Hybrid intubation technique for the management of a difficult airway: A case report

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There are circumstances when induction of general anesthesia followed by direct laryngoscopy and intubation is contraindicated. This case report describes and presents a protocol for a method of endotracheal intubation that combines the benefits of light wand and fiberoptic techniques.

The patient was a 73-year-old male with a history of two cervical fusions. He was reported to be “unintubatable” at the time of his last surgery. A physical examination revealed limited neck extension.

Awake endotracheal intubation was accomplished by a hybrid technique, using a light wand and fiberoptic bronchoscope simultaneously. The light wand facilitated positioning of the endotracheal tube at the glottis and provided surface clues concerning the position of the tip of the endotracheal tube. The bronchoscope allowed direct visualization of the pharyngeal, laryngeal, and tracheal anatomy.

Since our initial experience, the hybrid technique has been modified by replacing the light wand with a conventional stylet. Subsequent uses of the technique have been successful and free of complications.

Key words: Difficult intubation, fiberoptic intubation, light wand.

Introduction
When faced with a potentially challenging airway, the anesthetist has many intubation options including traditional direct laryngoscopy, blind methods, and fiberoptic, retrograde, and light wand techniques. Each of these techniques has unique advantages and disadvantages. As practitioners become more versatile at intubation techniques, modifications can be made to take advantage of the optimal characteristics of each method. This case report describes a hybrid method of endotracheal intubation that combines the most attractive aspects of light wand and fiberoptic intubation techniques.

Case summary
A 73-year-old ASA physical status III white male, 173 cm tall, weighing 69 kg, presented to the operating room for repair of an abdominal wall incisional hernia. His previous medical history was remarkable for chronic obstructive pulmonary disease. His significant surgical history included a pyeloureteroplasty and two cervical fusions for a vertebral fracture he sustained 8 years earlier. The patient was unable to provide an anesthetic history; however, his sister reported that he was “unintubatable” at the time of his most recent operation. His physical examination was unremarkable except for limited neck extension.

The anesthesia plan that was initially developed included an awake light wand intubation and oral fiberoptic intubation if the initial attempt was unsuccessful. This proposed plan was modified by using the fiberoptic bronchoscope and light wand simultaneously.

Prior to endotracheal intubation, the patient received glycopyrrolate, 0.2 mg, and fentanyl, 200 µg, intravenously. Anesthesia for intubation included 2% lidocaine, 3 mL, administered transtracheally and lidocaine, 3 mL, injected bilaterally into the thyrohyoid membrane to anesthetize the superior laryngeal nerve. A combination of 14% benzocaine and 2% tetracaine (Cetacaine®) was sprayed topically to anesthetize the oropharynx.

A bronchofiberscope (Olympus® LF-1, Olympus Medical Products, Strongsville, Ohio) and a light wand (Flexi-lum® surgical light, Concept, Clearwater, Florida) were lubricated with 5% lidocaine ointment and inserted into the lumen of a...
9.0-mm internal diameter endotracheal tube (Figure 1). The endotracheal tube, light wand, and fiberscope were advanced in unison through the oropharynx into the trachea using both the surface visual cues of the light wand and direct visual information from the fiberscope.

Intubation was successful on the first attempt. The position of the endotracheal tube was confirmed directly by inspection of the anatomical structures through the fiberscope and indirectly by capnography and chest auscultation. The intubation sequence, from initial insertion of the tube through confirmation of placement, was accomplished in less than 1 minute while maintaining spontaneous ventilation. Vital signs remained unchanged from baseline.

The patient appeared comfortable throughout intubation and subsequent induction of general anesthesia. The surgery progressed without incident. The endotracheal tube was removed at the end of surgery when airway protective reflexes, adequate tidal volume, and intact neuromuscular function were demonstrated.

Postoperatively, the patient had no recall of the intubation procedure and no complaints concerning anesthesia. He was afebrile, his lungs were clear to auscultation, and there was no evidence of anesthesia-related complications.

**Discussion**

Airway management has been discussed in detail by many authors.1-4 Awake endotracheal intubation has been recommended when a potentially difficult airway is suspected. In this case, the patient's limited neck extension and history of difficulty with endotracheal intubation were considered to be indications for an awake intubation.

Available options included the direct visual techniques of traditional rigid laryngoscopy, rigid bronchoscopy, use of the Bullard® laryngoscope (American ACMI, Stamford, Connecticut), and fiberoptic laryngoscopy; blind nasotracheal intubation or light wand intubation; percutaneous retrograde intubation, percutaneous transtracheal intubation, cricothyroidotomy, and tracheostomy.5

Considering the elective nature of the surgical procedure, the most reasonable and available choices were blind nasal intubation, light wand, and fiberoptic intubation. The blind nasal approach was not used to avoid potential trauma to the nose, nasopharynx, periglottic region, edema, and bleeding.

Light wand intubation is easy to perform, requires a minimum amount of equipment, and has a low complication rate.7-9 The light wand is a malleable stylet that allows the endotracheal tube to be shaped most effectively for insertion into the trachea. At the distal end of the stylet is a light that provides visual clues concerning tube location during placement.

Fiberoptic laryngoscopy enables the anesthetist to visualize the laryngeal anatomy; however, the procedure for insertion of the endotracheal tube is more complicated. With the fiberscope threaded completely through an endotracheal tube, the scope is inserted into the trachea through either the nose or mouth. The endotracheal tube is then advanced blindly over the fiberscope which acts as a guide. The technique is highly effective but requires practice.

The use of the light wand and fiberoptic techniques together combines the most desirable characteristics of each. The light wand, which acts as a stylet, is a simple mechanism for delivery of the fiberscope and endotracheal tube to the glottis. The fiberscope allows direct visualization of the pharyngeal, laryngeal, and tracheal anatomy. Compared to traditional fiberoptic techniques, simultaneous insertion of the fiberscope and endo-

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**Figure 1**

Endotracheal tube prepared for hybrid intubation technique

Both a coated wire stylet and fiberscope have been inserted into the endotracheal tube in preparation for the hybrid intubation technique. The wire stylet is a modification of that used in the initial case, where a light wand was used.
tracheal tube reduces the number of steps required in the intubation sequence.

Since the first application, we have used our technique to intube six additional patients following the induction of general anesthesia; all but one were intubated successfully. In the unsuccessful attempt, the procedure was discontinued because copious secretions made recognition of the anatomical structures impossible. In all other cases, intubation was accomplished without trauma on either the first or second attempt. In this limited trial, the intubation time has been comparable to that seen with light wand intubation. None of the patients has demonstrated changes in vital signs or hemoglobin saturation, and no complications have been observed.

Based on our experience, we have modified the initial technique by substituting a conventional stylet for the light wand. The smaller diameter of the stylet still provides rigidity and has allowed us to decrease to 7.5 mm the minimum endotracheal tube size that will accommodate the fiberscope. The following technique for hybrid intubation is recommended:

1. Prepare the endotracheal tube by bending the stylet into a "hockey stick" shape and lubricating the surfaces of the stylet and fiberscope.
2. Insert the fiberscope and stylet into the endotracheal tube. The stylet should terminate just proximal to the Murphy eye. The fiberscope should be positioned as distally as possible to reduce restriction of view from the endotracheal tube, but it should be sufficiently proximal to avoid an undesired accumulation of secretions.
3. Prepare the patient for induction or awake intubation with nerve blocks, topical anesthesia, and sedation as desired. Consider the administration of an antialagogue (such as glycopyrrolate) to decrease oral secretions.
4. Insert the tube, stylet, and fiberscope in unison in the midline following the curvature of the tongue. If visual clues of the light wand technique are being used, dim the operating room lights.
5. Continue to advance the tube over the posterior aspect of the tongue until the epiglottis and/or arytenoid cartilages are visualized.
6. Maneuver the tube through the vocal cords into the larynx.
7. While holding the fiberscope and tube securely in place, remove the stylet.
8. Continue to advance the endotracheal tube and fiberscope to the desired depth.
9. Remove the fiberscope, inflate the endotracheal tube cuff, and confirm the tube location using capnography and chest auscultation.

Summary
Use of the hybrid intubation technique may be considered in an elective situation when difficulty with endotracheal intubation is anticipated. This method of airway management capitalizes on the benefits of both fiberoptic and light wand intubation techniques. The rigidity and shape of the light wand (or stylet) provide a mechanism for advancing the endotracheal tube to the glottis, while the fiberscope allows visualization of the larynx and direct confirmation of appropriate tube placement. In the hands of experienced clinicians, it is reasonable to assume that this technique can be used as effectively as any other intubation technique.

REFERENCES

AUTHORS
Alfred E. Lupien, CRNA, MSN, earned his BS from the Walter Reed Army Institute of Nursing and the University of Maryland and his MSN from the University of Alabama at Birmingham. He is a graduate of the Anesthesiology Program for Army Nurse Corps Officers at Walter Reed Army Medical Center. Prior to retiring from the Army, he was director of the U.S. Army/Texas Wesleyan University Program in Anesthesia Nursing at Tripler Army Medical Center, Honolulu, Hawaii. Currently he is a doctoral candidate in Educational Psychology at the University of Hawaii and coordinator of the Anesthesia Nursing Program under development at the Medical College of Georgia, Augusta, Georgia.

CPT Carol Taylor, CRNA, MHS, United States Army Nurse Corps, earned her diploma in Nursing from E.J. Meyer Memorial Hospital School of Nursing, Buffalo, New York, a BSN from the University of South Alabama, Mobile, Alabama, and a master's degree in Health Science from Texas Wesleyan University, Fort Worth, Texas. She is a graduate of the U.S. Army/Texas Wesleyan University Program in Anesthesia Nursing at Tripler Army Medical Center. Currently, she is a staff anesthetist at Fitzsimons Army Medical Center, Aurora, Colorado.

The conclusions and opinions expressed are those of the authors and do not necessarily reflect the position or policy of the Department of Defense, the Department of the Army, the Army Medical Department, or the Army Nurse Corps.
Under opioid/nitrous oxide/oxygen anesthesia in adult patients. At the initial recommended dose of 0.6 mg/kg, the median time to 280% blockade is 60 seconds with a range of 0.4 to 6 minutes, providing a median clinical duration of 31 minutes with a range of 15 to 85 minutes. At 0.45 mg/kg, the median time to 280% blockade is 78 seconds with a range of 0.8 to 6.2 minutes, providing a median clinical duration of 22 minutes with a range of 12 to 31 minutes. Please see following page for brief summary of full prescribing information.
Injection
ZEMURON
(rocuronium bromide)
Before prescribing, please consult full prescribing information, a summary of the Research and Development of
Neuromuscular Blocking Agents
PRINTED IN USA NOVEMBER 1994©1995 ORGANON INC. ORG-005386

ZEMURON
(rocuronium bromide) injection is a nondepolarizing neuromuscular blocking agent with a rapid to intermediate onset dependent on dose and immediate duration and is indicated for inpatients and outpatients as an adjunct to general anesthesia to facilitate both rapid sequence and routine tracheal intuba-
tion, and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

CONTRAINDICATIONS
ZEMURON
(rocuronium bromide) injection is contraindicated in patients known to have hypersensitivity to rocuronium bromide.

WARNINGS
ZEMURON
(rocuronium bromide) INJECTION SHOULD BE ADMINISTERED IN CAREFULLY ADJUSTED DOSAGES OR BY UNDER THE SUPERVISION OF EXPERIENCED CLINICIANS WHO ARE FAMILIAR WITH THE DRUG’S ACTIONS AND THE POSSIBLE COMPLICATIONS OF ITS USE. THE DRUG SHOULD NOT BE ADMINISTERED TO PATIENTS WHO ARE INTRINSICALLY HYPERMETABOLIC, AND AN ANTIDOTE IS IMMEDIATELY AVAILABLE. IT IS RECOMMENDED THAT CLINICIANS ADMINIST-
RATE NONDEPOLARIZING NEUROMUSCULAR BLOCKING AGENTS IN THE ABSENCE OR SUSPECTION OF A NERVE STIMULATOR TO MONITOR DRUG RESPONSE, NEED FOR ADDITIONAL RELAXANT, AND ADEQUACY OF SPONTANEOUS RECOVERY OR ANTAGONISM.

ZEMURON
(rocuronium bromide) is known to affect CONSCIOUSNESS, PAIN THRESHOLD, OR CEREBRAL FUNCTION. THEREFORE, ITS ADMINISTRATION MUST BE ACCOMPANYED BY ADEQUATE ANESTHESIA OR SEDATION.

In patients with myocardial or cardiac (Eaton-Lambert) syndrome, small doses of nondepolarizing neuromuscular blocking agents may have profound effects. In such patients, a peripheral nerve stimulator and use of a small test dose may be of value in monitoring the response to administration of muscle relaxants. 

ZEMURON
(rocuronium bromide), which has an acid pH, should not be mixed with alkaline solutions (e.g., barbiturate solutions) in the same syringe or administered simultaneously during intravenous infusion through the same needle.

PRECAUTIONS

Long-term Use in I.C.U.: ZEMURON
(rocuronium bromide) injection has not been studied for long-term use in the I.C.U. As used clinically, neuromuscular blocking drugs, such as ZEMURON
rocuronium bromide may develop rarely during chronic administration in the I.C.U. While the mechanism for develop-
ment of this resistance is not known, receptor up-regulation may be a contributing factor. It is STRONGLY
recommended that patients on long-term I.C.U. administration of ZEMURON
rocuronium bromide should have a scheduled period of administration and recovery with the help of a nerve stimulator. ADDITIONAL DOSES OF ZEMURON
rocuronium bromide should be administered in succession.

There is a DEFINITE RESPONSE (ONE TWITCH OF THE TRAIN-OF-FOUR) TO NERVE STIMULATION. Prolonged paralysis and/or skeletal muscle weakness may be noted during initial attempts to wean from the ventilator when patients who have been paralyzed with ZEMURON
rocuronium bromide in the I.C.U. Therefore, ZEMURON
rocuronium bromide should only be used in this setting if, in the opinion of the prescribing physician, the specific advanced clinical indication for the drug outweighs the risks.

Labor and Delivery: The use of ZEMURON
rocuronium bromide) injection in cesarean section has been studied in a limited number of patients. ZEMURON
rocuronium bromide is not recommended for rapid sequence induction in cesarean section.

Hepatic Disease: Since ZEMURON
rocuronium bromide) injection is primarily excreted by the liver it should be used with caution in patients with clinically significant hepatic disease. ZEMURON
rocuronium bromide) 0.6 mg/kg has been tested in patients with moderate hepatic insufficiency (Child-Pugh Class B). There was no apparent alteration of the duration of action of ZEMURON
rocuronium bromide) in patients with significant hepatic disease (see Pharmacokinetics subsection of CLINICAL PHARMACOLOGY).

These findings are consistent with the increase in volume of distribution at steady state observed in patients with hepatic disease compared to 20 minutes in patients with normal hepatic function. Four of eight patients with cirrhosis, who received ZEMURON
rocuronium bromide) 0.6 mg/kg under opioid/nitrous oxide/oxygen anesthesia, did not achieve complete block. 

The mean recovery time of 53 minutes was also prolonged in patients with cirrhosis compared to 40 minutes in patients with normal hepatic function. Four of eight patients with cirrhosis, who received ZEMURON
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Intra-arterial and perivenous administration with only a slight irritation of surrounding tissues observed and no cases of significant accidental or intentional overdose with ZEMURON
rocuronium bromide) injection.

The use of ZEMURON
rocuronium bromide) Injection did not suggest mutagenic potential.

In patients with myasthenia gravis or myasthenic (Eaton-Lambert) syndrome, small doses of nondepolarizing neuromuscular blocking agents may have profound effects. In such patients, a peripheral nerve stimulator and use of a small test dose may be of value in monitoring the response to administration of muscle relaxants.

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In the European studies, the most commonly reported adverse events were transient hypertension (2%) and hypertension (2%). It is in greater frequency than the U.S. studies (0.1% and 0.1%). Changes in heart rate and blood pressure were defined as changes from baseline. Changes from baseline in hemodynamic and respiratory parameters were not considered as adverse events unless judged by the investigator as unexpected, clinically significant, or thought to be histamine related.

ZEMURON
(rocuronium bromide) injection is available in the following forms: 10 mL multiple dose vials containing 100 mg rocuronium bromide injection (10 mg/mL) in an oil-in-water emulsion of soybean oil and ethanol. These formulations are not intended for IV administration.

Temperature: ZEMURON
(rocuronium bromide) injection is stable in the refrigerator for at least 24 months, but the clinical duration or recovery characteristics following recommended doses of ZEMURON
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Storage: ZEMURON
(rocuronium bromide) injection should be stored under refrigeration, 2 to 8°C (36 to 46°F). DO NOT FREEZE.

Effective temperature range for refrigeration to room temperature storage conditions (25°C/77°F), use ZEMURON
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STADOL* (butorphanol tartrate) Injectable
Before prescribing, see complete prescribing information in Apothecon • Bristol-Myers Squibb Company
Princeton, New Jersey 08540 USA

Injectable. There has been no attempt at route

NURSING MOTHERS
Injectable should be used with caution.

Reproduction
Pregnancy
Butorphanol was not studied in reproduction studies in animals. butorphanol has precipitated withdrawal symptoms in neonatal rats. However, pregnant rats treated subcutaneously with butorphanol during the period of organogenesis had no evidence of increased fetal loss or major fetal anomalies. Pregnant rabbits dosed subcutaneously with butorphanol had an increased incidence of resorptions. There was no evidence of carcinogenic potential of butorphanol in long-term animal studies.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY
Reproduction
Pregnancy

HEAD INJURY AND INCREASED INTRACRANIAL PRESSURE
As with other opioids, the use of butorphanol in patients with head injury may be associated with increased intracranial pressure. In patients with head injury, butorphanol should not be used if there is evidence of increased intracranial pressure or if delivery is expected to occur within 4 hours.

OVERDOSAGE
Clinical manifestations of overdose are those of opioid drugs, the most serious of which are hypotension, respiratory depression, and/or coma. Overdose can occur due to accidental or intentional misuse of butorphanol, especially in young children who may gain access to the drug in the home.

TREATMENT
The management of suspected butorphanol overdose includes maintenance of adequate ventilation, control of pulmonary edema, and control of the airway. Patients should be under continuous observation with adequate serial measurements of mental state, responsiveness, and vital signs. Oxygen and ventilatory support should be available with continuous monitoring by pulse oximetry if indicated. In the presence of coma, placement of an artificial airway may be required. An endotracheal intubation could be considered in patients with hypoxemia or respiratory depression. The use of a specific opioid antagonist such as naloxone should be considered.

The duration of butorphanol action usually extends from one to two hours. There are insufficient clinical data to recommend single doses above 4 mg.

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The most commonly reported adverse events in patients receiving ZOFRAN in clinical trials were headache (5% to 25%), diarrhea (<1% to 16%), constipation (<1% to 7%), and fever (2% to 8%). In the postoperative setting, the rates of these events were not significantly different from those of placebo.1,2,3

Please consult references and Brief Summary of Prescribing Information for ZOFRAN Injection on following page.
For IV Injection Only

The following is a brief summary only. Before prescribing, see complete prescribing information in Zofer Injection product labeling.

INDICATIONS AND USAGE:

1. Prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including high-dose cisplatin. Efficacy of the 32-mg single dose beyond first-day administration of ondansetron is not established. There is no experience beyond first-day administration of ondansetron.

2. Prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting may be avoided postoperatively, Zofer Injection is recommended even where the incidence of postoperative nausea and/or vomiting is low. For patients who have nausea and/or vomiting postoperatively, Zofer Injection may be given to prevent further episodes (see CLINICAL TRIALS section of the product package insert).

CONTRAINdications:

Zofer Injection is contraindicated for patients known to have hypersensitivity to the drug.

PREcautions:

1. Ondansetron is not a drug that stimulates gastric or intestinal peristalsis. It should not be used instead of nasogastric suction. As with other antiemetics, the use of ondansetron in intravenous surgical or hepatic resections may result in a progressive loss of gastric output, and gastric distention.

Drug Interactions: Ondansetron does not itself appear to induce or inhibit the cytochrome P-450 drug-metabolizing enzyme system of the liver. Because ondansetron is metabolized by hepatic cytochrome P-450, the drug-drug interactions are similar to those of enzymes inducing or inhibiting these enzymes may change the clearance and, hence, the half-life of ondansetron. On the basis of limited available data, patients who are currently taking drugs that are recommended for use with these drugs. Tumor response to chemotherapy in the P-388 mouse leukemia model is not affected by ondansetron. In humans, carcinogenesis, mutagenesis, and impairment of fertility have been observed with potentially hepatotoxic cytotoxic chemotherapy and antibiotics. The etiology of the liver failure is unclear.

2. Because the metabolism of the hepatic drug-metabolizing enzymes is variable, in some patients hepatic function may be reduced, and in others it may be increased. In usual clinical practice, drug interactions are likely to be minimal unless the concomitant use of Zofran® Injection is necessary. For patients who are undergoing cancer chemotherapy, including high-dose cisplatin, and who are also receiving concomitant chemotherapy, antibiotics, or other drugs that are metabolized by the hepatic drug-metabolizing enzyme system, the effects of these drugs may be altered by changes in the activity of the hepatic drug-metabolizing enzymes. If the concomitant use of these other medications becomes necessary or if the concomitant use of these medications is stopped, the dosage of these medications may have to be adjusted. There are no clinical studies specifically evaluating the efficacy or safety of the concomitant use of Zofran® Injection with other medications. There is no evidence that Zofran® Injection will affect the clearance or side effects of concomitant medications. There is also no evidence that Zofran® Injection will affect the clearance or side effects of other medications.

3. Administration of ondansetron up to 15 mg per day did not affect fertility or general reproductive performance of male and female rats.

4. Pregnancy: Pregnancy Category B: Reproduction studies have been performed in pregnant rats and rabbits at intravenous (IV) doses up to 4 mg/kg per day and have revealed no evidence of impaired fertility or harm to the fetus due to ondansetron. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, Zofran® Injection should be used during pregnancy only if clearly needed.

5. Lactation: Ondansetron is excreted in the breast milk of rats. It is not known whether ondansetron is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ondansetron is administered to a nursing woman.

Pediatric Use: Little information is available about dosage in children 3 years of age or younger (see CLINICAL PHARMACOLOGY section for use in children 4 to 18 years of age receiving cancer chemotherapy). Use in Elderly Patients: Dosage adjustment is not needed in patients over the age of 65 (see CLINICAL PHARMACOLOGY section for use in children 4 to 18 years of age receiving cancer chemotherapy).

Use in the Elderly: Use in the Elderly: Delute Before Use. Zofran® Injection should be diluted in 15 mL of 5% dextrose injection or 0.9% sodium chloride injection before administration. The recommended IV dosage of Zofran injection is a single 32-mg dose or three 0.15-mg dosages. A single 32-mg dose is infused over 15 minutes beginning 30 minutes before the start of emetogenic chemotherapy. Following infusion of 32 mg over only a 4-minute period, a vaso-occlusive episode with transient second degree heart block was observed. In all instances, the events resolved completely.

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Pediatric Use: There is no experience with the use of Zofran injection in the prevention or treatment of postoperative nausea and vomiting in children.

Use in the Elderly: Delute Before Use. The dosage is the same as for the general population.

Prevention of Postoperative Nausea and/or Vomiting: No DILUTION NECESSARY. Immediately, before induction of anesthesia, or postoperatively if the patient experiences nausea and/or vomiting occurring shortly after surgery, administer 4 mg undiluted intravenously in not less than 30 seconds, preferably 10 to 15 minutes after the start of emetogenic chemotherapy. Recommended infusion rate should not be exceeded (see OVERDOSAGE). With the three-dose (0.15-mg/kg) regimen, the first dose is infused over 15 minutes beginning 30 minutes before the start of emetogenic chemotherapy. Subsequent doses (0.15 mg/kg) are administered at 4 and 8 hours after the first dose of Zofran injection. Zofran injection should not be mixed with solutions for which the physical and chemical compatibility have not been established. In particular, this applies to alkaline solutions as a precipitate may form.

Pediatric Use: There is no experience with the use of Zofran injection in the prevention or treatment of postoperative nausea and vomiting in children.

Use in the Elderly: Delute Before Use. The dosage is the same as for the general population.

Dosage Adjustment for Patients With Impaired Renal Function: No specific studies have been conducted in patients with renal insufficiency. Dosage Adjustment for Patients With Impaired Hepatic Function: In patients with severe hepatic impairment according to Child-Pugh criteria, a single maximal daily dose of 8 mg to be infused over 15 minutes beginning 30 minutes before the start of emetogenic chemotherapy is recommended. How supplied: Zofran injection, 2 mg/mL, is supplied in 2-mL single-dose vials (NDC 0173-0344-02) and in 20-mL multidose vials (NDC 0173-0344-00). Store between 2° and 30°C (36° and 86°F) & Protect from light.


CERENEX PHARMACEUTICALS

June 1994

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ZOF 2330R0

Printed in USA December 1994


ZOFRAN (ondansetron hydrochloride) Tablets

Pharmacotherapeutic Group: 5 mg INJECTION

ZOFTRAN (ondansetron hydrochloride) Injection

For POSTOPERATIVE NAUSEA AND VOMITING

POSTOPERATIVE NAUSEA AND VOMITING: The following adverse events have been reported in a 2% of people receiving ondansetron at a dosage of 4 mg IV over 2 to 5 minutes in clinical trials. Rates of these events were not significantly different in the ondansetron and placebo groups. These patients were receiving multiple concomitant perioperative and postoperative medications.

Zofran Injection 4 mg IV n=547 patients Placebo n=547 patients

Headache 92 (17%) 77 (14%)

Diarrhea 67 (12%) 88 (16%)

Vomiting 57 (10%) 58 (10%)

Drowsiness/sedation 44 (8%) 37 (7%)

Nausea 38 (7%) 39 (7%)

Malaise/fatigue 25 (5%) 30 (5%)

Injection site reaction 21 (4%) 18 (3%)

Urinary retention 17 (3%) 15 (3%)

Postoperative CO2-related pain* 12 (2%) 19 (3%)

Chest pain (unspecified) 12 (2%) 13 (2%)

Anxiety/gallopitation 0 (0%) 4 (1%)

Diabetes 11 (2%) 9 (2%)

Hypertension 10 (2%) 12 (2%)

Hypotension 10 (2%) 6 (1%)

Cough 9 (2%) 8 (1%)

Pruritus 9 (2%) 5 (1%)

Paresthesia 9 (2%) 2 (1%)

*Site of pain included abdomen, stomach, joints, rib cage, shoulder.

Drug Abuse and Dependence: Animal studies have shown that ondansetron is not discriminative as a benzodiazepine nor does it substitute for benzodiazepines in direct addiction studies.

OVERDOSAGE: Zofran® Injection is contraindicated for patients who are being managed with appropriate supportive therapy. Individual doses as large as 145 mg and total daily dosages (three doses) as large as 252 mg have been administered intravenously without significant adverse events. These doses are more than 10 times the recommended daily dose.

"Sudden blindness" (amauropia) of 2 to 3 minutes' duration plus severe constipation occurred in one patient that was administered 72 mg of ondansetron intravenously as a single dose. Hypotension (and faintness) occurred in another patient that took 48 mg of oral ondansetron. Following infusion of 32 mg over only a 4-minute period, a vasovagal episode with transient second degree heart block was observed. In all instances, the events resolved completely.
Ready, aim, fire with accuracy.

Disposable spray cannulas deliver Xylocaine (lidocaine) in precise, targeted shots designed to kill pain fast.

- Topical anesthesia for accessible mucosa of the mouth and oropharynx
- Works in 1-2 minutes
- An amide not an ester to reduce the potential for allergic reactions
- Reduces gag reflex
- Pleasant citrus taste
- Available in 26.8 mL metered dose bottles
- 10 mg lidocaine base in every spray

Disposable Cannulas

- Ready-to-use
- Reduce the risk of cross-contamination
- Improve maneuverability
- Available in packages of 50

Lidocaine is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type or to other components of Xylocaine 10% Oral Spray.

Please see full prescribing information on reverse side.

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Brief Summary of Prescribing Information

10% Xylocaine® Oral Spray
(lidocaine)

Flavored Topical Anesthetic Aerosol For Use In The Oral Cavity

Full and Part Time

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Labor and Delivery: Xylocaine is not contraindicated in labor and delivery. Should Xylocaine 10% Oral Spray be used concomitantly with other products containing lidocaine, the total dose contributed by all formulations must be kept in mind.

Nursing: 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 Xylocaine is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children below the age of 12 years have not been established.

ADVERSE REACTIONS

Adverse experiences following the administration of lidocaine are similar in nature to those observed with other amide local anesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage or rapid absorption, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature. The following types are those most commonly reported:

Central Nervous System: CNS manifestations are excitatory and/or depressant and may be characterized by tinnitus, numbness, dizziness, clumsiness, confusion, disorientation, drowsiness, slurred, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. The excitatory manifestations may be very brief or may occur at all, in which case the first manifestations of toxicity may be drowsiness merging into unconsciousness and respiratory arrest.

Drowsiness following the administration of lidocaine is usually an early sign of a high blood level of the drug and may occur as a consequence of rapid absorption.

Cardiovascular System: Cardiovascular manifestations are usually depressant and are characterized by bradycardia, hypotension, and cardiovascular collapse, which may lead to cardiac arrest.

Allergic: Reactions are characterized by cutaneous lesions, urticaria, edema or anaphylactoid reactions. Allergic reactions may occur as a result of sensitivity either to the local anesthetic agent or to other ingredients in the formulation. Allergic reactions as a result of sensitivity to lidocaine are extremely rare and, if they occur, should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

OVERDOSAGE

Acute emergencies from local anesthetics are generally related to high plasma levels encountered during therapeutic use of local anesthetics. (See ADVERSE REACTIONS, WARNINGS, and PRECAUTIONS.)

Management of Local Anesthetic Emergencies: The first consideration is prevention, best accomplished by careful and constant monitoring of cardiovascular and respiratory vital signs and the patient's state of consciousness after each local anesthetic administration. At the first sign of change, oxygen should be administered.

The first step in the management of the convulsions consists of immediate attention to the maintenance of a patent airway and assisted or controlled ventilation with oxygen and a delivery system capable of permitting immediate positive airway pressure by mask. Immediately after the institution of these ventilatory measures, the adequacy of the circulation should be evaluated, keeping in mind that drugs used to treat convulsions sometimes depress the circulation when administered intravenously. Should convulsions persist despite adequate respiratory support and if the status of the circulation permits, small increments of a short-acting barbiturate (such as thioental or thiamylal) or a benzodiazepine (such as diazepam) may be administered intravenously. The clinician should be familiar, prior to use of local anesthetics, with these anticonvulsant drugs. Supportive treatment of circulatory depression may require administration of intravenous fluids and, when appropriate, a vasopressor as directed by the clinical situation (e.g., ephedrine). If not treated immediately, both convulsions and cardiovascular depression can result in hypoxia, acidosis, bradycardia, arrhythmias and cardiac arrest. If cardiac arrest should occur, standard cardiopulmonary resuscitative measures should be instituted.

Dialysis is of negligible value in the treatment of acute overdose with lidocaine.

The intravenous LD50 of lidocaine HCl in female mice is 26 (21-31) mg/kg and the subcutaneous LD50 is 254 (203-306) mg/kg.

Manufactured by Armstrong Laboratories, Inc., West Roxbury, MA 02132.

Manufactured for Astra USA, Inc.

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