

## Mini Review

# Therapeutic Modalities: Best Practices to Protecting Patients from Harm During Treatment

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## ABSTRACT

Healthcare providers and clinicians such as athletic trainers and physical therapists utilize therapeutic modalities to administer treatment to patients in the clinical setting. It is the responsibility of these healthcare providers to ensure the safe use of therapeutic modalities during treatment sessions, as well as effective delivery of treatment. Thermal-heat, ultrasound, cryotherapy and electro-stimulation treatments have the potential for causing harm to patients. Proper care and maintenance of modalities can minimize the risk to patients and avoid legal issues for physical therapists and athletic trainers. This article will explore some of the legal issues, case studies and reports as well as providing information on what healthcare providers can do to protect patients.

### Keywords

Risk management; Negligence; Malpractice; Best practices; Injury prevention; Athletic Trainer; Physical Therapists; Accreditation.

## INTRODUCTION

All healthcare facilities and professional clinicians must have the interest of the public, especially providing healthcare delivery. Institutions that provide therapeutic modality treatment should have the proper state-licensed professionals to conduct such treatment and patient care.<sup>1,2</sup> In addition, the healthcare provider should examine their facility to insure patients are not exposed to hazards from any of the therapeutic modalities equipment at the venue.<sup>1,3</sup> One way to examine their professional role is to review the basic principles of “duty of due care” and “breach of duty”. Athletic Trainers (ATs) and Physical Therapists (PTs) owe a duty to a patient to provide services such as treatment of the medical condition in a professional manner. They also owe a duty to insure that the equipment used to deliver the treatment is maintained and safe to use.<sup>1,4</sup> A “breach of duty” occurs when there is insufficient supervision of the patient, or there is a failure to properly maintain or inspect therapeutic modalities used in patient care.<sup>1,4</sup>

## ISSUES AND CONCERNS REGARDING MALPRACTICE

There is no sufficient data on ATs, but regarding PTs and looking at an analysis of closed claims by insurance sources, provided by certified nursing assistant (CNA) HealthPro and Healthcare Providers Service Organization (HPSO), the percentage of closed claims related to failure to monitor patients during treatment was 85.5% and with the average patient receiving \$80,000 in an injury settlement. This accounted for over 5 million dollars paid out to all the patients injured from improper supervision.<sup>5</sup> According to the same analysis, the malfunction of equipment had the highest percentage (53%) of closed claims. In addition, the percentage of claims for failing to test the equipment (6.3%) and claims on not properly maintaining the equipment accounted for over one million dollars paid out to all patients injured from improper care and maintenance. The average patient received a settlement of between \$31,000 and \$85,000.<sup>5</sup> One study by Mun et al,<sup>6</sup> of 864 patients found that 94 were injured from burns delivered by hot (hydro collar) packs.<sup>6</sup> This study did not indicate if improper supervi-

sion or improper use or maintenance of the heating unit lead to the burns. Another case of malpractice, the PT was administering a “cupping treatment”. The PT was allegedly involved in improper management over the course of treatment, failure to supervise/monitor the patient, failure to supervise/monitor the PT assistant.<sup>7</sup> In addition, the owner of the clinic was allegedly involved in failure to maintain a safe environment, making sure the clinical staff were qualified to administer cupping treatments. In this case, the patient suffered a burn and blistering to the area treated. The patient later developed an infection to the treated area. The patient discontinued coming to the clinic and suffered over a month with pain and discomfort. The patient settled out of court with an indemnity settlement payment greater than \$25,000.<sup>7</sup>

In terms of risk management, healthcare professionals need to adhere to the U.S. Department of Labor-Occupational Safety and Health Administration (OSHA) which oversees all national standards to protect workers and the public consumer such as patients.<sup>8</sup> OSHA violations and fines for non-compliance are dependent on the specific violation and if an injury occurred. In addition, the U.S. Food and Drug Administration (FDA) has regulatory authority over various therapeutic modalities and their uses.<sup>9</sup> Federal laws associated with the FDA will have their own specific guidelines for compliance. Other organizations such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)<sup>10</sup> oversee quality care in hospitals, clinics and other healthcare facilities, and this would include checking the calibrations of therapeutic modalities and maintenance and upkeep of electrical outlets such as Ground Fault Interrupters (GFI). In terms of education programs, The Commission on Accreditation of Athletic Training Education (CAATE)<sup>11</sup> and the Commission on Accreditation in Physical Therapy Education (CAPTE)<sup>12</sup> oversee the educational standards of schools and colleges offering educational programs in physical therapy and athletic training. These organizations have standards specific to ensuring student and patient safety during the clinical instruction of students. Although independently owned clinics and sports care facilities may not be affiliated with CAATE or CAPTE programs, nor have JCAHO accreditation, they still must adhere to OSHA and FDA standards.

Here is the issue, what of those programs and institutions such as high schools, junior colleges and clinics that do not have to adhere to specific accreditation standards on GFIs compliance and modalities equipment checks and calibrations? Although all institutions must adhere to OSHA standard, there is always the possibility that GFI compliance and modalities calibrations will not be discovered until there is an injury or harm to a patient. The legal concern comes from the injury to a patient or athlete through the improper use of a therapeutic modality, OR the use of a therapeutic modality that is not operating properly. Lack of GFIs in treatment areas are another concern. Hydrotherapy areas that have both water and electricity exposure, can pose serious risks, so the annual checking of GFIs is very important. As a CAATE accredited program, we budget for this expenditure each year. Reviewing our records, we have spent between \$700 to \$900 for an independent technician to annually calibrate our therapeutic modalities and check all our electrical outlets/GFIs. Some institutions may see

this expense as an elective budgetary item that can be cut to save funds.

Another method is to have the institutions electrician complete a work-order annually, review all GFIs, and document the results of the work order. One more important point, a qualified electrician should review the entire electrical system, especially in older buildings and check the GFIs and for plugs that are eroded.<sup>2</sup> The entire electrical system in the facility needs to conform to national and local codes. According to Prentice and Starkey,<sup>2,3</sup> not all three-pronged outlets are GFI and needs to be checked for grounding. Multiple adaptors and extension cords should not be in use, as this may pose a danger to patients.<sup>2,3</sup>

Please note that a qualified electrician should check any modality or any outlet that “trips” or shuts down, before returning it to service.<sup>3</sup> Spending funds on maintenance and upkeep will save you millions in a lawsuit should a patient/athlete be injured or electrocuted from defective therapeutic equipment.

## RECOMMENDATIONS ON RISK MANAGEMENT

To avoid legal problems and lawsuits, here are some tips to remember regarding specific therapeutic modalities and GFIs.

## CUPPING THERAPY

Cupping involves applying a heated or suction type cup to generate a partial vacuum that mobilizes the blood flow and promotes effective healing.<sup>13</sup> Cupping therapy has gained popularity and acceptance as a method of treating pain as well as sports injuries and other medical conditions.<sup>13</sup> Healthcare professionals should complete appropriate course work and hands-on learning towards a certification in cupping therapy. Prior to administering this treatment, explain all treatment concerns to the patient as well as determining any contraindications, skin conditions or skin sensitivity for administering the cupping therapy.<sup>13</sup>

## DRY NEEDLING

According to the American Physical Therapy Association (APTA)<sup>14</sup> and their resource paper description of dry needling (DN) in clinical practice, “dry needling is a skilled intervention that uses a thin filiform needle to penetrate the skin and stimulate underlying myofascial trigger points, muscular, and connective tissues for the management of neuromuscular skeletal pain and movement impairments”.<sup>14</sup>

Clinicians should be trained in administering this treatment technique and insuring a safe and comfortable environment. The clinician also needs to be cautious of patients who may have an allergic reaction to the metal in the needle (nickel or chromium) and may need to use silver or gold plated needles.<sup>14</sup> In addition; patients in their first trimester of pregnancy, patients taking anti-coagulant medications or patients with local or systemic infections may need to avoid dry needling treatment.<sup>14</sup>

## LASER THERAPY

Low-Level Laser Therapy (LLLT) is a therapy approved by the U.S. FDA for certain medical procedures.<sup>9</sup> According to Starkey,<sup>1</sup> there is growing evidence to support the use of LLLT for treating inflammation and assist in wound healing, arthritis, fracture healing and pain reduction, as well as other medical conditions.<sup>1</sup> The precautions that need to be followed by the clinician is to observe caution with patients taking medications that increase sensitivity to light.<sup>1</sup> This would include patients taking certain anti-histamines, oral contraceptives, non-steroidal anti-inflammatory drugs (NSAIDs), tetracycline, and antidepressants.<sup>1</sup> There are certain tattoo inks that may increase the absorption of laser injury, so patients that have body art, should be wary of such treatment. Patients may experience dizziness during the treatment and the treatment should be stopped and if needed, discontinue using LLLT for treatment.<sup>1</sup> It is also suggested because of the lack of evidence, that lasers should not be applied to small children with unfused epiphyseal plates.<sup>1</sup> Prentice<sup>2</sup> further lists contraindications such as not applying over suspected or known cancerous growth or tumors, or directly over the eyes. Pregnancy should also be contraindicated.<sup>2</sup> The US FDA regulates the use of Lasers and LLLT modalities.<sup>9</sup> With any new therapy or therapeutic modality, clinicians should be trained in their use.

## ULTRASOUND UNITS

This independent review can discover several things that may become a concern. Items such as broken sound heads (interchangeable soundheads can be improperly inserted and the pins can be bent or broken) for your ultrasound unit could result in improper levels of heat being delivered to a treatment area. A broken sound head could also prevent the patient from receiving any ultrasound output or therapeutic benefit. A recommendation is to have dedicated soundheads and limit interchanging soundheads. This will prevent or lessen the chance of damage to the pins that insert into the ultrasound unit.

## ELECTROSTIMULATION UNITS

Electrostimulation units (E-stim) are used to produce either change in pain response or muscle contraction.<sup>1,2</sup> In addition, there may be some chemical and ion effects on the muscle tissue.<sup>1,3</sup> E-stim units should be calibrated annually. In addition, during the annual review, broken lead wires and bad connections can be discovered and if needed replaced. It is important to eliminate any electro pad wires, connections or leads that could cause a shock or electrical burn. For hygiene purposes, the clinic should provide patients with their own individual adhesive lead pads. It is always good practice to examine your leads and pads and replace those pads with wires that appear frayed or broken and/or lose their adhesion.<sup>1,2</sup>

## MOIST HEATING UNITS

Moist heating units (Hydrocollator Heat Packs) need to maintain a constant temperature between 164 °F and 170 °F (73.33 °C-77.66 °C).<sup>1,3</sup> Neglect of the heating unit can pose some legal issues given

the aforementioned case study of 94 patients who had received burns from hot pads. If the water level is not at the proper levels, this could result in the unit running dry and becoming a fire hazard. Lower water levels also raise the temperature of the water in the unit above the recommended temperature range. Recommendation to prevent problems is to measure the temperature each day, record it and monitor both the temperature range and the water levels. Regulate the thermostat so it measures within the temperature range. If the temperature continues to be above the manufacture recommended temperature range, you may wish to consider replacing either the thermostat or the unit.

## PARAFFIN BATH

Paraffin bath units should be free from dirt and debris and should be maintained at constant temperature of 118 °F to 126 °F (47.8 °C to 52.2 °C).<sup>2,4</sup> Specific units have an internal thermostat and as an extra precaution, check and log the temperature of the unit each day. This is especially important if you have a large volume of use. If this modality is not frequently used, it ought to be cleaned and stored.

## WHIRLPOOL UNITS

Anytime you mix water and electricity, there is the possibility of danger.<sup>1,4</sup> GFIs need checking annually to ensure a secure ground. Any indication of shock needs to be dealt with immediately to prevent harm to a patient.<sup>4</sup> On the occasion a GFI “trip” and shuts off, the patient needs to be removed from the area. After resetting the GFI, the whirlpool unit restarted without the patient. Should the GFI “trip” and shut off again, the whirlpool should be placed out of service and off-limits until you can have the unit serviced to ensure a safe treatment environment.<sup>4</sup> Engine turbine needs to be checked for rust as well as appropriate function of the jets. Water seals exiting from the tub need checking to insure no water is leaking on the floor, since this may cause a patient to slip.

## CONCLUSION

Risk management and patient safety should always be at the forefront of patient care. ATs and PTs need to review their educational preparation, treatment protocols, and treatment environments. Injuries from improper training, and improper use or maintenance of therapeutic equipment can result in burns and tissue damage to a patient. Another purpose of this article was to bring attention to the need for continued education and annual calibrations and GFI checks. This review was not inclusive of all therapeutic modalities you may have in your clinic or facility. The cost of annual calibrations and checking on electrical equipment may seem like a luxury to some clinics and athletic training facilities; however, the legal costs in a negligence lawsuit could soar into the millions.

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