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ULTRASOUND-GUIDED HYDRODILATATION VS INTRA-ARTICULAR CORTICOSTEROID INJECTION FOR PRIMARY ADHESIVE CAPSULITIS: A RAPID REVIEW OF CLINICAL EFFECTIVENESS AND IMPLEMENTATION CONSIDERATIONS

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ULTRASOUND-GUIDED HYDRODILATATION VS INTRA-ARTICULAR CORTICOSTEROID INJECTION FOR PRIMARY ADHESIVE CAPSULITIS: A RAPID REVIEW OF CLINICAL EFFECTIVENESS AND IMPLEMENTATION CONSIDERATIONS

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ABSTRACT

Background: Primary adhesive capsulitis (frozen shoulder) causes pain and restricted range of motion (ROM). Two common injection strategies are hydrodilatation (HD) and intra-articular corticosteroid injection (IACI), yet their comparative effectiveness remains uncertain.

Objective: To rapidly synthesize randomized evidence and recent reviews comparing HD versus IACI in adults with primary adhesive capsulitis, focusing on pain, ROM (especially external rotation), patient-reported outcomes (PRO), and safety.

Methods: We conducted a rapid review (2018–2025) of PubMed, PubMed Central, Europe PMC, and Google Scholar. Eligible studies were randomized controlled trials (RCTs) and systematic reviews/meta-analyses (SR/MA) directly comparing HD with IACI. Primary outcomes were pain (VAS/NRS) and ROM; secondary outcomes were PRO (SPADI/ASES/DASH) and adverse events. Risk of bias was assessed using RoB 2 (RCTs) and a condensed AMSTAR-2 (SR/MA). We performed a narrative synthesis and reproduced pooled estimates reported in SR/MA.

Results: Searches identified 72 records; 60 remained after deduplication; 6 full-texts were assessed and 6 studies were included (3 SR/MA; 3 RCTs). SR/MA suggested short-term advantages of HD—particularly for disability and external rotation—whereas head-to-head RCTs reported no added benefit of HD over IACI and, in one trial, better early outcomes with IACI alone. Longer-term differences (≥ 6 months) were not consistent. Adverse events were infrequent and mild. SR/MA credibility was moderate; RCTs were at some concerns or high risk of bias.

Conclusions: Evidence is inconsistent; durable superiority of either HD or IACI is unproven. Practically, IACI plus structured rehabilitation is a reasonable first-line choice; image-guided HD may be reserved for selected patients with predominant stiffness or inadequate response. Standardized, well-powered RCTs with harmonized HD parameters and core outcomes are needed.

KEYWORDS

Adhesive Capsulitis, Frozen Shoulder, Hydrodilatation, Corticosteroid Injection, External Rotation, Systematic Review

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Abbreviations (alphabetical)

- **AC** — adhesive capsulitis
- **Abd** — abduction
- **AE** — adverse event(s)
- **AMSTAR-2** — A Measurement Tool to Assess Systematic Reviews 2
- **ASES** — American Shoulder and Elbow Surgeons score
- **CI** — confidence interval
- **CS** — corticosteroid
- **DASH** — Disabilities of the Arm, Shoulder and Hand
- **DOI** — digital object identifier
- **ER** — external rotation
- **Flex** — flexion
- **HD** — hydrodilatation / hydrodistension
- **IACI** — intra-articular corticosteroid injection
- **IQR** — interquartile range
- **ITT** — intention-to-treat
- **LA** — local anesthetic
- **MRA** — MR arthrography
- **MRI** — magnetic resonance imaging
- **N** — sample size
- **NaCl** — 0.9% normal saline

- **NMA** — network meta-analysis
- **NR** — not reported
- **NRS** — Numerical Rating Scale
- **PMID** — PubMed identifier
- **PRISMA** — Preferred Reporting Items for Systematic Reviews and Meta-Analyses
- **PRO** — patient-reported outcomes
- **RCT** — randomized controlled trial
- **RoB 2** — Cochrane Risk of Bias 2
- **ROM** — range of motion
- **SD** — standard deviation
- **SPADI** — Shoulder Pain and Disability Index
- **US** — ultrasound
- **VAS** — Visual Analogue Scale

Introduction

Adhesive capsulitis (“frozen shoulder”, AC) is a debilitating shoulder disorder characterized by pain and progressive limitation of glenohumeral range of motion (ROM) that can persist for months and substantially restrict function [1,2]. AC may arise idiopathically (primary AC) or secondarily after trauma, surgery, or immobilization, and it is frequently reported in association with endocrine comorbidities such as diabetes and thyroid disease [2,11]. Despite its clinical and economic relevance, the etiology remains incompletely understood and there is no universally accepted gold-standard treatment pathway [1,2,8].

Current biological models converge on a low-grade inflammatory milieu that triggers fibroproliferation within the joint capsule. Early immune signaling—including transforming growth factor- β -driven pathways—promotes fibroblast proliferation and differentiation into myofibroblasts, disturbs extracellular matrix turnover, and leads to deposition of collagen types I and III, capsular thickening, and contracture—mechanisms that plausibly account for pain and stiffness in AC [1,3,4,12]. This mechanistic framework provides a rationale for both anti-inflammatory approaches and procedures that mechanically address capsular tightness.

Diagnosis is primarily clinical; however, imaging is routinely used to support diagnostic confidence and to exclude mimicking conditions. Magnetic resonance imaging (MRI) and MR arthrography (MRA) commonly demonstrate thickening of the coracohumeral ligament and the capsule within the rotator interval, reduced distensibility and volume of the axillary recess, obliteration of the subcoracoid fat triangle, and capsular T2 hyperintensity or post-contrast enhancement [5,6,7]. High-resolution ultrasound can reveal comparable capsular changes and, importantly, serves as a guidance technology for targeted intra-articular procedures in AC [5,7]. Thus, both the diagnostic work-up and the delivery of minimally invasive interventions are closely intertwined with imaging technologies.

Management spans a continuum from conservative measures (education, analgesia, and structured physical therapy) to minimally invasive interventions and, in refractory cases, operative options such as manipulation under anesthesia or arthroscopic capsular release [8,9,11]. Among minimally invasive options, intra-articular corticosteroid injection (IACI) is widely employed and, when administered early, may shorten the overall duration of symptoms [9]. Hydrodilatation (also termed hydrodistension)—a mechanical capsular distension under ultrasound or fluoroscopic guidance using saline with or without local anesthetic and/or corticosteroid—has been evaluated in randomized trials directly contrasting HD and IACI as well as in systematic reviews and meta-analyses [13–18]. Across head-to-head randomized trials and contemporary systematic reviews/meta-analyses, the evidence is **mixed** [13–18].

A recent meta-analysis suggests that hydrodilatation may confer short-term improvements—particularly in disability and external rotation—compared with intra-articular corticosteroid injection [13]. However, two head-to-head randomized trials reported no added benefit of hydrodilatation [16] and, in one study, better early outcomes with corticosteroid injection alone [17]; a recent single-blinded RCT likewise found no clear superiority of either approach [18]. This pattern aligns with earlier narrative reviews and guideline statements [8,14,15]. At the same time, heterogeneity in protocols (injectate composition and volume, ultrasound versus fluoroscopic guidance, anterior versus posterior approach) complicates direct comparisons and likely contributes to between-study variability [5–8,13–18]. Given this background, a focused synthesis comparing hydrodilatation with IACI in adults with primary AC is warranted. The present review collates recent evidence on effectiveness and safety—using pain intensity and ROM as core outcomes—and outlines how imaging-enabled techniques are operationalized within contemporary care pathways for AC [1–18].

Methods

1. Study design and objective

This study is a rapid review of the literature comparing hydrodilatation (HD) with intra-articular corticosteroid injection (IACI) in primary adhesive capsulitis (AC). The primary endpoints were pain (Visual Analogue Scale [VAS] or Numerical Rating Scale [NRS]) and range of motion (ROM). Secondary endpoints included patient-reported outcomes (PRO) (e.g., SPADI, ASES, DASH) and adverse events.

2. Eligibility criteria

Population. Adults (≥ 18 years) with primary/idiopathic adhesive capsulitis (AC). Primary AC includes cases with common systemic comorbidities (e.g., diabetes, thyroid disorders) but excludes post-traumatic or post-operative stiffness. Human studies only; full-text available in English or Polish.

Interventions. Hydrodilatation (HD) of the glenohumeral joint (synonyms: hydrodistension/hydrodistention/capsular distension), performed under ultrasound or fluoroscopic guidance, any injectate composition/volume, with or without corticosteroid.

Comparators. Intra-articular corticosteroid injection (IACI) into the glenohumeral joint (any corticosteroid, dose/regimen; single or repeated; with or without image guidance).

Outcomes. Studies had to report at least one primary outcome: pain (VAS/NRS) or range of motion (ROM in degrees, especially external rotation). Secondary outcomes (when available): patient-reported outcomes (PRO; e.g., SPADI/ASES/DASH) and adverse events.

Study designs. Systematic reviews/meta-analyses (SR/MA) and randomized controlled trials (RCT) that directly compare HD vs IACI.

Time window. Publications from 2018 to 2025.

Minimum follow-up. Short-term outcomes assessed within 6–12 weeks (accept ≥ 4 weeks if 6–12 weeks unavailable); long-term defined as ≥ 6 months.

Exclusions. Secondary AC (post-trauma/surgery), animal/in-vitro studies, conference abstracts or theses without peer-reviewed full-text, narrative/opinion pieces, case reports/series with < 10 participants, studies without a direct HD–IACI comparison, and studies of subacromial/periarticular injections only (i.e., non-glenohumeral targets).

Handling overlap. For overlapping datasets or multiple reports from the same trial, the most complete/most recent report was retained. For overlapping SR/MA, the most recent and/or most comprehensive was prioritized; older reviews were used as supplementary context only.

3. Information sources & search strategy

Databases. PubMed; PubMed Central (PMC); Europe PMC; Google Scholar (for forward/backward citation chasing and newest RCTs).

Last search. 2025-09-04.

Language. No a priori limits; full-texts in English or Polish prioritized.

Grey literature. Not searched; conference abstracts without peer-reviewed full-text excluded.

Deduplication. By DOI/PMID (e.g., Zotero/EndNote) before screening.

3.1 Core queries (PubMed / PMC / Europe PMC)

(A) *Systematic reviews / meta-analyses*

```
("adhesive capsulitis"[MeSH] OR "adhesive capsulitis"[tiab] OR "frozen
shoulder"[tiab])
AND ("shoulder joint"[MeSH] OR glenohumeral[tiab] OR shoulder[tiab])
AND (hydrodilatation[tiab] OR hydrodilation[tiab] OR hydrodistension[tiab]
OR hydrodistention[tiab]
OR "capsular distension"[tiab] OR "capsular distention"[tiab]
OR "arthrographic distension"[tiab] OR "arthrographic
distention"[tiab])
AND (corticosteroid*[tiab] OR steroid*[tiab] OR triamcinolone[tiab] OR
methylprednisolone[tiab])
AND ("systematic review"[Publication Type] OR "meta-analysis"[Publication
Type] OR meta-analy*[tiab] OR systematic[sb])
AND ("2018/01/01"[Date - Publication] : "2025/12/31"[Date - Publication])
NOT (subacromial[tiab] OR periarticular[tiab])
```

(B) Randomized controlled trials (HD vs IACI)

```

("adhesive capsulitis"[MeSH] OR "adhesive capsulitis"[tiab] OR "frozen
shoulder"[tiab])
AND ("shoulder joint"[MeSH] OR glenohumeral[tiab] OR shoulder[tiab])
AND (hydrodilatation[tiab] OR hydrodilation[tiab] OR hydrodistension[tiab]
OR hydrodistention[tiab]
    OR "capsular distension"[tiab] OR "capsular distention"[tiab]
    OR "arthrographic distension"[tiab] OR "arthrographic
distention"[tiab])
AND (intra-articular[tiab] OR intraarticular[tiab])
AND (corticosteroid*[tiab] OR steroid*[tiab] OR triamcinolone[tiab] OR
methylprednisolone[tiab])
AND (randomized controlled trial[Publication Type] OR randomized[tiab] OR
randomised[tiab])
AND ("2018/01/01"[Date - Publication] : "2025/12/31"[Date - Publication])
NOT (subacromial[tiab] OR periarticular[tiab])

```

3.2 Google Scholar (years set to 2018–2025; sort by date)

```

meta-analysis hydrodilatation "adhesive capsulitis"
"frozen shoulder" hydrodistension AND corticosteroid randomized trial
"adhesivecapsulitis" (hydrodilatation OR hydrodilation OR hydrodistension)
AND (corticosteroid OR triamcinolone) AND randomized
("capsular distension" OR "arthrographic distension") "frozen shoulder"
randomized

```

3.3 Logging & reproducibility

For each search run, we recorded the database, exact query, date/time, hit count, and export file (RIS/BibTeX). Search logs (queries, dates, hit counts) and screenshots of applied filters/date limits are provided in Appendix A (PDF). Duplicates were removed by deduplication (PMID/DOI/title) prior to screening.

4. Study selection

Team & roles. Screening was performed by seven reviewers Zbigniew Klimek, Kamil Nieroda, Olaf Jadanowski, Piotr Misiorek, Michalina Pastuszka. All reviewers completed a calibration exercise on 20 records to align use of eligibility criteria.

Workflow. We used a two-stage, double-independent process with rotating pairs drawn from the seven reviewers:

1. **Title/abstract screening** (each record screened independently by two reviewers);
2. **Full-text assessment).**

Disagreements were resolved by discussion; if unresolved, a third reviewer adjudicated. Multiple reports from the same study were consolidated; the most complete/most recent report was retained.

Deduplication. Records were deduplicated before screening using DOI/PMID and metadata matching, then verified manually.

Reasons for exclusion. For each full-text exclusion, a primary reason was recorded using standardized categories: wrong population (secondary/post-op/post-trauma AC), wrong intervention (non-glenohumeral or subacromial/periarticular injections), wrong comparator (no HD–IACI arm), wrong outcomes (no pain/ROM/PRO), wrong design (non-SR/MA/non-RCT), abstract only/no peer-reviewed full-text, duplicate.

5. Data extraction

Team & independence. Data were extracted independently by two reviewers (from a seven-member team) working in rotating pairs. Disagreements were resolved by consensus, with third-reviewer adjudication when needed.

Tools. We used a structured spreadsheet and a brief codebook to standardize variables, units, and time windows.

Data items captured (per study):

- **Identification:** first author & year, DOI/PMID, country/setting, funding.
- **Population:** primary/idiopathic AC only? diagnostic criteria; key exclusions.
- **Design & size:** study design (RCT or SR/MA); sample size (N randomized / N analyzed, where applicable).
- **Interventions:**
 - **HD:** guidance (ultrasound/fluoroscopy), volume (mL), injectate composition (saline, local anesthetic, steroid type + dose if used), number of injections, co-interventions (e.g., physiotherapy).
 - **IACI:** corticosteroid drug, dose/regimen, image guidance (yes/no), number of injections, co-interventions.
- **Time points:** short-term (6–12 weeks; accept ≥ 4 weeks if necessary) and long-term (≥ 6 months).
- **Outcomes:** pain (VAS/NRS), ROM (degrees; priority to external rotation, also abduction/flexion if reported), patient-reported outcomes (PRO: SPADI/ASES/DASH), and adverse events (type and count by arm).
- **Effect reporting:** direction of effect and, when available, author-reported point estimates with 95% CIs (no re-calculation).
- **Quality/risk of bias:** RoB 2 for RCTs; AMSTAR-2 for SR/MA.
- **Notes:** protocol nuances, missing data, attrition.

Harmonization rules.

- **Pain scales:** convert VAS 0–100 $\rightarrow$ 0–10 (divide by 10); NRS 0–10 unchanged.
 - **ROM:** extract degrees only; do not impute if reported differently (report narratively).
 - **PRO directionality:** record the instrument and whether higher scores indicate better or worse status (e.g., SPADI: higher = worse).
 - **Missing statistics:** do **not** derive SD from IQR; if only medians/IQR are provided, report narratively.
- Multiple reports / overlapping data.** When multiple publications described the same study, we consolidated them into a single record (prioritizing the most complete or most recent report).
- Contact with authors.** Not planned; unavailable items were recorded as NR (not reported).

6. Risk-of-bias (quality) assessment

Risk of bias was assessed independently by two reviewers (rotating pairs), with third-reviewer adjudication for disagreements.

• **Systematic reviews/meta-analyses (SR/MA):** we applied a condensed AMSTAR-2, focusing on four key domains: (I) protocol/registration, (II) comprehensiveness of the search, (III) risk-of-bias assessment and its use in interpretation, and (IV) appropriateness of synthesis (including heterogeneity and small-study/publication bias considerations). Each review received an overall credibility rating (high / moderate / low).

• **Randomized controlled trials (RCT):** we used Cochrane RoB 2 at the outcome level for primary endpoints and the primary time point (6–12 weeks), covering five domains: randomization process; deviations from intended interventions; missing outcome data; measurement of the outcome; selection of the reported result. Overall judgments were low risk, some concerns, or high risk according to RoB 2 algorithms.

We planned to prioritize low-risk evidence in the narrative synthesis and report sensitivity statements when conclusions differed by risk-of-bias level.

7. Synthesis methods

Because of clinical and methodological heterogeneity in hydrodilatation (HD) protocols (e.g., injectate composition and volume; ultrasound vs fluoroscopic guidance; anterior vs posterior approach) and non-uniform outcome timing, we conducted a qualitative (narrative) synthesis. For outcomes that had already been pooled in eligible systematic reviews/meta-analyses (SR/MA), we reproduced the authors' point estimates and 95% CIs without re-meta-analysis, noting the review date range and included trials to avoid double-counting.

Grouping and hierarchy. Results are organized by time horizon (short-term 6–12 weeks [accepting ≥ 4 weeks if necessary] vs ≥ 6 months) and by intervention details (HD with vs without corticosteroid; guidance modality). Within each stratum, we prioritized (i) pain (VAS/NRS on a 0–10 scale), (ii) ROM (degrees; priority to external rotation), and (iii) patient-reported outcomes (SPADI/ASES/DASH), followed by adverse events. If multiple pain instruments were reported, we used the prespecified hierarchy VAS $\rightarrow$ NRS, converting VAS 0–100 to 0–10 by division.

Use of risk-of-bias. We highlighted trials at low risk of bias (RoB 2) when formulating conclusions and provided sensitivity statements if interpretations differed after down-weighting or excluding high-risk studies. For SR/MA, we reported an overall credibility (condensed AMSTAR-2) and used it to contextualize pooled effects.

Overlaps and conflicts. When multiple SR/MA covered overlapping RCT sets, we cited the most comprehensive and/or most recent for each outcome/time stratum and cross-checked constituent studies to avoid double counting. Apparent discrepancies between SR/MA and individual RCTs were explored qualitatively (e.g., protocol differences, co-interventions, follow-up windows).

Data handling. We did not compute new pooled estimates, impute missing statistics, or back-calculate SD from IQR. If only medians/IQRs were available, results were reported narratively. Adverse events were summarized as type and count by arm, where reported.

8. Subgroup and sensitivity considerations

Rationale and approach. Owing to heterogeneity in hydrodilatation (HD) protocols and patient context, we planned descriptive (non-pooled) subgroup explorations and qualitative sensitivity analyses. We did not run new interaction tests or meta-regression; subgroup findings are hypothesis-generating.

Pre-specified subgroups (qualitative):

1. HD with steroid vs HD without steroid.

Definition: HD performed with a concomitant intra-articular corticosteroid (in the injectate or co-administered) versus HD without steroid.

2. Guidance modality (ultrasound vs fluoroscopy).

Definition: primary imaging modality guiding capsular distension; injection approach (anterior vs posterior) recorded and discussed exploratorily if reported.

3. Injectate volume (<20 mL vs ≥20 mL).

Definition: total distension volume delivered during the index procedure.

4. Timing / disease stage (early vs later).

Operationalization: early = symptom duration ≤3 months; later = >6 months; studies reporting 3–6 months were summarized narratively due to mixed staging.

Sensitivity analyses (qualitative):

- **Study quality:** emphasize higher-credibility SR/MA (condensed AMSTAR-2: high/moderate) and low-risk or some-concerns RCTs (RoB 2); de-emphasize high-risk RCTs.

- **Population purity:** exclude or down-weight studies with secondary AC or unclear AC definition.

- **Co-interventions:** down-weight trials with imbalanced physiotherapy/analgesia across arms.

- **Outcome framing:** prioritize pain on a 0–10 scale (convert VAS 0–100 → 0–10) and external rotation (°); verify direction consistency across pain/ROM/PRO.

- **Reporting consistency:** prefer ITT or pre-specified primary analyses where available.

- **Overlap control (SR/MA):** where reviews share constituent RCTs, rely on the most recent/comprehensive review and avoid double counting.

Insufficient data handling. If a subgroup is represented by <2 independent datasets or definitions are inconsistent, we provide narrative remarks without subgroup-specific conclusions.

Presentation. Subgroup observations are embedded in Results for each time horizon (6–12 weeks; ≥6 months), with concise flags (e.g., “HD+steroid → greater short-term pain reduction vs IACI; certainty low–moderate”).

9. Protocol and deviations

Protocol status. This rapid review was not prospectively registered (e.g., in PROSPERO). The methodological plan (Sections 2–8) was defined a priori before screening.

Planned scope. Eligibility (primary AC; HD vs IACI; designs limited to SR/MA and RCTs), information sources and search strings, data items, risk-of-bias tools (condensed AMSTAR-2; RoB 2), and synthesis approach (qualitative, with reproduction of SR/MA pooled estimates) were pre-specified.

No deviations from the pre-specified plan were identified. A top-up search was performed on 2025-09-04 to ensure currency.

10. Ethics

This study is a review of previously published literature and involved no interaction with human participants or animals and no access to identifiable data. Therefore, ethics committee/IRB approval and informed consent were not required.

11. Results

11.1 Study selection.

Database searches identified 72 records; 60 remained after deduplication. We assessed 6 full-texts for eligibility and included SR/MA (n = 3) and RCTs (n = 3) directly comparing hydrodilatation (HD) with intra-articular corticosteroid injection (IACI). Reasons for full-text exclusion are summarized in Appendix A (Table S2). The selection process is shown in Figure 1 (PRISMA-lite).

Searches conducted: 2025-09-04. Numbers reflect identification, deduplication and screening per protocol (Sections 3–4).

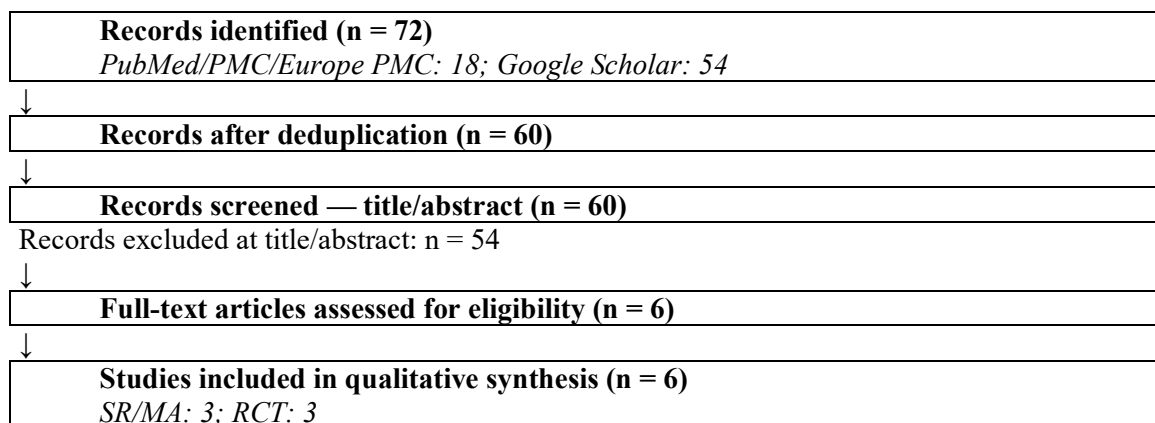


Fig. 1. PRISMA-lite study flow (HD vs IACI in primary adhesive capsulitis)

11.2 Study characteristics.

The included evidence comprised systematic reviews/meta-analyses published between 2018–2023 [14–16] and randomized controlled trials published between 2020–2025 [13, 17, 18]. Across RCTs, HD protocols varied by guidance (ultrasound or fluoroscopy), approach (anterior or posterior), injectate composition (saline ± local anesthetic ± corticosteroid), and volume (reported ranges included lower and higher volumes). Co-interventions (e.g., physiotherapy) were variably applied. Primary outcomes were pain (VAS/NRS), ROM (priority to external rotation), and PRO (SPADI/ASES/DASH). Risk-of-bias judgments are provided in Table Y (RCTs, RoB 2) and credibility ratings for SR/MA in Table X (condensed AMSTAR-2).

11.3 Short-term outcomes (6–12 weeks; ≥4 weeks accepted if needed).

RCTs. One trial found no additional benefit of HD over IACI [13]; another reported better short-term outcomes with IACI versus HD+steroid [17]; a third showed no clear superiority between HD and IACI under single-blind conditions [18].

SR/MA. A comprehensive review reported short-term advantages of HD for some outcomes—particularly disability and external rotation [14]—while an earlier review suggested that HD+steroid may accelerate early ROM recovery versus steroid alone, with quality caveats [15].

Synthesis: Short-term findings are inconsistent across RCTs, with some pooled signals favoring HD (especially when combined with steroid) but contradictory head-to-head trial data [13–18].

11.4 Longer-term outcomes (≥6 months).

Across reviews and trials that reported longer follow-up, between-group differences attenuated and consistent superiority of either HD or IACI was not demonstrated [13–18].

11.5 Adverse events.

Where reported, adverse events were infrequent and mostly mild (e.g., transient pain); no serious complications were described in the abstracts of included RCTs [16–18]. Reporting was limited and heterogeneous.

11.6 Subgroup observations (qualitative).

Exploratory patterns suggested that HD+steroid may yield greater short-term symptom relief than HD without steroid in some datasets; effects may also vary by guidance modality and injectate volume. Definitions of timing/stage and protocols differed substantially, so these signals are hypothesis-generating [13–18].

11.7 Risk of bias and review credibility.

Detailed RoB 2 judgments for the included RCTs are shown in Table Y, and credibility ratings for SR/MA (condensed AMSTAR-2) are shown in Table X. In brief, two trials were judged some concerns and one high risk of bias; SR/MA were of moderate credibility overall. (See Tables X–Y).

Table X. Credibility of SR/MA (condensed AMSTAR-2)

Review (year)	Protocol / registration	Comprehensive search	Dual screening / deduplication	RoB handling used in interpretation	Synthesis & small-study bias	Overall credibility
Poku et al., 2023 (Br Med Bull)	Not reported	Broad (PubMed, Embase, Scopus, CENTRAL, WoS, CINAHL; to mid-2023)	Yes (independent screening; dedup)	Partial (methodology score used; limited RoB integration)	Pairwise meta-analysis; publication bias not assessed (<10 studies)	Moderate
Catapano et al., 2018 (PM&R)	Not reported	MEDLINE, EMBASE, CINAHL (to 2017)	Yes	Partial/unclear	Narrative synthesis (limited quantitative pooling)	Moderate
Zhang et al., 2021 (Am J Sports Med; NMA)	Unclear in abstract	PubMed, Embase, Cochrane, WoS (to 2019)	Unclear	Unclear	Network meta-analysis; heterogeneity explored	Moderate

Table Y. RoB 2 for RCTs directly comparing HD vs IACI (primary outcomes ≈6–12 weeks)

Trial (year, journal)	Randomization process	Deviations from intended interventions	Missing outcome data	Measurement of outcomes	Selection of the reported result	Overall RoB
Paruthikunnan et al., 2020 (Skeletal Radiology) — HD+CS vs CS	Some concerns (allocation concealment not detailed)	Low	Low/Unclear	Low (double-blind; PRO-based)	Some concerns	Some concerns
Swaroop et al., 2023 (Malays Orthop J) — HD+CS vs CS	Some concerns	Some concerns (likely unblinded procedures)	Unclear	High (no blinding for subjective outcomes)	Some concerns	High
Nasiri et al., 2025 (J Pain Palliat Care Pharmacother) — HD vs CS	Some concerns (randomization details not specified)	Low (single-blind, protocolized arms)	Unclear	Some concerns	Some concerns	Some concerns

12. Discussion

Principal findings.

Across head-to-head randomized trials and contemporary systematic reviews/meta-analyses, the comparative effectiveness of hydrodilatation (HD) versus intra-articular corticosteroid injection (IACI) in primary adhesive capsulitis (AC) remains mixed [13–18]. A recent meta-analysis reports short-term advantages of HD—particularly for disability and external rotation (ER) [13]. In contrast, individual RCTs show no added benefit of HD over IACI [16] and, in one study, better early outcomes with IACI alone [17]; a recent single-blinded trial likewise found no clear superiority of either approach [18]. At longer follow-up (≥ 6 months), consistent between-group differences were not demonstrated [13–18].

Integration with prior evidence and guidance.

Our synthesis aligns with narrative reviews and guideline-type statements suggesting that many patients improve with conservative management, that corticosteroid injection can abbreviate the painful phase, and that capsular distension may provide transient improvements in ROM/disability in selected contexts [8,14,15]. However, pooled signals from SR/MA necessarily aggregate heterogeneous protocols; when evidence is examined at the trial level, inconsistency is more apparent, especially in the 6–12-week window [13–18].

Mechanistic considerations.

HD aims to mechanically expand the contracted capsule and rotator interval, potentially disrupting adhesions and reducing nociceptive drive; when combined with corticosteroid, an anti-inflammatory effect may further facilitate early gains [5–7,13–15]. Yet the net clinical effect is a function of (i) capsular biology (inflammatory “freezing” vs fibrotic “frozen” stage), (ii) volume and pressure achieved during distension, (iii) injectate composition (saline $\pm$ local anesthetic $\pm$ steroid), and (iv) guidance/approach (ultrasound vs fluoroscopy; anterior vs posterior). Variability in these parameters plausibly contributes to between-study heterogeneity and divergent short-term results [5–8,13–18].

Heterogeneity and potential effect modifiers.

Four domains likely modify response:

1. Steroid co-administration (HD+steroid vs HD alone): several datasets suggest that adding a steroid may augment early pain/function gains versus HD alone, but the increment over IACI remains uncertain [13,14,16–18].
2. Guidance and approach: ultrasound guidance allows targeted delivery (e.g., rotator interval), while fluoroscopic hydrodistension emphasizes capsular volume and pressure. Approach (anterior vs posterior) may influence ER gains and patient comfort; these aspects vary across trials and reviews [5–6,13–15].
3. Volume: thresholds <20 mL vs ≥ 20 mL could yield different degrees of capsular stretch; however, volumes are not uniformly reported, and the relationship with outcomes is inconsistent [13–15].
4. Timing/stage: patients in an earlier, more inflammatory phase may respond differently from those in a fibrotic phase; staging was inconsistently defined, limiting firm subgroup conclusions [5–7,13–15].

Why RCTs and SR/MA disagree.

Discrepancies likely reflect protocol diversity, small samples, and blinding challenges (subjective pain/PRO prone to performance/detection bias), as well as co-interventions (e.g., physiotherapy intensity), selective reporting, and different measurement windows. SR/MA average across these differences and may detect pooled, modest, short-term effects, whereas individual RCTs—particularly when well-controlled—can show no superiority or even favor IACI in the early period [13–18].

Clinical implications (practice-oriented).

- For patients in whom steroid injection is already planned, IACI alone is an appropriate first-line option and, in some trials, performed as well as or better than HD at 6–12 weeks [16,17].
- HD (image-guided) can be considered when stiffness dominates and ROM is the priority, or after an insufficient response to IACI/physiotherapy—recognizing that benefits are often short-lived and technique-dependent [13–15,18].
- Shared decision-making should incorporate patient preferences, comorbidities (e.g., diabetes), tolerability, access to image-guided procedures, and local expertise.
- Regardless of injection strategy, structured rehabilitation remains essential to consolidate any gains in ROM.

Safety and tolerability.

Reported adverse events (AEs) were infrequent and mild (e.g., transient post-procedural pain) in included RCTs; serious complications were not described in abstracts [16–18]. Nonetheless, systematic AE capture was variable; careful counseling regarding transient pain flares and post-procedure rehabilitation is advisable.

Methodological quality and certainty.

The credibility of SR/MA was mainly moderate (condensed AMSTAR-2), and RCTs were rated some concerns or high risk of bias (RoB 2), often due to unclear allocation concealment, limited blinding for subjective outcomes, small sample sizes, and heterogeneous co-interventions. These limitations temper certainty, especially for short-term pain/PRO endpoints.

Health-system and resource considerations.

IACI is comparatively simple, low-cost, and widely available; HD requires imaging, procedural resources, and operator expertise. In the absence of consistent superiority of HD over IACI, cost-effectiveness may favor IACI as initial therapy, reserving HD for selected cases (e.g., marked stiffness, prior suboptimal response to IACI), pending more definitive economic evaluations.

Implications for research.

Future studies should: (i) pre-register protocols; (ii) ensure robust allocation concealment and blinded outcome assessment; (iii) standardize HD parameters (injectate composition, volume thresholds, guidance/approach); (iv) adopt core outcomes (pain 0–10, ER in degrees, SPADI/ASES/DASH) at harmonized time points (6–12 weeks, ≥ 6 months); (v) report AEs systematically; and (vi) consider comparative cost-effectiveness. Trials stratified by disease stage and diabetes status could clarify effect modification and improve generalizability.

Overall interpretation.

Taken together, current evidence does not consistently support the superiority of HD over IACI in primary AC. Some pooled analyses indicate short-term advantages of HD (particularly when combined with steroid), but head-to-head trials do not uniformly confirm this, and long-term differences remain uncertain. Pragmatically, IACI is a sound first-line choice when injection is indicated; HD may be deployed selectively, with realistic expectations and attention to technique and rehabilitation [13–18].

13. Limitations**Limitations of the evidence base.**

The comparative evidence on hydrodilatation (HD) versus intra-articular corticosteroid injection (IACI) in primary adhesive capsulitis (AC) is constrained by: (i) small sample sizes and short follow-up in several randomized trials; (ii) protocol heterogeneity in HD (injectate composition, total volume, ultrasound vs fluoroscopic guidance, anterior vs posterior approach); (iii) variable and sometimes inconsistently reported outcomes (pain scales, ROM planes, PRO instruments) and time points; (iv) co-interventions (e.g., physiotherapy) that differ across arms or studies; (v) risk-of-bias concerns (allocation concealment/blinding challenges for subjective outcomes); and (vi) limited adverse-event reporting, which may under-estimate harms. These features likely contribute to between-study variability and temper the certainty of short-term effects. Publication and small-study biases cannot be excluded.

Limitations of this review (rapid design).

This was a rapid review without prospective registration. Although eligibility criteria, search strings, data items, and risk-of-bias tools (condensed AMSTAR-2; RoB 2) were pre-specified, the approach entailed: (i) a narrative synthesis without de-novo meta-analysis; (ii) a restricted time window (2018–2025); (iii) prioritization of English-language full-texts (with Polish accepted)—introducing potential language bias; (iv) no grey-literature search by design; and (v) reliance on abstract-level details for certain risk-of-bias judgments where full-text information was not accessible at drafting. We did not impute missing statistics or contact authors for additional data; VAS 0–100 values were converted to 0–10 per protocol, and medians/IQR were summarized narratively. Deduplication counts were conservative and based on DOI/PMID/title matching across databases.

Generalizability.

Findings apply to adult primary (idiopathic) AC; studies of secondary AC (post-trauma/surgery) were excluded. External validity may vary with disease stage, comorbidity profiles (e.g., diabetes), local procedural expertise, and access to image-guided injections.

Mitigation steps.

We attempted to address these limitations by pre-specifying subgroup/sensitivity procedures, prioritizing higher-credibility SR/MA and lower-risk trials, documenting the study flow (PRISMA-lite), and providing transparent methods and search logs. Nonetheless, residual uncertainty remains, especially for early time windows and PRO endpoints.

Net impact on conclusions.

Taken together, these limitations suggest that the overall certainty of evidence comparing HD and IACI is low-to-moderate, particularly for short-term outcomes. More robust, standardized RCTs with harmonized HD protocols, core outcomes at common time points, and systematic safety reporting are warranted.

14. Conclusions and implications**Conclusions.**

Across head-to-head randomized trials and contemporary reviews, the comparative effectiveness of hydrodilatation (HD) versus intra-articular corticosteroid injection (IACI) in primary adhesive capsulitis is inconsistent. Meta-analytic summaries indicate short-term improvements with HD—particularly for disability and external rotation—yet individual RCTs report no added benefit of HD and, in one trial, better early outcomes with IACI alone; durable (≥ 6 months) superiority of either strategy has not been demonstrated [13–18]. Given protocol heterogeneity and risk-of-bias concerns, the overall certainty is low-to-moderate as summarized in Figure 2.

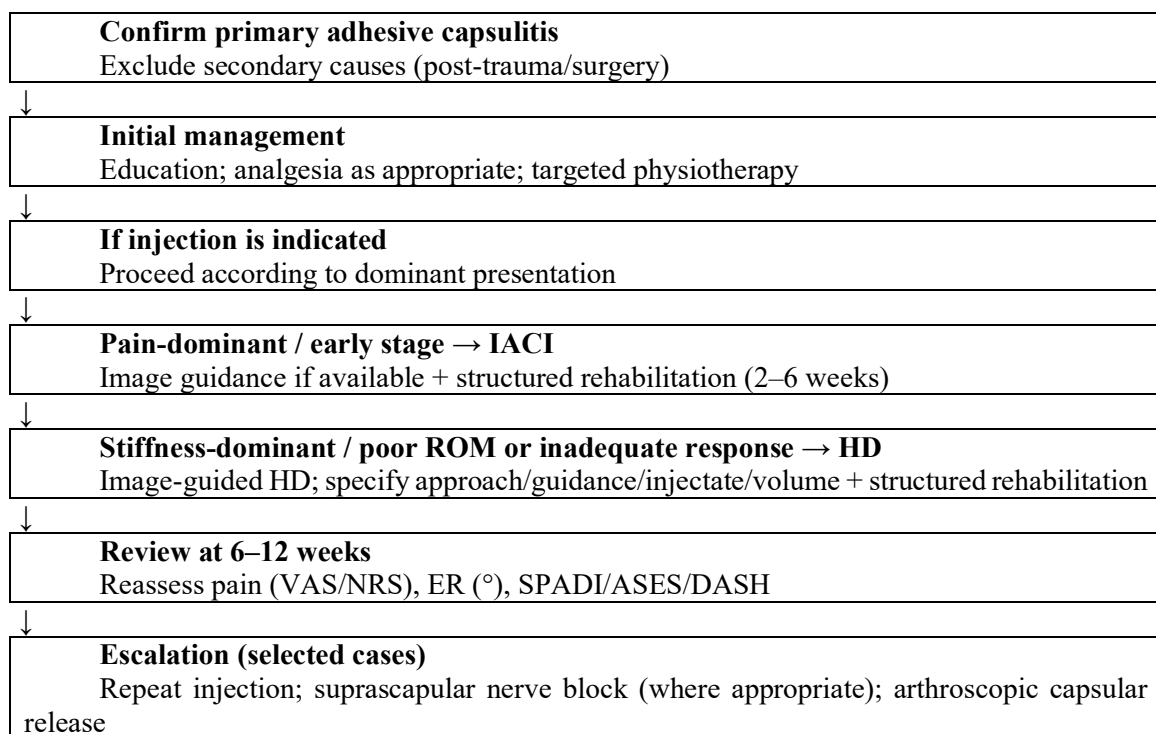


Fig. 2. Pragmatic pathway for injection choices in primary adhesive capsulitis

14.1 Implications for clinical practice

A. First-line injection choice

- When an injection is indicated, IACI alone is an appropriate first-line option; early outcomes can match or exceed those of HD in some settings [16–18].

- HD (image-guided) may be considered selectively when stiffness predominates and restoration of range of motion (especially external rotation) is the primary goal, or after a suboptimal response to IACI and structured physiotherapy [13–15,18].

B. Technique & protocol considerations (when HD is chosen)

- Guidance: Prefer ultrasound or fluoroscopy; document the approach (anterior vs posterior) and target (e.g., rotator interval).

- Injectate: Specify composition (saline ± local anesthetic ± corticosteroid) and steroid dose if used.

- Volume: Predefine a volume plan (<20 mL vs ≥20 mL) with a safety cap; record achieved volume/pressure and patient tolerance.

- Co-interventions: Pair the procedure with structured rehabilitation (early, supervised ER-focused stretching and scapular control).

C. Pragmatic decision pathway (simplified)

1. Confirm primary AC; exclude secondary causes.

2. Initial management: education, analgesia as appropriate, targeted physiotherapy.

3. If injection is indicated:

- Pain-dominant or early stage → IACI (image-guided if available).

- Stiffness-dominant / poor ROM or inadequate response to IACI/PT → consider HD (image-guided).

4. After injection (either strategy): prescribe 2–6 weeks of focused rehab (priority to ER); schedule review at 6–12 weeks.

5. Escalation: persistent stiffness/pain despite conservative care → discuss repeat injection, suprascapular nerve block (where appropriate), or arthroscopic capsular release in selected patients.

D. Safety & counseling

- Adverse events are typically infrequent and mild (e.g., transient post-procedural pain); advise on possible 24–48 h pain flare and the importance of continuing exercises [16–18].

- In patients with diabetes, monitor glycemia after steroid; consider smaller steroid doses or HD without steroid with cautious expectations for analgesia.

E. Documentation essentials (clinic-ready)

- Stage/symptom duration; dominant issue (pain vs stiffness); instruments (VAS/NRS; SPADI/ASES/DASH); ER (degrees).

- Procedure parameters (guidance, approach, volume, injectate, steroid dose).

- Rehab plan and follow-up timing (6–12 weeks; ≥6 months).

14.2 Implementation tips

- Rehab first—and always: irrespective of injection strategy, implement a ROM program (daily ER/flex/abd stretching, capsular glide work, progressive functional exercises).

- Standardize locally: create local protocols for HD/IACI (checklists, consent templates, parameter sheets) to reduce heterogeneity and improve documentation.

- Measure what matters: track VAS/NRS (0–10), ER (°) and SPADI/ASES/DASH at 6–12 weeks and ≥6 months using the same tools each time.

14.3 Health-system and cost considerations

- IACI is generally less costly, more accessible and less resource-intensive; HD requires imaging resources and operator expertise.

- In the absence of consistent superiority of HD, a step-wise approach (IACI first → selective HD) is likely cost-sensible, pending formal economic evaluations.

- Centres with established HD expertise may achieve better outcomes via standardized protocols and training.

14.4 Implications for research

- Design: adequately powered, pre-registered RCTs with robust allocation concealment and blinded outcome assessment.
- Standardisation: harmonise HD parameters (injectate composition, volume thresholds such as <20 mL vs ≥20 mL, guidance/approach) and stage definitions.
- Core outcomes: pain on 0–10 scale, external rotation (degrees), SPADI/ASES/DASH at 6–12 weeks and ≥6 months; systematic adverse-event capture.
- Effect modifiers: prospective stratification by disease stage and diabetes; explicit reporting of co-interventions (physiotherapy).
- Economics & implementation: comparative cost-effectiveness and pragmatic trials with rehabilitation components and adherence monitoring.

14.5 Key practice points (optional box)

- Start simple: for first injection, IACI + structured rehabilitation.
- Selectively add HD: when stiffness dominates or response to IACI/PT is suboptimal—recognize technique-dependence and transient effects.
- Measure ER & PROs: external rotation (°), VAS/NRS, SPADI/ASES—use the same scales at follow-up.
- Set expectations: explain the typical time course, potential post-injection flare, and the central role of rehabilitation.

Box 1. Key practice points

Key practice points

- Start simple: for the first injection, choose intra-articular corticosteroid injection (IACI) plus structured rehabilitation.
- Selectively add hydrodilatation (HD) when stiffness predominates or after suboptimal response to IACI/physiotherapy; ensure image guidance.
- Technique matters: predefine approach (anterior/posterior), guidance (US/fluoroscopy), injectate (saline ± local anesthetic ± steroid), and volume (<20 mL vs ≥20 mL).
- Measure what matters: pain (VAS/NRS 0–10), external rotation (degrees), and SPADI/ASES/DASH at 6–12 weeks and ≥6 months—use the same tools at follow-up.
- Set expectations: HD benefits may be transient and technique-dependent; counsel about possible 24–48 h pain flare and the central role of rehabilitation.

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