The doctrine of Res Ipsa Loquitur

Malpractice is a specific area of the law of “negligence.” Under the law of negligence, if one party owes a duty of care to another and the duty is breached, causing harm to someone, the person who is harmed is entitled to recover damages.

In a professional setting, it is presumed that the standard of care is too difficult and complex for the jury to understand and expert testimony is introduced to establish the standard of care. It is the profession which determines the standard of care.

A key element of the law of both negligence and malpractice is fault; the defendant must have caused the damage. The theoretical basis of negligence or malpractice is the concept that the defendant should pay for damage caused to the plaintiff because, between the two parties, the one at fault should bear the damage. In terms of prevention, the knowledge that one can be held liable for malpractice or negligence is supposed to make people more careful and avoid negligent actions in the future.

In cases involving anesthesia, these legal concepts become somewhat unfair because the field is too complicated for the average patient to understand, and the patient is unconscious when the actions which cause the damage, if any, are taken. As a result, many cases involving malpractice of anesthetists involve the concept of Res Ipsa Loquitur.

Basis of Res Ipsa Loquitur

Res Ipsa Loquitur, literally translated as “the thing speaks for itself” had its basis in a case decided in 1863 in which a barrel of flour rolled out of a warehouse window and fell on a passing pedestrian. (Byrne v. Boadle, 1863, 159 Eng. Rep. 299). Although the pedestrian had not personally observed whatever went wrong on the upper floor of the warehouse, it was clear to the court that this type of accident would not have happened without someone’s negligence and whoever caused it must have been under the control of the warehouse owner. (See discussion in Law of Torts, William L. Prosser, page 217).

The doctrine of Res Ipsa Loquitur depends on three things: (1) the injury must occur under circumstances such that in the ordinary course of events, the injury would not have occurred if someone had not been negligent; (2) the injury must be caused by something within the exclusive control of the defendant; and (3) the injury must not have been due to any voluntary action or contribution on the part of the plaintiff.

Classic examples are exploding boilers, defective food in sealed containers and various types of falling objects including not only barrels of flour but elevators and, in one case, a 600-pound cow.

Anesthesia accidents and Res Ipsa Loquitur

Anesthesia accidents almost invite the application of the doctrine of Res Ipsa Loquitur. In an anesthesia accident, the third requisite, that the plaintiff did not contribute to the accident, is almost always true, especially where the patient is unconscious. Similarly, if an anesthesia injury has occurred, the instrumentality
which caused the damage will be within the exclusive control of the anesthetist.

It is the application of the first requisite, that the event must be of a kind which ordinarily does not occur in the absence of someone's negligence, which has caused whatever theoretical disputes there may be over the application of the doctrine to anesthesia.

As we have seen, the basis of the law of negligence is fault. There are many accidents which can occur without anyone being at fault. Someone slipping and falling, a blow-out of a tire, skidding cars and fires of unknown origin have all been held to be situations where the doctrine of Res Ipsa Loquitur would not apply because it could not be said that the injury could not have occurred without negligence (see Prosser, page 220).

Theoretically, laymen are supposed to understand that anesthesia is an area where accidents can happen without anyone being at fault. Realistically, however, it is a tribute to anesthetists in this country that anesthesia accidents occur so infrequently that there is a common tendency, albeit incorrect, to believe that the accident would not have occurred without someone being negligent.

There is also a great economic incentive for the patient to base the case on Res Ipsa Loquitur. Lawsuits can be very expensive and they can be made even more expensive by having to hire expert witnesses to testify as to the standard of care. The major benefit to a patient of the doctrine of Res Ipsa Loquitur is that it throws the burden of proof on the defendant. Plaintiff's lawyers love Res Ipsa Loquitur. Expert testimony becomes simpler. Instead of having to testify after an extensive investigation that what was done in this case failed to meet anesthesia standards, experts need only testify that the injury would not have occurred in the absence of negligence. Not only is this testimony simpler for the jury to understand but it is less expensive to prepare. Moreover, the nature of Res Ipsa Loquitur almost gives the jury a "free hand" in finding for the patient if the jury is sympathetic.

Defense of Res Ipsa Loquitur in anesthesia

How can a defendant-anesthetist defend a case of Res Ipsa Loquitur? The defendant must introduce the defendant's own proof that (1) whatever instrumentalities were in the defendant's exclusive control during the operation were not those that caused the injuries; and/or (2) there were numerous ways in which the incident could have occurred other than the anesthetist's negligence. Thus, in anesthesia cases, the role of the jury becomes one of choosing to believe the defendant's expert witnesses or the plaintiff's expert witnesses as to whether the injury would have occurred without negligence.

One issue which the courts often address is the question of whether the doctrine can be applied when the plaintiff has some proof of how the injury occurred. In Kemalyan v. Henderson, 277 P.2d 372, the court pointed out that the plaintiff's evidence establishes how an injury occurs, the plaintiff cannot rely on the doctrine of Res Ipsa Loquitur. In the Kemalyan case, the hospital alleged that because there was some testimony (one of the doctors testified that the accident was likely to have occurred because of a negligent intubation), the plaintiff should not be allowed to rely on the doctrine of Res Ipsa Loquitur. The court held that the doctrine could still be used by the plaintiff, nonetheless.

In Marrero v. Goldsmith, 486 So.2d 530 (Florida, 1986), the plaintiff complained of numbness, weakness and pain in her left arm and produced expert medical testimony that this type of injury is one that ordinarily does not occur in the absence of negligence and that it was probably caused by incorrect arm positioning during surgery. The court noted that a plaintiff could still rely on Res Ipsa Loquitur even if some direct evidence of negligence had been introduced. The court agreed, however, that there comes a point when a plaintiff can introduce enough direct evidence of negligence to eliminate the justification for the doctrine.

The court said, "It is quite clear that under traditional Res Ipsa Loquitur analysis, the defendant doctors in this case cannot be said to have each possessed exclusive control at all times when plaintiff's injury may have occurred. Yet the patient is in no position to prove which defendant or combination of defendants caused her injury to an area of her body remote from the site of surgery, because she was unconscious when it occurred. We are persuaded that the fairest course to take under these particular circumstances is to allow the plaintiff to go to the jury with the benefit of Res Ipsa Loquitur instruction."

In a case involving similar facts, the defendant argued that a patient could begin to rise out of an appropriate level of unconsciousness despite the exercise of due care. However, the court pointed out that the damage in the case was caused by disconnection from the anesthesia equipment and there was "no testimony that this disconnection could have occurred without negligence." Kittov v. Gilbert, 570 P.2d 544 (Colo. 1977).

In Morgan v. Children's Hospital, 480 N.E.2d 464 (Ohio 1985, also reported at 49 ALR 4th 51 with an extensive annotation on the application of Res Ipsa Loquitur to anesthesia malpractice cases), the expert witnesses agreed that the patient suffered brain damage as a result of oxygen deprivation. The plaintiff requested
that the jury be instructed on the application of *Res Ipsa Loquitur* and was refused, and the jury returned a verdict in favor of the defendant anesthetist. On appeal, the court held that the jury should have been instructed on *Res Ipsa Loquitur*. A dissent in the case pointed out the difficulty in establishing whether there was evidence sufficient to prove that the injury would have occurred in the absence of negligence.

In a California case, there was a verdict against both the surgeon and an anesthesiologist who apparently failed to communicate on how long each expected the operation to take. The anesthesiologist had given a spinal which became ineffective prior to the completion of the operation, and although he testified that he could have extended the spinal if he had known the operation would have taken longer, the surgeon became uneasy as the effects of the anesthetic wore off and quickly terminated the operation.

The court noted that there was sufficient evidence to support a conclusion of negligence against both doctors, but nonetheless determined that an instruction on *Res Ipsa Loquitur* should have been given to the jury. Interestingly, the opinion stated that “courts have relied upon common knowledge and upon expert testimony” in determining the application of the principle to medical cases. *Clark v. Gibbons*, 66 Cal. 2d 399, (Apr. 21, 1967).

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**Letters**

*(continued from page 3)*

**To the Editor:**

The use of disposable, molded plastics in anesthesia circuits is fast becoming universal. Although hygienic and convenient in an age of paranoia concerning disease transmission and increasing labor costs, they are not without their hazards. We shall now describe an event illustrating one of these hazards.

On this occasion following an otherwise smooth induction of anesthesia the 90 degree elbow connector and straight wye piece twice disconnected following a build up of pressure in the circuit. Close inspection of the 90 degree elbow connector revealed a bubble of air in the wall of the distal limb. (Figure 1) *This considerably reduced* the size of its lumen and made a tight fit onto the endotracheal tube impossible.

The 90 degree elbow connector was changed and the patient came to no harm. Disposable circuits and connectors have made our jobs easier, however, we should be vigilant to their potential hazards.

SUSIE DANIELE, CRNA
Jackson Memorial Medical Center
Department of Anesthesiology
Miami, Florida

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**Figure 1**

[Image of a bubble in a plastic connector.]
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Florida

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We have immediate openings in our modern 205-bed open heart JCAH accredited hospital which adjoins Daytona Beach, FL. Enjoy year-round warm climate, beautiful beaches, swimming, golfing, tennis, hunting, fishing and other outdoor activities. Candidate must be Florida licensed and be a member of the American Association of Nurse Anesthetists.

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The first stable water...
Virtually no pain or phlebitis with I.V. injection

In double-blind multicenter studies, water-soluble VERSED (brand of midazolam HCl/Roche) produced less pain or burning during I.V. administration than diazepam.\(^2\) VERSED also produced less postprocedural irritation: One week following I.V. administration, only 1.4% of 512 VERSED patients had tenderness of the vein compared with 3.0% of 503 patients who received diazepam \((P = 0.07)\).\(^2\)

Less postprocedural recall than with diazepam I.V.

Patients treated with VERSED also had significantly less recall of endoscopic procedures than patients receiving diazepam. Of 256 VERSED patients, well over half—60%—had no recall of their procedures when questioned one hour later. By contrast, only 21% of 262 diazepam patients had a similar lack of recall.\(^1\)

Faster onset and better sedation than with diazepam I.V.

In the majority of clinical studies, the time required to reach slurred speech was significantly shorter when patients received VERSED I.V. rather than diazepam I.V. For most procedures, mean time to achieve sedation with VERSED ranged from 2.8 to 4.8 minutes, compared to a range of 2.6 to 9.0 minutes with diazepam.\(^1\) Physicians also tended to prefer the quality of sedation achieved with VERSED in cystoscopy and cardiac diagnostic procedures.\(^1\) (See chart below.)

### PERCENT OF PHYSICIANS WHO ASSESSED QUALITY OF SEDATION AS EXCELLENT

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th>VERSED I.V.</th>
<th>Diazepam I.V.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cystoscopy Procedures</strong> (^1)</td>
<td>Outstanding 61% (66/108)</td>
<td>Average 48% (52/109)</td>
</tr>
<tr>
<td><strong>Cardiovascular Procedures</strong> (^2)</td>
<td>Outstanding 78% (36/46)</td>
<td>Average 36% (17/47)</td>
</tr>
</tbody>
</table>

\(^1\)Angiography or cardiac catheterization.

As a standard precaution, prior to the I.V. administration of VERSED in any dose, oxygen and resuscitative equipment should be immediately available and a person skilled in maintaining a patent airway and supporting ventilation should be present. Extra care should be observed in the elderly or debilitated (such as lowering dosage 25% to 30%), and in those with limited pulmonary reserve. Dosage of VERSED should also be lowered by about 25% to 30% if narcotic premedication is used. Caution patients against driving or operating hazardous machinery after receiving VERSED.

Compatible in the same syringe with other common premedicants

VERSED can be mixed in the same syringe with morphine sulfate, meperidine, atropine or scopolamine. When given concomitantly with narcotics, doses of VERSED should be reduced. (See dosing guidelines below.)

### DOSAGE AND ADMINISTRATION GUIDELINES FOR I.V. CONCUSSION SEDATION

#### Usual Adult Dose

<table>
<thead>
<tr>
<th>Dose</th>
<th>(0.035 \text{ mg/kg})</th>
<th>(0.15 \text{ mg/kg})</th>
<th>(0.2 \text{ mg/kg})</th>
</tr>
</thead>
<tbody>
<tr>
<td>(2.0) mg</td>
<td>(0.06 \text{ mL})</td>
<td>(0.1 \text{ mL})</td>
<td>(0.2 \text{ mL})</td>
</tr>
</tbody>
</table>

Recommended dose: 2.0 mg (0.06 mL) for initial titration in average healthy adult. Up to 0.2 mg/kg may be needed in rare cases, particularly when concomitant narcotics are omitted. Doses in excess of 0.15 mg/kg may result in increased risk of respiratory depression or drowsiness in elderly or debilitated patients. Lower dosage by 25-30% when narcotic premedication is given.

#### Administration

Slow I.V. administration over 2 to 3 minutes; titrate to desired sedative endpoint, i.e., until the initiation of slurred speech is reached. Administer immediately before the procedure. Use of a topical anesthetic for peroral procedures and narcotic premedication for bronchoscopies is recommended.

**IMPORTANT:** Start with the lowest appropriate dose and titrate slowly.

VERSED can be diluted with 5% dextrose in water, normal saline or lactated Ringer's solution.

**NOTE:** Potency of VERSED is approximately three to four times that of diazepam.

VERSED is contraindicated in patients with a known hypersensitivity to the drug. Benzodiazepines are contraindicated in patients with acute narrow angle glaucoma; however, they may be used in patients with open angle glaucoma only if they are receiving appropriate therapy.

---

**solute benzodiazepine**
VERSED* (brand of midazolam HCI/Roche) INJECTION

References:

Before prescribing, please consult complete product information, a summary of which follows:

INDICATIONS: IM: preoperative sedation; to impair memory of perioperative events. IV: conscious sedation prior to short diagnostic or endoscopic procedures, alone or with a narcotic. IM: general anesthesia before administration of other anesthetic agents; as a component of intravenous supplementation of nitrous oxide and oxygen (balanced anesthesia) for short surgical procedures (longer procedures have not been studied). IM: IV: VERSED is associated with a high incidence of partial or complete impairment of recall for the next several hours.

CONTRAINDICATIONS: Hypersensitivity to benzodiazepines or to the drug. Benzo- diazepines are contraindicated in patients with acute narrow angle glaucoma; may be used in open angle glaucoma only if patients are receiving appropriate therapy.

WARNINGS: PRIOR TO IV ADMINISTRATION OF VERSED IN ANY DOSE, ENSURE THAT OXYGEN AND RESUSCITATIVE EQUIPMENT FOR MAINTAINING A PATIENT AIRWAY ARE AT HAND. PRE-OXYGENATION AND SERVING AS PART OF VENTILATION ARE IMMEDIATELY AVAILABLE. IV VERSED depresses respiration, and opioid agonists and other sedatives can add to this depression; should be administered as induction agent only by a person trained in general anesthesia.

Do not administer in shock, coma, acute alcohol intoxication with depression of vital signs.

Guard against unintended intra-arterial injection: hazards in humans unknown. Avoid extravasation.

Higher risk surgical or debilitated patients require lower dosages for induction of anesthesia, premicated or not. Patients with chronic obstructive pulmonary disease are unusually sensitive to the respiratory depressant effect of VERSED. Patients with chronic renal failure have a 1.5- to 2-fold increase in elimination half-life, total body clearance and volume of distribution of midazolam. Patients with congestive heart failure have a 2- to 3-fold increase in the elimination half-life and volume of distribution of midazolam. Patients over 55 require lower dosages for induction of anesthesia, premicated or not. Because elderly patients frequently have insufficient function of one or more organ systems, and because dosage requirements have been shown to decrease with age, reduce initial dosage and consider possibility of a profound and/or prolonged effect. Concomitant use of barbiturates, alcohol or other CNS depressants may increase the risk of underventilation or apnea and may contribute to profound and/or prolonged drug effect. Narcotic premedication also depresses the ventilatory response to carbon dioxide stimulation.

Hypotension occurred more frequently in the conscious sedation studies in patients pretreated with narcotics.

Gross tests of recovery from the effects of VERSED cannot alone predict reaction time under stress. This drug is never used alone during anesthesia, and the contribution of other perioperative drugs and events can vary. The decision as to when patients may be able to engage in activities requiring mental alertness must be individualized; it is recommended that no patient should operate hazardous machinery or a motor vehicle until the effects of the drug, such as drowsiness, have subsided or until the day after anesthesia, whichever is longer. Usage in Pregnancy: An increased risk of congenital malformations associated with the use of benzodiazepines (diazepam and chlordiazepoxide) has been suggested in several studies. If VERSED is used during pregnancy, apprise the patient of the potential hazard to the fetus.

PRECAUTIONS: General: Increased cough reflex and laryngospasm may occur with general endoscopic procedures. Use topical anesthetic and make necessary countermeasures available; use narcotic premedication for bronchospasm. Decrease intravenous doses by 25% to 30% for elderly and debilitated patients. These patients will also probably require a longer induction period, and a higher dose of IV VERSED for maintenance of anesthesia. VERSED does not protect against increased intracranial pressure or circulatory effects noted following administration of succinylcholine.

VERSED does not protect against increased intracranial pressure or against the heart rate rise and/or blood pressure rise associated with endotracheal intubation under local anesthesia.

Information for patients: Communicate the following information and instructions to the patient when appropriate:
1. Inform your physician about any alcohol consumption and medicine you are now taking, including nonprescription drugs. Alcohol has an increased effect when consumed with benzodiazepines. Therefore, caution should be exercised regarding simultaneous ingestion of alcohol and benzodiazepines. 2. Inform your physician if you are pregnant or are planning to become pregnant. 3. Inform your physician if you are or were a confirmed drug user.

Drug interactions: The hypnotic effect of intravenous VERSED is accentuated by premedication, particularly narcotics (e.g., morphine, meperidine, fentanyl) and also secobarbital and Innovar (fentanyl and droperidol). Consequently, adjust the dosage of VERSED according to the type and amount of premedication. Use a rate reduction in induction dosage requirements of thipenthal (about 15%) has been noted following use of intramuscular VERSED for premedication. The use of VERSED as an induction agent may result in a reduction of the inhalation anesthetic requirement during maintenance of anesthesia.

Drug/Laboratory test interactions: Midazolam has not been shown to interfere with clinical laboratory test results.

Carcinogenesis, mutagenesis, impairment of fertility: Midazolam maleate was administered to mice and rats for two years. At the highest dose (80 mg/kg/day) female mice had a marked increase in incidence of hepatic tumors and male rats had a small but significant increase in benign thyroid follicular cell tumors. These tumors were found in a chronic use, whereas hepatocellular carcinoma will ordinarily be seen in single or several doses.

Midazolam did not have mutagenic activity in tests that were conducted.

A reproduction study in rats did not show any impairment of fertility at up to ten times the human IV dose.

Precautions: Teratogenic effects: Pregnancy Category D. See WARNINGS section. Midazolam maleate injectable, at 5 and 10 times the human dose, did not show evidence of teratogenicity in rabbits and rats.

Labor and delivery: The use of injectable VERSED in obstetrics has not been evaluated. Because midazolam is transferred transcortically and because other benzodiazepines given in the last weeks of pregnancy have resulted in neonatal CNS depression, VERSED is not recommended for obstetrical use. Nursing mothers: It is not known whether midazolam is excreted in human milk. Because other benzodiazepines are excreted in human milk, nursing should be discontinued when VERSED is administered to a nursing woman.

Precautions: Safety and effectiveness of VERSED in children below the age of 18 have not been established.

ADVERSE REACTIONS: Fluctuations in vital signs following parenteral administration are the most frequently seen findings and included decreased tidal volume and/or respiratory rate decrease (23.3% of patients following IV and 10.8% of patients following IM administration) and apnea (15.4% of patients following IV administration), as well as variations in blood pressure and pulse rate. These are common occurrences during anesthesia and surgery and are affected by the lightening or deepening of anesthesia, instrumentation, intubation or use of concomitant drugs.

In the conscious sedation studies, hypotension occurred more frequently after IV administration in patients concurrently premedicated with meperidine. During clinical investigations, these cases (0.2%) of transient fall in blood pressure greater than 50% were reported during the induction phase.

Following IM injection: headache (1.3%), local effects at IM site: pain (3.7%), induration (0.5%), redness (0.5%), muscle stiffness (0.3%). Following IV administration: hic- coughs (3.9%), nausea (2.8%), vomiting (2.6%), coughing (1.3%), "oversedation" (1.8%), headache (15.1%), induration (1.2%), local effects at IM site: tenderness (5.6%), pain during injection (5.0%), redness (2.6%), induration (1.7%), phlebitis (0.4%). Other effects <1%: allergy, urticaria, rash, itching, flushing, CNS/Nervous system: Restlessness, coordination impairment, myoclonus, extrapyramidal reactions. Gastrointestinal: Nausea, vomiting, abnormal bowel function, excessive salivation, retching. CNS: Convulsion, confusion, dizziness, dreams, nervousness, agitation, anxiety, giddiness, restlessness, disturbance of sleep patterns. Cardiac: Ventricular extrasystoles, bradycardia, sinus bradycardia, tachycardia. Integumentary: Bigeminy, premature ventricular con- tractions, vasovagal episodic vasomotor, facial flushing, vasovagal sympatho- adrenergic, vasovagal reaction. Respiratory: Committee on Drugs and Laboratory Tests: Drug/laboratory test interactions:

Drug abuse and dependence: Available data concerning the drug abuse and dependence potential of midazolam suggest that its abuse potential is at least equivalent to that of diazepam.

DOSE AND ADMINISTRATION: Individualize dosage. Elderly and debilitated patients generally require lower doses. Adjust dose of IV VERSED according to type and amount of premedication. IM use: Inject deep in large muscle mass. IV use: Administer slowly; rapid injection may cause respiratory depression or apnea requiring assisted or controlled ventilation. Administer initial dose over 20 to 30 seconds for induction of general anesthesia. May be mixed in the same syringe with morphine sulfate, meperidine, atropine sulfate or scopolamine. Compatible with 5% dextrose in water, 0.9% sodium chloride and lactated Ringer's solution.

OVDOSAGE: Overdosage has not been reported, but manifestations would resemble those observed with other benzodiazepines (e.g., sedation, somnolence, confusion, impaired coordination, diminished reflexes, coma, untoward effects on vital signs). No specific organ toxicity would be expected.

SUPPLIERS: A: All packages contain: Midazolam hydrochloride equivalent to 5 mg/mL. Vials: 1 mL (5 mg), 2 mL (10 mg), 5 mL (25 mg), 10 mL (50 mg)—boxes of 10; Tel-E-JECT disposable syringes; 2 mL (10 mg)—boxes of 10.

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- Onset of reversal significantly faster than with neostigmine or pyridostigmine—60 seconds versus 7 minutes for neostigmine, 12 minutes for pyridostigmine.\(^1,2\)

- Duration of reversal comparable to that of neostigmine—66 minutes versus 76 minutes for neostigmine.\(^1,2\)

- Significantly fewer muscarinic side effects and lower atropine requirement than with neostigmine—edrophonium, 0.5 mg/kg, with only 7 µg/kg atropine, produced minimal change in heart rate or mean arterial pressure compared to noticeable changes in both indexes following neostigmine, 0.04 mg/kg, using twice the atropine dose (15 µg/kg).\(^1,2\)

- May be the preferred reversal agent for atracurium and vecuronium

  "...compared with neostigmine, edrophonium has a more complete spectrum of atracurium reversal characteristics, and... antagonizes more rapidly residual atracurium-induced neuromuscular blockade."\(^3\)

  "Edrophonium may in fact be the preferred reversal agent for routine use with [vecuronium], having the advantages that restoration of voluntary muscle function is very rapid, and that the relatively small dose of atropine required minimizes the unwanted side-effects of this drug."\(^4\)

*Note: When duration of action is adjusted for differences in onset of action, the relative durations are 65 minutes for edrophonium and 69 minutes for neostigmine.*


Please see use information on next page.
DESCRIPTION

ENLON (edrophonium chloride injection, USP) is a rapid acting cholinergic (cholinesterase inhibitor). Chemically edrophonium chloride is ethyl (m-hydroxyphenyl) dimethylammonium chloride and its structural formula is:

\[
\text{C}_2\text{H}_5\text{N}^+ \text{(CH}_3\text{)}_2\text{Cl}^- 
\]

ENLON contains in each mL of sterile solution.

10 mg edrophonium chloride compounded with 0.45% phenol and 0.2% sodium sulfite as preservative, buffered with sodium citrate and citric acid. Its pH is adjusted to approximately 6.4.

CLINICAL PHARMACOLOGY

ENLON (edrophonium chloride injection, USP) activates neuromuscular transmission primarily by inhibiting or reversing acetylcholinesterase. By inhibiting the acetylcholinesterase enzyme, acetylcholine is not hydrolyzed by acetylcholinesterase and is thereby allowed to accumulate. The accumulation of acetylcholine at the sites of cholinergic transmission facilitates transmission of impulses across the myoneural junction.

INDICATIONS AND USAGE

ENLON (edrophonium chloride injection, USP) is recommended as a reversal agent for patients with myasthenia gravis. It is effective in the differential diagnosis of myasthenia gravis. It may also be used as an adjunct to evaluate treatment requirements of the disease and for evaluating emergency treatment in myasthenic crisis. It is not recommended for maintenance therapy in myasthenia gravis.

CONTRAINDICATIONS

ENLON (edrophonium chloride injection, USP) is not to be used in patients with known hypersensitivity to anticholinesterase agents, or in patients having urinary obstructions of mechanical type.

WARNINGS

It is recommended that 1 mL stenile solution be made available for immediate use, to counteract any severe cholinergic reaction. ENLON (edrophonium chloride injection, USP) should be used with caution in patients with bronchial asthma or cardiac autonomic neuropathy. Transient bronchial asthma may occur and be relieved by atropine. Stenile solution isolated instances of cardiac and respiratory arrest following administration of edrophonium chloride have been reported. It is postulated that these are vagomimetic effects.

PRECAUTIONS

General: As with any antagonist of nondepolarizing muscle relaxants, adequate recovery and voluntary respiration and neuromuscular transmission must be established prior to discontinuation of respiratory assistance. Should a patient develop "anticholinesterase insensitivity" for brief or prolonged periods, the patient should be carefully monitored and the dosage of anticholinesterase drugs reduced or withheld until the patient again becomes sensitive to them.

Drug Interactions: The drug should not be administered prior to the administration of any nondepolarizing muscle relaxants. The drug should be administered with caution to patients with symptoms of myasthenic weakness who are also on anticholinesterase drugs. Anticholinesterase over dosage (cholinergic crisis) symptoms may mimic underdosage (myasthenic weakness) so the use of this drug may worsen the condition of these patients (see OVERDOSAGE section for treatment).

Pregnancy Category C: It is not known whether ENLON (edrophonium chloride injection, USP) Thet to fetuses at a rate of 2 mL (5 mg) may be injected after one minute with another intramuscular injection of 0.2 mL (0.5 mg). All signs of hyperreactivity (cholinergic reaction) noted in the intravenous test will be demonstrated in the intramuscular test; however, there is a two to ten minute delay before reaction.

ENLON (edrophonium chloride injection, USP) Test to Evaluate Treatment Requirements in Myasthenia Gravis

The test of ENLON should follow one hour after oral intake of the drug being used to treat the disease. The recommended dose is 0.1 mL to 0.2 mL (1 mg to 2 mg) administered intravenously. Response to ENLON test dose in treated myasthenic patients is summarized as follows:

Underdosed patient: Myasthenic response; characterized by increased muscle strength and severe side reactions

Overdosed patient: Cholinergic response; characterized by decreased muscle strength (ptosis, diplopia, dysphonia, dysphagia, dysarthria, respiration, limb weakness). This indicates inadequate treatment of the myasthenic condition.

Contraindicated patient: Adequate response, characterized by no change in muscle strength. With minimal side reactions (tachycardia, diaphoresis, ptosis, abdominal cramps, nausea, vomiting, diarrhea). Pancillations (irritability, irritability, facial muscle) may or may not occur. The responses indicate that therapy is stabilized.

OVERDOSAGE

Muscarinic-like symptoms (nausea, vomiting, diarrhea, sweating, increased bronchial and salivary secretions and bradycardia) may appear with overdosage (cholinergic crisis). ENLON (edrophonium chloride injection, USP) may be managed by the use of atropine. Obstruction of the airway by bronchial secretions can arise and may be managed with suction. If an endotracheal tube has been inserted) and by the use of atropine. Signs of atropine overdosage such as dry mouth, flush and tachycardia should be avoided as tachycardic reactions and bronchial plugs may form. Should edrophonium chloride overdose occur:

1. Maintain respiratory exchange.
2. Monitor cardiac function.

Appropriate measures should be taken if convulsions or shock are present.

DOSEAGE AND ADMINISTRATION

The recommended adult intravenous injection for antagonism of neuromuscular block:

Administer 1 mL (10 mg) slowly within a period of 30 to 45 seconds, the dosage may be repeated to a maximum total dose of 4 mL (40 mg). If onset of action is manifest within 30 to 60 seconds after injection. Response should be monitored carefully and assisted ventilation should always be employed. When given to counteract muscle relaxant overdosage, the dose effect on respiration should be observed prior to repeat doses and assisted ventilation should be employed.

ENLON (edrophonium chloride injection, USP) Test in Differential Diagnosis of Myasthenia Gravis:

Adults:

Intravenous Dose: Prepare a tuberculin syringe with 1 mL (10 mg) of ENLON and an intravenous needle; intravenously inject 0.2 mL (2 mg) within 15 to 30 seconds. The needle should be left in situ. If a cholinergic reaction (muscarinic side effects, skeletal muscle fasciculations and overshoot) occurs, discontinue test and intravenously administer 0.4 mg to 0.5 mg atropine sulfate. Inspect the response within 15 seconds. If no reaction occurs after 45 seconds the test may be repeated after one-half hour.

Intramuscular Dose: Intramuscularly inject 1 mL (10 mg) of ENLON. If hypereactivity (cholinergic reaction) is demonstrated, retest the patient after one-half hour with another intramuscular injection of 0.2 mL (2 mg). ENLON will eliminate the possibility of false-negative reactions.

Children:

Intravenous dose in children weighing up to 75 pounds: Intravenously inject 0.1 mL (1 mg) ENLON. If there is no response within 45 seconds, intravenous dose of 0.1 mL (1 mg) given every 30 to 45 seconds may be administered to a maximum total dose of 0.5 mL (5 mg). The recommended dose in infants is 0.05 mL (0.5 mg).

Intravenous dose in children weighing above 75 pounds: Intravenously inject 0.2 mL (2 mg) ENLON. If there is no response within 45 seconds, incremental doses of 0.1 mL (1 mg) given every 30 to 45 seconds may be administered to a maximum total dose of 1 mL (10 mg).

Intramuscular Dose: Intramuscularly inject 0.2 mL (2 mg) ENLON in children weighing up to 75 pounds. Above this weight, the dose is 0.5 mL (5 mg). All signs of hyperreactivity (cholinergic reaction) noted in the intravenous test will be demonstrated in the intramuscular test; however, there is a two to ten minute delay before reaction.

ENLON (edrophonium chloride injection, USP) Test to Evaluate Treatment Requirements in Myasthenia Gravis

The test of ENLON should follow one hour after oral intake of the drug being used to treat the disease. The recommended dose is 0.1 mL to 0.2 mL (1 mg to 2 mg) administered intravenously. Response to ENLON test dose in treated myasthenic patients is summarized as follows:

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OVERDOSAGE

Muscarinic-like symptoms (nausea, vomiting, diarrhea, sweating, increased bronchial and salivary secretions and bradycardia) may appear with overdosage (cholinergic crisis). ENLON (edrophonium chloride injection, USP) may be managed by the use of atropine. Obstruction of the airway by bronchial secretions can arise and may be managed with suction. If an endotracheal tube has been inserted) and by the use of atropine. Signs of atropine overdosage such as dry mouth, flush and tachycardia should be avoided as tachycardic reactions and bronchial plugs may form. Should edrophonium chloride overdose occur:

1. Maintain respiratory exchange.
2. Monitor cardiac function.

Appropriate measures should be taken if convulsions or shock are present.
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Pavulon® (pancuronium bromide injection)

Now...tangibly different.


Contraindications: Sufentanl should be administered with caution due to the importance of these organs in metabolism and excretion.

Dosages:

- Onset:
- Duration:

Warnings:

- Sufentanl may obscure signs of respiratory depression produced by sufentanl.
- It may last longer than the duration of the opioid antagonist action, appropriate surveillance should be maintained.
- Sufentanl should be used with caution in patients with pulmonary disease, decreased respiratory reserve or potentially compromised respiratory. In such patients, opioids may additionally decrease respiratory drive and increase airway resistance. During anesthesia, this can be managed by assisted or controlled respiration. Impaired Hepatic or Renal Function: In patients with liver or kidney dysfunction, sufentanl should be administered with caution due to the importance of these organs in the metabolism and excretion.

Indications:

- Sufentanl is a sterile, preservative-free, aqueous solution containing sufentanl citrate equivalent to 50 g per ml of sufentanl base for intravenous injection. The solution has a pH range of 3.5-6.0.

Contraindications:

- Sufentanl is contraindicated in patients with known hypersensitivity to the drug.

Precautions:

- General: The initial dose of sufentanl should be appropriately reduced in elderly and debilitated patients.
- The effect of the initial dose should be considered in determining supplemental doses.
- Vital signs should be monitored closely. Nifedipine may proce cardiovascular depression when given with high doses of sufentanl (see CLINICAL PHARMACOLOGY). The hemodynamic effects of a particular muscle relaxant and the degree of skeletal muscle relaxation required should be considered in the selection of a neuromuscular blocking agent. High doses of pancuronium may produce increases in heart rate during sufentanl-oxygen anesthesia.

Interactions:

- Phoenix and barbiturates, tranquilizers, other opioids, general anesthetics or other CNS depressants. In such cases of combined treatment, the dose of one or both agents should be reduced.
- Head injuries: Sufentanl may obscure the clinical course of patients with head injuries.
- Impaired Respiration: Sufentanl should be used with caution in patients with pulmonary disease, decreased respiratory reserve or potentially compromised respiration. In such patients, opioids may additionally decrease respiratory drive and increase airway resistance.

Adverse Reactions:

- Respiratory depression produced by sufentanl can be reversed by opioid antagonists such as naloxone.
- Respiratory depression caused by opioid analgesics can be reversed by opioid antagonists such as naloxone.

Antidotes:

- Respiratory depression produced by sufentanl can be reversed by opioid antagonists such as naloxone.
- Respiratory depression caused by opioid analgesics can be reversed by opioid antagonists such as naloxone.
THE PRIMARY ANESTHETIC THAT KEEPS PATIENTS ON TRACK

SUFENTA (sufentanil citrate) Injection C1

Predictable control for longer, more stressful procedures

PROVIDES smooth induction
BLUNTS hemodynamic response to intubation and surgical stimulation
REDUCEs need for vasoactive drugs in the intraoperative and postoperative periods
RESULTS in lower postoperative morbidity after aortic surgery compared with isoflurane

CONVENIENT: Fewer ampoules to open

of SUFENTA

Carcinogenesis, Mutagenesis and Impairment of Fertility: No long-term animal studies of SUFENTA have been performed to evaluate carcinogenic potential. The microsomal test in female rats revealed that single intravenous doses of SUFENTA as high as 30 μg/kg (approximately 2.5 times the upper human dose) produced no structural chromosomal mutations. The Ames Salmonella/Escherichia coli metabolic activation test also revealed no mutagenic activity. See ANIMAL TOXICOLOGY for reproduction studies in rats and rabbits.

Pregnancy Category C: SUFENTA has been shown to have an embryocidal effect in rats and rabbits when given in doses 2.5 times the upper human dose for a period of 10 days to over 30 days. These effects were most probably due to maternal toxicity (decreased food consumption with increased mortality) following prolonged administration of the drug. No evidence of teratogenic effects has been observed after administration of SUFENTA in rats or rabbits. There are no adequate and well-controlled studies in pregnant women. SUFENTA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery: There are insufficient data to support the use of SUFENTA in labor and delivery. Therefore, such use is not recommended.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when SUFENTA is administered to a nursing woman.

Pediatric Use: The safety and efficacy of SUFENTA in children under two years of age undergoing cardiovascular surgery have been documented in a limited number of cases.

Animal Toxicology: The intravenous LD₅₀ of SUFENTA in male rats is 34 to 72.5 mg/kg (see ANIMAL TOXICOLOGY for LD₅₀ in other species). Intravenous administration of an opioid antagonist such as naloxone should be employed as a specific antidote to manage respiratory depression. The duration of respiratory depression following overdose with SUFENTA may be longer than the duration of action of the opioid antagonist. Administration of an opioid antagonist should not preclude more immediate countermeasures; in the event of overdose, oxygen should be administered and ventilation assisted or controlled as indicated for hyperventilation or apnea. A patent airway must be maintained, and a nasopharyngeal airway or endotracheal tube may be indicated. If depressed respiration is associated with muscle rigidity, a neuromuscular blocking agent may be required to facilitate assisted or controlled respiration. Intravenous fluids and vasopressors for the treatment of hypotension and other supportive measures may be employed.

DOSAGE AND ADMINISTRATION: The dosage of SUFENTA should be individualized in each case according to body weight, physical status, underlying pathological condition, use of other drugs, and type of surgical procedure and anesthesia. In obese patients (more than 25% above ideal total body weight), the dosage of SUFENTA should be determined on the basis of lean body weight. Dosage should be reduced in elderly and debilitated patients (see PRECAUTIONS).

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Catalyst Research has expanded its continuous oxygen monitoring line by introducing the MiniOx 100 Pulse Oximeter. The MiniOx 100 continues the tradition of dependable, sophisticated, easy-to-operate instrumentation. Dependability! You've come to expect it from Catalyst Research. The MiniOx 100 provides immediate, accurate, non-invasive measurements of arterial oxygen saturation and pulse rate.

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To get to the next chapter of MiniOx and further details on the MiniOx 100 Pulse Oximeter, call 1-800-851-4500

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Chapter I
MiniOx Oxygen Monitors can be found in virtually every hospital in North America. That's because today, more and more hospitals are turning to MiniOx, quality instruments that respiratory therapists, neonatologists and anesthesiologists now rely on in critical situations.

END OF CHAPTER I.

Chapter II
Introducing the MiniOx 100 Pulse Oximeter from the makers of MiniOx. It's pulse oximetry with all the qualities users have come to expect from MiniOx. Expect more in the chapters to come.

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In response to a small request

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(droperidol) Injection

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Most O.R. nurses join the Army Reserve for the challenge. The chance to learn more. Be more. "It may sound corny but it's true." They join, despite busy schedules and previous accomplishment, to grow in new and exciting ways. "You're a counselor, a teacher, a program developer, a leader." Many join for the educational opportunities, often unavailable in the private sector. "I've studied staff development, curriculum design, O.R. nurse management, and taken courses at The American College of Surgeons and The Academy of Ophthalmology — all as part of my Army Reserve training."

They join to refine their nursing skills and to learn new ones. Other O.R. nurses join the Army Reserve for the chance to work part-time outside the O.R. To gain skills and proficiency in unfamiliar fields like mass casualty medicine, triage and the organization and management of a field hospital. "Every time I go into the field, the thing I learn the most about is me."

Still others join for the rewards of being an officer. For the respect, pay and privileges that go with the rank. For the chance to lead and grow in confidence and effectiveness. For the pride that comes with accomplishment. "And the retirement benefits aren't bad, either."

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