

Is Suprascapular Nerve Block Better Than Intra-articular Corticosteroid Injection for the Treatment of Adhesive Capsulitis of the Shoulder? A Randomized Controlled Study

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SUMMARY

Background. Adhesive Capsulitis of shoulder (AdCS) is a treatment dilemma for surgeons. Intraarticular Corticosteroid Injection (IACI) has shown only short-term benefit in improving shoulder-related disability. Suprascapular nerve block (SSNB) has shown promise in trials in reducing chronic shoulder pain. Thus a RCT was conducted to compare the efficacy of SSNB versus IACI in the treatment of AdCS.

Material and methods. 86 patients with AdCS were divided into SSNB and IACI groups by block randomization. SSNB group received single Suprascapular Nerve Block with 10ml of 0.5% Bupivacaine while IACI group received single injection of 40mg Triamcinolone and 1ml 2% Lignocaine in the shoulder; both followed by physiotherapy and followed-up and evaluated with SPADI and modified Constant scores at 1, 6 and 12 weeks.

Results. Statistically significant improvements occurred in both groups. At 12 weeks, the SPADI and Constant score for SSNB improved to 9.62±10.07 and 36.95±3.43 respectively ($p < 0.001$); and for IACI improved to 11.65±5.56 and 35.07±3.32 respectively ($p < 0.001$). The difference in the scores between the 2 groups at 1st and 6th week was insignificant, but was statistically significant in favour of SSNB at 12 weeks ($p = 0.002$).

Conclusions. 1. Thus, from the present study it can be concluded that both Suprascapular Nerve Block and Intra-articular Corticosteroid injection are effective modalities of treatment for Adhesive Capsulitis of the shoulder. 2. Suprascapular Nerve Block increased patients' pain tolerability for effective mobilization, the effect being persistent even at 12 weeks following injection. 3. It was safer than Intra-articular Corticosteroid injection with less incidence of adverse effects in our study and the literature. 4. It is an easy-to-perform outpatient procedure, with minimal chance of infection and other complications. 5. In light of the above, we may recommend Suprascapular Nerve Block as the initial procedure of choice in patients with Adhesive Capsulitis of Shoulder.

Key words: suprascapular nerve block, intra-articular corticosteroid injection, adhesive capsulitis of shoulder

BACKGROUND

Adhesive capsulitis of the shoulder is characterized by insidious onset of pain and a gradual loss of active and passive movements in all planes [1,2]. No definite cause has been found for this condition; it has a self-limiting course, usually resolving in 6-24 months [1-4]. The prevalence is around 2-5% in the general population, although this is increased with other co-morbid conditions such as Diabetes Mellitus, Dupuytren's contracture, hyperthyroidism and hypertriglyceridemia [2,5,6].

The treatment for idiopathic Adhesive Capsulitis or Frozen Shoulder remains controversial. Various treatments have been employed such as simple analgesia, NSAIDs, manipulation under anaesthesia and surgery, all having their limitations [7,8]. Physiotherapy is also often prescribed; it can help in early stages but in established cases, physiotherapy seems to be of little benefit and its efficacy alone has not been established [7,9]. Intra-articular Corticosteroid Injection (IACI) has shown benefit in improving shoulder related disability, but its long term effectiveness is not established [10]. Suprascapular nerve block (SSNB), on the other hand, has shown promise in clinical trials in reducing chronic shoulder pain [7]. Its rationale is to block the suprascapular nerve, which innervates 70% of the shoulder sensory at suprascapular fossa [11].

The goal of our study was to evaluate the efficacy of SSNB individually and in comparison to IACI for the treatment of Adhesive Capsulitis of the shoulder. To assess the outcome of SSNB and IACI individually, we used the Null Hypothesis: There is no difference between baseline and post-SSNB/IACI Scores for assessing shoulder pain and disability. Further, to compare the efficacy of SSNB and IACI, we used the Null Hypothesis: There is no difference in post-procedure scores for assessing shoulder pain and disability between the SSNB Group and the IACI Group.

MATERIAL AND METHODS

This study was in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of our hospital (IRB No.-AMC/EC/PG/13135). Written informed consent was obtained from each patient. Power calculations were performed to determine the sample size at the study design stage assuming a power of 80% ($\beta=0.2$) and a Type 1 Error (α) of 0.05. The primary outcome measure, determined before the start of the study, was the Shoulder Pain and Disability Index (SPADI) score at 12 weeks. Previous studies found that differences in the SPADI score of 10 indicate clinically relevant change of shoul-

der function [12-14]. Sample size calculations were thus based on the ability to detect a difference between treatment groups of 10 in the total SPADI scores. The standard deviation was assumed to be 15 as per previous studies [12,14]. Using this parameter, we calculated that a sample size of 36 subjects per group (using software G*Power 3.1) would be adequate with 80% power to detect such a difference at the 5% level of significance (2-sided tests). Allowing for a maximum drop-out rate of 20% (drop-out rates were 11% and 30% in 2 groups in a study by Dahan et al.), the sample size was increased to 43 per group [15].

Adult patients (age >18 years), giving informed consent, presenting with 1) Insidious onset shoulder pain, not responding to conservative treatment comprising of NSAIDs and physical therapy only for a minimum of 3 months duration and maximum of 12 months duration 2) Decreased active and passive ROM as per criteria given by Rizk et al. were included in the study [16]. Exclusion criteria included history of recent trauma or surgery or known chronic disease (like rotator cuff lesions) involving same shoulder, injection in the shoulder or SSNB, allergy to Bupivacaine, any known systemic disease (including Diabetes Mellitus), Arthritis like rheumatoid, infective or osteoarthritis involving the Glenohumeral or Acromioclavicular joint, cervical radiculopathy/upper trunk brachial plexopathy, neoplasm and pregnancy.

Thus, a total of 86 patients (Females-50, Male-36), who met the inclusion criteria, were enrolled in the study between September 2014 and July 2016. The patients were Randomized into Suprascapular Nerve Block (SSNB) Group (n=43) and Intra-Articular Corticosteroid (IACI) Group (n=43) (CONSORT flow diagram – Figure 1). Randomization was 'Adaptive', done by block randomization method to ensure equal sample size in each group. Consenting patients were randomised by computer generated, simple randomisation sequence in permuted blocks of four to receive either SSNB or IACI (meaning that there were two SSNB and two IACI in random order within each block of four patients). The sealed pre-numbered envelopes containing the assignments were kept by the outpatient front-desk and a register was maintained. The patients were taken to an adjacent minor procedure room for completion of questionnaire and evaluation of range of motion at all visits. The procedure was carried out and the results were later evaluated by separate persons.

Both the injections were given in the outpatient minor procedure room under aseptic environment. The patients were made to sit comfortably, following which the concerned shoulder was exposed and the

skin disinfected with povidone-iodine and alcohol based spirit solution. In the SSNB Group, the method described by Dangoisse et al. was used [17]. Anatomical landmarks were used to identify the injection site. Agent used was 10 ml of 0.5% Bupivacaine Hydrochloride. A line was drawn along the length of

spine of the scapula (Line AB in Figure-2). The midpoint of this line AB was marked. A 21 gauge needle was introduced through the skin 2.5 cm cephalad to the midpoint (Point C in Figure 2). The needle was directed over the spine in the plane of the scapula and advanced until contact was made with the floor of

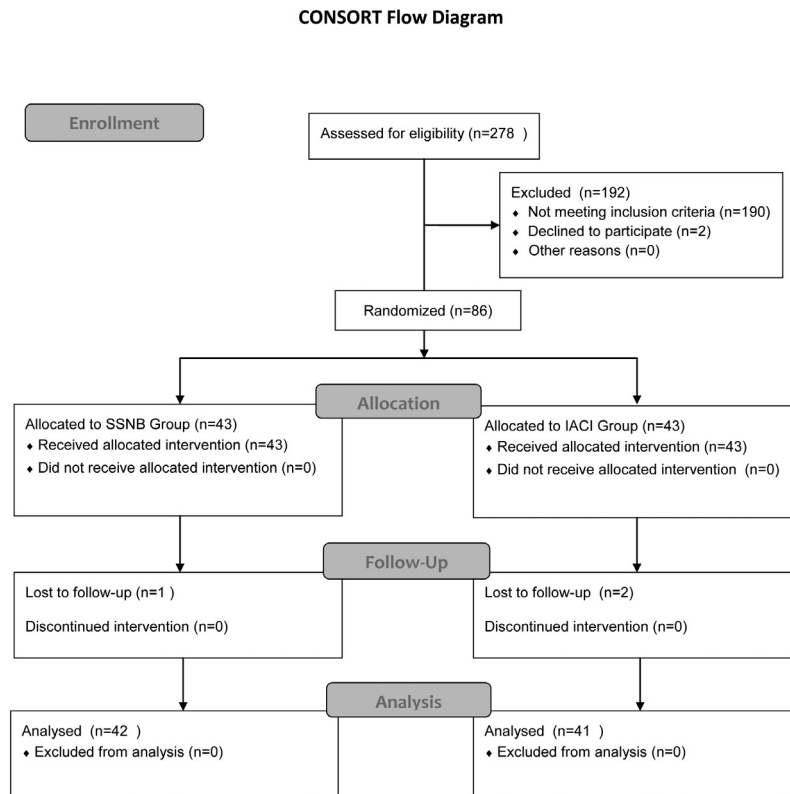


Fig. 1. CONSORT Flow Diagram of the progress through different phases of the study

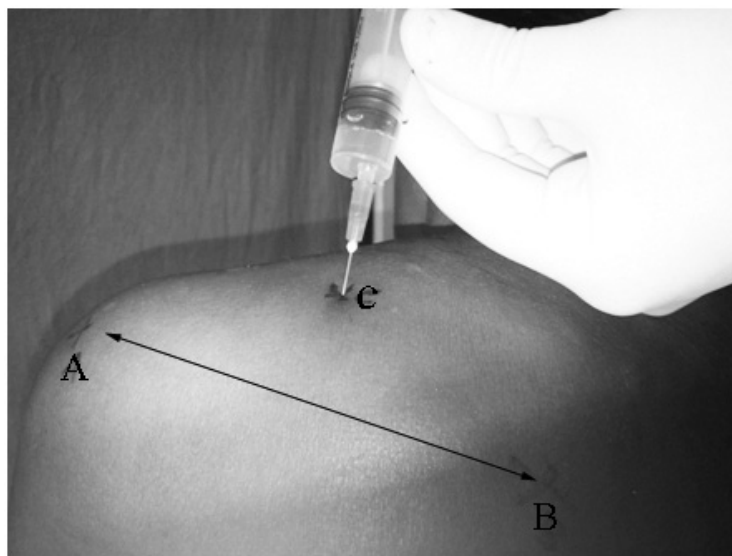


Fig. 2. The anatomical landmarks as described by Dangoisse et al.

suprascapular fossa. After attempting the aspiration the agent was slowly injected to fill the fascial contents of the fossa to produce indirect suprascapular nerve block. In the IACI Group the agent used was 40 mg of Triamcinolone (1 ml) and 1ml of 2% Lignocaine hydrochloride. An imaginary oblique line running anteriorly from the posterior angle of the acromion to the coracoid process passes through the shoulder joint. A 21 gauge needle was inserted along this line, passing through deltoid, infraspinatus and posterior capsule into the glenohumeral joint, where the agent was introduced.

Follow-up

After each procedure, the patient were given verbal and written instructions for exercise program at home. It included self-mobilization, joint stretching and static Rotator Cuff and Deltoid strengthening exercises. NSAIDS, both oral and local were prescribed for 3 days. Each patient was followed up in the outpatients at 1, 6 & 12 weeks and results were recorded. Pain levels & ROM were recorded at the start and at subsequent follow-ups by the SPADI score and Constant-Murley Score (Modified) [18,19]. The Constant-Murley score was modified to include only the objective component- Range of Motion (ROM) as the inter-rater and the test-retest reliability of the objective component has also been validated independently [19]. This helped to sum up the ROM values into a single number for easy comparison.

The data was checked for Normal Distribution with help of Shapiro-Wilk Test and it was found that it was not normally distributed. Therefore Non-Para-

metric tests were employed for statistical analysis. The improvement in each individual group was analysed for significance by Wilcoxon Signed Rank Tests whereas comparison between SSNB Group and IACI Group was done with help of Mann-Whitney U Test. Qualitative data were analysed with Fischer’s Exact test. A *p value* of < 0.05 was considered to be statistically significant. All statistical analyses were performed with IBM SPSS Statistics for Windows, Version 20.0 (Armonk, NY: IBM Corp).

RESULTS

Out of the 43 patients in the SSNB Group, 1 patient did not turn for follow-up (drop-out rate- 2.3%), whereas out of the 43 patients in the IACI Group, 2 patients did not turn for follow-up (drop-out rate- 4.7%). Thus, a total of 83 patients (Female-48, Male-35), of which 42 patients were in the SSNB Group and 41 patients were in the IACI Group, were evaluated and analyzed (post-hoc Power-85%).

The demographic characteristics of the two groups showed that there was no significant differences between them (Tab. 1). The results of Mean SPADI Pain scores (%), Mean SPADI Disability scores (%), Mean SPADI Total Scores (%) and Mean Modified Constant-Murley scores at Baseline, 1st, 6th and 12th weeks along with *p value* of the change in scores for each group and difference of scores between the two groups have been listed as Tables 2, 3, 4 and 5 respectively.

The results of Mean SPADI Pain scores (%), Mean SPADI Disability scores (%), Mean SPADI Total Scores (%) (Fig. 3) and Mean Modified Constant-Murley

Tab. 1. Demographic Characteristics of patients in both groups

		SSNB Group		IACI Group		p	Sig
		N	%	N	%		
Sex	Male	17	40.48	18	43.9	0.826	Not Sig
	Female	25	59.52	23	56.1		
Age	Mean Age	50.10 ± 9.25 years		51.88 ± 9.68 years		0.394	Not Sig
Side	Right	19	45	16	39.02	0.658	Not Sig
	Left	23	55	25	60.98		
Dominance	Dominant	17	40.48	15	36.59	0.823	Not Sig
	Non-Dominant	25	59.52	26	63.41		
Duration	3-5 Months	18	42.86	16	39.02	0.824	Not Sig
	5-8 Months	19	45.24	17	41.46		
	>8 Months	5	11.9	8	19.51		

Tab. 2. Mean SPADI Pain Scores (%)

Procedure	Baseline	1 Week	6 Weeks		12 Weeks		
			p ^a	p ^a	p ^a	p ^a	
SSNB Group	56.19	23.71	0.000	14.05	0.000	10.48	0.000
IACI Group	53.71	24.39	0.000	15.61	0.000	12.49	0.000
SSB VS IACI^b (p^c)	0.474	0.368		0.067		0.002 ^d	

a. Wilcoxon Signed Ranks Test, b. Null Hypothesis: The distribution of Mean SPADI Disability Scores (%) is the same across SSNB Group and IACI Group, c. Independent-Samples Mann-Whitney U Test, d. Reject the Null Hypothesis (sig <0.05).

Tab. 3. Mean SPADI Disability Scores (%)

Procedure	Baseline	1 Week	6 Weeks	12 Weeks
			p^a	p^a
SSNB Group	50.30	23.33	0.000	13.04
IACI Group	49.97	23.60	0.000	12.80
SSB VS IACI ^b (p^c)	0.419	0.296	0.121	0.011 ^d

a. Wilcoxon Signed Ranks Test, b. Null Hypothesis: The distribution of Mean SPADI Disability Scores (%) is the same across SSNB Group and IACI Group, c. Independent-Samples Mann-Whitney U Test, d. Reject the Null Hypothesis (sig <0.05).

Tab. 4. Mean SPADI Total Scores (%)

Procedure	Baseline	1 Week	6 Weeks	12 Weeks
			p^a	p^a
SSNB Group	52.56	23.48	0.000	13.39
IACI Group	51.41	23.90	0.000	13.88
SSB VS IACI ^b (p^c)	0.387	0.270	0.051	0.002 ^d

a. Wilcoxon Signed Ranks Test, b. Null Hypothesis: The distribution of Mean SPADI Disability Scores (%) is the same across SSNB Group and IACI Group, c. Independent-Samples Mann-Whitney U Test, d. Reject the Null Hypothesis (sig <0.05).

Tab. 5. Mean Modified Constant Murley Scores

Procedure	Baseline	1 Week	6 Weeks	12 Weeks
			p^a	p^a
SSNB Group	21.00	32.19	0.00	35.48
IACI Group	20.73	30.93	0.00	34.83
SSB VS IACI ^b (p^c)	0.250	0.117	0.081	0.002 ^d

a. Wilcoxon Signed Ranks Test, b. Null Hypothesis: The distribution of Mean SPADI Disability Scores (%) is the same across SSNB Group and IACI Group, c. Independent-Samples Mann-Whitney U Test, d. Reject the Null Hypothesis (sig <0.05).

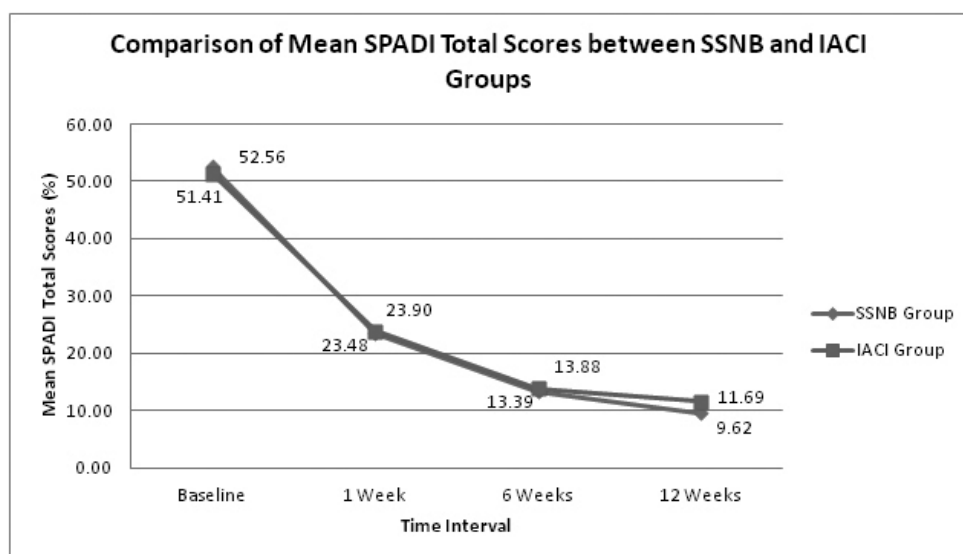


Fig. 3. Comparison of Mean SPADI Total Scores between SSNB and IACI Groups

scores (Fig. 4) showed statistically significant ($p < 0.001$) improvement from baseline at 1st, 6th and 12th weeks in both SSNB and IACI groups. Thus, the first Null hypothesis comparing the baseline and post-injection scores for each group individually was rejected for both SSNB and IACI groups.

On comparing the improvements in Mean SPADI Pain Scores (%) between SSNB Group and IACI Group, at 1st and 6th week the difference was not sta-

tistically significant; however at 12th week the difference was statistically significant ($p = 0.002$), improvement being greater in SSNB Group than IACI Group. Similarly, Mean SPADI Disability Scores (%), Mean SPADI Total Scores (%), and Mean Modified Constant-Murley Scores showed no statistically significant difference between the two groups at 1st and 6th weeks. However, at 12th week the improvements were statistically significant in favour of the SSNB Group

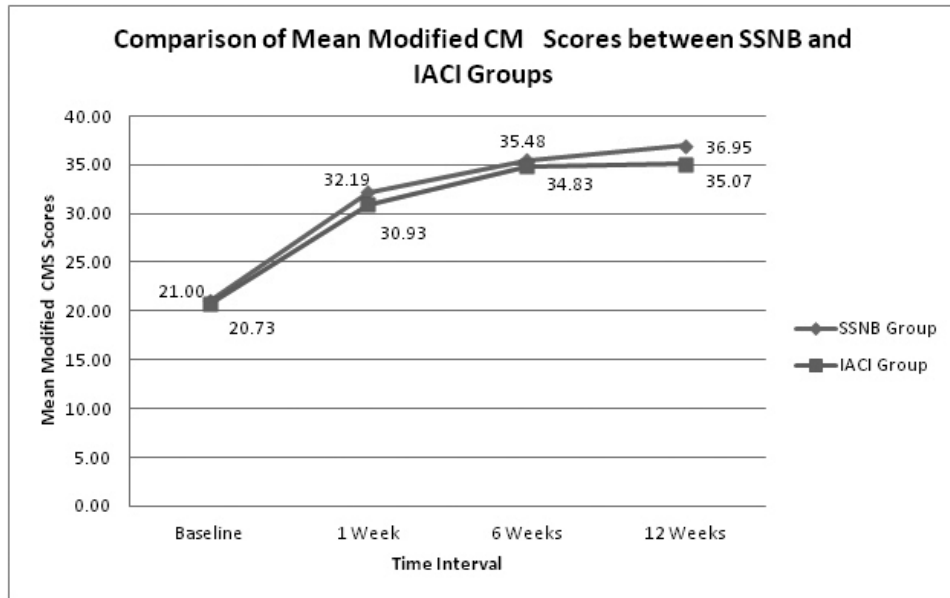


Fig. 4. Comparison of Modified Constant-Murley Scores between SSNB and IACI Groups

for Mean SPADI Disability Scores (%) ($p=0.011$), Mean SPADI Total Scores (%) ($p=0.002$), and Mean Modified Constant-Murley Scores ($p=0.002$). Thus, the second Null hypothesis comparing the outcomes of SSNB versus IACI was also rejected.

There were no major complications in our study in any of the groups. There was only one case of vasovagal attack after the procedure in the SSNB Group, which resolved immediately as the patient lied down supine for fifteen minutes. Further course in her was uncomplicated. In the IACI Group, there were two minor complications. In one case, there was minor bruising post-injection, on which sterile dressing was done and sterile adhesive plaster applied. Further recovery was uneventful. The other case had mild superficial infection near the injection site. On investigation, the post-injection random blood sugar was elevated as compared to pre-injection value. The patient was given short course oral antibiotic following which infection subsided and on repeat random blood sugar measurement after 5 days, the value was found in normal range value.

DISCUSSION

Although multiple conservative and invasive interventions have been described for Adhesive Capsulitis, no consensus has been reached regarding the best treatment. The treatment strategy usually includes relief from symptoms and modifying limitations in ADLs as well addressing the pathology which would provide durable relief. Various treatment modalities have been employed and recently SSNB has

been successfully used in clinical trials to improve pain and disability in Adhesive Capsulitis [20,21].

We performed a RCT to compare the efficacy of SSNB versus IACI for the treatment of Adhesive Capsulitis of the shoulder. The method of randomization eliminated Selection Bias, and involvement of separate persons to carry out the procedure and to evaluate the results eliminated any Observer Bias.

We selected the primary outcome measure to be SPADI [18]. It is self-administered, simple with good internal consistency, test-retest reliability, and criterion and construct validity [14]. It takes into account both pain and disability. Objective measurement for assessment of ROM was done with the help of the Constant-Murley Score modified to include only the Range of Motion (40 points), as it has also been shown to have high inter-rater and test-retest reliability independently [19].

Method of SSNB was indirect – from the posterior side. Although direct techniques have been described – from the anterior side as described by Wassef or direct from the posterior side, we chose the indirect technique described by Dangoisse because of its safety [17,22]. We used a 10 ml volume as it has been reported to be sufficient to infiltrate the whole of suprascapular fossa [23]. We further corroborated this by anatomical dissection of 5 cadavers at our Anatomy Department. Although ultrasound-guided SSNB has been described to be very accurate, it has been recently shown that there is no clinical difference between it and the anatomical landmark-guided technique used by us, especially with the amount of ana-

esthetic used in our study [24]. Being able to circumvent the need for ultrasound machine and additional manpower meant that the patients could not only be injected at the outpatient facility at the time of consultation with relative ease and without any additional waiting time but also it decreased the resources spent without any additional risks or side-effects.

For the Block we opted for the frequently used 0.5% Bupivacaine, though 1% lidocaine and 0.5% levobupivacaine, 0.75% ropivacaine has also been suggested [11,25]. We did not use methylprednisolone as described in some other studies as it was intended to achieve a block only and not to have any loco-regional anti-inflammatory effect [14]. We did not use the same anaesthetic agent and in same quantity for IACI, as our primary objective was to compare the two different procedures done in traditional manner at our institute as well as reported in majority of literature. The principal purpose of IACI was to achieve an anti-inflammatory effect without distension of the gleno-humeral joint, whereas that of SSNB was to achieve blockage of the suprascapular nerve in the suprascapular fossa away from the glenohumeral joint. However, further studies with same agent and in similar quantity without risk of distension of the joint would eliminate the possibility of confounding due to this.

The final follow-up in this study was at 12 weeks. Our main focus was to evaluate the short term effect of both the techniques in improving the pain and disability, given that the natural history of resolution of the disease might be a confounding factor in longer follow-ups as we included patients with onset of disease from 3 to 12 months. The effect of natural history of resolution could be minimized but certainly not eliminated by excluding patients beyond 12 months onset and evaluating the short term effect after the procedures. Nevertheless, longer follow-up would have helped understanding the long term benefits as well as risks of the procedures and is one of the drawbacks of the paper.

Another drawback of the study was to not include another group with only protocolised physiotherapy to eliminate the possibility of placebo effect in the improvement of shoulder pain and disability for both the procedures.

Our study revealed that a majority of the patients presented between 50-59 years. Females were in majority in both the groups – 59.52% in SSNB and 56.10% in IACI Group. Also the left shoulder and non-dominant shoulder were in majority in both the groups, and a majority of patients were treated between 3-6 months from the onset of disease. The results were mostly consistent with the literature [7,11,15,21].

Our clinical results agreed with Jones and Chattopadhyay, where improvements in pain and ROM were more in SSNB patients and the difference was statistically significant [20]. The results are also consistent with the findings of Abdelshafi et al., where there was significant improvement in pain at all times of follow-up, with best improvement in SSNB + Physiotherapy Group more than IACI + Physiotherapy Group and only Physiotherapy Group in patients with chronic shoulder pain, including patients with Adhesive Capsulitis [7]. However, opposed to our findings, the SPADI disability score showed non-significant difference over the three time periods. Again, the SPADI Total score showed significant improvement at week 4 & 12 of follow-up. Similar results in favour of SSNB over placebo were found by Shanahan et al. [14]. Even in cases of chronic arthritis of shoulder (Lewis) and non-specific shoulder pain (Tas-kaynatan et al.), SSNB showed better longer-term relief of pain and disability [11,26]. However, our final results were in partial contrast with Dahan et al. and Mehmet et al., who found non-significant improvement in the shoulder ROM at the end of their studies. This difference may be due to the fact that the patients were not prescribed specific shoulder exercises after the injections [15,27].

There were no major complications in our study. The results are consistent with the findings of Tas-kaynatan et al. where there were no side effects in an SSNB group compared to occasional side effects in a steroid injection group, which led to the conclusion that SSNB could be considered as the preferred treatment due to its better safety and equal efficacy [11]. Similarly no side effects of SSNB were encountered by Shanahan et al. and only a minor side-effect of vaso-vagal attack, as in our study, was reported by Dahan et al [14,15]. In another study, an SSNB group had no side-effect but an IACI Group had a case of vaso-vagal attack which improved subsequently [20].

The low incidence of reported side effects is an advantage. Pneumothorax has been reported as a complication of this procedure [14]. However, in our study we had no such events. Our findings confirm that indirect SSNB using the anatomical approach of Dangoisse is safer than previous methods [17]. In contrast to SSNB, IACI has a lot of adverse effects reported in the literature like dysregulation of blood glucose, increased risk of infection and steroid arthropathy [20,28]. In our study we faced temporary dysregulation of blood glucose in one patient who also had superficial infection. The lack of such side-effect profile in SSNB patients may make it the preferred procedure for at-risk patients.

Now the question comes how Bupivacaine injection could produce such a durable effect. That pain relief from the block extends beyond the pharmacological effect of the drug is well described and possible explanations for this are:

1. decrease in sensitization of dorsal horn nociceptive neurons by bupivacaine (“wind down” phenomenon) [26];
2. a depletion of substance P and nerve growth factor in synovium and diffuse C fibres of the glenohumeral joint after blockade may also contribute to the long term relief [29];
3. SSNB improves aberrant central neurophysiology in chronic shoulder pain: Short Afferent Inhibition are normalised immediately and Cortical Silent Periods modulated after 1 week of SSNB [30].

Another possible explanation is that the pathology of Adhesive Capsulitis has been described to be Reflex Sympathetic Dystrophy [22,31]. There is sensitization of Wide Dynamic Range (WDR) Neurons in the dorsal horn, which starts reacting to A mechanoreceptors and sympathetic efferent action on sensory receptors in addition to unmyelinated C-nociceptors. This produces the ‘sympathetic mediated’ pain and produces a vicious cycle. These sympathetic nerves that supply the shoulder joint travel along the Suprascapular nerve [22]. Their blockade by SSNB ends the deadlock and the sensitization of WDR neurons stops. It supposedly breaks the symbiotic rela-

tionship between pain and joint stiffness and further mobilization improves the ROM and produces a durable effect.

CONCLUSIONS

1. Thus, from the present study it can be concluded that both Suprascapular Nerve Block and Intra-articular Corticosteroid injection are effective modalities of treatment for Adhesive Capsulitis of the shoulder.
2. Suprascapular Nerve Block increased patients’ pain tolerability for effective mobilization, the effect being persistent even at 12 weeks following injection.
3. It was safer than Intra-articular Corticosteroid injection with less incidence of adverse effects in our study and the literature.
4. It is an easy-to-perform outpatient procedure, with minimal chance of infection and other complications.
5. In light of the above, we may recommend Suprascapular Nerve Block as the initial procedure of choice in patients with Adhesive Capsulitis of Shoulder.

Ethical approval: IRB/Ethical Committee Approval taken prior to start of study.

Name of Board: Institutional Ethics Committee (H), Assam Medical College, Dibrugarh 786002, India. Study Number: AMC/EC/PG/13135.

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