The nature of supervision

Key words: Captain of the ship, standard of care, supervision.

In some states, nurse anesthetists must be supervised or directed by a physician. Even in states where there is no statute requiring nurse anesthetists to be supervised, hospitals or other institutions may require it. “Supervision,” despite its frequent appearance remains one of the least understood concepts in nurse anesthetist practice. Its genesis is traced to the historical development of nurse anesthetist practice. A few months ago, yet another court rejected arbitrary constraints concerning supervision and followed the reality of practice in upholding a jury determination that a surgeon was not liable for the improper supervision of a nurse anesthetist.

In recent years, enemies of nurse anesthesia have attempted to increase responsibilities associated with supervision. The dispute about the nature of supervision has nothing to do with patient care. No study has ever shown that anesthesia administered by an anesthesiologist or administered by a nurse anesthetist supervised by an anesthesiologist is any safer or otherwise “better” than anesthesia administered by a nurse anesthetist working alone. Nonetheless, both the American Association of Nurse Anesthetists (AANA) and the American Society of Anesthesiologists (ASA) have much different positions on supervision. The AANA has stated that “Supervision or direction refers to a variety of different practice settings within a continuum. While all satisfy the legal requirement, practice settings take into account the education, experience and capabilities of the nurse anesthetist, the rules and guidelines of the institution in which anesthesia is to be provided, and the needs and desires of the patient, nurse anesthetist, physician, dentist, podiatrist or other health care professional.”

ASA’s position

The ASA’s position is set forth in its “Guidelines for the Ethical Practice of Anesthesiology.” Anesthesiologists working with nurse anesthetists are expected by ASA, to carry out the following responsibilities:

a. Preanesthetic evaluation of the patient.

b. Prescription of the anesthesia plan.

c. Personal participation in the most demanding procedures in this plan, especially those of induction and emergence.

d. Following the course of anesthesia administration at frequent intervals.

e. Remaining physically available for the immediate diagnosis and treatment of emergencies.

f. Providing indicated postanesthesia care.

The ASA standards look remarkably like the Tax Equity and Fiscal Responsibility Act (TEFRA) standards which were adopted in 1982 to determine when a CRNA was “medically directed.” Although it may appear that TEFRA supports the ASA position, such a conclusion would be incor-
rect. The TEFRA requirements are for reimbursement purposes only and, even then, only if the anesthesiologist is to be reimbursed at the same rate as if the anesthesiologist had personally performed the procedure. The Health Care Financing Administration (HCFA) will reimburse anesthesia services provided by a nurse anesthetist whether or not the nurse anesthetist is medically directed by an anesthesiologist and whether or not the supervising anesthesiologist performs the TEFRA conditions.

While the words may be the same, there is a vast difference between a level of supervision which entitles an anesthesiologist to be paid as if he or she administered the service himself or herself and a level of supervision needed to satisfy certain state licensing requirements that there be physician involvement when anesthesia is administered. Nonetheless, ASA has attempted to maintain that “ethical anesthesia” requires that an anesthesiologist evaluate the patient, be present for induction, and perform the remainder of the steps outlined above.

Standards adopted by JCAHO

The Joint Commission on the Accreditation of Health Care Organizations (JCAHO) has adopted standards for supervising anesthesia care which are quite different from the ASA's requirements. JCAHO standards require that anesthesia care for each patient is provided directly by a licensed independent practitioner or by an individual who is “directed or supervised” by a licensed independent practitioner. A JCAHO publication explains: "The standards do not require that a supervising, licensed independent practitioner (for example, surgeon or obstetrician) have privileges to administer anesthesia, but the practitioner must be capable of reviewing the results of the preanesthesia evaluation, of determining that the patient is an appropriate candidate to undergo the planned anesthesia (SA.1.5.2), and of determining that the patient can be discharged (SA.1.5.6)."

Some history

Nor does history support the ASA's restrictive position. What was meant by “supervision” when nurse anesthetist statutes were originally enacted? Even in the early days of anesthesia, nurse anesthetists, being bright and capable, rapidly became more adept at anesthesia than the physicians “supervising” them. Consider three nurse anesthetists (these examples are derived from Virginia Thatcher's book, History of Anesthesia with Emphasis on the Nurse Specialist, and the historic notion of supervision. Thatcher found the first group of nurse anesthetists to be Catholic sisters and she reported an interview with a Sister Secundina Mindrup, CRNA, who had developed a timing device for administering a mixture of ether and chloroform depending on how much relaxation was required: “a decade of prayers on her rosary and it was time to give a little more." Is it likely that the physician “supervising” Sister Secundina would have told her to give anesthesia by timing it with her prayers?

Alice Magaw, the famous nurse anesthetist at the Mayo Clinic, devised her own method of administering open-drop chloroform and ether anesthesia superior to virtually anything that was being used at the time. Physicians came to Mayo to learn her methods. It is obvious that the physicians who admired her work could have added little to her methods or safety through “supervision.” Finally, George Crile, MD, wrote that Agatha Hodgins had learned to skillfully adjust dosages based on her experience and experimentation with anesthetic agents.

Thus, historically, those who supervised nurse anesthetists acknowledged that nurse anesthetists were more knowledgeable, got better results, and had better techniques than the “supervisors.” It was not necessary that Dr. Crile be able to administer anesthesia to “supervise” Agatha Hodgins, CRNA. Being the bright and dynamic woman that she was, it was obvious that after a relatively short period of time of specialization Agatha Hodgins would clearly know more about anesthesia than Dr. Crile. Yet, under the statutes then being adopted, it was understood that Dr. Crile was “supervising” Agatha Hodgins. ASA's requirements for medical direction were never what licensing laws contemplated by “supervision.” Physicians provided some medical input but they were not expected to control the anesthetic process.

In contemporary times, the dispute between AANA and ASA has raged for many years. Since the issue involves the meaning of “supervision” in laws and statutes, it can be assumed that the courts would be involved. However, it has been difficult to find cases in which a court reviews these issues. Licensing and regulatory bodies permit healthcare wide latitude. Since the practice of nurse anesthetists working directly with surgeons is so well accepted, regulatory procedures involving supervision of nurse anesthetists rarely come to court. Similarly, issues of supervision seldom arise in malpractice cases. Nurse anesthetists are expected to administer anesthesia with the same quality and results as anesthesiologists. Thus, most anesthesia malpractice cases are decided on the basis of the standard of care rather than the level of supervision. A surgeon's liability is usually based on
whether the surgeon controlled or had the right to control the procedure which gave rise to the negligence. Cases based on a claim that the surgeon failed to carry out some obligation to supervise are rare. Consequently, it is “news” that the Mississippi Supreme Court recently had an opportunity to discuss supervision in a decision upholding a jury verdict in favor of a surgeon working with a nurse anesthetist.

**Starcher v Byrne**

In *Starcher v Byrne*, 687 So. 2d 737 (Mississippi, 1997), a patient was admitted to a hospital to correct a ventral hernia. Anesthesia was administered by a CRNA employed by an anesthesiologist. As the CRNA began induction, the surgeon received an emergency page. He went into the hallway outside the operating room, but, in compliance with hospital policy, remained within the operating suite to answer the page while the CRNA induced the patient. The nurse anesthetist had trouble inducing the patient. When the surgeon returned, he and the nurse anesthetist determined that the patient was suffering from a bronchospasm. Based on their diagnosis, the operating team conducted emergency treatment. Due to the patient's condition, her heart rate began to fall rapidly. The surgeon successfully administered cardiopulmonary resuscitation to the patient and she was stabilized. However, as a result of her inability to breathe and the failure of her heart to adequately pump blood to all regions of her body, specifically her brain, for several minutes, the patient suffered brain damage resulting in decreased intellectual and physical capacity. The patient remained comatose for several days following the incident.

The plaintiffs (the patient and her husband) brought suit against the surgeon contending that he was negligent because he was not present in the operating room at the induction of anesthesia by the nurse anesthetist. They contended that the standards of practice for nurse anesthetists required that a CRNA work under the direction of and in the physical presence of a licensed physician. Because the nurse anesthetist's employer, the anesthesiologist, was not in the operating room or even at the hospital, the plaintiffs claimed that the surgeon was in charge of the operating room. Therefore, his failure to be present at the induction of anesthesia constituted a breach of the standard of care. At trial, the jury returned a verdict in favor of the surgeon. The plaintiffs appealed, claiming that the jury's verdict was contrary to the weight of the evidence and that the surgeon's absence from the operating room should mean that he was liable because he failed to properly supervise the nurse anesthetist.

Mississippi does not have a statute on nurse anesthesia practice. The Mississippi Board of Nursing requires that nurse practitioners, which includes nurse anesthetists in Mississippi, practice in a collaborative/consultative relationship with a licensed physician or dentist. Interestingly, the Mississippi Supreme Court never mentioned licensing requirements in its decision. Instead, the case was decided based on practice standards and legal doctrines concerning tort liability. The Supreme Court of Mississippi upheld the jury verdict and dismissed the appeal. Basically, the Supreme Court held that the standard of care did not require the supervising physician to be in the operating room while anesthesia was being induced.

**Judge disagrees with decision**

The decision in the *Starcher* case was not unanimous. One of the judges did not agree with the majority and wrote his own opinion. His dissent is interesting because it gives us a hint of what the arguments were on the other side. Those arguments are quite familiar to nurse anesthetists.

The dissenting judge quoted a well-known legal work: “In most states, surgeons may be found liable for the failure to supervise a nurse anesthetist or vicariously liable for a nurse anesthetist's negligence. 8 Am.Jur. Proof of Facts 2d, Surgeon's Failure to Exercise Supervision and Control over Anesthetist § 1,6 (1976). Such liability is usually predicated upon the captain of the ship doctrine... That the surgeon is captain of the ship does not expose him to unfettered liability for the acts of all personnel in the operating room. Rather, at least one court has found that the 'vital test' is whether the surgeon has the right to control the employee. Harris v Miller, 103 N.C.App. 312, 322, 407 S.E.2d 556, 562 (1991). In... [this case],... the issue of whether [the surgeon] had the right to control [the nurse anesthetist] was a proper matter for the jury to consider.”

Unlike the dissenting judge, the majority of the Mississippi Supreme Court was willing to analyze the relationship of the defendants and not rely on labels, as the dissent urged. The statement quoted by the dissent from *Proof of Facts* has caused a number of problems for nurse anesthetists. Someone probably assumed that surgeons “may be found liable for the failure to supervise a nurse anesthetist” because of a number of legal doctrines which once prevailed, such as “captain of the ship.” These doctrines are now outdated and seldom followed. Even when they were followed, the statement gives an inaccurate picture. It is unclear how it came to
be published or who purported to count the cases. There have been any number of decisions in which surgeons were not held liable for the negligence of nurse anesthetists. (In fact, in the Starcher case, there is no suggestion or evidence in the report of the case that the nurse anesthetist was negligent.)

The majority of justices of the Mississippi Supreme Court analyzed the relationship between surgeon and nurse anesthetist and concluded that there was sufficient evidence to uphold the jury's verdict. At trial, testimony had showed that the surgeon had little, if any, say over and was not expected to inject himself into the anesthesia process. There was testimony which the court said the jury could have believed that the surgeon could not tell the nurse anesthetist what to do. Nor could the surgeon expect the nurse anesthetist to obey the surgeon's commands if the nurse anesthetist thought that the surgeon was wrong. Moreover, the court found that it was common practice for a CRNA to perform the anesthesia for surgical procedures, in the absence of an anesthesiologist, so long as a physician was available in case of an emergency.

The plaintiffs had claimed that the standard of practice required that a nurse anesthetist work under the direction of and in the physical presence of a licensed physician. The Mississippi Supreme Court said there two reasons why the plaintiff's argument must fail. First, the standards of practice apply to CRNAs, not physicians. The plaintiffs failed to present any evidence that the standards apply to physicians. Second, with the exception of the plaintiffs' expert witness, no doctor called by either side stated that a physician must be physically present in the operating room at the induction of anesthesia. Every other doctor called unequivocally stated that the common practice was only that the surgeon be in the operating suite. It was the general consensus of all doctors who testified, except for the plaintiffs' expert, that the operating physician had a tendency to get in the way more than anything else when he or she was in the operating room at the induction of anesthesia. Further, the head of a neighboring hospital testified that it was their hospital policy that the operating physician be within the operating suite, not in the operating room at the induction of anesthesia.

The plaintiffs had made a number of claims concerning "captain of the ship" and "borrowed servants" which the court dismissed because the nurse anesthetist was an employee of the anesthesiologist. What made the case of interest was the court's holding on supervision. The court rejected artificial rules and looked to the reality of practice in its holding: "There was adequate evidence that the CRNA could administer anesthesia where neither a surgeon nor an anesthesiologist is present in the operating room, that Mississippi CRNAs are licensed to do so, and that this was a fairly common practice."

REFERENCES


Changes in the health care industry have brought many new challenges to CRNAs and we want to make sure you have the right insurance products to meet those challenges. Anesthesia Professional Liability Services, (A+) now has policies for virtually every practice setting including:

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Naropin™
(ropivacaine HCl)
safety/control
Dose tolerability

In two clinical pharmacology studies, equal infusion rates of Naropin™ (ropivacaine HCl) and bupivacaine were compared. In one clinical pharmacology study, the mean maximum IV dose of Naropin tolerated was significantly higher than that of bupivacaine (124 ± 38 mg of Naropin vs. 99 ± 30 mg of bupivacaine, p < 0.01); in the other clinical pharmacology study, the difference in doses was not statistically significant (115 ± 29 mg of Naropin vs. 103 ± 30 mg of bupivacaine).1,2

Less depression of cardiac conductivity than bupivacaine

In the same two studies, Naropin caused significantly less depression of cardiac conductivity (less QRS widening) than bupivacaine at the end of IV infusion.*1,2

Administration of higher than recommended doses of Naropin to achieve greater motor blockade or increased duration of sensory blockade may negate the advantages of Naropin’s favorable cardiovascular depression profile in the event that an inadvertent intravascular injection occurs. Naropin should be administered in incremental doses.

For obstetrical anesthesia, eg, cesarean section, the 5.0 mg/mL (0.5%) Naropin solution in doses up to 150 mg is recommended. As with all local anesthetics, Naropin should be administered in incremental doses.

Reactions to Naropin are characteristic of those associated with other amide-type local anesthetics. Most adverse events reported in clinical trials were mild and transient, and may reflect the surgical procedures, patient characteristics (including disease) and/or medications administered. Adverse events reported with an incidence >5% were hypotension, fetal bradycardia, nausea, bradycardia, vomiting, paresthesia, and back pain.

Solutions of Naropin should not be used for the production of obstetrical paracervical block anesthesia, retrobulbar block or spinal anesthesia (subarachnoid block) due to insufficient data to support such use. Intravenous regional anesthesia (Bier block) should not be performed due to lack of clinical experience and the risk of attaining toxic blood levels of Naropin. For further information, please see attached brief summary of prescribing information.

*Not an indicated use of Naropin. Please see a brief summary of prescribing information on the following pages.

Limited motor blockade with 2.0 mg/mL (0.2%)³

MOTOR BLOCKADE AT STAGE II OF LABOR²

<table>
<thead>
<tr>
<th>Flow Rate</th>
<th>n</th>
<th>Bromage 3</th>
<th>Bromage 2</th>
<th>Bromage 0-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 mL/hr</td>
<td>31</td>
<td>19%</td>
<td>81%</td>
<td>81%</td>
</tr>
<tr>
<td>8 mL/hr</td>
<td>28</td>
<td>10%</td>
<td>86%</td>
<td>16%</td>
</tr>
<tr>
<td>10 mL/hr</td>
<td>31</td>
<td>3%</td>
<td>86%</td>
<td>16%</td>
</tr>
</tbody>
</table>

Bromage Scale⁴
1 - No motor paralysis
2 - Inability to raise extended leg (just able to move knee and foot)
3 - Inability to flex knee (able to move foot only)
4 - Inability to flex ankle joint (unable to move foot or knee)

Fewer instrumental deliveries with Naropin than bupivacaine

■ In a prospective meta-analysis of six double-blind studies, there were significantly fewer instrumental deliveries in mothers receiving Naropin as compared with bupivacaine (p = 0.004).⁵

Reliable management of acute pain

■ Analgesia during labor was judged as “good” or “excellent” by 87% of patients with 2.0 mg/mL (0.2%) at 6 to 10 mL/h.³

Effective surgical anesthesia with Naropin 10.0 mg/mL (1.0%)

■ Incidence of complete analgesia and complete muscle relaxation similar to bupivacaine 0.75%.⁶
CONTRAINdications
Naropin is contraindicated in patients with a known hypersensitivity to Naropin or to any local anesthetic agent of the amide type.

WARNINGS
For cesarean section, the 5 mg/mL (0.5%) Naropin solution in doses up to 150 mg is recommended. Regional anesthesia (Bier Block) should not be performed due to a lack of clinical experience and the risk of attaining toxic blood levels of Naropin. It is essential that a test dose be aspirated before or concurrent with the initial injection. Adverse reactions may result if the test dose is not successful. If a test dose is unsuccessful, additional doses may be administered only if the patient is monitored for central nervous system and cardiovascular effects. When appropriate, patients should be informed in advance that they may experience temporary loss of sensation and motor activity in the anesthetized part of the body following proper administration of a local anesthetic such as 30 to 40 mg of lidocaine is recommended to detect an unintentional intrathecal injection. Syringe aspirations should also be performed before and during each supplemental injection. During the administration procedure performed, the type and amount of drug used, and the technique of drug administration. Adverse reactions in the parturient, fetus and neonate involve alterations of the cerebral circulation. Patients receiving these blocks should have their circulation and respiration monitored and be constantly observed. Resuscitative equipment and personnel for treating adverse reactions should be immediately available. Dosage recommendations should not be exceeded (see Dose and Administration).

Use in Ophthalmic Surgery
The use of Naropin in retrobulbar blocks for ophthalmic surgery has not been studied. Unti...
excessive plasma levels, which may be due to overdosage, unintentional intravascular injection or slow metabolic degradation.

The reported adverse events are derived from controlled clinical trials in the U.S. and other countries. The reference drug was usually bupivacaine. The studies were conducted using a variety of premedications, sedatives, and surgical procedures of varying length. Most adverse events reported were mild and transient, and may reflect the surgical procedure, patient characteristics (including disease) and/or medications administered.

Of the 3558 patients enrolled in the clinical trials, 2404 were exposed to Naropin. Each patient was counted once for each type of adverse event.

Incidence >5%
- hypotension, postoperative complications, urinary retention, dizziness, pruritus, rigors, anxiety, agitation, amnesia, nausea, vomiting, paresthesia, back pain

Incidence 1-5%
- fever, headache, pain, postoperative complications, urinary retention, dizziness, pruritus, rigors, anxiety, agitation, amnesia, nausea, vomiting, paresthesia, back pain

Incidence <1%
- The following list includes all adverse and intercurrent events which were recorded in more than 1% of patients (see Tables 1a and 1b) and show adverse events (number and percentage) in patients exposed to similar doses in double-blind controlled clinical trials. In the trials, Naropin was administered as an epidural anesthetic/anesthetic for surgery, labor, or cesarean section. In addition, patients that received Naropin for peripheral nerve block or local infiltration are included.

Application Site Reactions - injection site pain Cardiovascular System - vasovagal reaction, syncope, postural hypotension, non-specific ECG abnormalities

Female Reproductive - poor progression of labor, uterine atony Gastrointestinal System - fecal incontinence, tenesmus General and Other Disorders - hypothermia, malaise, muscle spasm, accident and/or injury

Hearing and Vestibular - tinnitus, hearing abnormalities Heart Rate and Rhythm - extrasystoles, non-specific arrhythmias, atrial fibrillation Liver and Biliary System - jaundice Metabolic Disorders - hypokalemia, hypomagnesemia Musculoskeletal System - myalgia, cramps Myelitis/Polyradiculitis - segment changes, myocardial infarction Nervous System - tremor, Horner's syndrome, paraesthesia, dysesthesia, neuropathy, vertigo, convulsion, hypokinesia, hypotonia, paresis, stupor Psychiatric Disorders - agitation, confusion, somnolence, nervousness, amnesia, hallucination, emotional lability, insomnia, nightmares Respiratory System - dyspnea, bronchospasms, coughing Skin Disorders - rash, urticaria Urinary System Disorders - urinary incontinence, urinary tract infection, micturition disorder Vascular - deep vein thrombosis, phlebitis, pulmonary embolism Vision - vision abnormalities

For the indication epidural anesthesia for surgery, the 15 most common adverse events were compared between different concentrations of Naropin and bupivacaine. Table 2 is based on data from trials in the U.S. and other countries where Naropin was administered as an epidural anesthetic for surgery.

Using data from the same studies, the number (%) of patients experiencing hypotension displayed by patient age, drug and concentration in Table 4. In Table 3, the adverse events for Naropin are broken down by gender.
Neurologic Reactions

The incidence of adverse neurologic reactions associated with the use of local anesthetics may be related to the total dose and concentration of local anesthetics administered and are also dependent upon the particular drug used, the route of administration and the physical status of the patient. Many of these observations may be related to local anesthetic techniques, with or without a contribution from the drug.

During lumbar epidural block, occasional unintentional penetration of the subarachnoid space by the catheter or needle may occur. Subsequent adverse effects may depend partially on the amount of drug administered, the location and the physical state of the patient at the time of the block and the postures assumed by the patient during the administration of the drug and subsequent to the block.

Overtreatment of patients may result in a condition characterized by loss of consciousness, respiratory paralysis and bradycardia.

OVERDOSE

Acute emergencies from local anesthetics are generally related to high plasma levels encountered during therapeutic use of local anesthetics or to unintended subarachnoid or intravascular injection of local anesthetic solution. (See ADVERSE REACTIONS, WARNINGS, and PRECAUTIONS.)

Management of Local Anesthetic Emergencies

The practitioner should be familiar with standard contemporary textbooks that address the management of local anesthetic emergencies. No specific information is available on the treatment of overdosage with Naropin; treatment should be symptomatic and supportive. Therapy with Naropin should be discontinued.

The first consideration in prevention, best accomplished by incremental injection of Naropin, careful and constant monitoring of cardiovascular and respiratory vital signs and the patient's state of consciousness after each local anesthetic injection and during continuous infusion. At the first sign of toxicity, overdosage should be immediately treated.

The first step in the management of systemic toxic reactions, as well as underventilation or apnea due to unintentional subarachnoid injection of drug solution, consists of immediate attention to the establishment and maintenance of a patent airway and effective assisted or controlled ventilation. The use of 100% oxygen with a delivery system capable of permitting immediate positive airway pressure by mask. This may prevent convulsions if they have not already occurred. If necessary, use drugs to control convulsions. Intravenous barbiturates, anticonvulsant agents, or muscle relaxants should be administered by the clinician familiar with their use. Immediately after administration of the drug, the patient's condition should be evaluated. Supportive treatment of circulatory depression may require administration of intravenous fluids, and, when appropriate, a vasopressor dictated by the clinical situation (such as ephedrine or epinephrine) to enhance myocardial contractility.

The mean doses of rocuronium producing seizures, after intravenous infusion in dogs, nonpregnant and pregnant sheep were 4.9, 6.1 and 5.9 mg/kg, respectively. These doses were associated with peak plasma concentrations of 5.1, 4.0 and 3.6 mg/mL, respectively. In rats, the LD50 was 9.9 and 12 mg/kg by the intravenous route for males and females respectively.

In human volunteers given intravenous Naropin, the mean maximum tolerated total and free arterial plasma concentrations were 4.3 and 0.6 mg/mL, respectively, at which time moderate CNS symptoms (muscle twitching) were noted.

Clinic data from patients experiencing local anesthetic induced convulsions demonstrated rapid development of hypoxia, hypercarbia and acidosis within a minute of the onset of convulsions. These findings suggest that oxygen concentration and carbon dioxide production are dramatically increased during local anesthetic convulsions and emphasize the importance of immediate and effective ventilation with oxygen which may avoid cardiac arrest.

If difficulty is encountered in the maintenance of a patent airway or if prolonged ventilatory support is indicated, endotracheal intubation, employing different techniques familiar to the clinician, may be indicated after initial administration of oxygen by mask.

The supine position is dangerous in pregnant women at term because of aorta-caval compression which may decrease cardiac output and require the use of a left lateral position. The use of a left lateral position with the patient's mouth open, with the head forward, and the jaw extended to permit the tongue to fall posteriorly and prevent the oral airway from being obstructed.

During anesthesia, the risks of reaching a toxic plasma concentration or inducing local neural injury should be considered. Experience to date indicates that a cumulative dose of up to 770 mg Naropin administered over 24 hours is well tolerated in adults. When used for postoperative pain management, for the treatment of postoperative pain, the following technique can be recommended: If regional anesthesia was not used intraoperatively, then an epidural block with Naropin is induced via an L2 puncture. These observations may include spinal block of varying magnitude (including high or cervical), intraventricular injection, and drug deposition within the spinal subarachnoid space due to traction on nerves from loss of cerebrospinal fluid have been reported (see DOSAGE AND ADMINISTRATION discussion of lumbar epidural block). A high spinal is characterized by loss of consciousness, respiratory paralysis and bradycardia.

CAUTION:

Federal law prohibits dispensing without prescription.

021683R00 Iss.9/96

Dosage Recommendations

<table>
<thead>
<tr>
<th>Dosage Recommendations</th>
<th>CONC mg/mL</th>
<th>Volume mL</th>
<th>Dose mg</th>
<th>Smart min</th>
<th>Duration hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>LUMBAR EPIDURAL</td>
<td>5.0 (0.5%)</td>
<td>15-30</td>
<td>75-150</td>
<td>15-20</td>
<td>2-4</td>
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<tr>
<td>SACRUM</td>
<td>7.5 (1.0%)</td>
<td>15-25</td>
<td>113-180</td>
<td>10-20</td>
<td>4-6</td>
</tr>
<tr>
<td>FIELD BLOCK</td>
<td>5.0 (0.5%)</td>
<td>20-30</td>
<td>100-150</td>
<td>2-15</td>
<td>2-4</td>
</tr>
<tr>
<td>THORACIC EPIDURAL</td>
<td>5.0 (0.5%)</td>
<td>5-15</td>
<td>25-75</td>
<td>10-30</td>
<td>5-8</td>
</tr>
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</table>

**SURGICAL ANESTHESIA**

<table>
<thead>
<tr>
<th>Major Nerve Block</th>
<th>CONC mg/mL</th>
<th>Volume mL</th>
<th>Dose mg</th>
<th>Smart min</th>
<th>Duration hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>(e.g., median nerve block)</td>
<td>5.0 (0.5%)</td>
<td>35-50</td>
<td>175-250</td>
<td>15-30</td>
<td>5-8</td>
</tr>
<tr>
<td>Field Block</td>
<td>5.0 (0.5%)</td>
<td>1-40</td>
<td>5-200</td>
<td>1-5</td>
<td>2-6</td>
</tr>
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</table>

**LABOR PAIN MANAGEMENT**

<table>
<thead>
<tr>
<th>Labor Epidural Administration</th>
<th>CONC mg/mL</th>
<th>Volume mL</th>
<th>Dose mg</th>
<th>Smart min</th>
<th>Duration hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous infusion</td>
<td>2.0 (0.2%)</td>
<td>6-10</td>
<td>12-28</td>
<td>na</td>
<td>1-5</td>
</tr>
<tr>
<td>Incremental</td>
<td>2.0 (0.2%)</td>
<td>6-10</td>
<td>12-28</td>
<td>na</td>
<td>1-5</td>
</tr>
<tr>
<td>Infusion</td>
<td>2.0 (0.2%)</td>
<td>6-10</td>
<td>12-28</td>
<td>na</td>
<td>1-5</td>
</tr>
<tr>
<td>(e.g., minor nerve block)</td>
<td>5.0 (0.5%)</td>
<td>1-40</td>
<td>5-200</td>
<td>1-5</td>
<td>2-6</td>
</tr>
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</table>

**POSTOPERATIVE PAIN MANAGEMENT**

<table>
<thead>
<tr>
<th>Naropin® Astral-E® 20 mg Single Dose Vial</th>
<th>Device</th>
<th>Volume mL</th>
<th>Dose mg</th>
<th>Smart min</th>
<th>Duration hours</th>
</tr>
</thead>
</table>
| 7.5 mg Oxygen consumption and carbon dioxide production are significantly increased during local anesthetic convulsions and emphasize the importance of immediate and effective ventilation with oxygen which may avoid cardiac arrest.

If difficulty is encountered in the maintenance of a patent airway or if prolonged ventilatory support is indicated, endotracheal intubation, employing different techniques familiar to the clinician, may be indicated after initial administration of oxygen by mask.

The supine position is dangerous in pregnant women at term because of aorta-caval compression which may decrease cardiac output and require the use of a left lateral position. The use of a left lateral position with the patient's mouth open, with the head forward, and the jaw extended to permit the tongue to fall posteriorly and prevent the oral airway from being obstructed.

During anesthesia, the risks of reaching a toxic plasma concentration or inducing local neural injury should be considered. Experience to date indicates that a cumulative dose of up to 770 mg Naropin administered over 24 hours is well tolerated in adults. When used for postoperative pain management, for the treatment of postoperative pain, the following technique can be recommended: If regional anesthesia was not used intraoperatively, then an epidural block with Naropin is induced via an L2 puncture. These observations may include spinal block of varying magnitude (including high or cervical), intraventricular injection, and drug deposition within the spinal subarachnoid space due to traction on nerves from loss of cerebrospinal fluid have been reported (see DOSAGE AND ADMINISTRATION discussion of lumbar epidural block). A high spinal is characterized by loss of consciousness, respiratory paralysis and bradycardia.

**HOW SUPPLIED**

Naropin® Astral-E® 20 mg Single Dose Vial

<table>
<thead>
<tr>
<th>Naropin® Astral-E® 20 mg Single Dose Vial</th>
<th>Device</th>
<th>Volume mL</th>
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**CAUTION:**

Federal law prohibits dispensing without prescription.