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Comparative Evaluation of Efficacy of Fluoroscopy and Ultrasound for Iliopsoas Block: A Randomised Trial

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Abstract

Objective: To compare analgesic efficacy, improvement in the quality of life, psychology and learning curve for iliopsoas (IP) injection using ultrasound (US) versus fluoroscopy (FL).

Methods: Thirty-six patients with chronic low back pain secondary to IP myofascial pain were randomly allocated into two groups and were given IP injection in prone position, using either FL or US as a guide. Pain scores were assessed using numerical rating scale (NRS); learning curve was evaluated by the number of attempts, time taken and subjective ease of performing the procedure. The psychological and quality of life assessment were done using Depression Anxiety Stress Scale (DASS) and Oswestry Disability Index (ODI), respectively.

Results: FL and US guided IP injection had equianalgesic efficacy with a decrease in preprocedure NRS pain scores from mean value of 7.06 ± 0.24 and 6.78 ± 0.24, respectively, to 2.22 ± 0.29 and 1.78 ± 0.26 (at 24 hours), 1.50 ± 0.22 and 1.50 ± 0.23 (1 week), 0.50 ± 0.12 and 0.56 ± 0.15 (4 weeks) and 0.33 ± 0.11 and 0.44 ± 0.15 (12 weeks) ($P < .001$). The learning curve was easier for US intervention with average attempts of 1–2 compared to 1–3 for FL. The average time taken to perform IP intervention was lesser for US group. The improvement in DASS and ODI was comparable in both groups.

Conclusion: FL and US both are effective modalities for IP muscle injection as they provide equal relief from pain, disability and psychological stress. US guided IP injections are easier to learn and perform in comparison with FL.

Keywords: Low back pain, fluoroscopy, ultrasonography, ilio-psoas, myofascial pain

Introduction

Myofascial pain syndrome (MPS) is a known entity caused by pain and dysfunction of the musculoskeletal system. It accounts for approximately 30% of patient load at general medical clinics and pain management centres.[1] MPS is characterised by trigger points which are nodules or taut band that produce characteristic pattern of referred pain on palpation. Trigger points may result from trauma, overload or overuse injury, or a prolonged period during which a muscle is shortened. Therapeutic modalities commonly include analgesics, physical therapy like massage and exercises and finally trigger point injections.

The iliopsoas (IP) muscle is a composite muscle formed from the psoas major muscle and the iliacus muscle. The psoas major originates along the outer surfaces of the vertebral bodies of L1–L3 and their associated intervertebral discs and the iliacus originates in the iliac fossa of the pelvis. Both are inserted over the lesser trocanther of femur.[2] Prevalence of chronic low back pain (LBP) due to IP MPS is 30%.[3] Pain of IP myofascial origin presents as non-radicular, ipsilateral low back or anterior hip pain referring to the thigh or inguinal area or pain and weakness while squatting or transitioning from a seated position to standing. IP MPS is frequently found in high risk groups, such as dancing, ballet, cycling, resistance training (crossfit), rowing, running (particularly uphill), soccer and gymnastics.

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Injection of the IP muscle with local anaesthetic is often used for therapeutic benefit in the case of chronic LBP refractory to conservative treatment (physical therapy, oral medications and exercises).[4] Fluoroscopic guidance is commonly used to facilitate this procedure. Ultrasound (US) guidance has emerged as an alternative modality to fluoroscopy (FL) and is known to improve therapeutic efficacy. Its benefits compared to FL include affordability, reduction of radiation exposure, "real-time" visualisation of needle tip and surrounding tissues.[5]

We conducted a randomised, parallel group trial with the aim of comparative evaluation of efficacy and ease of applicability of FL and US for IP injection. The primary objective of the study was to evaluate the pain scores at the end of 1 month. The secondary objectives were to compare the pain scores, level of disability and the psychological aspects at different time intervals and to assess the learning curve between the two imaging modalities in terms of time taken, number of attempts and ease of performance.

Methods

Study Participants

After getting approval from the Sanjay Gandhi Post Graduate Institute of Medical Sciences (2012-188-IP-66), the study was undertaken. Patients were enrolled from 2013 to 2014. Procedure and follow-up continued till 2015, and it was retrospectively registered under Clinical Trial Registry India (CTRI No: CTRI/2017/10/009957, registered on: October 3, 2017). Following written and informed consent, 36 patients with chronic LBP secondary to IP MPS were prospectively enrolled into two groups of 18 patients each. Group A (FL): IP injection guided by FL; group B (US): IP injection guided by US.

Inclusion Criteria

Patients diagnosed as IP myofascial syndrome with characteristic history and physical examination,[6] not responding to conservative management >3 months, pain on palpation of IP muscle while flexing the hip against resistance.

Exclusion Criteria

Age <18 years or >60 years, severe anxiety or depression, allergy to local anaesthetics, pregnancy and multiple co morbidities.

Randomisation and Blinding

The study followed the Consolidated Standards of Reporting Trial guidelines (Figure 1). Out of 59 patients of IP MPS, 23 responded to conservative management by exercises, massaging and medications. Four patients requested for the intervention before the stipulated 3 month conservative trial due to severe pain affecting their daily routine. Hence, 36 patients were enrolled for IP injection. They were randomly distributed into two groups using chit method by outpatient department nurse who generated 36 chits with initials of U (for USG group) and F (for FL group) written in 18 chits equally. They were kept in a box, and 1 chit was picked up by each patient on getting enrolled for the study. The group assigned was conveyed to the performer on the day of procedure telephonically. Recording of all parameters of the procedure-related variables was done by operation theatre nurse, and follow-up of the patients in the pain clinic was done by a pain fellow who did not perform the procedure and, hence, was blinded to the imaging modality.

Interventions

Following consent patients were shifted to operation theatre, and an intravenous line and standard monitors were applied. Patients were positioned prone, and after ensuring asepsis, a 22-G, 8 cm long Quincke spinal needle was used for injection after local anaesthesia to skin and subcutaneous tissue. The target of the injection was in anterior third of psoas major muscle, because near the junction of dorsal and middle one-third of the muscle the lumbar plexus can get affected. Fluoroscope images in anterio-posterior and lateral views were used to confirm the final placement of the needle by instilling dye (0.5 mL omnipaque) in both the groups. After confirmation of the target, 8 mL of 0.5% preservative free lignocaine was injected.[7]

Under the fluoroscope, IP muscle appears as a curtain arising from the lumbar vertebrae. The entry point for IP myofascial block was in the space between the transverse processes of third and fourth lumbar vertebrae, along the lateral half of intertransverse space.[8] A gun barrel view was obtained, and the needle was pushed till anterior one-third of the vertebral body in lateral view. After dye confirmation, the local anaesthetic was delivered (Figure 2).

A Sonosite M-Turbo US machine (Sonosite Fujifilm Inc.) with a curvilinear transducer (frequency of 5-2 MHz) was used for US-guided injection. Probe was positioned longitudinally in the midline over the sacrum and moved cranially, to see the first inter-spinous gap between the L5 and S1

Main Points

- Chronic low back pain due to Iliopsoas myofascial pain syndrome is often treated by injection of iliopsoas muscle with local anaesthetic under fluoroscopy or ultrasound guidance.
- Ultrasound guidance has similar clinical benefits and procedural outcomes in terms of pain relief and ease of performance respectively as compared to fluoroscopy.
- Fluoroscopy is the common imaging modality used by pain interventionist but ultrasound can be an alternative modality that offers radiation protection which can be invaluable for pregnant patients with low back pain.

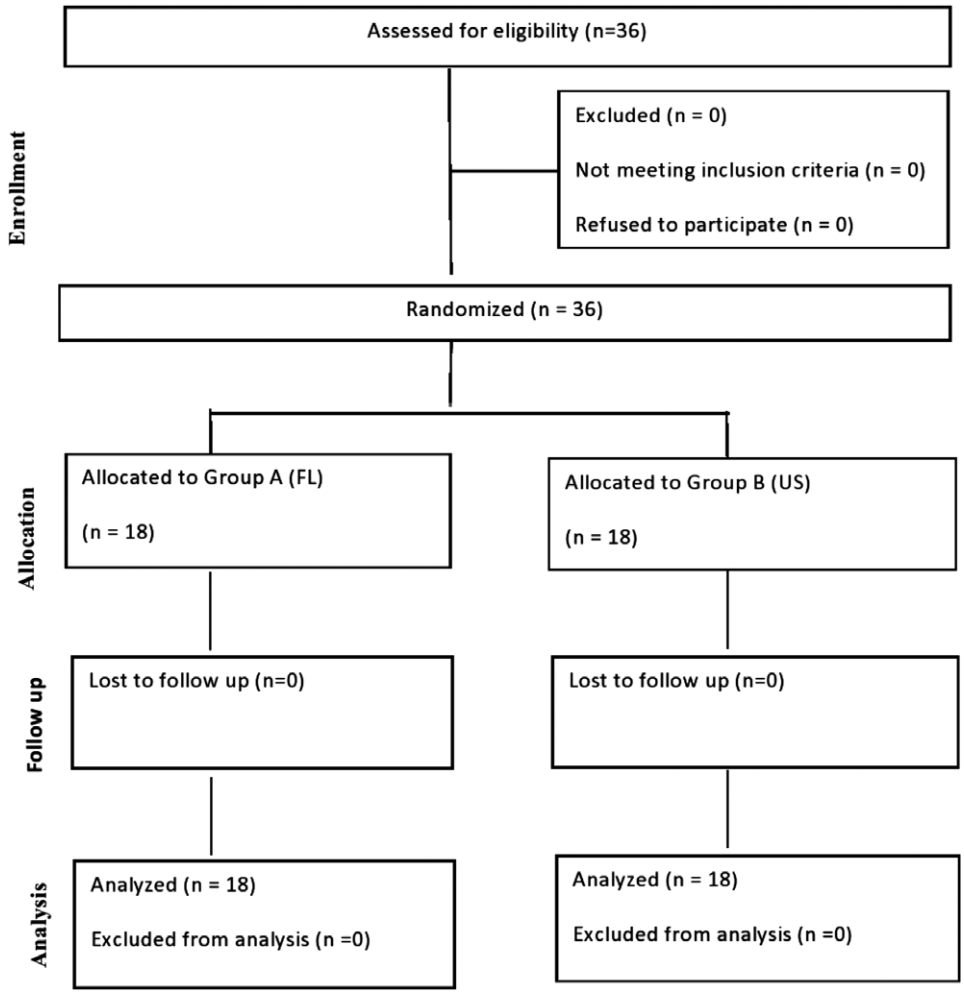

Figure 1. Flowchart according to Consolidated Standards of Reporting Trials statement (CONSORT).

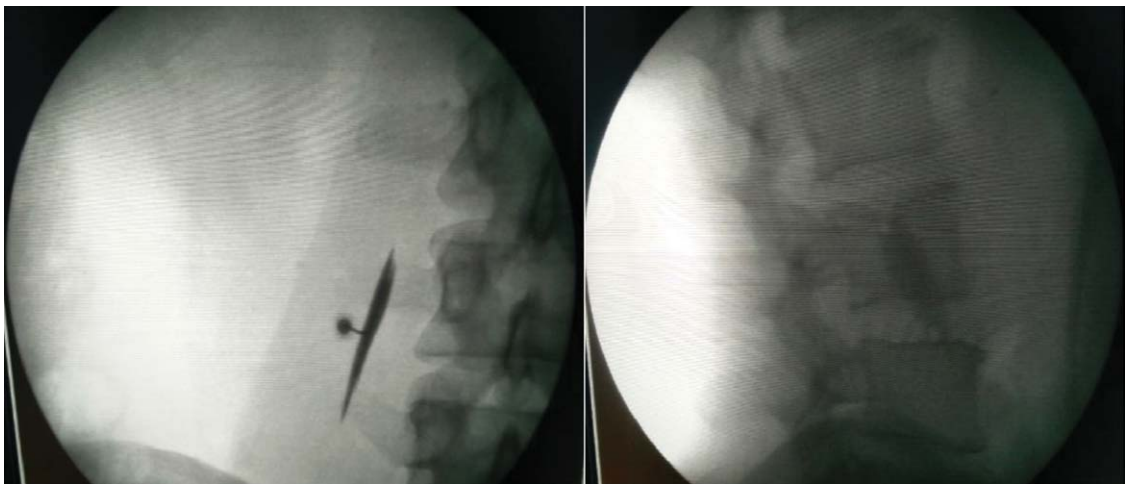

Figure 2. Iliopsoas muscle injection technique: Fluoroscopic approach.

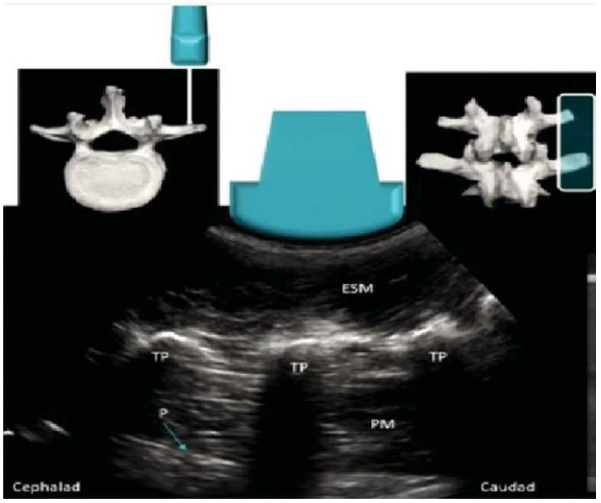

Figure 3. Sonographic anatomy of iliopsoas muscle.

vertebrae. Moving further cranial third lumbar vertebrae was identified, and the probe was moved slightly lateral to view the transverse process. Then, in the L3-L4 inter-transverse space the belly of the IP was seen (Figure 3). The needle was inserted out of plane, and when the tip approached the anterior one-third of the muscle belly, dye was injected. After confirmation, local anaesthetic was given.

Post-procedure patients of both of the groups were kept in observation for 2 hours to monitor hemodynamic parameters and any complications like soreness, bruising, haematoma at the site of injection, leg weakness, numbness, allergic reaction and temporary increase in pain following which they were discharged. All the patients were advised for icepack application on the site of injection intermittently for 24 hours. Non steroidal Anti Inflammatory Drugs (NSAIDS) were given for 5 days followed by paracetamol tablets (650 mg) only on needed basis. Low back stretching exercises were advised as a part of multidisciplinary approach.[9]

To assess the efficacy of the procedure numerical rating score (NRS), Depression Anxiety Stress Scale (DASS), Oswestry Disability Index (ODI) were measured at different time intervals.

NRS is a 11-point scale for patient self-reporting of pain. When using the NRS, patients are asked to rate their pain on a scale from 0 to 10, where 0 represents "no pain" and 10 represents "the worst pain possible", using whole numbers.[10] Pain scoring was done pre-procedure, and at 24 hours, 1 week, 1 month, 3 months after intervention.

DASSs (DASS 21) are made up of self-reported negative emotional symptom. Each of these is rated on a four-point Likert scale. The scores ranged from 0, meaning that the patient believed the item "did not apply to them at all", to 4 meaning they suffered the emotional symptom. The total sum of the relevant items becomes the DASS score.[11]

The ODI is a questionnaire to quantify disability for LBP.[12] The self-completed questionnaire contains 10 questions with six options and scores 0–5. After doubling the total score, it totals between 0 and 100.[13] DASS and ODI were measured preprocedure and at 1 month and 3 months after intervention.

To assess the performance of a novice based on two different modalities, the following data were collected and analysed: Number of attempts required to reach anterior one-third of the IP muscle based on the number of needle punctures; ease of performance of block scored in terms of 0–10 (0 being very easy and 10 being extremely difficult); time taken to perform the procedure (in minutes). The novice observed five cases initially and later assisted in another five cases each in FL and USG group before being allowed to perform under supervision. In the FL group, procedure timing was calculated between first fluoroscopic image and completion of injection, whereas in the US group, it was noted from application of the US probe to completion of injection, including fluoroscopic confirmation of needle tip location. Intervention was said to be accurate when the dye spread in the fluoroscopic image was confined to the belly of the IP muscle.

Assuming that patients with IP myofascial pain have visual analogue score (VAS) of 80/100 and post-trigger point injection would decrease the pain by 40%, along with minimum confidence interval 95% and power of study 80%, we needed to enroll eight patients in each group.[14]

Data were summarised as mean ± SE (standard error of the mean). Groups were compared by independent Student's t test. Groups were also compared by repeated measures two factor (groups and periods) analysis of variance and the significance of mean difference between (inter) the groups were done by Newman–Keuls post hoc test after ascertaining normality by Shapiro–Wilk's test and homogeneity of variance between groups by Levene's test. Categorical (discrete) groups were compared by Chi-square (χ^2) test. A two-tailed ($\alpha = 2$) $P < .05$ was considered statistically significant. Analyses were performed on Statistical Package for the Social Sciences (SPSS) version 17.0 (IBM SPSS Corp., Armonk, NY, USA).

Results

There was no difference between groups regarding age and gender (Table 1).

The mean NRS score decreased significantly from 7.06 ± 0.24 (FL group) and 6.78 ± 0.24 (US group) to 0.50 ± 0.12

Table 1. Demographic Characteristics of Two Groups

Basic characteristics	Fluoroscopy (n = 18) (%)	USG (n = 18) (%)	t/χ^2 value	*P*
Age (years), mean ± SE	44.17 ± 2.74	48.44 ± 2.37	1.18	.245
Gender:			0.00	1.000
Female	13 (72.2)	13 (72.2)		
Male	5 (27.8)	5 (27.8)		

Table 2. NRS, DASS and ODI Score (mean ± SE, n = 18) of Two Groups

Period	FL NRS*	US NRS**	FL DASS$	US DASS$$	FL ODI#	US ODI##
Preprocedure	7.06 ± 0.24	6.78 ± 0.24	41.89 ± 1.38	43.33 ± 2.41	52.94 ± 0.99	51.39 ± 1.47
24 hours	2.22 ± 0.29	1.78 ± 0.26				
1st week	1.50 ± 0.22	1.50 ± 0.23				
4th week	0.50 ± 0.12	0.56 ± 0.15	24.67 ± 0.56	25.44 ± 0.76	24.11 ± 0.80	24.78 ± 1.05
12th week	0.33 ± 0.11	0.44 ± 0.15	23.56 ± 0.57	22.78 ± 0.61	20.50 ± 1.04	19.39 ± 0.94

*$P < .001$—at 24 hours, 1st, 4th and 12th week as compared to preprocedure.
**$P < .001$—at 24 hours, 1st, 4th and 12th week as compared to preprocedure.
$$P < .001$—at 4th and 12th week as compared to preprocedure.
$$$P < .001$—at 4th and 12th week as compared to preprocedure.
#$P < .001$—4th and 12th week as compared to preprocedure.
##$P < .001$—at 4th and 12th week as compared to preprocedure.

Table 3. Comparison of Difference in Mean NRS, DASS and ODI Score

Period Mean diff.	Comparison of NRS (fluoroscopy vs. USG)		Comparison of DASS (fluoroscopy vs. USG)		Comparison of ODI (fluoroscopy vs. USG)	
	P	Mean diff.	*P*	Mean diff.	*P*	
Preprocedure	0.28	0.346	1.44	0.414	1.56	.306
24 hours	0.44	0.131				
1st week	0.00	1.000				
4th weeks	0.06	0.850	0.78	0.660	0.67	.660
12th weeks	0.11	0.706	0.78	0.660	1.11	.464

($P < .001$) and 0.56 ± 0.15 ($P < .001$), respectively, after month of treatment in both of the groups (Table 2). However, the difference in mean NRS score between the two groups was comparable ($P > .05$) at all time points (Table 3).

DASS score decreased significantly after the treatment from 41.89 ± 1.38 (FL group) and 43.33 ± 2.41 (US group) to 23.56 ± 0.57 ($P < .001$) and 22.78 ± 0.61 ($P < .001$), respectively, after 12 weeks. Comparing the difference in mean DASS score, Newman–Keuls test showed similar ($P > .05$). DASS scores between the groups at preprocedure, fourth week and 12th week suggest that it is comparable (Tables 2 and 3).

In both groups, the mean ODI score was comparable and decreased after the treatment from 52.94 ± 0.99 (FL group) and 51.39 ± 1.47 (US group) to 20.50 ± 1.04 ($P < .001$) and 19.39 ± 0.94 ($P < .001$), respectively (Tables 2 and 3).

The ease of performance (2.78 ± 0.17 in FL group vs. 2.72 ± 0.16 in US group, t = 0.24, $P = .814$) and number of attempts (1.50 ± 0.17 in FL group vs. 1.44 ± 0.12 in US group, t = 0.27, $P = .789$) were comparable in both of the groups (Table 4).

However, Student's t test showed significantly different and 59.3% lower time taken in USG group than FL group (6.14 ± 0.35 vs. 2.50 ± 0.19, t = 9.15, $P < .001$) (Table 4).

Table 4. Procedure-Related Variables-Outcome Measures (mean ± SE) Between Two Groups

Procedure-related variables	Fluoroscopy (n = 18)	USG (n = 18)	t value	*P*
Ease of performance	2.78 ± 0.17	2.72 ± 0.16	0.24	.814
No. of attempts	1.50 ± 0.17	1.44 ± 0.12	0.27	.789
Time taken (minutes)	6.14 ± 0.35	2.50 ± 0.19	9.15	<.001

USG, ultrasonography.

Discussion

IP interventions in our study were performed using either FL or USG as the imaging modality, and outcome was assessed in terms of pain relief by NRS, quality of life assessment by ODI and psychological assessment by DASS 21. The improvement in mean NRS score after a month, DASS scores and ODI scores after 3 months was significant ($P <$ .001) yet comparable in the two groups. The learning curve was easier for US intervention with average attempts of 1–2 compared to 1–3 for FL. The average time taken to perform IP intervention was lesser for US group. Kim et al.[15] investigated the effect of US guided trigger point injection of the abdominal muscles in patients of chronic pelvic pain syndrome. VAS decreased significantly from 6.3 pre-treatment to 2.9 after 1 month. The results were better replicated in our study, with a decrease in NRS scores from 7.06 pre-procedure to 0.33 in the FL group and from 6.78 pre-procedure to 0.44 in US group at the end of 12 weeks. Hence, we believe that results of our study are applicable to patients with LBP secondary to IP MPS.

The decrease in mean NRS score of FL group (95.3%) was found to be 1.9% higher than USG group (93.4%), but was statistically insignificant (*P* value .706). Hence, it can be concluded that both of the imaging techniques used for performance of the procedure are equally effective. Soreness at the site of injection was complained by four patients in FL group and five patients in USG group despite giving local anaesthetic. No other complication was noted in either group.

Pain of the groin, hip and leg could be secondary to pulled adductor muscles usually following jerky abduction and external rotation of thigh; femoral neck stress fracture in elderlies; IP bursitis in patients who have existing arthritis or prolonged overuse activity; avulsion fracture which occurs due to sudden resistance against active hip flexion and could be diagnosed radiologically by an avulsed lesser trochanter; hernia (femoral or inguinal) which could be examined in the inguinal or anterior thigh region on coughing or Valsalva; osteitis pubis with predominant pain over symphysis pubis; genito-femoral neuralgia with neuropathic pain features over lower abdomen or perineum; snapping hip syndrome which will have a reproducible audible snap during a particular movement; chronic prostatitis with radiation of pain to lower back or suprapubic region and increased pelvic floor muscle tone. Most of these have a striking history of a particular physical activity or age group along with a characteristic onset, location and nature of pain on specific local examination.[16] US examination helps in diagnosing IP bursitis by identifying fluid surrounding the IP tendon. Patients with chronic prostatitis and chronic pelvic pain have close association between groin pain and IP muscle which may be due to IP muscle acting as a pelvic stabiliser.[15] IP tendinopathy can also present as deep knee pain due to increased load across the knee and patellofemoral complex. Once all other causes LBP simulating IP MPS were ruled out and proper conservative management for trigger points were exhausted, these cases were posted for IP muscle injections.

Muscles harbouring a trigger point are often weak and cause a decrease in physical functioning.[17] The ODI is currently considered as the gold standard for measuring the degree of disability and estimating quality of life in a person with LBP. Chen and Nizar[18] have shown that with a multi-disciplinary approach to MPS treatment, there was a 73.5% decrease in ODI scores ranging from pre-treatment value of 49.02–12.99 at the end of 12 months. This shows that the patients who were having severe disability were transformed to minimal disability after treatment. Similar results were obtained in our study when the ODI decreased from 52.94 to 20.50 in the FL group and 51.39 to 19.39 in the US group, leading to a significant decrease in disability after interventions using either of the two imaging modalities.

There was no difference in ODI scores between the US and FL groups during the follow-up period after the study intervention. On final evaluation at 12th week, the decrease in mean ODI score of USG group (62.3%) was found to be 1.0% higher than FL group (61.3%); however, it was statistically insignificant (*P* value .464). A minimum clinically important difference (MCID) of at least 10–12 for change in ODI has been found to be clinically meaningful in patients with chronic back pain.[19,20] Our study found relatively significant changes in ODI and MCID, suggesting that both FL and US guided injections were associated with overall clinical improvement in function as measured by ODI.

Prominent and distressing emotions, cognitions and behaviours frequently accompany chronic pain. In many cases, these psychological symptoms will be sufficiently severe to qualify the patient for a diagnosis of a mental disorder. MPS is associated with stress, anxiety, lack of sleep, anger and depression.[21] To analyse various psychological aspects and to determine its impact on patient's life, we have used DASS 21 in our study. Within-group analysis in our trial did reveal that patients in both the groups had a statistically significant reduction in DASS scores at all the time intervals, and there was no difference in DASS scores between the groups during the follow-up period. Till date, no study has quantified the psychological outcome with regard to MPS treatment. In this trial, the decrease in mean DASS score (i.e., mean change from pre-procedure to 12 week) of USG group (47.4%) was found to be 3.6% higher than FL group (43.8%); however, it was statistically insignificant (*P* value .66). This shows that both FL and US guided injections are associated with overall improvement in the quality of life in terms of psychological aspect as measured by DASS 21.

All the procedures of the study were performed by a single novice performer, and the variables of learning curve indicated improved skills along with experience. In the study, greater time was required for FL guided intervention compared to US guidance (6.14 and 2.5 minutes, respectively, $P < .001$). The additional time required using FL guidance could be due to technical issues as the physician has to move away from the patient by approximately 3–4 ft during each fluoroscopic imaging to avoid radiation exposure.[22] However, the number of attempts required to perform the procedure and the ease of performance of the procedure were found to be similar between the two groups at different time intervals.

FL is the prime imaging modality by most of the pain interventionist, but with its own set of time proportional biological side-effects.[23,24] A minute of continuous FL at 2 rads min^{-1} is equivalent to the exposure during 130 chest radiographs. Kim et al.[25] in their study performed over 500 procedures, including lumbar, thoracic, cervical spine interventions using C-arm FL over a 3-month period. The cumulative exposure time reached a total of 676 minutes and 14 seconds, with average of 80 seconds of radiation exposure per each procedure, and despite radiation protection, the operator was exposed to 6–10 times as much as the natural radiation exposure dose. In view of such concerns, US can be used as an effective alternative technique to prevent radiation exposure. Prevalence of myofascial LBP among women is 23%.[26] One of its causes is pregnancy, in such situation US can be an effective tool, preventing radiation exposure to both the mother and foetus, as validated from our study.

On US evaluation, the trigger points appear as a hyperechoic spot.[27] In our study, we have targeted the ventral IP muscle belly for injections rather than the hyperechoic spots as it was technically challenging to sight out hyperechoic spots in such deep muscle. If we would have given our therapeutic injections within these hyperechoic spots which is possible only by using USG, along with a possibility of visualising local twitch response in a deep-seated muscle, then the efficacy of the results would have been much improved. In future, further trials have to be done evaluating fluoroscopic guided injections with that of targeting these hyperechoic spots by USG. Based on our findings, we propose that it is reasonable to consider the use of US over FL for procedural guidance in such patients.

We acknowledge that this study has several limitations. Our study had 18 patients in each arm, a larger patient population would be required to adequately qualify for better analysis in terms of outcome and procedure-related variables. Furthermore, we followed patients for a duration of 3 months, but trials could focus on longer term outcomes up to 6 months to 1 year after the interventions. USG can be a limiting factor for post-op cases. We can have future studies with a greater number of novice performers so as to ascertain the minimum number of patient exposure under supervision, to be incorporated in our pain fellowship programs.

Conclusion

In conclusion, US guidance may be a better and easy alternative to fluoroscopic guidance for IP muscle injection in patients with chronic mechanical LBP secondary to IP MPS as it reduces radiation exposure, cost burden, infrastructure requirement, with similar clinical and procedural outcomes.

Ethics Committee Approval: Ethical committee approval was received from the Sanjay Gandhi Post Graduate Institute of Medical Sciences (2012-188-IP-66).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Conception - A.A.; Design - C.S.; Supervision - C.S., A.A.; Data Collection and/or Processing - V.V.K.; Data analysis and/or Interpretation - V.V.K.; Literature Review - A.A., R.M.; Writing - C.S.; Critical reviews - A.A., R.M.

Conflict of Interest: The authors have no conflicts of interest to declare.

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