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CONTINUOUS AIRWAY ACCESS FOR THE DIFFICULT EXTUBATION: THE EFFICACY OF THE AIRWAY EXCHANGE CATHETER

Anesth Analg 2007;105:1357-1362

Mort TC

Abstract

Purpose The purpose of this study was to compare reintubation outcomes with and without the use of an Airway Exchange Catheter (AEC) in patients with known or suspected difficult airways.

Background While many studies have examined safety issues related to endotracheal intubation, few studies have examined the risks, complications, morbidity, and mortality associated with extubation. Complications are common during reintubation of patients with a difficult airway. Closed claims analysis has identified a need for extubation studies. Airway exchange catheters are available to facilitate changing an endotracheal tube (ETT). AECs can also be inserted prior to extubation to facilitate reintubation if extubation fails. Previous studies in which an 11 French AEC was inserted before extubation and left in the trachea reported that the AEC was well tolerated.

The complication and success rates of reintubation are not known. While patients commonly tolerate extubations performed in the operating room, extubation in the Intensive Care Unit (ICU) fails at a rate reported to be between 0.4% and 25%. Patients with a known or suspected difficult airway may benefit from the placement of an AEC before extubation. If extubation is not tolerated the AEC can then be used to expedite reintubation.

Methodology This retrospective observational study included 87 patients with known or suspected difficult airways who were reintubated in the operating room (OR), post anesthesia care unit (PACU), or ICU. All data was collected by the author who was personally involved in some of the reintubations. Some data was collected and verified by the author through interviews of other airway management team members (CA-2 or CA-3 residents).

Before extubation, patients had a Cook (Cook Critical Care, Bloomington, IN) AEC inserted through the ETT and left in the trachea for a variable period after extubation. Three different sizes of Cook AECs were used, 11 French, 14 French, and 19 French. The 19F catheter had a 6.3 mm external diameter. The Cook catheter was inserted as part of an ongoing clinical plan to facilitate reintubation, if needed. It was not part of a research protocol. Cook catheters were removed from the trachea of extubated patients when the need for reintubation was considered to be unlikely.

For the purpose of comparison, the 87 patients included in this analysis were divided into two groups. The AEC group included 51 patients who had the AEC in place when reintubation was attempted. The No-AEC group included 36 patients who had their AEC removed before reintubation was attempted.

In the AEC group, reintubation was attempted first using the AEC as a stylet. In the No-AEC group (and when reintubation over the AEC failed) reintubation proceeded in the usual manner. Intubation was first attempted by direct laryngoscopy, then using alternate intubation devices. These devices included an intubating LMA, a flexible bronchoscope, a rigid fiberoptic laryngoscope, a bougie, or a surgical tracheostomy.
All 87 patients were extubated over an AEC. The distribution of AEC sizes was as follows: 50% were 14F, 46% were 11F, and 4% were 19F. Patients were extubated in the ICU (81%), the PACU (7%), and the OR (5%). (Editors Note: the article did not comment on why the location of extubation did not sum to 100%.) The AEC remained in the trachea for a mean of 3.9 hours (range 5 minutes to 72 hours). All AEC group patients were reintubated within 24 hours of extubation. Most patients had a history of previous difficult intubation (72%). The remaining patients were classified as difficult airway based upon physical assessment.

Reintubation was successful on the first attempt in 87% of AEC patients and 14% of No-AEC patients (P<0.02). During reintubation, SpO$_2$ was <90% in 8% of AEC patients and 50% of No-AEC patients (P<0.01). Similarly, SpO$_2$ was <70% in 6% of AEC patients and 19% of No-AEC patients (P=0.05). Three or more intubation attempts, with, or without an accessory airway device, were required in 10% of AEC patients and 77% of No-AEC patients (P<0.02). Esophageal intubation occurred in 0% of AEC patients and 18% of No-AEC patients (P<0.01).

In four cases, reintubation over the AEC failed. In three of these cases the AEC was accidentally removed from the trachea during reintubation attempts. In the fourth case reintubation probably failed due to laryngeal edema. All patients who underwent tracheostomy to regain their airway were in the No-AEC group.

**Conclusion**

Airway Exchange Catheters facilitated reintubation more effectively and with fewer complications than traditional reintubation methods.

**Comment**

While we have historically given a lot of attention to the risks and problems surrounding intubation, much less attention has been paid to extubation. This is probably due, at least in part, to the fact that the vast majority of extubations we perform are in the operating room under relatively controlled circumstances. And, if a problem does develop following extubation, we are in just about the best place one could imagine to reintubate the patient. Nevertheless, there is morbidity and mortality associated with endotracheal extubation, especially in the critical care areas outside the OR. More recent research is beginning to define the risks associated with extubation, and ways to reduce those risks.

This study looked at patients with a difficult airway that were reintubated either over an Airway Exchange Catheter (AEC) or reintubated in the usual fashion. When AECs were used, they had been placed before extubation and left in the trachea in case reintubation was needed. This was apparently the standard procedure in the author’s practice. The results were so striking that, despite the retrospective nature of the study, they deserve careful attention. Difficult airway patients reintubated with the aid of an AEC were clinically significantly more likely to be successfully reintubated without multiple attempts and without extra “difficult airway” equipment (fiberoptic scope, etc.). Patients reintubated over an AEC were also less likely to become hypoxic, bradycardic, or have an esophageal intubation.

I’m puzzled at how long patients seemed to tolerate an AEC in their trachea (up to three days!). The author reported that all but the largest diameter AECs were well tolerated by patients. I wonder if the ability to tolerate a catheter dangling in their trachea might speak to just how sick the study patients were.

It should be noted that the data used in this study was acquired over a nine year period starting during or before 1998. Since that time, several new difficult intubation devices have become available. It would be interesting to know if leaving an AEC in place improved the ability to reintubate patients compared to reintubation with a Glidescope or McGrath videolaryngoscope, for example. (For abstracts and comments on other difficult airway equipment go to AnesthesiaAbstracts.com and search “subject” for the term “airway.”)
Based upon this report, I’m going to think about placing an AEC prior to extubating a patient with a difficult airway, but I’m not ready to do so routinely. I’m anxious to see some truly prospective studies of this technique that tell us, for example, how much faster reintubation can be performed and whether or not outcomes are improved. It would also be helpful to know if the AEC itself results in any complications and how well tolerated the AEC is in a broad range of patients.

Michael Fiedler, PhD, CRNA

**Retrospective and Observational?**

You may have noted that this study was described as both “retrospective” and “observational.” That may have struck you as odd or even impossible; and rightly so.

Historically, retrospective studies looked back at records that were kept in the normal course of health care delivery without any plan to later use the records for the research purpose at hand. It is now becoming more common to keep databases of information for the express purpose of later quality improvement analysis or research. The information in these databases is focused on specific problems of interest and collected in a purposeful and systematic way. In this study, for example, a “difficult airway quality improvement database” was used. Prospective research requires that a research plan be completely devised before data is collected. Thus, carefully collecting information about difficult airways before a research plan is made does not qualify as prospective research. The original data collected for this difficult airway database was observational. The research was then conducted looking back (retrospectively) at the data already collected. Thus, while not a perfect description, the best way I could think to describe it was as “retrospective and observational.”

Retrospective studies have a number of limitations. Evidence rating scales commonly classify retrospective studies as a level IV, just above expert opinion (V). (I = strongest evidence, V = weakest evidence.) Studies like this one, drawn from quality improvement databases, are still retrospective. But, if the database was carefully constructed and the data carefully and completely gathered they have the potential to yield “stronger” results than traditional retrospective studies that used whatever data was available.

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Abstract

Purpose The purpose of these guidelines was to suggest practices to improve the overall quality of obstetric anesthesia care. Three areas were addressed: overall quality of care, the incidence and severity of obstetric anesthesia complications, and overall patient satisfaction.

Background Practice guidelines are recommendations intended to provide information to the clinician when making clinical decisions. Practice guidelines are not intended to define the standard of care. Practice guidelines are supported by current literature and expert opinion. They are revised from time to time as information becomes available. They provide basic recommendations. The original “Practice Guidelines for Obstetrical Anesthesia” were adopted by the American Society of Anesthesiologists in 1998.

Methodology These Guidelines address peripartum anesthesia and analgesia for labor and vaginal delivery, cesarean delivery, removal of retained placenta, and postpartum tubal ligation. The Guidelines do not apply to patients undergoing surgery during pregnancy or patients with chronic disease.

The American Society of Anesthesiologists (ASA) appointed a task force to review the published evidence and obtain the opinion of a panel of consultants. The Task Force developed the Guidelines by means of a seven step process. First, they reached consensus on the criteria for evidence. Second, journals relevant to obstetric anesthesia were reviewed. Third, the panel of expert consultants was asked to participate in opinion surveys and, review and comment on a draft. Forth, opinions about the Guideline recommendations were solicited from active members of the ASA. Fifth, the task force held open forums at national meetings. Sixth, consultants were surveyed to assess their opinions. Seventh, all available information was used to build consensus within the Task Force and finalize the Guidelines.

This process produced guidelines in seven different areas.

Result Guideline I. The Perianesthetic evaluation should include maternal health and anesthesia history, obstetric history, baseline blood pressure; airway, heart, and lung examination, and examination of the back when neuraxial anesthesia is planned. A routine platelet count does not predict anesthesia related complications in healthy parturients, therefore a routine platelet count is not recommended. A routine blood cross match is not necessary for healthy parturients undergoing uncomplicated vaginal or operative delivery. The Fetal Heart Rate (FHR) should be monitored before and after neuraxial analgesia / anesthesia. FHR monitoring may, however, not always be necessary or feasible on a continuous basis.

Guideline II. Drinking reasonable amounts of clear liquids during labor does not increase maternal complications in healthy parturients. Patients undergoing elective cesarean delivery may have limited clear liquids up to two hours before anesthesia. The volume is less important than the lack of particulate matter in the liquid. Depending on the fat content, patients should not have solid food for six to eight hours prior to elective cesarean delivery or postpartum tubal ligation. Laboring women should not eat solid food.
Guideline III. Not all women require an anesthetic during labor and delivery. The choice of analgesic technique depends on the health status of the patient, progress of labor, and resources available. The primary goal of regional techniques during labor should be to provide adequate maternal analgesia with minimal motor block. Resources for the treatment of complications should be available which include the establishment of an intravenous line before initiation of regional analgesia. Regional analgesia should not be withheld based on achieving an arbitrary cervical dilatation and no evidence exists that the use of regional analgesia increases the incidence of cesarean section. Studies suggest that epidural analgesia may be used in a trial of labor following previous cesarean delivery patients without adversely affecting the incidence of vaginal delivery. It is appropriate to insert an epidural or spinal catheter prior to the initiation of labor if the risk of an emergent procedure is significant.

The technique selected should be based on patient preference, practitioner preferences and skills, and available resources. There is not sufficient evidence to recommend a specific anesthetic agent or combination of agents for regional anesthesia, but there is consensus that a single spinal dose of opioid is effective when delivery is eminent. However, if the single dose regional technique is not expected to last as long as the labor and delivery, a catheter technique should be considered. The literature indicates that a pencil point spinal needle reduces the risk of a post dural puncture headache.

Other techniques that are recommended include the use of a combined spinal and epidural technique as well as patient controlled intravenous analgesia with or without a continuous infusion.

Guideline IV. There is no preferred anesthetic technique for the removal of a retained placenta. If an epidural catheter is in place and the patient is hemodynamically stable, the epidural anesthesia is preferred. In cases involving major maternal hemorrhage, general anesthesia with an endotracheal tube may be a safer choice. Nitroglycerin can be used as an alternative to terbutaline or general anesthesia for uterine relaxation during removal of retained placental tissue.

Guideline V. Equipment, facilities and support personnel available in the labor and delivery operating suite should be comparable to those available in the main operating suite. Regional techniques are preferred to general anesthesia for most cesarean deliveries. However, general anesthesia may be appropriate in some circumstances, such as profound fetal bradycardia, ruptured uterus, severe hemorrhage, severe placental abruption, etc. Uterine displacement should be maintained until delivery regardless of the anesthetic technique used. Preloading of intravenous fluid may help in reducing maternal hypotension during spinal anesthesia. Intravenous ephedrine and phenylephrine are both acceptable drugs for treating maternal hypotension but phenylephrine may be preferable when there is no maternal bradycardia because of improved fetal acid-base status in uncomplicated pregnancies. Epidural or spinal opioids are preferred over intravenous opioids for postoperative pain management.

Guideline VI. Patients for postpartum tubal ligation should have no oral intake of solid foods within six to eight hours of surgery. Aspiration prophylaxis should be considered. The anesthetic technique should be individualized to the patient and situation, however, regional techniques are preferred.

Guideline VII. Resources should available to manage hemorrhagic emergencies. In an emergency, the use of type specific or O negative blood is acceptable. Intraoperative cell salvage should be considered, if available. A plan and equipment for the management of airway emergencies should be available. Basic and advanced life support equipment should be immediately available in the operative area of labor and delivery units.

Conclusion These guidelines are an update of the 1998 American Society of Anesthesiologists Obstetric Guidelines and include data published since that time. These recommendations cover a wider range of techniques than were previously addressed.
Comment

The Guidelines are a substantial improvement over previous Obstetric Guidelines developed by the ASA. There is a great deal of thoughtful discussion about the pros and cons of each recommendation, and a genuine attempt to incorporate clinical experience even when it is not substantially backed up with scientific studies. I believe this is a positive approach because development of guidelines based solely on scientific studies has a tendency to incorporate urban, academic, and sometimes political biases that are not always the most effective or even the safest practices when applied to individual situations.

Guidelines developed by professional organizations are often used to drive professional practice. Although “not intended as standards or absolute requirements,” guidelines often either reflect the “standards of care” or are presented as such. Because of this, it is important that recommendations and guidelines have a scientific basis grounded in practice. Indeed, this is not just a scientific based document, but includes research and literature information as well as practice opinion. It goes even further and attempts to reach consensus among the “experts” even when the scientific evidence is not substantial. For that reason, I believe that “trends” could be misinterpreted as scientifically based “facts” just because they have been included in this consensus document and have come from a panel of “experts”. However, I do think the authors of this document have done an excellent job of explaining this even though it is likely the “Summary of Recommendations” will be used by facilities as well as medical and nursing staffs to develop policies. Unfortunately, the summary does not explain the flexible practice approach that was used to develop these recommendations. And this is exactly how guidelines which are “not intended as standards” become interpreted as standards.

With all of that being said, I think there is a variety of very useful information in this document, along with evidence and practical suggestions that can be used by the everyday provider. Just be aware that policies bases on consensus guidelines are difficult to change when the consensus changes.

Steven R. Wooden, MS, CRNA


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INTRAOPERATIVE FORCED AIR WARMING DURING CESAREAN DELIVERY UNDER SPINAL ANESTHESIA DOES NOT PREVENT MATERNAL HYPOTHERMIA

Anesthesiology 2007;105:1413-1419

Butwick AJ, Lpiman SS, Carvalho B

Abstract

Purpose The purpose of this study was to compare oral temperatures in patients undergoing cesarean section under spinal anesthesia with, or without, lower body forced air warming.

Background Redistribution of thermal energy from the core to the periphery results in significant falls in core body temperature during the first hour of subarachnoid and epidural anesthesia. Forced air warming blankets do not completely prevent this initial temperature drop. Major conduction anesthesia decreases he vasoconstriction and shivering thresholds, reducing the body’s ability to maintain a normal core temperature. Forced air warming is effective for treating core hypothermia.

Core hypothermia develops during procedures performed under subarachnoid block, just as it does during general anesthesia. The risk of hypothermia may be greater during subarachnoid block than during an epidural block. Hypothermia is associated with shivering, wound infection, and coagulopathy. Forced air warming is an effective way to prevent or treat core hypothermia. The combination of preoperative and intraoperative upper body forced air warming and warmed IV fluids has been shown to reduce the drop in body temperature in women having cesarean sections with epidural anesthesia.

Methodology This prospective, randomized study included pregnant women of at least 37 weeks gestation scheduled for elective cesarean section with subarachnoid block anesthesia. All women were ASA class I or II, between 18 years and 40 years of age, and carried a single fetus. Women with a body mass index >40 kg/m² were excluded.

After the subarachnoid block was performed and a Foley catheter inserted, all women had a lower body Bair Hugger (Augustine Medical, Eden Prairie, MN) blanket applied with the upper (adhesive strip) end just below the inguinal fold. A single cotton blanket was placed over the lower body warming blanket. Another cotton blanket was placed over the upper chest and arms. In the Warmed group, the lower body blanket was inflated with a model 501 warming unit set at 43°C. In the Control group the warming unit was not turned on.

All patients were premedicated with metoclopramide 10 mg and ranitidine 50 mg. All patients were hydrated with 500 mL of room temperature Hespan before the block was placed. All blocks were performed in the sitting position with a 25 gauge Whitacre needle at the L3-4 interspace by the same anesthesiologist. Hyperbaric bupivacaine 12 mg, fentanyl 10 µg, and morphine 200 µg was used to produce the block. All blocks produced a sensory level of T-4 or higher.

Data collection began before the block was placed and continued until the patient was discharged from recovery. Temperature was measured with an oral electronic thermometer. Ambient temperature in the operating room was at or near 23°C (73.4°F). Hypothermia was defined as a core (oral) temperature of 35.5°C or less. Active warming with a forced air warming blanket was begun in Control group patients when they met the criteria for hypothermia at any time during the data collection period of the study.

Result The maximum decrease in core temperature was 1.3°C (± 0.4°C) in the Warmed group and 1.3°C (± 0.3°C) in
the Control group (P not significant). There was also no difference between groups in the number of patients who became hypothermic, 8 in the Warmed group and 10 in the Control group (P=0.5). In the Control group, 10 of 15 patients became hypothermic during data collection and received forced air warming.

**Conclusion**

Intraoperative lower body forced air warming did not prevent hypothermia in women undergoing cesarean section with spinal anesthesia.

**Comment**

If what is written in this article accurately depicts the study, it is of extremely limited value. After reading the article I almost discarded it several times. Ultimately, I included it because it is the first study I’ve read about forced air warming during subarachnoid block for cesarean section and because it may yet have something to teach us.

It is well known that there is an initial fall in core temperature associated with both general anesthesia and major regional anesthesia due, not to a loss of heat energy from the body, but from a redistribution of heat energy from the core of the body to the periphery. Because the heat energy isn’t lost from the patient to her surroundings it is very hard to prevent the core temperature drop. This initial drop occurs in about the first hour of the anesthetic. Forced air warming can help reduce the speed and magnitude of this initial drop, and forced air warming is good at increasing the temperature again after the drop, but it doesn’t eliminate it. In this study, the lowest temperatures were recorded at 1 hour and 1 hour 15 minutes in the Warmed and Control groups respectively; they fit the pattern.

These patients had a pretty short surgery and recovery, in terms of core temperature decline, making it hard to see the effects of forced air warming. Surgical times averaged under 60 minutes and total OR and recovery time averaged only about 2 hours. It would be hard to see the benefit of forced air warming under these circumstances even if only the Warmed group had received warming. And herein lies one of the major problems of the study. The investigators report that 10 of the 15 “Control” patients became hypothermic and received forced air warming. What they don’t tell us is when warming of “Control” patients began. If it was fairly early in the data collection period then this really isn’t a study at all. If it was uniformly late in the data collection period then the data before the onset of warming in “Control” patients would still be useful. We just don’t know.

So what can we learn from this “study?” No matter when “Control” patients were warmed, patients who received lower body forced air warming dropped from an average of 36.5° C to 35.2°C over the first hour of the case. Clearly, lower body forced air warming was insufficient by itself to prevent hypothermia during a cesarean section with spinal anesthesia. And this, by itself, is an important delimitation. Infusing a liter of room temperature crystalloid IV fluid reduces the core temperature of an average sized adult by about 0.25° C. (Probably somewhat less in a term pregnant woman.) Women tend to receive a fair volume of IV fluid during a cesarean section. In the study the investigators cited where warming did prevent hypothermia during cesarean sections with epidural anesthesia, warmed IV fluids were used.

Overall, I believe that forced air warming is the single best tool we have for maintaining normal body temperature during anesthesia. It is clearly not always enough by itself to maintain normothermia. Maintaining normothermia in women undergoing cesarean section with regional anesthesia will require multiple interventions and close attention to the details.

Michael Fiedler, PhD, CRNA
**INTRATHECAL ANALGESIA FOR POSTOPERATIVE PAIN RELIEF AFTER RADICAL PROSTATECTOMY**

Ene KW, Nordberg G, Johansson FG

**Abstract**

The purpose of this pilot study was to evaluate subarachnoid local anesthetic and opioid analgesia following open radical prostatectomy.

**Background**

Continuous epidural analgesia has been commonly used to treat pain after open radical prostatectomy. Single dose subarachnoid opioids are less commonly used, despite being more convenient for anesthesia providers. Some studies have concluded that the combination of epidural analgesia and general anesthesia increased the length of hospital stay. After evaluating the effectiveness of continuous epidural analgesia for postoperative pain in their own practice, the authors changed to subarachnoid analgesia. This was the initial evaluation of their experience with subarachnoid postoperative analgesia.

**Methodology**

This prospective, descriptive study included patients who underwent open radical prostatectomy. All patients received a single injection subarachnoid block as the foundation of their postoperative pain management. Blocks were performed before induction of general anesthesia. The injectate was 10 mg hyperbaric bupivacaine and 0.1 to 0.2 mg morphine. General anesthesia included propofol or pentothal, fentanyl, a nondepolarizing muscle relaxant, nitrous oxide, and isoflurane. Crystalloid, colloid, and blood was administered at the discretion of the anesthesiologist. All patients received acetaminophen preoperatively and postoperatively. Diclofenac (an NSAID) was administered postoperatively at the discretion of the surgeon. Ketobemidone was used as a rescue analgesic in all patients. (Editors Note: ketobemidone is an opioid chemically related to meperidine. It is equianalgesic to morphine, mg per mg. Ketobemidone is used chiefly in Scandinavian countries.)

Pain was assessed with a visual analogue scale (VAS) as none or mild (VAS 0-30), moderate (VAS 31-70), or severe (VAS >70).

**Result**

Data was collected on 50 ASA class I, II, or III patients. Their average age was 65 years old (range 52-73). All but eight patients received the smaller dose of subarachnoid morphine, 0.1 mg. The larger 0.2 mg dose of subarachnoid morphine did not significantly reduce pain scores. During the first four hours postoperatively, 82% of patients reported no or mild pain, 19% reported moderate pain, and no patient reported severe pain. During the first 24 hours postoperatively, approximately 45% of patients reported moderate pain and 11% reported severe pain. Ketobemidone was administered to 41 of the 50 patients during the first 24 hours (nine patients did not receive any). The average dose of ketobemidone administered within the first 24 hours was 5.9 (±6.8) mg. Diclofenac was administered to about half of patients during the first 24 hours. Over the first three postoperative days, patients who received diclofenac reported less pain and received less ketobemidone (P <0.05).

Only five patients received an antiemetic during the first 24 hours postoperatively. Postoperative nausea and vomiting (PONV) were positively correlated with high pain scores. There was no correlation between total opioid dose and PONV.

**Conclusion**

Despite inadequate pain relief in some patients during the first 24 hours postoperatively, subarachnoid morphine and bupivacaine was recommended for postoperative analgesia in patients undergoing open radical prostatectomy.
Comment

This elementary study had only one group and made no comparisons. It had no complicated statistical analysis. It was simply an organized way to describe experience with an anesthetic technique. The scientific method is, at its core, an organized process for gathering and reporting information.

Because the general anesthetic wasn’t standardized, we don’t know how much fentanyl patients got intraoperatively, not all patients received an NSAID and those who did began receiving NSAIDs at different times it is hard to judge the impact of the authors acute pain management strategy. Further complicating the assessment is the fact that “moderate” pain included visual analogue scores (VAS) from 31 to 70. People don’t score pain on a VAS in a linear fashion. We can compare two scores and tell that one is more or less than another, but we can’t tell how much more or less. The low and high ends of the VAS tend to bunch together. Given that, a score in the 30’s is fairly low while a score nearing 70 is fairly high. Knowing that someone had moderate pain (VAS 31-70) might mean they had a little or that they had quite a bit. (This is a good example of why we prefer not to aggregate data into clumps like “low,” “medium,” and “high.”) During the first 24 hours, 56% of patients reported moderate or severe pain. If that “moderate” pain was near the 70 end of the VAS then about half of patients were quite uncomfortable for the first day. Not what I would call a big success.

What might we learn from this report? Pain results from multiple causes and multiple treatments are needed to prevent or relieve it. A good example here is the use of an NSAID (diclofenac). While not enough by itself, patients who received it had less pain and used less supplemental opioid analgesia. In this report, PONV was correlated not with opioid administration but with pain. Pain and PONV go together and should be treated together. Lastly, despite the author’s enthusiasm for a single dose spinal for postoperative pain, I’m not impressed that almost half of patients experienced moderate or severe pain during the first 24 hours despite supplemental opioids. This particular single spinal injection technique may be easier for anesthesia to manage but we should strive to do better for our patients.

Michael Fiedler, PhD, CRNA
Abstract

Purpose This was an evaluation of an anesthesia protocol developed for total knee arthroplasty and total hip arthroplasty. The protocol emphasizes preemptive pain management, the use of peripheral nerve blockade, and aggressive postoperative pain management.

Background Surgical advances in total hip arthroplasty (THA) and total knee arthroplasty (TKA) have been accompanied by rapid rehabilitation protocols, and changes in patient education as well as surgeon and patient expectations. Because pain and medication side effects decrease the ability of patients to actively participate in rehabilitation, delaying recovery and leading to poor or suboptimal surgical outcome, some anesthesia providers have embraced the concept of “preemptive multimodal perioperative analgesia.” Preemptive analgesia involves the administration of analgesics prior to painful stimuli in order to prevent central sensitization. Multimodal analgesia refers to the use of a combination of anesthetic techniques including the use of regional anesthesia and multiple analgesics for post operative pain relief. The approach evaluated in this document was referred to as the “Mayo Clinic Department of Anesthesiology Total Joint Regional Anesthesia Clinical Pathway, or ACP. This study was performed as a pilot study to assess the reliability, reproducibility, and efficiency of such a protocol. The overall value of this protocol was evaluated on the basis of the time to hospital discharge as well as on the assessment of complications.

Methodology Data was collected prospectively on 20 patients who underwent minimally invasive THA and 20 patients who underwent minimally invasive TKA. All patients were treated with the ACP. All patients in the study were matched with historical controls who had undergone the same procedures within the previous five years with the use of conventional surgical and anesthesia techniques which included either general anesthesia, neuraxial anesthesia, or peripheral nerve block anesthesia only.

The ACP provided for the use of OxyContin 20 mg PO and Rofecoxib 50 mg PO in the preoperative holding area. In the anesthesia procedure room each patient was injected with a posterior lumbar plexus block with continuous nerve catheter placement, and sciatic nerve block. Some patients undergoing TKA were provided with a continuous femoral catheter and block as an alternative. In the Postanesthesia Care Unit, patients were given Tylox two tablets PO and their continuous catheters were bolused with 0.2% bupivacaine (10 mL) along with a continuous infusion at 10mL/h. In addition, orders were left for ketorolac 15mg IV q 6 h, acetaminophen 1000 mg PO TID, OxyContin 20 mg PO BID, OxyContin 5 mg q 4 h PRN, and a heploc IV.

Postoperative verbal analog pain scores, opioid requirements, and side effects were recorded. Evaluating the ACPs impact on patient length of stay was the primary focus with a secondary focus on verbal analog pain score, opioid requirements, and side effects. The study had 90% power to detect a 0.8 day difference in length of stay between patients in the prospective study group and the historical control group.

Result

Results of the study were similar between the TKA and THA groups. The ACP group was discharged sooner than the control group (2.8 days compared to 5.0 days) and also sooner than the reported national average for TKA and THA patients. Postoperative verbal analog pain scores with and without activity were significantly different between the historic control and ACP groups. The
ACP was found to be quite effective, with all patients reporting excellent analgesia during the first three postoperative days. In addition, the patients in the ACP group used half of the opioids as compared with the control group, had fewer opioid related side effects, and achieved ambulation much more rapidly than the control group.

**Conclusion**

Multimodal perioperative analgesia using peripheral nerve blockade and scheduled oral pain medications for TKA and THA patients provided excellent perioperative analgesia. Multimodal perioperative analgesia also resulted in a reduction in analgesic side effects and a shorter hospital stay.

**Comment**

In my experience, one facilities routines do not always transfer easily to another facility or another region of the state or country because of the variability of surgical technique, staff experience and resources, and patient population differences. However, the Mayo concept of pre-emptive analgesia combined with continuous peripheral nerve blockade and oral analgesics showed great promise in post operative pain management for total joint replacement surgery.

Each practitioner has his or her favorite combinations of post operative pain medications which they feel are most effective in their individual environments, with their particular patient populations. Those medications can be developed into a similar protocol using the concepts developed by this Mayo study, and might be equally effective. The key concepts are to provide the patient with preoperative analgesia which reduces the sensitization to painful stimulation, intraoperative regional anesthesia which provides for more rapid recovery from anesthesia and prolongation of postoperative analgesia, and finally the use of a variety of postoperative oral medication in an attempt to reduce medication side effects and minimize post operative pain. The results of this study are very impressive, and the concepts are well established by other similar studies of pre-emptive analgesia and peripheral nerve block anesthesia.

Steven R. Wooden, MS, CRNA

Editor’s Note: for two related articles addressing pain after orthopedic joint surgery see “**EVALUATING THE ANALGESIC EFFICACY OF ADMINISTERING CELECOXIB AS A COMPONENT OF MULTIMODAL ANALGESIA FOR OUTPATIENT ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION SURGERY**” in Volume 1 Number 3 (June 2007) and “**THE EFFECT OF INITIATING A PREVENTATIVE MULTIMODAL ANALGESIC REGIMEN ON LONG-TERM PATIENT OUTCOMES FOR OUTPATIENT ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION SURGERY**” in Volume 1 Number 4 (July 2007).
Abstract

Purpose  The purpose of this study was to compare the effectiveness of 0.5 mg/kg metoclopramide and 0.1 mg/kg ondansetron for prevention of vomiting following tonsillectomy in children.

Background  Serotonin blockers effectively prevent vomiting in children after tonsillectomy. Metoclopramide is a dopamine antagonist thought to exert an antiemetic effect by blocking dopamine receptors in the Chemoreceptor Trigger Zone (CTZ). Traditionally, metoclopramide 0.1 mg/kg has been used as an antiemetic in children, but higher doses have been reported to exert an antiserotonergic action which could increase its antiemetic efficacy. Historically, metoclopramide doses have been limited in children due to concerns about extrapyramidal side effects that can result from dopaminergic blockade. Extrapyramidal side effects occur in about 0.2% of adults but up to 25% of children.

It is standard clinical practice at the Royal Children’s Hospital, Melbourne, Australia to administer metoclopramide 0.5 mg/kg IV intraoperatively for prevention of postoperative nausea and vomiting (PONV). The appropriateness of administering this higher dose is based upon long clinical experience during which 0.5 mg/kg metoclopramide appeared to be significantly more effective at preventing PONV than 0.1 mg/kg. Even higher doses are used in pediatric oncology.

Methodology  This randomized, double-blind study included ASA class I, II, and III patients aged 6 months to 12 years undergoing tonsillectomy. The patients were divided into two groups. The metoclopramide group received 0.5 mg/kg metoclopramide IV intraoperatively for prevention of postoperative vomiting. The ondansetron group received 0.1 mg/kg ondansetron (maximum 8 mg). All patients were premedicated with acetaminophen 20-30 mg/kg per os 30 minutes before induction of general anesthesia. General anesthesia was induced with either 2-4 mg/kg propofol IV or inhaled sevoflurane. Anesthesia was maintained with nitrous oxide, isoflurane, morphine 0.05 – 0.1 mg/kg, and atracurium 0.3-0.5 mg/kg. All patients received dexamethasone 0.1 mg/kg intraoperatively. Neuromuscular block was antagonized with neostigmine 0.05 mg/kg and atropine 0.02 mg/kg. Postoperatively, acetaminophen and codine were administered for analgesia.

Result  Six hundred patients were recruited into the study and randomized. Cancelled surgeries eliminated 43 patients. Thus, 557 patients were included in the analysis, 284 in the metoclopramide group and 273 in the ondansetron group. The average age of participants was 5.5 years in the metoclopramide group and 5.0 years in the ondansetron group.

More children in the metoclopramide group vomited after tonsillectomy than those in the ondansetron group, 37.3% vs. 25.3%. Metoclopramide patients also vomited sooner after surgery. The median time to first vomit was 2.1 hours in the metoclopramide group vs. 6.5 hours in the ondansetron group ($P<0.002$).
Conclusion

In children, metoclopramide 0.5 mg/kg is somewhat less effective than a standard dose of ondansetron at preventing vomiting. Children who received metoclopramide also vomited several hours sooner, on average, than those who received ondansetron.

Comment

Although the evidence is abundant that metoclopramide is ineffective as an anti-nausea agent and antiemetic in adults\(^1\), even in large dosages of 1 mg/kg (max. 50 mg)\(^2\), the research findings regarding the use of metoclopramide for pediatric patients is not as clear. Reviewing the literature, a dose of 0.25 mg/kg is the most frequently studied in pediatric patients. In comparison to placebo, metoclopramide had a statistically significant antiemetic effect.

This study was conducted in a facility where metoclopramide was the commonly used antiemetic for patients having a tonsillectomy. As noted in the study, metoclopramide was less effective than ondansetron, with those receiving the former experiencing vomiting sooner postoperatively. The researchers did note the increased cost of ondansetron; if it was used as the routine antiemetic, the increased cost to prevent vomiting in an additional person would be (AUS) $142.00.

The researchers noted that the earlier vomiting in the metoclopramide group may be altered if the metoclopramide was re-dosed to allow improved effector-site levels. The “oh-by-the-way” finding in this study was that patients who received the large doses of metoclopramide had no reported extrapyramidal side-effects as might have been anticipated.

Based on this study, I will not likely change my antiemetic prophylaxis to include metoclopramide; however, if I used metoclopramide routinely, I would be encouraged to study the possibility of improving efficacy by giving higher dosages and re-dosing.

Terri M. Cahoon, MSN, CRNA


Abstract

Purpose The purpose of this study was to determine if autonomic activity was suppressed to a greater degree using the alpha 2 adrenoreceptor agonist dexmedetomidine, compared to fentanyl, during laparoscopic gastric banding procedures.

Background Morbidly obese patients are at risk for sleep apnea; the incidence of obstructive sleep apnea in these individuals is reported to be as high as 77%. During bariatric procedures, fentanyl is often used as the narcotic of choice providing a decrease in the body’s sympathetic response to surgical stimulation. Clearly, we know that fentanyl is a potent respiratory depressant and respiratory depression exhibited by the morbidly obese individual undergoing anesthesia for bariatric surgery can create significant untoward affects, particularly post-operatively. The alpha 2 agonist dexmedetomidine has been reported to offer less respiratory depression compared to fentanyl, as well as improved post-operative pain scores compared with fentanyl. In the studies prior that demonstrated this, the amount of inhalation anesthesia used, specifically desflurane, was not standardized or controlled for, therefore, the effects of dexmedetomidine compared with fentanyl could not be analyzed. In this study, the authors hypothesized that the autonomic effects of both dexmedetomidine and fentanyl could be compared if the desflurane end tidal level was controlled and similar.

Methodology IRB approval was attained and 40 patients undergoing general anesthesia for laparoscopic gastric banding procedures were enrolled in the study. Appropriate randomization technique placed the patients into one of two groups; group one patients (n=20) received dexmedetomidine 0.5 µg/kg intravenously over 10 minutes during induction (to avoid transient hypertension), and group two patients (n=20) received fentanyl 0.5 µg/kg during induction. All patients received midazolam 2 mg in the pre-operative holding area as well as a standardized induction drug sequence of propofol, lidocaine, and succinylcholine. The fentanyl group received an infusion of fentanyl as part of their maintenance anesthetic regime at 1 µg/kg/h. The dexmedetomidine group received an infusion of 0.4 µg /kg/h of dexmedetomidine. For both groups end-tidal desflurane concentrations were adjusted to maintain a response entropy of 45 ± 5. Both groups were maintained on their respective infusions until the end of the surgical procedure. Data collection included the following: mean response entropy EEG values, heart rate, noninvasive blood pressure measurements, and end-tidal desflurane measurements. Via spectral analysis, electrocardiographic (ECG) data were collected and autonomic activity was determined of heart rate variability. Regarding tone entropy, autonomic function was evaluated from the ECG using a tone-entropy analysis process modified from previous researchers. Successive differences of the heart periods and a percentage index of each heart period variation were calculated. Tone represents the balance between a decrease in heart period and an increase in heart period (of the heart). A negative value indicated vagal tone, whereas a positive shift indicates sympathetic enhancement of sympathovagal balance.

Result The results of the analysis showed no difference between the groups in terms of height, weight, age, gender, or ASA physical status. Body mass index averaged 50 to 51 kg/m² in both groups. Length of surgery time was also comparable in both groups. There was no difference in the tone response or response entropy between the fentanyl and dexmedetomidine groups via
statistical analysis; the end-tidal desflurane concentration necessary to maintain response entropy at 45 averaged 4.0-4.1% in both groups. Spectral analysis of heart rate variability showed no difference between the groups. In both groups, the power (low frequency power and high frequency power) decreased during anesthesia indicating sympathovagal balance was decreased. The decrease in the low frequency to high frequency (power) ratio was greater in the dexmedetomidine than fentanyl group; this was statistically significant and indicated that dexmedetomidine decreased sympathovagal balance more so than fentanyl when both were used as part of the general anesthesia drug sequence. Both drugs inhibited overall sympathetic activity during anesthesia. One major limitation to this study was the fact that it was difficult compare the autonomic effects of fentanyl and dexmedetomidine because there was little knowledge about how both drugs interacted with desflurane. Additional limitations included a small sample size and the fact that other drugs used during general anesthesia may have influenced the autonomic responses.

**Conclusion**

Dexmedetomidine appeared to produce suppression of autonomic activity similar to fentanyl in a group of high risk patients undergoing desflurane anesthesia. This was clinically significant because reduction of sympathetic activity of these individuals was definitely warranted and demonstrated when fentanyl is used, yet fentanyl contributes to post-operative respiratory depression and this is not acceptable for a group of individuals who are already at risk for respiratory compromise. Dexmedetomidine appeared to offer the same or greater degree of suppression of sympathetic activity yet doesn’t appear to have the post-operative side effects of respiratory depression. This may be the drug of choice for this population of individuals; further studies are warranted.

**Comment**

As an alpha 2 adreno-receptor agonist that has been approved for sedation purposes in the ICU setting, it is very exciting to see what appears to be a significant place for dexmedetomidine in anesthesia. Due to its mechanism of action of decreasing sympathetic outflow from the central nervous system and therefore reducing the plasma concentration of the potent catecholamines, this drug is known to produce sedation, analgesia, stable ventilatory patterns, and rather predictable cardiovascular responses. For patients such as the morbidly obese with obstructive sleep apnea, providing additional and yet very needed sedation and analgesia during a general anesthetic with a volatile agent, can prove to be very challenging and lead to unfavorable post operative outcomes. Dexmedetomidine may be the answer in these challenging settings!

Mary A. Golinski, PhD, CRNA
INTRAOPERATIVE ESMOLOL INFUSION IN THE ABSENCE OF OPIOIDS SPARES POSTOPERATIVE FENTANYL IN PATIENTS UNDERGONG AMBULATORY LAPAROSCOPIC CHOLECYSTECTOMY

Anesth Analg 2007;105:1255-1262


Abstract

Purpose The purpose of this study was to compare intraoperative fentanyl, esmolol, and remifentanil with regards to postoperative pain, opioid use, and side effects after laparoscopic cholecystectomy.

Background Laparoscopic cholecystectomy has generally improved patient outcomes compared with open cholecystectomy. Nevertheless, pain, postoperative nausea and vomiting (PONV), urinary retention, and surgical complications still occur. Some of these side effects may be related to opioid use. The pain following a laparoscopic cholecystectomy is somewhat different than pain from other surgical procedures. A multimodal approach to postoperative pain relief is likely to be most effective.

Esmolol is a selective β₁ antagonist. Some previous studies have suggested that esmolol may either have a direct antinociceptive effect or reduce pain formation that is due to an adrenergic stress response. As a result, esmolol has been suggested as an alternative to opioids for management of the stress response during general anesthesia.

The hypothesis of this study was that esmolol infusion would reduce the total dose of fentanyl needed in the Post Anesthesia Care Unit (PACU) for pain relief after laparoscopic cholecystectomy.

Methodology This prospective, randomized study included ASA I and II patients between the ages of 18 years and 85 years scheduled for laparoscopic cholecystectomy. Exclusion criteria included chronic use of β-blockers or opioids and asthma or reactive airway disease. All patients were premedicated with 0.03 mg/kg midazolam. General anesthesia was induced with 2.5 mg/kg propofol and 0.8 mg/kg rocuronium and maintained with 4% to 8% desflurane. After induction, 1.3 gm acetaminophen was administered rectally and 8 mg dexamethasone was administered IV. Fifteen minutes before the end of the case 30 mg ketorolac and 0.625 mg droperidol were administered IV. Two surgeons performed all study cases. They injected the points of trocar insertion with lidocaine before incision and with bupivacaine with epinephrine at the end of the case.

Before induction of anesthesia, patients were block randomized into one of three groups to receive fentanyl, esmolol, or remifentanil intraoperatively. The fentanyl group received 1 µg/kg fentanyl at induction followed by 50 µg every 30 minutes during the case. The esmolol group received 1.0 mg/kg esmolol during induction followed by 5-15 µg/kg/min during the case. The remifentanil group received 1 µg/kg remifentanil followed by 0.1-0.5 µg/kg/min during the case. Esmolol and remifentanil infusions were turned off when the incisions were closed. Fentanyl, esmolol, and remifentanil were used to maintain heart rate within 20% of baseline. Desflurane was titrated to maintain systolic blood pressure within 20% of baseline.

Result The study included 90 patients, 30 in each group. Patients who were converted to an open cholecystectomy were not included in the statistical analysis, three in the fentanyl group and two in the remifentanil group. The remifentanil group had a higher percentage of female patients than did the other two groups. The groups were demographically similar otherwise. The average MAC-hours of desflurane administered to each group was also similar. PACU nurses and those assessing study patients were
Clinical trials evaluating the role of esmolol in an intraoperative setting during laparoscopic cholecystectomy have demonstrated its effectiveness in reducing the need for opioids in the post-anesthesia care unit (PACU). A recent study compared the use of esmolol, fentanyl, and remifentanil as intraoperative anesthesia agents. Patients were blinded to their group membership and did not have access to the intraoperative anesthesia record. 

Pain scores were no different between the three groups during the first two hours postoperatively. But, the average dose of fentanyl administered in the PACU was significantly less in the esmolol group; 168 µg in the fentanyl group, 92 µg in the esmolol group, and 238 µg in the remifentanil group (P=0.0001). Half as many esmolol patients experienced nausea in the PACU as did fentanyl and remifentanil patients (P=0.004). Likewise, fewer esmolol patients received ondansetron (P=0.001) and the total dose they received was lower (P=0.0003). Lastly, the time from PACU admission to discharge home averaged 180 minutes in the fentanyl group, 120 minutes in the esmolol group, and 163 minutes in the remifentanil group (P=0.0033).

After discharge home, pain sores, the amount of analgesics used, and the incidence of PONV were similar between groups.

**Conclusion**

An intraoperative infusion of esmolol during laparoscopic cholecystectomy reduced the amount of opioid analgesia needed in the PACU, reduced PONV in the PACU, and resulted in earlier achievement of discharge criteria.

**Comment**

I have been reading studies that suggested either that esmolol had analgesic properties or prevented pain formation for a few years now. This is not the first study to suggest it. I’m not at all sure anyone has a good idea how esmolol might reduce postoperative pain. There are a number of possibilities and probably a lot we don’t know. Up until now, I’ve been skeptical because: A) I couldn’t think of a mechanism by which esmolol could produce analgesia or prevent pain, and B) the studies weren’t that convincing. But this well designed study is a convincing argument that substituting esmolol for fentanyl intraoperatively can reduce postoperative pain by some mechanism, direct or indirect, in at least some surgical procedures. PACU pain scores were almost identical between groups (the P values were very high), yet the esmolol group needed only about half as much fentanyl in the PACU to make patients comfortable. Perhaps related to the reduced PACU fentanyl administration, the esmolol group also experienced less PONV, received lower total doses of ondansetron, and were discharged home sooner. Each of these differences were highly significant, both clinically and statistically. And each of these differences is exactly what we want to achieve. This study is strong enough, the potential benefit to patients great enough, and the risk to patients small enough that it is probably worth trying in our own clinical practice.

The other point this study makes is the importance of a multimodal approach to pain prevention and treatment. Esmolol was not the only drug used to achieve the outstanding results reported. Patients had local anesthetic injected at their trocar insertion sites before surgical stimulation and at the end of the case. They each received acetaminophen (Tylenol), ketorolac (Torodol), dexamethasone (Decadron), and droperidol (Inapsine) during the case. Preemptive analgesia and PONV prophylaxis was an important part of the anesthetic plan. Those other drugs were an important part of the success of this protocol. I doubt that substituting esmolol for fentanyl during laparoscopic cholecystectomy without addressing the local anesthetic, anti-inflammatory, analgesic, and antiemetic effects provided by the other drugs in the protocol would be effective.

Michael Fiedler, PhD, CRNA
A RANDOMIZED, DOSE-FINDING, PHASE II STUDY OF THE SELECTIVE RELAXANT BINDING DRUG, SUGAMMADEX, CAPABLE OF SAFELY REVERSING PROFOUND ROCURONIUM-INDUCED NEUROMUSCULAR BLOCK

Anesth Analg 2007;104:555-562

Groudine S, Soto R, Lien C, Drover D, Roberts K

Abstract

Purpose The purpose of this study was to assess the safety and efficacy of five different doses of sugammadex, the new selective relaxing binding agent, and its ability to reverse profound rocuronium-induced neuromuscular blockade. A primary objective of the study was to understand the dose-response relationship of sugammadex in reversing a block defined as one or two post-tetanic counts (termed a profound block). The researchers hypothesized that the intubating dose of rocuronium, 0.6 or 1.2 mg/kg, would not influence the dose of sugammadex required to reverse a block induced by rocuronium if indeed the reversal was attempted at the same level of a deep block.

Background Cholinesterase inhibitors are the current drugs used to reverse nondepolarizing neuromuscular blocking drugs. When a surgical procedure is complete, it is optimal to reverse the blockade as rapidly and completely as possible, which often presents a challenge depending on many variables related to the surgical procedure, the anesthetic, and the patient physiology. When a profound block is present upon culmination of a surgical procedure, cholinesterase inhibitors are not effective and residual neuromuscular blockade places the patient at risk for several problems. Additionally, anticholinesterases can result in negative cardiovascular and respiratory effects. Sugammadex is in a new class of drugs termed selective relaxant binding agents. It is a γ-cyclodextrine developed to reverse the effects of aminosteroid neuromuscular blocking agents, specifically rocuronium. Sugammadex encapsulates the rocuronium molecule and forms a tightly bound complex thereby reversing the effects of the blockade. In previous clinical trials, sugammadex was found to be well tolerated at doses up to 16.0 mg/kg and doses of 2.0–4.0 mg/kg have been shown to reverse a moderate neuromuscular block.

Methodology This study was conducted as a Phase II, randomized, assessor-blinded, parallel-group, dose-finding trial at four sites in the United States. IRB approval was obtained at each trial site and the subjects were enrolled between August 2004 and May 2005. Patients were asked to give written informed consent who were age greater than 18 years, ASA physical status I-III, scheduled to undergo an elective surgical procedure anticipated to last greater than 45 minutes and who required endotracheal intubation with the use of a non-depolarizing neuromuscular blocking drug. The subjects were randomized to receive one of two doses of rocuronium, 0.6 mg/kg or 1.2 mg/kg, and one of five doses of sugammadex, 0.5, 1.0, 2.0, 4.0, or 8.0 mg/kg. Six patients were anticipated for each group.

Since there were no prior data available on sugammadex at the time of this study regarding profound neuromuscular block, the researchers had to propose the sample size per dose group using ‘practical reasoning’. As this was a Phase II trial, a safety assessor was assigned to each subject and this assessor was blinded to treatment groups. A standardized anesthetic protocol was followed and neuromuscular function was monitored using a calibrated acceleromyograph. Each patient was given one of the two doses of rocuronium for intubation as well as maintenance doses when post-tetanic counts were greater than 2. The maintenance dose of rocuronium given during the surgical procedure was 0.15 mg/kg. As soon as muscle relaxation was no longer needed for the surgical procedure and the acceleromyograph reading was 1-2 post-tetanic counts, a single IV bolus dose (one of the five different doses) of...
Sugammadex was given. Patients remained intubated after the sugammadex for a minimum of 30 minutes. No other reversal drugs were given unless 30 minutes had passed and the Train-of-4 (TOF) ratio remained \(<0.9\). Standard clinical tests of muscular strength were used post-operatively such as a five second head lift, a tongue depressor test, and whether or not the patient complained of diplopia. Appropriate and pertinent other physiologic measures were obtained on each patient at defined times during the surgery and anesthetic as well as post-operatively, such as body temperature, vital signs, oxygen saturation and respiratory rate. A 12 lead ECG was performed pre-operatively, just prior to the administration of rocuronium, and 2 and 30 minutes after sugammadex was administered. Additionally, a physician blinded to the treatment groups performed a post-anesthetic assessment between 10 and 24 hours after the sugammadex dose. Laboratory values were obtained pre-operatively and 20 minutes, 4-6 hours, and 24 hours after the sugammadex was administered.

Recovery from the neuromuscular blockade was studied in all patients in the intent-to-treat population. A safety analysis was done on all who received a dose of sugammadex. The primary dependent variable (efficacy variable) was the time from the start of administration of sugammadex to recovery of the TOF ratio to 0.9. Secondary dependent (efficacy) variables were the time from the start of administration of sugammadex to recovery of the TOF ratio to 0.7 and 0.8. Dose-response curves were estimated for each patient for each dependent variable. The statistical analysis was done to assess the dose relationship between the primary and secondary dependent variables and the dose of sugammadex for each of the two rocuronium groups.

**Result**

Forty-three total patients were enrolled in the study after 17 were excluded. The groups were all demographically similar. In both rocuronium groups (0.6 or 1.2 mg/kg) there was a significant decrease in time to recovery of the TOF ratio to 0.9 as demonstrated on the acceleromyograph, with increasing doses of sugammadex. A similar observation was noted for the secondary variables too; there was a decrease in the mean time to recovery to a TOF ratio of 0.7 and 0.8 with increasing doses of sugammadex. On admission to the post-anesthesia care unit, 16 of the 24 patients who received 0.6 mg/kg of rocuronium and 11 of the 19 patients who received 1.2 mg/kg rocuronium were oriented. All but one of these patients was able to perform a 5 second head lift. All patients except the edentulous were able to hold the tongue depressor between their teeth while the blinded assessor tried to remove it. None of the subjects enrolled in the study had complaints of diplopia or generalized muscle weakness in the recovery room. The most common adverse events observed included post-procedural pain, nausea, vomiting, hypertension, hypotension, and brief period of oxygen desaturation. None of the adverse events were felt to be related to dosing relationships of the study drug. No patients suffered any permanent morbidities or mortalities while participating in this Phase II study. No clinically significant laboratory abnormalities were observed which appeared to be related to the study drug nor were abnormal vital signs noted on the ECG data. Of the adverse events that were reported, only two patients had an adverse event that presented itself as an incomplete reversal. One patient was reported as an incomplete reversal who received 0.6 mg/kg of rocuronium and sugammadex 0.5mg/kg; the other patient received 1.2 mg/kg of rocuronium and 0.5 mg/kg of sugammadex. Few other patients appeared to have an unexpectedly quick reversal which was not surprising in this dose finding study.

**Conclusion**

The data presented in this study is consistent with previous research on sugammadex, although still very limited, demonstrating that sugammadex provides a fast and safe reversal from rocuronium induced neuromuscular blockade. Previous studies have indicated that in doses greater than 2 mg/kg sugammadex is not likely associated with muscle weakness. Additionally, this Phase II clinical trial demonstrated that sugammadex, at doses of 4.0 mg/kg and 8.0 mg/kg reversed profound neuromuscular blockade with a mean time of 1.7 minutes. The researchers did not conclude from the limited evidence that safety of this drug was problematic. A major limitation of this study was its small sample size and therefore the inability to perform rigorous statistical testing.

**Comment**

The introduction of sugammadex into the practice of anesthesia has great potential to positively influence the outcomes of patients. While the anticholinesterase (combined with anticholinergic medications) method of reversing neuromuscular blockade has been in
existence for decades, incomplete reversal, muscle weakness associated with respiratory insufficiency, delayed emergence from anesthesia, and re-intubation incidences remain unacceptably high. Often times we are faced with a patient who is not a candidate to receive succinylcholine, yet the intended surgical procedure is very short in length. Or we are faced with a difficult airway or inability to secure an airway and a non-depolarizing muscle relaxant was indicated as safest for the induction. These situations are very serious and influence not only the quality of care we deliver, but the outcome of the patient. While still in the latter phase (phase 3) of clinical trials, sugammadex appears to have promising traits that may finally change the fact that airway management remains the most problematic as an anesthetic induced crisis situation. It is critical that we understand the mechanism of action of the drug as well as the clinical trial research that has delineated safety, dosing, and efficacy.

Mary A. Golinski, PhD, CRNA

Phase two clinical trials usually involve approximately 100-300 human volunteers. During phase two clinical trials, the safety and efficacy of the drug being testing is the primary objective.

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FINANCIAL IMPACT OF FAILING TO PREVENT SURGICAL SITE INFECTIONS


Abstract

The purpose of this study was to identify the financial impact of surgical site infections occurring in a sample of pediatric patients at Cincinnati Children’s Hospital Medical Center.

Purpose

It has been noted that surgical site infections (SSI) account for up to 16% of all nosocomial infections among hospitalized patients. There have been several infection control medical advances with efforts to prevent post operative surgical site infections; however, they still remain a significant cause of morbidity and mortality among hospitalized patients. Previous studies have identified that contracting an SSI can increase one’s length of stay within a hospital up to 10 days at a cost in this era exceeding $5,000. The more complex SSIs involving visceral organs or body cavities are associated with even higher costs and lengthier hospital stays. An SSI is operationally defined in accordance with the criteria established by the Centers for Disease Control and Prevention (CDC) in its national Nosocomial Infections Surveillance (NNIS) system. Therefore according to these criteria, SSIs occurring within 30 days of an operation are classified as either incisional or organ/space. If deemed incisional, further division is noted into those involving only skin and subcutaneous tissue and those involving deeper soft tissues of the incision. Organ/space SSIs involve any part of the anatomy other than the incised body wall layers, which were opened or manipulated during surgery.

Methodology

A matched cohort design was used to compare costs and length of stay for pediatric patients with an SSI versus control patients who did not have an SSI. The matched control patients (those with no SSI) had a similar operative procedure during the same time period as those who developed an SSI. Those included in the study were inpatients with an SSI during 2004. Only patients with clean or clean-contaminated surgical wound classification were studied. Exclusion criteria involved those who had a diagnosis of cancer or immune deficiency, had contaminated or dirty-infected surgical wound classifications, or were less than 30 days old or greater than 19 years of age. A SSI was deemed potentially preventable if it met the clean or clean-contaminated classification as aforementioned, and the patient did not have infection prone co-existing diseases. Seventy-eight patients were initially identified; of those, 46 met the inclusion criteria. The medical records were retrospectively reviewed by nurses and physicians skilled in pediatric, surgical and infectious disease management. Patients were further excluded if they could not be properly matched. Sixteen patients met the final inclusion criteria and had a suitable matched control patient identified. Furthermore, matching was conducted with critical consideration of same or equivalent surgical procedures, age within 1 year if possible, procedure date within one year if possible, ASA physical status classification + one level, similar co-morbidities, diagnosis codes, and whether the admission was of an elective or emergent basis. The final decision of an appropriate and suitable match was determined by a pediatric surgeon.

Result

The 16 patients who met the inclusion criteria for an SSI were appropriately matched with those who did not suffer an SSI in terms of patient characteristics and demographics listed. The mean total length of stay for those with an SSI was 15 days; this was significantly shorter than the control group without an SSI who had a mean total length of stay of 4.4 days. The difference in the length of stay was both clinically and statistically significant. The mean total cost for patients with an SSI was $52,706.00 versus the mean total cost of the matched patient without an SSI of $25,418.00. This also was statistically significant. Costs on day 3,
post-surgical procedures, were 36% higher for those with an SSI. Ultimately the SSIs resulted in costs totaling almost half a million dollars for the 16 study patients.

**Conclusion**  
One key impact of this study was the case matched design methodology; it allowed critical and meaningful dialogue of those who can work to influence further reductions in SSIs. Looking at total financial outcomes and hospital length of stay information allowed a concentrated focus on efforts to rectify the situation. The authors clearly identify that attempting to further eliminate SSIs is not only the right thing to do and is in the best interest of their patients, but that is goes to the core of a mission of providing the best possible care. Additionally, at this particular Children’s Hospital, there is not an increase in payment made for those who incur greater costs related to infections, rather the opposite is true. More than half of these cases are cost-fixed, meaning there is little or no reimbursement as the reimbursement is based on fixed diagnosis-related-group rates. For the other half of the group, the reimbursement is on a fee-for-service basis and reimbursement is only for a percentage of the SSI related charges. While the limitation of the study are obvious and include the retrospective approach, small sample size, and limited generalizability to different institutions, it does offer a template for future research, and a motivating force to eliminate SSIs for a variety of appropriate reasons.

**Comment**

This is a timely article, written and researched in an era where prevention of surgical site infections, prevention of sepsis, and prevention of other post-operative related untoward outcomes is the primary focus of quality patient care. Infections in general are occurring at an unacceptable rate; and all efforts are appropriately focused towards reducing the poor outcomes related to infections, and maximizing the favorable outcomes by preventing infections. Antibiotic use in isolation is clearly not enough. There are numerous other practices, many of them common sense, such as good hand washing technique, that can not only save money but often times save a life. And there is minimal cost to hand washing! Interesting to note, placing a monetary amount or quantification often times allows us healthcare workers to put things in a much different perspective. The costs incurred and the potential for worsening of a physical state are striking when a post-operative surgical infections occurs. Additionally, improving care techniques which prevent hospital acquired infections is truly the right thing to do.

Mary A. Golinski, PhD, CRNA
Abstract

Purpose The purpose of this audit was to describe the success and complication rates of internal jugular central line insertions with and without Ultrasound (US) guidance.

Background Central line insertion is a common procedure that has known morbidity and mortality. Complications of central venous cannulation include: arterial puncture, pneumothorax, hemothorax, hematoma, and infection. After conducting a meta-analysis comparing US with traditional surface landmark methods for inserting central lines, the National Institute for Health and Clinical Excellence (United Kingdom) recommended that US be used during central line insertion. Using US guidance during central line insertion has been associated with fewer complications, faster central line insertion, and fewer attempts needed for central line insertion. Little information is available, however, with which to evaluate these potential benefits for anesthesia providers or in patients presenting for surgery.

Methodology This prospective audit of internal jugular (IJ) central line insertion by anesthesiologists included patients greater than 18 years old. In general, the patients had advanced malignancies. Many had risk factors for difficult internal jugular central line insertion. The choice of whether or not to use US during central line insertion was made by the clinician, not by study protocol or randomization. Chest films were reviewed for proper placement and evidence of complications after each central line insertion. Complications were defined as arterial puncture, pneumothorax, hemothorax, and other. Insertion was a failure if a change in technique or insertion location was made.

Result Data was collected on 284 internal jugular central line insertions. US was used during the placement of 59.5% (169 of 284). Surface landmarks were used during the placement of 41.5% (115 of 284). The overall central line complication rate during the audit period was 4.6% (13 of 284) (this included central lines inserted with, and without US guidance). This compares to an historic complication rate of 10.5% (16 of 152) immediately before the audit at the same institution.

During the audit period, the central line failure rate was 6.1% in the surface landmark group and 0.6% in the US group. The complication rate was 8.7% in the surface landmark group and 1.8% in the US group. More experienced anesthesiologists had fewer complications and US guidance reduced their complication rate from 4% to 2.6% (not statistically significant).

Conclusion This audit supported increased use of US guidance during the insertion of internal jugular central lines by anesthesia personnel.
First, a word of caution. Despite the fact that some comparisons were made between two different groups in this audit (pre-ultrasound recommended complication rate vs. post-ultrasound recommended complication rate, surface landmark group vs. ultrasound group), this is not a research study. Many or most of the patients were at high risk of difficult internal jugular line insertion and clinicians self selected whether or not to use ultrasound during any particular central line insertion. Both these factors make it more likely that the complication rate would be lower when ultrasound was used. (I’m more likely to use ultrasound when the central line insertion looks like it will be difficult.)

OK, then what does this report tell us? Like the research studies before it, this audit shows that ultrasound is a useful tool that can help increase the success rate and reduce the complication rate of internal jugular central line insertion. Even though clinicians decided when to use or not use ultrasound, the failure rate for central line insertion fell by 90% when clinicians chose to use ultrasound during line placement. Likewise, the overall complication rate fell by 75% when clinicians chose to use ultrasound. There are a couple of limitations to this good news, however. During the first 100 patients, clinicians used ultrasound for less than 20% of line placements. During the last 100 patients, clinicians used ultrasound for between 70% and 80% of line placements. We don’t know when those failures and complications occurred. Perhaps ultrasound was initially being underutilized and the failures and complications occurred mostly during that time. Comparisons would be more meaningful if the rate at which clinicians chose to use ultrasound had been fairly constant. Also, the greatest improvement in success and complication rates were found in the less experienced clinicians. More experienced clinicians did show improvement as they used ultrasound more frequently, but the improvement was neither statistically nor clinically significant. This suggests that clinicians with a lot of central line insertion experience don’t benefit from using ultrasound all the time and know when to use it and when they don’t need it.

Some read reports like this one and say, “Ultrasound should always be used during central line insertion.” (In fact, that is almost what the National Institute for Health and Clinical Excellence guidelines say.) There are really two sides to all of this. On the one hand, when a particular device or clinical practice reduces the overall complication rate of a procedure, patient care is improved. There is merit in making it part of one’s routine. On the other hand, if a device or clinical practice is deemed mandatory for a procedure and I don’t use it when it truly isn’t needed, then I’m wrong even when I did everything right and didn’t have a complication. So, for what it’s worth, here is how I see ultrasound and central lines right now. Ultrasound is a valuable tool for inserting central lines. Some clinicians are really good at IJ central line insertions and using ultrasound routinely won’t make them any better. (Think of the cardiovascular anesthetist who has put in two or three IJs every day for the last 10+ years.) Other clinicians are skilled at IJ central line insertion but don’t place them every day. If my complication rate is very low, it is hard to argue that I should be using ultrasound routinely. I would still be wise to use it when my assessment indicates a potentially difficult central line insertion if my complication rate is average or higher I would be wise to use ultrasound routinely.

Michael Fiedler, PhD, CRNA

The guidelines for use of ultrasound during the insertion of internal jugular central lines referred to in this abstract and comment were published by the National Institute for Health and Clinical Excellence. Their web site is located at: http://www.nice.org.uk/. Their recommendation states, in part, “Two-dimensional (2-D) imaging ultrasound guidance is recommended as the preferred method for insertion of central venous catheters (CVCs) into the internal jugular vein (IJV) in adults and children in elective situations.”
TRANSIENT NEUROLOGICAL SYMPTOMS AFTER ISOBARIC SUBARACHNOID ANESTHESIA WITH 2% LIDOCAINE: THE IMPACT OF NEEDLE TYPE

Evron S, Gurstieva V, Ezri T, Gldkov V, Shopin S, Herman, Sidi A, Weitzman S

Abstract

Purpose The purpose of this study was to compare the incidence of Transient Neurologic Symptoms (TNS) following lidocaine subarachnoid block with two different types of spinal needles.

Background TNS results in pain or dysesthesia in the buttocks and/or legs following subarachnoid block. The precise cause is unknown. Spinal anesthetics performed with lidocaine, surgery performed in lithotomy position, and outpatient surgery are each associated with an increased risk of TNS following a subarachnoid block. The overall incidence of TNS has been reported to be 4% to 37%. Previous studies with Quinke and Whitacre needles have not shown a difference in the incidence of TNS between needles.

Methodology This prospective, single blind study included ASA class I and II patients undergoing genitourinary procedures with subarachnoid block anesthesia. Blocks were performed with 40 mg isobaric 2% lidocaine with 15 µg fentanyl. Patients were randomized to receive their block with either a 26 gauge pencil-point Eldor needle with two lateral openings (TSK Laboratory, Baldoyle Ind, Ease Dublin, Ireland) or a 26 gauge cutting-point Atraucan needle with one opening at the tip of the needle.

All patients were premedicated with 7.5 mg diazepam orally and received 10 mL/kg lactated Ringer’s IV over 20 minutes. The block was performed via a midline approach by one of two anesthesia providers at either the L3-4 or L2-3 interspace. Local anesthesia was injected over 20 seconds with the lateral openings of the Eldor needle aimed cephalad and caudad or the bevel of the Atraucan needle facing cephalad. Immediately thereafter patients were placed in the supine or lithotomy position depending upon the surgical procedure. Patients were interviewed postoperatively by an investigator who was unaware of their group assignment. A neurologic assessment was performed daily in patients with TNS.

The study was terminated early because the investigators perceived a “frequent” incidence of TNS.

Result Data was collected on 99 patients; 47 in the Eldor needle group (two openings) and 52 in the Atraucan group (single opening). The incidence of TNS was 8.5% in the Eldor group and 28.8% in the Atraucan group (P=0.006). Among patients who underwent surgery in the lithotomy position (a risk factor for TNS), the incidence of TNS was 50% in the Eldor group (4 of 8 patients) and 100% in the Atraucan group (12 of 12 patients) (P=0.014). Among patients who underwent surgery in the supine position, the incidence of TNS was 0% in the Eldor group and 100% in the Atraucan group (P=0.014). TNS was resolved in all patients in 48 hours or less.

Conclusion The Eldor spinal needle (two lateral openings) was associated with a lower incidence of TNS than the Atraucan spinal needle (single opening at the tip) when used to perform subarachnoid block with 2% lidocaine with 15 µg fentanyl.
Reports of Transient Neurologic Symptoms (TNS) following spinal anesthesia began showing up in the anesthesia literature about 1995. Early reports all involved lidocaine. TNS was initially blamed on lidocaine, this, despite the fact that lidocaine spinals had been performed for decades without reports of TNS. Subsequently, TNS was reported following bupivacaine(1), tetracaine(2), mepivacaine(3,4), and meperidine(5) subarachnoid blocks. (Yes, Demerol does have local anesthetic properties when injected into the CSF.) In fact, TNS can occur in patients who haven’t even had a spinal anesthetic. In a series of almost 1,000 patients who received general anesthesia for surgery in the lithotomy position, 1.5% developed TNS.(6) Those who were in lithotomy position for over 2 hours were most likely to develop TNS. While lidocaine subarachnoid block does appear to be a risk factor for TNS(7), one certainly can’t blame TNS on lidocaine.

So what changed? Why did we begin noticing TNS following spinal anesthetics when spinals had been used for so many years? One possibility is that signs of TNS were there all along and we only began to notice them as we increased our focus on patient satisfaction. This seems unlikely to me.

Another possibility is that something changed in how subarachnoid blocks were administered. A good argument for this hypothesis is the fact that, even now, some individual anesthetists or anesthesia groups see very little TNS, while others see a troubling incidence. Individual techniques vary, and technique may have an important part in the genesis of TNS.

How did spinal anesthetic techniques change in the early 1990’s? One change was the availability of small gauge spinal needles, some with very small lateral openings. Both these factors increased the resistance to flow through the needle, and, thus, reduced the rate at which local anesthetic could be injected through them. Previously, many of us routinely used a 22 gauge spinal needle for subarachnoid blocks. We changed to the smaller gauge needle in an effort to reduce the likelihood of post dural puncture headaches. Several years earlier, spinal microcatheters had been withdrawn from the market due to their association with Cauda Equina Syndrome. These long, small gauge catheters produced a very high resistance to injection which resulted in a very slow injection rate and pooling of hyperbaric local anesthetic around just a few nerve roots. This extremely concentrated exposure to local anesthetic was neurotoxic and caused Cauda Equina Syndrome. TNS and Cauda Equina Syndrome are distinctly different pathophysiologic entities. Yet, they are similar in that both involve injury to spinal nerves associated with local anesthetic administration. Perhaps very, very slow injection of a hyperbaric local anesthetic through a spinal microcatheter allows enough pooling to cause permanent nerve injury while slow injection through a small gauge spinal needle causes only spinal nerve irritation. If that irritation is exacerbated by other factors, for example the lithotomy position, TNS may result. If not, there are no Transient Neurologic Symptoms. If this hypothesis is at least partly correct then perhaps having two lateral openings on the end of the spinal needle allows for faster injection and wider distribution of local anesthetic, thus reducing the likelihood of spinal nerve irritation and TNS.

If this hypothesis about the clinical cause of TNS is even partially correct then one’s technique may make the difference between patients being at risk for TNS or not, following a subarachnoid block. A multiple side hole spinal needle might then be a beneficial part of that technique. To date, however, I’m only aware of spinal needles with a single opening through which to inject the local anesthetic being available in the USA.

One caution about this study. Be careful not to focus too hard on the spinal needle having two openings rather than one. While this factor is the one the investigators emphasized, and may be the factor that resulted in the difference in their reported incidence of TNS, it was most certainly not the only factor that was different between the two groups. One of those other factors may have been partly or completely responsible for the differences seen in the incidence of TNS.


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