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Original Article

Comparison between Intra-articular and Intramuscular Depot Methylprednisolone Injection in Functional Improvement of Hand in Patients Suffering from Early Rheumatoid Arthritis

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Abstract

Objective: The objective of this study was to compare the improvement in hand function and disease activity among patients receiving intra-articular with intramuscular depot methylprednisolone injections.

Design: A prospective cohort of 136 patients with rheumatoid arthritis were randomly allocated in two parallel groups (IA and IM) who were given depot methylprednisolone injection either intraarticularly or intramuscularly after assessment of wrist ROM, grip strength, CDAI and KFT scores on 1st visit and reassessed at 1 month and 3 months post-injection.

Results: Wrist flexion and extension, power grip and all pinch grips of both hands have shown statistically significant improvement over time between any two visits, except right wrist extension, right and left lateral pinch grip did not have statistically significant improvement between 2nd and 3rd visits. CDAI scores reduced and KFT scores improved in persistent manner more in IM group over time between any two visits which are statistically significant. It is also seen that with decrease in disease activity there is improvement of functional ability in the subjects.

Conclusions: Intra-articular injections have sustained effects throughout the study period in ROM improvement, and intramuscular injections have short-lived effects and are more effective in improving outcomes of functional status and disease activity.

Key words: Grip strength, Hand function, Intra-articular corticosteroid, Rheumatoid arthritis

INTRODUCTION

Rheumatoid arthritis (RA) is the most common form of chronic inflammatory arthritis and often results in joint damage and physical disability.[1] We encounter a lot of patients in our hospital who have significant difficulties in performing activities of daily living due to hand deformities arising due to RA. The incidence of RA increases between 25 and 55 years of age, after which it plateaus until the age of 75 and then decreases.[2] As the disease affects people of working age group, any deformity is likely to cause vocational loss. Thus, avoiding or reducing joint damage by appropriate rehabilitation in both early and established/late RA is very essential to maintain function.

Normal hand function is very important for every person in every aspect of their lives. In RA patients, hand function is severely impaired in basic activities in daily life, professional life and affects the patient physically, socioeconomically, and psychologically.

Both intra-articular and intramuscular corticosteroid injections are well-established methods to control inflammation in RA. Intra-articular corticosteroid injections are predominantly used for treating RA patients with mono or oligoarthritis. Intra-articular injections are performed by allocation of drugs in the intra-articular space aiming to control local inflammation and to promote atrophy of

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the synovial "pannus".[3-5] There are a number of studies showing significant improvement in inflammatory process and reduction of pain in such RA patients. However, there is paucity of literature regarding effectiveness of intra-articular corticosteroid injection in functional improvement and reduction of disease activity of RA patients as compared to systemic steroid administration.

The major goal of treatment for RA is to eliminate articular inflammation, prevention of bone erosion and cartilage damage and, consequently, avoid irreversible functional disability.[6] Hence, it is our earnest endeavor to study the effectiveness of intra-articular versus intramuscular depot methylprednisolone injections in functional improvement of the hand of RA patients.

Aims and Objectives of the Study

The study aimed to compare the improvement in hand function and disease activity among patients receiving intra-articular with intramuscular depot methyl prednisolone injections in patients suffering from early RA.

MATERIALS AND METHODS

Study Period

The study period was 18 months.

Study Design

This was a open-label prospective parallel group observational study.

Study Population

Patients with RA who are attending OPD of the Department of Physical Medicine and Rehabilitation and Department of Rheumatology, Institute of Post-Graduate Medical Education and Research and Seth Sukhlal Karnani Memorial Hospital, Kolkata, India.

Inclusion Criteria

The following criteria were included in the study:

1. Diagnosis of RA as per ACR/EULAR 2010 classification criteria
2. Unilateral or bilateral inflamed wrist joints
3. Age between 18 years and 65 years
4. DMARDS naive newly diagnosed RA with disease duration less than 2 years

Exclusion Criteria

The following criteria were excluded from the study:

1. Advanced RA with hand deformities
2. Uncontrolled diabetes, hypertension, bleeding diathesis, h/o leprosy or any other neuropathic disorder
3. Associated fracture or traumatic injury to tendons
4. Open wound or local skin infection
5. Overlap syndromes
6. Who have received intra-articular steroid earlier or is on systemic steroid at time of presentation.

SAMPLE SIZE CALCULATION

The sample size for the study was calculated on the basis of Clinical Disease Activity Index (CDAI) score as primary outcome measure. It was calculated that minimum 31 subjects should be required per group to detect a difference of 5 in CDAI score between groups with 80% power and 5% probability of Type – 1 error. This calculation assumes a standard deviation of five for CDAI score and two-sided testing. Sample size calculation was done by nMaster 2.0 (Department of Biostatistics, CMC, Vellore, India) Software.

LABORATORY INVESTIGATIONS

Routine baseline investigation reports including complete hemogram, fasting blood sugar, postprandial blood sugar, urea, creatinine, TSH, LFT, BT, and CT, reports of rheumatoid factor, anti-CCP antibody.

Schedule of Data Collection

The patients with completed baseline investigation reports were given intra-articular or intramuscular depot methylprednisolone injections on day 1 and were re-assessed after intervals of 1 month and 3 months post-intervention.

Parameters and the Procedures

- Parameters of objective are as follows:
  1. Range of motion of wrist joints
  2. Handgrip strength measurements
  3. Patient's disease activity assessment by CDAI
  4. Hand function assessment using Keitel Functional Test (KFT).
- Study tools
  1. Hand dynamometer, goniometer
  2. Injection depot methylprednisolone (40mg/ml), xylocaine chloride 2% (1 ml)
  3. 5cc and 2cc syringes, Band-aid.

Methodology

Institutional Ethics Committee approval was received (Inst/IEC/523 dated 11th Jan 2014 of IPGME&R, Kolkata, India. Chairperson: Dr. Hemanta Majumder).

Informed consent from all patients was taken for this study.

For this study, patients with diagnosed RA as per ACR/EULAR 2010 criteria having disease duration of <2 years were first

selected according to inclusion and exclusion criteria of the study and who agreed to participate in the study. The routine baseline blood reports were investigated, and those who did not have any contraindications for receiving injections were finally selected.

The consent forms along with the prefixed pro forma were filled with detailed history, clinical examination (including handgrip strength and ROM assessment), CDAI scoring, and hand function assessment by KFT were done. Patients were then allocated randomly in intra-articular (IA) and intramuscular (IM) groups.

On 1st visit, all patients received methotrexate 10 mg weekly. They were taught ROM exercises and joint protection techniques. No other DMARDs were added until the end of follow-ups (i.e. 3 months). Patients in IA group were given intra-articular (IA) depot methylprednisolone injection in inflamed wrist joints (40 mg in each). Patients in IM group were given intramuscular (IM) depot methylprednisolone injection (80 mg) in the gluteal region on the 1st day and another dose of 80 mg on the same day of 3rd week. Patients were asked to follow-up after 1 month from the day of 1st visit and after 2 months from the day of 2nd visit (i.e., 3 months post-intervention). In both the follow-up visit, patients were assessed as per the study parameters.

Range of motion assessment

By goniometer for wrist flexion and extension, goniometry was performed on each follow-ups in each patient in both groups for assessing the improvement.

Grip strength measurement

Power and pinch grip strength was measured using Jamar Hand Dynamometer. Power grip measured with detachable handle at second position with dynamometer supported on a flat surface in erect position. Average of three trials in 10 min interval is recorded. Pinch grip (both palmer and lateral) is measured between thumb and index finger with weight of the dynamometer supported by examiner.

All these grip strengths were assessed on each follow-up to look for any improvement.

Patient's disease activity assessment

A thorough physical examination was performed on each patient to determine a total number of tender and swollen joints of the patient.

Patient's and providers global assessment (VAS) of disease activity was obtained on a 0–10 mm scale. CDAI score was then calculated by summation of above parameters to assess patient's disease activity ranging from 0 to 76. This score was taken as the primary outcome measure and was calculated on each follow-ups in each patient in both groups for assessing the improvement.

Hand function assessment

KFT parameters 1–9 for hand function assessment of small joints of hand were taken and scoring done for both hands. The total score was taken for observing improvement in three follow-ups in each patient in both groups.

RESULTS AND ANALYSIS

Method for Statistical Analysis

For statistical analysis the following software was used – Statistica version 6 [Tulsa, Oklahoma: StatSoft Inc., 2001] and GraphPad Prism version 5 [San Diego, California: GraphPad Software Inc., 2007].

The improvement between visits was calculated in percentages by taking the mean of the different parameters of the 1st visit as baseline data. The mean of subsequent visits was subtracted from baseline data, and the difference between the two means was calculated as percentage for each group. The main outcome measure of each parameter was taken, namely, range of motion of wrist joint in goniometry, power and pinch grip strengths, CDAI and KFT scores.

DEMOGRAPHIC PROFILE

Out of 136 patients in the study, 70 were included in IA group and 66 in IM group.

Sex

Out of 136 patients, 108 (79%) were female and 28 (21%) were male. In IA group, out of 70 patients 58 (83%) were female and 12 (17%) were male. In IM group, out of 66 patients 50 (76%) were female and 16 (24%) were male. Evidently, there is female preponderance in the study population.

Age

In the total sample of 136 patients, age ranged from 23 to 62 years with mean age being 41.15 years. Mean age in IA group is 41 years (range 23–57 years) and in IM group 41.3 years (range 23–62 years). Therefore, most patients were middle-aged; maximum age in IA being 57 years and IM being 62 years.

DURATION OF DISEASE

Duration of disease at the time of 1st visit varied from 3 months to 24 months. Mean duration in total sample

is 16.06 months, in IA group 1.74 months and IM group 17.45 months.

CLINICAL PARAMETERS COMPARISON RESULTS

Range of Motion

Wrist flexion and extension of both hands had statistically significant improvement overime between any two visits ($P < 0.05$) [Table 1], except improvement of right wrist extension between 2nd and 3rd visit, which is not statistically significant and the effect of intra-articular steroid is sustained until the 3rd month [Figure 1].

Grip Strength

It is seen that power grip (Figure 2) and all pinch grips of both hands (Table 2) have shown.

PINCH GRIPS

From Figures 1 and 2, it is seen that power grip and all pinch grips of both hands have shown statistically significant improvement overtime between any two visits ($P < 0.05$), except improvement of the right and left lateral pinch grip between 2nd and 3rd visits.

CDAI and KFT

From Figure 3, it is evident that CDAI scores reduced over time between any two visits, which is statistically significant, most significant reduction has occurred in the 1st month after intervention. The above figures also depict that KFT score improvement was statistically significant between any two visits in persistent manner. It is also seen that with decrease in disease activity there is improvement of functional ability in the subjects.

DISCUSSION

In our prospective parallel-group randomized controlled study conducted at the Department of Physical Medicine and Rehabilitation and Department of Rheumatology, Institute of Post Graduate Medical Education and Research, Kolkata, India, over the period of 18 months, we tried to compare the functional improvement of hand in RA patients between those who received intra-articular depot methylprednisolone injection with those receiving intramuscularly. There are a number of studies assessing improvement by either local or systemic steroid administration in these patients, but there is paucity of literature regarding any comparison between these groups pertaining to hand function evaluation and in DMARDS naïve newly diagnosed RA patients having disease duration <2 years,

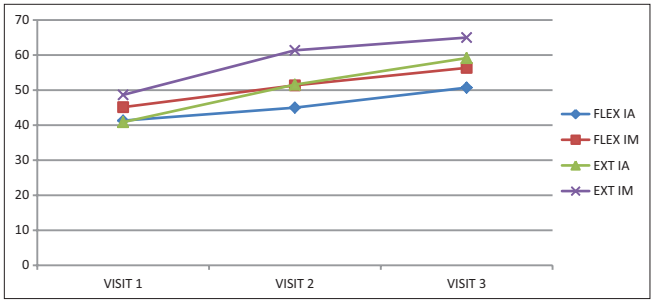

Figure 1: Improvement in range of motion of the right wrist joint in IA and IM groups overtime

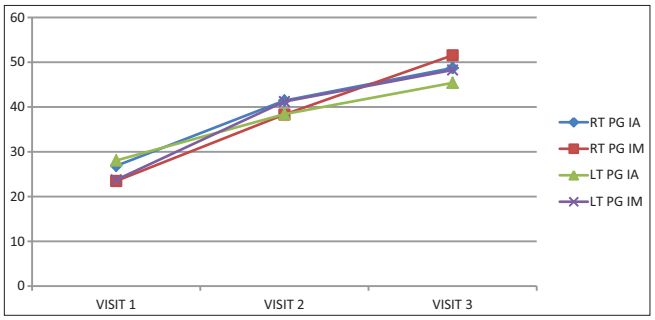

Figure 2: Improvement in power grip strength in IA and IM groups over time

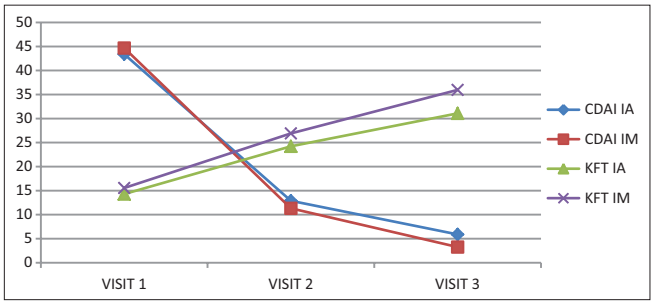

Figure 3: Improvement in CDAI and KFT in IA and IM groups overtime

Table 1: Comparison in % improvement between visits as a percentage for bilateral wrists

% improvement between visits	RT. wrist FLX.		RT. wrist EXT.		LT. wrist FLX.		LT. wrist EXT.	
	IA	IM	IA	IM	IA	IM	IA	IM
After 1 m	8.06	13.75	26.21	26.15	20.14	36.52	28.65	13.74
After 3 m	22.81	24.82	44.74	33.63	41.28	51.66	33.95	21.16
Between 1 and 3 m	14.75	11.07	18.53	7.48	21.14	15.14	5.30	7.42

Table 2: Comparison in improvement between visits as a percentage for bilateral palmer and lateral pinch grip

% improvement between visits	RT palmar pinch grip		LT. palmar pinch grip		RT lateral pinch grip		LT lateral pinch grip	
	IA	IM	IA	IM	IA	IM	IA	IM
After 1 m	43.77	33.17	28.23	51.02	11.12	31.23	11.20	45.55
After 3 m	51.33	63.32	36.49	84.42	21.02	42.64	21.74	60.21
Between 1 and 3 m	7.56	30.15	8.26	33.40	9.90	11.41	10.54	14.06

before the development of any hallmark deformity. Initially, we included 75 patients in each group for the study, but nine patients in IM group and five patients in IA group dropped out of subsequent visits. Hence, we concluded the study with 66 patients in IM group and 70 patients in IA group.

We used the blind technique for intra-articular injection as it was shown earlier by Joanna Cunnington *et al*.[7] in his study that although US guidance significantly improves the accuracy of joint injection but it did not improve the short-term outcome of joint injection. Furthermore, Lopes *et al*.[8] showed that blind IAIs (intra-articular injections) in peripheral joints exhibit good accuracy when performed by good dexterity according to the anatomical landmarks with better accuracy in elbow, wrist, MCP joints, and knee joints and are associated with a satisfactory clinical response in RA.

In our study, there is clear female preponderance with 108 out of 136 patients being female and most of the patients were middle-aged, mean age being 41.15 ± 9.84 years with maximum age being 62 years in IM group and 57 years in IA group. One hundred thirty-six patients were evaluated twice in two follow-up visits at 1 month and 3 months post-intervention in each group. They were assessed for improvement of wrist joint ROM, grip strengths, KFT, and CDAI scores.

It was seen by goniometric evaluation in our study that both groups showed statistically significant improvements in flexion and extension of both wrist joints ($P < 0.001$ for both groups, intragroup analysis), except left wrist extension in IA group and right wrist extension in IM group did not show statistical significance between 2nd and 3rd visits.

Unfortunately, in our study, in intergroup comparison of wrist goniometry, the data could not be compared as it differed significantly between groups at baseline data (1st visit). Only in case of left wrist flexion, significant better improvement in IM group at 1 month post-intervention ($P = 0.015$) with no difference in outcome at 3 months post-intervention ($P = 0.320$) was noted. However, interestingly, when we calculated the improvement in percentage among the visits, it revealed more improvement in intra-articular group at 3 months, more between 2nd and 3rd visits, as compared with intramuscular group [Table 1]. Konai *et al*.[9] supported this finding in their study by concluding that intra-articular glucocorticoids injection is superior to its systemic use for the management of monoarticular synovitis in rheumatoid patients but they intervened in knee joints who were on stable doses of oral corticosteroid for the past 30 days and stable doses of DMARDs for the past 3 months, whereas we excluded patients who were on any form of systemic steroid in past 3 months. Häkkinen *et al*.[10] (2003) also recorded range of motion large joints like us in their study, but their aim was to correlate joint mobility with health assessment questionnaire (HAQ). They found limited motion of wrist, shoulder, and knee joints are associated with increased disability (higher total HAQ scores). The possible explanation for this finding may be that the restriction of wrist ROM leading to poor hand function may be primarily due to synovitis and pain in early-stage which when resolved by the effect of local steroid, improves the ROM as well as functional capability. Therefore, the effect of intramuscular steroid was fast but short-lived in contrast to delayed but sustained benefit of intra-articular steroid.

Not only these, we also looked for improvement in handgrip strength in our study and found that in both IA and IM group, bilateral power grips and all pinch grips had statistically significant improvement over time between any two visits ($P < 0.05$), except bilateral palmer pinch grip in IA group and bilateral lateral pinch grip in IM group did not any significant improvement between 2nd and 3rd visits. The findings of Skogh *et al*.[11] (2006) matched ours with respect to improvement pattern of the grip strength. They measured peak and average grip force over 10 s in the right and left hand by an electronic device and concluded it was profoundly affected at diagnosis, but improved significantly within 3 months.

While comparing these data between groups, it revealed that power and pinch grip strength in both groups improved equally well with no statistically significant difference ($P > 0.05$), but then, calculation in terms of improvement percentage disclosed intramuscular group

had better results [Figure 2 and Table 2]. There is evidence from several other studies that grip strength correlates well with disease activity and improves with time as disease activity diminishes. Shipham *et al*.[12] (2003) and Häkkinen *et al*.[10] (2003) further inferred from their studies that highest correlation exists between grip strength and difficulty in ADL and decreased grip strength was associated with increased disability as reflected by higher total HAQ scores. On the contrary, Poulisa *et al*.[13] (2003) concluded from their study that there are no statistical differences in grip and pinch strength between healthy persons and early RA patients, but our patients had at least 2 years of disease duration. Hence, the general ability and well-being of the patient is reflected by the grip strength also,[14] which might not merely be a measure of hand function, as it showed more improvement in systemic steroid rather than local steroid.

Further, in our study, it was also shown that both routes of administration of steroid were equally effective in reducing disease activity reflected by CDAI score reduction and also had significant improvement in both groups between follow-ups. Similarly, we found almost identical improvement percentages in both groups [Figure 3]. A study by Pereira *et al*.[15] also patients showed marked improvement of CDAI scores following injection ($P < 0.001$) although they intervened in wrist with painful refractory synovitis of RA patients. In the CIMESTRA study,[16] Hetland and Hørslev-Petersen although assessed disease activity by ACR outcome measures but their conclusion goes with ours that at 1 year, 85% of patients achieved ACR 20, 68% ACR50, and 59% ACR 70 in combination group receiving methotrexate and intra-articular injections of glucocorticoids. Both the studies came to the same conclusion that steroid retards joint damage and induces higher remission rate in early RA patients with decreased disease activity which was our finding too.

To evaluate the functional status of our patients, we applied the KFT in our study. KFT improved significantly in either group in both follow-up visits ($P < 0.001$). Not only intergroup comparison revealed that the patients were functionally impaired in 1st visit in both groups equally but also in the follow-up visit there is more improvement in IM group than IA group which is significant statistically ($P = 0.046$ in 2nd visit, and 0.000 in 3rd). The percentage improvement in IM group was more prominent between 1st and 3rd month whereas it is equitable at 1 month in both groups [Figure 3]. This trend is assumed to be due to the overall reduction of disease activity by the higher systemic dose of IM steroid that improved the functional scores consequently. After thorough search of literature, we found only one study by Dellhag and Bjelle[17] in 1999 that used KFT as functional parameter in RA patients, but their objective was to follow the fate of hand function with ADL capacity over a period of 5 years in their study. They showed that hand function deteriorated during a 5-year period in female RA patient's more than male patients.

In our study, all the study parameters have improved significantly in both IA and IM group. Although statistical analysis exhibited that KFT has shown more improvement in IM group than IA group while grip strength and CDAI improved equally in both groups and incomparable data on goniometry, but on percentage improvement calculation, we found that in grip strength; KFT and CDAI, improvement was more in IM group. On the other hand, wrist ROM improved better in IA group. Therefore, it can be assumed that for functional improvement of hand in RA patients with disease duration <24 months, intra-articular injections might be considered when local effects are sought for, and intramuscular corticosteroid can be given if systemic improvement appertains to disease activity is the target of treatment. But keeping in mind the higher side effect profile and abuse potential of the systemic steroid, intra-articular administration might be preferred when applicable.

Therefore, we conclude that all the study parameters have significant improvement concerning hand function and disease activity in IA and IM group, but when compared between IA and IM groups, grip strength and CDAI scores revealed no difference in improvement pattern whereas KFT showed better results in IM group. The percentage improvement calculations revealed that wrist goniometry had better results in IA group whereas grip strength, CDAI, and KFT had better results in IM group.

Finally, to summarize, intra-articular injections have sustained effects throughout the study period in the range of motion improvement, and intramuscular injections have short-lived effects and are more effective in improving outcomes of functional status and disease activity. Thus, in short term, intra-articular injections have more prominent local effects whereas intramuscular injections improve the systemic parameters more.

DISCLOSURE STATEMENT

This study was not funded by any governmental or non-governmental organization or any pharmaceutical company. And no financial or other benefit was related to this study, and no commitment or agreement was there to provide such benefit from a commercial entity.

What is known?

Intra-articular corticosteroid injections (IACSI) are predominantly used for treating RA patients with refractory and persistent mono or oligoarthritis. IACSIs show significant improvement in inflammatory process and reduction of pain in such RA patients. In most studies, IACSIs are given in knee joints of RA patients. Systemic corticosteroids are predominantly used for control of pain and inflammation in case of RA flare and at initiation of DMARDS as bridging therapy. Grip strength is used as a measure of hand function.

What is new?

Intra-articular injections have sustained effects throughout the study period in range of motion improvement whereas intramuscular injections have short-lived effects and are more effective in improving outcomes of functional status and disease activity. Grip strength is a measure of disease activity along with hand function. There is improvement of functional ability in patients with decrease in disease activity.

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