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BJO



## ■ SHOULDER & ELBOW

# Expert clinical consensus in the delivery of hydrodilatation for the management of patients with a primary frozen shoulder

A MODIFIED DELPHI STUDY

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### Aims

To achieve expert clinical consensus in the delivery of hydrodilatation for the treatment of primary frozen shoulder to inform clinical practice and the design of an intervention for evaluation.

### Methods

We conducted a two-stage, electronic questionnaire-based, modified Delphi survey of shoulder experts in the UK NHS. Round one required positive, negative, or neutral ratings about hydrodilatation. In round two, each participant was reminded of their round one responses and the modal (or 'group') response from all participants. This allowed participants to modify their responses in round two. We proposed respectively mandating or encouraging elements of hydrodilatation with 100% and 90% positive consensus, and respectively disallowing or discouraging with 90% and 80% negative consensus. Other elements would be optional.

### Results

Between 4 August 2020 and 4 August 2021, shoulder experts from 47 hospitals in the UK completed the study. There were 106 participants (consultant upper limb orthopaedic surgeons,  $n = 50$ ; consultant radiologists,  $n = 52$ ; consultant physiotherapist,  $n = 1$ ; extended scope physiotherapists,  $n = 3$ ) who completed round one, of whom 97 (92%) completed round two. No elements of hydrodilatation were "mandated" (100% positive rating). Elements that were "encouraged" ( $\geq 80\%$  positive rating) were the use of image guidance, local anaesthetic, normal saline, and steroids to deliver the injection. Injecting according to patient tolerance, physiotherapy, and home exercises were also "encouraged". No elements were "discouraged" ( $\geq 80\%$  negative rating) although using hypertonic saline was rated as being "disallowed" ( $\geq 90\%$  negative rating).

### Conclusion

In the absence of rigorous evidence, our Delphi study allowed us to achieve expert consensus about positive, negative, and neutral ratings of hydrodilatation in the management of frozen shoulder in a hospital setting. This should inform clinical practice and the design of an intervention for evaluation.

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**Keywords:** Frozen shoulder, Hydrodilatation, Expert consensus, Modified Delphi Study

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### Introduction

Frozen shoulder, also known as adhesive capsulitis, occurs when the capsule of the

shoulder joint becomes inflamed, then scarred and contracted.<sup>1</sup> The exact cause remains unknown, which means it is often

labelled as primary or idiopathic frozen shoulder. It most commonly affects people in the sixth decade of life, and around 8% of men and 10% of women of working age.<sup>2</sup> The pain and stiffness from a frozen shoulder means people can struggle with basic daily activities and have sleep disturbance.<sup>3</sup>

Multiple treatment choices are available and often offered from least to most invasive. This includes standard supportive care, physiotherapy that may include corticosteroid injection, hydrodilatation to distend the shoulder capsule, manipulation of the shoulder joint under anaesthesia, and arthroscopic capsular release of the contracted tissue.<sup>4</sup> Systematic reviews on treatments for frozen shoulder do not provide conclusive evidence of the effectiveness of these interventions, although overall physiotherapy and intra-articular steroid injections can have some benefit.<sup>5</sup> The UK Frozen Shoulder (FROST) trial compared the clinical effectiveness and cost-effectiveness of physiotherapy and intra-articular steroid injection, manipulation under anaesthesia, and arthroscopic capsular release. All three treatments improved patient-reported shoulder pain and function, but none were clinically superior when compared to each other. Manipulation under anaesthesia was the most cost-effective option to the UK NHS.<sup>6</sup> When designing UK FROST, only 6% of UK practitioners used hydrodilatation from a survey of practice.<sup>7</sup> Therefore, it was not identified as a priority intervention for evaluation.

More recently, the popularity of hydrodilatation appears to have increased. Systematic reviews have found that it may be more effective than other treatment options for short-term pain relief.<sup>8,9</sup> An evidence gap, however, remains for high-quality evidence demonstrating its effectiveness.<sup>10</sup> There is also uncertainty about how hydrodilatation should be performed, such as whether to use air instead of saline, include a steroid, or continue to capsular rupture.<sup>11,12</sup> In the absence of rigorous evidence and likely variation in clinical practice of a rapidly emerging treatment, we undertook a modified Delphi survey of shoulder experts. The aim of the study was to achieve expert clinical consensus in the delivery of hydrodilatation to inform clinical practice and the design of an intervention for evaluation in an adequately powered randomized controlled trial (RCT).

## Methods

**Study design.** This was a two-stage, electronic questionnaire-based, modified Delphi survey to reach a degree of consensus on how to define hydrodilatation in terms of, for example, approach to hydrodilatation, use of an anaesthetic, volume, liquid for injection, use of pain relief, use of physiotherapy and whether to repeat the procedure. This methodology is used to answer research questions that are not supported by a strong

evidence base or where there is contradictory evidence.<sup>13</sup> We also applied the CHERRIES checklist for reporting on the design and the results of an internet-based electronic survey.<sup>14</sup>

The University of York Health Sciences Research Governance Committee approved the study on 5 July 2019 (HSRGC/2019/346 /F). We acquired regulatory approval to undertake the study at participating NHS organisations in England and Wales on 18 December 2019 and in Scotland on 19 October 2020.

**Developing and distributing the questionnaire.** The Delphi survey was undertaken as an electronic questionnaire, over two rounds, that was prepared in Qualtrics (USA) and provided as a link to participants in an email. Participants were asked to complete both questionnaires to provide information about their practice in a non-pandemic setting, and could review and change their answers before submission.

The questionnaire to round one began with questions about the participants (e.g. profession, years of experience) and general questions about the use of hydrodilatation (e.g. contraindications, patient positioning). The first round then included statements about whether elements of hydrodilatation 'should be used', 'should be optional', or 'should not be used' to allow positive, neutral, or negative ratings. Participants could record free-text responses to support their statements. At the end of the questionnaire, participants could list other important elements of hydrodilatation for inclusion in the next round. Questions about change to practice in light of the COVID-19 pandemic were included. In round two, each participant was reminded of their round one responses and the modal (or 'group') response from all participants. This meant individual participants' responses to round two were informed by those of the group and could be modified at this stage. Participants were sent email reminders to complete both rounds of the questionnaire. In each round, participants were informed of a prize draw for a £100 gift voucher on completion of the two questionnaires.

To identify the elements of hydrodilatation on which to reach consensus, two of the authors (HT, SB) reviewed all of the RCTs that were screened for inclusion in a recently published systematic review about treatments for the management of a frozen shoulder.<sup>10</sup> HT and SB also reviewed the responses to a brief survey about hydrodilatation that had been conducted with Principal Investigators and physiotherapists of two orthopaedic surgical trials of the shoulder: UK FROST and PROFHER 2. The Delphi multidisciplinary study team included an upper limb physiotherapist practitioner, consultant radiologist, consultant orthopaedic surgeons and methodologists who reviewed the questionnaire for content. The final draft of the questionnaire was piloted on five of each of the three specialist groups (physiotherapists, consultant

**Table 1.** Consensus thresholds.

Definition of consensus	Consensus threshold	Implementation of elements of hydrodilatation
'Should always be used'	100%	Mandatory
'Should always be used'	80%	Encouraged
'Should not be used'	80%	Discouraged
'Should not be used'	90%	Disallowed

radiologists, and consultant orthopaedic surgeons). One of the authors (HT) sat with the clinical experts as they completed the questionnaire, which helped to amend some of the questions and to estimate the length of time to complete the questionnaire.

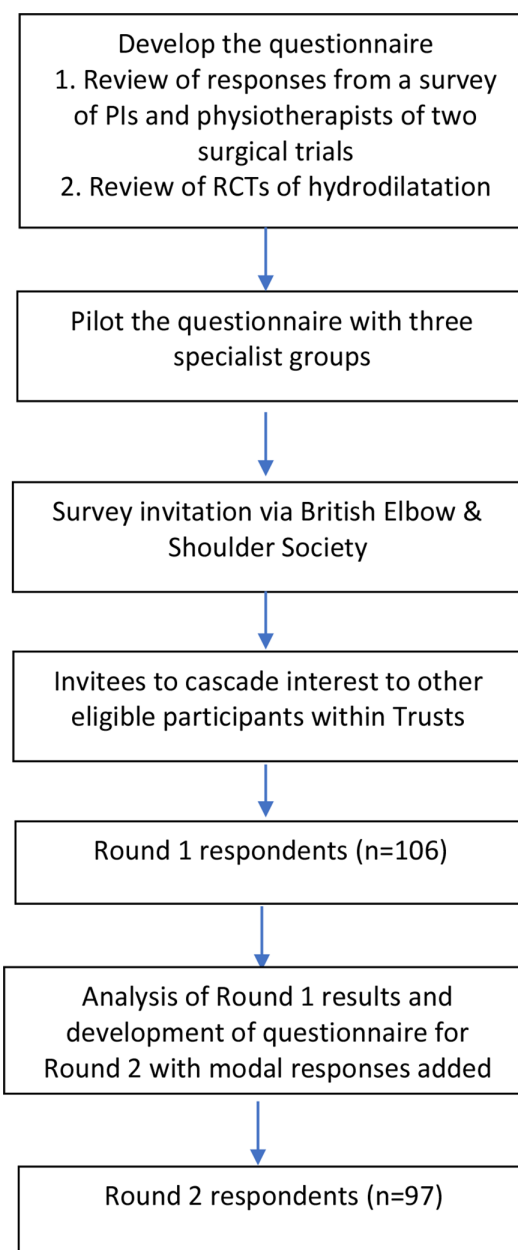
**Participants.** The target population were NHS staff shoulder experts (i.e. consultant orthopaedic upper limb surgeons, consultant radiologists, consultant physiotherapists, and extended scope physiotherapists) in the UK who had experience of performing hydrodilatation in patients with a frozen shoulder in a hospital setting. Participants were identified following an email invitation from the British Elbow and Shoulder Society (BESS), and were encouraged to cascade the invitation to other eligible staff within their Trust. When eligible staff were identified from a Trust, we sought permission from the local Research and Development departments for them to participate in the study. Survey respondents confirmed that completing their questionnaire was giving consent to take part, and were informed of how identifiable information would be stored and the duration the anonymized dataset would be kept.

There was no formal sample size calculation. We judged that enrolling a convenience sample of shoulder experts from up to 50 hospitals (i.e. estimated around 100 participants) in the UK would be sufficiently large and representative to reach a consensus.

**Survey analysis.** Table 1 shows the implementation of the Delphi consensus thresholds in defining the hydrodilatation procedure. Descriptive statistics were used to summarize the positive, negative and neutral rating scores. We decided a priori that to 'mandate' or 'encourage' elements of hydrodilatation required 100% or 90% positive consensus, respectively. To 'disallow' or 'discourage' elements of hydrodilatation required 90% and 80% negative consensus, respectively. The neutral rated elements would be optional. We set a threshold of 100% positive consensus to mandate that an element of hydrodilatation be used, to ensure that this should be achievable across centres with different facilities, equipment, or skills. The study results are tabulated and described narratively.

## Results

Figure 1 presents the flowchart of the study. Round one began on 4 August 2020 and ended on 2 January 2021. Round two began on 23 May 2021 and ended on 4

**Fig. 1**

Study flowchart. PIs, principal investigators; RCT, randomized controlled trial.

August 2021. Therefore, between 4 August 2020 and 4 August 2021, shoulder experts from 47 hospitals in the UK (44 in England, two in Wales, and one in Scotland) completed the study.

**Background information.** In round one, we collected background information about the participants and delivery of hydrodilatation. There were 106 participants (consultant upper limb orthopaedic surgeons,  $n = 50$ ; consultant radiologists,  $n = 52$ ; consultant physiotherapist,  $n = 1$ ; extended scope physiotherapists,  $n = 3$ ) who completed round one, of whom 97 (92%) completed

**Table II.** Speciality of participants in the Delphi study.

Speciality	n (%)	Mean yrs of experience in speciality (SD)	Mean yrs of experience in performing hydrodilatation (SD)
Consultant upper limb orthopaedic surgeon	50 (47.17)	11.79 (6.80)	8.71 (5.92)
Consultant radiologist	52 (49.06)	11.33 (6.72)	7.85 (4.83)
Consultant physiotherapist	1 (0.94)	30	8
Extended scope physiotherapist	3 (2.83)	13.33 (5.03)	2.33 (2.52)

SD, standard deviation.

**Table III.** Contraindications to hydrodilatation.

Contraindication	Number (%)
Infected skin lesion	93 (85.57)
Bad cold or flu	68 (64.78)
Use of anticoagulants	49 (46.67)
Allergy to local anaesthetic, steroid, or X-ray contrast (iodine)	92 (87.62)
Uncontrolled diabetes	64 (60.95)
Pregnancy or breast-feeding	67 (63.81)
Patient with COVID-19	90 (85.71)
Other contraindications*	25 (23.81)

\*Most common other contradiction suggested was rotator cuff tear (n = 9).

round two. Table II presents the years of experience of participants in a speciality and performing hydrodilatation. The number of patients with a primary frozen shoulder (including those with diabetes) listed for hydrodilatation in a department in a typical month were: one to two patients (n = 20, 19%), three to five patients (n = 36, 34%), or six or more patients (n = 50, 47%).

Table III presents contraindications to hydrodilatation, with the highest frequency being for allergies (88%), COVID-19 infection (86%), or infected skin lesion (86%). Table IV presents the frequency of the position of a patient used to deliver hydrodilatation, with the most common being supine (n = 57, 56%). Additionally, 101 of 106 (95%) participants agreed that hydrodilatation should be performed on our definition of frozen shoulder, i.e. patients who have restriction of passive external rotation of less than 50% when compared to the unaffected shoulder.<sup>15</sup> There were 101 of 102 (99%) participants who agreed that hydrodilatation could be used for patients with controlled diabetes.

There were 64 participants (63%) who responded that their likelihood of delivering hydrodilatation in light of the COVID-19 pandemic was the “same as before”, followed by 11 (11%) and 27 participants (26%) who respectively were “more likely” or “less likely” to perform hydrodilatation in light of COVID-19. Out of 102 participants, 93 (91%) would still deliver a steroid injection with hydrodilatation in light of COVID-19. When asked about offering hydrodilatation in the context of the pandemic, participants highlighted that risk assessments were required, that discussion with

**Table IV.** Position of patient for hydrodilatation.

Position	Number (%)
Supine	57 (55.88)
Prone	9 (8.82)
Side lying	31 (30.39)
Sitting	39 (38.24)
Other	8 (7.84)

individual patients was important, and patient consent needed. There were conflicting experiences of the uptake of the procedure by patients:

*“We offer enhanced counselling regarding the risk of immunosuppressive and mitigation of this. We therefore are offering the treatment as before but some patients are declining the treatment on the basis of perceived risk.”*

*“If conservative management has failed, symptoms are debilitating and the patient is prepared to accept the small risk of immune suppression then I would proceed. I am yet to encounter a patient who is not willing to take on this additional risk.”*

Reasons to be less likely to offer hydrodilatation in light of the pandemic were mainly attributed to uncertainty at the time about the effect of steroids on immunosuppression. Some participants reported that Trust guidelines had been amended to stop or restrict the use of steroids. Of those participants who would be more likely to offer hydrodilatation in light of the pandemic, the main reasons centred around surgery for frozen shoulder not being performed at all, or being avoided due to “less risk of hospital acquired infection” during the pandemic. Hydrodilatation therefore “enabled quicker access to treatment and pain relief” for patients.

**Initial ratings from round one.** Table V presents the frequency with which elements of hydrodilatation were rated as positive (“should be used”), neutral (“should be optional”), or negative (“should not be used”). The most frequent approach to perform hydrodilatation was anteriorly (n = 46, (46%). When using an anaesthetic, participants were more likely to suggest a local anaesthetic should be used (n = 62, 61%) and a regional or interscalene block should not be used (n = 58, 57%).

Most participants would use image guidance, and an almost equal number would use an image intensifier or ultrasound, to deliver the injection (n = 89,

**Table V.** Responses from round one on use of hydrodilatation.

Element of hydrodilatation	Should be used, n, (%)	Should be optional, n (%)	Should not be used, n (%)	Total number of respondents
<b>Approach</b>				
Anterior	46 (46)	48 (48)	6 (6)	100
Posterior	24 (24)	71 (71)	5 (5)	100
Posterolateral	13 (13)	52 (52)	35 (35)	100
Other	4 (4.76)	23 (27.38)	57 (67.86)	84
<b>Use of anaesthetic</b>				
Skin injected with local anaesthetic	62 (61.39)	37 (36.63)	2 (1.98)	101
Use of regional block or interscalene block	1 (0.99)	42 (41.58)	58 (57.43)	101
<b>Image guidance</b>				
Use of image guidance to deliver the injection*	89 (88.12)	12 (11.88)	0 (0.00)	101
Image intensifier is used to confirm joint position with contrast	62 (76.54)	18 (22.22)	1 (1.23)	81
<b>Delivery into joint</b>				
Local anaesthetic into the joint once the joint space is confirmed†	85 (84.16)	13 (12.87)	3 (2.97)	101
A set volume of sterile saline used‡	54 (53.47)	41 (40.59)	6 (5.94)	101
Normal saline	82 (87.23)	12 (12.77)	0 (0.00)	94
Hypertonic saline§	0 (0.00)	22 (23.40)	72 (76.60)	94
Include steroid¶	81 (81.00)	19 (19)	0 (0.00)	100
<b>Volume to inject</b>				
According to patient tolerance and feedback	83 (83.00)	16 (16.00)	1 (1.00)	100
Until there is capsular rupture**	31 (31.00)	57 (57.00)	12 (12.00)	100
<b>Pain relief</b>				
Entonox to treat a patient experience of pain during the procedure	3 (3.03)	68 (68.69)	28 (28.28)	99
<b>Mobilization of the shoulder</b>				
Gentle manipulation such as a small amplitude, low-velocity, end of range, passive movement after the injection††	22 (22.22)	59 (59.60)	18 (18.18)	99
A programme of physiotherapy. This could include passive mobilizations, active-assisted exercise, and active exercises‡‡	89 (89.9)	10 (10.10)	0 (0.00)	99
Home exercise. This could include passive mobilizations, active-assisted exercise, and active exercises‡‡	92 (92.93)	7 (7.07)	0 (0.00)	99
<b>Repeat hydrodilatation</b>				
Hydrodilatation to be repeated in a hospital setting if the patient's frozen shoulder has not sufficiently improved§§	29 (29.29)	59 (59.60)	11 (11.11)	99

\*Image intensifier (n = 81/101, 80.20%); Ultrasound (n = 80/101, 79.21%).

†Lidocaine (n = 28/98, 28.57%); Bupivacaine (n = 32/98, 32.65%); Levobupivacaine (n = 28/98, 28.57%); Other (n = 10/98, 10.20%).

‡20 ml (n = 25/94, 26.6%); 30 ml (n = 15/94, 15.96%); 40 ml (n = 4/94, 4.26%); 50 ml (n = 9/94, 9.57%); Other (n = 41/94, 43.62%).

§3% concentration (n = 13/22, 59.09%); 5% concentration (n = 2/22, 9.09%); Other (n = 7/22, 31.82%).

¶Depomedrone (n = 33/100, 33.0%); Kenalog (n = 63/100, 63.00%); Other (n = 4/100, 4.00%).

\*\*Sudden change in the force required to instil the fluid (n = 77/86, 89.53%); contrast leaks out of the joint (n = 64/86, 74.42%); patient feeling a pop or release of pressure (n = 70/87, 80.46%).

††There were varied and inconsistent responses as to when this should start after the injection, such as 15 minutes later, next few hours, wait for local anaesthetic to be effective, as tolerated by the patient, and to be cautious about the risk of soft-tissue injury or fracture.

‡‡Optimum time to start physiotherapy following hydrodilatation: 2 to 3 working days (n = 70/99, 70.71%); 4 to 7 days (n = 23/99, 23.23%); and 1 to 2 weeks (n = 6/99, 6.06%).

§§When should home exercise start following hydrodilatation: within 2 hours (n = 29/99, 29.29%); following day (n = 44/99, 44.44%); within 1 week (n = 26/99, 26.26%).

§§Timeframe within which to repeat hydrodilatation: 1 month (n = 7/88, 7.95%); 1 to 2 months (n = 21/88, 23.86%); 3 to 4 months (n = 48/88, 54.55%); 5 to 6 months (n = 12/88, 13.64%).

88%) using contrast (n = 62, 77%). The majority would deliver the local anaesthetic into the joint (n = 85, 84%), using normal saline (n = 82, 87%) and include a steroid injection (n = 81, 81%). Participants were largely equivocal about the set volume of sterile saline to use. None suggested the use of hypertonic saline. When delivering the injection, it was suggested this should be done according to patient tolerance and

feedback (n = 83, 83%) and be optional as to whether it should be until there is capsular rupture (n = 57, 57%). If capsular rupture is to be performed, it was suggested to be done until there is a sudden change in the force required to instil the fluid (n = 77, 90%). Whether to provide Entonox during the procedure for pain relief would be optional (n = 68, n = 69%).



**Table VI.** Consensus about hydrodilatation after round two.

Element of hydrodilatation	Should be used, n, (%)	Should be optional, n (%)	Should not be used, n (%)	Total number of respondents	Consensus
<b>Approach</b>					
Anterior	30 (30.93)	65 (67.01)	2 (2.06)	97	Optional
Posterior	5 (5.15)	87 (89.69)	5 (5.15)	97	Optional
Posterolateral	2 (2.06)	66 (68.04)	29 (29.90)	97	Optional
<b>Use of anaesthetic</b>					
Skin injected with local anaesthetic	62 (63.92)	33 (34.02)	2 (2.06)	97	Optional
Use of regional block or interscalene block	0 (0.00)	26 (26.80)	71 (73.20)	97	Optional
<b>Image guidance</b>					
Use of image guidance to deliver the injection	90 (92.78)	7 (7.22)	0 (0.00)	97	Encouraged
Image intensifier is used to confirm joint position with contrast	55 (56.70)	40 (41.24)	2 (2.06)	97	Optional
<b>Delivery into joint</b>					
Local anaesthetic into the joint once the joint space is confirmed	91 (93.81)	3 (3.09)	3 (3.09)	97	Encouraged
A set volume of sterile saline used	33 (34.02)	60 (61.86)	4 (4.12)	97	Optional
Normal saline	81 (87.10)	12 (12.90)	0 (0.00)	93	Encouraged
Hypertonic saline	0 (0.00)	8 (8.60)	85 (91.40)	93	Disallowed
Include steroid	90 (92.78)	6 (6.19)	1 (1.03)	97	Encouraged
<b>Volume to inject</b>					
According to patient tolerance and feedback	88 (90.72)	8 (8.25)	1 (1.03)	97	Encouraged
Until there is capsular rupture	17 (17.53)	72 (74.23)	8 (8.25)	97	Optional
<b>Pain relief</b>					
Entonox to treat a patient experience of pain during the procedure	1 (1.03)	70 (72.16)	26 (26.80)	97	Optional
<b>Mobilization of the shoulder</b>					
Gentle mobilization such as a small amplitude, low-velocity, end of range, passive movement after the injection	15 (15.46)	67 (69.07)	15 (15.46)	97	Optional
A programme of physiotherapy. This could include passive mobilizations, active assisted exercise, and active exercises	92 (94.85)	5 (5.15)	0 (0.00)	97	Encouraged
Home exercise. This could include passive mobilization, active assisted exercise, and active exercise	96 (98.97)	1 (1.03)	0 (0.00)	97	Encouraged
<b>Repeat hydrodilatation</b>					
Hydrodilatation to be repeated in a hospital setting if the patient's frozen shoulder has not sufficiently improved	12 (12.37)	81 (83.51)	4 (4.12)	97	Optional

For mobilization of the shoulder after hydrodilatation, the majority of participants responded that a programme of physiotherapy should be used ( $n = 89$ , 90%), and home exercises ( $n = 92$ , 93%). The optimum time to start physiotherapy was suggested to be two to three working days later ( $n = 70$ , 71%) and home exercises on the first day, following hydrodilatation ( $n = 44$ , 44%). The need for gentle manipulation was considered optional ( $n = 59$ , 60%). Participants' ( $n = 59$ , 60%) ratings also found it to be optional as to whether to repeat hydrodilatation in a hospital setting if the patient's frozen shoulder had not sufficiently improved.

**Expert clinical consensus from round two.** In round two, each participant was reminded of their round one responses and the modal (or 'group') response from all participants. This allowed participants to modify their responses.

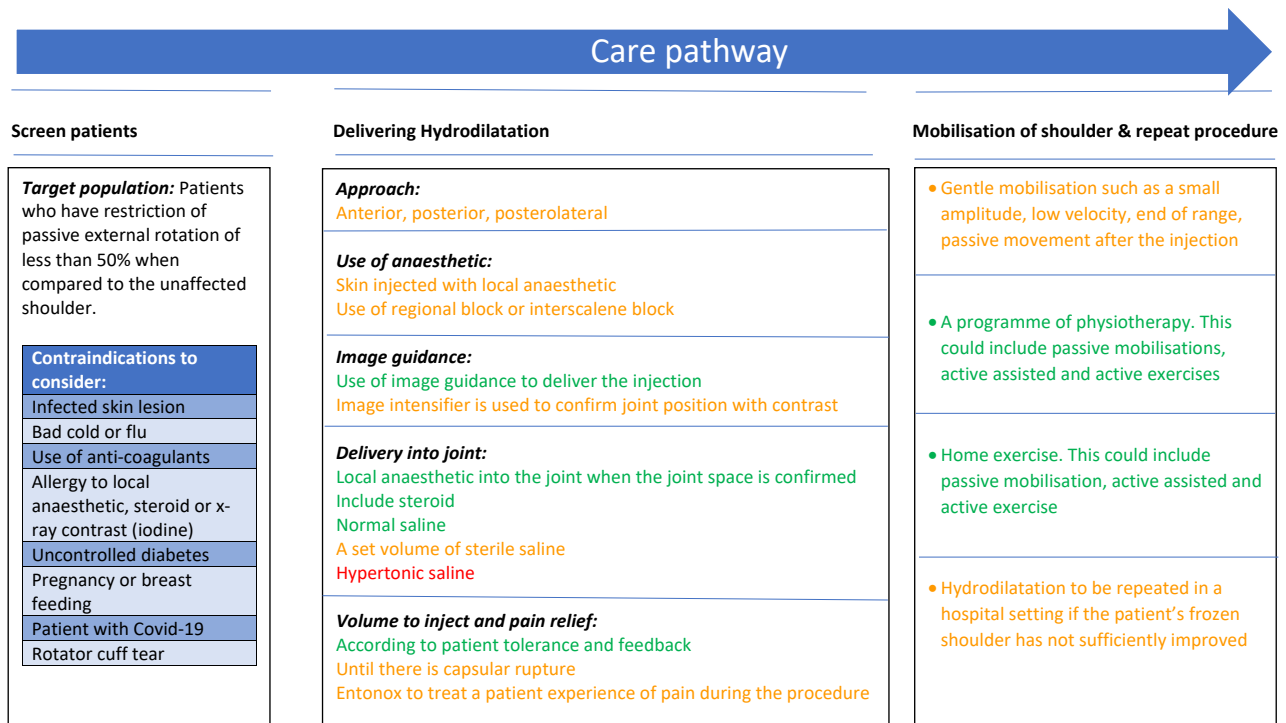
Table VI shows that no elements of hydrodilatation were "mandated" (100% positive rating). Elements that were "encouraged" ( $\geq 80\%$  positive rating) were the use of image guidance, local anaesthetic, normal saline, and steroids to deliver the injection. Injecting according

to patient tolerance and the use of physiotherapy and home exercises were also "encouraged". No elements were "discouraged" ( $\geq 80\%$  negative rating), although the use of hypertonic saline was rated as being "disallowed" ( $\geq 90\%$  negative rating). Figure 2 graphically illustrates the expert consensus care pathway.

Table VII presents the findings from round two about additional elements of hydrodilatation that were suggested for inclusion by participants in round one. The majority responded that they would not perform a bilateral hydrodilatation ( $n = 59$ , 61%). Very few would use room air ( $n = 10$ , 12%) or water ( $n = 21$ , 25%) as an alternative to normal or hypertonic saline. Most participants would give any of local anaesthetic, steroid, and saline separately ( $n = 73$ , 75%), and were equivocal as to whether a patient should stop using anticoagulants before hydrodilatation.

## Discussion

**Summary of findings.** Nearly all participants agreed with our definition of a frozen shoulder.<sup>15</sup> Only one participant disagreed that hydrodilatation could be used for



Key: Green = Encouraged, Amber = Optional, Red = disallowed

Fig. 2

Expert consensus hydrodilatation care pathway for patients with a frozen shoulder.

**Table VII.** Additional elements of hydrodilatation identified in round one that were included in round two.

Element of hydrodilatation	Response
<b>Perform bilateral hydrodilatation, n (%)</b>	
Yes	38/97 (39.18)
No	59/97 (60.82)
<b>Alternative to normal saline or hypertonic saline, n (%)</b>	
Room air	10/83 (12.05)
Water	21/83 (25.30)
Other	52/83 (62.65)
<b>(a) give local anaesthetic, steroid, and saline in one syringe, n (%)</b>	
Yes	32/97 (32.99)
No	65/97 (67.01)
<b>(b) give any of the above separately, n (%)</b>	
Yes	73/97 (75.26)
No	24/97 (24.74)
<b>Ask a patient to stop using anticoagulants before doing a hydrodilatation, n (%)</b>	
Yes	47/96 (48.96)
No	49/96 (51.04)

patients with controlled diabetes. The most likely contraindications to hydrodilatation were reported as being allergies, having COVID-19, and infected skin lesions.

The most frequent approach used was anteriorly with the patient supine. In terms of expert clinical consensus, the use of image guidance, either image intensifier with contrast or ultrasound, to deliver the injection was to be encouraged, as was delivering the local anaesthetic into the joint using normal saline and a steroid injection. This should be according to patient tolerance and feedback. For mobilization of the shoulder after hydrodilatation, experts agreed that starting home exercises after a day and physiotherapy after two to three days should be encouraged. No elements of hydrodilatation were mandated or discouraged, and only the use of hypertonic saline was to be disallowed.

Zhang et al<sup>9</sup> conducted a recent network meta-analysis of non-surgical treatment strategies for frozen shoulder. Hydrodilatation was one of the highest ranked treatments for short-term pain relief. However, the diverse group of interventions included and lack of longer-term follow-up (i.e. 12 months) makes it difficult to make definitive conclusions for clinical practice and policy. While Chaloumas et al<sup>8</sup> undertook another network meta-analysis, which also concluded hydrodilatation is better for short-term pain relief, the mid-term results favoured physiotherapy with a steroid injection. A ten-year review of 2,432 hydrodilations conducted by Nicholson et al<sup>16</sup>



found the repeat intervention rate to be 7.6% and only 1.7% requiring a more costly and invasive arthroscopic capsular release. Rex et al,<sup>10</sup> however, recently published a systematic review that included four RCTs that evaluated hydrodilatation with a duration of follow-up ranging from six months to two years. With limited sample sizes (ranging from 20 to 60 patients in the hydrodilatation arm), and two of the four RCTs being at risk of more than three types of bias, the conclusion was that an evidence gap remains for high-quality evidence for the effectiveness of hydrodilatation compared with other commonly used treatments for primary frozen shoulder. The modified Delphi study that we have used is recommended for use in the healthcare setting to reliably determine consensus for a defined clinical problem.<sup>17</sup> In the absence of rigorous evidence, it allowed us to reach an expert clinical consensus about how to deliver hydrodilatation to inform clinical practice, and to evaluate in future research.

**Study limitations.** We achieved our a priori objective of enrolling around 100 participants from nearly 50 hospitals which we judged to be sufficiently large and representative to reach a consensus from NHS shoulder experts in the UK. Moreover, 92% of participants responded to round two, thus continuing to represent the majority of expert clinical opinion. The evidence generated from this study is, however, limited to that of the current opinion of experts.

Our participants comprised shoulder experts who were either consultants or advanced practitioners. It could be argued that the findings of the survey do not represent that of the wider NHS, but the specific purpose of the survey was to achieve consensus with experts. There was only minimal representation of physiotherapists. This may reflect that there are fewer expert physiotherapists who deliver hydrodilatation than for other specialties, and the extent to which the initial email invitation was cascaded to eligible staff within Trusts. Hydrodilatation could also be delivered in primary care or intermediate care services, but we focused on reaching consensus for the hospital setting, as this is predominantly where it is delivered.

The Delphi technique allows the gathering of views of experts who can respond in light of the contribution of others, which allows an element of reflection that can be missed from studies based on single interviews or focus groups. The anonymity among the expert groups promotes honesty and standardization, and reduces the risk that dominant or high-profile members of the group are given extra credence. However, there is a trade-off between the number of rounds required to reach resolution among experts, as they can be burdensome to the participants.<sup>18</sup> To minimize participant fatigue, we used two rounds in our study to achieve consensus, as we expected that further rounds would not substantively alter the findings that most elements of hydrodilatation

would be optional. There were a few elements of hydrodilatation that we only asked about in round two which participants asked us to consider when completing round one. Responses to these additional elements of hydrodilatation did not reach our consensus thresholds and are reasonable to consider as being optional.

Finally, while preparing the questionnaire for round one of the study, the COVID-19 pandemic struck the NHS, which impacted on the organization of orthopaedic services and research. Consequently, we did not commence round one until the summer of 2020, when there was some lifting of pressures on NHS staff and a restart to research. We asked participants to complete the questionnaire considering a non-pandemic setting, assuming that in time there would be a return to the more routine delivery of orthopaedic services. Reassuringly, most participants responded that they would deliver hydrodilatation in light of the pandemic the same as before, and nearly all would still deliver a steroid injection.

In the absence of rigorous evidence, our modified Delphi study allowed us to achieve expert consensus about the delivery of hydrodilatation in the management of primary frozen shoulder in a hospital setting. These findings can inform clinical practice and the design of hydrodilatation as an intervention for evaluation in an adequately powered RCT.



### Take home message

- Frozen shoulder is a common condition that leads to pain and stiffness. Multiple treatments are available, including hydrodilatation, which usually involves image guidance to dilate the contracted shoulder joint capsule with a mixture of fluid.
- Hydrodilatation's popularity appears to have increased rapidly, despite the absence of rigorous evidence.
- This two-stage, modified Delphi study of shoulder experts allowed us to achieve consensus about positive, negative, and neutral ratings of hydrodilatation in the management of patients with a primary frozen shoulder.

### Twitter

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