Dry Needling in Physical Therapy Practice: Adverse Events Part 2: Serious Adverse Events

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ABSTRACT

Dry needling (DN) is a modality that is increasingly being used by physical therapists in the treatment of pain and dysfunction related to the musculoskeletal system. Knowledge of the frequency and types of adverse events (AEs) associated with DN is essential in the risk management of physical therapy practice. **Part 1** of this clinical commentary reviewed the types and frequencies of mild AEs associated with DN treatments. **Part 2** will consider the more serious and severe AEs that may occur with DN. A discussion of the concerns of treating pregnant patients with this modality is also included.

Key Words: acupuncture, pneumothorax, trigger point

INTRODUCTION

Most tracking of adverse events (AEs) related to dry needling (DN) in physical therapy practice has shown that the modality, in the hands of trained competent practitioners, is very safe.[1,2] As outlined in **Part 1** of this clinical commentary, most AEs are mild and transient in nature. Although rare, significant, and serious AEs have been reported in the literature and include pneumothorax and hemothorax, infections, serious bleeding, cardiac tamponade, and nerve injuries. Special concerns related to possible needle breakage or forgotten needles and complications related to pregnancy must also be considered when choosing this modality. Serious AEs are commonly associated with practitioner negligence and poor adherence to practice standards.[3] A review of these various AEs and their prevention and management follows.

SERIOUS AND SEVERE ADVERSE EVENTS

Pneumothorax/Hemothorax

The AE that garners the most media attention is a pneumothorax or hemothorax. It is the most common serious complication of acupuncture or DN interventions and is of legitimate concern since needling around the rib cage and upper trapezius region is common. Most patients who sustain a pneumothorax will fully recover and mortality is rare but prevention of this AE is essential as it has the potential to be life threatening. Physical therapists must be conversant in the clinical presentation of a pneumothorax in order to help manage this condition.

A pneumothorax is the presence of air or gas (or blood in the case of a hemothorax) in the pleural cavity. Pneumothorax can be spontaneous or traumatic in nature. A spontaneous pneumothorax can be primary or secondary dependent on a concurrent pre-existing lung condition. Primary spontaneous pneumothorax is associated with smokers and is much more common in males (6:1 ratio). Other risk factors include a tall, slender body type, Marfan's syndrome, pregnancy, or a positive family history of spontaneous pneumothorax. Secondary spontaneous pneumothorax may be associated with chronic lung conditions like tuberculosis, chronic obstructive pulmonary disease, cystic fibrosis, and severe asthma. The incidence of spontaneous pneumothorax is between 7.4 and 18 cases per 100,000 in males and 1.2 and 6 cases per 100,000 in females.[4]

A traumatic pneumothorax can be classified as non-iatrogenic or iatrogenic. Examples of causes of non-iatrogenic traumatic pneumothorax include trauma (both penetrating and non-penetrating), rib fractures, and high-risk sports like SCUBA diving or flying (due to increased barometric stresses). A practitioner may induce an iatrogenic traumatic pneumothorax inadvertently when inserting a needle too far into the tissue and puncturing the pleura or lungs. The incidence of acupuncture-induced pneumothorax has been reported as less than 0.01/10,000 interventions.[5] This low estimate may not reflect the true frequency as many acupuncture interventions may not even include needling over the high-risk thoracic region. The signs and symptoms may develop after a treatment session and a practitioner may not even be aware of the development of a pneumothorax. A complication of an iatrogenic pneumothorax is the development of a tension pneumothorax when the pressure in the plural space is positive throughout the respiratory cycle. This can result in a decrease in venous return, hypoxia, and hypotension.

A pneumothorax or hemothorax can present with symptoms similar to musculoskeletal pain (pain in the chest that can radiate into the shoulder or back) and will affect ventilation and impair oxygenation. The clinical signs and symptoms are dependent on the degree of lung collapse and may include dyspnea, increased respiratory rate, dry cough, malaise, cyanosis, and diaphoresis. They may present with decreased breath sounds on auscultation and present with a mediastinal shift. It must be noted that an iatrogenic DN induced pneumothorax may take several hours to develop and may not be evident initially. The signs and symptoms can vary as a result of a person's overall health. If in poor health, a small pneumothorax can result in severe symptoms but in a healthy person, mild symptoms may prevent a patient from seeking immediate medical attention. The rate of intrapleural gas absorption in untreated lesions is 1.25% of the thoracic volume per day. A small pneumothorax may reabsorb spontaneously, which may result in under-diagnosing or underreporting of the AE.[6]

The treatment of a pneumothorax is dependent on the degree of lung collapse. According to the American College of Chest Physicians,[7] patients who are clinically stable and present with a spontaneous pneumothorax of less than 3 centimeters from apex to cupola are usually treated conservatively with observation. Larger pneumothorax may require needle aspiration or chest tube placement. Oxygen supplementation may be required if oxygen saturation levels are low.

Dry needling in the area of the upper trapezius, the thoracic erector spinae, and levator scapulae region have been associated with an increased risk of iatrogenic pneumothorax. The subclavicular and supraclavicular regions, the intercostal and interspinal spaces, and abnormal congenital foramen in the scapulae and sternum have also been linked to increased risk.[8] Practitioners needling these areas understand the relevant and vital anatomical structures in the area. Iatro-

genic pneumothorax mostly is unilateral but cases of bilateral iatrogenic pneumothorax have been described.[9,10]

Knowledge and practice in the correct needling direction and needle depth, and palpation of these areas are essential when being trained in DN techniques. Lack of training, practitioner negligence, and poor knowledge of surface and underlying anatomy can put a patient at risk of an AE. The safe needling depth over the lungs to avoid a pneumothorax can be as small as 10 to 20 mm.[11] Mitchell et al[12] using ultrasound imaging demonstrated that there are differences in the skin-to-lung tissue depth dependent on the patient's position on a treatment table. When a person is lying in a prone position and a bolster is placed under the shoulder to bring it into a more retracted position, there is an increase in the depth to the lung tissue. Body composition differences between males and females and the body mass index (BMI) can also affect the distance to the lung tissue when needling the thorax. Grusche et al[13] reported 3 cases of traumatic pneumothorax following acupuncture or DN interventions seen at an emergency room in Victoria, Australia. All involved young women with low BMI. Karavis et al[14] also presented a case study of an acupuncture-induced haemothorax involving a woman with a low BMI.

Infections

Infection rates with DN and acupuncture have decreased over the decades through improvements in educational standards and the use of single-use disposable needles. Since 1984, the Council of Colleges of Acupuncture and Oriental Medicine have developed and administered the *Clean Needle Technique* (CNT) course, which is mandatory training for acupuncture licensing in the United States. These guidelines were developed to reduce the risk of spreading infections and avoid other risks associated with acupuncture and ensure the safety of both patients and practitioners. The course material is regularly updated with information from the Centers for Disease Control and the Occupational Safety and Health Administration (OSHA) as best practices change and evolve. This course is only available at present for acupuncture students but the manual, currently in the 7th edition, is a good resource for practitioners performing needling interventions. All physical therapists in the United States study the Occupational Safety and Health Administration's blood-borne pathogen regulations (standards – 29 CRF) and this will not be discussed in great detail in this paper.

Infections are a concern when needling, as the skin normally acts as a barrier to infection. Infections can be either autogenous (caused by an infectious agent that the patient already carries) or a cross-infection where a pathogen is acquired from another person or the environment. A percutaneous infection at the needle entry site will show the classic signs and symptoms of redness, swelling, local heat, and pain. Severe infections can also be accompanied by fever. Most infections related to DN are associated with mycobacterium or methicillin-resistant *S. Aureus* (MRSA).

Xu et al[15] reviewed case reports published between 2000 and 2011 and found 239 cases of infection associated with acupuncture interventions. The vast majority of the cases occurred in Korea, and were related to non-sterile needles or inadequate disinfection of other equipment. The routes of infection and their frequency have changed over the years now that disposable needles are the current clinical norm, but the increased pervasiveness of MRSA and mycobacterium infections in health care settings further illustrate the continuing importance of hygiene in clinical environments. Dry needling and acupuncture can be complicated by autogenous infections caused by organisms on the patient's own skin flora. The most commonly used skin disinfectant used prior to needling is 60% to 70% isopropyl (or ethanol) alcohol yet some mycobacteria have been shown to be relatively resistant to it.[16] For patients with a compromised immune system, or poor hygiene, cleaning the skin with products containing 0.5% chlorhexidine or povidone iodine may be a better choice. Formal regulations regarding skin disinfection prior to needling must be followed in a practitioner's jurisdiction.[17]

Infections related to DN are rare. In fact, Hoffman reported that bacterial infections caused by deep needling are uncommon because the needle tip is too small to carry a sufficient amount of inoculum from the skin.[18] Recently, however, 3 case studies related to DN and infections have been published. Kim et al[19] described a case study of a 16-year-old boy who developed an abscess in the posterolateral distal aspect of the right thigh after undergoing DN intervention for iliotibial band syndrome. The infection resolved but required a hospitalization and the continuation of intravenous antibiotics for an additional 3 weeks after the hospital discharge. The CNT was documented by the treating physical therapist and it was uncertain if the abscess development was coincidental or a clinical error associated with improper CNT. Two other cases discussed the development of infections after DN with patients who had undergone previous surgical interventions. A 15-year-old who had had spinal arthrodesis for treatment of an idiopathic scoliosis 21 months prior, developed a deep spine infection after having DN in the medial periscapular region for chronic back and shoulder pain. The periscapular abscess necessitated an operative debridement and 2 months of antibiotic therapy. The authors concluded that the deep infection from DN might have contaminated existing spinal instrumentation.[20] A Dutch case study described a 57-year-old patient who underwent a total hip replacement and then developed a bacterial infection after DN interventions 7 months after the surgery. Antibiotic interventions were unsuccessful and debridement and irrigation of the area was required.[21] Although there was no strong evidence for a causal relationship between DN and these infections, caution should be used in patients with joint replacements or other hardware in the area of DN.

Cardiac Tamponade

Another serious, although rare, complication related to needling in the area of the sternum has been reported. The presence of a rare congenital abnormality called a sternal foramen occurs in 5% to 8% of the population as a result of an incomplete fusion of the sternal plates. The foramen is usually at the level of the 4th intercostal space but cannot be reliably palpated as tendon fibers, thin connective tissues, or bone lamella may conceal it. If a needle punctures this hole, a cardiac tamponade may occur. A compression of the heart may occur when blood or fluids build up around the pericardium, and can be fatal. The signs and symptoms of a cardiac tamponade may include chest pain, which may radiate into the neck, shoulder or abdomen, and worsens with deep breathing or coughing, anxiety, hypotension, difficulty breathing, palpitations, and fainting. Caution must be taken when needling the sternalis or pectoralis major muscle trigger points that overlie the sternum. (It is noted that the sternalis muscle is highly variable in its presence and laterality). Injury to the pericardium or heart can occur if needling deeper than 13 to 25 mm over the sternum occurs.[22] Needling in this area must be performed in an oblique cephalad direction.

Nerve damage (peripheral and central nervous system)

For over a century there have been pub-

lished reports of neurological damage that can occur as a result of intramuscular needling using hypodermic needles.[23-25] The resultant motor and sensory nerve damage can be catastrophic and only 28% have a favorable recovery.[26] The signs and symptoms associated with traumatic nerve damage depend on the severity of the nerve injury. The structural and functional changes can categorize the injury as a neuropraxia, axonotmesis, or neurotomesis.[27] Fortunately, the smaller gauge needles used with DN interventions make complications from nerve injury far less common and less serious than those encountered with hypodermic needles. The most common type of nerve injury related to DN or acupuncture is a neuropraxia resulting from a hematoma causing nerve pressure. Prognosis of neuropraxia injuries is good with symptom regression generally occurring spontaneously within days or weeks. If bleeding is severe, an axonotmesis could occur. Axonotmesis recovery, although good, is often longer and symptoms can last for months.

Research validating needle placement in relationship to target tissues using cadavers has been done but it is uncertain whether such knowledge obtained in vivo can be helpful in guiding practitioners on how to avoid structures such as nerves.[28-30] The use of fluoroscopy or ultrasound imaging to verify needle placement during DN is impractical.[31] Research is also continuing to determine if patient positioning can help reduce the risk of injury to nerves or other underlying tissues.

If a patient experiences a sharp electrical-type sensation distal to the needling site during DN, a nerve may have been encountered. Peuker[22] has described several peripheral nervous system injuries associated with acupuncture and notes that peripheral nerves often have a variable anatomical course. For example, peroneal nerve palsy with a resultant foot drop has occurred after needling the area around the fibular head.

More recently, McManus and Cleary[32] described a case of a 27-year-old woman who developed a neuropraxia of her left radial nerve (at the level of the spinal groove) after DN intervention for shoulder pain. She developed a left-hand muscle spasm after a needle insertion and a subsequent left wrist drop. Despite intensive hand therapy and splinting, the patient continued to present with profound weakness. Follow-up nerve conduction and EMG testing showed no sign of nerve recovery.

In addition to peripheral nerve injuries, cases of injury to the spinal cord or spinal nerve roots associated with acupuncture and DN have been reported. Peuker[22] reviewed 10 cases of injury that were the result of direct injury to nerves or the result of needle fragments that occurred in the cervical and lumbosacral regions. The severity of injury varied from focal neurological signs to paraplegia. The authors noted that the distance from the skin to the nerve roots or spinal cord varies from 25 to 45 mm depending on the size of the person.

Forgotten needles or broken needles

Practitioners must be meticulous in ensuring that no needles are forgotten during an intervention. As most DN does not involve needle retention, this is less of a concern than acupuncture, which involves numerous needles and longer retention times. Maintaining and documenting accurate counts of needles "in" and "out" helps. Practitioners should keep used, empty needle packaging until the end of the intervention session to help maintain a correct needle count.

Needle breakage is rare now that single-use disposable needles are the standard of practice. Prior to this, metal fatigue was a concern when needles were repetitively used and sterilized with an autoclave. The most common area for a needle to break is at the root of the needle where the shaft and the body meet. When inserting a needle, one-quarter to one-third of the shaft should always be kept above the skin level. This requires the practitioner to use the correct needle length for the patient size and the area of the body that is being treated. Breakage may occur if there is a crack in or erosion of the needle, which may be a factor when using needles of poor quality. Breakage could also occur if the patient suddenly moves or has a strong muscle spasm, an external force hits the needle, or if a practitioner tries to forcibly remove a bent needle.

Leow et al[33] studied the mechanical compression forces needed to break a filiform acupuncture needle. A variety of needle diameters and lengths (.25 x 40 mm, .30 x 25 mm, .18 x 13 mm) were bent using an Instron 3343 single column universal testing system. The authors were unable to break the needles but permanent bending did occur with high loads. They concluded that needle breakage is unlikely to occur with muscle spasm or sudden movement of a patient but recommended avoidance of excessive force when manipulating needles.

If a needle does break during intervention, it is important for the patient and practitioner to stay calm and the patient to remain still. If part of the needle is visible above the skin, it should be gently removed with forceps. If it is at the skin level, the tissue around should be gently pressed until the broken end is exposed and can then be removed. If removal is not possible, the needle's point of entry on the skin should be marked and medical transportation to the hospital arranged.

Case studies have illustrated the danger of needles breaking or being forgotten during interventions. Chaput and Foster[34] reported of a healthy 46-year-old woman went to an emergency room and complained of a foreign body sensation after eating some potato chips and feeling one lodge in her throat. An x-ray and a subsequent laryngoscopy showed a needle in the wall of the esophagus. Six months prior she had been receiving acupuncture for a whiplash injury. She could not recall if one of the needles had broken but she had continued neck pain, which she had attributed to the motor vehicle accident. Snyder also described the case of a 52-year-old man who had acupuncture treatments for chronic neck pain while out of the country on a business trip. During the session, one of the needles inserted in the upper cervical region broke. The acupuncturist was unable to remove the needle segment and the patient was transported to the hospital for x-rays. The radiography showed that in addition to the needle near the C1-2 junction another needle was discovered at the C6-7 level, presumably from a previous acupuncture session. It was determined that both needles did not pose an immediate threat and the patient boarded a plane back to the United States. During the flight, however, the upper cervical needle migrated over 3 centimeters. Upon landing, further imaging was done and the upper cervical needle was found only 2 millimeters from the vertebral artery. Surgical removal of the needles was required followed by extensive physical therapy to regain cervical mobility.[35]

USING NEEDLING MODALITIES DURING PREGNANCY

There is little published evidence on the safety of treating pregnant women with DN. Physical therapists may be uncertain about using the modality during pregnancy and may be concerned about the potential risks to the unborn fetus or the mother. However, lower back and pelvic girdle pain are common ailments during pregnancy. Dry needling is an intervention that may be helpful in symptomatic relief of pain since pharmaceutical intervention is often not an option.

It is noted that physical therapists are often reluctant to treat pregnant women with needling modalities as a defensive practice. Miscarriage occurs in over 10% of all pregnancies with 80% occurring in the first trimester. The Fanslow study, a random sample of 2,391 New Zealand women, reported that a spontaneous abortion had affected almost 1 in 3 women.[36] If a patient has a DN treatment and has a spontaneous abortion soon afterwards, the therapist and the intervention may be suspected of causing the event.[37] The "fear of blame" for a potential miscarriage may influence physical therapists to choose not to treat pregnant patients with DN.[38]

CONCLUSION

Although there are few recorded serious AE associated with DN, there is an absence of national or international standards in the training of physical therapists in DN interventions. In the United States, there is considerable variation in DN training standards and the efficacy of the training is not regulated. The length of a program is not necessarily a valid measure of competency. The DN educational programs and federal and state professional regulatory agencies must ensure the competency of practitioners who needle these vulnerable areas. Some individual states have mandated initial competency requirements, since profession-wide national standards do not exist. Individual physical therapists performing DN must always comply with the standards of their own state regarding the educational and competency requirements.

At the present time, there is no consistent tracking of the AE associated with DN. The ability to systematically report AE associated with DN in a blame-free and voluntary way can help the profession to focus on reducing accidents.[39]

Dry needling education must emphasize anatomical knowledge with advanced training when needling the trunk, thorax, head, and cervical regions. It is essential that practitioners screen for individual risk factors associated with each patient, practice strict adherence to sterile needle practices and be able to recognize acute AE complications. It is also important to obtain informed consent prior to treatment, document treatments well, and have adequate follow-up of any AE. This article contributes to the literature on DN to inform the reader of potential AEs to consider.

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