

Original Research Article

The effectiveness and safety of triamcinolone hexacetonide intra-articular injection in adhesive capsulitis: results from a prospective, multicentre, single-arm, open-label, post-marketing observational study

Tadikonda Bhawani Prasad¹, Anil Kumar Sharma², Manju Adithya Nayak³, Ashwani Bilandi⁴, Swapnil Deshpande^{5*}, Milind Bhole⁵

¹Visakha Institute of Medical Sciences, Hanumanthavaka, Visakhapatnam, Andhra Pradesh, India

²Pushpanjali Hospital and Research Centre PVT LTD, Agra, Uttar Pradesh, India

³Medstar Speciality Hospital, Sahakarnagar, Bengaluru, Karnataka, India

⁴ManglamPlus Medicity Hospital, Jaipur, Rajasthan, India

⁵Department of Medical Affairs, Abbott India Limited, BKC, Bandra (E), Mumbai, Maharashtra, India

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*Correspondence:

Dr. Swapnil Deshpande,

E-mail: swapnil.deshpande@abbott.com

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ABSTRACT

Background: Adhesive capsulitis is a painful shoulder disorder causing progressive stiffness and restricted mobility. Despite widespread use of intra-articular corticosteroids, real-world evidence on triamcinolone hexacetonide in India remains limited. This prospective study assessed the effectiveness and safety of a single ultrasound-guided intra-articular injection in routine practice.

Methods: This prospective, multicenter, single-arm post-marketing observational study was conducted at four sites in India. Adults with symptomatic adhesive capsulitis received a single ultrasound-guided intra-articular injection of triamcinolone hexacetonide (20-40 mg). Effectiveness was measured by changes in SPADI total and subscale scores over 12 weeks, while safety was assessed through adverse event monitoring.

Results: A total of 60 patients (37 males, 23 females) with a mean (SD) age of 46.60 (15.56) years were enrolled, and all completed the study. Compared to the mean (SD) baseline score of 74.14 (14.40), total SPADI score declined significantly ($p < 0.0001$) by 11.15 (8.19) and by 28.70 (27.19) points at week 4 and 12, respectively, with clinically meaningful improvement observed from week 1 and sustained through week 12. Pain and disability subscales demonstrated parallel statistically significant reductions. Treatment was well tolerated; mild, transient adverse events (AEs) were reported in 8.3% of patients and were not treatment-related.

Conclusions: In routine clinical practice, a single intra-articular injection of triamcinolone hexacetonide performed with ultrasound guidance was effective in alleviating pain and improving functional outcomes in patients with adhesive capsulitis, while demonstrating a favorable safety profile. These findings support its use as a practical treatment option for frozen shoulder and provide preliminary real-world evidence to inform future prospective studies.

Keywords: Adhesive capsulitis, Frozen shoulder, Triamcinolone hexacetonide, Intra-articular injection, Shoulder pain and disability index, Real-world observational study

INTRODUCTION

Adhesive capsulitis, commonly known as frozen shoulder, causes stiffness and gradual mobility loss of the shoulder, leading to a disabling and painful condition.¹ It is suspected that inflammation and fibrosis of the

glenohumeral joint capsule are major causes of adhesive capsulitis.^{2,3} The reported annual incidence of the condition is approximately 2.4 per 100,000 individuals, with prevalence estimates ranging from 0.75% to 5%.^{2,3} Adhesive capsulitis predominantly affects individuals between 40 and 60 years of age and demonstrates a higher

incidence among women.⁴⁻¹¹ The condition typically follows a steady progression through three successive phases -commonly described as the freezing, frozen, and thawing stages-spanning an overall course of approximately 2 to 3 years.^{4,12,13} Although it is a self-limiting disease, a prospective study showed that while 39% of patients eventually became symptom-free, 54% experienced some clinical limitations without functional impairment, and 7% continued to have movement restrictions over 5-10 years.¹³

Techniques like physical therapy, electrotherapy modalities, and therapeutic ultrasound are conservative non-invasive management for adhesive capsulitis, which uses thermal effects, electrical stimulation, neuromodulation, sound waves, etc., to manage pain and improve shoulder function.¹⁴⁻¹⁷ The various forms of energy imparted via these therapies increases the tissue temperature, ultimately leading to improved tissue healing and muscle relaxation.^{17, 18} However, conservative management techniques have variable efficacy.¹⁵

Corticosteroids administered via intra-articular injections are frequently used for the reduction of pain and inflammation.¹⁹⁻²² Corticosteroids directly enter the inflamed joint and show intense and expedited anti-inflammatory effect.²³ The intervention is often carried out with ultrasound imaging to assist procedural accuracy.^{24,25} Triamcinolone hexacetonide, a synthetic corticosteroid, exhibits high lipophilicity and limited solubility, properties that promote extended persistence within the intra-articular environment.²⁶ The resulting delayed clearance allows for gradual drug release, thereby supporting prolonged therapeutic activity and potentially reducing the need for repeated injections.²⁷

Despite its established role in inflammatory joint disorders, evidence for the use of triamcinolone hexacetonide in adhesive capsulitis remains scarce, particularly in the Indian clinical setting.

This prospective observational study therefore evaluated the effectiveness and safety of intra-articular triamcinolone hexacetonide (20-40 mg) administered in routine practice among Indian patients with adhesive capsulitis.

METHODS

Study design

This was a prospective, multicentre, open-label, post-marketing study with a single-arm design (CTRI/2024/06/069688; registered on June 28, 2024) that examined the clinical effectiveness and safety profile of triamcinolone hexacetonide administered intra-articularly for adhesive capsulitis in Indian patients. The study was conducted from July to December 2024 at four sites across diverse geographic regions in India.

The study was conducted in compliance with the International Council for Harmonization guidelines on Good Clinical Practice (ICH-GCP), applicable local regulatory standards, and the ethical principles of the Declaration of Helsinki. It also adhered to the New Drugs and Clinical Trials Rules, 2019, established by the Ministry of Health and Family Welfare, Government of India, as well as relevant institutional standard operating procedures. Before study initiation, the protocol, informed consent documents, and any amendments were reviewed and approved by the appropriate ethics committee.

Patients

Eligibility criteria included patients aged 18 years and above presenting with symptomatic adhesive capsulitis of the shoulder of less than one year's duration, with a diagnosis of adhesive capsulitis established at the investigator's discretion, a baseline shoulder pain and disability index (SPADI) total score of ≥ 30 , and a prescription for a single intra-articular injection performed with ultrasound guidance triamcinolone hexacetonide (20 mg or 40 mg) for the treatment of frozen shoulder as part of routine clinical practice. Patients were required to be willing and able to comply with all study procedures and to provide written patient authorization, either personally or through a legally acceptable representative (LAR).

Patients were excluded if adhesive capsulitis was attributable to an underlying condition, including inflammatory, degenerative, metabolic, or infectious arthritis, history of cerebrovascular accident, dislocation, or fracture; a significant deformity of the target joint requiring surgical correction; or any concomitant inflammatory or other disease or condition that could affect joints (e. g., metabolic bone disease, psoriasis, gout, pseudogout, or chondrocalcinosis). Patients were also excluded if there was a history of sepsis of the target joint or any clinical concern for an acute or sub-acute infectious process involving the target joint (e. g., active tuberculosis, herpes simplex keratitis, systemic mycoses, or parasitic infections such as strongyloidiasis), clinically apparent tense effusion of the target joint, or cutaneous disease or infection at the injection site. Additional exclusion criteria included arthrocentesis of the target joint within the past three months, known allergy to the study drug or its components, participation in another clinical study within the preceding 30 days, receipt of intra-articular and/or periarticular systemic steroids within the previous three months, or any contraindication to intra-articular and/or periarticular injection. Female patients of child-bearing potential who were pregnant, planning pregnancy, lactating, or unwilling to use appropriate contraceptive measures were excluded. Patients with any other disease or comorbidity that could be exacerbated by triamcinolone hexacetonide administration, as judged by the investigator, as well as those with known blood coagulation disorders, were also excluded.

Study endpoints

This study assessed the effectiveness and safety of a single intra-articular injection of triamcinolone hexacetonide (20-40 mg) performed with ultrasound guidance in the management of adhesive capsulitis in Indian patients. The primary endpoint was the assessment of the mean (SD) change in the total SPADI score from baseline to week 4.

Secondary endpoints included mean (SD) changes in the total SPADI score from baseline to weeks 1, 8, and 12, as well as changes related to pain and disability subscales of SPADI at weeks 1, 4, 8, and 12 following treatments. Safety outcomes included the occurrence of adverse drug reactions (ADRs), other pharmacovigilance-relevant information (OPRI), and serious ADRs and OPRI following administration of the single intra-articular injection of triamcinolone hexacetonide performed with ultrasound guidance.

Statistical analysis

The sample size of the study was computed to detect a clinically meaningful improvement in the total SPADI score at weeks 4 and 12 following a single intra-articular injection of triamcinolone hexacetonide performed with ultrasound guidance. Based on data reported by Carrette et al the standard deviation of the mean change in SPADI score from baseline at both 6 and 12 weeks was estimated to be 25.²⁸ Assuming a clinically meaningful improvement of 10 points in the SPADI score, a sample size of 50 evaluable subjects was required to achieve 80% power. To account for potential dropouts, 60 subjects were enrolled.

All patients who received intra-articular injection of triamcinolone hexacetonide were included in the safety population. Patients in the safety population who completed at least one follow-up assessment were included in the intention-to-treat (ITT) population. The per-protocol (PP) population comprised patients in the ITT population who had data available up to 12 weeks of follow-up and completed the study without major protocol deviations; this population was used for the effectiveness analysis.

Continuous variables for the primary and secondary endpoints were summarized using mean and standard deviation (SD). Safety parameters were summarized using descriptive statistics (frequency [n] and percentage [%]). Changes in continuous outcomes (primary and secondary endpoints) from baseline to follow-ups were analysed using paired t tests at a 5% level of significance (two-sided).

Mean, SD, and mean change were rounded to two decimal places. All statistical analyses were performed using SAS® Software (release 9.4).

RESULTS

Demographics and baseline characteristics

A total of 60 patients (male: female, 37:23) with adhesive capsulitis were enrolled in the study, with a mean (SD) age of 46.60 (15.56) years. The most reported comorbid condition was periarthritis (86.67%), followed by musculoskeletal stiffness (10%) and type 2 diabetes mellitus (8.33%).

All enrolled patients received a single intra-articular injection of triamcinolone hexacetonide (20-40 mg) performed with ultrasound guidance at baseline, with the dose determined at the investigator's discretion in accordance with the approved label. Of these, 54 (90%) patients received a 20 mg dose, and 6 (10%) patients received a 40 mg dose.

All patients completed the study as per protocol. Demographic and baseline characteristics are detailed in Table 1.

Table 1: Demographic and baseline characteristics of patients, safety population.

Parameters	Overall (n=60) (%)
Sex	
Male	37 (61.7)
Females	23 (38.3)
Age (in years), mean (SD)	46.60 (15.56)
Height (cm), mean (SD)	162.17 (6.62)
Weight (kg), mean (SD)	65.48 (7.79)
BMI (kg/m²), mean (SD)	24.89 (2.59)
Medical history	
Arthralgia	01 (1.67)
Pain in extremity	01 (1.67)
Hypertension	03 (5.0)
Type 2 diabetes mellitus	05 (8.33)
Musculoskeletal stiffness	06 (10.0)
Periarthritis	52 (86.67)

Effectiveness of triamcinolone hexacetonide intra-articular injection

Significant improvement in symptoms of adhesive capsulitis was reported, post-treatment with a single intra-articular injection of triamcinolone hexacetonide performed with ultrasound guidance.

The mean (SD) total SPADI score declined significantly ($p < 0.0001$) from baseline at all post-baseline time points. Compared to the baseline mean (SD) pain score of 74.14 (14.40), total SPADI score declined by 4.72 (3.93) (95% CI: -5.73, -3.70) at week 1, by 11.15 (8.19) (95% CI: -13.26, -9.03) at week 4, by 18.09 (13.52) (95% CI: -21.59, -14.60) at week 8 and 28.70 (27.19) (95% CI: -35.72, -21.68) at week 12 (Figure 1).

The mean (SD) SPADI pain subscale score showed a significant reduction ($p < 0.0001$) from baseline to all follow-up visits. The mean (SD) decrease was 5.10 (4.36)

(95% CI: -6.23 to -3.97) at Week 1, 12.40 (7.96) (95% CI: -14.46 to -10.34) at week 4, 20.17 (13.02) (95% CI: -23.53 to -16.80) at week 8, and 31.07 (26.10) (95% CI: -37.81 to -24.33) at week 12, relative to the baseline mean (SD) pain score of 76.03 (14.19) (Figure 2).

Likewise, compared to the baseline mean (SD) SPADI disability subscale score of 72.25 (16.21) mean (SD), SPADI disability subscale score declined significantly ($p < 0.0001$) by 4.33 (4.42) (95% CI: -5.48, -3.19) at week 1, 9.90 (8.87) (95% CI: -12.19, -7.60) at week 4, 16.02 (14.33) (95% CI: -19.72, -12.32) at week 8, and 26.33 (28.49) (95% CI: -33.69, -18.97) at week 12 (Figure 3).

Safety and tolerability

No ADRs or OPRI were reported during the 12-week study period following administration of a single intra-articular injection of triamcinolone hexacetonide performed with ultrasound guidance at baseline. Five patients (8.3%) reported a total of 5 AEs. These included two cases (3.3%) of headache and one case (1.7%) each of diarrhoea, vomiting, and pyrexia. All reported AEs were mild in severity, were assessed as unrelated to the study medication, and resolved during the 12-week follow-up period.

Overall, intra-articular administration of triamcinolone hexacetonide was well tolerated in Indian patients with adhesive capsulitis.

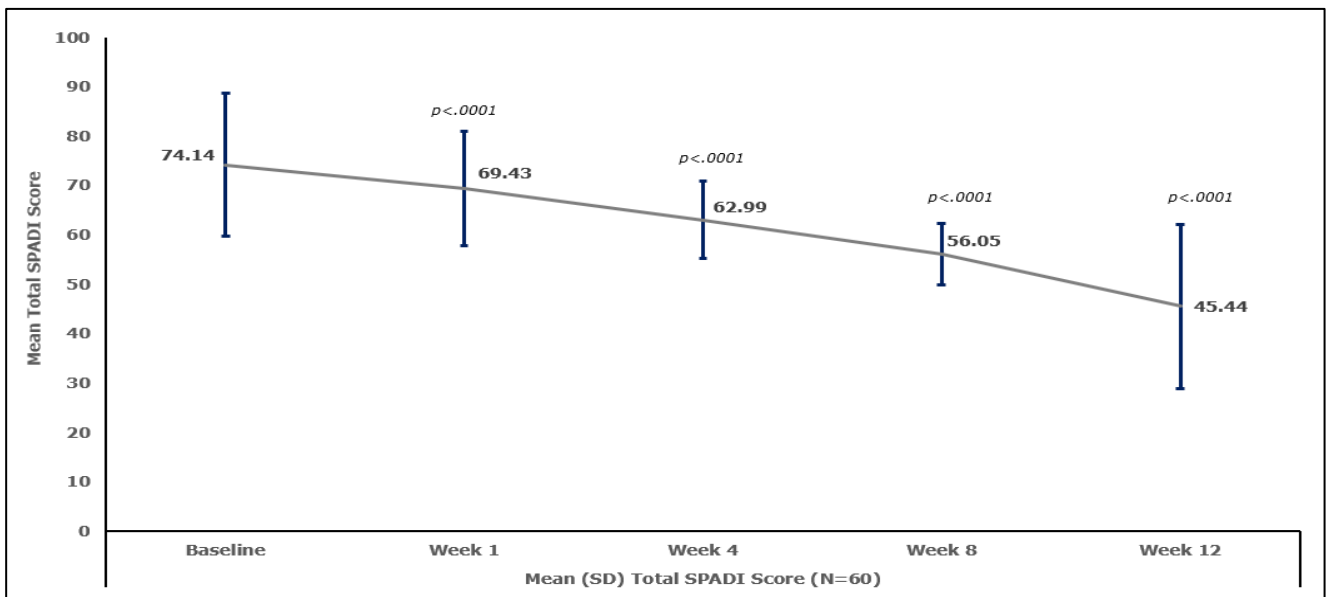


Figure 1: Mean (SD) total SPADI score, from baseline to week 12 (n=60).

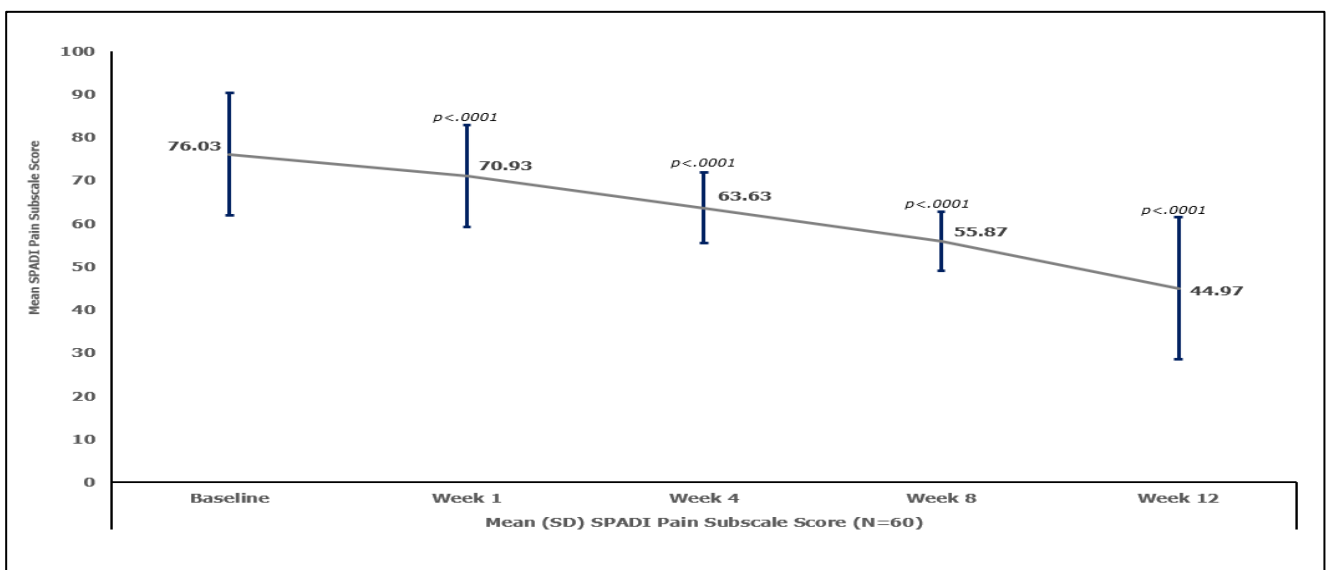


Figure 2: Mean (SD) SPADI pain subscale score, from baseline to week 12 (n=60).

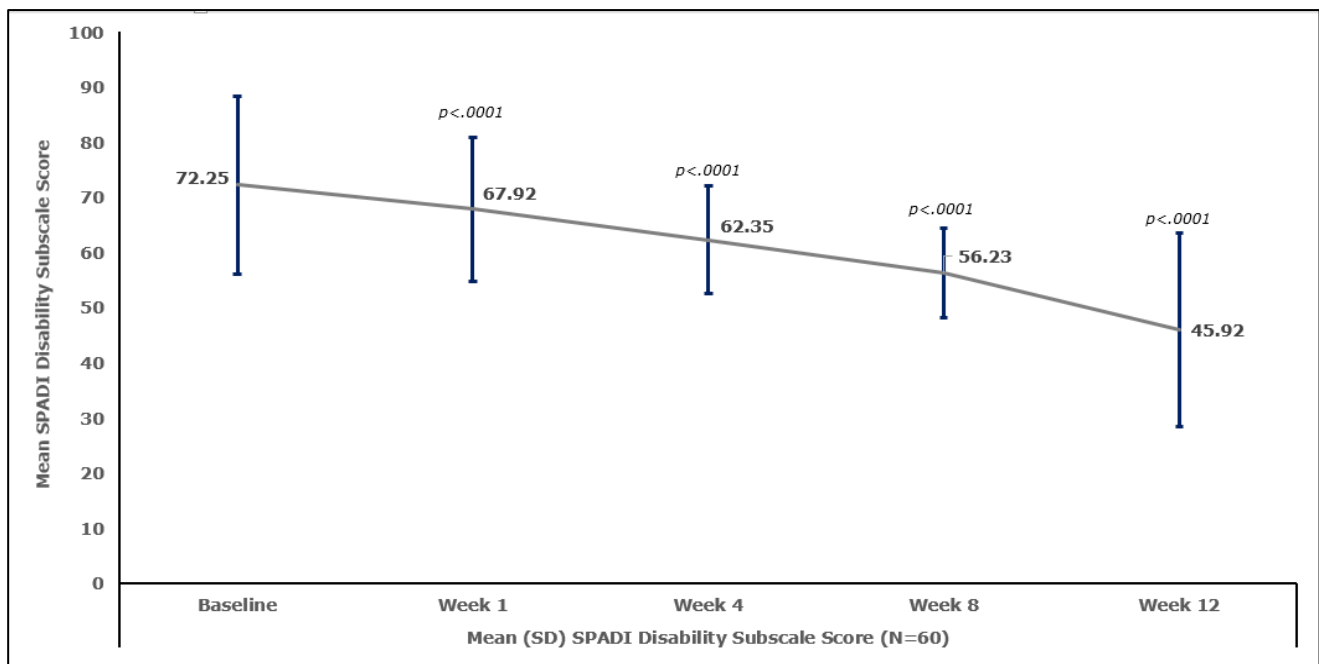


Figure 3: Mean (SD) disability subscale score of SPADI, from baseline to week 12 (n=60).

DISCUSSION

Administration of intra-articular corticosteroids is associated with significant improvement in adhesive capsulitis, as reported via various assessments like passive range of motion (ROM), or other functional scores.^{29,30} Comparative study has also demonstrated faster pain relief and improved shoulder motion by these corticosteroid injections than oral NSAIDs.³¹ Therefore, the present study aimed to assess the effectiveness and safety of triamcinolone hexacetonide for treating adhesive capsulitis as part of routine clinical practice in India.

The study enrolled 60 participants. The study population represented a typical middle-aged cohort with a predominance of periarthritis and associated musculoskeletal comorbidities. The high proportion of patients with periarthritis reflects the common clinical presentation encountered in routine orthopedic practice. Patients were administered a single intra-articular injection of triamcinolone hexacetonide (20-40 mg) performed with ultrasound guidance at baseline.

The present findings indicate significant improvement in symptoms of adhesive capsulitis with a single intra-articular injection of triamcinolone hexacetonide performed with ultrasound guidance. A progressive reduction in the mean (SD) total SPADI score was observed in the affected shoulder over the 12-week follow-up period. Compared to the baseline score of 74.14 (14.40), the total SPADI score decreased by 4.72 (3.93) points at week 1, and with further reductions of 11.15 (8.19) points at week 4, indicating that patients felt an overall improvement in both pain and ability to perform physical activities after treatment. By week 8 and week 12,

further mean (SD) reduction by 18.09 (13.52) and 28.70 (27.19) points was observed, indicating a sustained and clinically meaningful improvement over time.

These findings are consistent with the earlier investigations demonstrating that fluoroscopy-guided administration of triamcinolone hexacetonide (40 mg) is associated with significant reductions in total SPADI scores by week 6, accompanied by improvements in both active and passive ranges of shoulder motion.²⁸ Moreover, these benefits were shown to persist at the 3-month follow-up, indicating a sustained therapeutic effect.²⁸ A recent randomized comparative study by Kumar et al reported that ultrasound-guided intra-articular injection of triamcinolone hexacetonide (40 mg) resulted in significant improvements in SPADI scores within one month, with maximal differences evident at three and six months.³²

The findings of the present study demonstrated that a similar temporal pattern was observed for the mean (SD) SPADI pain subscale and disability score. Relative to the baseline value of 76.03 (14.19), the pain subscale score decreased by 5.10 (4.36) points at week 1, with further reductions of 12.40 (7.96) points at week 4, indicating steady improvement. By week 8 and 12, the score significantly reduced by 20.17 (13.02) and 31.07 (26.10) points, respectively, reflecting a sustained improvement in pain severity over the study period. The mean (SD) SPADI disability subscale score of 72.25 (16.21) declined significantly by 4.33 (4.42), 9.90 (8.87), and 16.02 (14.33) points from week 1 to 12, respectively. Similar observations were reported by a previous investigation, where injection of triamcinolone (20 mg) significantly improved the shoulder disability questionnaire (SDQ) score at week 6.³³

In this study, intra-articular administration of triamcinolone hexacetonide demonstrated a favourable safety profile and was generally well tolerated over the 12-week follow-up period. The AEs observed were few, mild in severity, transient, and assessed as unrelated to the study treatment, with complete resolution during follow-up. Importantly, no new safety concerns were identified, supporting the clinical acceptability of ultrasound-guided intra-articular injection in this patient population.

Limitations of the present study should be considered. As this was an observational study conducted in real-world clinical settings, residual confounding could not be fully controlled. Pain assessment, being inherently subjective and influenced by individual tolerance, may have been underestimated in patients with higher pain thresholds. Despite these constraints, the study benefits from a statistically adequate sample size, the use of validated outcome measures, standardized definitions, and the inclusion of relevant clinical variables, all of which contribute to the reliability and precision of the findings. Conducting the study within routine clinical practice enhances the generalizability of the results and supports their relevance to real-world care. Observational research of this nature provides valuable practical insights to inform clinical decision-making. Furthermore, considering the limited availability of long-term data on the efficacy of corticosteroids for frozen shoulder, these findings offer important preliminary evidence that may guide the design of future prospective investigations.

CONCLUSION

This real-world observational study indicates that a single intra-articular injection of triamcinolone hexacetonide performed with ultrasound guidance represents an effective and well-tolerated treatment approach for adhesive capsulitis. The study demonstrated sustained improvements in shoulder pain, functional performance, and overall symptom control throughout the observation period, suggesting meaningful clinical benefit. The favorable tolerability profile, marked by mild and transient adverse events, supports its use in routine clinical settings. By assessing outcomes in patients treated under standard care conditions, the findings offer clinically relevant evidence applicable to everyday practice. Overall, the results support the utility of intra-articular triamcinolone hexacetonide as a practical therapeutic option for frozen shoulder and provide a foundation for future prospective studies aimed at further elucidating its long-term effectiveness and optimizing treatment strategies.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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