Review of Stakeholder Input: “Dry Needling” Use by Arizona Licensed Physical Therapists

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I.Summary

The enclosed documents have been submitted to the Arizona Board of Physical Therapy in relation to the use of treatment called “Dry Needling” by physical therapists in Arizona and the Board’s ongoing review of the matter. The documents are included with the original compiling of records concluded September 17, 2013.

Statements Received September 30, 2013 to October 6, 2013:

A. Sean Flannagan Comments

B. DN Safety Research

C. DN Workgroup Commentary

D. Kim Rondina DN Position Statement

October 2, 2013

Dear Physical Therapy Board Members,

Thank you for taking the time to professionally address this issue of dry needling as performed by physical therapists. Your willingness and dedication to lead, guide, develop and protect our profession, and to protecting the public we serve is much appreciated and needed. I will address a few areas of concern to the board as they are deliberating this issue:

CURRENT DN EDUCATION PROVIDERS:

I have taken over 125 hours of dry needling continuing education from three different continuing education providers, and am certified through two of them. Having reliable knowledge of the four major continuing education providers, I know that each provider thoroughly goes over:

1. Indications, Precautions and Contra-Indications
2. Safety, Infection Control and relevant standards of the Center for Disease Control and Prevention, and Occupational Safety and Health Administration blood borne pathogen standards and how they apply to dry needling, as well as, management of DN adverse events and emergencies
3. Clinical reasoning, current evidence, and the review of pertinent anatomy for each area needled, as well as, psychomotor skill development needed to safely, competently and proficiently perform dry needling
4. All four providers have oral and practical testing, and three of the four have written examinations

Each of these providers emphasized patient safety and competent practice.

FOUNDATIONS

My doctoral education gave me the foundations with which allow me to grasp and grow into the full understanding of dry needling. Anyone who believes trigger point therapy, acupressure and Travell and Simons approaches to trigger point needling are not discussed within current graduate level physical therapy curriculums have either not gone through PT school in the recent decade, or are ignorant of the training of physical therapists. Every physical therapy student that I have recently encountered has heard of dry needling as an advanced practice area that is used to treat nueromusculoskeletal conditions. I know of 6 PT schools that have introductions to DN within their entry level curriculums, and in each of those curriculums it is described as advanced practice that students would have to pursue additional training post graduation. In physical therapy there are eight specialty areas of physical therapy: Cardiovascular and Pulmonary, Clinical Electrophysiology, Geriatrics, Neurology, Orthopaedics, Pediatrics, Sports, and Women's Health. Now as a student of physical therapy I was introduced to many concepts in my education that I have never used or been trained in because they go beyond the entry level eduction requirements and are outside my current area of specialization. Although I was taught about wound care and sharps debridement with a

scalpel, along with nerve conduction testing through the insertion of needles into the body, I don't practice them, because, to be deemed competent I would need to attain additional training. This board has already said nerve conduction testing, through the insertion of needles is within the scope of practice of physical therapy, but it was because the therapist in question at the time was competent through training. PTs that desire to perform DN need advanced training.

SAFETY

Being a member of the AzPTA DN Task Force, and closely following this issue, I know within the information you have had to review, you will find that the public safety concern around this issue has been answered thoroughly. Attached you will find a very recently published article that also addresses the safety issue, and shows "there were no significant adverse events in 7,629 dry needling treatments offered by physical therapists. The risk of a significant adverse event for dry needling by PTs was calculated to be 0.04%, which is considerably lower than the risk of taking ibuprofen (Brady S, et. al 2013). As a licensed therapist, I am required by law to practice safely and competently, and to not engage in activities that go beyond my scope of practice or which I am not competent in.

DIFFERENCE BETWEEN DN and Acupuncture

According to ARS 32-3901 "Acupuncture" means puncturing the skin by thin, solid needles to reach subcutaneous structures, stimulating the needles to affect a positive therapeutic response at a distant site and the use of adjunctive therapies. One of the major differences between dry needling and acupuncture is found in this definition. Yes, both professions use solid needles for treatment, but so do MDs, DOs, naturopaths, homeopaths, chiropractors, nurses, occupational therapists, athletic trainers and physician assistants, but it is agreed by most legal advisories, that one profession does not solely own a tool or technique thus each profession is regulated by it's own board and regulations.

The primary difference in this instance comes when you look at where that therapeutic response is directed. According to the acupuncturist definition they are attempting to and I quote: "affect a positive therapeutic response at a distant site." Please understand, every time I put a needle into a patient, I am directing my treatment to that particular location, in real, palpable, dissectible anatomical structures.

The foundations of acupuncture and oriental medicine are founded on ancient Chinese concepts and understandings of how the body works. This creates a lot of confusion in the medical model of treating patients. It also explains why there is a claimed 92 plus percentage correlation between acupuncture points and trigger points, because it's simply how they look at life and the body. For example: the lateral pterygoid muscle, was the lateral pterygoid muscle before it was called the pterygoid muscle or identified as ST 7 along Stomach Channel or meridian, however you name it, it is still what it is. The problem with this, is that ST 7 is listed as the corresponding point to 4 different muscle areas: The lateral pterygoid superior, lateral pterygoid inferior, superficial layer of the upper portion of the masseter posterior, and the upper portion of the deep layer of the masseter muscle. As a therapist, the acupuncture point ST 7 tells

me a general region that was treated and not the specific target tissue of treatment. For me to learn the Traditional Chinese Medicine (TCM) system of looking at the body would add confusion and possibly decreased the specificity of how I treat the body.

According to National Certification Commission for Acupuncture and Oriental Medicine, in order for someone to become an acupuncturists, they have to buy into Qi or essential energy, they have to believe that this energy travel along invisible lines in the body, that when disrupted or blocked cause human disease and dysfunction. I would have to believe in the concepts of Yin-Yang, and the 5 Elements theory and would have to look at the body in relation to a philosophical viewpoint of correlating the body to wood, fire, earth, metal and water.

The problem is, I don't believe that I have to look at a patient through those lenses in order to help them. TMC does not hold with, or support my western medical education or how I've been trained to look at the body. When I look at a patient who has low back pain, wether it be an acute or chronic lumbar radiculopathy, mechanical low back pain, sacroiliac dysfunction, or facet syndrome and I treat them with dry needling, it is because I know the neuromusculoskeletal anatomy and have arrived at a theoretical physical therapy diagnosis though my physical therapy evaluation. I then treat based on clinical reasoning directed by what the research and evidence suggests in regards to the mechanical, hypoalgesic (centrally and peripherally), neurophysiologic, chemical, and hormonal effects of dry needling, and what the evidence says about treating those conditions. I can identity the tissue I desire to treat, I can look at in texts, I can dissect in a cadaver and I can aim at it and treat it with a needle. For someone to say, I have to understand and buy into Chinese philosophy to attain a therapeutic response "safely" in my patients is simply wrong. TCM believes in Qi and an energy meridian system that isn't proven in the research or literature, and it would go against my training and personal world view. I'm not saying that TCM does not have value or a positive therapeutic affect, I'm saying it is not the only way to treat and look at the body. In contrast to providing a physical therapy diagnosis, acupuncturist, according to MacPherson et al 2004, LBP is diagnosed by acupuncture as "Qi and Blood Stagnation in 88% of patients, followed by Kidney Deficiency in 53% of patients, and the Bi Syndrome in 28% of patients, and more than one syndrome was identified in 65% of patients. I don't understand these diagnoses, nor do I feel I need to understand these diagnosis to treat my patients safely, competently and efficiency.

CONSUMER/PRACTITIONER FREEDOM OF CHOICE

In addition, there is a risk in restricting consumer choice if dry needling is taken away from therapists. Many patients do not buy into acupuncture due to it's roots in eastern philosophy. Case in point, one of my clients has a Doctorate of Theology and the thought of going himself, or taking his son to someone trained in TCM bothers him because his world view does not align with how they have chosen to look at the body. Taking dry needling away from physical therapists would restrict access for patients that would desire to receive the benefits of dry needling without them having to subject themselves to philosophies used in oriental medicine. As a consumer, if oriental beliefs do not fit within my world view, should I not be able to have access to practitioners that do not treat in line with oriental medicine, but that have a foundation in western medicine. It would be wrong to take consumer choice away from an informed public.

SUGGESTIONS

34 states have already approved DN as within the scope of PT, with Maryland being the first to approve it 20 years ago in 1984. In all but one of those cases this issue of scope was address by regulatory boards and not legislative actions. The only state in which DN is actually in the PT practice act is Georgia, and that was not done intentionally. PT's and acupuncturists in GA have had a history of working together, however, when recent legislation was passed, PT's were excluded as an oversight from needling. Once this oversight was noted the legislature promptly added an addendum allowing PTs to also perform DN.

It is my suggestions that this board release a statement that aligns with the AzPTA that:

"Dry Needling for the management of neuromusculoskeletal conditions is [a manual therapy technique] consistent with the scope of practice of licensed physical therapists in Arizona. Dry Needling is a skilled intervention performed by a physical therapist (PT), that uses a thin filiform needle to penetrate the skin and stimulate underlying neural, muscular and connective tissues for the management of neuromusculoskeletal pain and movement impairments."

This is a comprehensive definition that fully covers what we do as therapists in the clinic and the wording of the definition is crucial in that it will allow the practice of dry needling to grow with future research. Other definitions of dry needling have brought confusion and division to the practice by calling it intramuscular dry needling or trigger point dry needling and a number of other titles . . . but those are just single types of dry needling that have the potential to give preference to certain dry needling continuing education providers that are perpetuating calling dry needling by something beyond what it is and has the potential to restrict how therapist practice dry needling. (See letter to APTA DN Workgroup Commentary for further clarification.)

In addition, I believe it would be a wise decision of this board to require therapist to take at least 50 hours of advanced DN education, to be completed over a 6 month period in order to perform dry needling, with a provision that providers may needle the muscles they were originally instructed in during their 6 month training period.

I would not recommend the board to put a 1-2 year experience requirement on therapist wishing to perform dry needling. Only 2 states have a 2 year waiting period and although DN is considered advanced practice, the training programs available to therapist give thorough anatomical and palpation reviews that reinforce and already strong foundation provided through our entry level education. PT's have a quite extensive education background in anatomy, more than almost any other profession, and a number of Orthopedic Residency Programs that are including dry needling in their programs. Can you think of any other practitioner that comes out with a better anatomical foundation than PTs? When PTs first graduate, their anatomy knowledge is

probably the strongest and freshest in their minds. Childs et al. 2005 also showed PT students ranked above many MD's in their knowledge of musculoskeletal conditions. I think we should honor where we are as an entry level profession and put the responsibility on the individual PT and the continuing education providers.

Thank you for your time and energies you've put into the issue of dry needling. Please feel free to contact me with any questions, concerns or comments.

Professionally,

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Adverse events following trigger point dry needling: a prospective survey of chartered physiotherapists

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Objectives: Trigger point dry needling (TrP-DN) is commonly used to treat persons with myofascial pain, but no studies currently exist investigating its safety. The aim of this study was to determine the incidence of Adverse Events (AEs) associated with the use of TrP-DN by a sample of physiotherapists in Ireland.
Methods: A prospective survey was undertaken consisting of two forms recording mild and significant AEs. Physiotherapists who had completed TrP-DN training with the David G Simons Academy (DGSA) were eligible to take part in the study. Data were collected over a ten-month period.
Results: In the study, 39 physiotherapists participated and 1463 (19.18%) mild AEs were reported in 7629 treatments with TrP-DN. No significant AEs were reported giving an estimated upper risk rate for significant AEs of less than or equal to (≤) 0.04%. Common AEs included bruising (7.55%), bleeding (4.65%), pain during treatment (3.01%), and pain after treatment (2.19%). Uncommon AEs were aggravation of symptoms (0.88%), drowsiness (0.26%), headache (0.14%), and nausea (0.13%). Rare AEs were fatigue (0.04%), altered emotions (0.04%), shaking, itching, claustrophobia, and numbness, all 0.01%.
Discussion: While mild AEs were very commonly reported in this study of TrP-DN, no significant AEs occurred. For the physiotherapists surveyed, TrP-DN appeared to be a safe treatment.

Keywords: Myofascial pain, Dry needling, Adverse events

Introduction

Trigger point dry needling (TrP-DN) is an invasive treatment approach whereby a solid filament needle is inserted into a myofascial trigger point (TrP) in a muscle.[1,2] A TrP consists of a hyperirritable spot in skeletal muscle, associated with a palpable nodule in a taut band. When compressed, TrPs may give rise to characteristic pain, tenderness, or motor dysfunction.[3] Superficial dry needling (SDN) involves inserting the needle into the skin, fascia, and muscle overlying a TrP,[4] whereas, with deep dry needling (DDN) the needle is inserted into the TrP with the aim of eliciting Local Twitch Responses (LTRs).[5] Essential for obtaining therapeutic benefit with TrP-DN, LTRs are reflex spinal cord contractions of the muscle fibers in a taut band.[6–8] Eliciting LTRs can reduce concentrations of nociceptive chemicals, such as substance P and calcitonin gene-related peptide, found in the immediate vicinity of active TrPs.[9,10]

Trigger point dry needling is commonly used in clinical practice by physiotherapists in conjunction with other physical therapy modalities.[1] In many countries, including Ireland, the United Kingdom, Canada, and Spain, TrP-DN has been recognized to fall within the scope of physiotherapy practice.[1] In fact, the term 'intramuscular manual therapy' is considered by some to be a more appropriate term for TrP-DN as this technique is closely associated with manual therapy.[2] Research is emerging supporting the use of TrP-DN for conditions such as back and neck pain,[11–13] shoulder pain,[14] and upper quadrant myofascial pain.[15] Furlan *et al.*[16] conducted a systematic Cochrane meta-review of randomized controlled trials investigating acupuncture and TrP-DN for back pain. Trigger point dry needling was found to be a useful adjunct to other therapies in the treatment of persons with chronic low back pain. When used to treat individuals with temporomandibular pain and dysfunction, TrP-DN can also improve pain and movement.[17–19] Non-invasive approaches, including TrP compression release and spray and stretch, are also used to treat TrPs.[20–24]

Trigger point dry needling is an invasive technique with potential for Adverse Events (AEs).

Searches of Pubmed, Medline, and CINAHL by the authors did not find any studies investigating AEs and TrP-DN beyond the level of case study.[25]

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Evidence on the safety of needling techniques comes primarily from prospective studies investigating AEs following acupuncture.[26–31] Results from acupuncture AE studies cannot be extrapolated and applied to TrP-DN as it differs from acupuncture in the points treated and the method and depth of needle stimulation. As both involve the insertion of a solid filament needle, these studies do provide, however, potentially useful information about risks of needling therapies, similar to TrP-DN.

Witt *et al.*[30] carried out the largest prospective acupuncture study to date. Of the 229 233 patients who received 2.2 million acupuncture treatments, 8.6% of patients (n=19 726) experienced at least one AE. In this study, 24 377 AEs were reported, amounting to approximately one AE per 90 treatments (0.9%). Most were mild, including bleeding, hematomas, and pain. More serious events did occur with two reported cases of pneumothorax.[30] A prospective survey by White *et al.*,[28] involving physiotherapists and doctors, reported 2178 AEs in 31 822 consultations, giving an AE rate of 7%. The majority of these were considered minor AEs, including bleeding and bruising. Forty-three significant AEs were reported including one seizure, anxiety lasting 60 hours, cellulitis, and headache lasting 3 days. A significant event was defined as 'unusual, novel, dangerous, significantly inconvenient or requiring further information'. The lowest rate of AEs found in a prospective acupuncture study was in a study by Yamashita *et al.*,[26] whereby 94 mild AEs were reported in 65 482 acupuncture treatments (0.14%). The higher rates of reactions to acupuncture found in the literature include 11.4% (402 AEs in 3535 treatments) in a prospective acupuncture study by Ernst *et al.*,[29] which were not classified into mild or significant; and 15% in a prospective acupuncture study by MacPherson *et al.*,[27] however the majority of these could be viewed as positive such as feeling relaxed, and feeling energized.

The acupuncture evidence, although useful, is not sufficient for ensuring the safety of patients undergoing TrP-DN due to the differences that exist between the two techniques. Trigger point dry needling, especially DDN, is performed with greater needle depth and involves manipulating the needle within the muscle to elicit multiple LTRs,[1] whereas, with acupuncture, the needle commonly is inserted to the depth of the acupoint and manipulated gently until a dull ache called '*deqi*' is achieved.[32] The needle may then be left *in situ* for as long as 15–20 minutes. Furthermore, the education of acupuncturists and physiotherapists using TrP-DN is considerably different.[5] A specific study of AEs following TrP-DN was, therefore, deemed necessary. The aim of this study was to determine the incidence of AEs associated with the use of TrP-DN as practiced by a sample of physiotherapists with David G Simons Academy (DGSA) training in Ireland.

Methods

Definition

For the purposes of this study, an AE was defined as 'any ill-effect, no matter how small, that is unintended and non-therapeutic'.[33] This was chosen to include mild events and events that occurred through error.[28] Based on severity, AEs were sub-classified as 'significant' or 'mild'. The definitions for 'significant' and 'mild' events were adapted from those proposed by Carnes *et al.*[34] In the current study, a 'mild' AE was defined as short-term and non-serious, with no change in function, whereas the term, 'significant', was chosen to represent moderate or major AEs, described by Carnes *et al.*[34] as medium to long-term events that are serious, distressing and may require further treatment. In the study by Carnes *et al.*,[34] specific time frames were not included in the final definitions of mild, moderate, or major AEs. However, the general consensus (>74%) was that mild AEs lasted hours, moderate AEs lasted days and major AEs lasted weeks. These differed from the time frames discussed in a separate study considering AEs from the patient perspective.[35] In that study, a mild AE was described as lasting from a matter of hours to 2 days by different participants. Moderate AEs could last from 1–5 days and major for more than 2 days. Due to these discrepancies in the literature and the multi-factorial nature of defining an AE,[35] it was decided not to impose a strict time frame on distinguishing a mild AE from a significant one.

Ethical approval

Exemption from ethical approval was granted by the Human Research Ethics Committee of University College Dublin on 23 June 2011.

Study design

A prospective questionnaire design was used in this study to avoid recall error.

Survey forms

The questionnaire consisted of two forms, modified with permission from those used by White *et al.*,[28] and a demographic data form. The forms were piloted by two physiotherapists for 2 weeks and subsequently, small changes were made.

Form A was used to record the number of TrP-DN treatments completed monthly and any mild AEs experienced. Specific headings for recording mild events included: bruising, bleeding, pain during treatment, pain after treatment, headache, and other mild AEs. This form was completed and returned monthly to the researchers. The form used to record

physiotherapists' demographic data was returned with Form A following month one.

On a separate form (Form B) participants recorded any significant AEs. This could include: needling problems (e.g. forgotten needles, pneumothorax); systemic effects (e.g. fainting, vomiting); influence on symptoms (prolonged aggravation); or other significant events. Participants were asked to record the muscle being treated when the event occurred, the technique used, any necessary medical intervention, and the outcome. Form B was returned with Form A at the end of each month.

Subjects

In the study, 183 physiotherapists who had completed TrP-DN training with the DGSA were eligible to take part. Training with the DGSA in Ireland takes 64 hours[36] and is available only to physiotherapists. This includes a two-day course on foundations of myofascial pain and MTrP palpation. Physiotherapists then complete two, three-day TrP-DN courses. DN 1 is concerned with needling safety as well as needling techniques for the upper and lower extremities. DN 2 is completed some months later with emphasis on the muscles of the trunk spine and pelvis. This model has been used extensively in Switzerland and other European countries.

Recruitment

Eligible physiotherapists were invited by email to take part in the study by one of the authors (JM). Potential participants were advised to email the principal investigator (SB) directly if they wished to volunteer for the study. Reminder emails were sent at two and four weeks to non-respondents.

Distribution

Following recruitment, packs were mailed to participants containing: an information leaflet, contact details of the researchers, nine copies of Forms A and B, a demographic data form and nine stamped addressed envelopes. Participants were informed that each respondent would be assigned a code for reporting and only the principal investigator (SB) would have access to the codes. Confidentiality was assured and participants informed that by volunteering for the study they were giving consent for data to be used for this purpose.

Survey size

The study aimed to identify any rare AEs, meaning a sample size of greater than 10 000 treatments was necessary.[37] It was hoped to recruit a third of the 183 eligible physiotherapists ($n=61$). Through discussion with physiotherapists, it seemed reasonable that participants would use TrP-DN 20 times per month. A time frame of 9 months was calculated as being required to record 10 000 treatments.

Analysis

Results were analyzed using Statistical Package for the Social Sciences 18 (SPSS). Descriptive statistics were used to calculate frequencies of various AEs and rates of occurrence per 100 treatments.

Adverse Events were classified based on how frequently they occurred, ranging from very common (more that once in ten treatments) to very rare (less than once in 10 000 treatments) following the European Commission's (EC) recommended classification of AEs (Table 1).[37] Spearman's Rank Order Correlation (rho) coefficients were calculated to test for associations between participants' age, experience, TrP-DN experience, choice of SDN over DDN, and number of TrP-DN treatments completed with their rate of AEs. The Mann–Whitney test was used to compare medians for the seven most common AEs of participants with particularly high rates of AEs and the remaining participants.

Where an AE does not occur in a certain number of treatments (n), Hanley's Rule of Three[38] states that the upper risk rate is at most, three in n (i.e. $3/n$). This was used to estimate the upper risk rate of AEs that did not occur.

Results

In the study, 183 physiotherapists were invited to take part. Of these, 51 volunteered to participate and questionnaire packs were posted to all 51. Of the 51 volunteers, 39 returned at least one Form A giving a response rate of 76.47%. Demographic data (Table 2) were provided by 35 of the 39 participants (89.74%). Of the remaining four participants, one reported forgetting

Table 1 European Commission's (EC) recommended classification of Adverse Events (AEs)[37]

Very common	Common	Uncommon	Rare	Very rare
>1/10	1–10/100	1–10/1000	1–10/10 000	<1/10 000

Table 2 Demographic data for participating physiotherapists, $n=35$

	Age	*Experience (years)*	*TrP-DN experience (months)*
Mean	34.03	10.29	23.74
Standard deviation	8.21	8.89	16.73
Range	24–52	1–30	3–60

the form, the others did not respond to follow-up. The mean age of participants was 34 years (SD=8.21) with 30 females and five males taking part. The majority of participants worked in private practice (n=23, 65.7%), with four participants (11.42%) working within the Health Service Executive, which is the Public Health Sector in Ireland, and eight (22.86%), worked in both sectors. The respondents' physiotherapy experience varied from 1–30 years (mean=10.29) and TrP-DN experience from 3–60 months (mean=23.74).

Data were collected from September 2011 until June 2012 with each respondent asked to participate for 9 months. In total, 273 Form A were returned, detailing 7629 TrP-DN treatments. The majority of treatments (82.7%, n=6312) used DDN, with the remainder (17.3%, n=1317) using SDN. Three reports were excluded from analysis as two did not record the number of treatments completed and one was a duplicate. The number of treatments completed per practitioner varied from 10 to 990 (mean=195, sd=204.16). In this study, 1463 AEs were recorded, giving a rate of 19.18 per 100 treatments. All AEs were reported on Form A and considered mild. No Form B was returned, therefore no significant AEs were reported. Using Hanley's Rule of Three, the risk for significant AEs can be estimated to be at worst 1/2543 treatments (≤0.04%).[38]

Table 3 displays all mild AEs reported in the study. Data are presented in this table with rates per 100 treatments. The 'Extreme Values' column shows the highest recorded values for individual participants for each AE expressed as a rate per 100 treatments. Results are subsequently discussed using the guidelines suggested by the EC[37] and categorized from common (1–10/100 treatments) to rare (1–10/10 000 treatments).

According to the EC,[37] common AEs occur 1–10 times per 100 treatments. Four common AEs were recorded in the study. Bleeding was the most frequently reported AE, with 576 reported incidents, giving a rate of 7.55/100 treatments. Bruising was the second most frequently reported with 355 cases (4.65/100), followed by pain during treatment (n=230, 3.01/100), and pain after treatment (n=167, 2.19/100). Using the EC classification,[37] five uncommon AEs were identified. These occur 1–10 times per 1000 treatments. Aggravation of symptoms occurred 67 times, giving a rate of 8.78 incidents per 1000 treatments (8.78/1000). This was followed by drowsiness (n=20, 2.62/1000), feeling faint (n=17, 2.23/1000), headache (n=11, 1.44/1000), and nausea (n=10, 1.31/1000).

Although the target of 10 000 treatments was not reached, an approximate rate for rare AEs was calculated based on the EC classification (occurs 1–10 times per 10 000 treatments).[37] Patients experiencing fatigue or altered emotions were each recorded three times in 7629 treatments giving an estimated rate of 3.93/10 000 treatments. Each of the following AEs were recorded once: shaking, itching, claustrophobia, and numbness, by different physiotherapists giving an estimated rate for each of 1.31/10 000 treatments. Further information was provided for these rare AEs. The patient who was shaky recovered after 3 minutes. Itching was felt in the referral area of the gluteus medius for 2–3 minutes, which then dissipated. Numbness was experienced in the area of needling for 12 hours, a complete recovery ensued. Prone lying was the cause attributed to one patient experiencing claustrophobia during TrP-DN. The practitioner was unsure if TrP-DN was a contributing factor and changing the patient's position relieved this.

A large range was noted in the rate of AEs recorded per participant. The mean rate of AEs per 100 treatments was 24.18 (sd=20.09) with figures ranging from 3.13 to 93.1. Analysis using the Kolmogorov–Smirnoff test revealed data were not normally distributed therefore non-parametric tests

Table 3 Types of Adverse Events (AEs) reported in 7629 treatments with trigger point dry needling (TrP-DN)

Event	*Cases reported*	*Number per 100 treatments*	*Number (%) of physiotherapists reporting none*	*Extreme values recorded by individual practitioners per 100 treatments*
Bleeding	576	7.55	4 (10.25)	32.23, 30
Bruising	355	4.65	3 (7.69)	26.09, 21.84
Pain during treatment	230	3.01	9 (23.08)	20.75, 20.69
Pain after treatment	167	2.19	14 (35.9)	20.69, 18.4
Aggravation	67	0.88	22 (56.41)	10.99, 5.75
Drowsiness	20	0.26	32 (82.05)	4.44, 3.26
Feeling faint	17	0.22	28 (71.79)	4.17, 2.5
Headache	11	0.14	31 (79.49)	1.15, 1.1
Nausea	10	0.13	31 (79.49)	2.7, 2.22
Fatigue	3	0.04	37 (94.87)	1.77,.27
Emotional	3	0.04	37 (94.87)	1.59,.27
Shaky	1	0.01	38 (97.44)	3.03
Itching	1	0.01	38 (97.44)	0.47
Claustrophobia	1	0.01	38 (97.44)	0.16
Numbness	1	0.01	38 (97.44)	0.47

were chosen for analysis. Analysis using Spearman's Rank Order Correlation (rho) revealed no significant correlation between the participant's age (Correlation coefficient (r_s)=−0.113, P=0.520), experience (r_s=−0.175, P=0.316), TrP-DN experience (r_s=−0.121, P=0.487), choice of SDN over DDN (r_s=−0.027, P=0.878), or number of TrP-DN treatments (r_s=−0.164, P=0.346) with the rate of AEs.

Six participants reported rates of AEs per 100 treatments that were greater than 1 sd above the mean (>44.27 AEs per 100 treatments) greater than 1 sd above the mean (>44.27 AEs per 100). The Mann–Whitney test was used to compare medians for the seven most common AEs between these six participants and the remaining 33 participants. Medians were significantly higher among the outliers for bleeding (P=0.003), bruising (P=0.001), and pain during treatment (P=0.003). Medians were higher for the remaining AEs but were not statistically significant for pain after treatment (P=0.758), aggravation (P=0.154), drowsiness (P=0.898), and feeling faint (P=0.148).

Discussion

In this study, AEs were reported in 19.18% (n=1463) of treatments using TrP-DN. Adverse Events would therefore be considered very common.[37] All AEs reported were mild and no significant AEs were reported. This implies that the estimated risk of significant AEs using Hanley's Rule of Three[38] was ≤0.04% (3/7629). Therefore, in this study, the estimated rate of significant AEs can be considered, at worst, rare. Although no significant AEs occurred, the results should be interpreted in light of the sample size of the current study. Studies using greater numbers of treatments are needed to determine a more accurate rate of significant AEs.

When compared with similar prospective studies on acupuncture, the AE rate of 19.18% reported in this study appears high. Yamashita *et al.*[26] reported a rate of 0.14%, followed by Witt *et al.*[30] at 0.9%, White *et al.*[28] at 7%, and Ernst *et al.* at 11.4%.[29] Many factors may have contributed to the comparatively high rate observed in the current study. A different methodology was used by Witt *et al.*,[30] whereby AEs were reported by the patient. Patients view AEs differently from practitioners, with a change in function an important factor in whether a patient defines an event as adverse.[35] This may mean under-reporting of mild AEs if function is unaffected. AE reporting by practitioners versus patients has not been investigated for physiotherapeutic modalities, but, in other disciplines differences have been found.[39,40] In Yamashita's study,[26] AEs were only reported if the practitioner or patient felt it was a problem, which may account for the low rate of AEs in their study (0.14%).

The current study used a similar methodology to White *et al.*,[28] but that study reported a lower rate of AEs, 7%. Acupuncture and TrP-DN differ in the points treated and methods and depth of needle stimulation, and therefore are not directly comparable. It should be noted that there are many different schools of acupuncture with different treatment points and techniques.[5] The manipulation of the needle with TrP-DN to elicit multiple LTRs[1] is distinctly different from acupuncture where the needle is normally inserted to the depth of the acupoint and manipulated gently until a dull ache called *'deqi'* is achieved.[32] It is likely that compared with acupuncture, TrP-DN could lead to more local microtrauma resulting in bruising, bleeding, and pain.[41] In the current study, however, no significant AEs were reported in 7629 treatments, giving an upper risk rate for significant AEs of ≤0.04%.[38] This compares favorably with 0.14% in the study by White *et al.*[28] and 0.22% (AEs requiring further treatment) in the study by Witt *et al.*[30] The estimated risk of significant AEs in this study (≤0.04%) is also much lower than that reported for some over-the-counter pain medications (aspirin, 18.7%; ibuprofen, 13.7%; and Paracetamol, 14.5%).[42]

In the current study a large variation is seen in the rate of AEs reported per participant with figures ranging from 3.13–93.1/100 treatments with six of the 39 participants reporting particularly high rates of AEs. Among these six participants, rates of reporting of bruising (P=0.003), bleeding (P=0.001), and pain during treatment (P=0.003) were significantly higher compared with the other 33 participants. Participants were instructed to record any bruise as an AE, but the recording forms did not state how much bleeding or what level of pain constituted an AE. The definition of an AE was printed on all forms, but it is conceivable that different participants made interpretations as to what was meant by an AE. Varied rates of reporting could also arise due to differences in needling techniques or patient cohorts. The reasons for these differences are unknown as a follow-up of participants was not part of this study's methodology. White *et al.*[28] carried out a follow-up of participants with high rates of reporting and found that these participants had reported slight discomfort or a single drop of blood as an AE. Similar follow-up may be beneficial in future studies on TrP-DN. The definition used in the current study was chosen to be capable of identifying mild and significant events,[33] however, the delineation between what constitutes an expected and acceptable consequence of treatment and what is adverse is unclear. A recent Delphi study introduced the term 'not adverse' for events that are mild and transient with no alteration in function,[34] which were deemed by experts to be an acceptable consequence of treatment. When the patient perspective is considered,

mild pain with unaltered function may not be considered adverse.[35] Further studies may use an alternative system of reporting to account for events considered 'not adverse'. Problems can also arise due to the lack of consistency in the terms used for recording recording AEs. Calls have been made to standardize being made to standardize terminology.[43] This variation in terminology makes comparisons between similar studies difficult.

There are a number of limitations to the current study. No significant AEs were reported, therefore, the risk of significant AEs could only be estimated using Hanley's Rule of Three.[38] This should be interpreted with caution as it is only an estimation, and further large-scale studies are indicated. Participants may have been reluctant to report events where negligence could be inferred, as participants were potentially identifiable. Future studies should consider the benefits of anonymous reporting. Some AEs may have been wrongly attributed to TrP-DN, as participants were not asked to judge causality, thus leading to possible over-reporting of mild AEs. This study was designed as a prospective study in an effort to obtain the most accurate results. However, as forms were returned at the end of each month, it is possible that participants completed the forms retrospectively at the end of each month rather than as each event occurred, introducing the possibility of inaccurate reporting.

Adverse Events can and do occur with needling therapies and when choosing a treatment approach, the risk of both mild and significant AEs must be discussed with patients.[44] Clinicians should strive to maintain safety at all times and this paper provides practitioners using TrP-DN with a means of discussing the known risks in order to obtain informed consent.

Conclusion

Almost 20% of treatments with TrP-DN by the physiotherapists in this study resulted in a mild AE. Common AEs include bruising, bleeding, and pain. No significant AEs occurred and the estimated risk of significant AE was $\leq 0.04\%$ by Hanley's Rule of Three.[38] This must be viewed in light of the scale of the study and further large-scale studies are warranted.

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Dry Needling Definition Commentary

To whom it may concern;

My name is Sean Flannagan, PT, DPT and I've used dry needling daily in my practice over the last three years, and I am part of the AZ Dry Needling Task Force for the AzPTA. Through this process I was able to view the current draft definition which the APTA Workgroup has come up with:

Dry Needling: a skilled intervention performed by a physical therapist (PT) that uses a thin filiform needle to penetrate the skin and stimulate underlying myofascial trigger points, muscular and connective tissues for the management of neuromusculoskeletal pain and movement impairments.

As physical therapists, we treat neuromusculoskeletal conditions/diseases/syndromes through the neuromusculoskeletal systems/tissues. In reading the above definition, I have some concerns in-relation to how a manual physical therapist may look at the body and practice dry needling when treating patients.

In the above definition I see the muscular tissues, as well as, the skeletal tissues as implied by the connective tissue inclusion. Connective tissues is a more encompassing description than just skeletal tissues, which I like. Connective tissue includes bone, cartilage, loose connective tissues, and fibrous connective tissues which includes tendons and ligaments. This includes such structures as joint capsules (e.g. in TMD, I needle the joint capsule as well as the pterygoids, masseter etc.), or a tendon or teno-osseus junction which is needled/pecked for chronic tendonitis, or even includes scar tissue for that matter. Subsequently, this falls in line with the first peer-reviewed published journal article, Lewit, 1979[5] on "dry needling" by a Western medical physician who did not limit needle insertion into just muscular "trigger points"; in fact, just 2 of 14 named structures in this study of 241 patients were trigger points or muscle tissue—the other structures needled included ligaments, scars, tendons, bones, and teno-osseus insertion sites. They found the "needle effect", or immediate analgesia was obtained in 271/312 (86.8%) painful structures. It was concluded that dry needling is highly effective in the therapy of chronic myofascial pain, which is why we use needling within our practice of physical therapy. It seems inline with the literature that the APTA definition includes such anatomical or structural targets (muscular & connective tissues) in its definition of dry needling.

Where I have concern, is in the above definition there is no mention of neural tissues. As a manual therapist I attempt to treat and stimulate all three systems, and without adding in "neural" tissues we leave out one of the primary systems we are attempting to treat. I'm not a massage therapist, who primarily purposes to treat muscular tissues, but as a manual physical therapist, when treating a patient, I should take all three systems into account, especially with neuropathic conditions. My knowledge of neuroanatomy, neurophysiology, and neurodynamics should help guide my treatment. When it comes to neuropathic pain, at times, the nervous system is the primary system I'm attempting to stimulate, as well as, the musculoskeletal systems.

For example, at times I may use neuro-tensioning or flossing techniques aimed at promoting nerve mobility, or alternatively, I may purpose peri-neural dry needling for stimulation of the median nerve with carpal tunnel patients to stimulate healing. I am desiring to increase microcirculation, nerve conduction speeds, and decreased pain. In this case, I'm not purposing to treat either connective tissue, muscle or MTrPs during that treatment, but I'm targeting the neural tissues. Furthermore, I'm not purposing to move energy, chi or using meridians during this treatment, as TCM does. The treatment is based on a thorough understanding of neuroanatomy and physiology. The above definition does not appear to include this type of treatment.

Audette et al.[1] suggests, that with active MTrP, that the perpetuation of pain and muscle dysfunction in active MTrPs may be related to abnormal central nervous system processing of sensory input at the level of the spinal cord. It was demonstrated that in subjects with active MTrPs, bilateral motor unit activation could be obtained with unilateral needle stimulation of the trigger point. The presence of bilateral or mirror image LTRs in subjects with active MTrPs argues strongly for a "central" abnormality rather than a purely peripheral abnormality in patients with active MTrPs. Should we not include the nervous system and tissue in our definition? Should we limit it to MTrPs if their is a suggestion of central component that is neural in nature? Should we not research this more thoroughly in the future?

Without the inclusion of the neural tissues in our statement, there could be an argument against physical therapist needling with the purpose of affecting that system in either treatment or in future research. Our definition should be one that allows us to explore, through future research, the possibilities and not tie us to solely our current understandings. It is important that the research guide our practice, and not singular schools of thought.

I would suggest the following ending to the definition:

<u>. . . stimulate underlying neural, muscular and connective tissues for the management of neuromusculoskeletal conditions and movement impairments to improve pain, disability and function.</u>

You'll see I've left out "myofascial trigger points," which was done on purpose. A myofascial trigger point is a "condition" present in the neuromusculoskeletal systems, within the muscular tissues. It's not an anatomical structure, although you can see chemical and histological changes in the tissue, it's a condition within a muscle (structure). Am I really "stimulating" a trigger point, or is that just the condition I am treating? Am I not stimulating the three tissue systems in order to "deactivate" the condition of a trigger point? Do I just treat MTrPs? What about chronic tendonitis, when we needle teno-osseus structures, are we not doing so with the theory of recreating the fibroblastic stage of healing? Isn't this what a manual physical therapist does when they perform cross-friction massage on a structure? Chronic myofascial pain can go far beyond just MTrPs, as discussed in earlier in the Audette et al study.[1] Why should we narrow our definition to MTrPs? As a manual physical therapist, why should I think like a massage therapist, when my understanding of the body is goes far beyond that?

In addition, we say we are treating MTrPs, but the literature doesn't even support that we have a reliable construct of identifying them. We are treating muscle tissues where we "believe"

there to be a MTrP, so is it not enough just to state muscular tissues? I say this for the following reasons:

In a recent systematic review on the reliability of the physical examination for the diagnosis of myofascial trigger points, Lucas et al[6] noted, "There is no accepted reference standard for the diagnosis of trigger points, and data on the reliability of physical examination for trigger points is conflicting." Moreover, Lucas et al conclude, "…a predictable pattern of pain referral and the local twitch response are each no longer considered to be sufficient or necessary for the diagnosis of a trigger point."[6] In that same systematic review, after reviewing nine studies on reliability, Lucas et al further concluded the following, "None of the nine studies in this systematic literature review specifically reported inter-rater reliability estimates for the identification of the location of active trigger points in symptomatic participants…. At present, there is no data on the reliability of pinpointing the exact location of active trigger points…. The existing data on reliability pertain only to agreeing if a muscle has the signs of a trigger point and not the exact location of the taut band or the nodule within the taut band . . . It is not yet evident that examiners can agree on the precise location of an active TrP; hence, they cannot be relied upon to accurately insert the needle into the nodule of the taut band." One study[4] reported inter-examiner agreement was only 21%, and the other study[8] reported error rates of 3.3 cm to 6.6 cm between examiners for the specific location of the latent TrP in the upper trapezius muscle. In yet another recent literature review, Myburgh et al 2008[7] found "insufficient evidence" for the reproducibility (i.e. poor inter-examiner reliability) of manual palpation of trigger points in various muscle groups, and only "tenderness" of the upper trapezius was found moderately reliable, not the actual location of the trigger point. Furthermore, in another recent systematic review, Tough et al[9] concluded, "There is a lack of robust empirical evidence validating the clinical diagnostic criteria [for TrP identification or diagnosis] proposed by both Travell & Simons (1999) and Fischer (1997)."

If acupuncturist really knew what the literature actually reports, and we base our whole argument on "myofascial" trigger points that we've shown we can't reliably identify, our current definition could potentially weaken, and not strengthen our position as a profession. Evidence based or informed practice is what we are touting as a profession, should not our definition reflect the evidence and what we are doing?

Can I really say to my patients and the public I am stimulating a trigger point I cannot even reliably locate according to the literature? It would be more appropriate and correct to inform them I am treating the muscle in which I believe there is a trigger point in. Yes, in practice, my goal is to needle the exact primary active TrP initially, but that is in theory and not what the evidence shows, since we are not reliable or valid in our ability to locate the exact location.

Do we treat MTrPs? Yes, but we also treat much more, and their are multiple schools of thought on dry needling. I believe our definition should allow us to explore other possibilities beyond the MTrP model, such as the radiculopathy model (Gunn), the superficial dry needling (Baldry), as well as, paraspinal/segmental dry needling coupled with distal dry needling, allowing us to investigate various neuromusculoskeletal conditions and tissues. We should be allowing the evidence to guide our practice and not just one school of thought. This models where manual therapy currently is, with multiple schools of thought all attempting to research

and be guided by the evidence. Our definition should encompass the various theoretical models of dry needling, allowing us to research each in the future.

Lastly, I like "conditions" better than "pain" at the end of the statement . . . we treat so much more than just pain, we treat cervicogenic headaches, TTH, migraines, knee OA, shoulder impingement, plantar fasciitis etc . . . which may be better described as conditions and not merely pain. Pain is usually the result or the symptom of the condition or underlying pathological process or disease. We alleviate pain by not treating pain, but the neuromusculoskeletal systems/tissue that are signaling the brain to say pain. In addition, by adding . . . "to improve pain, disability and function" . . . the APTA would be aligning its definition with how the literature reports results: pain, disability and function (movement).

Our definition should be one that encompasses multiple schools of thoughts and allows each to contribute to the research and so we may grow beyond our current understanding.

Thank you for taking your time to consider this unsolicited commentary, and for the dedication and time you have taken to protect and promote our profession.

Professionally,

Sean O. Flannagan, PT, DPT (drsean@oneaccordpt.com)

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Date: October 28, 2012

To: Arizona State Board of Physical Therapy

Re: Dry Needling and Physical Therapist practice in Arizona

Position: In favor

Board members:

My name is Kim Rondina and I have been licensed to practice physical therapy in the state of Arizona for the past 11 years. I was grateful for the opportunity to attend Wednesday night's public meeting and to experience what influences our practice at the state level.

I fully respect the passion that was demonstrated by the licensed acupuncturists that shared their position, yet the missing element of fact throughout their statements cannot be overlooked. Numerous physical therapists addressed issues from a position of objective data rather than opinion. Those are now part of the record and I trust the Board to further investigate any missing information that is objectively available including APTA's Dry Needling resource paper prior to making any decision.

I had initially planned to speak on a variety of issues related to dry needling including patient safety, training / competence, 'ownership' of a technique and scope of practice, but as the evening progressed I found myself identifying a different theme, that being WHO defines our scope of practice as physical therapists in the state of Arizona and how that definition is influenced.

Our profession began as 'reconstruction aides' during World War I and has evolved and progressed over the decades. During that time we have shared many responsibilities and skills with medical physicians, osteopathic doctors, chiropractors, athletic trainers, massage therapists, nurses, occupational therapists, personal trainers, wellness coaches within the scope of our practice.

Any one of those professions could claim the same concerns that acupuncturists are now presenting to the Board, that we are performing a skill that we are somehow less competent to perform or those that 'belong' to another profession, let it be manipulative therapy or an injury assessment.

As a very proud member of our profession and the functional impact that we have on the individuals and communities that we serve, I am concerned that any action by the Board that limits our ability to skillfully utilize techniques that integrate our extensive knowledge, training and expertise would have long term implications to the public's health. Dry needling's purpose as performed by physical therapists is NOT acupuncture and eliminating our ability to perform this technique focusing on improving neuromusculoskeletal function would starve the public of a valuable, proven and safe treatment option. In 2011, properly prescribed and correctly taken pharmaceutical drugs were the third leading cause of death in the U.S (investigative reports by the Institutes of Medicine), many of which could potentially be prevented with the use of safer alternatives such as dry needling.

I heard many opinions Wednesday night that described the use of dry needling by licensed and trained physical therapists as unethical, incompetent, and negligent none of which have been substantiated.

Public safety is the primary responsibility of not only the Board, but of every licensed healthcare professional. If our practice is governed by fear of potential injury, then many of our therapeutic interventions could potentially fall to such regulation. Are doctors prohibited from performing surgery because there is a risk of serious injury even with 'routine' procedures? Competence is established, patients give and sign informed consent, and a regulatory board has been established to protect the public from incompetent, unprofessional, unlawful practice and to investigate and adjudicate complaints against licensees.

This is not simply an issue about dry needling, but rather WHO defines WHAT we are as physical therapists. The potential implications are significant if we allow other provider types to establish the scope in which we practice, not only to our profession but to the hundreds of thousands of individuals that benefit from skilled physical therapy every year.

Respectfully,

Kim Rondina, PT