

CLINICAL AND FUNCTIONAL RESULTS OF INTRA-ARTICULAR INJECTIONS OF HYALURONIC ACID IN PATIENTS AFFECTED BY PAINFUL PERIARTHRITIS OF SHOULDER JOINT

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ABSTRACT

BACKGROUND

Promising outcome of intra-articular injections of hyaluronic acid for treatment in patients affected by periarthritis of shoulder joint. Frozen shoulder or adhesive capsulitis or shoulder periarthritis was defined in the seminal work of Reeves (1975) as a condition of uncertain aetiology characterised by spontaneous onset of pain with significant restriction of both active and passive range of movement of the shoulder. Shoulder periarthritis or primary adhesive capsulitis is a common shoulder condition characterised by painful loss of both active and passive range of motion in all planes of glenohumeral joint, especially external rotation. Although, the pathogenesis progresses through fibrosis and culminates in joint contractures. It is generally recognised as a self-limiting process with an unknown aetiology.

MATERIALS AND METHODS

60 patients assessed for frozen shoulder in the OPD of our department were divided in two groups of 30 each in the year 2016 and 2017. One group (PNH group) was treated with physiotherapy (in the form of shortwave diathermy and exercises), analgesics (NSAIDs) and 5 intra-articular injections of hyaluronic acid at weekly interval. The other group (PN group) was treated with physiotherapy (in the form of shortwave diathermy and exercises) and analgesics (NSAIDs) only. These patients were not given hyaluronic acid injections. These patients had a yearlong follow up at regular intervals (0 week, 6 weeks, 3 months, 6 months and 1 year). Data was analysed within groups with the help of constant score to assess the effects of each intervention on the outcome measures and between groups to compare the effects of the intervention.

RESULTS

Over the period of one year, PNH group showed improvement of 57.76 points, i.e. the difference of scores at 0 week and one year (81.03-23.27) compared to the PN group, which showed improvement of 54.20 points (76.40-22.2) over the period of one year. Statistical analysis showed that the improvement was not significant in PNH group compared to the PN group (p -value=0.322) at one year.

CONCLUSION

Hyaluronic injection into the glenohumeral joint significantly improves the shoulder range of motion, constant scores and pain at short-term follow up following treatment of shoulder periarthritis. PNH group has significantly better outcomes than PN group. Intra-articular hyaluronic injection was safe with no reported complications within this study.

KEYWORDS

Frozen Shoulder, Hyaluronic Acid Injections, Constant Score, PNH Group, PN Group.

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BACKGROUND

Frozen shoulder or adhesive capsulitis or shoulder periarthritis was defined in the seminal work of Reeves (1975)¹ as a condition of uncertain aetiology characterised by spontaneous onset of pain with significant restriction of both active and passive range of movement of the shoulder.² Shoulder periarthritis or primary adhesive capsulitis is a common shoulder condition characterised by painful loss of both active and passive range of motion in all planes of glenohumeral joint, especially external rotation.³ Although,

the pathogenesis progresses through fibrosis and culminates in joint contractures.⁴ It is generally recognised as a self-limiting process⁵ with an unknown aetiology.⁶

The clinical picture commonly characterised by spontaneous onset of shoulder pain and progressive global stiffness of glenohumeral joint is accompanied by decreased function and significant disability.^{1,7} The presence of night pain leads to disturbance of sleep and often difficulty lying on the affected shoulder.^{8,9} As the restriction in the motion increases, more difficulties are encountered with activities of daily living.¹⁰ Routine radiographs are typically normal.¹¹ These are important to rule out serious pathology, abnormalities in the bone, joint or in the local soft tissues, e.g. calcific deposit and are a prerequisite to a definitive diagnosis of frozen shoulder.¹²

Despite reports of 96% to 100% of patients returning to normal shoulder function by two-year and four-year follow-up.¹³ Some authors have described severe limitations in range of motion, persistent pain and weakness at similar durations of follow-up.

Nevertheless, several treatments are recognised and utilised to reduce pain and improve range of motion faster than the disease's natural history course.

These treatments in isolation or combined include intra-articular corticosteroid injection into the distention and eventual rupture of the glenohumeral joint capsule, intra-articular sodium hyaluronate injection into the glenohumeral joint, suprascapular nerve block, shoulder manipulation under anaesthesia, physical therapy with modalities, oral corticosteroid tapers oral NSAIDs (non-steroidal anti-inflammatory drugs) and analgesics and open or arthroscopic surgery with synovectomy and glenohumeral capsular releases.

Sodium hyaluronate injection into the glenohumeral joint for the treatment of adhesive capsulitis has shown similar clinical improvements as those seen following corticosteroid injection with fewer side effects. The effects seen following hyaluronate injection include, but are not limited to reduction in pain and improved range of motion.¹⁴ Anti-inflammation chondroprotection and improved synovial fluid characteristics.¹⁵

Further, it is not entirely clear how much a specific treatment improves long-term outcomes if a specific treatment expedites clinical improvement and if a specific treatment results in faster or better clinical outcomes than other treatments. Sodium hyaluronate is a well-recognised, safe and minimally-invasive treatment that results in improved outcomes in adhesive capsulitis of the shoulder. To the authors' knowledge, no study has fully evaluated the literature reporting clinical outcomes following sodium hyaluronate intra-articular glenohumeral joint injection for the treatment of adhesive capsulitis.¹⁶⁻¹⁸

The purpose of this systematic review was to comprehensively analyse the evidence regarding the effectiveness of intra-articular sodium hyaluronate injections in the treatment of primary adhesive capsulitis. We hypothesised that intra-articular sodium hyaluronate injections would result in significant improvements in passive

range of motion, shoulder and general clinical outcome measures and pain scales at short- and mid-term follow-up.

MATERIALS AND METHODS

Source of Data- Data is to be collected from patients who will come to the outpatient orthopaedics department and diagnosed with shoulder periarthritis after obtaining informed consent. Ethical clearance shall be obtained from the ethical committee of our institution to carry out the investigations and interventions on patients necessary for study.

Informed Consent- Patients will participate in the study on a voluntary basis and written consent will be obtained from the patient prior to the commencement. The patients will receive written and verbal explanations of the purposes and procedure of the study. This will be in the form of the patient information sheet and will provide explanation of the study. This consultation will enable patients to verbally establish comprehension of the study requirements, clarify individual queries and will confirm agreement to enter the study. If no decision is made or a negative response is obtained, then standard treatment will be offered to the patients.

Method of Collection of Data- Patients diagnosed to have shoulder periarthritis will be recruited for the study after obtaining informed consent. Subjects who fulfil the inclusion and exclusion criteria will be randomly assigned to one of two groups (PNH group and PN group).

1. PNH group is the one in which patients diagnosed with shoulder periarthritis will be treated with physiotherapy (in the form of shortwave diathermy and exercises), non-steroidal anti-inflammatory drugs (NSAIDs), and 5 intra-articular injections of hyaluronic acid at weekly interval.
2. PN group is the one in which patients diagnosed with shoulder periarthritis will be treated with physiotherapy (in the form of shortwave diathermy and exercises) and non-steroidal anti-inflammatory drugs (NSAIDs) only. These patients will not be given hyaluronic acid injections.

Inclusion Criteria- Patients of all sexes between the age group of 40 to 70 years with complaint of restricted mobility and pain in the shoulder joint with no pathology on radiographs of their shoulder joint.

Exclusion Criteria- Patients with any infection, calcification in the shoulder joint or with any significant rotator cuff tears or radiographs showing joint pathology.

Sample Size- Standard method of sample size will be used as calculation of adequate sample size is important in order to make sure the sample is representative of the population, the larger the sample size the less likely the researcher is to obtain negative or make incorrect inferences about the

collected data.¹⁹ Null and experimental hypothesis will be used to obtain a significant result.

Sampling Method- Random sample method will be used as a sampling method. Patients meeting the inclusion criteria and agreeing to participate in the study will be then randomly allocated into one of the two treatment groups.

Methodology- Each group should consist of patients of both genders within the age group of 40 to 70 years. Experimental group (PNH group) will be treated with physiotherapy, NSAIDs and injection hyaluronic acid and control group (PN group) will be treated only with physiotherapy and NSAIDs.

Method of Administration of Intra-Articular Injections/Injection Hyaluronic Acid- Injection hyaluronic acid comes in 2.5 mL prefilled syringes.

Injection into the Glenohumeral Joint- The glenohumeral joint can be injected via an anterior, posterior or superior approach. In this study, the posterior approach was used for the administration of the injection. The joint is most easily accessible with the patient sitting, the arm resting comfortably by the side and the shoulder externally rotated.

Method

- The needle should be inserted 1-2 cm inferior and medial to the posterolateral corner of the acromion and directed anteriorly in the direction of the coracoid process up to the full depth of an 18-gauge needle.

Cautions

- Aseptic technique has to be followed at all times.
- Before injection, aspiration should be performed to ensure that there is no puncture of a blood vessel.
- The injection should be performed slowly, but with consistent pressure.
- Injection directly in the bone and periosteum is very painful and should be avoided.
- Following injection, patient will be warned about the possibility of worsening of symptoms during the first 24-48 hours, which can be treated with icepacks and non-steroidal anti-inflammatory drugs.

Method Analysis- Data was analysed within groups to assess the effects of each intervention on the outcome measures and between groups to compare the effects of the intervention. Descriptive statistics including mean and standard deviations on interval/ratio, data and frequencies with percentages on categorical data were presented. All data was tested to determine, if it is normally distributed and once confirmed. A repeated measures one-way analysis of variance (RM ANOVA) on the outcome was conducted. This includes the prognostic measures using the baseline value of the outcome measure as a covariate. Pair wise comparisons using the least squares difference was

conducted to investigate the difference between the different treatment groups and at different time intervals following intervention.

The baseline (pre-intervention) measurement was included as a covariate as it will be related to the repeated measurements following introduction of the different intervention rather than being an outcome of the intervention. The effect of the intervention (strictly speaking the average effect of the intervention over time) will then be tested via the main effect of intervention group, whether the effect of the intervention varies over time is represented by the interaction between the intervention group and the repeated group and the repeated factor over time.

RESULTS

The results of this study were analysed on the basis of constant score. Improvement in the constant score indicates improvement in the shoulder range of active movement, decrease in the pain and disability of the patient. Comparisons were made between the constant scores at the beginning of the study, i.e. at 0 week, then at 6 weeks, 3 months, 6 months and 1 year. Comparison was done both between the two groups as well as within the group as to evaluate the intragroup and intergroup effectiveness of the two treatments under consideration in the study.

Number of Patients- There were total of 60 patients enrolled in the study. Group PNH and group PN both had equal number of patients 30 each.

		Count (n)	Column n%
Group	PNH	30	50%
	PN	30	50%
	Total	60	100%

Table 1. Number of Patients in PNH and PN Groups

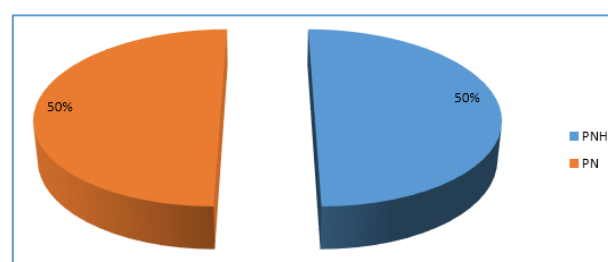


Figure 1. Percentage of Patients in the PNH and PN Groups

Sex Distribution- Total 60 peoples were enrolled in the study, out of them, 29 were males and 31 were females. Males constituted 48.3% and females contributed 51.7%.

The difference in the sex ratio was not significant ($\chi^2 = 0.601$, $df=1$, $p=0.438$).

		Count (n)	Column n%
Sex	Male	31	48.3%
	Female	29	51.7%
	Total	60	100.0%

Table 2. Total Number of Males and Females in the Study

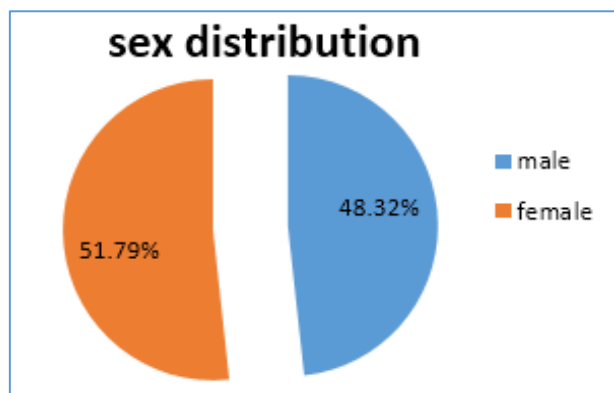


Figure 2. Percentage of Male and Female Patients in the Study

The number of patients in PNH group was 16, and in PN group, there were 13 male patients. The number of female patients in PNH group was 14, and in PN group, there were 17 females.

PNH group had 16 males (53.3%) and 14 females (46.7%).

PN group had 13 males (43.3%) and 17 females (56.7%).

		PNH		PN	
		Count (n)	Column n%	Count (n)	Column n%
Sex	Male	16	53.3%	13	43.3%
	Female	14	46.7%	17	56.7%
	Total	30	100.0%	30	100.0%

Table 3. Percentage Wise Distribution of Male and Female Patients in the PNH and PN Groups

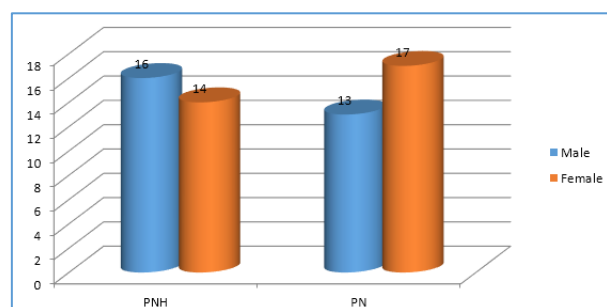


Figure 3. Distribution of Total Number of Male and Female Patients in the PNH and PN Group (Y-Axis=Number of Patients, X-Axis=Male and Female Patients in PNH and PN Groups)

Pearson's Chi-Square Tests

		Group
Sex	Chi-square	0.601
	df	1
	P value	0.438

Table 4. Statistical Significance of Difference in Male and Female Ratio in the Study

The difference in the sex ratio was not significant ($\chi^2=0.601$, $df=1$, P Value=0.438).

Age Distribution- Age of the patients in the study was born between 40 to 70 years. The mean age of male patients in

the study was 57.2 (standard deviation=8.594) and female patients was 53.26 (standard deviation=8.066).

The mean age of total patients in the PNH group was 56.23 years and the mean age of total patients in PN group was 54.6 years. The difference between the mean age of two groups was not statistically significant (p value=0.464).

Sex	Mean Age	Number of Patients	Standard Deviation
Male	57.72	29	8.594
Female	53.26	31	8.066
Total	55.42	60	8.555

Table 5. Mean Age (in Years) of the Total Number of Male and Female Patients in the Study

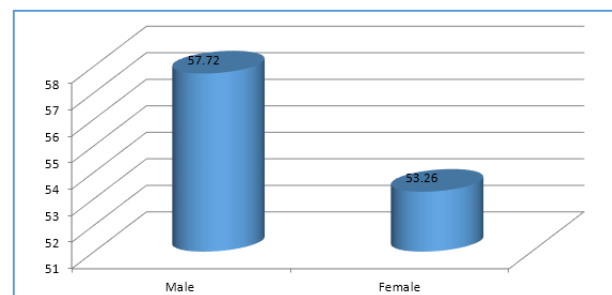


Figure 4. Mean Age (in Years) of the Male and Female Patients in the Study (X-Axis=Male and Female Patients in the Study, Y-Axis=Mean Age (in Years) of Male and Female Patients)

		Count (n)	Column n%
Age in years	40-50	20	33.3%
	51-60	26	43.3%
	61-70	14	23.3%
	Total	60	100.0%

Table 6. Age Wise Distribution of Patients in the Study

On age wise distribution of the patients in three strata of 10 years each.

There were 20 patients between age group of 40 to 50 years (33.3% of the total patients), 26 patients were in the age group of 51-60 years (43.3% of total patients), 14 patients fall between the age group of 61-70 years (23.3% of total patients).

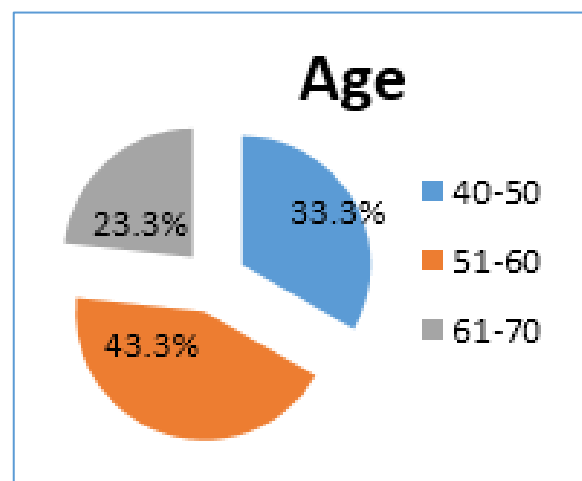


Figure 5. Percentage Wise Distribution of Total Patients in Three Age Groups

	Groups	Number of Patients	Mean	Standard Deviation	P value
Age	PNH	30	56.23	9.504	0.464
	PN	30	54.60	7.564	

Table 7. Independent t-Test of Mean Age (in Years) Difference PNH and PN Group

The mean age of patients in PNH group was 56.23 years, and in PN group, it was 54.6 years. This difference of mean age in the two groups was not significant as shown by the p-value of 0.464.

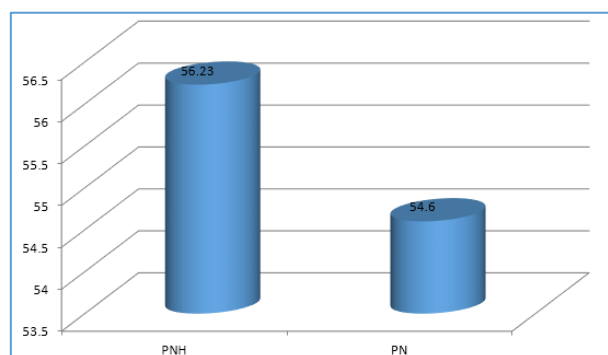


Figure 6. Mean Age of Patients in the PNH and PN Group (X-Axis=PNH and PN Group, Y-Axis=Mean Age of Patients in Years)

Distribution of Left and Right Side Involvement- Out of total patients, 32 patients (i.e. 53.3%) had involvement of left shoulder and 28 patients (i.e. 46.7%) had involvement of right shoulder.

In the PNH group, out of 30 patients, there were 16 patients with left side involvement and 14 patients with right side involvement.

In the PN group of 30 patients, 14 had involvement of left side and 16 had involvement of right side.

		Count (n)	Column n%
Side	Left	32	53.3%
	Right	28	46.7%
	Total	60	100.0%

Table 8. Involvement of Left and Right Shoulder in 60 Patients

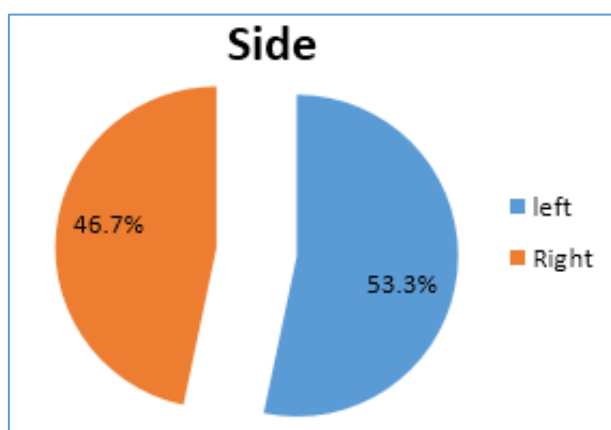


Figure 7. Percentage Wise Distribution of Left and Right Shoulder in PNH and PN Group Respectively

		PNH		PN	
		Count (n)	Column n%	Count (n)	Column n%
Side	Left	16	53.3%	16	53.3%
	Right	14	46.7%	14	46.7%
	Total	30	100.0%	30	100.0%

Table 9. Percentage Wise Involvement of Left and Right Shoulder in PNH and PN Group Respectively

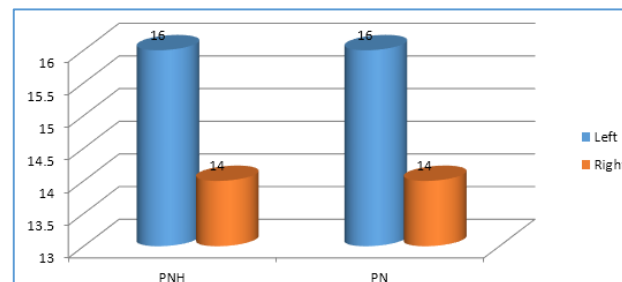


Figure 8. Left and Right Side Affection in PNH and PN Group

Pearson Chi-Square Tests

		Group
Side	Chi-square	0.000
	df	1
	P value	1.000

Table 10. Chi-Square Test showed that the Number of Left Side and Right Side Involvement was Equal in Both the Age Groups and were Statistically not Significant

Analysis of the Outcome Measure (Constant Score)-

The constant score combines subjective and objective measure to produce a 100-point score. This is derived of four parameters- Activities of Daily Living (ADL), Range of Movement (ROM), pain and strength.

Analysis of Mean Constant Score Between PNH and PN Group T Different Time Interval-

Comparison of mean constant scores using repeated measures ANOVA between two treatment groups showed that the difference was statistically significant at 6 weeks (p-value=0.010) between the two groups means that PNH group showed significant improvement compared to PN group at short term. But, the difference in constant score at 3 months (p-value=0.060), 6 months (p-value=0.76) and at 1 year (p-value=0.195) was not statistically significant between the two treatment groups as shown in the table below means that the PNH group did not show statistically significant improvement long term compared to the PN group.

	Group	Count (n)	Mean	Standard Deviation	P Value
Constant score at 0 week	PNH	30	23.27	3.552	0.190
	PN	30	22.20	2.605	
Constant score at 6 weeks	PNH	30	50.03	14.092	0.010
	PN	30	40.10	14.622	

Constant score at 3 months	PNH	30	68.70	17.185	0.060
	PN	30	59.27	20.794	
Constant score at 6 months	PNH	30	78.37	12.824	0.076
	PN	30	70.87	18.785	
Constant score at 1 year	PNH	30	81.03	10.070	0.195
	PN	30	76.40	16.515	

Table 11. Mean Constant Score Values of PNH and PN Group and their Statistical Significance

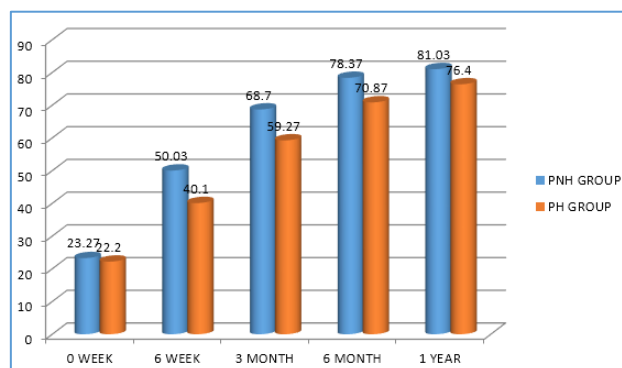


Figure 9. Mean Constant Score Value for Both Treatment Groups at the Start, i.e. at 0 Weeks, 6 Weeks, 3 Months, 6 Months and at 1 Year

Mean constant score improved significantly for both the treatment groups over the period of one year with PNH group performing slightly better compared to PN group over the same period of time.

Improvement in the Mean Constant Score Values between the Two Groups at Six Weeks

	Group	Count (n)	Mean Score	Standard Deviation	P value
Difference in mean constant scores at 6 weeks	PNH	30	26.7667	12.39211	.012
	PN	30	17.9000	14.15274	

Table 12. Improvement in the Mean Constant Score Values and Statistical Significance at 6 Weeks

Over the period of 6 weeks, PNH group showed improvement of 26.76 points, i.e. the difference of scores at 0 week and 6 weeks (50.03-23.27) compared to the PN group, which showed improvement of 17.9 points (40.10-22.2) over the period of 6 weeks. Statistical analysis showed that the improvement was significant in PNH group compared to PN group (p-value=0.012).

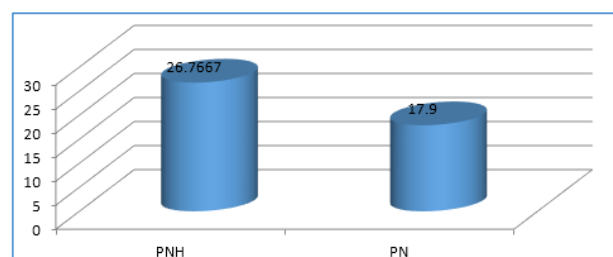


Figure 10. Improvement in the Mean Constant Score Values between the PNH and PN Groups at 6 Weeks (X-Axis=PNH and PN Groups, Y-Axis=Improvement in the Mean Constant Score Values)

Improvement in the Mean Constant Score Values between the Two Groups at Three Months-

	Group	Count (n)	Mean Score	Standard Deviation	P value
Difference in mean constant scores at 3 months	PNH	30	45.4333	15.48900	0.085
	PN	30	37.0667	21.06138	

Table 13. Improvement in the Mean Constant Score Values and Statistical Significance between the Two Groups at 3 Months

Over the period of 3 months, PNH group showed improvement of 45.4333 points, i.e. the difference of scores at 0 week and 3 months (68.70-23.27) compared to the PN group, which showed improvement of 37.06 points (59.27-22.2) over the period of 3 months. Statistical analysis showed that the improvement was not significant in PNH group compared to the PN group (p-value=0.085) at 3 months.

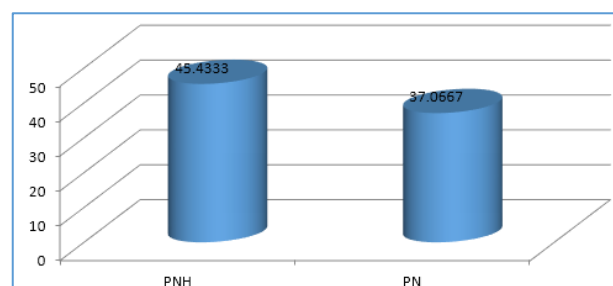


Figure 11. Improvement in the Mean Constant Score Values between the PNH and PN Groups at 3 Months (X-Axis=PNH and PN Groups, Y-Axis=Improvement in the Mean Constant Score Values)

Improvement in the Mean Constant Score Values between the Two Groups at 6 Months

	Group	Count (n)	Mean Score	Standard Deviation	P value
Difference in mean constant scores at 6 months	PNH	30	55.1000	12.47991	
	PN	30	48.6667	19.00333	0.127

Table 14. Improvement in the Mean Constant Score Values and Statistical Significance between the Two Groups at 6 Months

Over the period of 6 months, PNH group showed improvement of 55.1000 points, i.e. the difference of scores at 0 week and 6 months (78.37-23.27) compared to the PN group, which showed improvement of 48.66 points (70.87-22.2) over the period of 6 months. Statistical analysis showed that the improvement was not significant in PNH group compared to the PN group (p-value=0.127) at 6 months.

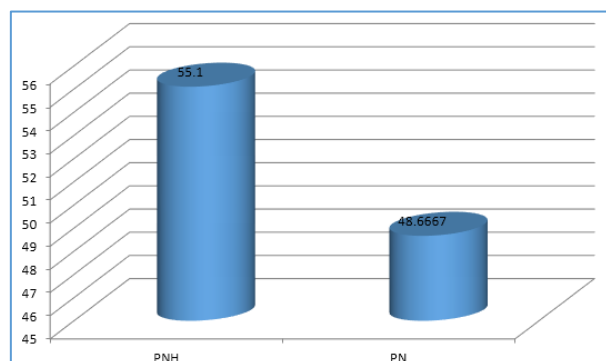


Figure 12. Improvement in the Mean Constant Score Values between the PNH and PN Groups at 6 Months (X-Axis=PNH and PN Groups, Y-Axis=Improvement in the Mean Constant Score Values)

Improvement in the Mean Constant Score Values between the Two Groups at 1 Year

	Group	Count (n)	Mean Score	Standard Deviation	P value
Difference in mean constant scores at 1 year	PNH	30	57.7667	9.90884	
	PN	30	54.2000	16.84288	0.322

Table 15. Improvement in the Mean Constant Score Values and Statistical Significance between the Two Groups at 1 Year

Over the period of one year, PNH group showed improvement of 57.76 points, i.e. the difference of scores at 0 week and 1 year (81.03-23.27) compared to the PN group, which showed improvement of 54.20 points (76.40-22.2) over the period of 1 year. Statistical analysis showed that the improvement was not significant in PNH group compared to the PN group (p-value=0.322) at 1 year.

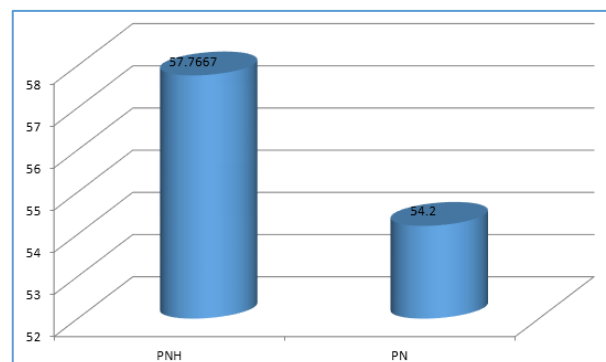


Figure 13. Improvement in the Mean Constant Score Values between the PNH and PN Groups at 1 Year (X-Axis=PNH and PN Groups, Y-Axis=Improvement in the Mean Constant Score Values)

Analysis of Mean Constant Scores of PNH Group at Different Time Interval- Comparison of mean constant scores using repeated Anova among PNH group showed that the difference was statistically significant throughout the study period of 1 year (p-value=0.0001). This means that the patients improved significantly overtime and the treatment was effective.

	Mean	Standard Deviation	Count (n)	P value
Constant score at 0 week	23.27	3.552	30	0.0001
Constant score at 6 weeks	50.03	14.092	30	
Constant score at 3 months	68.70	17.185	30	
Constant score at 6 months	78.37	12.824	30	
Constant score at 1 year	81.03	10.070	30	

Table 16. Repeated Measure ANOVA Among PNH Group

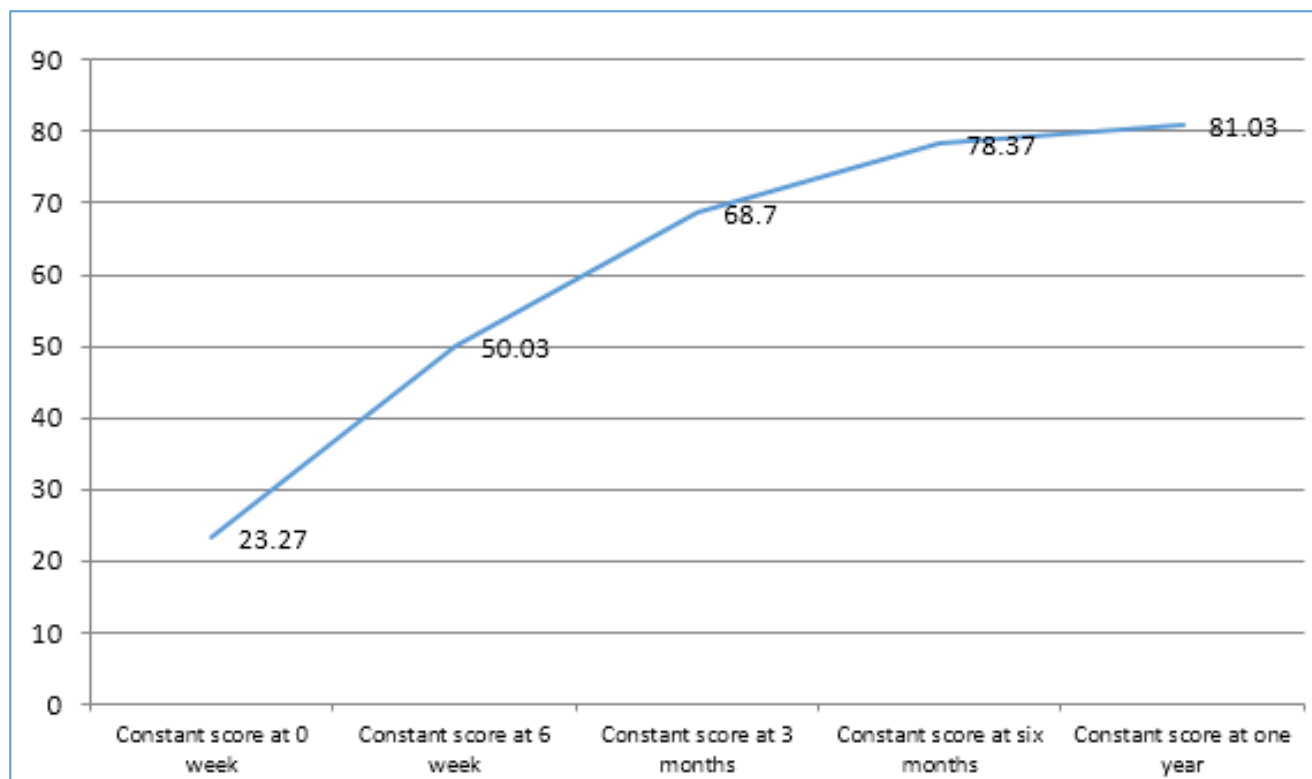


Figure 14. Graph of Mean Constant Score Values in PNH Group (X-Axis Time Interval, Y-Axis=Mean Constant Score Values)

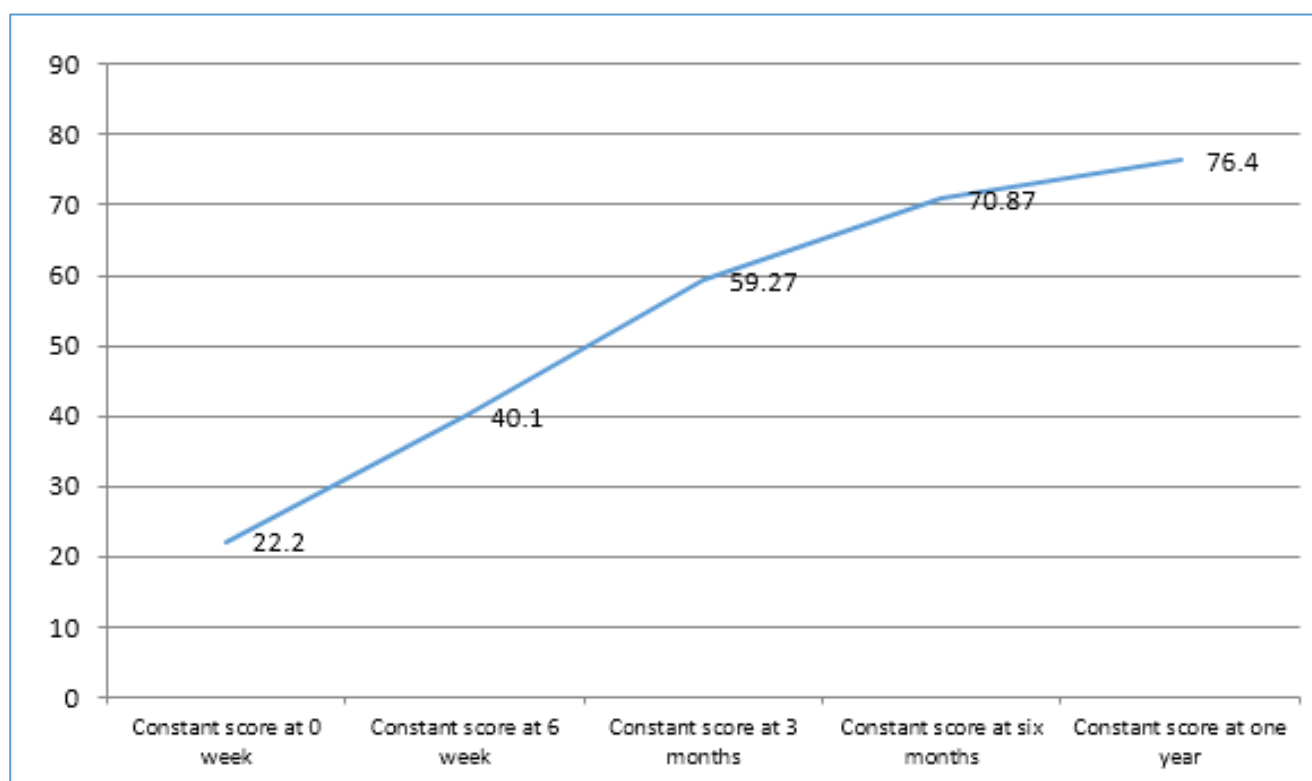


Figure 15. Graph of Mean Constant Score Values in PN Group (X-Axis Time Interval, Y-Axis=Mean Constant Score Values)

Analysis of Mean Constant Scores of PN Group at Different Time Interval- Comparison of mean constant scores using repeated ANOVA among PN group showed that the difference was statistically significant throughout the study period of 1 year (p-value=0.0001). This means that the patients improved significantly overtime and the treatment was effective.

	Mean	Standard Deviation	Count (n)	P value
Constant score at 0 week	22.20	2.605	30	0.0001
Constant score at 6 weeks	40.10	14.622	30	
Constant score at 3 months	59.27	20.794	30	
Constant score at 6 months	70.87	18.785	30	
Constant score at 1 year	76.40	16.515	30	
Table 17. Repeated Measure ANOVA among PN Group				

CONCLUSION

This study has completed the objectives of developing, implementing and evaluating the efficacy of the most appropriate management of shoulder periarthritis. The study considered 2 interventions used by the orthopaedicians in the treatment of shoulder periarthritis. The results suggest that an injection of hyaluronic acid is superior in relieving the signs and symptoms of shoulder periarthritis in combination to physiotherapy compared to physiotherapy alone. This study showed that hyaluronic injection into the glenohumeral joint significantly improves the shoulder range of motion, constant scores and pain at short-term followup following treatment of shoulder periarthritis. PNH group has significantly better outcomes than PN group. Intra-articular hyaluronic injection was safe with no reported complications within this study.

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