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Annison, David R, Smith, Neil, Salt, Emma et al. (2024) Physical harms associated with suprascapular nerve block interventions in the non-surgical management of acute and chronic shoulder pain: A systematic review. Shoulder and Elbow. ISSN: 1758-5732

https://doi.org/10.1177/17585732241255679

Physical harms associated with Suprascapular Nerve Block Interventions in the non-surgical management of acute and chronic shoulder pain: a systematic review.

Key words: suprascapular nerve block, shoulder pain, adverse events, adverse effects, harm, safety

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Abstract:

Background

The utility of the suprascapular nerve block (SSNB) in the non-surgical management of shoulder pain continues to be explored, whilst its associated physical harms have not. This systematic review aims to report the physical harms associated with the SSNB in the non-surgical management of shoulder pain.

Methods

A search was undertaken of AMED, CINAHL, Cochrane Library, EMBASE, Medline, Pubmed, and Scopus databases. Studies were included if they reported the presence or absence of harm following a SSNB intervention (injection, pulsed radiofrequency, ablation) in the non-surgical management of acute or chronic shoulder pain. Excluded studies were those which utilised SSNB for peri, intra, or post-surgical intervention. The McMaster tool for assessing quality of harms assessment and reporting was utilised.

Results

A total of 111 studies were included in this review of which 168 episodes of harm were reported across 4142 participants. Harm severity ranged from pneumothorax (n=5) to local pain and bruising (n= 50). The quality of harms assessment and reporting across all studies was poor.

Discussion

Despite heterogeneity in SSNB intervention, and low-quality evidence, SSNB carries a low risk of physical harm. Further work is needed in addressing the poor quality of harms assessment and reporting in SSNB studies.

Background/Introduction

A significant proportion of the world population will experience shoulder pain daily, yearly, and throughout a lifetime.[1] Shoulder pain can occur insidiously from pathology, such as osteoarthritis, post traumatically, such as dislocation, [2 3] as well as secondary to neurological conditions and neoplasia.

Acute and chronic shoulder pain can negatively impact activities of daily living, employment, social activities, sleep, and quality of life. [4 5 6] Chronic shoulder pain accounts for up to 80% of the total economic cost of all shoulder pain treatment and is a significant socio-economic and healthcare burden[7-9]. Timely appropriate management is therefore recommended to reduce pain intensity, improve function, and reduce chronicity risk.[10, 11] .

A suprascapular nerve block (SSNB) is a peripheral nerve block that has historically been reserved for chronic and refractory shoulder pain. A SSNB can inhibit ascending pain pathways from the suprascapular nerve which accounts for up to 70% of the sensory input of the shoulder[12 13]. The utility of a SSNB in the non-surgical management of shoulder pain is becoming increasingly evident. [14] Recent studies have shown its use in the management of acute traumatic dislocation [15 16-18], adhesive capsulitis, [19, 20] osteoarthritis, [21] rotator cuff related shoulder pain, [22-25] as well as pain post stroke, [26-29] and Motor Neurone Disease. [30]

Three distinctly different SSNB treatments are utilised in the non-surgical management of structural and non-structural shoulder pain. Injection (SSNBi), involving the delivery of an injectate to the perineural tissue, pulsed radio frequency (SSNBp), involving the delivery of a non-destructive pulsed radio frequency to the nerve, and lastly, nerve ablation (SSNa), the administration of a thermal or chemical neuro-destructive intervention. Both SSNBp and SSNa utilise electrical current, or radiofrequency, to disrupt the nerves' ability to transmit. Whilst

SSNa employs a continuous electrical current to destructive temperatures of 60-80°, pulsed radiofrequency preserves the nerve by allowing heat to dissipate. [31]

Anatomical landmark guided (LMG) techniques, nerve stimulation as well as medical imaging can guide treatment to three common areas: the supraspinous fossa, the suprascapular notch, and the spinoglenoid notch.

To date, SSNB interventions have not been evaluated in a large-scale multi-centre randomised controlled trial (RCT) for shoulder pain. Heterogeneity in the methods and drugs used, [32] perceptions and historical use, [33, 34] as well as perceived risk of harm may be factors. [34] Although harms following peripheral nerve block are rare, [35, 36] serious harm, such as pneumothorax are associated with SSNB. [37]

Despite an increase in the use of SSNB for shoulder pain, no review has systematically evaluated the physical harms associated with SSNB interventions. The aim of this systematic review is to identify, describe and synthesise all reported physical harms attributed to SSNB interventions in the non-surgical management of acute and chronic shoulder pain.

METHOD

The review objectives were to: 1) Descriptively analyse the data on physical harms attributable to the SSNB intervention, stratified where possible by method, nerve localisation, dosage, setting, and administering clinician. 2) Assess the included studies for risk of bias; specifically, the methods for identifying and reporting harms related to suprascapular nerve block interventions

The protocol was registered with PROSPERO (ID: CRD42022335268) in advance of data extraction and any protocol changes recorded. The review is reported in line with the Preferred Reporting Items for Systematic Reviews and the Meta-Analysis (PRISMA) guidelines [38] and the PRISMA harms checklist. [39]

Studies were eligible for inclusion if they reported the presence or absence of a physical harm following a suprascapular nerve block in the non-surgical management of shoulder pain (Table 1).

Physical harms were not pre-specified, nor was primary research study type, to conform to an exploratory approach to reviewing adverse effects. [40] Exclusion criteria were studies utilising SSNB for peri, intra or post operative pain management. In-situ catheter or continuous SSNB block, peripheral nerve stimulation/ neuromodulation, experimental, as well as cadaveric and animal studies were excluded.

Table 1: Eligibility criteria for the review

Inclusion criteria	
Patient	• Acute or chronic shoulder pain inclusive of pathology • Inclusive of age, gender, Country of origin
Intervention	• SSNB, SSNp, SSNa • Landmark, nerve stimulation, or image guided. • Single or multiple • Any qualified clinician, in any setting, in any healthcare tier • In isolation or as an adjunct • Any combination of the above
Comparison	• Comparator and non-comparator studies
Outcome	Include data on adverse events, serious adverse events, adverse effects, adverse reaction, side effect, harm, complication(s), or any other terminology related to physical harm(s). (If the report highlights the potential for physical harms related to SSNB intervention but does not include its own data, a single attempt to retrieve unpublished data will be made by author contact)
Exclusion criteria	
	• Cadaveric and animal studies • SSNB for Peri, intra, or post-surgical intervention • Experimental studies or patients without shoulder pain • Suprascapular nerve excision, debridement, or other intervention • Suprascapular nerve continuous block/ in-situ catheter • Suprascapular peripheral nerve stimulation/ modulation (SSNB prior to peripheral nerve/ modulation can be included)

Allied and complimentary Medicine, **AMED** (Ovid), Cochrane Central Register of Controlled Trials (**CENTRAL**) database of the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature, **CINAHL** Complete (EBSCO), Excerpta Medica Database, **EMBASE** (Ovid), **MEDLINE** (Ovid, ALL), **PubMed** (NCBI), and **Scopus** (Elsevier), were searched from inception to 22nd December 2022 without language restrictions.

A pragmatic grey literature search was undertaken. This included reports, recommendations, and guidelines from regulatory and professional bodies. The websites of the British Pain Society, The British Elbow Shoulder Society, The Faculty of Pain Medicine, and The International Association for the study of Pain were also searched. The World Health Organisation International Clinical Trials Registry Platform (who.int/trialsearch), CentralTrials.gov (clinicaltrials.gov), and the EU Clinical Trials register (https://www.clinicaltrialsregister.eu/) were searched on 22nd December 2022 for ongoing studies.

Search strategy

A search strategy focused on the population and intervention components of the PICO framework. Developed in collaboration with a School of Health librarian at the University of York. Medical Subject Heading (MeSH) were used for Shoulder pain, including common shoulder pathologies, with MeSH and free text words used for suprascapular nerve, and nerve block intervention methods.

Physical harm and related outcome terms were not searched. Harm and adverse effects may not feature in the title, abstract, keywords, or bibliographic database indexing system.[41] No

limits, tools, or exclusions were applied. The search strategy was modified for each database. The search strategy for AMED is provided (Appendix 1).

Study Selection

The electronic bibliographic software package, EndNote (Clarivate, Philadelphia), [42] was used to record, deduplicate, and manage the records throughout the review. Following deduplication, the search result set was imported into Covidence (Veritas Health Innovation, Melbourne).[43] One reviewer (DRA) screened all titles and abstracts. Second screening was completed by two reviewers (NS, ES) following equal distribution of records. The full texts of potentially eligible articles were obtained, and the same process used for screening them.

The review authors were not blinded to the article authors, institutions, or other identifiable information. If a review author was identified as a named author on an eligible paper, they were excluded from determining its inclusion, data extraction, and risk of bias assessment. Disagreement between reviewers throughout the screening and eligibility process was resolved by consensus.

Papers which failed to report harms data but satisfied the remaining eligibility criteria were 'tagged' in Covidence. As recommended, [39, 40] a request for unpublished harms data was then made to the lead author of 'tagged' articles, and if provided, were included in the review. Papers were excluded if they failed to respond to the author request, or there was an absence of reporting.

Data collection process and Data items

A data extraction tool created in Microsoft Excel (Microsoft Corporation, Washington) was piloted (DRA, NS) before use (appendix 2). Data extraction was undertaken by the lead author (DA) and independently checked by a second reviewer (NS).

Data on type of intervention, patient cohort, guidance method, injectate, administration, healthcare setting, administering professional, and experience were included. Harm specific data included total number of harms recorded per eligible treatment arm, severity of harm(s) (verbatim), duration of harm(s)(verbatim), and the nature of harm (verbatim).

As recommended, [39] where multiple harms are described, the severity and duration were extracted for each event, including if multiple events occurred in any one individual. Factors associated with the event, method and timing of harms measurement, and early participant withdrawal were also extracted. Where more than one treatment was delivered concurrently with another, and a harm was reported, all available data were collected.

Studies indicating the absence of physical harm using a generic statement are included for synthesis and the statement recorded verbatim. Although generic statements lack detail, the reported absence of an adverse event, i.e 'zero events' [39] is not the absence of reporting and is therefore included.

Quality assessment

Tools developed to evaluate methodological quality of studies often fail to adequately assess the quality of assessment and reporting of harms. [44] The McMaster Quality Assessment Scale of Harms for primary studies tool evaluates both the quality of reporting of adverse events and

the methodology used in their collection (McHarm tool)(http://hiru.mcmaster.ca/epc/mcharm.pdf.).[45] The tool is a validated and reliable instrument when used to assess interventional and pharmacological studies.[46] One reviewer (DRA) assessed all studies using the McHarm tool which were then independently checked by a second reviewer (NS). A McHarm score is assigned to each study and presented within the study characteristics table (Table. 1) and the full data set (Appendix 4), with higher scores indicating higher quality.

Synthesis methods

Meta-analysis was not possible given the considerable heterogeneity in treatment delivered and a narrative synthesis was undertaken. Physical harms data were stratified by type of harm and intervention type: Suprascapular Nerve Block Injection (SSNBi), Suprascapular Nerve Block Pulsed Radiofrequency (SSNBp), and Suprascapular Nerve Ablation (SSNa). Data are further grouped to guidance technique; i.e Landmark guidance (LMG), Ultrasound (US), and other (Computed Tomography, Fluoroscopy, Image Intensifier), as well as anatomical location.

RESULTS

Study selection.

The full texts of n=283 papers were assessed for eligibility, n=111 were included. The most common reason for full text exclusion was the failure to document the presence or absence of harm (n=57).

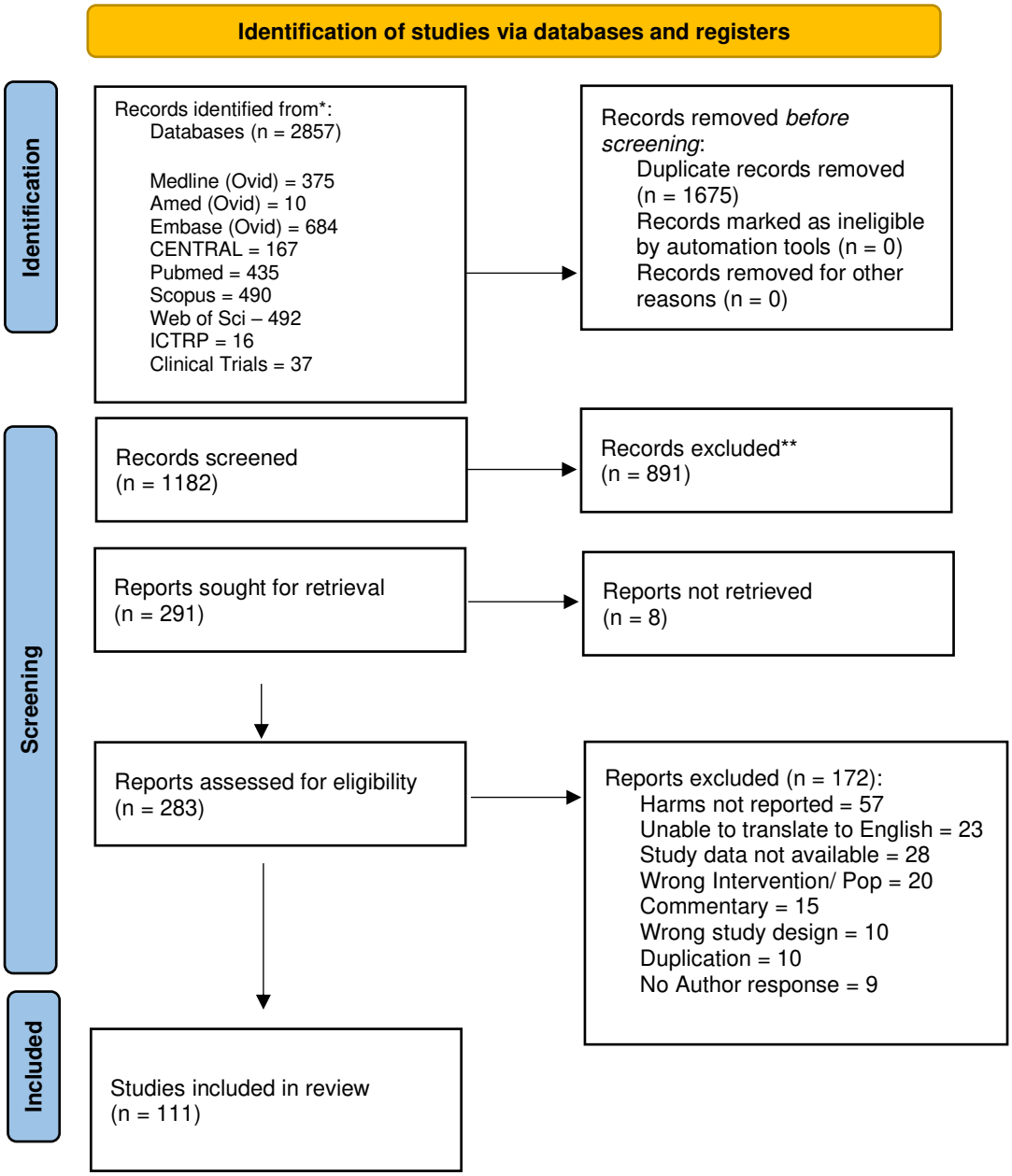

Figure 1. Preferred reporting items for systematic reviews and meta-analysis (PRISMA) flow chart

The characteristics of all 111 included studies are narratively described. Forty studies report the presence of a physical harm, 71 report its absence. The 40 studies that report the presence of a harm are presented in table 2, with all studies characteristics presented in Appendix 4.

Study type

Twenty-seven countries are represented across the 111 studies: with Turkey, the USA, and the UK contributing 24, 17, and 11 papers respectively. A total of 40 RCT's, 26 prospective case series, 25 retrospective case series, 10 case reports, four retrospective case series abstracts, three prospective case series abstracts, two RCT abstract and one service evaluation are included.

Population

A total of n=5062 participants are included across all 111 papers. Study sample size ranged from single participant case reports [15] to n=200 participant RCT[47]. Studies with a mixed pathology cohort (OA, tendinopathy, capsulitis) were most frequently conducted (n=31) with adhesive capsulitis the most frequently investigated single pathology (n=18). Rotator cuff related shoulder pain (n=14), chronic non-specific shoulder pain (n=14), and neurological disorder related shoulder pain populations are represented with 14 studies each. Degenerative joint disease (n=13) is accounted for in 13 studies and acute shoulder dislocation in seven.

Duration of symptoms

Duration of shoulder pain prior to study intervention varied from acute (seven studies of dislocation) to chronic (80 studies reported a three month or more duration). Four studies had a mixed cohort of chronicity, six reported sub-acute symptoms of one to three months, whilst in 14 papers it was unclear.

Intervention and number of treatments

Within the 111 studies included there were 187 intervention arms (referred to below as intervention groups or groups). Forty-two studies included one intervention group, 62 studies included two interventions groups, whilst seven studies included three intervention groups.

The suprascapular nerve block injection is utilised in 98 intervention groups, Pulsed radiofrequency in 36 and suprascapular nerve ablation in 10. Delivery of a single treatment application is reported in 122 groups, whilst up to 32 treatments (range 1-32) is reported in one study. [48] The number of treatments delivered in 13 intervention groups is not reported.

Location

The intervention is predominantly conducted at the suprascapular notch (82 intervention groups) and the supraspinous fossa (39 intervention groups). The supraclavicular approach is used in five, the spino-glenoid notch in two, [49 50] and the infraclavicular approach in one. [51] Treatment location is not reported in 17 study intervention groups.

Guidance

The intervention is guided to the anatomical location using one or a combination of techniques. These include variations of landmark guidance, medical imaging, and nerve stimulation. Ultrasound is most frequently used (n= 56 groups), followed by landmark (n=47 groups), fluoroscopy (n=18groups), image intensifier (n= 2 groups) and computerised tomography (n=2 groups). Combinations of imaging modalities are reported in Appendix 4.

Treatment Dose

Ten millilitres of 0.5% bupivacaine were the most common local anaesthetic, volume, and concentration combination (14 intervention groups). Anaesthetic choice is not reported in 25 groups. Corticosteroid Methylprednisolone (40mg/1ml) and triamcinolone (40mg/1ml) are administered in 29 and 20 groups respectively. Corticosteroid choice is not documented in 19 groups. Dosage of SSNBp and SSNa are poorly defined. Five SSNBp intervention groups reported the following dosage: 42c, 2Hz, 20ms, 45V, 240s, whilst for seven groups, no details were provided. The remaining SSNBp and SSNa studies failed to include sufficient dosage detail.

Needle length and gauge.

The most frequent needle choice within the SSNBi intervention groups is 100mm 22-gauge. SSNBp and SSNa interventions are most commonly delivered with 100mm 22g 5mm active tip needles. Needle length and gauge is not reported for 71, and 63 intervention groups respectively.

Professional, experience, and healthcare tier setting

Ninety-three studies were conducted in secondary care, eight in tertiary care, and it is unclear in 10. The intervention is delivered in a theatre setting in 19 intervention groups, a clinic setting in 17, a ward in seven, and a radiology department in three. Setting is unclear for 125 intervention groups (73%).

The most common professional title performing treatment is a ‘pain medicine clinician’ (20 intervention groups) and the least, a physiotherapist (one group) .[52] It is unclear in 123 intervention groups (72%). Clinician experience is expressed; from number of years in role, or

number of years delivering intervention, to the use of the term ‘experienced’. The experience level of the clinician delivering the intervention is not reported for 148 intervention groups.

Follow up

Few studies report the timing of harms assessment. Where reported, assessment of harm ranges from ‘continuous monitoring’ and ‘immediately post injection’ to 36 month follow up. One study reports information volunteered by the patient (passive approach), whilst another study documented weekly telephone calls for ‘additional questions’ (active approach). Timing is not reported in 97 treatment groups.

Quality assessment

Sixty of the 111 studies (54%) failed to achieve one positive response to the 15 questions of the McMaster Harm tool indicating very low quality in the assessment and reporting of harm. Studies with low scores were those reporting no adverse events, or those with a case report design. Of the 40 studies that report the presence of a physical harm, 73% (29 studies) achieved a McHarm score of at least one or more. The highest score of quality across the included studies was seven from a large RCT. [47]

Table 2. Study characteristics of studies reporting one or more harms

Author		Year	Study Type	Sample (n)	Indication for intervention	Intervention	Detail(s)	Guidance	Total no. of harms per eligible intervention group	Nature/ Definition of harm (s) (verbatim)	Severity (Verbatim free text)	Duration of harm (verbatim)	McHarm Score
Abbasi	1	2020	RCT	200	ASD	SSNBi	SSN	US (NR)	6	4 Haematoma, 1 Bp Fluctuation, 1 Hr Fluctuation	Not serious	NR	7
Bae	7	2019	Retro Case Series	60	Mix	SSNBi	Sup	US (IN)	1	1 Motor weakness	NR	transient (day)	2
Bae	8	2021	RCT	47	Frozen	SSNBi	Sup	US (IN)	9	Motor weakness	NR	1-2 days	4
						SSNBi	SSN	US (IN)	7	Motor weakness	NR	1-2 days	-
Brown	16	1988	Pro Case Series	22	Degen	SSNa	SSN	II	1	Motor weakness	NR	NR	0
Dahan	23	2000	RCT	34	Frozen	SSNBi	SSF	LMG	4	1 Vasovagal, 1 inj site tenderness (unclear numbers or arm)	NR	Transient	0
						SSNBi	SSF	LMG	NR	1 Vasovagal, 1 inj site tenderness (unclear numbers or arm)	NR	Transient	-
Dangoisse	24	1994	Pro Case Series	12	Mix	SSNBi	SSF	LMG	2	1 Motor weakness, 1 numbness and aching in the shoulder	NR	NR	0
Eyigor	31	2010	RCT	50	RCRSP	SSNBp	SSN	Fluro	2	Bruising	NR	NR	5
Gabrhelik	33	2010	Retro Case Series	28	Mix	SSNBp	SSN	Fluro	2	One hypotensive episode, one injection site pain (unclear which group)	NR	"Brief"	1
						SSNBp + Bup	SSN	Fluro	-	-	-	NR	-
Gofeld	38	2012	RCT	13	Mix	SSNBi	SSN	Fluro	1	Local injection site pain (equal in both groups)	NR	NR	1
						SSNBp	SSN	Fluro	1	Local injection site pain (equal in both groups)	NR	NR	-
Goldner	39	1952	Retro Case Series	300	Mix	SSNBi	SSN	LMG	4	1 Local injection site pain, 1 syncope (unclear)	Mild	NR	0
Author		Year	Study Type	Sample (n)	Indication for intervention	Intervention	Detail(s)	Guidance	Total no. of harms per	Nature/ Definition of harm (s) (Verbatim)	Severity (Verbatim free text)	Duration of harm (verbatim)	McHarm Score

									eligible Rx arm				
Gorthi	40	2010	RCT	50	NSSP	SSNBi SSNBi	SSN SSN	US (IN) LMG	0 5	There were no complications in the study group 2 Haematoma, 3 direct nerve injury	n/a NR	n/a NR	2 -
Hackworth	42	2013	Case Report	1	RCRSP	SSNBi SSNBp	Sup SSN	US (IN) US (IN)	1 0	Motor weakness No noted complications	NR n/a	1 day n/a	1 -
Haque	43	2021	RCT	86	Frozen	SSNBi	SSF	LMG	1	Vasovagal,	NR	15 minutes	5
Johal	47	2019	Retro Case Series	11 9	Mix	SSNa SSNa CRF	NR NR	NR NR	1 1	There were two complications which were classified as minor and self-limited (unclear) n/a	Minor n/a	"self limited" n/a	0 -
Kamal	50	2018	RCT	50	NSSP	SSNBi SSNBi	SSF SSN	LMG US (IN)	2 0	2 Vagal symptoms No complications were observed	NR n/a	Transient n/a	5 -
Kang	52	2012	Pro Case Series	20	Mix	SSNBi	Inf	Fluro	1	Motor weakness	NR	NR	5
Khan	55	2009	Pro Case Series	31	Frozen	SSNBi	SSN	LMG	1	Vasovagal Collapse after GHJ (unclear)	NR	15 minutes	2
Liliang	62	2009	Pro Case Series	19	NSSP	SSNBp	SSN	Fluro	1	Puncture wound	NR	1	3
Long	63	1987	Retro Case Series	50	NSSP	SSNBi SSNBi Subscap	SSN SGN n/a	LMG LMG LMG	1 - 1	Pneumothorax (unclear) - Seizure (unclear)	NR NR NR	NR NR NR	1 - -
Masoumi	68	2017	RCT (Ab)	100	ASD	SSNBi	NR	US (IN)	12	2 Hypoxia, 10 nausea and vomitting	n/a	n/a	2
Mortada	71	2015	RCT	96	Frozen	SSNBi SSNBi	SSF SSF	US (IN) US (IN)	2 2	Post injection drowsiness (unclear Injection site tenderness (unclear))	Continued treatment Continued treatment	NR NR	1 -

Author		Year	Study Type	Sample (n)	Indication for intervention	Intervention	Detail(s)	Guidance	Total no. of harms per eligible Rx arm	Nature/ Definition of harm (s) (verbatim)	Severity (Verbatim free text)	Duration of harm (verbatim)	McHarm Score
Malheiro	72	2020	Retro Case Series	71	Mix	SSNBi	NR	US (IN)	3	3 Vasovagal	NR	Transient	4
Okur	75	2017	Retro Case Series	18	Frozen	SSNBi	SSN	US (IN)	1	Upper Limb circumference increase	NR	"transient"	2
Pieran	80	2010	Pro Case Series	21	Mix	SSNBp	NR	Fluro	1	Not reported	"minor"	NR	0
Rowlingson	81	1986	Retro Case Series	36	Mix	SSNBi	SSN	LMG	1	"fainted"	NR	"easily recovered!"	1
Saadatniaki	82	2012	Retro Case Series (Ab)	108	RCRSP	SSNBi	SSN	LMG	4	4 Pneumothorax	Recovered with medical treatment	NR	0
Salt	84	2018	Service Evaluation	40 8	Mix	SSNBi SSNBi	SSF SSN	LMG US (IN)	1 0	"Light headedness" No reports of harm associated with the procedure	NR NR	"few hours" n/a	2 -
Schiltz	85	2022	RCT	35	Frozen	SSNBi SSNBi	SSN SSF	US (IN) US (IN)	11 4	5 Pain at injection site (intense), 3 motor weakness (mild, 2hrs), 2 dysethesia, 1 vasovagal 1 Motor weakness, 2 pain at injection site (mild, 2 hrs) 1 vasovagal	Intense Mild	NR 2hrs	2 -
Schneider-Kolsky	86	2004	Pro Case Series	40	Mix	SSNBi	SSN	CT	15	5 Pain at injection site (slight pain, few hours), 5 headaches (mild to moderate, 24-48hrs), 2 nausea (mild, few hours), 1 localised swelling at injection site (mild, few hours), 2 numbness (NR, few hours)	"slight pain"	"few hours"	3
Shanahan	88	2021	RCT (Ab)	54	Frozen	SSNBi + PT + GHJ Inj	NR	NR	1	Presyncopy episode	n/a	n/a	1
Shanahan	89	2003	RCT	83	Degen	SSNBi	SSF	LMG	1	Chest pain, 1 unrelated death (unclear)	NR	24hrs	0

Author		Year	Study Type	Sample (n)	Indication for intervention	Intervention	Detail(s)	Guidance	Total no. of harms per eligible Rx arm	Nature/ Definition of harm (s) (verbatim)	Severity (Verbatim free text)	Duration of harm (verbatim)	McHarm Score
Shanahan	91	2012	Retro Case Series	289	Mix	SSNBi	SSF	LMG	6	3 Vasovagal (few minutes), 2 motor weakness (within hours), 1 facial flushing	NR	"few minutes"	6
Shanahan	92	2004	RCT	67	Degen	SSNBi SSNBi	SSF SSN	LMG CT	2 2	Bruising 2 Local Injection site pain, Radiation exposure 1.5mSv	Minor NR	"settled quickly" "settled quickly"	1 -
Stogicza	97	2022	Retro Case Series	4	RCRSP	SSNBi SSNa	SSN SSN	US (IN) USS (IN) & NS	4 4	Post procedural discomfort Post procedural discomfort	NR NR	2-3 days 2-3 days	1 -
Suleiman	98	2015	Retro Case Series	5	Mix	SSNBi	SSN	Fluro	2	2 "intermittent short lived shooting sensations"		"short lived"	0
Vander Cruyssen	104	2018	Retro Case Series (Ab)	26	NSSP	SSNBp	NR	US (IN)	1	Neuropathic pain	NR	2	0
Vecchio	105	1993	RCT	28	RCRSP	SSNBi	SSN	LMG	25	9 Paraesthesia (transient), 16 aching in the region of the injection (mild, 1 week) (group not specified)	NR	"Transient"	0
Verma	106	2019	RCT	70	Frozen	SSNBi	SSN	US (IN)	2	2 Tenderness at the injection site (moderate, 24-48hrs)	"moderate"	24-48hrs	4
Wienkers	107	2011	Case Report	1	RCRSP	SSNBi	Sup	US (IN)	1	Motor weakness	NR	8hrs	2
Wu	108	2014	RCT	60	Frozen	SSNBp	SSN	USS (IN) & NS	4	4 "pain at the puncture site" (mild, 1hr)	"mild"	1hr	4

Pathology	Treatment Modality	Target location	Localisation method
RCRSP – Rotator Cuff Related Shoulder Pain	SSNBi - Suprascapular Nerve Block Injection	SSN – Suprascapular Notch	LMG – Land Mark guided
Mix – Mixed Pathology Cohort	SSNBp – Suprascapular Nerve Block Pulsed Radiofrequency	SSF – Supraspinous Fossa	US (IN) – Ultrasound (In Plane)
Degen – Degeneration	SSNa – Suprascapular Nerve Ablation	SGN – Spinoglenoid Notch	US (IN) NS – Ultrasound (In Plane) and Nerve Stimulator
ASD – Anterior Shoulder Dislocation		GHJ – Glenohumeral Joint	US (NR) – Ultrasound (Not reported)
NSSP – Non Specific Shoulder Pain		Sup – Supraclavicular	II – Image Intensifier, Fluro – Fluoroscopy
			NS – Nerve Stimulator
			CT – Computerised Tomography
			NR – Not reported

Results *(Harms)*

A total of 168 individual episodes of harm are reported across n= 4 142 participants (4%) that received a SSNB intervention.

Across the studies, the use of a recognised or validated classification system to report severity, duration, or nature of harm was not detailed. Harm severity ranged from 'mild' to 'intense', with nine different statements reported. Twenty-three different statements indicated harm duration, from "a few hours" (n=5), "to "8 weeks". Fifty unique statements reported the nature of harm. To aid analysis and presentation of results, these statements have been grouped into seven broader categories (Table 3).

Local pain and bruising

Physical harms pertaining to needle penetration of the skin and subsequent sequelae such as "local pain", "bruising", "pain at puncture site", "local injection site pain", and "small haematoma" are labelled as 'local pain and bruising' to reflect the terminology used. Fifty episodes are recorded (across n=4142 participants (1.2%) (SSNBi = 42, SSNBp = 4, SSNa = 4 episodes).

Transient Motor weakness

Twenty-seven episodes of transient motor weakness were reported across all methods (27/4142; 0.65%). Three episodes of transient weakness (3/754; 0.4%) were recorded in the landmark guided SSNBi supraspinous fossa method and one in the image guided SSNa. Ultrasound guided SSNBi intervention accounted for 23 episodes with 12 occurring in the 75 participants within the supraclavicular approach (12/ 75 participants; 6%). Where reported, symptom duration across all methods ranged from eight to 24 hours. Severity was not reported.

Pre-Syncope and *Vasovagal Syncope*

Descriptions of 'light headedness' "fainting", "blood pressure fluctuation", "pre-syncope" and "vasovagal" are combined as pre-syncope and vasovagal syncope. Twenty-three participants were reported symptomatic (23/ 4142; 0.5%). Eleven episodes occurred in both the landmark and ultrasound guided SSNBi groups and one episode in the SSNBp group.

Paraesthesia/ anaesthesia

Episodes of “a few hours” paraesthesia occurred in two participants in the ultrasound guided SSNBi suprascapular notch group, whilst nine occurred in the landmark alternative. Only one episode occurred within the landmark SSNBi supraspinous fossa group.

Nausea

Twelve episodes of nausea occurred across two studies. Ten occurred within an ultrasound guided SSNBi approach, whilst two episodes occurred with a CT guided SSNBi approach.

Pneumothorax

Five pneumothorax across two retrospective case series are reported (5/ 4142; 0.1%). Both studies combined a landmark guided SSNBi suprascapular notch intervention with either another, or multiple site additional injections.[49, 53] In one study, fifty patients underwent tri-scapular block of which SSNBi (Erickson approach) was used,[49] whilst in the other, 108 participants received a SSNBi (Meier) and subacromial injection. [53]

Peripheral Nerve Injury

Three episodes of “direct nerve injury with prolonged neurological deficit” were recorded in one study in which participants were randomised to a landmark guided SSNBi intervention. No nerve injury was reported within the ultrasound guided group. [54] Although severity is not detailed, recovery is reported at eight weeks. Peripheral nerve injury is not reported in SSNa, SSNBp, or ultrasound guided SSNBi approaches.

Single events

No episodes of Local anaesthetic systemic toxicity (LAST) or serious infection requiring treatment is explicitly reported in the included studies. Single episodes of harm included unrelated death,[48] upper limb swelling,[55] facial flushing,[48] seizure,[49] and chest pain.[56]

Table 3. **Harms (number of physical harms/ adverse events recorded)**

SSNBi (n = 3122 eligible participants)			**Local pain/ bruising**	**Transient motor Weakness**	**Pre syncope and Vasovagal syncope**	**Paraesthesia/ Anaesthesia**	**Nausea**	**Pneumothorax**	**Peripheral Nerve Injury**
No. of harms across all SSNBi methods			*(42)*	*(26)*	*(22)*	*(17)*	*(12)*	*(5)*	*(3)*
Number of studies reporting harm (publications)			***10*** *(1, 23, 39, 40, 85, 86, 89, 92, 105, 106)*	***7*** *(7, 8, 24, 42, 85, 91, 107)*	***13*** *(1, 23, 39, 43, 50, 55, 68, 71, 72, 81, 84, 85, 91)*	***6*** *(24, 52, 85, 86, 98,105)*	***2*** *(68, 86)*	***2*** *(63, 82)*	***1*** *(40)*
USG									
Study number	*Received intervention*	**Location**							
10, 35, 64, 66, 71, 78	*n = 219*	SSF (in-direct)	2 (85)	1 (85)	3 *(71,85)*				
1, 19, 40, 49, 53, 54,69, 70, 75, 76, 85, 94, 95, 97	*n = 764*	SSN (direct)	11 (1, 85, 106)	10 (8, 85)	3 (1, 85)	2 (85)			
7, 8, 20, 42, 107	*n = 75*	Supra-clavicular		12 (7, 8, 42, 107)					
22, 68, 72, 77	*n = 123*	Not Reported			5 (68, 72)		10 (68)		
LMG									
2, 11, 14. 15, 23, 24, 26, 28, 37, 43, 48, 50, 56, 59, 83, 84, 89, 90, 91, 92, 111	*n = 754*	SSF (in-direct)	4 (23, 89, 92)	3 (24, 91)	8 (23, 43, 50, 84, 91)	1 (24)			
34, 36, 39, 40, 55, 61, 63, 81, 82, 100, 105	*n = 679*	SSN (direct)	18 (39, 40, 105)		3 (39, 55, 81)	9 (105)		4 (82)	3 (40)
	n = 0	Supraclav							
63	*n = 50*	Tri block (spino/ sub/						1 (63)	
Other									
9, 29, 67	*n = 100*	SSF (in-direct)							
3, 12, 27, 38, 60, 86, 92, 93, 98	*n = 332*	SSN (direct)	7 (86, 92)			*4 (86, 98)*	*2 (86)*		
20, 52	*n =26*	Supra/ infra-clavicular				*1 (52)*			

SSNBp (n = 775 eligble participants)			**Local pain/ bruising**	**Transient motor Weakness**	**Pre syncope and Vasovagal syncope**	**Paraesthesia/ Anaesthesia**	**Nausea**	**Pneumothorax**	**Direct Nerve Injury**
No. of harms across all SSNBp methods			*(4)*	*()*	*(1)*	*(1)*	*()*	*()*	*()*
Number of studies reporting harm (publications)			*4* *31, 33, 62, 108*		*1* *33*	*1* *104*			
USG									
Study number	*Received intervention*	**Location**							
29, 45, 67	*n = 101*	SSF (in-direct)							
42, 57, 108, 109	*n = 96*	SSN (direct)							
	n = 0	Supra-clavicular							
104	*n =26*	Not Reported				1 (104)			
LMG									
45	*n = 5*	SSF (in-direct)							
	n =	SSN (direct)							
	n = 0	Supraclav							
Other									
29, 67	*n = 96*	SSF (in-direct)							
4, 6, 30, 31, 32, 33, 46, 51, 58, 62, 65, 74, 79, 93, 95, 96, 99, 108, 110	*n = 451*	SSN (direct)	4 (31, 33, 62, 108)		*1 (33)*				
	n = 0	Supra/ infra-clavicular							

SSNa (n = 245 eligble participants)			**Local pain/ bruising**	**Transient motor Weakness**	**Pre syncope and Vasovagal syncope**	**Paraesthesia/ Anaesthesia**	**Nausea**	**Pneumothorax**	**Direct Nerve Injury**
No. of harms across all SSNa methods			*(4)*	*(1)*	*(0)*	*(0)*	*(0)*	*(0)*	*(0)*
Number of studies reporting harm (publications)			*1*	*1*	*0*	*0*	*0*	*0*	*0*
USG									
Study number	*Received intervention*	**Location**							
0	*n =*	SSF (in-direct)							
21	*n = 4*	SSN (direct)							
0	*n = 0*	Supra-clavicular							
77	*n =1*	Not Reported							
LMG									
	N = 0								
Other									
	n =0	SSF (in-direct)							
13, 16, 21, 93, 97	*n =95*	SSN (direct)	4 (97)	*1 (16)*					
69	*n = 101*	SGN (direct)							
103	*n = 12*	Tri-block							
17, 47	*n = 32*	NR							

Pathology	Treatment Modality	Target location	Localisation method
RCRSP – Rotator Cuff Related Shoulder Pain	SSNBi - Suprascapular Nerve Block Injection	SSN – Suprascapular Nerve	LMG – Land Mark guided
Mix – Mixed Pathology Cohort	SSNBp – Suprascapular Nerve Block Pulsed Radiofrequency	SSF – Supraspinous Fossa	US (IN) – Ultrasound (In Plane)
Degen – Degeneration	SSNa – Suprascapular Nerve Ablation	SGN – Spinoglenoid Notch	US (IN) NS – Ultrasound (In Plane) and Nerve Stimulator
ASD – Anterior Shoulder Dislocation		GHJ – Glenohumeral Joint	US (NR) – Ultrasound (Not reported)
NSSP – Non Specific Shoulder Pain		Sup – Supraclavicular	II – Image Intensifier, Fluro – Fluoroscopy
			NS – Nerve Stimulator
			CT – Computerised Tomography
			NR – Not reported

Discussion

We undertook a systematic review to investigate the evidence on the physical harms associated with SSNB intervention in the non-surgical management of acute and chronic shoulder pain. One hundred and eleven studies met the eligibility criteria, 40 of which reported the presence of one or more associated physical harms.

Main findings

SSNB interventions were most commonly administered for chronic shoulder pain of varying pathology by pain medicine consultants in a hospital theatre setting. Most frequently applied was a single, ultrasound guided injection, to the suprascapular notch, containing 10mls of 0.5% bupivacaine and 40mg/ml methylprednisolone.

A total of 168 individual episodes of harm were reported across 4 142 participants (4%) that received a SSNB intervention. Generic harms associated with injection therapy, and specific harms associated with suprascapular nerve block are noted.

Descriptive data on intervention equipment, delivery method, use of guidance, and setting was poorly documented across many studies. Professional clinical title and experience was not disclosed in many studies, including insufficient reporting on the number, location, and dosage of treatment.

Terminology used to describe harm, such as the nature, severity, and duration varied considerably. The use of a recognised and validated classification system harm was not detailed across the studies. Many of the included studies failed to adequately assess and report harm and did not report the use of a standardised approach in the collection or reporting of harms data.

Overall, the quality of reporting was poor. Over half of the studies failed to achieve one positive response to the 15 McHarm tool criteria, with the highest score in this review less than half of the potential points available. A trend for higher McHarm scores was noted with studies with a greater number of harms potentially indicating such studies may have been conducted with more rigor.

Comparisons with previous studies/ implications for clinical practice

Conclusions that suprascapular nerve block interventions are ‘safe’ have previously been drawn from studies and reviews of effectiveness. [14, 48] Studies and reviews of effectiveness may however

inadequately assess, and report harm, so should be interpreted with caution. [57] Studies that report no harm may appear to conduct safer interventions than those that do; but no, or a low number of harms, may simply indicate poor assessment and reporting.

The most frequently reported harm in this review was 'local pain and bruising', though the rate was low (50/ 4142; 1.2%) and episodes were low in severity. Although the rate is higher than previously reported in a systematic review of SSNB treatments for shoulder pain (0.5%), [14] our review included acute conditions, SSNa methods, and the number of interventions were nearly sixfold. The low rate and severity of pain post SSNB treatment within the review may provide some reassurance to consenting clinicians and patients. Local anaesthetic administered prior to intervention (skin, subcutaneous, and muscle layers) could be a contributing factor, but the analysis of this data was not within our original protocol.

Pneumothorax, often cited in the literature as a harm of SSNB, occurred in five participants across two studies (5/4142, 0.1%). No direct causation of harm however can be inferred as both studies combined SSNB intervention with either a single or multiple other invasive injections within the same episode. In one study, SSNBi is also combined with multiple landmark guided subscapularis injections. Multiple 'blind' passes are described to target the superior, mid, and inferior portions of the subscapularis using a 90mm spinal needle. The described injection target was the subscapularis musculature on the anterior face of the scapular, not the tendon at the anterior shoulder, consequently placing the needle in close proximity to the chest wall. The other study combined SSNBi with a landmark subacromial injection. The 100mm 23g hypodermic needle was directed between the glenoid and coracoid process using an anterior approach. Despite pneumothorax occurring in the two studies, a substantially greater number have been reported across acupuncture case series, with certain thoracic points now being 'out of scope' for physiotherapists. [58] [59] [60-62]

In both studies participant habitus is unknown but both utilised a minimum 90mm 22-gauge hypodermic needle with a landmark suprascapular notch approach to deliver the SSNBi. Over half of the paraesthesia episodes in this review were also associated with this approach. A 2019 cadaveric study may provide some insight into the increased episodes of paraesthesia. [63] The authors concluded that landmark guided injection of dye at the suprascapular notch sufficiently covered the three sensory branches of the SSNB, and advised a 'do it yourself' approach was feasible to its

orthopaedic surgeon readership. The authors acknowledged the limitation of their study highlighting pleuropulmonary injuries, system toxicity, nerve injury and intravascular injection would not be detected. [63] Clinicians considering SSNBi may wish to consider body habitus, needle length, target location and cross adduction of the arm, [64] to ensure risk is minimised.

Permanent motor weakness and peripheral nerve injury following peripheral nerve block is rare, [35] and was not identified in this, or a recent systematic review of SSNB treatments for shoulder pain. [14] Dynamic triple monitoring; the adoption of imaging and other safety measures during peripheral nerve block, has however been recommend as it may decrease nerve injury risk. [65] Monitoring however can be costly, time consuming, and difficult to conduct in a clinical setting. [65] Although no clinical or electrophysiological evidence of nerve injury is reported after intraneural injection,[66] further research to evaluate the impact of single and repeated SSNB treatment on nerve function, with or without triple monitoring, should be undertaken.

Transient (<24hr) weakness is reported in 27 episodes (27/4142, 0.65%), with 12 occurring in four studies adopting an ultrasound guided supra-clavicular approach. Supraclavicular and anterolateral neck approaches are more commonly associated with plexus blockade and performed for upper limb surgery [67, 68]. Although the incidence and severity of transient weakness is low in this review, clinicians should be mindful that anterior approaches also increase the potential for phrenic nerve palsy. [69, 70] A recent RCT of 84 patients undergoing anterior suprascapular nerve block for shoulder surgery reported a 40% incidence of hemi diaphragmatic paralysis despite ultrasound guidance. [71] A 2022 cadaveric study highlighted the impact of injectate volume on distribution, and reported a 4.2mL injectate volume as phrenic nerve sparing during an anterior approach to SSNBi using ultrasound guidance. [72] Clinicians should however remain vigilant and consent appropriately with posterior approaches. A recently conducted cadaveric study demonstrated motor branches of the suprascapular nerve to be proximal to the suprascapular notch in two of the six specimens used. [73]

Strengths and weaknesses of the review

This substantial review of 111 studies includes over 4 000 participants with acute and chronic shoulder pathology who underwent a SSNB intervention in clinical practice. The review includes reports from 27 countries, a variety of SSNB approaches across a spectrum of shoulder and populations. The search strategy incorporates database searches from inception to December 2022

and does not exclude primary studies based on study design, or those which fail to use harm terminology in the title or abstract. A comprehensive data extraction tool captured a breadth of variables across interventional methods and harms to ensure both elements are represented as close to the evidence as practicable whilst allowing synthesis.

We are reassured that pneumothorax was reported in only 0.1% of participants in this inclusive review. Furthermore, the presence of pneumothorax could not be directly attributed to the SSNB interventions within the studies due to multiple site injections, and multiple passes of the needle. Our search strategy excluded SSNB interventions for surgical intervention, and although not our intention to review this literature, there is the possibility that such harm is based on that evidence, and not when SSNBs are used in the non-surgical management of shoulder pain.

A limitation of this review is secondary to a lack of detailed reporting and the heterogeneity in the terminology used to describe harm nature, severity, and duration within the included studies. Although it was our intention to provide harms data stratified to variables such as treatment dosage, setting, and administering clinician and experience, a lack of descriptive detail across some variables meant we are unable. Variation in descriptors of harm data also meant we were unable to confidently associate harm severity and duration to SSNB methods.

It was also not possible to quantify the total number of treatments per participant, or the total number of interventions delivered within studies. Results presented therefore are based on each participant receiving one intervention only. Overestimation of harm however only further supports our findings of a low incidence of harm. Although not an objective of this review, we were unable to determine if co-morbidities impact harm reported. Data extraction did include study level participant co-morbidity inclusion and exclusion criteria, but not individual patient level data. As SSNB interventions are often recommended for elderly and higher-risk patients, [48] further research may provide improved clarity.

Significant heterogeneity in the methods, drugs, guidance methods, and anatomical locations across SSNB interventions is evident in this and past reviews. [14, 32, 74] Stratification of harms to broader SSNB methods was required to aid synthesis. This grouping may have inadvertently failed to identify causes of harm from subtle variations within methods. Grouping of harms to broader categories was also required to aid synthesis and subsequently may hide subtle variations in harm presentations.

Implications for future Research

The utility of SSNB interventions across shoulder pathologies and populations continues to be explored. [75] As polypharmacy and multimorbidity increase, so does the possibility of adverse events and drug reactions. [76] [77] [78] Although separate reviews of benefits and harms of interventions may reduce the likelihood that reviews of the same interventions reach inconsistent conclusions, [57] we recommend future clinical trials should increase harms assessment and reporting vigilance to ensure local and systemic harms are highlighted. Until separate reviews are commonplace, we recommend greater emphasis on the assessment and reporting of harms to improve quality.

Considerable heterogeneity in treatment methods exist. This review supports previous review findings of treatment method heterogeneity and that clinician preference may guide choice, rather than evidence. [32] Future consensus work is recommended to focus resources on identifying the most effective and safe treatment approaches for future clinical trials. It is therefore essential that detailed information exists on intervention, the setting, the clinician, and their experience, as well dose, number of treatments applied and in what timeframe. Further research surrounding single and repeated interventions on nerve health may guide clinical decision making as well as inform the shared decision-making process. Such detail may aid future comparisons of harm.

It is recommended that Randomised Controlled Trials report 'all important harms or unintended effects' according to the Consolidated Standards of Reporting Trials (CONSORT) statement, and the harms extension. [79, 80] This wording however may be open to interpretation. Where one study may consider nausea as important, and transient weakness as unintended, another may not.

Within this review there was notable inconsistency in the terminology used to detail harm and the lack of a recognised classification system used across the included studies. Not limited to secondary care or interventional practice, [81] differences in perception of harms [82] and classification systems have previously been identified in primary care, with a total of 21 different approaches reported.[83] Future consensus on the use of a recognised harm classification system, with clearly defined descriptors, definitions, grading systems and terminology is recommended to improve homogeneity of reporting. The use of a single system may improve vigilance, help reduce to disparity, improve synthesis, and reduce research waste in future clinical trials. Further research may lead to future recommendations on protocol items for harms assessment.

Conclusions

Despite substantial variation in suprascapular nerve block interventions for shoulder pain, low quality evidence suggests that SSNB interventions carry a low risk of harm. We remain cautious with the conclusion that they are 'safe', when, true safety and risk remains relatively unknown.

Clinicians may wish to combine the findings in this review with those of effectiveness to aid their choice of treatment approach. The review may also support on-going development of best practice and the shared decision-making process by providing data on common physical harms reported. We recommend greater consideration of the assessment and reporting of harms in primary research to improve the risk and benefit data available to clinicians and patients.

Appendix. 1

Name of saved search: AMED (Allied and Complementary Medicine) <1985 to May 2022>	
1	shoulder pain/ or shoulder pain.mp.
2	exp Shoulder joint/ or shoulder joint.mp.
3	glenohumeral joint.mp.
4	acromioclavicular joint.mp. [mp=abstract, heading words, title]
5	sternoclavicular joint.mp. [mp=abstract, heading words, title]
6	exp Rotator cuff/ or rotator cuff.mp.
7	exp Joint disease/ or arthropathy.mp.
8	rotator cuff tendinitis.mp.
9	rotator cuff tendinopathy.mp.
10	tendon rupture.mp.
11	exp Tendon injuries/ or tendon tear.mp.
12	shoulder impingement.mp. or exp Shoulder impingement syndrome/
13	exp Bursitis/ or subacromial bursitis.mp.
14	shoulder tendinitis.mp. [mp=abstract, heading words, title]
15	exp Hemiplegia/ or exp Shoulder dislocation/ or shoulder dislocation.mp. or exp stroke/
16	shoulder contracture.mp. or exp Contracture/
17	shoulder capsulitis.mp.
18	adhesive capsulitis.mp.
19	frozen shoulder.mp.
20	(stroke adj5 shoulder pain).mp. [mp=abstract, heading words, title]
21	(hemiplegic adj5 shoulder pain).mp. [mp=abstract, heading words, title]
22	(cancer adj5 shoulder pain).mp. [mp=abstract, heading words, title]
23	(metastatic adj5 shoulder pain).mp. [mp=abstract, heading words, title]
24	(metastasis adj5 shoulder pain).mp. [mp=abstract, heading words, title]
25	(neoplasm adj5 shoulder pain).mp. [mp=abstract, heading words, title]
26	(tumour adj5 shoulder pain).mp. [mp=abstract, heading words, title]
27	(tumor adj5 shoulder pain).mp. [mp=abstract, heading words, title]
28	(fracture adj5 shoulder pain).mp. [mp=abstract, heading words, title]
29	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
30	suprascapular.mp.
31	supra-scapular.mp. [mp=abstract, heading words, title]
32	supra scapular.mp. [mp=abstract, heading words, title]
33	30 or 31 or 32
34	exp Nerve block/ or nerve block*.mp.
35	nerve block injection*.mp.
36	exp Injections/ or injection*.mp.
37	pulsed radiofrequency.mp.
38	pulsed radio-frequency.mp.
39	radiofrequency ablation.mp.
40	radio-frequency ablation.mp.
41	radio frequency ablation.mp.
42	nerve ablation.mp.
43	thermal radiofrequency denervation.mp.
44	denervation.mp. or exp Denervation/
45	34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44
46	29 and 33 and 45

Appendix 2. Data extraction tool

Country
Study Type
No of participants
Sex
Indication for intervention
Chronicity
Exclusions
Age
Follow up
Intervention Type (a)
Intervention Type (b)
Location of treatment (Direct/ in-direct)
Nerve localisation method (landmark, guidance)
Maximum number of treatments per patient
Needle Gauge
Needle Length
Sub cutaneous local anaesthetic (drug choice and dose)
Anaesthetic drug choice and potency
Anaesthetic dosage/ volume
Corticosteroid drug choice and potency
Corticosteroid dosage/ volume
Radiofrequency/ Ablation dosage
Repeated frequency/ interval
Professional registration
Professional Experience
Procedure setting
Adverse event statement verbatim
Harm as primary or secondary outcome
Description of who reported harms data
Timing of harms assessment
Harms follow up period
Total number of harms per eligible treatment arm
Nature/ definition of harm
Severity (verbatim)
Harm duration
Multiple events in an individual
Harm associated with co-moribity and description
Assessment of possible causality
Early withdrawl (lost to follow up)
Health care tier setting

Appendix 3.

McMaster tool for assessing quality of harms assessment and reporting in study reports (McHarm)

1. Were the harms PRE-DEFINED using standardized or precise definitions?
2. Were SERIOUS events precisely defined?
3. Were SEVERE events precisely defined?
4. Were the number of DEATHS in each study group specified OR were the reason(s) for not specifying them given?
5. Was the mode of harms collection specified as ACTIVE?
6. Was the mode of harms collection specified as PASSIVE?
7. Did the study specify WHO collected the harms?
8. Did the study specify the TRAINING or BACKGROUND of who ascertained the harms?
9. Did the study specify the TIMING and FREQUENCY of collection of the harms?
10. Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection?
11. Did the authors specify if the harms reported encompass ALL the events collected or a selected SAMPLE?
12. Was the NUMBER of participants that withdrew or were lost to follow-up specified for each study group?
13. Was the TOTAL NUMBER of participants affected by harms specified for each study arm?
14. Did the author(s) specify the NUMBER for each TYPE of harmful event for each study group?
15. Did the author(s) specify the type of analyses undertaken for harms data?

Appendix 4. Study characteristics of 111 included articles.

Author		Year	Study Type	Sample (n)	Indication for intervention	Intervention	Detail(s)	Guidance	Total no. of harms per eligible Rx arm	Nature/ Definition of harm (s) (verbatim)	Severity (Verbatim free text)	Duration of harm (verbatim)	McHarm Score
Abbasi	1	2020	RCT	200	ASD	SSNBi	SSN	US (NR)	6	4 Haematoma, 1 Bp Fluctuation, 1 Hr Fluctuation	Not serious	NR	7
Adey-Wakeling	2	2013	RCT	64	Neuro	SSNBi	SSF	LMG	0	No adverse effects reported	n/a	n/a	1
Ahuja	3	2011	Pro Case Series (Ab)	80	Frozen	SSNBi	SSN	N.Stim	0	No significant adverse effects were noted	n/a	n/a	1
Alanbay	4	2020	RCT	30	NSSP	SSNBp	SSN	USS & NS	0	No side effects or complications were observed during or after the treatment	n/a	n/a	0
						SSNBi	SSN	US (IN)	0	n/a	n/a	n/a	0
Antonopoulou	5	2011	Retro Case Series (Ab)	104	Degen	SSNBi	NR	Landmark+NS	0	There were no significant adverse effects in the patients due to the peripheral nerve block	n/a	n/a	0
Arici	6	2018	RCT	60	NSSP	SSNBp	SSN	Fluro	0	None of the patients experienced serious side effects or complications	n/a	n/a	3
						SSNBp	SSN	Fluro	0	n/a	n/a	n/a	-
						SSNBp	SSN	Fluro	0	n/a	n/a	n/a	-
Bae	7	2019	Retro Case Series	60	Mix	SSNBi	Sup	US (IN)	1	1 Motor weakness	NR	transient (day)	2
Bae	8	2021	RCT	47	Frozen	SSNBi	Sup	US (IN)	9	Motor weakness	NR	1-2 days	4
Bae						SSNBi	SSN	US (IN)	7	Motor weakness	NR	1-2 days	-
Bamgbade	9	2018	Pro Case Series	4	NSSP	SSNBi	SSF	USS & NS	0	The procedures were uneventful	n/a	n/a	2
Beleil	10	2012	Case Report	1	NSSP	SSNBi	SSF	US (IN)	0	No complications were reported	n/a	n/a	0
BelinchÃ³n de Diego,	11	2011	Pro Case Series	10	ASD	SSNBi	SSF	LMG	0	None of the patients experienced complications associated with the regional anesthesia.	n/a	n/a	2

Bennett	12	2014	Retro Case Series	155	Mix	SSNBi	SSN	Fluro	0	There were no immediate complications reported	n/a	n/a	0
Bone	13	2013	Pro Case Series	62	Mix	SSNa	SSN	II & NStim	0	No serious adverse effects were reported.	n/a	n/a	0
Boonsong	14	2009	RCT	10	Neuro	SSNBi	SSF	LMG	0	There was no complication or adverse event detected during the study period	n/a	n/a	0
Bradnam	15	2016	Case Control	8	RCRSP	SSNBi	SSF	LMG	0	There were no adverse events during TMS reported by any participant	n/a	n/a	0
Brown	16	1988	Pro Case Series	22	Degen	SSNa	SSN	II	1	Motor weakness	NR	NR	0
Campos	17	2020	Pro Case Series (Ab)	12	Mix	SSNa	NR	N.Stim	0	No motor injuries occurred	n/a	n/a	0
Cannon	18	2012	Retro Case Series (Ab)	2	NSSP	SSNBp	SSN	Fluro	0	without muscle weakness or a loss of function	n/a	n/a	0
ÇETINGÖK	19	2022	Retro Case Series	160	Mix	SSNBi	SSN	US (IN)	0	"There were no complications reported to me or detected by me during this study"	n/a	n/a	0
ÇETINGÖK						SSNBp	SSN	US (IN)	0		n/a	n/a	-
Chang	20	2015	Retro Case Series	6	Mix	SSNBi	Sup	USS & NS	0	No patients had procedure-related complications, aggravation of neuropathic pain, or adverse events	n/a	n/a	0
Colon-Conde	21	2019	Case Report	1	Neuro	SSNa	SSN	US (IN)	0	No peri-procedural complications occurred	n/a	n/a	0
Cristiani	22	2020	Case Report	1	Degen	SSNBi	NR	US (IN)	0	"No complications were reported"	n/a	n/a	3
						SSNBp	SSN	USS (IN) & NS		n/a	n/a	n/a	-
Dahan	23	2000	RCT	34	Frozen	SSNBi	SSF	LMG	4	1 Vasovagal, 1 inj site tenderness (unclear numbers or arm)	NR	Transient	0
						SSNBi	SSF	LMG	NR	1 Vasovagal, 1 inj site tenderness (unclear numbers or arm)	NR	Transient	-
Dangoisse	24	1994	Pro Case Series	12	Mix	SSNBi	SSF	LMG	2	1 Motor weakness, 1 numbness and aching in the shoulder	NR	NR	0

Dey	25	2021	Retro Case Series	4	Mix	SSNBp	SSN	USS & NS	0	No patient reported any immediate or late complications	n/a	n/a	0
DiLorenzo	26	2006	RCT	40	RCRSP	SSNBi	SSF	LMG	0	No major complications reported	n/a	n/a	1
Dogan	27	2022	RCT	40	RCRSP	SSNBi	SSN	USS (IN) & NS	0	No complications were encountered in either group in the present study	n/a	n/a	1
						SSNBi	Sup	USS (IN) & NS	0	n/a	n/a	n/a	-
Dorn	28	2015	Pro Case Series	20	RCRSP	SSNBi	SSF	LMG	0	No side-effects or complications were observed.	n/a	n/a	2
ErgÃ¶nenÃ§	29	2018	Pro Case Series	74	Mix	SSNBi	SSF	USS (IN) & NS	0	No early and late complications were observed in any patient.	n/a	n/a	1
						SSNBp	SSF	USS (IN) & NS	0	n/a	n/a	n/a	-
Esparza-MiÃ±ana	30	2019	Case Report	1	NSSP	SSNBp	SSN	USS (IN) & NS	0	we have not experienced any major complications in clinical practice	NR	NR	0
Eyigor	31	2010	RCT	50	RCRSP	SSNBp	SSN	Fluro	2	Bruising	NR	NR	5
Flores	32	2016	Pro Case Series (Ab)	23	Mix	SSNBp	SSN	Fluro + NS	0	0% incidence of pneumothorax in the uni or bilateral approach.	n/a	n/a	0
Gabrhelik	33	2010	Retro Case Series	28	Mix	SSNBp	SSN	Fluro	2	One hypotensive episode, one injection site pain (unclear which group)	NR	"Brief"	1
						SSNBp + Bup	SSN	Fluro	-		NR	NR	-
Gado	34	1993	RCT	29	Degen	SSNBi	SSN	LMG	0	No significant side effects were noted	n/a	n/a	0
						SSNBp + Bup	SSN	LMG	0	n/a	n/a	n/a	-
Gencer-Atalay	35	2021	RCT	40	Frozen	SSNBi	SSF	US (IN)	0	None of them reported any types of side or adverse events during or after the procedures.	n/a	n/a	4
Gjonovich	36	2011	Pro Case Series	40	Mix	SSNBi	In-direct	LMG	0	all patients completed the study and no major sideeffects or adverse events were recorded	n/a	n/a	0
Gleeson	37	1997	Pro Case Series	20	ASD	SSNBi	SSF	LMG	0	there were no complications seen in any patient.	n/a	n/a	1

Gofeld	38	2012	RCT	13	Mix	SSNBi	SSN	Fluro	1	Local injection site pain (equal in both groups)	NR	NR	1
						SSNBp	SSN	Fluro	1	Local injection site pain (equal in both groups)	NR	NR	-
Goldner	39	1952	Retro Case Series	300	Mix	SSNBi	SSN	LMG	4	1 Local injection site pain, 1 syncope (unclear)	Mild	NR	0
Gorthi	40	2010	RCT	50	NSSP	SSNBi	SSN	US (IN)	0	There were no complications in the study group	n/a	n/a	2
						SSNBi	SSN	LMG	5	2 Haematoma, 3 direct nerve injury	NR	NR	-
Gulevich	41	2009	Retro Case Series	56	NSSP	SSNBi	NR	NR	0	Suprascapular nerve block produced no complications	n/a	n/a	0
Hackworth	42	2013	Case Report	1	RCRSP	SSNBi	Sup	US (IN)	1	Motor weakness	NR	1 day	1
						SSNBp	SSN	US (IN)	0	No noted complications	n/a	n/a	-
Haque	43	2021	RCT	86	Frozen	SSNBi	SSF	LMG	1	Vasovagal,	NR	15 minutes	5
Hassen	44	2022	Case Report	1	ASD	SSNBi	NR	NR	0	Without complications	n/a	n/a	0
Hulagu	45	2014	Retro Case Series	NR	NSSP	SSNBp	SSF	LMG	0	No complication was established.	n/a	n/a	0
						SSNBp	SSN	US (IN)	0	-	n/a	n/a	-
Jang	46	2013	Pro Case Series	11	Mix	SSNBi	NR	NR	0	No complications were reported.	n/a	n/a	0
Jang						SSNBp	SSN	Fluro	0	-	n/a	n/a	-
Johal	47	2019	Retro Case Series	11	Mix	SSNa	NR	NR	1	There were two complications which were classified as minor and self-limited (unclear)	Minor	"self limited"	0
Johal				9		SSNa CRF	NR	NR	1	n/a	n/a	n/a	-
Jones	48	1999	RCT	30	Frozen	SSNBi	SSF	LMG	0	n/a	n/a	n/a	2
Jung	49	2019	Retro Case Series	102	Frozen	SSNBi & Intra-articular GHJ	SSN	US (IN)	0	No complications occurred in either group	n/a	n/a	0
Kamal	50	2018	RCT	50	NSSP	SSNBi	SSF	LMG	2	2 Vagal symptoms	NR	Transient	5

						SSNBi	SSN	US (IN)	0	No complications were observed	n/a	n/a	-
Kane	51	2008	Pro Case Series	12	Degen	SSNBp	SSN	II	0	There were no intraprocedural complications and no postprocedural complications.	n/a	n/a	0
Kang	52	2012	Pro Case Series	20	Mix	SSNBi	Inf	Fluro	1	Motor weakness	NR	NR	5
KasapoÄŸlu-Aksoy	53	2020	RCT	60	Neuro	SSNBi	SSN	US (IN)	0	None of the patients had side effects	n/a	n/a	0
Kaya	54	2017	Case Report	1	ASD	SSNBi	SSN	US (IN)	0	observed no complications	n/a	n/a	0
Khan	55	2009	Pro Case Series	31	Frozen	SSNBi	SSN	LMG	1	Vasovagal Collapse after GHJ (unclear)	NR	15 minutes	2
KiliÃ§	56	2015	RCT	41	Frozen	SSNBi	SSF	LMG	0	no complications were observed	n/a	n/a	0
Kim	57	2021	RCT	20	Neuro	SSNBp	SSN	US (IN)	0	No adverse events were observed in either group	n/a	n/a	0
Korkmaz	58	2010	RCT	40	NSSP	SSNBp	SSN	Fluro	0	No serious side-effects or complications were observed	n/a	n/a	1
KÃ¼lcÃ¼	59	2017	RCT	26	CVA/MND	SSNBi	SSF	LMG	0	We have not identified any	n/a	n/a	0
						SSNBi	SSF	Landmark+NS	NR	-	n/a	n/a	-
Lee	60	2020	Pro Case Series	52	Mix	SSNBi	SSN	Fluro	0	none reported adverse effects during and after the procedure.	n/a	n/a	0
Lewis	61	1999	Pro Case Series	16	Degen	SSNBi	SSN	LMG	0	No complications were observed during the present study.	n/a	n/a	0
Liliang	62	2009	Pro Case Series	19	NSSP	SSNBp	SSN	Fluro	1	Puncture wound	NR	1	3
Long	63	1987	Retro Case Series	50	NSSP	SSNBi	SSN	LMG	1	Pneumothorax (unclear)	NR	NR	1
						SSNBi	SGN	LMG	0	-	NR	NR	-
						Subscap	n/a	LMG	1	Seizure (unclear)	NR	NR	-
Lotero	64	2018	Retro Case Series	62	OA/ Degen Jt Disease	SSNBi	SSF	US (IN)	0	There were no complications	n/a	n/a	0

Luleci	65	2011	Pro Case Series	57	Mix	SSNBp	SSN	LMG	0	No side effects were reported at the peri-procedural period	n/a	n/a	0
Mardani-Kivi	66	2022	Pro Case Series	97	Frozen	SSNBi	SSF	US (IN)	0	We had no complications	n/a	n/a	1
Martin	67	2007	Pro Case Series	22	RCRSP	SSNBi	SSF	Fluro	0	There were no complications post treatment	n/a	n/a	0
						SSNBp	SSF	N.Stim	0	n/a	n/a	n/a	-
Masoumi	68	2017	RCT (Ab)	100	ASD	SSNBi	NR	US (IN)	12	2 Hypoxia, 10 nausea and vomitting	n/a	n/a	2
Mermekli	69	2022	Retro Case Series	101	Degen	SSNa	SGN	USS (IN) & NS	0	There were no significant immediate or long-term complications or adverse effects reported in our case series	n/a	n/a	0
				119		SSNBi	SSN	US (IN)	0	n/a	n/a	n/a	-
Monsour	70	2021	Pro Case Series	5	CVA/MND	SSNBi	SSN	US (IN)	0	There were no reported adverse event	n/a	n/a	0
Mortada	71	2015	RCT	96	Frozen	SSNBi	SSF	US (IN)	2	Post injection drowsiness (unclear)	Continued treatment	NR	1
						SSNBi	SSF	US (IN)	2	Injection site tenderness (unclear)	Continued treatment	NR	-
Malheiro	72	2020	Retro Case Series	71	Mix	SSNBi	NR	US (IN)	3	3 Vasovagal	NR	Transient	4
Noor	73	2021	RCT	60	CVA/MND	SSNBi	NR	Imaging (NR)	0	No significant side effects observed in any of our patients	n/a	n/a	0
Okmen	74	2017	RCT	59	RCRSP	SSNBp	SSN	Fluro	0	no complications were reported in both groups	n/a	n/a	1
Okur	75	2017	Retro Case Series	18	Frozen	SSNBi	SSN	US (IN)	1	Upper Limb circumference increase	NR	"transient"	2
Parashar	76	2021	RCT	60	Frozen	SSNBi	SSN	US (IN)	0	Few of the reported complications of SSNB like pneumothorax was not seen in our study	n/a	n/a	0
Pelloso	77	2022	Case Report	1	Degen	SSNBi	NR	US (IN)	0	There were no adverse events or harms	n/a	n/a	0
						SSNa	NR	US (IN)	0	-	n/a	n/a	-
Picelli	78	2017	Retro Case Series	10	Neuro	SSNBi	SSF	US (IN)	0	No adverse events occurred during the study	n/a	n/a	0

Picelli	79	2018	Retro Case Series	6	Neuro	SSNBp	SSN	USS (IN) & NS	0	No adverse events occurred during the follow-up period	n/a	n/a	0
Pieran	80	2010	Pro Case Series	21	Mix	SSNBp	NR	Fluro	1	Not reported	"minor"	NR	0
Rowlingson	81	1986	Retro Case Series	36	Mix	SSNBi	SSN	LMG	1	"fainted"	NR	"easily recovered!"	1
Saadatniaki	82	2012	Retro Case Series (Ab)	108	RCRSP	SSNBi	SSN	LMG	4	4 Pneumothorax	Recovered with medical treatment	NR	0
Saglam	83	2020	RCT	72	Mix	SSNBi	SSF	LMG	0	No adverse effects were seen in either group related to nerve block	n/a	n/a	2
						SSNBi	SSF	US (IN)	0	-	n/a	n/a	-
Salt	84	2018	Service Evaluation	40	Mix	SSNBi	SSF	LMG	1	"Light headedness"	NR	"few hours"	2
				8		SSNBi	SSN	US (IN)	0	No reports of harm associated with the procedure	NR	n/a	-
Schiltz	85	2022	RCT	35	Frozen	SSNBi	SSN	US (IN)	11	5 Pain at injection site (intense), 3 motor weakness (mild, 2hrs), 2 dysethesia, 1 vasovagal	Intense	NR	2
						SSNBi	SSF	US (IN)	4	1 Motor weakness, 2 pain at injection site (mild, 2 hrs) 1 vasovagal	Mild	2hrs	-
Schneider-Kolsky	86	2004	Pro Case Series	40	Mix	SSNBi	SSN	CT	15	5 Pain at injection site (slight pain, few hours), 5 headaches (mild to moderate, 24-48hrs), 2 nausea (mild, few hours), 1 localised swelling at injection site (mild, few hours), 2 numbness (NR, few hours)	"slight pain"	"few hours"	3
Shah	87	2003	Case Report	1	Degen	SSNBi	NR	Fluro	0	There have been no complications	n/a	n/a	0
						SSNBp	NR	Fluro	0	n/a	n/a	n/a	
Shanahan	88	2021	RCT (Ab)	54	Frozen	SSNBi + PT + GHJ Inj	NR	NR	1	Presyncopy episode	n/a	n/a	1
Shanahan	89	2003	RCT	83	Degen	SSNBi	SSF	LMG	1	Chest pain, 1 unrelated death (unclear)	NR	24hrs	0

Shanahan	90	2020	Pro Case Series	27	Neuro	SSNBi	SSF	LMG	0	There were no complications reported during the study.	n/a	n/a	2
Shanahan	91	2012	Retro Case Series	289	Mix	SSNBi	SSF	LMG	6	3 Vasovagal (few minutes), 2 motor weakness (within hours), 1 facial flushing	NR	"few minutes"	6
Shanahan	92	2004	RCT	67	Degen	SSNBi	SSF	LMG	2	Bruising	Minor	"settled quickly"	1
						SSNBi	SSN	CT	2	2 Local Injection site pain, Radiation exposure 1.5mSv	NR	"settled quickly"	-
Simopoulos	93	2012	Retro Case Series	9	Mix	SSNBi	SSN	Fluro	0	No adverse side effects were observed.	n/a	n/a	1
				6		SSNBp	SSN	Fluro	0	-	n/a	n/a	-
				6		SSNa	SSN	Fluro	0	-	n/a	n/a	-
Singhania	94	2021	RCT	60	Frozen	SSNBi	SSN	US (IN)	0	No adverse event noted pertaining to the procedure during the study duration.	n/a	n/a	0
Sinha	95	2020	Pro Case Series	30	Mix	SSNBi	SSN	US (IN)	0	Mild discomfort during the procedure was noted during the study period (unclear)	n/a	n/a	0
				27		SSNBp	SSN	USS (IN) & NS	0	Mild discomfort during the procedure was noted during the study period (unclear)	n/a	n/a	-
Sir	96	2019	Retro Case Series	31	RCRSP	SSNBp	SSN	USS (IN) & NS	0	No adverse effects or complications were observed throughout the follow-up period of 6 months.	n/a	n/a	0
Stogicza	97	2022	Retro Case Series	4	RCRSP	SSNBi	SSN	US (IN)	4	Post procedural discomfort	NR	2-3 days	1
						SSNa	SSN	USS (IN) & NS	4	Post procedural discomfort	NR	2-3 days	-
Suleiman	98	2015	Retro Case Series	5	Mix	SSNBi	SSN	Fluro	2	2 "intermittent short lived shooting sensations"		"short lived"	0
Taskaynatan	99	2012	Pro Case Series	27	Mix	SSNBp	SSN	USS (IN) & NS	0	No complication was observed	n/a	n/a	0
Taskaynatan	100	2005	RCT	60	Mix	SSNBi	SSN	LMG	n/a	No complications occured in the SSNB group	n/a	n/a	2
Terlemez	101	2020	RCT	34	Neuro	SSNBi Betha	SSN	US (Out)	0	No adverse events occurred during the study	n/a	n/a	0

						SSNBi	SSN	US (Out)	0	-	n/a	n/a	-
Tezel	102	2014	RCT	41	ASD	SSNBi	SSN	US (IN)	0	No side effects developed in any patient in the SNB group	n/a	n/a	2
Tran	103	2022	Pro Case Series	12	Degen	SSNBi	SSN	Fluro	0	Not reported	n/a	n/a	1
						SSNa CRF	SSN	Fluro	0	There were no reported signifcant adverse events that were related to the ablation procedure	n/a	n/a	-
Vander Cruyssen	104	2018	Retro Case Series (Ab)	26	NSSP	SSNBp	NR	US (IN)	1	Neuropathic pain	NR	2	0
Vecchio	105	1993	RCT	28	RCRSP	SSNBi	SSN	LMG	25	9 Paraesthesia (transient), 16 aching in the region of the injection (mild, 1 week) (group not specified)	NR	"Transient"	0
Verma	106	2019	RCT	70	Frozen	SSNBi	SSN	US (IN)	2	2 Tenderness at the injection site (moderate, 24-48hrs)	"moderate"	24-48hrs	4
Wienkers	107	2011	Case Report	1	RCRSP	SSNBi	Sup	US (IN)	1	Motor weakness	NR	8hrs	2
Wu	108	2014	RCT	60	Frozen	SSNBp	SSN	USS (IN) & NS	4	4 "pain at the puncture site" (mild, 1hr)	"mild"	1hr	4
Yalcin	109	2022	Retro Case Series	64	RCRSP	SSNBp	SSN	US (Out)	0	No complications were observed in the follow-up examinations of any of the patients	n/a	n/a	0
						SSNBp	SSN	US (Out)	0	-	n/a	n/a	-
Yang	110	2020	RCT	20	Neuro	SSNBp	SSN	USS (IN) & NS	0	No adverse events occurred during the follow-up period.	n/a	n/a	0
						SSNBi	SSN	US (IN)	0	-	n/a	n/a	-
Yasar	111	2011	RCT	26	Neuro	SSNBi	SSF	LMG	0	No complication related to the injections were observed in our study	n/a	n/a	0

Pathology	Treatment Modality	Target location	Localisation method
RCRSP – Rotator Cuff Related Shoulder Pain	SSNBi - Suprascapular Nerve Block Injection	SSN – Suprascapular Nerve	LMG – Land Mark guided
Mix – Mixed Pathology Cohort	SSNBp – Suprascapular Nerve Block Pulsed Radiofrequency	SSF – Supraspinous Fossa	US (IN) – Ultrasound (In Plane)
Degen – Degeneration	SSNa – Suprascapular Nerve Ablation	SGN – Spinoglenoid Notch	US (IN) NS – Ultrasound (In Plane) and Nerve Stimulator
ASD – Anterior Shoulder Dislocation		GHJ – Glenohumeral Joint	US (NR) – Ultrasound (Not reported)
NSSP – Non Specific Shoulder Pain		Sup – Supraclavicular	II – Image Intensifier, Fluro – Fluoroscopy
			NS – Nerve Stimulator
			CT – Computerised Tomography
			NR – Not reported

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