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Lack of standardization in dry needling dosage and adverse event documentation limits outcome and safety reports: a scoping review of randomized clinical trials

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ABSTRACT

Objectives: Examine: (1) whether variability in dry needling (DN) dosage affects pain outcomes, (2) if effect sizes are clinically important, and (3) how adverse events (AE) were documented and whether DN safety was determined.

Methods: Nine databases were searched for randomized controlled trials (RCTs) investigating DN in symptomatic musculoskeletal disorders. Methodological quality was assessed using the Physiotherapy Evidence Database (PEDro) scale. Included RCTs met PEDro criteria #1 and scored > 7/10. Data extraction included DN dosage, pain outcome measures, dichotomous AE reporting (yes/no), and AE categorization. Clinically meaningful differences were determined using the minimum clinically important difference (MCID) for pain outcomes .

Results: Out of 22 identified RCTs, 11 demonstrated significant between-group differences exceeding the MCID, suggesting a clinically meaningful change in pain outcomes. Nine documented whether AE occurred. Only five provided AEs details and four cited a standard means to report AE.

Discussion: There was inconsistency in reporting DN dosing parameters and AE. We could not determine if DN dosing affects outcomes, whether DN consistently produces clinically meaningful changes, or establish optimal dosage. Without more detailed reporting, replication of methods in future investigations is severely limited. A standardized method is lacking to report, classify, and provide context to AE from DN. Without more detailed AE reporting in clinical trials investigating DN efficacy, a more thorough appraisal of relative risk, severity, and frequency was not possible. Based on these inconsistencies, adopting a standardized checklist for reporting DN dosage and AE may improve internal and external validity and the generalizability of results.

KEYWORDS
Dry needling; safety; dosing; pain; trigger points

Introduction

Dry needling (DN) has been defined as the insertion of solid filament needles to treat pain and dysfunction of body tissues[1] without the use of injectate [2,3]. Systematic reviews have increasingly focused on DN<apos;>s efficacy, and the clinical application of DN [4–6]. While conclusions have been mixed, DN has demonstrated post-treatment pain reduction [5,7,8], increased pressure pain thresholds [4,9,10], and improved pain-related disability [4,6,8]. In comparison with other interventions, DN has been cautiously recommended over sham/placebo or no treatment [5,9,11] and recommended in conjunction with other common physical therapy interventions [4,12,13].

Other reviews concluded that there was insufficient evidence to support DN [12,14] or that DN was not significantly superior to other interventions [6,7,9]. Although some research supports DN, many authors recommend cautious interpretation of conclusions due to small sample sizes[11], heterogeneous populations [5,6,11], very-low [6,9,14] or low-quality studies [4,5,8], unclear risk of bias[15], no significant between-group differences [10–12], or no clinically meaningful between-group differences[15].

Although much of the focus has been on determining support for DN application, no review has attempted to account for how dosing variability impacts reported patient outcomes. A survey[16] of American physical therapists demonstrated variability in DN practice patterns, including frequency, technique and application with other multi-modal interventions. Only one systematic review[9] briefly mentions DN dosage variability. Pragmatic decision-making and specific training in different DN theoretical models may account for some variability in the DN technique [17–22]. For example, Hong[18]

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described a 'fast in and fast out' technique to elicit a local twitch response (LTR). While this technique is likely the most widely implemented, the literature is controversial regarding its use[23] and the importance of eliciting an LTR[23]. Furthermore, there is a lack of literature investigating DN dosage[24] or comparing different techniques [15,25,26]. Dosing parameters to consider include: (1) number of LTRs; (2) number of needles used; (3) number of muscles treated; (4) visit frequency; (5) total visits; and (6) speed and depth of pistoning[27].

In addition to questionable clinical efficacy on patient outcomes, there is growing concern over recorded adverse events (AE) and DN safety [16,28]. Only a handful of recent systematic reviews [4,6,7] have addressed AE and safety. The risk of AE and safety of DN application should be considered due to the invasive nature of the technique [29–31]. Recent surveys [16,28] suggest AE following DN may be more common than previously reported[32]. The surveys [16,28,32] that classified reported AE used or adapted several proposed methods [33–35]. Carlesso et al [34]. suggested standardized terminology and reporting in orthopedic physical therapy for cervical spine AE. Carnes et al [35]. proposed a more descriptive taxonomy to define and classify the severity of AE following manual therapy. Finally, White et al [33]. reported a method to classify AE following acupuncture. Unfortunately, there is no widely accepted method to quantify, describe or report AE in DN studies, which could impact the reported DN safety.

Therefore, the objectives of this scoping review were to: (1) examine whether variability in DN dosage affects clinical pain outcomes in symptomatic musculoskeletal disorders, (2) determine whether effect sizes from clinical trials with a significant between-group difference are clinically important, and (3) explore how AE were documented and whether the safety of DN was determined in symptomatic musculoskeletal disorders.

Methods

Literature search

In November 2020, a literature search was performed in nine databases: Academic Search™ Complete (EBSCOhost), Cumulative Index of Nursing and Allied Health Literature, CINAHL Complete® (Ovid), Embase® (Elsevier), PubMed® (National Library of Medicine), Rehabilitation Reference Center (EBSCOhost), Scopus® (Elsevier), SPORTDiscus (EBSCOhost), TRIP Pro and Web of Science™ (Clarivate Analytics) by an experienced medical librarian. Subject headings were used in CINAHL Complete, MeSH in PubMed, EMTREE in Embase. Topic search field tags were used in Web of Science, Academic Search Complete, Scopus, SPORTDiscus, and TRIP Pro were searched using keyword/text word searches. In addition, the databases that used subject headings (CINAHL, Embase, and PubMed) were also searched using either keywords or text words. These results were then combined (OR<apos;>d) with the results of subject heading searches. A spreadsheet was maintained throughout the process to capture data and search strategies for each of the individual databases and for reproducibility. Selected keyword/text word/field tags included: 'dry needling', 'dry needles', 'intramuscular stimulation', 'trigger point', dosage, effectiveness, efficacy, outcome, and exposure. Inclusion criteria limits were comprised of: (1) English language, (2) peer-reviewed, (3) academic journals, and (4) publication within the last twenty years. Selected exclusion criteria included: (1) acupuncture, (2) electric, (3) electro, (4) injection, (5) feasibility, and (6) overview.

Eligibility criteria

Eligibility criteria included randomized controlled or clinical trials from 2000–2021 investigating symptomatic subjects with musculoskeletal diagnoses and recording the Visual Analog Pain Scale (VAS) and/or Numeric Pain Rating Scale (NPRS). Trials investigating acupuncture, electro-acupuncture, electric dry needling, non-musculoskeletal diagnoses, asymptomatic populations, or non-muscle target tissue were excluded.

Selection process

Covidence software (Veritas Health Innovation, 2021), an online systematic review management tool, automatically duplicated the search results and was used to analyze search results. It was used for the initial screening and full-text analysis. Identified articles were independently reviewed by two authors (GK and TD). Review sequentially included removing any duplicates, appraisal of title and abstract of the articles for potential eligibility, and a full-text read of potentially eligible studies. Investigators were required to achieve a consensus on trials included. In case of discrepancy between both reviewers, a third author (SWP) independently participated to reach consensus for inclusion or exclusion from the study.

Assessment of methodological quality

A methodological quality assessment was performed using the Physiotherapy Evidence Database (PEDro) scale [36,37]. The PEDro scale is reliable [38,39] and valid[37] for assessing the quality of an RCT via scoring on 11 criteria. The first criterion represents the trial external validity, while criteria 2–11 represent the trial repeatability. The second through eleventh criteria are included in the overall PEDro score, ranging from 0 to

10. Certified PEDro scores were used for RCTs listed on the PEDro website. Two independent authors (GK and SWP) scored each RCT for Criteria #1 and independently scored any RCTs that did not have an official score listed on the PEDro website[36]. Consensus was reached by the two independent authors (GK and SWP) on hand-scored trials. A trial was considered moderate to high quality[37] when the PEDro score was > 6 out of 10 total points with scores 8 out of 10 total points rated as ideal quality[40].

Refinement of included trials

Further refinement of included trials allowed us to narrow the review and improve methodological quality. Trials were excluded based on the following criteria: (1) did not meet Criteria #1 on the PEDro Scale, (2) < 7/10 on the PEDro Scale, and (3) no statistically significant between-group differences reported. A hand search of RCTs was performed from January to July 2021. Articles that met the inclusion criteria were assessed using the process detailed above for inclusion in our data analysis.

Data collection process

For all RCTs included in the review, one author (GK) extracted data into a spreadsheet under the following categories: DN dosage, outcomes and reporting of AE. Dry needling dosage variables included local twitch response (LTR), number of LTR elicited, visit frequency, total visits, pragmatic vs. prescriptive design, needles per session, DN technique, region treated, and the number of muscles treated. Outcome measures included the VAS and NPRS. Reporting of AE comprised a dichotomous yes/no, details of AE reported if 'yes,' and any standardized means to classify/categorize AE.

Synthesis of results

The results of DN dosage variables and outcomes reported in included RCTs were organized into four categories: (1) DN compared to sham DN or placebo, (2) DN compared to other interventions, (3) comparison of DN in addition to other interventions, and (4) comparison of DN parameters. Furthermore the results of AE reporting were grouped together regardless of DN comparison.

Results

This scoping review adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[41] (Figure 1). Following hand screening for exclusion criteria, the original search yielded 92 RCTs. A hand search of the literature from January 2021 to July 2021 produced an additional 14 RTCs for a total of 106 RCTs sought for retrieval and eligibility assessment. Further full-text hand screening of the 106 RCTs excluded 12 as duplicates, four not meeting inclusion criteria, 33 with a PEDro score < 7/10, seven not

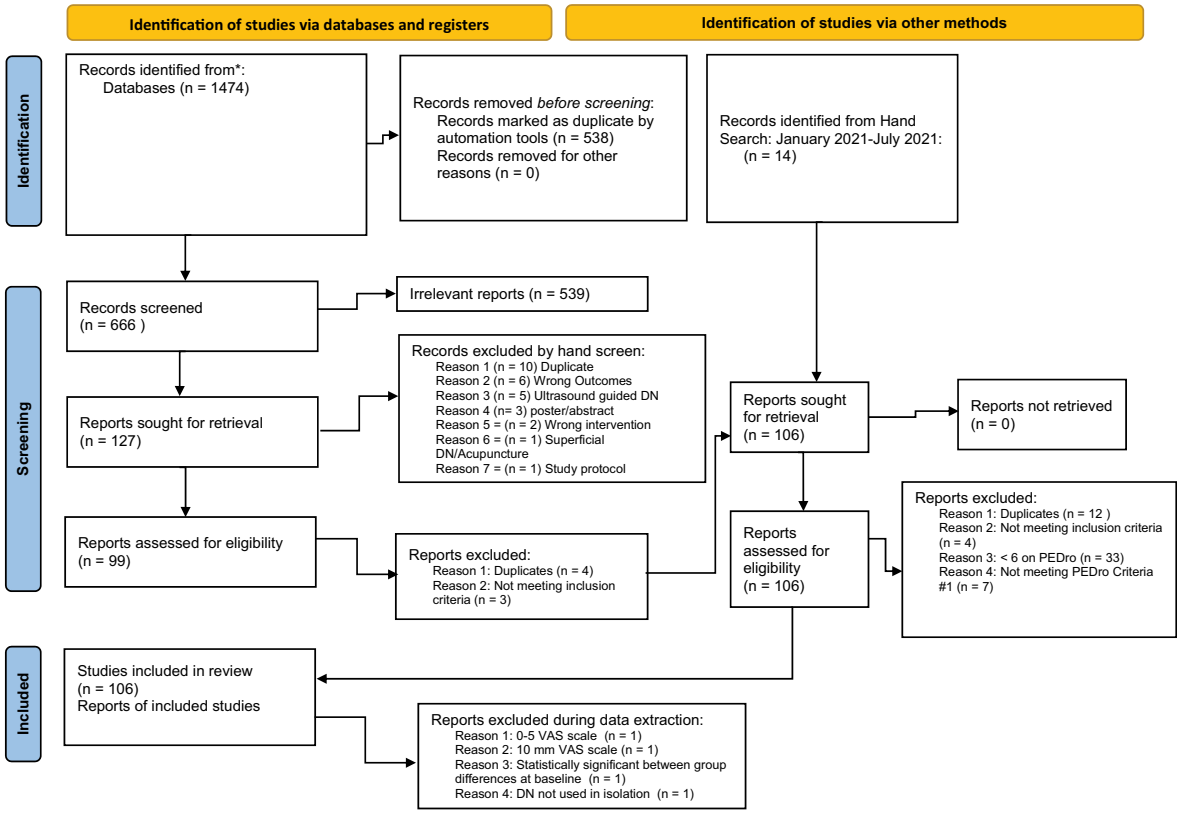

Figure 1. PRISMA Flow Diagram.

meeting PEDro criteria #1, and 28 not demonstrating statistically significant between-group differences. Twenty-two RCTs were included for final data extraction and analysis. The only consistently reported outcomes across the identified RCTs were pain measures. The pain measures included the VAS on a horizontal or vertical line of 100 mm, and the NPRS of 0–10. The VAS and NPRS are highly correlated in patients with low back pain (r = 0.92, p < 0.001)[42], knee osteoarthritis (r = 0.941, p < 0.001)[43], and treated in emergency room pain triage (r = 0.93, p < 0.001)[44]. Clinically meaningful differences were determined using the minimal clinically important difference (MCID) for the VAS [45–51] and NPRS [52–58] for the diagnoses studied to determine if the potential statistically significant differences were clinically meaningful from the patients' perspective[59]. The MCID values for the VAS included the following diagnoses: hip osteoarthritis (18.6 mm)[45], myofascial pain (24.8 mm)[46], plantar heel pain (19 mm)[47], patellofemoral pain (20 mm)[48], shoulder pain (9.9 mm)[49], low back pain (20 mm)[50], and cervical pain (4.6–21.4 mm)[51]. The MCID values for the NPRS included the following diagnoses: mechanical neck pain (1.3 points)[52], chronic mechanical neck pain (1.5 points)[53], patellofemoral pain (1.5–2 points)[54], chronic musculoskeletal pain (2.1 points)[56], chronic low back pain (2.4 points)[57], and shoulder pain (2.17 points)[58].

During the data extraction process, four additional RCTs [60–63] were excluded. Two [60,62] used pain outcome measures that, to our knowledge, do not have documented psychometric properties. One of the studies used a 0–5 scale to measure headache intensity[60], while another used a 10 mm VAS[62]. Another study had statistically significant between-group differences at baseline on the 100 mm VAS[50]. Lastly, an RCT combined the use of DN and ischemic compression without DN alone[63].

Comparison to placebo or sham DN

Six pragmatic RCTs [64–69] compared DN to either placebo or sham DN. Diagnoses included mechanical neck pain[68], plantar heel pain[67], patellofemoral pain[65], hip osteoarthritis[66], myofascial pain syndrome[69], and shoulder pain[64]. The DN dosage, type of pain outcome measure used (VAS vs. NPRS), p-values, and between-group mean differences larger than the MCID value reported as Yes or No are presented in Table 1.

Comparison to other interventions

Two pragmatic RCTs [70,71] compared DN to other interventions. Comparator interventions included pressure release[70] and Depo medrol injection [71]. Diagnoses investigated in the RCTs included chronic neck pain and plantar fasciitis. The DN dosage, type of pain outcome measure used (VAS vs. NPRS), p-values, and between-group mean differences larger than the MCID value reported as Yes or No are presented in Table 2.

Comparison of dry needling in addition to other interventions

Eight pragmatic trials [72–79] investigating DN in addition to other common musculoskeletal interventions. The studied diagnoses included in the RCTs were plantar fasciitis [73,76], discogenic low back pain[77], chronic ankle instability[78], chronic mechanical neck pain [74,79], female athletes with patellofemoral pain syndrome[75], and upper trapezius myalgia[72]. The DN dosage, type of pain outcome measure used (VAS vs. NPRS), p-values, and between-group mean differences larger than the MCID value reported as Yes or No are presented in Table 3.

Comparison of dry needling dosage parameters

Two trials [80,81] compared the influence of varying DN treatment parameters on outcomes. Both [80,81] were prescriptive and targeted one muscle during a single session [80,81]. Diagnoses investigated in these RCTs included nonspecific shoulder pain[80] in older adults and the lower trapezius in patients with mechanical neck pain[81]. The DN dosage, type of pain outcome measure used (VAS vs. NPRS), p-values, and between-group mean differences larger than the MCID value reported as Yes or No are presented in Table 4.

Adverse events

Nine [64,67,68,70,74,75,78–80] of 18 trials documented whether AE occurred in the DN group. Only five [64,67,78–80] trials provided details of the AE, whereas the remaining four [68,70,74,75] simply stated that no AE were reported. Four [68,70,78,79] trials cited a standardized means to report AE.

Discussion

This is the first scoping review to investigate whether variability in DN dosage affects clinical pain outcomes, determine whether effect sizes of DN are clinically important, and explore how AE documentation impacts reported DN safety. To narrow the scope of this review, studies with moderate to high quality (7 out of 10)[36] and ideal quality (≥ 8 out of 10)[40] on the PEDro scale were included.

Dosage

Multiple DN dosage variables were considered, including the number of needles per session, region treated, muscles targeted, elicitation of an LTR, number of LTRs,

Table 1. Dosage & Outcomes: Dry Needling compared to Placebo or Sham Dry Needling.

		Dosage							Outcomes		
Study	PEDro	Number of Needles	LTR	Number of LTR	Visit Frequency	Total Visits of DN	Technique	Region	Number of Muscles Treated	Outcome Measure	Between Group Change	MCID
Pai et al. 2021[64]	7	NR	No	No	One session	1	NR	CT	1	NPRS	$p < 0.01$	No
Ma et al. 2021[65]	7	NR	Yes	NR	One session/week x 6 weeks	6	Hong's fast in/ fast out	LE	3	VAS	$p < 0.05$	No
Ceballos-Laita et al. 2019[66]	7	NR	Yes	NR	One session/week x 3 weeks	3	Hong's fast in/ fast out	LE	5	VAS	$p < 0.004$	Yes
Cotchett et al. 2014[67]	9	2–8	Yes	NR	One session/week x 6 weeks	6	Pistoning and in-situ	LE	15	VAS	$p < 0.002$	No
Mejuto-Vazquez et al. 2014[68]	7	NR	Yes	NR	One session	1	Hong's fast in/ fast out	CT	1	NPRS	$p < 0.01$	Yes
Tekin et al. 2013[69]	7	NR	Yes	NR	2 sessions/week x 2 weeks, then one session/week x 2 weeks	6	NR	CT	NR	VAS	$p < 0.001$	Yes

C: Cervical; CT: Cervicothoracic; DN: Dry Needling; LE: Lower Extremity; LTR: Local Twitch Response; MCID: Minimally clinically important differences; NR: Not reported; NPRS: Numeric Pain Rating Scale; PEDro: Physiotherapy Evidence Database; VAS: Visual Analog Scale

Table 2. Dosage & Outcomes: Dry Needling Compared to Other Interventions.

		Dosage							Outcomes		
Study	PEDro	Number of Needles	LTR	Number of LTR	Visit Frequency	Total Visits of DN	Technique	Region	Number of Muscles Treated	Outcome Measure	Between Group Change	MCID
Arias-Buria et al. 2020[70]	8	NR	Yes	2 to 3	One session	1	Hong's fast in/fast out	C	1	NPRS	$p = 0.01$	Yes
Rastegar et al. 2018[71]	7	NR	No	No	One session	1	Pistoning	LE	NR	VAS	$p < 0.001$	Yes

C: Cervical; DN: Dry Needling; LE: Lower Extremity; LTR: Local Twitch Response; MCID: Minimally clinically important differences; NR: Not reported; NPRS: Numeric Pain Rating Scale; PEDro: Physiotherapy Evidence Database; VAS: Visual Analog Scale

technique(s) used, visit frequency, and total visits. Although the studies included in this review are considered moderate-to-high quality (PEDro score > 7), there was a lack of clarity and broad inconsistency reporting dosing parameters. Much of the variability may be attributed to the pragmatic nature of many investigations. For example, two included RCTs were prescriptive [80,81], and the remaining had pragmatic dosing [64–79]. Without more detailed reporting of all dosing parameters, replication of methods in future investigations is severely limited. The lack of detailed descriptions of dosing variables limits the generalizability of the findings to clinical application. Furthermore, due to variability across multiple parameters, we were unable to make any definitive conclusions on our primary purpose of whether DN dosing affects clinical outcomes in symptomatic musculoskeletal disorders.

The most poorly reported variable was the number of needles used per session with only two RCTs [67,80] providing details. There is currently no gold standard for an acceptable number of needles used per session. This dosing parameter was not a component in recent surveys [16,28] investigating DN practice patterns. There was variability within the two trials [67,80] that provided details with as few as one needle[80] and as many as eight needles[67] per session. A possible explanation was the variability in the body regions investigated and the number of muscles targeted per session. The most commonly investigated regions included the cervicothoracic spine [64,68,69,72,74] and lower extremity [65–67,71,73,76–78]. Other regions include the cervical spine [70,79], shoulder[80], lumbopelvic spine [75,77], and thoracic spine[81]. Some regions are larger and include more potential target muscles, which may explain the range of muscles targeted per session ranging from 1[64] [68,70,72,73,76,78,80,81], to 15[67]. Two investigations [69,71] did not specify the muscles targeted.

Across all of the studies included in this review, there was variability in the DN technique name and description. Four studies [64,69,77,79] failed to provide any detail of the technique investigated. The two most commonly cited techniques were Hong'>s fast

Table 3. Dosage & Outcomes: Comparison of Dry Needling in Addition to Other Interventions.

		Dosage								Outcomes		
Study	PEDro	Number of Needles	LTR	Number of LTR	Visit Frequency	Total Visits of DN	Technique	Region	Number of Muscles Treated	Outcome Measure	Between Group Change	MCID
Aras et al. 2020[72]	8	NR	Yes	NR	Three sessions/ week x 5 weeks	15	Pistoning	CT	1	NPRS	$p < 0.01$	No
Bagcier et al. 2020[73]	7	NR	Yes	NR	One session/week x 3 weeks	3	Processing or retracting	LE	1	VAS	$p < 0.001$	Yes
Gallego-Sendarrubias et al. 2020[74]	8	NR	Yes	NR	One session/week x 2 weeks	2	Pistoning	CT	2	NPRS	$p < 0.001$	Yes
Zarei et al. 2020[75]	8	NR	Yes	NR	One session/week x 4 weeks	4	Pistoning	LP	2	NPRS	$p < 0.01$	Yes
Eftekharsadat et al. 2016[76]	7	NR	Yes	To exhaustion	One session/week x 4 weeks	4	Pistoning followed by in-situ	LE	1	VAS	$p < 0.01$	No
Mahmoudzadeh et al. 2016[77]	7	NR	Yes	To exhaustion	Every other day. DN on visits 2, 4, 6, 8 and 10	5	NR	LP & LE	10	VAS	$p = 0.004$	No
Salom-Moreno et al. 2015[78]	7	NR	Yes	NR	Two sessions/week x 8 weeks	16	Hong's fast in/fast out	LE	1	NPRS	$p < 0.001$	Yes
Stieven et al. 2020[79]	8	NR	Yes	Up to 6	Not specified	4–6	NR	C	6	NPRS	$p < 0.001$	Yes

C: Cervical; CT: Cervicothoracic; DN: Dry Needling; LE: Lower Extremity; LP: Lumbopelvic; LTR: Local Twitch Response; MCID: Minimally clinically important differences; NR: Not reported; NPRS: Numeric Pain Rating Scale; PEDro: Physiotherapy Evidence Database; S: Shoulder; VAS: Visual Analog Scale

Table 4. Dosage & Outcomes: Comparison of Dry Needling Dosing Parameter.

		Dosage							Outcomes			
Study	PEDro	Number of Needles	LTR	Number of LTR	Visit Frequency	Total Visits of DN	Technique	Region	Number of Muscles Treated	Outcome Measure	Between Group Change	MCID
Calvo-Lobo et al. 2018[80]	7	2 (Active & Latent) 1 (Active only)	No	No	One session	1	Hong's fast in/fast out	S	1	NPRS	$p < 0.001$	No
Pecos-Martin et al. 2015[81]	8	NR	No	No	One session	1	Hong's fast in/fast out	T	1	VAS	$p < 0.001$	Yes

DN: Dry Needling; LTR: Local Twitch Response; MCID: Minimally clinically important differences; NR: Not reported; NPRS: Numeric Pain Rating Scale; PEDro: Physiotherapy Evidence Database; S: Shoulder; T: Thoracic; VAS: Visual Analog Scale

in/fast out [65,66,68,70,78,80,81] and pistoning [71,72,74,75,82]. Two investigations [67,76] coupled pistoning with leaving the needles in situ while one study[73] described the technique used as 'processing and retracting.' Despite the cited DN techniques having similarities, the inconsistency in technique name or description used in higher-quality RCTs introduces potential confusion when comparing outcomes.

One of the more consistently documented dosage parameters was the goal of eliciting an LTR [65–70,72–79] with the DN groups. This is likely reflective of the two most commonly used DN techniques, Hong<apos;>s fast in/fast out and pistoning, both of which aim to elicit an LTR[18]. The number of LTR elicited with needle manipulation is another dosage consideration in these studies. However, only four studies [70,76,77,79] specified the number of LTR recorded, ranging from 2–3[70] to complete exhaustion of the LTR [76,77]. Despite many studies included in this review documenting LTR, the lack of specifying the number of LTR elicited may lead to difficulty comparing results due to inherent pragmatic variability of the relative aggression of DN techniques used.

Variability in visit frequency and total number of visits was likely secondary to many of the pragmatic investigations included in this review. Visit frequency ranged from once per week [65–67,73–76] up to three visits per week[72] while the total number of sessions ranged from one single session [64,68,70,71,80,81] up to 16 total[78]. The only consistent pattern noted was that the two studies [80,81] comparing DN parameters all had a single session. Although variability in frequency and total visits of DN is likely reflective of pragmatic decision-making in clinical practice, it limits the generalizability of findings and provides little guidance on the most effective frequency of DN.

Clinical importance

Statistical significance does not always produce effect sizes resulting in clinically meaningful differences. Consequently, clinically meaningful differences on the VAS and NPRS were determined using the MCID. Eleven [66,68–71,73–75,78,79,81] of 18 trials reported effect sizes exceeding the MCID suggesting DN produced a clinically meaningful change. When DN was compared to sham or placebo, three [66,68,69] of six trials exceeded the MCID. When compared to other interventions, a single DN session produced outcomes exceeding the MCID in both trials [70,71]. When DN was used in addition to other interventions, five [73–75,78,79] of eight trials exceeded the MCID. Finally, when investigating different DN dosage parameters, only one[81] of two reported a clinically significant change.

The two most commonly investigated body regions were the cervicothoracic spine [64,68–70,72,74,79] and lower extremity [65–67,71,73,76–78]. Despite these regions representing 15 out of 18 included studies, there were no strong trends favoring DN. Five [68–70,74,79] of seven cervicothoracic spine investigations and only half [66,71,73,78] of the lower extremity investigations demonstrated clinically meaningful changes.

Whether assessing the included RCTs based off comparator type or body region, there was no strong trend suggesting DN consistently produces clinically meaningful changes. The clearest trend of outcomes exceeding MCID occurred when DN was combined with other interventions, which is consistent with prior recommendations [4,12,13] that DN be used in a multimodal patient care approach as opposed to an isolated treatment. Despite this small trend, we were unable to determine whether DN consistently produces clinically important changes in symptomatic musculoskeletal disorders. Some of the inconsistency in outcomes may be reflective of variability in DN dosage reporting.

Adverse events

There have been recent case reports [83–87] documenting significant AE following DN. However, there is inconsistency in the reporting of these events in the literature. Of the 22 studies included in this scoping review, only nine [64,67,68,70,74,75,78–80] explicitly recorded AE that occurred during the investigation. Four [68,70,74,75] simply reported that no AE occurred

in the DN group whereas five [64,67,78–80] provided specific details of the AE recorded. Adverse event details recorded included muscle soreness [78], needle stick pain[67], temporary exacerbation of pain[79] or headache symptoms[79], visible hematoma[80], and localized pain[64]. Beyond inconsistent detailed AE reporting, there was little to no standardized method to describe or classify the severity of AE. For example, three studies [68,70,78] cited Carlesso et al [34], and one[79] cited White et al [33]. as a standard method to classify and report AE. However, only two [78,79] actually recorded AE in detail. Given the lack of standardized AE reporting involved in the studies and the lack of documentation in those RCTs that did not report AE, the relative risk of DN remains unclear. Furthermore, none of the RCTs made any definitive conclusions or recommendations regarding DN safety.

Without standardized methods to report, classify, and provide context to AE from DN, reporting relative risk is lacking. Furthermore, without more explicit reporting of AE in DN clinical trials, a more thorough appraisal of relative risk, severity, and frequency is impossible. Without reporting standards, clinicians can only rely on surveys or case reports as a guide to report AE. Unfortunately, surveys or case reports often report rare AE only and are therefore unlikely to represent the relative risk accurately.

Several surveys [16,28,32] have attempted to capture the prevalence of AE from DN. While each survey uses a slightly different method of classifying AE severity, they all conclude that minor AE are common and may occur as often as 39.6%[16]. Common minor AE reported include bleeding, bruising, and pain during/after treatment [16,28,32]. Significant AE incidence has been estimated to range between < 0.04 %[32] and < 0.1%[28] with prolonged symptom aggravation as the most common [16,28]. Less common significant AE included pneumothorax[16], subdural hematoma[16], and infection [16,28].

Without more explicit recording and reporting of AE in peer-reviewed clinical trials, there will continue to be a lack of robust data on the relative risk and/or frequency of AE following DN that may guide clinical practice. Surveys [16,28,32] certainly provide a glimpse into the frequency of AE from practicing clinicians, but can only report data from those clinicians who willingly disclose the cause of an AE from DN and return the survey, leading to the possibility that AE may be underreported. Beyond AE reporting, there is no standard method to describe or classify the severity of region-specific AE. While there were many similarities in classifying AE in recent surveys [16,28,32], several different classification structures [32–35] were used or adapted.

Consequently, a standard method to describe and classify the severity of AE by body region would provide clinicians with more data on relative risk to consider before choosing DN as an intervention. Only Carlesso et al [34]. and White et al [33]. were cited as a standard method for reporting AE. Carlesso et al [34]. proposed standardized terminology and reporting of AE to the cervical spine, while White et al [33]. classified AE following acupuncture as serious, significant, or mild. Although not cited in any RCTs included in this scoping review, Carnes et al [35]. proposed a more descriptive taxonomy of defining AE from manual therapy treatment. Adverse events were classified as major, moderate, minor, or not adverse[35]. A standard method of reporting, classifying, and describing AE in future clinical trials would provide a more accurate estimate of DN relative risk.

Implications for future research

This scoping review found wide variability in DN dosage reporting. Therefore, we recommend more explicit reporting of all potential DN dosage parameters, including number of needles used per session, technique, region treated, number of muscles treated, whether eliciting an LTR was desired, number of LTRs elicited, visit frequency, total visits, and pragmatic vs. prescriptive design. While clinical decisions on the technique(s) chosen and dosage are often pragmatic, future investigations may address some inherent variability reported above by comparing different techniques, dosages, visit frequency, and using standardized functional outcome measures in addition to pain as an outcome to ascertain the most productive dosing of DN clinically.

Additionally, there was broad inconsistency and lack of transparency in reporting AE. Therefore, the most viable recommendation is to adopt a standard taxonomy[35] and terminology[34] for reporting DN AE during investigations. This would provide more clarity on the severity of AE, duration of AE, and context surrounding the AE. Furthermore, authors may consider specifying the acceptable post-treatment response to DN vs. what constitutes an AE *a*-priori. With a consistent method to classify and report AE from DN, the results of future studies would provide more robust data on the relative risk and incidence of AE that may guide clinical decision-making.

We propose adopting a standardized checklist (Supplementary Material) to address these inconsistencies for reporting DN dosage parameters and AE. A standard reporting system will improve the internal and external validity of future DN research design, create more consistency for DN dosage, enable better comparison between study results, and ultimately provide clinicians with more generalizable results.

Limitations

This scoping review has several limitations. First, the review was broad and exploratory, with results focusing on descriptive analysis of the data extracted. While the quality of each included RCT was evaluated using the PEDro, and all studies included in this scoping review had a PEDro score of ≥ 7/10, representing moderate to high quality, the risk of bias was not addressed.

Conclusion

Significant variability and lack of detailed description of DN dosage variables may reflect the pragmatic design of many included investigations but poses challenges replicating the design or comparing the results to other investigations. Therefore, we could not establish a specific DN dosage as superior to others in treating symptomatic musculoskeletal disorders. Furthermore, we were unable to establish whether DN consistently produces effect sizes that reflect clinically important changes. In addition, adverse event documentation was deficient in many investigations and, when included, lacked sufficient detail to give context to the AE. Inconsistent documentation of AE in DN trials may contribute to underestimating of the prevalence of AE. Based on these findings, future investigators may need to consider reporting more detailed DN parameters and adopting a more descriptive taxonomy to document AE to improve the generalizability of results.

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