

Provision of Intravenous EDTA Chelation as a Complementary and Alternative Medicine

Guideline

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To serve the public and guide the medical profession

Alberta Guidelines for the Provision Of Intravenous EDTA Chelation as a Complementary and Alternative Medicine

The College of Physicians and Surgeons of Alberta (CPSA) approves requests to provide complementary health care therapies from physicians who meet the College's requirements for training and standards of practice.

Although the College does not approve therapies themselves, the development of a standardized approach based on published research or on expert experience is desirable for some therapies. This particular guideline was developed by Alberta physicians who provide chelation therapy. The protocol for chelation therapy of the American College for Advancement in Medicine (ACAM) forms the basis for the safe provision of intravenous EDTA chelation therapy and should be used together with this guideline when reviewing chelation practices in Alberta.

This guideline applies only to the intravenous administration of disodium ethylene diamine tetra acetate (EDTA). The use of other chelating agents requires consideration of their differing pharmacological properties.

A. Personnel – Medical

1. Physicians are eligible for approval to provide chelation therapy if they have:
 - i) a license to practice medicine in Alberta;
 - ii) a certificate of competence in chelation therapy from the American College for Advancement in Medicine;
 - iii) evidence of continuing education in chelation therapy;
 - iv) an active practice or recent upgrading in chelation therapy; and
 - v) a current certification in cardiopulmonary resuscitation.

B. Personnel – Other

1. At least one other staff member must be present in the facility when patients are being chelated.

C. Restricted Duties

1. Calculating dosages, and mixing and preparation of medications must be performed by:
 - i) an approved physician;
 - ii) a registered nurse, under the direction of an approved physician;
 - iii) a licensed practical nurse with a certificate of competence in intravenous medications, under the direction of an approved physician; or
 - iv) a pharmacist, under the direction of an approved physician.
2. Patients must be monitored during intravenous infusion by:
 - i) an approved physician;
 - ii) a registered nurse knowledgeable about chelation therapy, under the medical supervision of an approved physician; or
 - iii) a licensed practical nurse knowledgeable about chelation therapy with a certificate of competence in intravenous therapy, under the medical supervision of an approved physician.

3. The maximum number of patients that should be monitored by each staff member is twelve (12).

D. Relative Contraindications to chelation therapy include:

1. a creatinine clearance less than 30 ml/min (as calculated by the Cockcroft-Gault formula);
2. uncontrolled congestive heart failure;
3. hypocalcemia (i.e. corrected serum calcium less than 2.10 mmol/L);
4. significant hepatic dysfunction;
5. active tuberculosis within one year;
6. allergy to EDTA or other ingredients used in this therapy;
7. pregnancy or breastfeeding; or
8. ongoing dialysis for renal failure.

E. Patient Assessment includes:

1. a medical assessment prior to the first chelation treatment, which includes:
 - i) a medical history, including past and current treatments;
 - ii) a complete physical examination;
 - iii) a review of relevant past medical records; and
 - iv) all necessary investigations and consultations to ensure optimum and safe chelation treatment; and
2. discussion with the patient, which includes:
 - i) available options for treatment;
 - ii) evidence for the efficacy of chelation therapy for the indication chosen;
 - iii) the safety and potential toxicity or adverse effects of chelation therapy;
 - iv) the physician's professional experience with chelation;
 - v) the number of chelation treatments and time frames recommended;
 - vi) the costs involved to the patient;
 - vii) a recommended minimum period of reflection of 72 hours prior to commencement of treatment and the patient's right to waive the 72 hour period of reflection;
 - viii) a signed consent by the patient acknowledging the above.

F. Laboratory Investigations

1. Laboratory investigations prior to initiating chelation therapy should include, but are not limited to:
 - i) urinalysis, CBC, serum creatinine, fasting blood glucose, calcium and serum albumin; and a recent electrocardiogram for patients with atherosclerotic disease.
2. Other pre-treatment laboratory investigations should be performed only when indicated from the medical history or the physical examination, and include:

- i) hepatic enzymes, serum electrolytes, coagulation studies (INR), serum digoxin, TSH and lipid profile, and chest radiography.
3. Laboratory investigations performed periodically during the course of chelation therapy should include:
 - i) serum creatinine and urinalysis for all patients;
 - ii) blood glucose for patients with diabetes mellitus; and
 - iii) INR studies for patients treated with anticoagulant medications.

G. Physical Assessments

1. Physical assessments prior to each infusion must include:
 - i) blood pressure;
 - ii) pulse – rate and rhythm; and
 - iii) weight.
2. Physical assessments following each infusion must include:
 - i) blood pressure; and
 - ii) pulse – rate and rhythm.

H. Equipment and Supplies

1. EDTA must be mixed according to written protocols, and in a specified area of the clinic that minimizes interruptions and facilitates aseptic technique.
2. All infused solutions must be labeled as to their content.
3. The dosage of EDTA must not exceed 50 mg per kg of lean body mass (to a maximum of 3 grams of EDTA) on any single treatment and must be administered at a rate not exceeding 16.7 mg/kg per hour.
4. EDTA solutions must be administered through an infusion set with a small gauge needle or catheter (24 or 25 gauge) or a programmable rate controlling device.
5. A glucometer must be available and tested (using two control solutions) on a regular basis, and staff must be instructed on its use.
6. The following must be immediately available for the management of medical emergencies:
 - i) sufficient space for two rescuers and the patient;
 - ii) a backboard for compressions during cardiopulmonary resuscitation;
 - iii) an emergency tray containing the following drugs which are clearly labeled and stored in an orderly and easily accessible manner:
 - (a) epinephrine
 - (b) atropine
 - (c) calcium gluconate
 - (d) 50% dextrose in water
 - (e) nitroglycerin spray
 - (f) acetylsalicylic acid (ASA)

- iv) oral airways;
 - v) a self-inflating bag-valve-mask device;
 - vi) an oxygen supply equipped for emergency administration by mask, nasal prongs or a bag-valve-mask device; and
 - vii) suction equipment to clear the airway
7. All drugs must be stored:
- i) in a manner suitable for their security, re-stocking and renewal of out-dated supplies; and
 - ii) according to manufacturers' instructions, if any.

I. Documentation

1. Documentation in the patient's clinical record pertaining to chelation therapy must include:
- i) the preliminary assessment and consent;
 - ii) medication flow sheets which include the dosage, route and time of administration;
 - iii) flow sheets for laboratory test results; and
 - iv) progress notes containing assessments of symptoms and physical findings during the course of chelation therapy.

J. Quality Improvement

1. A central record should be kept of all adverse incidents (e.g. needlestick injuries, medication errors, complications) and action taken to prevent recurrences.

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