Functional Outcome of Intra-Articular Corticosteroid Injections for Knee Osteoarthritis in Bangladeshi Patients

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Abstract

Introduction: Knee osteoarthritis is common joint disease, with an incidence of 30% of the population older than 60 years. Intra-articular injection of steroid is a common treatment option for osteoarthritis of the knee. However, there is scarcity of studies regarding the outcome of intra-articular corticosteroid therapy for osteoarthritis of knee joint. Therefore, the aim of this study was to evaluate the functional outcome of intra-articular corticosteroid injections for the management of knee osteoarthritis.

Methodology: In this prospective hospital based clinical trial, patient >45 years of age presented with knee osteoarthritis (Kellgren Lawrence grades 1 to 3) was assigned. Study was conducted for six months from January 2022 to July 2022 in Chittagong Medical College Hospital. Total 30 samples were included in this study and follow up was done after 3 months. The overall functional outcomes were measured by Visual Analog Scale (VAS) and Oxford Knee Score. Data was analyzed by using windows-based computer software devised with SPSS-25.

Results: In this study, out of 30 cases, 20 (66.7%) were male and 10 (33.3%) were female, there was male predominance with male to female ratio about 2:1. Majority of the cases (57.7%) was in 55 to 64 years of age group. The mean ± SD age of the cases was 56.83 ± 5.742 years (range: 45-69). Out of 30 cases, most of the cases {16 (53.3%)} were affected at left side. Before getting injection, both severe and very severe pain was observed among 13 (43.3%) patients and 4 (13.3%) patients had moderate pain. After 3 months of injection, there was no pain among 8 (26.7%) patients and 22 (73.3%) patients had mild pain according to VAS. Pre-injection group, 21 (70%) patients had severe knee arthritis and 9 (30%) patients had moderate to severe knee arthritis. After getting injection, there was satisfactory joint function among the 4 (13.3%) patients and 26 (86.7%) patients had mild to moderate knee arthritis according to Oxford Knee Score. Both VAS and Oxford Knee Score changed significantly 3 months after intra-articular corticosteroid injection.

Conclusion: This present study concludes that intra-articular corticosteroid injection for osteoarthritis of knee produces significant pain relief for most patients even in severe cases and may provide better functional outcomes.

Keywords: Knee; Osteoarthritis; Intra-articular injection; NSAIDs; Corticosteroid

Abbreviations

VAS: Visual Analog Scale; NSAIDs: Non-Steroidal Anti-Inflammatory Drugs; OA: Osteoarthritis; KOA: Knee Osteoarthritis; HTO: High Tibial Osteotomy; COX-2: Cyclooxygenase-2; HA: Hyaluronic Acid; PRP: Platelet Rich Plasma; OKS: Oxford Knee Score; WHO: World Health Organization; WOMAC: Western Ontario and Mc Master

Introduction

Knee Osteoarthritis (OA) is a chronic, degenerative, and progressive disease of articular cartilage, producing discomfort and physical disability in older adults. Thirteen percent of elderly people complain of knee osteoarthritis [1]. Osteoarthritis (OA) is a leading cause of disability

among older adults [2]. It is the most frequent form of arthritis and a cause of pain and disability [3], affecting an estimated 302 million people worldwide [4]. A study conducted in India among adults had shown a significant difference in the prevalence of OA between rural (56.6%) and urban areas (32.6%) [5]. Due to lifestyle habits, Asians have a higher risk for knee joint arthritis compared to Americans and Europeans [6]. As OA spans decades of a patient's life, patients with OA are likely to be treated with a number of different pharmaceutical and non-pharmaceutical interventions, and often in combination [7].

The pathological characteristics of Knee Osteoarthritis (KOA) include joint structure degradation, cartilage destruction with joint pain, dysfunction and joint deformity as the main clinical symptoms. KOA affects about 50% of >60-year-old individuals, especially women and it is associated with post-menopausal osteoporosis and significant bone mass reduction. This condition is characterized by complex causes and long course, which lead to progressive exacerbation and ineffective conservative treatment. Surgical methods for KOA include arthroscopic debridement, High Tibial Osteotomy (HTO), proximal fibular osteotomy and uni-compartmental or artificial total knee arthroplasty [8].

The cause of OA remains unknown, though there is clear evidence for major risk factors, such as age, obesity, joint trauma and heavy work load. The risk factors can be divided into two categories; general (for e.g., age, gender, genetics, and overweight) and local biomechanical factors, such as joint injury, mal-alignment, overweight and muscle weakness. Abnormal mechanical loading in various sport activities or during heavy work may activate the biochemical cascade that leads to joint degeneration and pain [9].

Management options for knee OA could be divided into the following categories: Conservative, pharmacological, procedural, and surgical. Joint replacement is the gold standard, reserved for severe grades of knee OA, due to its complications rate and increased risk of joint revision. A nonsurgical approach is the first choice in the adult population with cartilage damage and knee OA [1]. Pharmacological therapy consists of analgesics and anti-inflammatory agents that are administered gradually. According to guidelines, therapy should start with acetaminophen (up to 4 g/day), which is suggested as first-line systemic treatment for symptomatic OA, because its effectiveness has been found to be similar to Nonsteroidal Anti-Inflammatory Drugs (NSAIDs), but with lower gastrointestinal adverse effects and a stronger association with maintenance of warfarin [10,11].

NSAID therapy (ibuprofen, naproxen, diclofenac) is recommended when symptoms are moderate to severe or when there is no response to acetaminophen. NSAIDs are the most frequently utilized pharmacological molecules, although their use is limited because of their high incidence of gastrointestinal side effects, such as peptic ulcer and gastrointestinal bleeding, but also renal dysfunction and blood pressure elevation [12]. The role of Cyclooxygenase-2 inhibitors (COX-2) is to reduce the gastrointestinal adverse effects and to improve the safety profile, but cyclooxygenase-2 inhibitors are associated with higher cost and cardiovascular complications, such as myocardial infarction and stroke [12,13].

Opioids (such as tramadol) may be used to treat OA pain in patients who do not respond to acetaminophen or NSAID therapy; it is also used to reduce the side effect of these drugs. Opioids should be provided starting at the lowest effective dose and carefully monitored to avoid dependence or abuse; however, they can cause

chronic constipation and increase the risk of falls in older patients. Intra-articular injection can primarily provide short-term relief from symptoms and lead to improvements in pain and function [12].

Yearly, more than 10% of knee OA-affected patients undergo intra-articular injections of different drugs, especially within three months after OA diagnosis. Several molecules, such as corticosteroids injection, Hyaluronic Acid (HA), and Platelet-Rich Plasma (PRP), are used to reduce the symptoms of patients with knee OA [1].

Intra-articular injection of steroid is a common treatment for osteoarthritis of the knee. Clinical evidence suggests that benefit is short lived, usually one to four weeks [14]. Intra-articular corticosteroid injections are common non-operative treatment used inpatients resistant to oral analgesics and physiotherapy even in severe cases who are not willing for surgery [15].

Evidence supports short term (up to two weeks) improvement in symptoms of osteoarthritis of the knee after intra-articular corticosteroid injection. Significant improvement was also shown in the only methodologically sound studies addressing longer term response (16-24 weeks) [16]. There is scarcity of studies regarding the outcome of intra-articular corticosteroid for OA of knee joint. Therefore, evaluation the functional outcome of intra-articular corticosteroid injections for osteoarthritis of the knee joint is required.

Under this circumstance, the purpose of this study was to evaluate the functional outcome of intra-articular corticosteroid injection for management knee osteoarthritis based on Oxford Knee Score and Visual analog score.

Research Question

What is the overall outcome and safety of intra- articular corticosteroid injections for osteoarthritis of the knee Joint?

Objectives

General objective:

• To evaluate functional outcome of intra- articular corticosteroid injections for osteoarthritis of the knee joint.

Specific objectives:

1. To determine the pre-injection and 3 months post-injection Oxford Knee Score.

2. To ascertain the pre-injection and 3 months post-injection Visual Analog Score.

3. To discuss about the sociodemographic profile of the patients.

Operational definitions

• **Osteoarthritis (OA) of Knee:** Osteoarthritis (OA) of the knee joint is a chronic, degenerative problem often associated with pain involving the affected joint, decreased range of motion, and deformity [17].

• **VAS score:** Figure 1 [18]

Methodology

1. **Study design** : It was a prospective hospital based clinical trial.

2. **Place of study** : Outdoor Department of Orthopedic Surgery, Chittagong, Medical College Hospital.

3. **Study period** : From January 2022 to July 2022.

4. **Study population**: All knee osteoarthritis patient visiting the outdoor of CMCH

5. **Sampling technique**: Purposive sampling method was followed as per inclusion and exclusion criteria.

6. **Study Participants**: Patients who fulfill the eligibility criteria & provide informed written consent.

7. **Sample size:**

To observe outcome the sample size for a Clinical trial will be determined by the following formula:

$n = z^2pq/d^2$

Were,

z = z- distribution at a given confidence level

p = prevalence of the event searched out from previous study

q = 1-p

d = precision in the estimate of 'p'

Here,

Z=1.96 at 95% confidence level, p= Prevalence of OA, 3.8% (0.038)[15], q= (1-0.038) = 0.962, d=0.05

n= {(1.96)2 × 0.038 × 0.962}/(0.05)2=56.2 56

So, n=56

Due to some constraints, total 30 patients were included in this study, who were available during the study period.

Selection criteria

Inclusion criteria:

1) Patients with primary osteoarthritis of knee.

2) Kellgren Lawrence grades 1 to 3 who will symptomatic.

3) Even very severe cases of osteoarthritis knee who are not willing for surgery.

Exclusion criteria:

1) Secondary osteoarthritis

2) Past history of Intra-articular injection

3) Unwilling to participate

4) Kellgren Lawrence grade 4

Study variable

- Demographic variables –

1. Age

2. Gender

- Clinical variables-

Side of involvement

- Measurement variables-

VAS score

Oxford Knee Score

Following getting approval by the Ethical and Research Committee of Chittagong Medical College Hospital all patients with knee osteoarthritis vising outdoor of orthopedic surgery, were assessed for eligibility. Written informed consent was taken from the patient and guardian of the patients after explaining detailed procedure and probable outcome.

All the patients were given injection Methylprednisolone 80 mg (2 ml) without local anesthesia into lateral tibiofemoral compartment with knee flexed. In this study the patients were evaluated before administration of injection with routine blood investigations, any abnormal values such as blood glucose, thyroid function; were corrected before injection.

Follow up

The outcome was assessed using Oxford Knee Score and VAS scores, pre injection and 3 months post injection and the results were compared. Patients were contacted over telephone if they were not coming for follow up. At presentation we assessed for pain using VAS and for any improvement in functional outcome using Oxford knee score.

Data collection tool: A data collection form containing history, examination finding of the patient, and follow up were used to collect data.

Statistical analysis

Once data collection is completed, data were compiled and tabulated according to key variables. Analysis of different variables were done according to standard statistical method using SPSS 25. Continuous variables were expressed as mean ± SD and dichotomous variables were expressed as percentages. Two-tailed t test was applied to analyze the mean VAS and Oxford knee score. To determine whether any of the difference between pre-injection and post-injection VAS and Oxford knee score, the nonparametric test (Wilcoxon's signed rank test) was applied. P value less than 0.05 was considered to be significant.

Data presentation

Suitable chart, figures, tables and diagrams was presented the observation and results of the study and statistical analysis. In case of continuous variable mean, range, percentage and Standard Deviation (SD) was used. In case of categorized variable cross table and composite graph was used.

Ethical implication

Intra-articular corticosteroid injection knee osteoarthritis is an invasive procedure. Patients or their legal guardians were consulted about procedure, possible outcome and any complications. Institutional clearance was obtained from the Principal of Chittagong Medical College and Director of Chittagong Medical College Hospital. Written informed consent was taken from all patients. Detailed study related information was read out and explained in the local language from a printed hand out. All aspects including confidentiality and rights not to participate in the study were specially considered.

As per rule of ethical committee of Chittagong Medical College

- Participation was voluntary.

- Consent was obtained after a brief of the study in Bangla or local language to all respondents.

- It was made clear to them that they are free to take part or

withdraw from any part of the study at any stage.

- All answers were kept confidential and was not disclosed without prior permission of respondent.

- Interview was taken in a suitable time and place that was convenient to the responder.

- Refusal to take part or withdrawal from the study was not hamper his/her treatment.

Results

In this study, a patient >45 years of age presented with knee osteoarthritis was the study sample. Total 30 samples were included in this study; patients were followed up after 3 months. The overall functional outcomes were measured by Visual Analog Scale (VAS) and Oxford Knee Score.

Majority of the cases (57.7%) was in 55 to 64 years of age group. The mean ± SD age of the cases was 56.83 ± 5.742 years (range: 45-69 years) (Table 1).

Bar diagram shows the gender distribution of the study cases and it depicts that, there was male predominance with male to female ratio about 2:1. Among 30 cases, 20 (66.7%) were male (Figure 2).

Pie chart shows, in the present study, out of 30 cases, maximum of the cases {16 (53.3%)} were affected at left side and {14 (46.7%)}

Table 1: Distribution of the study population by their age (n=30).

Age (years)	Frequency	Percentage
45-54	10	33.30%
55-64	17	57.70%
≥ 65	3	10.00%
Total	30	100%
Mean ± SD	56.83 ± 5.742	
Range	45-69 years	

Table 2: Pre-injection and post-injection VAS score of the cases (n=30).

VAS	Pre-injection	Post-injection	P value
Mean ± SD	7.13 ± 1.408	2.10 ± 0.803	
Range	5-9	1-3	<0.001***

P value derived from student-t test
***: Very highly significant

Table 3: Mean rank.

Time point	Mean rank	P value
VAS score before injection	3.3	<0.001 from Wilcoxon's signed rank test
VAS score 3 months after injection	0.73	

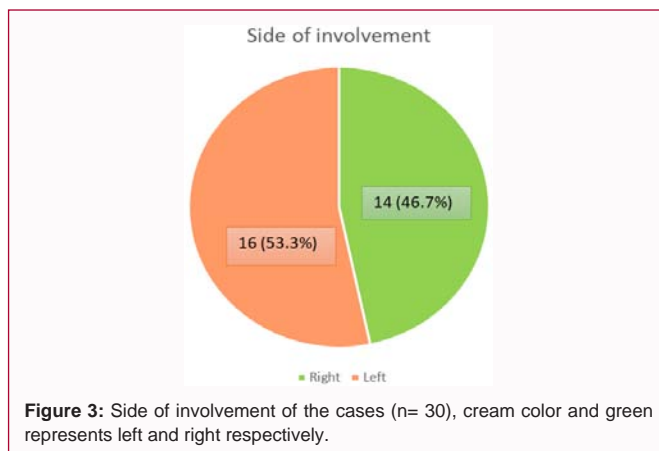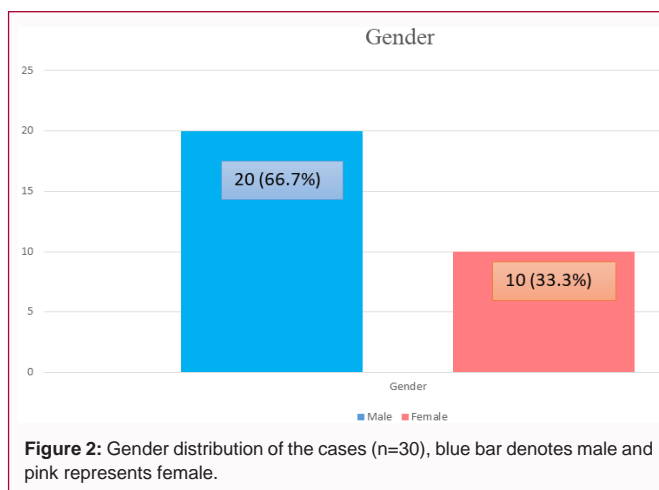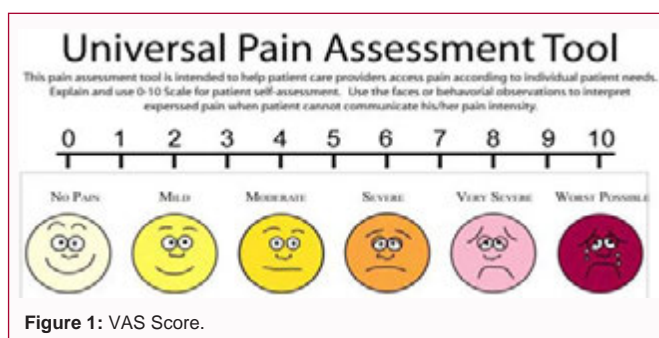**Table 4:** Pre-injection and post-injection Oxford Knee Score of the cases (n=30).

Oxford Knee Score	Pre-injection	Post-injection	P value
Mean ± SD	18.00 ± 2.117	36.53 ± 2.403	
Range	15-22	32-41	<0.001***

P value derived from student-t test
***: Very highly significant

Table 5: Mean rank.

Time point	Mean rank	P value
Oxford knee score before injection	1.3	<0.001 from Wilcoxon's signed rank test
Oxford knee score 3 months after injection	3.13	

Figure 1: VAS Score.

Figure 2: Gender distribution of the cases (n=30), blue bar denotes male and pink represents female.

Figure 3: Side of involvement of the cases (n= 30), cream color and green represents left and right respectively.

affected at right (Figure 3).

Table shows that, mean ± SD pre-injection and post-injection VAS score were 7.13 ± 1.408 (range: 5-9) and 2.10 ± 0.803 (range: 1-3) respectively. P value shows statistically very highly significant changes before and after administration of injection (Table 2).

Before getting injection, both severe and very severe pain were observed among 13 (43.3%) patients and 4 (13.3%) patients had moderate pain. After getting injection, there was no pain among the 8 (26.7%) patients and 22 (73.3%) patients had mild pain. Wilcoxon's signed rank test showed that, the mean rank was significantly reduced from 3.30 to 0.73 after 3 months of treatment (p<0.001) as shown in Figure 4 (Table 3).

According to Oxford Knee Score (OKS), pre-injection and post-injection mean ± SD were, 18.00 ± 2.117 (range: 15-22) and 36.53 ± 2.403 (range: 32-41). P value shows statistically very highly significant

Figure 4: Pre- and post-injection severity of pain (n=30).

Figure 5: Pre- and post-injection joint function (n=30).
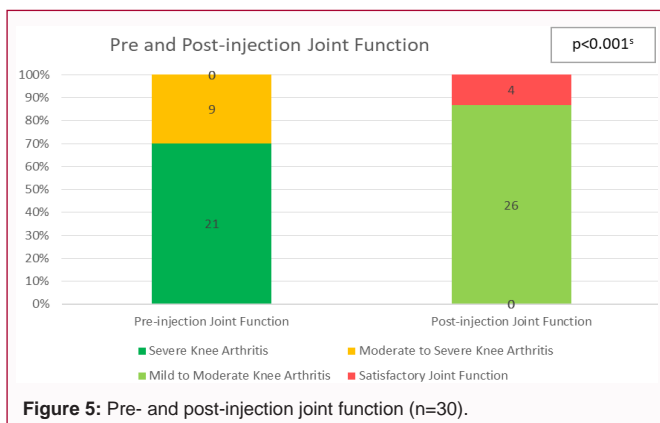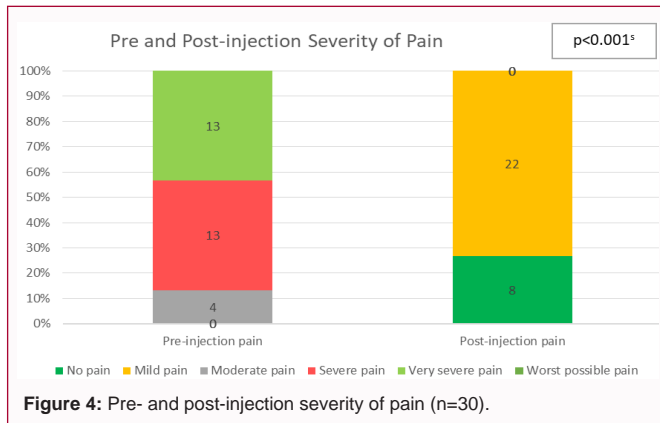
changes before and after administration of injection (Table 4).

Bar chart shows the pre- and post-injection joint function according to Oxford Knee Score. Before injection, 21 (70%) patients had severe knee arthritis and 9 (30%) patients had moderate to severe knee arthritis. After getting injection, there was satisfactory joint function among the 4 (13.3%) patients and 26 (86.7%) patients had mild to moderate knee arthritis. Wilcoxon's signed rank test showed that, the mean rank was significantly increased from 1.30 to 3.13 after 3 months of treatment (p<0.001) (Figure 5 and Table 5).

Discussion

Osteoarthritis of the knee is a common degenerative disorder encountered in a day-to-day practice. Most of the people in our setup take long term Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) to get relief from pain. According to the World Health Organization (WHO), 9.6% of men and 18.0% of women aged over 60 years have symptomatic osteoarthritis worldwide [19].

In our study, majority of the cases (57.7%) was in 55 to 64 years of age group. Study conducted by Laik et al. showed that the maximum number of patients with knee osteoarthritis were found to be in the 6th decade of life with a mean Standard Deviation (SD) age of 55.80 (± 4.41) years [20]. The mean age of patients was 51.8 ± 4.1 years in another study on proximal fibular osteotomy for the management of knee osteoarthritis [21].

Out of 30 patients, 20 (66.7%) were male, there was male predominance with male to female ratio about 2:1. But, gender distribution in Bansal study showed female preponderance with 54 female and 18 male patients [22]. Moreover, Laik et al. in their study on OA of knee found that there were 10 male and 20 female patients

[20]. Dissimilarity was found in case of gender distribution of present study.

Our study showed that most of the involvement of OA of knee was predominantly in left sided. Dissimilarity was reported by Laik et al., where sixteen patients were affected on the right knee with 14 on the left side [20].

Table 2 shows, in present case series, mean ± SD pre-injection and post-injection VAS score were 7.13 ± 1.408 (range: 5-9) and 2.10 ± 0.803 (range: 1-3) respectively. Before getting injection, both severe and very severe pain was observed among 13 (43.3%) patients and 4 (13.3%) patients had moderate pain. After getting injection, there was no pain among the 8 (26.7%) patients and 22 (73.3%) patients had mild pain. Wilcoxon's signed rank test showed that, the mean rank was significantly reduced 3 months after treatment (p<0.001) (Figure 3). P value shows statistically very highly significant changes before and after treatment. Similarly, study done by Sampath and Harshvardhan revealed the mean recorded levels of VAS for pain before injection was 7.2 and after injection was 4.3 (p<0.05) [15]. After treatment in both groups Visual Analogue Scale (VAS) and Western Ontario and Mc Master Universities (WOMAC) index gradually decreased which were statistically significant in the study by Islam et al. [23].

According to Oxford Knee Score (OKS), pre-injection and post-injection mean ± SD were, 18.00 ± 2.117 (range: 15-22) and 36.53 ± 2.403 (range: 32-41) (Table 3). Before injection, 21 (70%) patients had severe knee arthritis and 9 (30%) patients had moderate to severe knee arthritis. After getting injection, there was satisfactory joint function among the 4 (13.3%) patients and 26 (86.7%) patients had mild to moderate knee arthritis. Wilcoxon's signed rank test showed that, the mean rank was significantly increased from baseline to 3 months after treatment (p<0.001) (Figure 4). P value showed statistically significant changes before and after administration of injection. However, the KSS scores were statistically non-significant compared with the pre-injection values in a study done by Sampath and Harshvardhan [15]. A meta-analysis by Arroll et al. describe that, in high quality studies, the pooled relative risk for improvement in symptoms of osteoarthritis of the knee at 16 to 24 weeks after intra-articular corticosteroid injections was 2.09 (95% confidence interval 1.2 to 3.7). The pooled relative risk for improvement up to two weeks after injections was 1.66 (1.37 to 2.0) [16]. More studies are required for evaluation the effectiveness of the Intra-articular corticosteroid injection therapy in knee osteoarthritis.

Conclusion

This present study concludes that Intra-articular corticosteroid injection for osteoarthritis of knee produces significant pain relief for most patients even in severe cases and may provide better functional outcomes. According to the severity of the pathology, intra-articular injections of corticosteroid could be an optimal treatment options with minor adverse events for pain relief and symptom alleviation and can delay surgical treatment. We expect that this study may provide the clinical basis & evidence that is required to perform such managements in routine practice.

Acknowledgement

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