-4: Showing distribution of symptomatic relief of pain and swelling.

Treatment options	Outcome measures initiation	Time point of relief
Conservative	Instant	Very short lasting
I-A corticosteroid	4 weeks (approx)	< 8 weeks
I-A hyaluronan	4 weeks (approx)	>12 weeks

By restoration of Physical function/ limiting disability->Achieving Activity Daily Living (ADL) and/or Instrumental Activity Daily Living (IADL)

ADL i.e., person himself is capable of dressing, bathing, eating, toileting, walking and climbing a plight of stairs in his or her daily activities and able to take care of own. IADL i.e., person himself is also capable of shopping, financing, banking, attending telephones, cooking, laundering, washing etc. which require little skill. Analgesics or braces are usually very quickly omitted after treatment with hyaluronan injection.

Table-5: Showing restoration of physical function (ADL/ IADL).

Treatment options	Time elapsed since restoration	Effectivity of restoration
Conservative	Nothing suggestive	Nothing suggestive
I-A corticosteroid	6 weeks (approx)	< 20 weeks
I-A hyaluronan	4 weeks (approx)	>24 weeks

By patient global assessment->

U.S. study=> age-wise: 45-64 years----21.3 million
 65 & older-----18.4 million (Rarely below 40 years)
 gender-wise: women-----38.2 million
 men-----25.7 million

The importance of a multi disciplinary care pathway in the management of osteoarthritis is now well recognized globally. A community-wide approach encompassing the involvement and education of both patient and primary care physician will lead to earlier diagnosis, speedier and more appropriate secondary care referrals, quicker treatment and ultimately improved clinical outcomes.

SUMMARY

Osteoarthritis is defined as a heterogeneous group of conditions that leads to joint symptoms and signs which are associated with defective integrity of articular cartilage in addition to related changes in the underlying bone at the joint margins. It refers to a clinical syndrome of joint pain accompanied by varying degrees of functional limitations and reduced quality of life. It is the most common form of arthritis and one of the leading causes of pain and disability worldwide. Knees, hips and small joints of hands are most commonly affected. Although pain, reduced function and participation restriction can be important consequences of osteoarthritis, structural changes often occur without accompanying symptoms.

Clinical variants of osteoarthritis

- Monoarticular and pauciarticular osteoarthritis
- Polyarticular (Generalised) osteoarthritis
- Osteoarthritis in unusual sites

- Rapidly destructive osteoarthritis

Osteoarthritis is a metabolically active repair process that takes place in all joint tissues and involves localized loss of cartilage and remodeling of adjacent bone. Osteoarthritis is a slow but efficient repair process that often compensates for the initial trauma, resulting in a structurally altered but symptom-free joint. In some people, either because of overwhelming trauma or compromised repair potential, the process cannot compensate, resulting in continuing tissue damage and eventual presentation with symptomatic osteoarthritis or 'joint failure'. This explains the extreme variability in clinical presentation and outcome that can be observed between people and also at different joints in the same person. This study was conducted to establish the effective implementation of intra-articular hyaluronic acid injection therapy in osteoarthritis of knee in comparison with the results of conservative therapy and intra-articular steroids injection therapy. We come to the conclusion that injection Hylan G-F 20, if its cost is reduced, might be at least used for the treatment of primary OA knee very early to better avoid the costly surgical intervention like prosthesis or total joint replacement. Also it may be attempted in cases of oldest-old patients where surgery is contraindicated otherwise. However, if we assume that the effect of corticosteroids is largely absent by the 26-week time point, we might infer that the absolute effect of hyaluronic acid at this time point is modest. I-A corticosteroid appears to be relatively more effective for pain than I-A hyaluronic acid. By week 4, the 2 approaches have equal efficacy, but beyond week 8, hyaluronic acid has greater efficacy. Understanding this trend is useful to clinicians when treating knee OA.

Recommendations

The goals of medical management of Knee OA in an aged person are to:

- (a) Provide patient education and information access
- (b) Relieve pain
- (c) Optimize physical function and
- (d) Minimize disease progression

Intra-articular corticosteroids injection is a valuable treatment that often gives effective quick relief of pain that may last just a few weeks to few months. It may be particularly useful to tide a patient over an important event (e.g., family wedding, holiday) and to improve pain during initiations of other interventions such as an exercise programme.

But, nevertheless, a variety of hyaluronan preparations are available, given as a single injection or a course of one per week for 3-5 weeks, although a modest, relatively prolonged (several months) improvement in pain may result, the cost and logistics of this treatment are limiting. It may be regarded as an alternative management guideline in respect of end-stage knee OA where surgical maneuvers like joint replacement could be delayed or avoided, if contraindicated, or as the latter is concerned with the issues of huge funding, waiting times, choice of prosthesis and revision have to be faced.

Future scope of the study

It is hoped that further exploration may be carried out in near future, since the structure of an effective health education programme for this highly susceptible group would depend to a large extent on the findings of such study to carry out initiation of treatment at the outset rather than at a mature state, which is a major stumbling block to successful achievement of activity of daily living (ADL) in elderly persons and to reduce the burden of the cost of financial budget of the nation.

Recognition of corticosteroids' adverse effect, if absorbed in the system, has been entirely neglected and variables leading to causation of the side effects have not been enlightened.

The issues discussed in this study have global application, as the burden of illness from musculoskeletal conditions is high in both the developed world and developing countries alike, particularly with an ever-increasing elderly population worldwide. In developing countries, it is essential to involve local community leaders and community health workers in the management of patients with these conditions. For patients with osteoarthritis, optimal management depends on developing an efficient triage system that include health care professionals, governments and members of the public. In spite of a number of studies which were conducted abroad no definite profile of non-pharmacological and pharmacological treatment of osteoarthritis has yet been defined.

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