Original Research Article

Randomized controlled trial of functional outcome of periarthritis of shoulder (Adhesive Capsulitis) in a group of 60 patients using intraarticular triamcinolone vs. intraarticular platelet rich plasma

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A R T I C L E I N F O

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A B S T R A C T

Background: Periarthritis shoulder is the most common cause of shoulder pain and stiffness encountered in day to day practice. Though the condition is self-limiting it may not be practical to wait for spontaneous resolution as it is associated with significant morbidity hampering routine activities. The various treatment options available include simple physiotherapy, intra articular injections, manipulation under general anaesthesia and surgical intervention. This study was undertaken to compare the efficacy and safety of two intraarticular injections that is triamcinolone acetonide and platelet rich plasma (PRP).

Materials and Methods: Patients with periarthritis shoulder were randomly allocated into two groups. Group A receiving intraarticular triamcinolone acetonide injection and Group B receiving intra articular platelet rich plasma. Patients were followed up every four weeks for 24 weeks. And outcome was assessed using SPADI score before treatment and at every visit. Results were assessed using EpiData version 2.2.2.186.

Results: PRP treatment resulted in statistically significant improvement over triamcinolone acetate therapy in both SPADI and VAS scale.

Conclusion: Intraarticular PRP is more effective and safe in treatment of periarthritis shoulder.

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1. Introduction

Frozen shoulder also termed as periarthritis shoulder or adhesive capsulitis of shoulder, is one of the common cause of shoulder pain and stiffness in day to day practice. It is a self-limiting condition resolving over 2-3 years rarely persisting beyond 3 years in few cases. Though it is a self-limiting condition, often it becomes impractical to wait till spontaneous resolution because of severe pain and restricted movements. The various treatment options available include simple physiotherapy, intra articular injections, manipulation under general anaesthesia and surgical intervention. Choice of treatment depends on severity of the disease, patient occupation and comorbidities. This study was under taken to compare the efficacy of intraarticular injection of time tested drug triamcinolone acetonide with platelet rich plasma in the management of pain and stiffness associated with frozen shoulder.

2. Materials and Methods

In this study, sixty patients of periarthritis shoulder attending the out patient Department of Orthopaedics, Kempegowda Institute of Medical Sciences and Research Centre, Bangalore fulfilling the inclusion and exclusion criteria (Table 1) were included. Institutional ethical clearance and informed consent were taken prior to the intervention. Detailed history of all the patients was taken. All patients were assessed clinically and functionally using the SPADI scores. Routine investigations and pre-anesthetic evaluations and radiological evaluation were

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done. Manipulation under short general anesthesia was done. Standard guidelines were followed. The patients were divided into two groups A and B after randomization such that group A patients received intraarticular triamcinolone 40 mg with distilled water 19cc for dilution and group B received 20 cc of intraarticular PRP (extracted from autologous 50 mL blood).

Preparation of triamcinolone injection – 1ml of 40 mg/ml of triamcinolone acetonide was diluted with 19ml distilled water so that the final concentration concentration of triamcinolone acetonide is 2mg/ml.

Platelet rich plasma was prepared from 50 mL of autologous blood. The extracted blood mixed with acid citrate dextrose was subjected to refrigerated centrifuge for double spin. Initially subjected to a soft spin of 1800 rotations per minute for 08 minutes followed by hard spin of 2600rpm for 08 minutes to obtain about 20 ml of PRP.

2.1. Procedure of administration: Anterior approach

An 18-gauge needle is inserted medial to the head of humerus, one cm lateral to the coracoid process and directed posteriorly at a slight superior and lateral angle. The needle should slip into the joint completely without any resistance followed by injection of therapeutic agent.

Patients were followed up every four weeks upto 24 weeks and the range of movements, were measured during every visit. SPADI score was also taken every month for 6 months.

2.2. Outcome measures

Treatment outcome was measured using SPADI scores. The parameters were initially recorded before the intervention (baseline) and then after the intervention at 4, 8, 12, 16 and 20, 24 wk. The outcome parameters in both the study groups were compared with each other. Any complications encountered in the study were also noted.

2.3. Statistical analysis

Microsoft Word and Excel were used to generate graphs, tables, etc. For descriptive statistics and correlation study, statistical analysis was done using EpiData version 2.2.2.186. Continuous variables like age were summarized as mean and standard deviation. Since pain and disability scores were non-normally distributed, they were summarized as median and interquartile range. Categorical variables like gender, comorbidities and overall condition were summarized as proportions.

Comparison of proportions between the two treatment groups was done using chi-square test. Comparison of age between the two groups was done using independent samples t test. Scores were compared at each follow up time point using the Mann Whitney U test. For all statistical analysis, p value <0.05 was considered significant.

3. Results

In the present study, the age of patients with Adhesive capsulitis ranged from 30 to 70 years. Peak incidence of the disease was seen in the 4th and 5th decade of life with 28% and 43%, respectively. A maximum of 81% of patients were of 50 years and above. Mean age distribution of the patients was between 55–56 yr (in intraarticular triamcinolone and PRP treatment groups).

Females (60%) were most commonly affected with frozen shoulder when compared to males (40%). In PRP group, 73.3% of females and in triamcinolone group, 53.3% males predominated.

A significant difference was seen in the diabetic and non-diabetic status of the study participants (p=0.001). Diabetes was the most common comorbidity associated in the study population which accounts for 35%, whereas hypertension accounted for 25%. Of 60 patients in the study, 15 patients were found to be with hypertension which is a known risk factor for per arthritis of the shoulder.

In the study population, 55.9% of the participants were affected on the left shoulder, whereas 44.1% of study population were affected on the right shoulder. In the intraarticular PRP group, 43.3% and 56.7% of patients were affected on right and left shoulders, respectively. Similarly in intraarticular triamcinolone group, 44.8% and 55.2% of patients were affected on the right and left shoulders, respectively.

Reduction of pain and disability (based on SPADI score) were seen in both intraarticular PRP and triamcinolone groups. But, intraarticular PRP group showed significant reduction in the pain (Table 1) and disability score associated with frozen shoulder (Table 2). PRP treatment resulted in statistically significant improvements over triamcinolone therapy in VAS scale. This reduction was seen from week 4 and was continued till the end of the study, i.e., week 24. In the 20th week and 24th week, interquartile range of pain was significant (p<0.001) with 0–6 in the PRP and 5.5–12.5 in the triamcinolone group. In the 20th and 24th week, interquartile range of disability was significant (p<0.001) with 0-6 in the PRP and 11.25-20 in the triamcinolone group. While assessing the condition of patients in both the treatment groups, PRP showed good response in 86.2% of patients when compared to triamcinolone group of 10.0%. Fairer response rate was seen in in 90% population in triamcinolone group and in 13.8% in intraarticular PRP treated group (Table 3).

Thus present prospective trial showed a significant difference in the pain and disability score in both the treatment groups from pre procedure to the 24 weeks, majority of group B patients showing significant improvement of score.
### Table 1: Change in pain scale score of the SPADI score over study period (n=59*)

<table>
<thead>
<tr>
<th></th>
<th>Intraarticular PRP</th>
<th>Intraarticular triamcinolone</th>
<th>P value**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median score</td>
<td>Interquartile range</td>
<td>Median score</td>
</tr>
<tr>
<td>Preprocedure</td>
<td>82</td>
<td>79–90.5</td>
<td>80</td>
</tr>
<tr>
<td>At 4 weeks</td>
<td>32</td>
<td>22–56</td>
<td>31</td>
</tr>
<tr>
<td>At 8 weeks</td>
<td>22</td>
<td>9–32</td>
<td>20</td>
</tr>
<tr>
<td>At 12 weeks</td>
<td>12</td>
<td>7–15</td>
<td>14</td>
</tr>
<tr>
<td>At 16 weeks</td>
<td>6</td>
<td>3–10</td>
<td>10</td>
</tr>
<tr>
<td>At 20 weeks</td>
<td>4</td>
<td>0–6</td>
<td>10</td>
</tr>
<tr>
<td>At 24 weeks</td>
<td>2</td>
<td>0–6</td>
<td>10</td>
</tr>
</tbody>
</table>

*One death in intraarticular PRP group excluded.

**Mann Whitney U test

*** Statistically significant

### Table 2: Change in disability scale score of the SPADI score over study period (n=59*)

<table>
<thead>
<tr>
<th></th>
<th>Intraarticular PRP</th>
<th>Intraarticular Triamcinolone</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median score</td>
<td>Interquartile range</td>
<td>Median score</td>
</tr>
<tr>
<td>Preprocedure</td>
<td>80</td>
<td>67–87</td>
<td>73</td>
</tr>
<tr>
<td>At 4 weeks</td>
<td>20</td>
<td>13–33</td>
<td>30</td>
</tr>
<tr>
<td>At 8 weeks</td>
<td>13</td>
<td>6–26</td>
<td>20</td>
</tr>
<tr>
<td>At 12 weeks</td>
<td>7</td>
<td>6–20</td>
<td>16.5</td>
</tr>
<tr>
<td>At 16 weeks</td>
<td>6</td>
<td>6–13</td>
<td>13</td>
</tr>
<tr>
<td>At 20 weeks</td>
<td>6</td>
<td>0–6</td>
<td>13</td>
</tr>
<tr>
<td>At 24 weeks</td>
<td>6</td>
<td>0–6</td>
<td>13</td>
</tr>
</tbody>
</table>

*One death in intraarticular PRP group excluded

** Statistically significant

### Table 3: Overall condition of the study participants (n=59*)

<table>
<thead>
<tr>
<th></th>
<th>Intraarticular PRP</th>
<th>Intraarticular triamcinolone</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Good</td>
<td>25</td>
<td>3</td>
<td>28</td>
</tr>
<tr>
<td>Fair</td>
<td>4</td>
<td>13.8</td>
<td>27</td>
</tr>
<tr>
<td>Total</td>
<td>29</td>
<td>100.0</td>
<td>30</td>
</tr>
</tbody>
</table>

Chi²= 34.343 df (1) p value<0.001

*One death in intraarticular PRP group excluded

4. Discussion

Periarthritis shoulder is the most common cause of shoulder pain and stiffness presenting in orthopaedic OPD. The various treatment options available include simple physiotherapy, intra articular injections, manipulation under general anaesthesia and surgical intervention. Triamcinolone acetonide being a long acting steroid is the commonly used intra articular injection which has anti-inflammatory and anti-fibrotic action. This study compares the efficacy and safety of intra articular injections of PRP in comparison with Triamcinolone acetonide.

In the present study the age of patients with periarthritis of the shoulders ranged from 40–80 years. Peak incidence of periarthritis of the shoulder was seen in the 4th and 5th decade of life. In intraarticular triamcinolone and PRP treatment groups, the mean age distributions were 56.9 and 55.03. This was also in similarity with the study conducted by Goswami MI, et al., which showed the age group of 30–65 years in patients with adhesive capsulitis. In another study, age of the participants ranged from 29–75 years with mean of 51.9 ± 10.1 and similar trend has been reported in literature. In a randomized controlled trial conducted by Reddy BC, et al., among 30 participants including both male and female were above the age of 50. Among 60 patients included in the study, 36 (60%) were female and 24 (40%) were male. A total of 73.3% of the females and 26.7% of males were treated with intraarticular PRP. Further, intraarticular triamcinolone was given to 53.3% of males and 46.7% of female patients. In a study conducted by Kothari SY, et al., periarthritis of the shoulder was seen more in females (52.2%) than males. In a study by Goswami et al., showed 3:2 female: male relation which is comparable to our study. Similarly other studies like Verma VK et al., Harris JD et al, and Sakeni showed...
et al. showed more female predominance as mentioned in our study.

In this study, significant comorbidities associated with the treatment groups included diabetes and hypertension. In the study population, 21 (35%) of patients were diabetic and 39 (65%) patients were non-diabetic. There was a significant difference in the diabetic and non-diabetic status of the study participants (p=0.001). Division of Physical Medicine and Research, RMMCH, Annamalai University conducted a study on data on comorbidities which revealed that maximum numbers of 35.9% (n=28) of the patients presented with diabetes mellitus. Analysis conducted by Bridgman JF showed that 10.8% diabetics and 2.3% nondiabetics were found to have periarthritis of the shoulder, a statistically significant difference between the two groups of patients (p<0.005). Bagheri F, et al., conducted a cross-sectional study in patients with phase II idiopathic frozen shoulder (n=120). The results showed that 24% of the patients had history of diabetes. The results from different studies were consistent with our present study, which shows that diabetes is the common risk factor associated with frozen shoulder.

Our study results showed a significant difference in the hypertensive (25%) and non-hypertensive (75%) status of the study participants (p<0.001). Study analysis by Pragassame SA, et al., showed that 66.7% have both diabetes and hypertension which is the most common combination of comorbidities.

In our study among group A and group B patients with diabetes, the group B patients showed significant improvement of both pain and disability score. So in case of periarthritis with diabetes; PRP infiltration shows significant improvement. This was proved in a study conducted by Sakeni RA, et al., which concluded that PRP is a good rescue for painful stiff shoulder particularly for resistant cases as with diabetes mellitus, and with long duration of illness. Also, its efficacy can be observed with less frequent injections.

Similarly 21 nondiabetic patients received triamcinolone and had a mean pre infiltration pain score of 78.76 and a mean pre-infiltration disability score of 74.1 and post infiltration pain score of 3.4 and a post-infiltration disability score of 5.9. 17 non diabetic patients received PRP and had a mean pre-infiltration pain score of 80.17 and a mean pre-infiltration disability score of 74.9 and a mean post infiltration pain score of 8.7 and a mean post infiltration disability score of 17.05. The group B patients showed significant improvement in both pain and disability scores.

These results were in relation to the study conducted by Kothari SY, et al., which was conducted to assess the efficacy of PRP injection, corticosteroid injection and ultrasonic therapy in the treatment of periarthritis shoulder. Assessment of patients was done at 0, 3, 6 and 12 weeks. PRP treatment showed statistically significant improvement over steroid injection in the mean active range of shoulder abduction, flexion, external rotation and internal rotation at 12 weeks. Even the study results showed statistically significant improvement in the passive range of motion, pain and disability score at 12 weeks. Also, at 6th week, PRP treatment resulted in statistically significant improvements over ultrasonic.

The current prospective study demonstrates that PRP significantly improves pain and disability when compared to the steroid injection. Our study results also showed a better improvement in theVAS score. PRP showed a good improvement over the steroids, suggesting its usage as the current treatment in the frozen shoulder.

A case report reported by Aslani H, et al., on PRP for patients with frozen shoulder showed that post first injection, the patient reported 60% improvement regarding diurnal shoulder pain, and no night pain. Also, two-fold improvement for ROM and more than 70% improvement for function were reported.

Hence, it can be concluded that intraarticular PRP is more effective in treatment of adhesive capsulitis. In our study, intraarticular PRP treatment for 24 weeks resulted in significant improvement in range of shoulder motion, pain and function than triamcinolone in patients with periarthritis of the shoulder. There was a significant evidence for PRP treatment in adhesive capsulitis. Being autologous PRP offers an economical and safe therapeutic option in the management of periarthritis shoulder. However high level of evidence for PRP are lacking in literature. Small sample size being the drawback of the study requires large scale studies in future.

5. Source of Funding
None.

6. Conflict of Interest
The authors declare that there is no conflict of interest.

References


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Ravish V N, Associate Professor

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