

STUDY TO EVALUATE THE ADDITIONAL BENEFIT OF THE HYDROLIC CAPSULAR DISTENTION USING NORMAL SALINE AND STEROID IN THE MANAGEMENT OF THE FROZEN SHOULDERS TREATED WITH CONVENTIONAL PHYSIOTHERAPY

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ABSTRACT: Although many treatment options have been advocated for the self-limiting disease of the frozen shoulder, there is no robust evidence of the superiority of one over other. This study intended to evaluate the outcome of hydrolic capsular distention followed by physiotherapy and its comparison with only physiotherapy regime in treatment of frozen shoulder. **AIMS AND OBJECTIVES:** Evaluate the additional benefit of the hydrolic capsular distention using normal saline and steroid in the management of the frozen shoulder treated with conventional physiotherapy. **MATERIALS AND METHODS:** In this randomized prospective study we have studied total 50 cases within the age group of 40-70 years with idiopathic frozen shoulder. They were divided into two groups of 25 patients each. Patients in the first group were treated with shoulder joint capsular distention using normal saline and steroid under local anesthesia at outpatient department followed by physiotherapy and the patients in second group were treated with physiotherapy only. The aim was to obtain earlier pain relief and earlier relief from functional disability. Shoulder pain and disability index (SPADI) & Visual analogue scale (VAS) score was used as a tool for evaluation and comparison. **RESULTS:** After confounding all the demographic factors it was found that the intra as well as inter group change in SPADI score revealed statistically extremely significant difference (p value - <0.0001) at the end of 12th week. Hydrotherapy group being superior than the only physiotherapy group. VAS score showed statistically extremely significant improvement in hydrotherapy group at the end of 1st week (p value- <0.0001) as compared to not much improvement in only physiotherapy group (p value - 0.0830). Similar results were observed with the SPADI score values at the end of first week, where 80% patient in hydrotherapy group felt some improvement in performing daily activities at the same time no one was quoted to say so in only physiotherapy group. **CONCLUSION:** From this study we conclude that in the management of frozen shoulder hydrolic capsular distention with intra-articular steroid and normal saline followed by physiotherapy gives dramatic relief from pain as early as within the first week. The improvement from the functional limitation is also earlier and the effects remain sustained till 12 weeks as compared to only physiotherapy regimen. **KEYWORDS:** Frozen shoulder, Hydrotherapy, Capsular distention, Conventional physiotherapy, Shoulder pain and disability index (SPADI) score.

ORIGINAL ARTICLE

INTRODUCTION: Frozen shoulder is a self-limiting condition characterised by gradually increasing pain, followed by progressive stiffness of the shoulder joint.¹ The pain and movements improve partially or completely over months to years.^{2,3} The term frozen Shoulder was first introduced by Codman in 1934 and described it as "a condition difficult to define, difficult to treat and difficult to explain from the point of view of pathology".⁴ Frozen shoulder can be a primary or idiopathic problem or it may secondarily be associated with another systemic illness. Both of which have similar clinical presentations.

Many treatment options have been proposed for frozen shoulder.⁵ These include benign neglect, non-steroidal anti-inflammatory drugs, active and passive physiotherapy, oral and intraarticular corticosteroids, hydrodilatation, manipulation under anaesthesia, arthroscopic and open surgical release. Yet there is no definite consensus regarding the single best treatment modality.⁶ Treatment with intraarticular steroid injection may reduce the inflammation.⁷ A single steroid injection in combination with physiotherapy is effective in reducing both pain and disability, but recovery of range of movement still takes a long time.⁸ Treatment with injection of large volume of normal saline into the joint, breaks down the adhesion of the capsule & distends the capsule to develop an anatomical plane of motion and decreases the amount of the effort required for physiotherapy.⁹

Variable nomenclature, inconsistent reporting of the disease stage and a multitude of the different treatments have created a confusing and the contradictory body of literature about this condition.¹⁰ Pain, duration and economic loss make it important to establish programme of treatment, which will enable patients to recover a full range of painless movement in the shortest possible time period.¹¹

Therefore in this study we have evaluated and compared two modalities of treatments: intra-articular steroid and normal saline with physiotherapy and only physiotherapy in terms of early pain relief and earlier functional improvement.

AIM & OBJECTIVES: To evaluate and compare the outcome of Hydrolic capsular distension using normal saline and steroid followed by physiotherapy with that of Only Physiotherapy as treatment options for frozen shoulder and to find out which treatment modality is superior in terms of early pain relief and earlier functional improvement.

MATERIALS & METHODS: In this randomised and prospective study we have evaluated total 50 patients of frozen shoulder, in the age group 40 to 70 years. The diagnosis was done purely on the clinical basis. Patients having symptoms of pain, stiffness with limited range of motion and who were having difficulty in performing routine activities for a period of two months at least, without any recent trauma and previous treatment around affected shoulder were considered for the study. Further, every patient was investigated with haemogram, blood sugar level and shoulder x-ray (Anteroposterior view) to rule out other pathologies. Patients with previously diagnosed diabetes mellitus were screened for glycosylated haemoglobin levels. Only those who had normal Hba_{1c} level were considered for the study. Patient with major medical illnesses, immunocompromised body status & allergic reaction to local anaesthetics were excluded.

ORIGINAL ARTICLE

After the diagnosis was made, pre-treatment VAS (visual analogue scale) score and Shoulder pain and disability index (SPADI) score (Fig. 1) noted along with the maximum passive range of motion in flexion, abduction and external rotation. Then the patients were randomly divided into two groups. Patients in HT+PT (Hydrotherapy with Physiotherapy) group were treated with hydrolic capsular distension using normal saline with steroid under local anesthesia followed by physiotherapy from next day while patients in Only PT (Only Physiotherapy) group were directly treated with physiotherapy. The physiotherapy schedule for both the groups involved mobilization exercises under supervision of the physiotherapist for 7days followed by similar home exercises till 12 weeks. Patients from both the groups were called for follow up at the end of 1st, 3rd, 6th and 12th weeks.

Fig. 1: Shoulder Pain And Disability Index (SPADI) Scoring System¹²

Shoulder Pain And Disability Index (SPADI)

Pain scale

How severe is your pain?

Circle the number that best describes your pain where: 0 = no pain and 10 = the worst pain imaginable.

At its worst?	0	1	2	3	4	5	6	7	8	9	10
When lying on the involved side?	0	1	2	3	4	5	6	7	8	9	10
Reaching for something on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Touching the back of your neck?	0	1	2	3	4	5	6	7	8	9	10
Pushing with the involved arm?	0	1	2	3	4	5	6	7	8	9	10

Disability scale

How much difficulty do you have?

Circle the number that best describes your experience where: 0 = no difficulty and 10 = so difficult it requires help.

Washing your hair?	0	1	2	3	4	5	6	7	8	9	10
Washing your back?	0	1	2	3	4	5	6	7	8	9	10
Putting on an undershirt or jumper?	0	1	2	3	4	5	6	7	8	9	10
Putting on a shirt that buttons down the front?	0	1	2	3	4	5	6	7	8	9	10
Putting on your pants?	0	1	2	3	4	5	6	7	8	9	10
Placing an object on a high shelf?	0	1	2	3	4	5	6	7	8	9	10
Carrying a heavy object of 10 pounds (4.5 kilograms)	0	1	2	3	4	5	6	7	8	9	10
Removing something from your back pocket?	0	1	2	3	4	5	6	7	8	9	10

Fig. 1

ORIGINAL ARTICLE

The Hydrolic capsular distension procedure was performed in the operation theatre with patient in supine and affected shoulder in neutral position and an image intensifier machine positioned from the opposite side. After the sterile preparation of the skin the glenohumeral crease was palpated and then superoinferior midpoint of the line forming radiological joint space was marked over skin, under guidance of image intensifier machine. This point was considered to enter the joint space. (Fig. 2) The skin and anterior soft tissue were anesthetized using 3ml of 2% lidocaine with 24 gauge, 1-inch needle. With same pierce point the joint space was entered with a 21-gauge 1.5-inch needle pointing toward the presumptive centre of the radiological glenoid fossa. The proper position of the tip of the needle within the radiological joint space was confirmed under image intensifier by slight elastic bending of needle between two joint surfaces. (Fig. 3) The overshooting of the needle, i.e. needle tip piercing the posterior capsule was prevented by placing the needle tip within the ellipsoid margin of radiological glenoid fossa. Once the joint space position of the needle was confirmed, 2ml (80 mg) of Methyl prednisolone Acetate mixed with 3ml of 2% lidocaine was injected within the joint.

Fig. 2: Position of patient and approach during the hydrolic distension procedure.

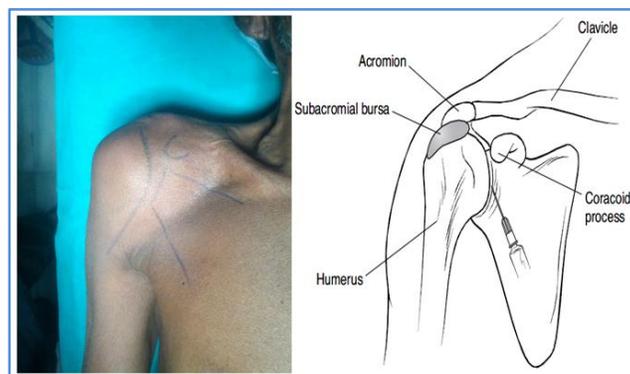


Fig. 2

Fig. 3: Picture showing the proper positioning (elastic bending) of the needle within the joint cavity during the procedure.



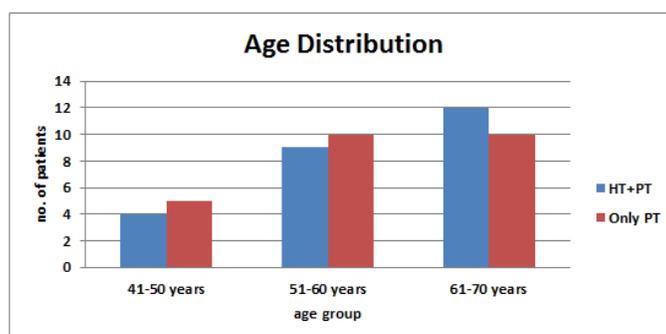
Fig. 3

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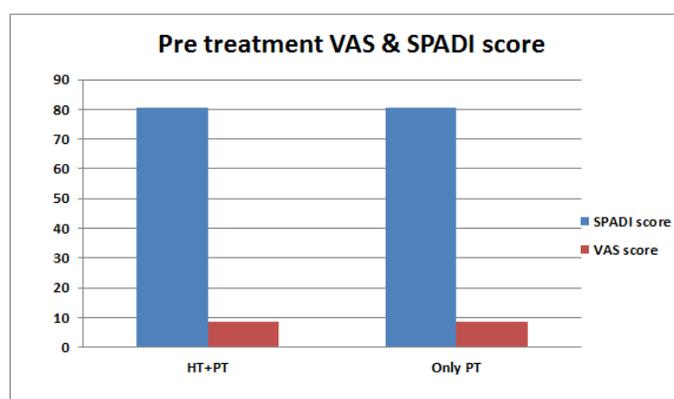
Then 25ml normal saline was forcefully injected into the joint without removing the properly placed initial needle. Efflux of fluid from the needle while changing the syringes or backing out of syringe piston (containing normal saline) when pressure over it was reduced, further confirmed the proper position of the needle within the joint. Then the needle was removed and pressure with cotton swab was applied for 2 minutes at the entry point. Increased in distance of radiological joint space at the ending of the procedure ensured the proper delivery of the drug within the joint cavity.

Evaluation and Comparison of treatment methods was done on the basis of amount of change in Visual analogue scale (VAS) score at the end of first week and Shoulder pain and disability index (SPADI) score at 1st, 3rd, 6th and 12th weeks. The passive range of movement of the shoulder joint was also recorded and was considered as an evaluating measure secondary to VAS and SPADI score, while comparison.

RESULTS AND ANALYSIS: The mean age of patients was 57.30 years with 54% males. (Graph 1) All pre-treatment findings for both the groups were statistically non-significant. (Graph 2). The mean VAS score in HT+PT group at the end of 1st week was 2.28 with mean difference of 6.16 with respect to pre-treatment VAS score (p value- <0.0001) while in Only PT group it was 8.36 with mean difference of 0.12 with respect to pre-treatment VAS score (p value – 0.0830).



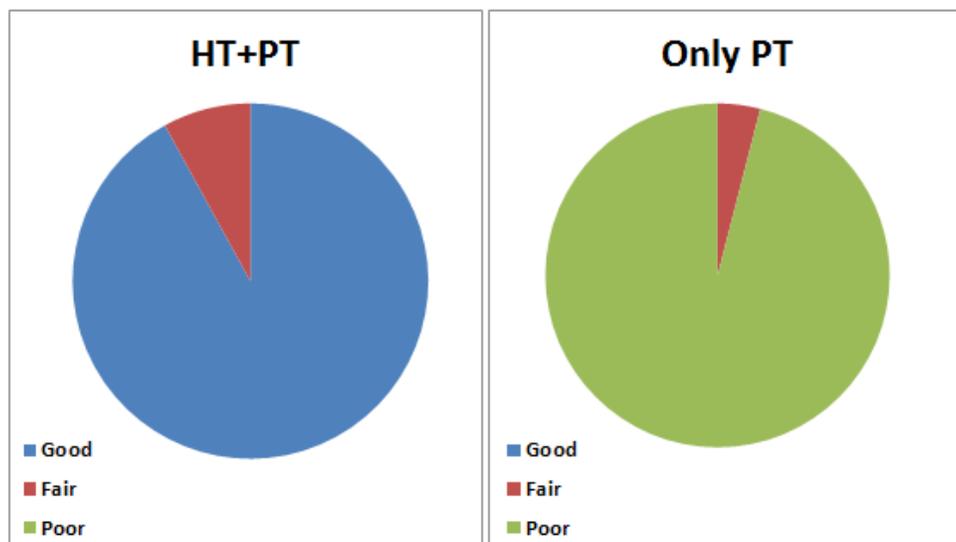
Graph 1: Age wise distribution of the patients



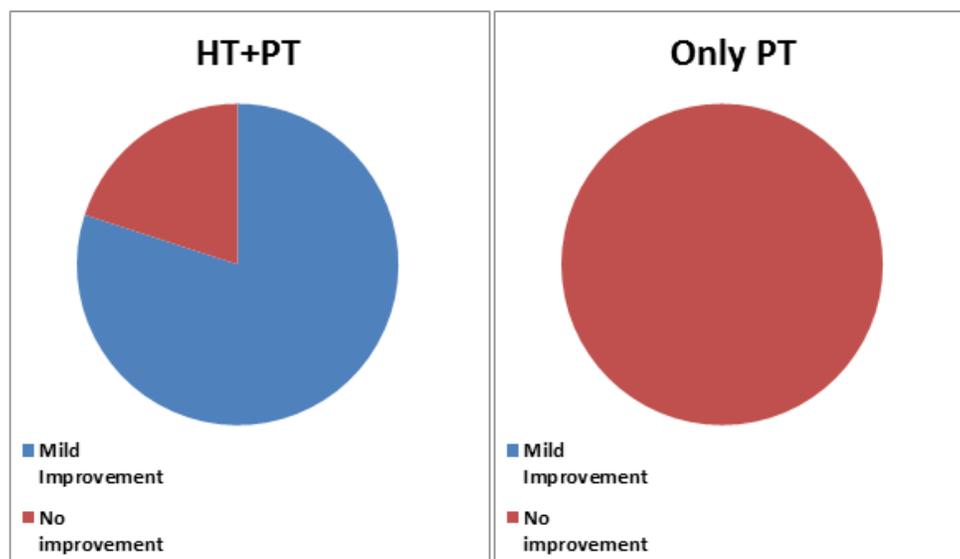
Graph 2: Pre-treatment VAS & SPADI score

ORIGINAL ARTICLE

At the end of 1st week, 92% patients in HT+PT group were found to be quoted to have good pain relief which was not seen in any patient of Only PT group. (p value – <0.0001). (Graph 3) The mean SPADI score in HT+PT group at the end of 1st week was 59.13 with mean difference of 21.48 with respect to pre-treatment SPADI score (p value- <0.0001) while in Only PT group it was 79.42 with mean difference of 1.01 with respect to pre-treatment VAS score (p value – 0.0846). At the end of 1st week, 80% patients in HT+PT group were found to be quoted to have some improvement in performing their daily activities which was seen in only 4% patient of Only PT group. (p value – <0.0001). (Graph 4)



Graph 3: Subjective pain improvement after 1st week

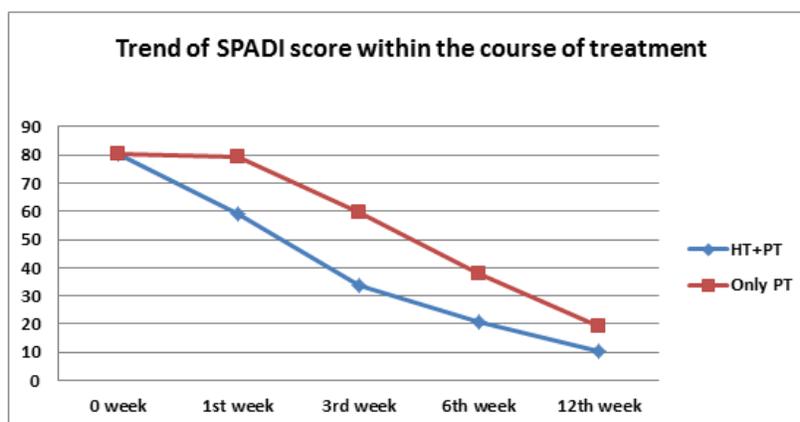


Graph 4: Functional improvement after 1st week

ORIGINAL ARTICLE

The mean SPADI score for HT+PT group at the end of 1st, 3rd, 6th & 12th weeks were 59.13, 33.81, 20.75 & 10.17 respectively. While the mean SPADI score for HT+PT group at the end of 1st, 3rd, 6th & 12th weeks were 79.42, 59.84, 37.75 & 19.05 respectively. (Graph 5) Both group showed extremely significant change in SPADI value at the end of the 12th week (p value- <0.0001) with HT+PT group being statistically more superior. Similar results were found while comparing the range of motion.

There was no complication noted with any patient of the either treatment group.



Graph 5: Trend of SPADI score within the course of treatment

DISCUSSION: In the treatment of the frozen shoulder the role of individual treatment modalities of Physiotherapy, steroid injection and saline distension has been already proven.^{13,14} It has been postulated that physiotherapy helps by improving the joint and soft tissue mobility by minimising the contracture formation and also by breaking the collagen bonds and realignment of the soft tissue fibres for permanent elongation which have adaptively become shortened and hypo-mobile in due course of the disease.¹⁵ The improvement in pain with physiotherapy management is comparatively less and delayed.¹⁶ Intra-articular steroid injection gives a good pain relief by reducing the capsular and pericapsular inflammation but studies have shown that this effect can be short lasting with repetition required and steroid injection alone has found to be less effective in improving range of motion.^{7,8} A forceful distension of joint using normal saline breaks the intracapsular adhesions strips the capsule from bony attachment and sometimes even causes capsular rupture, thus improving the pain and overall functional outcome in frozen shoulder.^{9,13} There are few studies^{13,17,18} who have analysed the combination of two treatment modalities; but there is hardly any study which has evaluated the combined effect of all three modalities i.e., steroid injection + saline distension + physiotherapy, which has been done in our study.

The amount of normal saline used for joint distension in our study is 30ml as compared to 50ml used in the study by Ghauri S. et al,¹⁹ 30-80 ml in the study by R. Buchbinder et al¹³ and 10ml in the study conducted by Einar K. et al.¹⁷ We have offered steroid injection and distension only once in our treatment modality for our patients as compared to the 3 injection given at

ORIGINAL ARTICLE

interval of six weeks in a study by Jacobs et al²⁰ and 3 injections given at interval of 2 weeks in study by Einar K. et al.¹⁷ No patient developed any complications related to hydrolic distension in our study, this was comparable to the study by Ghauri S. et al¹⁹ showing no complications and to study by Einar K. et al¹⁷ in which only one out of 38 patients developed infection in glenohumeral joint.

There are currently no published placebo controlled trials comparing the accuracy in delivering the drug, i.e. either a blind procedure or using plain radiology or arthrography assisted intra-articular method for distension of the shoulder joint. R. Buchbinder et al,¹³ in their study have raised the doubt about incorrect needle placement while delivering the drug. There are few studies mentioning arthrography assisted joint distension which has increased the cost of the treatment and also the complications.^{13,21} In our study we have used plain radiographic images via image intensifier to improve the accuracy joint distension. We have considered some intra-procedure observations which will ensure that proper placement of the needle within the joint before injecting the steroid and normal saline.

Namely they are-

1. Elastic bending of the needle between the two joint surfaces.
2. Keeping the needle tip within the ellipsoid margin of radiological glenoid fossa.
3. Efflux of the fluid from the needle while changing the syringes.
4. Backing out of syringe piston (containing normal saline) when pressure over it was reduced.
5. Increased radiological joint space immediately at the end of the procedure.

In this randomised and prospective study we have evaluated total 50 patients of frozen shoulder, in the age group 40 to 70 years. The mean age of patients was 57.30 years with 54% males. The age and sex distribution of the patients within the study groups was statistically insignificant. In the study carried out by Ghauri S. K. out of 60 patients there were 37 cases (63%) were males with mean age being 51years.¹⁹ In the study done by Larry Halverson, the mean age of patients was found to be 56 years ranging from 37 to 76 years.²¹ Almost similar observation was made in the study of Hamdan and AL Essa where out of 100 patients observed by them 61 were males and 39 were females and the mean age group was 52 years.²³ The onset of symptoms were gradual in all patients in our study average being 3.5 months, which was 4.5 months in the study conducted by Jorma K.⁷ There is a documented relationship between diabetes and frozen shoulder with incidence reported being 10-36%, in our study we found 16 patients out of 50 (32%) were diabetics.^{24,25}

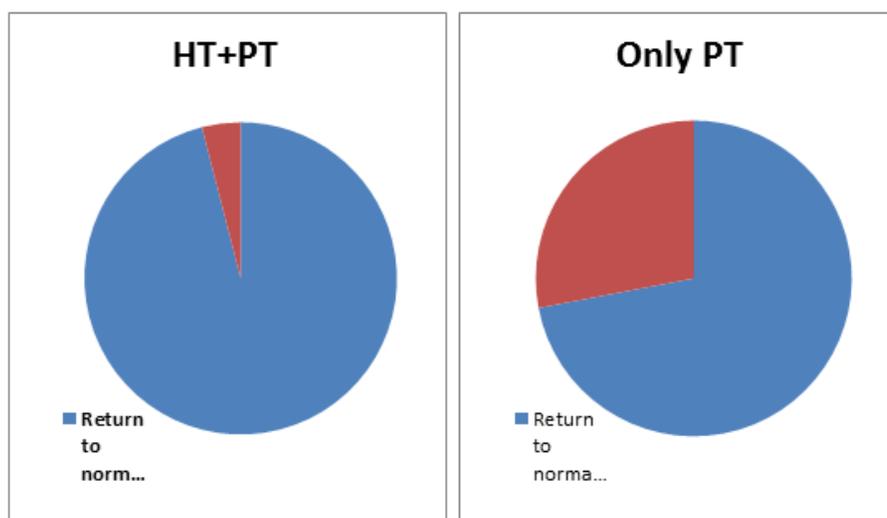
In our study after the intervention started, all the patients treated with hydrolic distension followed by physiotherapy had immediate relief in pain (92 % with good and 8% with fair improvement) by first week, they were found to be quoted to have a good night sleep with lying on the affected shoulder within couple of days. This was not seen in patients taking only physiotherapy as treatment, where 96% patients felt not much improvement in pain at the end of the first week. There was statistically extremely significant improvement in VAS score in HT+PT group at the end of 1st week (p value- <0.0001) as compared to not much improvement in Only PT group (p value -0.0830). The cross group difference of VAS score was also statistically extremely significant (p value - <0.0001). Almost similar scenario was observed with the SPADI

ORIGINAL ARTICLE

score values at the end of first week of commencing the treatment where 80% patient in HT+PT group felt some improvement in performing daily activities at the same time no one was quoted to say so in only PT group.

In the comparative study of Ghauri S. it was observed that all the patients with hydrolic distension achieved immediate pain relief and good return to range of motion and also had good night's sleep.¹⁹ Shah M. In his study showed that out of 20 patients treated with hydrolic distension 17 (85%) had no pain at the end of first week which is comparable to our study.²⁶ Lyn Watson in his study of treatment of frozen shoulder with hydrodilation followed by physiotherapy observed that the greatest magnitude of the change in SPADI score and range of motion occurred between 3-7 days after hydrodilation which remained significantly persistent till 6 months of follow up.²⁷ In the study by Larry Haverson it was observed that 15 out of 21 shoulders (71%) showed significant pain relief by first week of hydroplasty treatment.²²

The pre interventional mean SPADI scores were 80.61 and 80.43 in HT+PT and Only PT group respectively, whereas post interventional(12 weeks) SPADI scores were 10.17 and 19.05 in HT+PT and Only PT group respectively. Intra group change in SPADI score revealed statistically extremely significant difference. While inter group analysis of SPADI score also showed statistically extremely significant difference at the end of 12 weeks. Similar statistically extremely significant results were found for individual component of range of motion namely forward flexion, abduction and external rotation. We have found that during the course of treatment almost all patients in HT+PT group came for follow up voluntarily and showed a better compliance as they were quoted to feel quicker improvement with passage of time while 9 patients in Only PT group had to be pursued to attend follow up. 6 patients from those 9 had started adjusting their daily activities with residual disability and other 3 started showing disinterest to continue with the study. However with proper counselling all of them continued treatment protocol till 12 weeks. At the end of 12 weeks 24(96%) patients from HT+PT group quoted that they felt return to almost normal daily activity as they used to do before having the disease, but only 18 (72%) patients from Only PT group had such feeling. (Graph 6)



Graph 6: Trend of SPADI score within the course of treatment

ORIGINAL ARTICLE

In a placebo control trial by R Buchbinder et al of arthrographic joint distension with saline and steroid, it was concluded that there was statistically significant improvement in SPADI score at the end of 12 weeks.¹³ In the study conducted by Mohammad Siraj, 113 patients of frozen shoulder treated with corticosteroid injection followed by physiotherapy for 4 weeks showed pre and post treatment mean SPADI score of 81 and 14 respectively.¹⁸ Tewfik Rizk in his study showed improvement up to 69.9-90% of the normal in total range of movement at the end of 4 weeks after capsular distension and rupture.¹ Carette S. in his comparative study showed that corticosteroid along with physiotherapy or along with distension gives better results than corticosteroid alone or physiotherapy alone.²⁸ In the comparative study between hydrolic distension and intra-articular steroids by Ghauri S. observed that 88% patients had excellent result regarding their functional ability at the end of 45 days.¹⁹

CONCLUSION: From this study we conclude that in the management of frozen shoulder Hydrolic distension with intra-articular steroid and normal saline followed by physiotherapy gives dramatic relief from pain as early as within the first week. The improvement from the functional limitation is also earlier and the effects remain sustained, while physiotherapy alone gives delayed pain relief and delayed overall functional improvement. We also conclude that the benefits of hydrotherapy remain persistently superior with respect to physiotherapy alone as maximum patients receiving hydrotherapy return to normal daily activities by 12 weeks. Small sample size and no long term follow up remain the limitations of this study.

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