FAQ Dry Needling Adverse Events

Physiotherapy Alberta
College + Association

Introduction

Dry needling is associated with risks that can lead to adverse events. Physiotherapists are legally obligated to ensure they obtain informed consent from their patients. The dry needling informed consent process requires material risks and special risks of treatment be disclosed to patients.[14]

Research into adverse events related to dry needling is continually evolving. There are wide variations in research design including differences in the classification of adverse events which, for physiotherapists, makes interpretation and comparison between studies difficult, thus adding to the complexity of the risk disclosure process.[8]

Prior to 2014, only large scale studies examining adverse events related to acupuncture were available.[4,5,10,12,18,19-22] Brady et al are the first to publish a prospective study of adverse events related to trigger point/IMS dry needling.[1]

To support physiotherapist's communication with patients about the risks of dry needling, questions about adverse events associated with acupuncture and trigger point needling are answered.

Dry needling includes acupuncture, intramuscular stimulation, trigger point needling and other forms of needling with a solid filament style needle (i.e., Gokavi technique, motor point needling).

Adverse event: An unexpected and undesired incident directly associated with the care or services provided to the patient; an incident that occurs during the process of providing health care and results in patient injury or death; or an adverse outcome for a patient, including an injury or complication. The act of puncturing the skin comes with a number of predictable adverse events (bruising or bleeding, pain during or following treatment) which commonly occur and are mild in nature. A physiotherapist may consider these normal side effects of treatment. However, from the patient's perspective they may be considered adverse particularly if the patient has not been educated about the risks associated with their dry needling technique.

1. What types of adverse events are related to dry needling?

White et al used the following system to classify adverse outcomes associated with acupuncture combining several reports including a prospective study examining 31,822 treatments.[19,21]

- Mild (minor) – short duration, reversible, does not inconvenience the patient.
- Significant – requires medical intervention or interferes with patient's activities.
- Serious – requires hospital admission with potential persistent or significant disability or death.

Types of Acupuncture Adverse Events by Severity[#]		
Mild (Minor)	Significant	Serious
• Bruising • Bleeding • Pain during treatment • Pain following treatment • Aggravation of symptoms followed by improvement • Feeling relaxed/ energized • Feeling tired/ drowsy • Feeling faint • Dizzy • Nausea • Sweating	• Prolonged pain at site • Extensive bruising • Profuse sweating • Severe nausea • Vomiting • Fainting • Headache • Extreme fatigue • Severe emotional reaction • Gastrointestinal disturbance • Skin irritation • Slurred speech • Forgotten needle/ patient • Seizure	• Pneumothorax • Puncture of other vital tissue • Systemic Infection • Broken needle
[#] Adapted from White 19-21, MacPherson 10 Witt 22		

Other prospective acupuncture safety studies describe similar events but may group the mild and significant events differently.[5,10,12,18,23] Between studies there is general agreement as to what constitutes a serious adverse event.

Brady et al studied adverse events in 7,629 dry needling/ trigger point treatments and found that the types of adverse events that occurred are similar to that experienced with acupuncture.[1] A limitation of this groundbreaking study is the number of treatments is relatively small compared to acupuncture studies. All adverse events were classified as mild with the most frequent being bleeding, bruising, pain during treatment and pain after treatment.

Physiotherapists who perform needling are expected to regularly scan the literature to ensure their knowledge of probability and severity of risks associated with the dry needling technique they perform is current.

2. Are all significant or serious adverse events discussed in the information above?

No. For example cases of cardiac tamponade have been reported twice in the literature but in the large-scale prospective studies did not occur.[4,20] Only conditions that occurred more frequently in the large studies were listed herein.

3. How frequently do adverse events occur?

The European Commission Classification System for medicinal products[7] has been used to discuss adverse events related to dry needling.[1,22]

Very Common	Common	Uncommon	Rare	Very Rare
>1/10 people treated	1-10/100 people treated	1-10/1000 people treated	1-10/10,000 people treated	< 1/10000 people treated
≥10%	≥1-10%	≥0.1% - 1%	≥0.01% - 0.1%	<0.01%

The Health Quality of Council of Alberta compared dry needling adverse events across studies[8] and found that:

- Minor adverse events occur more frequently.
- Serious adverse event are very rare (0.04/10000 treatments).
- Pneumothorax is the most common serious adverse event and is very rare (0.01/10000 treatments).

Number of adverse outcomes reported in prospective research studies				
Research Study	# of treatments	Minor Adverse Outcome	Significant Adverse Outcome	Serious Adverse Outcome
White et al 2001	31,822 treatments	2,135	43	0
MacPherson et al 2001	34,407 treatments	10,920	43	0
Melchart et al 2004	760,000 treatments (97,733 patients)	6,936		6 (includes 2 pneumothorax cases)
Witt et al 2009	2.2 million treatments (229,230 patients)	1,976	4,963	5 (includes 2 pneumothorax cases)
Brady et al 2014	7,629 treatments	1,463	0	0
Total	3,033,858 treatments			11 serious events includes 4 pneumothorax cases

Case studies describing singular events of pneumothorax following dry needling indicate that patients were seeking treatment for a wide variety of conditions such as tension headaches, asthma, chronic cough or other breathing problems pain in the shoulder, neck, or low back regions, and complex regional pain syndrome.[4,5]

4. Are there differences in occurrence of adverse events between acupuncture and trigger point needling?

Yes.

Acupuncture Adverse Event Rates

- Acupuncture studies report varying adverse event rates ranging from 0.9% to 11.4% (0.9%[10], 0.14%[23], 7%[21], 8.6%[22], 11.4%[5]).
- Acupuncture adverse event rates in 2.2 million acupuncture treatments performed by physicians.[22]
  - 19,726 of 229,230 (8.6%) patients reported experiencing at least one side effect of acupuncture.
  - Adverse events requiring treatment occurred in 2.2% of patients.
  - 39.4% of events occurred during treatment.
  - 60.6% of events occurred after treatment.
- Adverse events ranked in order of frequency of occurrence were:
  - Minor bleeding and haematoma (6.1%)
  - Pain during treatment (0.21%)
  - Pain any type (2.04%)
  - Vegetative (i.e., adverse autonomic nervous system) symptoms (0.7%)
  - Inflammation (0.31)
  - Nerve irritation/injury (0.26%)
- Adverse events due to negligence such as forgotten needle, pneumothorax comprised 0.1% of all events.
- There were no acupuncture-associated deaths or permanent injuries associated with the acupuncture treatments.

Trigger Point Dry Needling Adverse Event Rates[1]

- Based on 7,629 trigger point needling treatments performed by physiotherapists.
- 1,463 adverse events were reported (19.18%).
- Adverse events ranked in order of frequency of occurrence were:
  - Bleeding 7.5% (7.55/100)
  - Bruising 5% (4.65/100)
  - Pain during treatment 3% (3.01/100)
  - Pain after treatment 2% (2.19)

Key points

- Using the European Commission Classification system,[1,7,22] adverse events are:
  - A common occurrence when performing acupuncture.
  - A very common occurrence for trigger point dry needling.
- Most adverse events are mild in nature.
- When comparing studies on adverse events associated with acupuncture and with trigger point needling there are similarities and slight differences in the side effects patients experience.
  - Bleeding, bruising and pain are the top three side effects for dry needling and are mild in nature.

- Pain during needling occurs more frequently with trigger point needling than with acupuncture.
- Pain (during and following treatment) occurs more frequently with trigger point needling than with acupuncture.
- Serious adverse events from dry needling are very rare.
- Pneumothorax is the most common serious adverse event associated with dry needling and is very rare.

5. How do I apply this information to the disclosure process?

- When informing patients about dry needling risks, you do not have to quote statistics from the research reports. Disclose the material and special risks related to your practice context meeting your patient's informational needs.
- Bear in mind, the information provided herein provides an overview of dry needling risks from published studies. It paints a broad overview of dry needling risks. Rates of adverse events will vary from practitioner to practitioner as exemplified in Brady's study[1] which identified a subgroup of physiotherapists who had higher rates of mild adverse events than the overall group. You may be missing factual information about the rates of adverse events in your practice. As such your challenge is to combine the research information with your rate of adverse events occurrence and apply this to your disclosure process.
- Analyze your practice to gain a sense of how frequently adverse events occur. Use this information to inform the disclosure process.
  - Can you adapt the classification system for European Medicinal Products to analyze the number of adverse events that occur in your practice?
  - How frequently do your patients experience mild adverse events?
  - Are the frequency of risks reported here the same for your practice?
  - Can you use your practice data in the risk disclosure process?
- When discussing risks with patients:
  - Most physiotherapists will be able to say with confidence that they have never had a patient with a serious adverse event and defer to the research that there is a very rare risk of pneumothorax.
  - Other physiotherapists may have experienced significant or serious dry needling adverse events at rates greater than reported literature and should defer to their own practice data when discussing dry needling risks.
  - The fact that one has never experienced a serious patient safety event in their practice does not predict that one will never experience one in the future.
- Remember consent is an ongoing process. In subsequent dry needling treatments it is prudent to remind patients about the risks of dry needling and, when appropriate, educate patients on self-management of adverse events when they occur.

References are listed in the Dry Needling Resources Reference List.

Physiotherapy Alberta regulates and leads the practice of physiotherapy in Alberta. Contact us for more information on this or other practice guidelines.

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