RISKS IN ELECTRODIAGNOSTIC MEDICINE

Key words: (Needle EMG, NCS, Infection Control, Lymphedema, Prosthetic Joints, Disturbances in Hemostasis, Electrically Sensitive Patients, Electrodiagnostic Studies in Pregnancy, Evaluation of Chest Wall, Abdominal Musculature)

When performing electrodiagnostic (EDX) testing on patients with certain underlying medical conditions, the EDX physician should consider the potential risks of the procedure. Literature regarding risks and complications of EDX testing is limited. The following provides information and guidance to the approach of some common problems encountered by EDX physicians. Ultimately, the manner the individual circumstances are managed relies on physician judgment.

INFECTION CONTROL

Infection control is an issue of central importance in the EDX laboratory. The chances of transmitting bloodborne pathogens from patients to EDX physicians and staff, from EDX physicians and staff to patients, and from EDX equipment to patients must be minimized.

The Occupational Safety and Health Administration (OSHA) has published standards[48] regarding bloodborne pathogens (29 Code of Federal Regulations§1910.1030; http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051). The rule applies to all persons occupationally exposed to blood or other potentially infectious materials. It outlines preventive measures (such as hepatitis B vaccination (HBV) and universal precautions) and certain methods of control (engineering and work practice controls, personal protective equipment, and housekeeping procedures) and specifies what to do if an exposure incident occurs. Use of masks and gowns may be required depending on the individual case. OSHA also requires the creation of an exposure control plan, whereby employees are informed of hazards associated with bloodborne pathogens, and that certain medical records be maintained. The OSHA document and certain publications from the Centers for Disease Control (CDC)[17,22,49,20,15,18] set the standards concerning occupational exposure to blood or other potentially infectious materials.

Transmission of Bloodborne Pathogens Between Patients and Healthcare Workers

Routes of Infection

Routes of transmission of infection with bloodborne pathogens[17,15,16,18,38] include percutaneous inoculation, or contact between blood or certain other bodily fluids with an open wound, nonintact skin, or mucous membranes. Blood is the single most important source of HIV and viral hepatitis infection in the EDX laboratory.

Universal Precautions

Universal precautions now are mandated by OSHA, which considers all patients' blood and certain body fluids to be potentially infectious.[48]

Use of Protective Barriers

Personal protective equipment[17,18,48] worn by healthcare workers, such as gloves and laboratory coats, reduces the risk of exposure of the healthcare worker's skin or mucous membranes to blood and other potentially infective materials. Personal protective equipment should be removed prior to leaving the work area and should be placed in an appropriately designed area or container for decontamination or disposal. Judgment must be exercised in choosing the type(s) of equipment needed in a given clinical situation. Gloves should be worn when it can reasonably be anticipated that the EDX physician or assistant may have hand contact with blood and other potentially infectious materials (e.g., during a needle electromyography (EMG) examination). The physician or assistant should minimize touching objects other than the patient and EDX equipment when wearing gloves. Gloves should be changed between patient contacts, when contaminated, or when torn or punctured. Gloves should be taken off before leaving the examination room. Hands should be washed immediately after gloves are removed. Electrodiagnostic physicians should be prepared to encounter patients with latex allergies and should have access to alternatives such as vinyl gloves.

Engineering and Work Practice Controls

Engineering and work practice controls should be used to eliminate or minimize healthcare workers' and patients' exposure to bloodborne pathogens.[17,18,48] Workers should wash hands and any other skin with soap and water, or flush mucous membranes with water as soon as feasible following contact with blood or other potentially infectious materials. Eating, drinking, smoking, and applying cosmetics are prohibited in work areas where there is a reasonable likelihood of occupational exposure. Food and drink should not be kept in containers (e.g. refrigerators) or on countertops where blood or other potentially infectious materials are present.

Unless proper gloves are worn, EDX physicians and staff who have exudative lesions or weeping dermatitis on their hands should refrain from all direct patient care and from handling possibly contaminated patient-care equipment until the condition resolves.[17,18]

Specific guidelines for the use of sharp instruments and electrodes in neurological procedures were adopted with permission from guidelines developed by the American Academy of Neurology AIDS Task Force.[36] All EDX physicians and staff should take precautions to prevent injuries caused by needle electrodes and other sharp instruments. In a survey of electromyographers, 64% reported at least one needlestick injury, [41] most commonly during a routine procedure, although patient movement and recapping were also identified as common causes. Contaminated needle electrodes should not be bent, sheared, or broken. Recapping through the use of a mechanical device or a 1-handed technique is preferred over a 2-handed technique. As soon as possible after use, contaminated needle electrodes should be placed in appropriate containers until properly processed or discarded. Such containers must meet OSHA standards and should be located as close as feasible to the immediate area where the electrodes are used.

Incidence of Transmission to Patients

A single needle electrode is typically used to make multiple insertions on the same patient during needle EMG testing. There is no evidence to suggest that multiple insertions into the same patient with a single needle electrode increase the risk of infection. Given the availability of inexpensive, single-use, disposable sensory testing devices, there is no role for lapel pins or reusable pinwheels to test sensation.

Needle EMG is not listed in American Heart Association guidelines as a procedure requiring prophylactic antibiotic treatment to prevent endocarditis in patients with valvular heart disease.[46,62] No data indicates that preparing the skin prior to needle insertion reduces the incidence of transmission to patients; however, alcohol is a simple, rapid, and effective antiseptic. The disadvantage of the stinging discomfort that may occur with alcohol preparation of the skin must be weighed against possible advantages. Most importantly, skin which is obviously dirty or contaminated must be cleaned with soap and water prior to any studies or to before preparing the skin with alcohol. Insertion of needle electrodes through infected skin or sores is contraindicated.

Two reports of soft tissue infections at sites of needle EMG electrode insertion have been published, one involving *staphylococcus epidermidis*[12] and the other involving *mycobacterium fortuitum*.[47] In the outbreak of infections due to *mycobacterium fortuitum*, reusable needle electrodes were routinely disinfected with 2% glutaraldehyde and then rinsed with tap water, the probable source of the infecting organism. This outbreak demonstrates that patient infection may be associated with needle EMG electrodes that are not sterilized according to current guidelines.

The transmission of HIV from an infected healthcare worker (a dentist) to patients has been reported.[19,21] HBV also has been transmitted to multiple patients in the practices of individual infected healthcare workers during invasive procedures.[1,30,51] To reduce the small risk of transmission of bloodborne pathogens from the EDX physician or assistant to the patient, care should be taken to protect the patient from contact with blood from the EDX physician or assistant, particularly through percutaneous injuries.

Disposable needle electrodes are recommended whenever possible. Reusable needle electrodes that are contaminated should not be stored or processed in a manner that requires workers to reach by hand into the containers where they have been placed.

Needles should be sterilized with techniques compliant with Joint Commission on Accreditation of Healthcare Organizations (JCAHO; http://www.jointcommission.org), local and institutional policies, as applicable.

Housekeeping

Contaminated work surfaces should be decontaminated with an appropriate disinfectant after completion of procedures; as soon as feasible when surfaces are overtly contaminated (e.g., after any major spill of blood); and at the end of the work shift if the surface may have become contaminated since the last cleaning.[17,18,48] Protective coverings, such as paper used to cover examination table surfaces, should be replaced after each patient. Environmental surfaces such as walls and floors are not associated with transmission of infections to patients or healthcare workers.[17,18] Therefore, extraordinary attempts to disinfect or sterilize these environmental surfaces are not necessary.

Regulated Waste

Regulated waste is defined by OSHA as: liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps and pathological and microbiological wastes containing blood or other potentially infectious materials. The actual volume of blood is not the determining
factor as to whether a particular material is to be considered regulated waste. Thus not all materials likely to be contacted by drops of blood in the EDX laboratory (patient gowns, table paper, gauze pads) need be considered regulated waste. Non-sharp regulated waste, including laundry, should be placed in containers which meet OSHA standards. Disposal of all regulated waste should be in accordance with applicable federal, state, and local regulations.

LYMPHEDEMA

Lymphedema is the abnormal accumulation of lymph in an extremity or on the trunk or face. It is commonly seen following lymph node dissection for malignancies or progression of tumor that disrupts lymphatic flow. Lymphedema can also result from a number of congenital disorders such as congenital lymphatic hypoplasia (Milroy's disease), rheumatologic disorders, morbid obesity, etc. Lymph node dissection and local irradiation may impair lymphatic flow with increased risk for cellulitis of the affected limb.[56] Patients with lymphedema or patients at risk for lymphedema are routinely cautioned to avoid percutaneous procedures in the affected extremity, namely venipuncture,[45,57] to prevent development or worsening of lymphedema or cellulitis. Despite the potential risk, the evidence for such complications subsequent to venipuncture is limited.[57] No published reports exist of cellulitis, infection, or other complications related to EMG performed in the setting of lymphedema or relating to lymph node dissection. However, given the unknown risk of cellulitis in patients with lymphedema, the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) believes that reasonable caution should be exercised in performing needle examinations in lymphedematous regions to avoid complications.[2] In patients with gross edema and taut skin, skin puncture by needle electrodes may result in chronic weeping of serous fluid. The potential bacterial media of such serous fluid and the violation of skin integrity may increase the risk of cellulitis. Prior to proceeding, the physician should weigh the potential risks of performing the study with the need to obtain the information gained.

PROSTHETIC JOINTS

Prosthetic joints may become infected postoperatively due to hematogenous spread of bacteria. Bacteria may enter the circulatory system through infections involving the surgical site or other noncontiguous tissues or following procedures producing bacteremia including dental procedures and gastrointestinal studies. [4,26,5,61,43] The risk for prosthetic joint infection declines rapidly during the first few postoperative months and continues to decline during the first 2 postoperative years.[11] There are no published reports of complications related to needle EMG in patients with prosthetic joints. Based upon current published literature, it is the opinion of the AANEM that there is no contraindication to needle EMG in

patients with prosthetic joints when sterile single patient use or properly autoclaved needle electrodes are utilized and infected spaces are not traversed by the needle electrode.

DISTURBANCES IN HEMOSTASIS

Bleeding and hematoma are potential risks of needle EMG in patients with or without disorders of hemostasis.

There is limited data regarding the incidence of clinically significant bleeding complications from needle EMG and additional risks in patients who are receiving antiplatelet or anticoagulant therapy or who suffer from thrombocytopenia or clotting factor deficiencies. Additionally, the use of subcutaneous partially fractionated heparin (e.g. Lovenox®) is becoming more commonplace. The degree of anticoagulation is not readily measurable, which may also result in increased risk of hemorrhagic complications. Some practitioners utilize vapocoolant spray to improve hemostasis, although there are no studies assessing the utility of this technique. Likewise, no data indicates that various needle parameters (e.g. gauge, monopolar vs. concentric, etc.) present different risks for bleeding complications.

In a retrospective, uncontrolled study of patients who were not receiving anticoagulants, [14] asymptomatic paraspinal muscle hematomas were identified by MRI in 5 of 45 muscles. In a survey of 47 EDX laboratories with ACGME-approved fellowships, 3 laboratories reported a single instance of serious bleeding complications (requiring intervention) occurring in anticoagulated patients.[31] One laboratory reported two instances of serious bleeding complications. In the only prospective study, subclinical hematomas were visualized by ultrasonography in 3 of 209 muscles. There was no statistical difference in hematoma rates in subjects taking anti-platelet or anticoagulant therapy compared to control subjects. [40]

There are few published case reports of bleeding complications following needle EMG. These include a 64-year-old man anticoagulated with coumadin (prothrombin time = 28s [control = 12.4s], partial thromboplastin time = 68 [26]). He developed subcutaneous bleeding following needle EMG examination with a drop in hematocrit from 43 to 29%, resulting in angina and requiring blood transfusion.[13] There are two cases of hematoma and compartment syndrome affecting the calf[27] (73-year-old man with recent aspirin usage) and forearm[60] (34-year-old woman with no bleeding risks). There is an additional report of calf hematoma and pseudoaneurysm in an 81-year-old woman with an INR = 2.5. [53]

The risks and benefits of needle EMG examination should be considered in patients with known disorders of hemostasis, and needle EMG should be performed with added caution. Each case should be considered individually with regard to the potential benefits of the study relative to the risks of intramuscular hemorrhage or other bleeding. If the decision is made to perform needle EMG in such a patient, it is advisable to first examine small, superficial muscles to watch for bleeding problems. Prolonged pressure over the needle site will usually produce hemostasis.

ELECTRICALLY SENSITIVE PATIENTS [23,28,55,58]

EDX Studies in the Critical Care Unit

The critically ill patient is at particular risk for electrical injury because certain protective factors may not be operative. [2] Two important defenses against electric injury are frequently lost in these patients. First, the high skin resistance provided by dry, intact skin is often breached by intravenous and intra-arterial catheters with leakage and spills around the catheter site. With lowered resistance, current applied in these areas will be conducted more efficiently to the rest of the body, including the heart.[42,35,32,24]

The second important protection against electric injury is the large volume of soft tissue which surrounds the heart (i.e., the trunk) and dilutes any electric current applied to the body, protecting the heart from direct electric current application. In the critically ill patient, intracardiac catheters are now commonplace. Such catheters bypass this large electric sink and provide small, otherwise harmless currents, potentially lethal, direct access to the immediate vicinity of the heart(microshock).[2]

Most manufacturers make intracardiac devices electrically isolated so that they will not conduct

electricity. The same attention, however, must be given to these catheters as to other percutaneous catheters; for example, stimulation in the immediate vicinity of the catheter should be avoided and should never be done in the presence of fluid spills or leakage.

Two common sources of current which might affect the hospitalized patient are leakage current from attached electric equipment and applied current from stimulators that are a part of electrodiagnostic machines. Stimulator complications can be avoided by refraining from stimulating next to areas with percutaneous catheters and especially avoiding areas where there is fluid leakage.

"Leakage current" is current that leaks to the instrument chassis and then can be delivered to the connected patient if improper grounding conditions exist. The maximum current allowed to leak from the case or from patient connections is 10µA.[59,9,8,7,6,37] The EDX physician is responsible for ensuring the machine in use meets these minimum specifications.
Providing proper patient grounding is necessary to protect patients from electric injury. The third ground wire is required on all electric equipment for patient use because it provides a harmless route for any chassis leakage current. The current flows directly to the ground, instead of to the patient. Testing of the third ground wire integrity and outlet grounds should be performed at regular intervals.[55]

Special safety considerations arise when patients are connected to multiple machines. Defects in outlet grounds or ground faults may occur in individual outlets. Thus, if a person is connected to equipment supplied from different outlets, one with a functional ground and the other nonfunctional, leakage current may flow from the machine connected to the nonfunctional outlet ground, through the patient into the functional outlet ground wire of lower voltage. Thus, it is recommended that the patient be disconnected from all nonessential electric equipment. The remaining equipment should be plugged into the same outlet or, at least, outlets in the same vicinity which are likely to share a common ground.

When using EDX equipment, it is recommended that the ground be placed between the stimulator and the recording electrodes, as well as keeping ground and needle electrodes in close proximity. This practice helps ensure that any leakage current or applied current will return to ground and not spread to the rest of the body.

If proper attention is given to equipment leakage current, grounding, and location and type of percutaneous catheters, EDX testing of the electrically sensitive patient can be performed without risk.

Electrodiagnostic laboratories should have in place a power outage and surge protection policy. In an effort to assist laboratories in meeting this standard, the AANEM has developed model policies: (http://www.aanem.org/accreditation/ModelPoweroutageSurgeProtectionPolicy.cfm)

Cardiac Pacemakers and Implanted Cardiac Defibrillators [3,10,29,39,52]

Cardiac pacemakers and implanted cardiac defibrillators (ICDs) are increasingly used in clinical practice, and no evidence exists indicating that performing routine EDX studies on patients with these devices poses a safety hazard. However, there are theoretical concerns that electrical impulses of nerve conduction studies (NCSs) could be erroneously sensed by devices and result in unintended inhibition or triggering of output or reprogramming of the device[54]. In general, the closer the stimulation site is to the pacemaker and pacing leads, the greater the chance for inducing a voltage of sufficient amplitude to inhibit the pacemaker. Despite such concerns, no immediate or delayed adverse effects have been reported with routine NCS.

A single study of 10 patients with pacemakers with bipolar sensing configurations and 5 patients with ICDs found no evidence of cardiac device sensing or malfunctioning with routine NCS utilizing surface stimulation (including left Erb's point stimulation in 9 patients).[54] The authors did not evaluate ICDs placed in the lower abdomen or pacemakers with unipolar sensing mode. Although percutaneous nerve stimulation may be performed in patients with implanted cardiac pacemakers with little risk, [39] complete inhibition of a unipolar pacemaker in conjunction with an interscalene nerve stimulator (utilized for regional anesthesia) was reported.[25]

A stimulator, therefore, should be used only with extreme caution if it is necessary to stimulate the brachial plexus ipsilateral to a pacemaker or ICD implantation site, particularly if it is unknown if the sensing mechanism is unipolar or bipolar. Caution is advised when performing intramuscular percutaneous stimulation, especially in the upper extremities, as the safety of its performance has not been established. Special care should be given to proper grounding of the patient. Routine consultation with the patient's cardiologist is not required.

In patients with external cardiac pacemakers, the conductive lead, inserted into the heart (usually transvenously) and connected to the external cardiac pacemaker, presents a serious potential hazard of electric injury to the heart.[2] NCSs are not recommended in any patient with an external conductive lead terminating in or near the heart.

The nature of recurrent and frequent electrical impulses that may occur with repetitive stimulation or eliciting somatosensory evoked potentials (SSEP) poses a special circumstance. Nerve stimulation in the lower extremities or in distal upper extremities would be unlikely to have untoward effects upon pacemakers or ICDs. Repetitive stimulation for assessing integrity of the neuromuscular junction typically necessitates study of proximal and/or cranial nerve-innervated muscles, which may place the stimulating electrode closer to the cardiac device. Nonetheless, as there are no data to determine the safety of performing these procedures in patients with pacemakers or ICDs, proximal upper extremity and cranial nerve stimulation sites should be avoided for repetitive and SSEP stimulation.

Needle EMG recording does not introduce electrical current into the body and, therefore, poses no risk of interference with implanted cardiac devices.

Deep Brain Stimulators

Deep brain stimulators (DBS) are increasingly prevalent in patients with Parkinson's disease, dystonia, and other disorders. The DBS devices consist of either (1) a single stimulator implanted on either side of the pectoralis muscle which is capable of stimulating the subthalamic nucleus bilaterally through two separate leads or (2) two stimulating devices, one placed on each side of the chest, stimulating only the ipsilateral side. The DBS leads typically traverse subcutaneously from the subclavicular area to the lateral-posterior neck and then over the occiput to penetrate the skull at variable sites in the parietal area.

Electromagnetic interference from medical and household devices may cause DBS devices to switch ON or OFF. Also, some patients may "experience a momentary increase in their perceived stimulation" described as uncomfortable (Medtronic Physician and Hospital Staff Manual; Soletra® & Kinetra® devices). More importantly, NCSs pose a theoretical risk of introducing electrical current through the leads, which could be transmitted directly to the brain. The typical stimulation intensity of DBS devices range from 12–50 μA, which is far below current employed in routine NCS (personal communication, Medtronics). The course of the DBS leads through the supraclavicular and occipital areas may pose additional risks to Erb's point and cervical root stimulation. As there currently are no studies assessing the safety of performance of NCS in patients with DBS devices, the physician should evaluate the risks and benefits of EDX testing in each case.

ELECTRODIAGNOSTIC TESTING OF PREGNANT WOMEN

No known contraindications exist from performing needle EMG and NCSs on pregnant patients. In addition, no complications from these procedures have been reported in the literature. Evoked response testing, likewise, has not been reported to cause any problems when performed during pregnancy.

NEEDLE ELECTRODIAGNOSTIC EVALUATION OF CHEST WALL AND ABDOMINAL MUSCULATURE

At times, needle nerve stimulation or needle EMG of intercostal muscles or muscles in the supraclavicular region, supraspinatus muscles, serratus, rhomboids, diaphragm or paraspinal muscles (cervical or thoracic) may be indicated. Because of the proximity of these nerves and muscles to the pleura and lung, pneumothorax is a

complication that may occur if the needle penetrates these structures. Peritonitis is a potential hazard following inadvertent penetration of the peritoneum during intercostal or abdominal muscle needle EMG. The EDX physician must use clinical judgment to decide if the value of the data to be obtained is greater than the risk involved.[33,34,44,50]

OTHER CONSIDERATIONS

In certain circumstances, the performance of needle EMG or NCSs may lead to an increased incidence of complications or erroneous results. These may include a patient who is agitated and unable to cooperate, a patient with a very recent myocardial infarction, a patient with hyperesthesia, or a patient with a neuromuscular problem in an edematous limb. Clinical judgment in each individual circumstance should be used in deciding if the risk of complication is greater than the value of the information to be obtained from an EDX examination.

DISCLAIMER

This report is provided as an educational service of the AANEM. It is based on an assessment of the current scientific and clinical information. It is not intended to include all possible methods of care of a particular clinical problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The
AANEM recognizes that specific patient care decisions are the prerogative of the patient and his/her physician and are based on all of the circumstances involved.

A search of medical databases (Cochrane Database of Systematic Reviews, PubMed NLM, MEDLINE (1966–2004), and MEDLINE In-Process) was performed in March 2009 by the AANEM Professional Practice Committee. Searches were performed using the terms “electromyography or EMG”, cross-referenced with relevant topics including “lymphedema or lymph node dissection or lymph node excision”, “joint prosthesis or arthroplasty, replacement”, “pacemaker or defibrillator”, “contraindications to performing needle EMG, NCSs, and EPs during pregnancy” and “standards, injuries, etc., related to EMG in pregnancy.” Additional pertinent articles were discovered through review of references from relevant articles.

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Approved December 16, 2009 by the AANEM Board of Directors