Clinician-Reported and Patient-Reported Incidence of Mild and Significant Adverse Events Associated with Dry Needling by Physical Therapists: A Pilot Study

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INTRODUCTION

- Dry needling (DN) is a skilled intervention that uses a thin filiform needle to penetrate the skin and stimulate underlying myofascial trigger points, muscular tissues, and connective tissues for the management of neuromusculoskeletal pain and movement impairments.[1]
- Evidence suggests that DN performed by physical therapists (PTs) is an effective adjunct intervention for patients with neuromusculoskeletal dysfunction[2]
- To date there is only one known study, conducted in Ireland, analyzing adverse events (AE) by PTs performing DN.[3] In that study, mild AEs were reported by providers in 19.18% of treatments. No serious AEs were reported.[3]
- Little is known about the incidence of AEs as reported by patients (Pts), and no studies have been published to date regarding the incidence of AEs associated with DN by PTs in the United States.

AIMS AND HYPOTHESES

Aim 1: To assess for differences in the rates of various adverse events as reported by physical therapists as compared to rates as reported by patients

- Hypotheses:
  - Therapist-reported incidence will be higher than patient-reported incidence for mild AEs.
  - Patient-reported incidence will be higher than therapist-reported incidence for significant AEs.

Aim 2: To assess for the incidence of adverse events during and/or following dry needling performed by physical therapists

- Hypotheses:
  - Incidence of mild AE's will be "common" or "uncommon" per the European Commission's (EC) recommended classification of adverse events.[4]
  - Incidence of significant AE's will be "very rare" per the EC recommended classification of adverse events.[4]

Table 1. EC recommended classification of AEs[5]

Very Common	Common	Uncommon	Rare	Very Rare
>1/10	1-10/100	1-10/1000	1-10/10,000	<1/10,000

METHODS

- Prospective Questionnaire Study (Brenau University IRB#: 1022968-2)
- Participating PTs were recruited from out-patient physical therapy clinics in the southeastern United States.
- Over a 4-month period, PTs tracked all DN interventions performed via a daily log and subsequently recorded any AE that occurred during or after intervention based on objective assessment and/or patient report.
- Following each DN intervention, the patients were given a card that contained a URL link to a survey and a unique code tied to that intervention session. They were instructed to go to the link, enter their code, and log any AE event(s) that occurred during or subsequent to that day's intervention.
- Clinician logs were collected weekly and entered into a database, while the patient survey responses were entered into the database in real time.
- The EC recommended classification of AE was used to categorize the observed incidence of AEs from very common (>1/10 treatments) to rare (1-10/10 000 treatments).[5]

RESULTS

Table 2. AEs as reported in 523 treatments with DN

Event	Incidence† as reported by PTs	Incidence† as reported by Pts
M1: Bruising/Hematoma	0.96	0.57
M2: Feeling faint or lightheaded - without fainting	0.19	0.38
M3: Mild-moderate nausea, without vomiting	0.19	0.19
M4: Headache	0.38	-
M5: Mild-moderate drowsiness that doesn't impair driving or operation of machinery	-	0.19
M6: Bleeding at needling site	20.84**	13.38**
M7: Needling site pain during treatment (more than expected)	5.16*	1.53*
M8: Needling site pain after treatment - lasting < 72 hours	1.34*	1.91*
M9: Mild-moderate aggravation of symptoms after treatment	5.74*	0.76
M10: Other mild adverse events	0.57	0.19
S7: Fainting/ Loss of Consciousness (LOC)	-	0.19
S9: Drowsiness Causing Hazard	-	0.19
S12: Sympathetic response	0.19	-

**Common, **Very Common; † Incidence is per 100 treatments*
M10 responses included: 2 "sweating", 1 "soreness"

RESULTS (cont.)

Table 3. Incidence of any, minor, and significant AEs

	PT Reported Incidence†		Pt. Reported Incidence†	
	Events	Incidence‡	Events	Incidence‡
Any AE	186	35.56	102	19.50
Minor AE	185	35.37	100	19.12
Significant AE	1	0.19	2	0.38

n = 523 treatments; †Incidence is per 100 treatments

CONCLUSIONS

- This pilot study provides valuable information that can be utilized in developing a large-scale study – including the finding that pts are more likely to report significant AEs - but less likely to report minor AEs - than PTs.
- Overall incidence of mild AEs was "very common".
- Overall incidence of significant AEs was "uncommon"; however, no AEs required follow-up medical care.
- DN performed by PTs appears to be a safe intervention.

LIMITATIONS AND DIRECTIONS FOR FUTURE RESEARCH

- Limitations include a small sample size of treating PTs and a small number of DN interventions. In addition, some PTs and Pts expressed confusion in how to answer some questionnaire items – particularly as related to S9 and S12.
- Future large-scale studies should incorporate pt reporting – as it appears their responses differ from that of PTs.
- Future studies should also include recruitment of a larger number of physical therapists and more robust training for PTs and Pts alike related to the individual items.

REFERENCE LIST

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