

A high level of scientific evidence is available to guide treatment of primary shoulder stiffness: The SIAGASCOT consensus

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Abstract

Purpose: Shoulder stiffness (SS) is a condition characterised by active and passive restricted glenohumeral range of motion, which can occur spontaneously in an idiopathic manner or be associated with a known underlying aetiology. Several treatment options are available and currently no consensus has been obtained on which treatment algorithm represents the best choice for the patient. Herein we present the results of a national consensus on the treatment of primary SS.

Methods: The project followed the modified Delphi consensus process, involving a steering, a rating and a peer-review group. Sixteen questions were generated and subsequently answered by the steering group after a thorough literature search. A rating group composed by professionals specialised in the diagnosis and treatment of shoulder pathologies rated the question–answer sets according to the scientific evidence and their clinical experience.

Results: Recommendations were rated with an average of 8.4 points out of maximum 9 points. None of the 16 answers received a rating of less than 8 and all the answers were considered as appropriate. The majority of responses

For author affiliations, please refer to page 44.

Abbreviations: HAS, Haute Autorité de Santé; ISAKOS, International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine; NSAIDs, nonsteroidal anti-inflammatory drugs; PRP, platelet-rich plasma; ROM, range of motion; SIAGASCOT, Società Italiana Ginocchio Artroscopia Sport Cartilagine Technologie Ortopediche.

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were assessed as Grade A, signifying a substantial availability of scientific evidence to guide treatment and support recommendations encompassing diagnostics, physiotherapy, electrophysical agents, oral and injective medical therapies, as well as surgical interventions for primary SS.

Conclusions: A consensus regarding the conservative and surgical treatment of primary SS could be achieved at a national level. This consensus sets basis for evidence-based clinical practice in the management of primary SS and can serve as a model for similar initiatives and adaptable guidelines in other European countries and potentially on a global scale.

Level of Evidence: Level I.

KEYWORDS

adhesive capsulitis, consensus, evidence, frozen shoulder, shoulder stiffness

INTRODUCTION

Shoulder stiffness (SS) is defined as a condition of restricted active and passive glenohumeral range of motion (ROM). It can be classified into primary (or idiopathic forms, also known as 'frozen shoulder') and secondary forms (which arise as a consequence of a known cause, like trauma, surgery or joint immobilisation) [1].

Several risk factors have been described, diagnostic approaches have been suggested and multiple treatment options have been proposed to address this disease, ranging from conservative therapies to surgical approaches [2]. As a general rule, it is accepted that treatment of SS should begin addressing known risk factors, in order to avoid relapses; the treatment is completed by strategies for pain reduction, ROM restoration, functional regain and shortening of symptoms duration [3]. The choice between treatments needs to be tailored to the stage of shoulder pathology and to the patient's clinical situation [4]. Although several studies have tried to outline the most appropriate treatment options, no consensus has been obtained on which treatment algorithm represents the best choice for the patient.

For this reason, Società Italiana Ginocchio Artroscopia Sport Cartilagine Tecnologie Ortopediche (SIAGASCOT), a national scientific society focusing on arthroscopy and sports traumatology, started a consensus project on the conservative and surgical treatment of primary SS.

This paper reports and discusses the results of the consensus, which could be considered a guide for local clinical practice and can serve as a model for similar initiatives in other European countries and potentially on a global scale. Given the alignment of patient needs and complaints as well as diagnostic and treatment options across various developed nations and the extensive expertise of the SIAGASCOT members in managing shoulder pathologies, the outcomes obtained from this Italian context are suitable to be extrapolated beyond

Italy's borders, paving the way to the creation of more universally applicable guidelines and best practices in the conservative and surgical management of primary SS at an international level.

MATERIALS AND METHODS

The consensus process was conducted between 2020 and 2023 following a modified Delphi methodology as described by the French National Healthcare Institution Haute Autorité de Santé [5], involving a steering group, a rating group and a peer-review group, for a total of 76 healthcare professionals and scientists including surgeons, physical therapists, radiologists and pain therapists. They were divided into four groups (steering group, $n = 14$; literature group, $n = 4$; rating group, $n = 20$ and peer review group, $n = 38$). For this consensus, considering the historic pandemic period, all group meetings were performed online. The International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine (ISAKOS) definition for SS was used throughout the consensus [1].

The preliminary phases necessary to define the frame of the project preceded the formal consensus and were started in 2020. In particular, a literature review was initially performed to identify randomised controlled trials (RCTs) reporting results of SS treatment [6], followed by a national survey proposed to the society members by the Basic Science Committee of SIAGASCOT [7]. Analysing the available evidences and the results of this national survey, several controversial points emerged, leading to the development of a list of 16 questions based on these points of contention and on discussion with participating experts. These questions served as a base for the formal consensus and were drafted after collegial discussion within the steering group with the aim of addressing areas of interest and of current controversy in the diagnosis and treatment of primary SS.

Between January 2022 and February 2022, a comprehensive literature research was performed by

the literature group with the support of a professional librarian of the University of Milan, to determine the current knowledge status and update the previous review; this search encompassed peer-reviewed articles sourced from PubMed and EMBASE, covering a range of publication types including meta-analyses, systematic reviews, reviews, RCTs, prospective cohort studies, retrospective comparative trials, therapeutic case series, case reports, expert opinions and commentaries. Only papers published in English were considered. This literature search generated a targeted literature set for each of the 16 questions. In addition, when deemed relevant, manual searches were performed by the literature group using books and manuals which focused on this topic. References in the identified studies were also examined to provide additional evidence-based information. Relevant papers published, while conducting the consensus study were also included. Historical papers were included but more attention was made to papers published from 2003 onwards. The title and abstract of all references were examined and any relevant article was obtained in full for the steering group.

At the end of the process, 16 questions focusing on diagnosis and treatment of primary SS were answered by the steering group, and related statements were produced. The statements were graded based on the quality of the best available scientific evidence and sorted into the appropriate grade of recommendation: Grade A, high scientific level; Grade B, scientific presumption; Grade C, low scientific level and Grade D, expert opinion [8]. After a general agreement was achieved within the steering group, the questions were then submitted to the rating group, which consisted of 20 Italian professionals specialised in the diagnosis and treatment of shoulder pathologies, including surgeons, radiologists, pain therapists and physical therapists. Each member of the rating group was asked to score the statements produced by the steering group according to the scientific evidence and their clinical experience using the Likert scale which ranges from 1 (totally inappropriate) to 9 (totally appropriate). Suggestions from the participants were included after the first round. A revised draft was then prepared and resubmitted to the rating group for a second assessment. A combined steering/rating group meeting was then held to discuss possible controversies and to validate the draft and finalise the statements text [9]. The draft document was then sent on to an unbiased peer review group constituted by 38 experienced Italian healthcare professionals active in the field of orthopaedics, sports traumatology and rehabilitation, who were asked to evaluate the question–answer set of the manuscript to determine the relevance, accuracy and clarity of the proposed recommendations. Data analysis was performed using Microsoft Excel (Microsoft Corporation).

RESULTS

After the second rating round, recommendations were rated with an average of 8.4 points out of maximum 9 points. None of the 16 statements received a rating of less than 8 (range: 8–9). Thus, all the statements were considered as appropriate and most of them were evaluated as grade A, indicating that a high level of scientific evidence was available for most of the answers. The complete set of questions and answers is briefly summarised in Table 1 and the best evidence available for each statement as well as the scientific grade and median rating is presented in Table 2. The short version of the final consensus document is available in English in Supporting Information S1: Appendix A, whereas the full consensus document is accessible on the website of the SIAGASCOT Society (<https://siagascot-orto.com/siagascot-shoulder-stiffness-consensus-project-2022-2023/>).

Diagnostic assessment

While a robust consensus has been established concerning the diagnosis of primary SS, there is a lack of extensive high-level literature evidence supporting some of the conclusions. The consensus emphasises the clinical basis for diagnosis, underlining the significance of radiographic assessments to rule out other conditions and acknowledges the role of magnetic resonance and ultrasound as viable but not indispensably essential secondary diagnostic tools.

Physiotherapy and electrophysical agents

Various physiotherapeutic methods and electrophysical agents have been proposed for managing SS, yet many lack substantial support from high-level literature evidence. Treatment modalities supported by meta-analyses and RCTs could be identified, forming a group of treatments suitable for inclusion within a multimodal approach which was deemed appropriate by the consensus group.

Medical therapy

Intra-articular corticosteroid injections are safe and effective, superior to oral corticosteroids and placebos and thereby recommended as the primary line of treatment. Conversely, due to inadequate evidence of superiority, platelet-rich plasma (PRP) injections, anaesthetic injections and hyaluronic acid injections as sole infiltrative procedures were not recommended.

TABLE 1 Essential summary of the consensus questions and their answers.

Question	Essential summary of the answer
1. What diagnostic tests are necessary?	Primarily clinical diagnosis; radiographic examination to rule out chronic other conditions. Follow-up imaging are not necessary.
2. What additional tests are recommended?	Magnetic resonance imaging is useful in uncertain cases. Ultrasound can be useful, if performed by specialised medical personnel. Blood tests are not necessary; advisable to rule out thyroid disorders and diabetes in patients with relevant history or risk factors.
3. What type of physiotherapy is recommended?	Multimodal approach (therapeutic exercise, stretching, joint mobilisation), including scapulothoracic girdle and rotator cuff exercises and stretching up to tolerable pain. Corticosteroid injections combined with physiotherapy provide additional benefit.
4. What electrophysical agents are recommended?	Extracorporeal shockwave therapy can be considered as alternative therapy to pharmacological treatment. Laser therapy can improve pain and disability, does not alter joint stiffness. Not sufficient evidence yet available for other electrophysical agents.
5. Are oral corticosteroids indicated?	Oral corticosteroids are more effective than placebo, nevertheless corticosteroid injections are significantly superior.
6. What other medications are recommended?	Nonsteroidal anti-inflammatory drugs safe and effective.
7. Are corticosteroid injections recommended?	Intra-articular injections are safe and effective and represent the recommended first-line treatment. One to three injections are recommended from the time of diagnosis, at weekly or biweekly intervals.
8. Is there a superior injection technique?	Glenohumeral joint injections, with anterior access based on anatomical landmarks or posterior access under ultrasound guidance.
9. Are platelet-rich plasma (PRP) injections indicated?	PRP injections are safe and well-tolerated, but there is not sufficient evidence yet to compare them with corticosteroid injections.
10. Are local anaesthetic and hyaluronic acid injections indicated?	Anaesthetic injections can immediately relieve pain during physiotherapy, the number of injections should be low due to concerns of chondral toxicity. Hyaluronic acid as a sole infiltrative procedure is not superior to other treatments.
11. What role do nerve blocks play?	Suprascapular nerve block has beneficial effects, superior to corticosteroid injection or physiotherapy alone. Specialised medical personnel is required to perform it, therefore it should be considered as a second-line treatment.
12. What role do alternative medicine approaches play?	Alternative medicine approaches seem to be safe and effective, but no high-level studies comparing with corticosteroid-based treatments. Not recommended.
13. Is hydrodilatation indicated?	No high-level studies isolated the effect of hydrodilatation from other associated procedures. Not recommended.
14. Is manipulation under anaesthesia or nerve block indicated?	Manipulation under anaesthesia or nerve block provide no benefits compared to physiotherapy or corticosteroid injection. Not recommended.
15. In which cases is surgical treatment indicated?	Surgery is not indicated as a first-line treatment. An evidence-based conservative treatment period of 3–6 months Three is recommended before considering surgical intervention in cases of treatment failure.
16. Is there a superior surgical technique?	Anterior–inferior capsular release. There is no consensus on additional procedures.

Nonoperative treatments

A significant body of high-quality evidence has shaped consensus-based recommendations concerning nerve blocks, hydrodilatation and manipulation under anaesthesia. While nerve blocks demonstrate beneficial effects and could be considered as a secondary treatment in the hands of specialised medical personnel, the consensus leans against the routine use of

hydrodilatation and manipulation under anaesthesia for the treatment of primary SS.

Surgery

Studies on surgical treatment for primary SS are limited; nevertheless, high-level investigations have been conducted to guide the panel's decision to

TABLE 2 Summary of the best scientific evidence available for each statement as well as of the scientific grade assigned to each question and of the median score obtained during the rating phase.

Question	Topic	Statement	Best evidence	Scientific grade	Rating score (median)
1	Diagnostic tests		Case series	C	9.0
2	Additional tests	S1	Meta-analysis	A	9.0
		S2	Meta-analysis	A	
		S3	Expert opinion	D	
3	Physiotherapy	S1	Meta-analysis	A	9.0
		S2	Multiple randomised controlled trials	A	
		S3	Multiple randomised controlled trials	A	
		S4	Multiple randomised controlled trials	A	
4	Electrophysical agents	S1	Multiple randomised controlled trials	A	8.0
		S2	Multiple randomised controlled trials	A	
		S3	Multiple randomised controlled trials/low-level comparative studies	A/C	
5	Oral corticosteroids		Multiple randomised controlled trials	A	8.0
6	Other oral medication	S1	Multiple randomised controlled trials	A	8.0
		S2	Single randomised controlled trial	A	
		S3	Single randomised controlled trial/comparative studies, not level I	A/B	
7	Corticosteroid injections		Meta-analysis	A	9.0
8	Injection technique		Meta-analysis	A	9.0
9	Platelet-rich plasma	S1	Multiple randomised controlled trials	A	8.0
		S2	Prospective cohort studies	B	
10	Local anaesthetics and hyaluronic acid	S1	Single randomised controlled trial	A	8.0
		S2	Multiple randomised controlled trials/case series	A/D	
11	Nerve blocks	S1	Multiple randomised controlled trials	A	8.0
		S2	Single randomised controlled trial	A	
12	Alternative therapies		Multiple randomised controlled trials	A	8.0
13	Hydrodilatation		Multiple randomised controlled trials	A	8.0
14	Manipulation under anaesthesia		Multiple randomised controlled trials	A	8.0
15	Surgery—indications		Single randomised controlled trial	A	9.0
			Comparative studies, not level I	B	
16	Surgery—techniques		Comparative studies, not level I	B	9.0

highlight the timing for arthroscopic anterior–inferior capsular release (secondary rather than primary treatment, after a conservative treatment period of three to 6 months). Due to the limited literature, no consensus could be reached regarding additional associated procedures.

DISCUSSION

This paper presents the results of the first attempt to reach a national-wide consensus based on evidence using a modified Delphi methodology and discusses the most relevant aspects of the obtained answers. The main

finding of this study is that a high level of scientific evidence is available to guide treatment of primary SS, enabling to reach a consensus among healthcare professionals at a national level (Table 2). Statements on diagnostics, physiotherapy and electrophysical agents, oral medical therapy, injective treatments, other nonoperative treatments and surgery were generated and commented according to recent literature evidence.

Diagnostic assessment

The diagnosis of primary SS is based on medical history, clinical examination and the exclusion of other conditions that may mimic its clinical presentation [2]. Specific magnetic resonance imaging findings strongly correlate with the clinical stage of primary SS making it valuable diagnostic tool in cases of uncertainty [10, 11]. Ultrasound allows for the identification of signs associated with primary SS (thickening of the coracohumeral ligament, inferior capsule and bicipital pulley; reduced mobility of the supraspinatus tendon; infiltration of the rotator interval with fibrovascular tissue as well as hypoechoic echotexture and increased vascularity within the rotator interval on doppler scan) and can be a very useful and cost effective tool for diagnosis [12]. Routinary use of ultrasound in the diagnostic approach to primary SS has been therefore proposed: its implementation is challenging in the national context the formal consensus was performed, leading to the absence of an indication in its favour, but is an interesting perspective for national settings with a larger diffusion of medical professionals with expertise in shoulder ultrasound [12].

Physiotherapy and electrophysical agents

A broad body of evidence is available to suggest a combination of comprehensive strategies involving mobilisations, stretching and therapeutic exercise, which are indeed rarely provided in isolation in clinical practice, which was reflected in the results of this consensus education of caregivers and patients to a psychosocial approach in physiotherapy appears of utmost importance [13–16].

Regarding electrophysical agents, shockwave therapy is the only one supported by high-level literature. Despite the unpleasant but tolerable effects during administration, shockwave treatment results in pain reduction and functional improvement even if it is worth noting that the minimal clinical important difference was rarely exceeded and the certainty of evidence was very low [17]. Such strategies could be suggested as an alternative therapy to pharmacological treatment in patients (e.g., diabetic patients) for whom corticosteroid treatments are contraindicated [18–20].

Medical therapy

The oral medical treatment for SS involves two key pharmacological principles: nonsteroidal anti-inflammatory drugs (NSAIDs) and corticosteroids. High-level clinical studies providing evidence for the treatment of primary SS with NSAIDs are rare, but they demonstrate the effectiveness of both selective and nonselective cyclooxygenase 2 inhibitors [21–23]. The use of opioid medications, although common in clinical practice, has not been extensively studied in clinical trials and, due to the side effects associated with this class of drugs, it is not recommended as the first choice of treatment [24]. The oral administration of corticosteroids has shown superior efficacy compared to a placebo with a rapid resolution of symptoms that persists long after drug discontinuation [25].

The intra-articular injection of corticosteroids is also effective in managing short- to medium-term pain for the treatment of idiopathic SS during the inflammatory phase and is superior to other conservative treatments, including oral corticosteroid administration [26, 27]. Based on available literature suggestions, performing one to three infiltrations starting from the time of diagnosis, on a weekly or biweekly basis appears reasonable [23]. Infiltration at the glenohumeral joint, if possible under ultrasound guidance, is described as the most effective technique [28–32]. While there is certain evidence endorsing PRP's application for addressing SS, currently there no sufficient scientific basis to assert its superiority over corticosteroid injections [33–36].

Infiltrative treatment with local anaesthetics is a quick and simple procedure that can provide immediate pain relief during physiotherapy sessions. However, considering the purely symptomatic nature of the treatment and the potential toxicity of local anaesthetics to the articular cartilage, the number of injections should be kept as low as possible [37].

The lack of effectiveness of hyaluronic acid treatment has been discussed in a systematic review by Lee et al., whereas a more recent four-arm randomised study suggested a possible role of a combination of hyaluronic acid with cortisone injections [38, 39]

Other nonoperative treatments

The suprascapular nerve block under ultrasound guidance has beneficial effects in terms of short to medium-term pain relief and thus appears to be suitable as a 'rescue' therapy in case of failure of conservative treatment and/or rejection of infiltrative therapy [40, 41]. Further proposed nerve blocks for the treatment of primary SS (brachial plexus block

and selective block of the C5 and C6 roots) showed good results in low-level studies, thus not allowing for recommendations with a high level of evidence.

Although widespread in the clinical practice, hydrodilatation does not offer significant clinical benefits over other approaches [42, 43].

Manipulation under anaesthesia or nerve block is a low-cost procedure that significantly improves the ROM, pain and clinical scores from short to long term. However, no recommendation in favour of this procedure was produced, since controlled RCTs have not shown the superiority of manipulation under anaesthesia or nerve block over rehabilitative treatment and intra-articular corticosteroid injection [16, 44] and clinical studies detected intra-articular injuries after this procedure [45, 46].

Surgery

Surgical treatment is not recommended as the first-choice treatment, and the majority of published studies indicate a period of 3–6 months for initial evidence-based conservative treatment before considering surgical intervention. When indicated, surgical treatment shows excellent results in terms of ROM and functional recovery and pain relief [47–52]. The anterior–inferior capsular release yields satisfactory results in terms of symptom resolution, pain reduction, functional recovery and ROM improvement. Additional manoeuvres may be performed in specific cases at the discretion of the surgeon, but none of them seem to be necessary for achieving better outcomes compared to the classical technique [53–55].

Limitations

This scientific work has some limitations; first, the definition of some clinical situations can vary between the literature and in the daily clinical practice, leading to limitations in the possibility of comparing different studies [56]. To avoid misunderstanding within the working group, the ISAKOS definition for SS was used throughout the consensus [1]. Furthermore, all answers were based on available literature evidence combined with the expert opinion of the professionals specialised in the diagnosis and treatment of shoulder pathologies, including surgeons, radiologists, pain therapists and physical therapists; nevertheless, the published studies guiding the clinical choices of these professionals and supporting this consensus have their own biases and weaknesses, which may be reflected in the final consensus.

Finally, this document presents the results of a formal consensus and is not to be intended as a systematic review or a meta-analysis, which greatly differ in the methodology and in the level of evidence they can generate. Obviously, future studies will enlarge the body of evidence available to derive the proposed recommendations, leading to updates and modifications.

Nevertheless, the here presented findings can assist every professional dealing with the diagnosis and treatment of shoulder pathologies in his/her decision-making when confronted with patients with SS. Especially, the condensed summaries found in Table 2 and Supporting Information S1: Appendix A can function as a convenient and user-friendly reference for daily use, supporting orthopaedic surgeons, physiotherapists and general practitioners in their daily practice. The assessments made in this consensus document were formulated by a national society following a comprehensive analysis of literature, and reflecting the specific context and requirements of the country in which the consensus originated. As this country stands as a wealthy European nation where patients can access various diagnostic and treatment options with no or minimal restrictions, the assertions presented can be readily extended to countries sharing comparable demographic and healthcare conditions. Consequently, this paper has the potential to serve as a base for guidelines and best practices in the conservative and surgical management of primary SS at an international level.

CONCLUSIONS

This national consensus sets basis for evidence-based clinical practice in the management of SS. The main finding of this study is that a high level of scientific evidence is available to guide treatment of primary SS and generate statements on diagnostics, physiotherapy and electrophysical agents, oral medical therapy, injective treatments, other nonoperative treatments and surgery. A consensus has been reached among specialised healthcare professionals at the national level. This consensus can serve as a valuable resource for professionals involved in the diagnosis and treatment of SS, and as a model for similar initiatives in other European countries and potentially on a global scale. Its results are transferable beyond the national borders, offering a base for widely adaptable guidelines and optimal strategies for the conservative and surgical treatment of primary SS.

AUTHOR CONTRIBUTIONS

All authors contributed to the study conception and design. The study was conceived by Davide Cucchi and

Laura de Girolamo (consensus chair). Material preparation and literature data collection were performed by Chiara Formigoni and Davide Cucchi; data analysis were performed by Giovanni Di Giacomo, Riccardo Compagnoni, Roberto Castricini, Arianna Carnevale, Francesco Rosa, Antongiulio Marmotti, Giuseppe M. Peretti, Massimo Berruto, Giuseppe Milano, Pietro Randelli, Giovanni Bonaspetti. The first draft of the manuscript was written by Mattia Radici, Barbara Melis, Fabrizio Brindisino, Silvana De Giorgi, Andrea De Vita, Andrea Lisai, Laura Mangiavini, Vincenzo Candela, Alessandro Carrozzo, Antonello Pannone, Alessandra Menon, Luca Dei Giudici, Raymond Klumpp, Roberto Padua and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

ETHICS STATEMENT

The paper reflects the author's own research and analysis in a truthful and complete manner. The paper properly credits the meaningful contributions of co-authors and co-researchers. The results are appropriately placed in the context of prior and existing research. All sources used are properly disclosed. All authors have been personally and actively involved in substantial work leading to the paper, and will take public responsibility for its content.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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