Management Of Acute Postoperative Pain: Experience With 11,937 Patients Managed With Epidural Catheters

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Abstract

INTRODUCTION

The management of postoperative acute pain has become one of the principal missions of the anesthesiologist. The establishment and organization of an Acute Pain Management Service is essential for the delivery of high quality acute pain management, but it is a complicated process. In this article, we will first present a brief history of the formation of the Acute Pain Management Service at the Methodist Hospital and then our experience with epidural analgesia in more than 11,000 cases. We hope that our experience will be of help to those seeking to establish an acute pain management service.

HISTORICAL BACKGROUND

In 1985, we began to use postoperative epidural analgesia in orthopedic surgery patients at the Methodist Hospital. Various research protocols, such as intrathecal and epidural Duramorph, fentanyl, sufentanyl and alfentanyl were used initially. All of these patients were assigned to an orthopedic research intermediate care unit for the duration of their epidural infusion. The nurses in this area were specially trained to assess for analgesia, side effects and complications. When epidural pain management was extended to other surgical services in 1991, patients with epidurals were still required to be admitted to the orthopedic intermediate care. This not only created a problem of availability of intermediate care beds but also problems between the orthopedic service and other surgical services who wanted to use “the orthopedic unit” for their patients.

In order to correct this situation and to provide quality postoperative pain management for all surgical services, the decision to create a hospital-wide acute pain management service was made in August, 1991, and an anesthesiologist Medical Director and a R.N. Clinical Coordinator were appointed to head the service. A multidisciplinary committee was formed to deal with the many details of establishing a pain service. The formation and operation of this committee, which met every two weeks initially and thereafter monthly, was essential for the establishment of an efficient service. Aside from the medical director and clinical coordinator, it included hospital and nursing administration, nursing, and pharmacy personnel. Using a program based upon one developed by Dr. Lex Hubbard and Chris Pasero, R.N. at Schumpert Medical Center, Shreveport, Louisiana, we developed standing orders, a pain management flow sheet, a daily rounding progress note, policies and procedures, and a continuous quality improvement program.

We gather patient data daily and use it for generating statistics, rounding sheets, and billing information. Gathering of outcome and complication data is essential for our quality improvement program.

Pharmacologically, we decided to base our epidural service on a fentanyl/bupivacaine combination. In order to avoid confusion, because of the potential size of the pain service and the number of anesthesiology staff involved, we initially used only one standard infusion (Fentanyl 20 mcg/ml and bupivacaine 0.125%). However, because most of the anesthesiologists were placing their catheters in the lumbar area, and thus the need for higher infusion rates, we decreased the concentration of fentanyl to10 mcg/ml and of bupivacaine to 0.1%. We now offer three standard solutions of fentanyl/bupivacaine, and the pharmacy can make custom solutions on request. Also, after much discussion and teaching, most anesthesiologists are now using a thoracic epidural approach. The quality improvement program serves as our tool to modify our procedures, such as the use of different epidural infusion solutions as more experience is gained.

We initiated the program in the OB and GYN units because their nursing staff were generally more familiar with the concept of epidurals. Initially, nurses were given a two hour inservice by the pain service nurse that included anatomy, physiology, pharmacology, side effects, titration of the infusion and troubleshooting the pump. There is now a self - directed manual and video tape that makes for a more individualized learning experience. Nursing education staff are responsible for seeing that each nurse is trained to manage patients with epidural infusions. Yearly refresher courses are required, in keeping with the Texas State Board of Nurse Examiners Policy.

The importance of knowledgeable and interested nursing staff cannot be underestimated.

We encounter an increased number of problems whenever a high turn-over of nursing staff occurred. Nurses, like physicians, do not receive a great deal of formal education about pain in their training. Often, attitudes and cultural differences can make it difficult for them to believe a patient's complaint of pain or to "buy into" the aggressive management of pain. One way we have attempted to deal with these problems is by publishing a quarterly newsletter written by the pain management nurses for the hospital nursing staff. In our newsletter, we have addressed issues such as:

- pain in the elderly,
- acute pain in the chronic pain patient,
- distinguishing between tolerance, dependence and addiction, and
- the use of anticoagulants in the epidural patient.

When the pain service began, there were comments from several surgeons that the we were "pushing" the service to the patients and being "entrepreneurs". Pain management had always been the surgeons' responsibility in our institution. However, as our techniques were refined and patient satisfaction grew, we have developed a steadily growing group of surgeons who feel that their patients truly benefit from epidural analgesia, and a majority of surgeons now consult us routinely. With time, we began receiving inquiries from physicians about management of their difficult patients with IV PCA. Initially we were reluctant to do this, but demand was such that we have expanded our services to include management of IV PCA patients. This service is rapidly expanding.

When the Pain Service is consulted, our orders include that no other analgesics, sedatives or antiemetics be given without first contacting the pain service. This is done to protect the patient from inadvertent oversedation. This has been a difficult problem and some physicians continue to write for a number of other sedative, analgesics and antiemetics. These orders are then taken off by the unit clerk and sedatives are sometimes administered to the patient. In an effort to improve communication, we designed a sign to be placed at the patient's beside indicating that the Pain Service was following the patient. This has helped, but not yet eliminated the problem.

Most healthcare providers now agree that adequate pain management is an important component to patients' ability to recover rapidly with less morbidity. The Federal government has also become involved in acute pain control. In 1992, the Agency for Healthcare Policy and Research (AHCPR) published its first practice guidelines: Treatment of Acute Postoperative Pain and Trauma. The guideline emphasizes that healthcare providers have an obligation to their patients to provide adequate pain management that includes careful assessment, and reassessment, titration of medication to the desired effect not based upon arbitrary numbers, the use of advanced analgesic technologies, such as IV PCA and epidurals, and a method of measuring quality and satisfaction with pain care. The AHCPR also offers a patient guideline on postoperative pain. It's purpose is to inform patients of the various options and to take a proactive stance in the planning of their pain care. The Joint Commission on Accreditation of Healthcare Organizations states that it is the ethical obligation of the institution to provide adequate pain management. Even with the above information available, however, there are still managed care companies that do not allow patients to have epidural analgesia. In today's competitive market, it is vital that pain management services work to make the advanced analgesic technologies they offer practical and outcome - based. This means collecting and evaluating data on an on-going basis and adapting each program based upon that data.

Figure 1

Patient information brochures

RESULTS

From August 1, 1991 through the Oct.31, 1997 we have collected prospective data on all patients treated with epidural analgesia at the Methodist Hospital. The number of patients seen quadrupled in 1992 and continued to grow. It has since leveled out somewhat. Presently, our service has an average daily census of 25 patients. The following data was collected based upon numerous quality improvement indicators (aspects of care), and includes patients treated up to October 31, 1997.

ASPECTS OF CARE

Treatment and Reduction of Minor Side Effects

- Pruritus
- Nausea
- Urinary Retention
- Numbness
- Weakness
- Dysphoria
- Hypotension

Treatment of Inadequate Analgesia

- Patient Satisfaction
- Patient Satisfaction Survey
- Failure Rate

Treatment and Reduction of Major Side Effects

- Respiratory Depression
- Somnolence
- Prevention of Infection, And other Safety Hazards
- Dural Puncture
- Blood Patch
- Disconnections
- Falls
- Infection
- Hematoma

Initially, incidence data to obtain thresholds was obtained from the literature, but with time and experience we have had to modify our thresholds to fit our practice. The incidence of side effects in our practice reflects that of most published series. By definition, pruritus, nausea, respiratory depression and somnolence were considered side effects only if they were treated medically.

PRURITUS

Pruritus, by far the most common and bothersome side effect, was initially treated with diphenhydramine (Benadryl). This was effective in approximately 70-80% of patients. For those failing to respond to Benadryl, a naloxone infusion was utilized. This usually was quite helpful, but required the patient to receive at least 100 cc/hr of fluid. Recently, we have utilized the new long-acting opiate antagonist, nalmefene (Revex), and found it to be an extremely effective treatment for pruritus. It can be given IV push which is quite helpful in the fluid restricted patient. Although most, if not all, patients will admit to some pruritus, our incidence of symptomatic pruritus needing specific treatment is 15.8% (1884/11937).

NAUSEA

The indicator for nausea was initially recorded any time the patient with an epidural suffered from nausea or vomiting. However, since there are numerous reasons besides epidural therapy why a postoperative patient develops nausea, we changed this indicator to be recorded only if the patient continued to be treated with an antiemetic twenty-four hours postoperatively. Nausea was treated initially with

metclopromide (Reglan) rather than promethazine or droperidol to avoid additional sedation. However, it was often only mildly effective. Ondansetron (Zofran) is our second line antiemetic. Our incidence of nausea is 5.4% (653pts).

URINARY RETENTION

Urinary retention was noted if the patient required catheterization. Since most of our patients requiring epidural analgesia are undergoing major surgical procedures and usually have a urinary catheter for a number of days, our true incidence of urinary retention is unknown.

However, in patients whose foley catheter is removed, the incidence of urinary retention requiring re-catheterization is 0.4%.

NUMBNESS / WEAKNESS

Numbness and weakness were noted upon patient complaint of altered sensation. In mid-1992, we noticed a higher incidence of numbness and weakness in the cesarean section population This resulted in some falls, even with our dilute (0.1 % bupivacaine) solution. We decided to change the concentration of the bupivacaine in this population to 0.0625%. Since implementing this change, this population maintains the same incidence of numbness and weakness that the general population experiences. Our incidence of numbness is 6.3% (748pts), and weakness is 1.4% (167pts).

DYPHORIA

On occasion, we were called to discontinue an epidural catheter because it was felt to be causing dysphoria. These patients were often in the ICU and were experiencing multiple medical problems which could cause their dysphoria. In many cases, the patient became only more agitated and/or confused after the epidural was discontinued because they were not receiving any analgesia. In an effort to understand the scope of this problem, we added an indicator for dysphoria in January, 1994. We initially included all patients who became confused, agitated or disoriented while receiving epidural analgesia, but in many of these patients there was another etiology. In September, 1994, we eliminated patients with a history of dementia, or suspected alcohol or benzodiazapine withdrawal from the data collection. The number dropped to 1 - 2%. Based on this data, we now believe that dysphoria does not necessarily warrant immediately discontinuing the epidural catheter. When dysphoria occurs, we simply turn the pump off for a period of time and give a mild sedative while trying to determine if another cause exists. If the sensorium clears, we will turn the infusion back on at a lower rate or alter the epidural narcotic concentration if needed.

HYPOTENSION

In 1995, we noted complaints from the urology department that their patients were having problems with orthostatic hypotension, such that some were unable to mobilize on a timely basis. We designed an indicator to examine the incidence of hypotension. It was defined as a systolic blood pressure of 80 or less, unresponsive to fluids OR two or more episodes of orthostatic hypotension. To decrease the incidence of hypotension, the bupivacaine concentration was changed to 0.0625%. This change was beneficial, and presently the inidence of hypotension is 1 - 2 %.

PAIN

The incidence of pain was more complex to track. The initial indicator defined pain as " a VAS of 5 or more". It was not unusual for a patient to have isolated episodes of increased pain, but feel that their epidural analgesia was an overall success. This lead to our tracking numerous incidents of "pain" in which the patient was not adversely affected and, therefore, did not necessarily need to be addressed by our quality improvement system. In 1994, we changed the definition of the indicator for pain to "...a VAS of 5 or more on four or more occasions, excluding the first six hours in the PACU, ICU or for an OB patient." The exclusion of the first six hours in PACU or ICU allowed time for adequate titration to occur. The OB patients are given an additional six hours because they all receive oxytocin postoperatively which often makes their postoperative pain similar to that of a laboring patient's breakthrough pain. Once the oxytocin infuson is completed, the patient is much more likely to have typical postoperative pain.

The addition of patient controlled epidural analgesia (PCEA) in 1993 has been very helpful in controlling the amount of pain patients experience.

PATIENT SATISFACTION

The incidence of patient satisfaction also proved difficult to determine. Until 1996, every patient was given a patient satisfaction survey with a self-addressed stamped envelope at the completion of therapy. They were asked to rate the overall effectiveness of the epidural analgesia, the incidence of side effects and if they would desire this form of analgesia again. Approximately 20% of these evaluations were returned. Out of these, there was an overwhelming tone of

patient satisfaction with this form of analgesia. In 1996, our anesthesia group merged with several other groups in the area that also operate pain services. We rewrote our patient satisfaction evaluation into a trifold brochure that is given to all patients in all participating institutions twice a year. We also keep statistics on primary epidural failure (1.9%, 224pts) as a way of looking at patient satisfaction. Our patient satisfaction by survey is consistently high (98.8%).

RESPIRATORY DEPRESSION

Respiratory depression is the most feared side effect of opiates and the primary reason why so many patients are undermedicated for pain. The overall incidence in the initial patient population of 10,000 was 0.02%. Each case was individually reviewed and we observed the following:

Summary Data on Patients with Respiratory Depression

- Average age: 69 yrs
- Oldest: 89 yrs
- Youngest: 35yrs
- 5 Poor pulmonary status
- 2 Poor renal status
- 2 Postoperative bleeding/severe anemia
- 1 Undiagnosed sleep apnea
- 1 Hemoptysis
- 6 Other sedative drugs given

In addition to the usually discussed risk factors such as age and poor respiratory or renal function, anemia also seemed to be a significant contributor to the incidence of respiratory depression in an otherwise healthy 35 year old patient who had undergone colon resection earlier that day. Incorrect and untimely nursing assessments also play a part in the problem of respiratory depression. Patient expectation of analgesia was another factor that we found contributed in some way to the incidence of respiratory depression. Some patients seemed to associate pain relief with being “knocked out” and if they were not significantly sedated, felt they were not being adequately managed. This ends in a “No Win” situation for the patient as well as the pain service. Proper management would include better preoperative preparation by both the surgeon and the anesthesiologist.

We do not routinely use pulse oximetry on our epidural patients outside of the ICU setting. While pulse oximetry provides somewhat of a “safety net”, only a vigilant nurse at the bedside can tell if a patient is becoming inordinately drowsy, which is the first sign of impending respiratory depression. As stated in the American Pain Society’s Principles for Analgesic Use in the Treatment of Acute Pain and Cancer Pain, “No patient has succumbed to respiratory depression while awake.”

Nurses are expected to assess the level of sedation of each patient every hour for the first four, then every four hours thereafter.

To decrease the risk of respiratory depression, we emphasize “aggressive weaning”.

A patient is expected to be comfortable, but not necessarily pain-free. In order to avoid side effects, the basal rate is gradually decreased beginning, in most cases, after the first twelve hours. Supplemental analgesia, such as Percocet or Toradol is offered as weaning is continued. This allows for a smooth transition to another form of analgesia. If a patient cannot tolerate weaning, the basal rate is continued and he/she is re-evaluated every four hours. The use of the PCA dose button is extremely helpful for weaning because the patient takes comfort in knowing analgesia can be supplemented when needed.

SOMNOLENCE

Because of the above mentioned need for the vigilant assessment of sedation, we have standing orders for the nursing staff to administer naloxone to patients if they are somnolent or difficult to arouse, even if the respiratory rate is normal. The incidence of somnolence has remained stable at approximately 0.1% (14pts).

DURAL PUNCTURE

Dural puncture is a known complication of epidural placement, occurring in approximately 1.8% of our patients. Operator experience and technical factors are most important. For example, in mid 1992 and through early 1993, the anesthesiologists evaluated a series of different epidural kits. During this evaluation, the incidence of dural puncture and post- dural puncture headache necessitating a blood patch increased. However, once a kit was selected and the thirty-four physicians became comfortable with it, the incidence again dropped below the threshold. (We offer a “king of the wet tap” award to the one with the highest rate

!)

BLOOD PATCH.

In patients who actually experienced a dural puncture (218), only 53 needed a blood patch (0.4% of all epidural patients).

DISCONNECTION

Disconnection of the epidural catheter from its connector was initially a bothersome problem that increased pain and decreased patient satisfaction and potentially increased the risk of infection. We tried various kits looking for a connector that would not come apart under normal circumstances. Once we found a connector that was dependable, (Braun) we nearly eliminated this problem, and the incidence is only 1%.

INFECTION

There was no incidence of epidural abscess in this patient population. However, we had 7 incidents of local cellulitis (0.06%). These were all treated with a broad-spectrum antibiotic and there were no further sequelae. No specific cause could be determined.

EPIDURAL LOCATION: THORACIC VS. LUMBAR

When using lipophilic narcotics, the location of the catheter is of utmost importance to maintain optimum analgesia and decrease incidence of side effects. Since we use only fentanyl and not morphine, we try to place our catheters in the thoracic area for all indicated procedures. We aim to insert the epidural in the T9-T12 area for lower extremity and pelvic surgery, T7-T10 for upper abdominal surgery, and T4-T8 for thoracic surgery. In order to determine the true effectiveness of this practice, we analyzed the data collected on a patient population from 1989-Oct.,1997. The incidence of pain, numbness and weakness as defined earlier was compared between patients who had lumbar catheters and those who had thoracic placement. This is presented below in Table1.

Figure 2

Table 1: Thoracic vs Lumbar Epidurals - Comparative Morbidity

	Lumbar 4116	Thoracic 6245
Numbness	360 (8.7%)	*243 (3.9%)
Weakness	101 (2.5%)	*50 (0.8%)
Pain	297 (7.2%)	*318 (5.1%)

*p<.001

There was lack of epidural site documentation in 1537pts.

Analysis of this data confirms what we have seen clinically: i.e., patients generally have less pain and fewer problems with numbness and weakness with a thoracic catheter.

EPIDURAL HEMATOMA

There have been two cases of epidural hematoma in this patient population. Both occurred in patients who received aspirin, and low molecular weight heparin concurrently, without our knowledge. A hospital-wide education campaign was begun to alert surgeons, residents, and nurses of the danger of simultaneous administration of heparin and antiplatelet drugs in patients with epidurals. The recent interest in DVT prophylaxis with low molecular weight heparin has hightened concerns, especially since there have been 22 cases of epidural hematoma in conjunction with epidural catheters and low molecular weight heparin in the United States in the last year (personal communication: J. Muntz, M.D., from FDA data).

At The Methodist Hospital, we have instituted the following guidelines, based on Dr. D. Horlocker's work at the Mayo clinic: PERIOPERATIVE ANTICOAGULANTS AND EPIDURAL CATHETERS GUIDELINES

Neurologic dysfunction and epidural hematoma formation after epidural anesthesia is a rare but dreaded complication with a reported incidence of 0.7 per 100,000 procedures.([1]) There are many questions about the use of epidural blockade in patients treated with perioperative anticoagulants, but no clear answers, and very little agreement. The following recommendations can serve as a guideline when faced with the following situations:

1. PRE-OPERATIVE ANTIPLATELET DRUGS

There is evidence that epidural blockade can be safely

performed in patients taking solely antiplatelet drugs(2), but patients should still be followed closely in the postoperative period for signs of cord compression. The bleeding time (BT) is not a very sensitive test and can be misleading.(3) If the patient is taking antiplatelet drugs in addition to s.q. heparin or coumadin, then epidural blockade should be delayed until the PT and PTT are normalized.(4)

2. PERIOPERATIVE USES OF FIBRINOLYTIC DRUGS (STREPTOKINASE, UROKINASE)

These agents lyse previously formed clot, and even though their half-life is short, epidural insertion is absolutely contraindicated within 24 hrs of their use.(5) (6) (7) (8)

3. SYSTEMIC HEPARINIZATION

Intravenous heparinization seems safe as long as insertion of spinal and epidural needles is performed at least 60 min prior to heparinization. Although the safe degree of anticoagulation, as measured by the ACT, is controversial, and has not been well studied, it seems that keeping the ACT between 200 and 250 sec is safe (1.5-2 times baseline).(9) (10) (11)Some authors recommend that the surgery be postponed if the epidural insertion was bloody, or that epidural blockade not be attempted if the platelet count is below 100,000. (9) (10)

4. PERIOPERATIVE ANTICOAGULATION FOR DVT PROPHYLAXIS

This is the area where the greatest controversy exists, and where the least information is available.

A) “Minidose heparin”

Epidural block appears safe when used in conjunction with minidose standard heparin.9 There is an added risk if antiplatelet drugs, dextran 40, or coumadin are given concurrently. It has been shown that the use of postoperative epidural analgesia decreases the incidence of deep venous thrombosis (12); however, many continue using postoperative anticoagulation in addition to the epidural catheter. When postoperative anticoagulation for prevention of DVT is carried out in a patient with an epidural catheter, only one type of anticoagulant should be used. The addition of aspirin, dextran 40, or coumadin increases the risk of epidural hematoma. (2), (4) Subcutaneous standard heparin “mini dose” has a highly variable effect on the coagulation system.(13)

An epidural catheter placement should not be attempted unless a minimum of 6-8 hrs have elapsed since the last dose of s.q. unfractionated heparin, and the minimum is increased to 12-14 hours after the last dose of low molecular weight heparin.

If the epidural catheter is to be inserted prior to this time, monitoring of the PTT is advisable. The prolongation should not be more than 30% greater than normal, but again this has not been well studied and remains controversial.(2), (4)

B) Postoperative coumadin

There is very little information in the literature regarding the postoperative use of coumadin coincident with epidural therapy. It seems that as long as it is the sole anticoagulant used, epidural analgesia can be safely used as long as the PT is no more than 30% greater than normal, or 1.3 times control. (2)

D) Removal of epidural catheters

Removal of an epidural catheter in a patient receiving i.v. or s.q. standard heparin should only occur 4-6 hrs after the end of the infusion, and 12 hrs after the last dose in case of subcutaneous low molecular weight (LMW) heparins. A standard heparin infusion must not be restarted for at least 1 hr. after removal of the epidural catheter (2 hours in case of s.q. LMWH). In case of coumadin, the PT should not be greater than 130% prior to removing the catheter. If using the international normalized ratio (INR), it should be 1.5 or less.

E) Inadvertent removal of epidural catheters

If the catheter is removed at a time other than the “trough” of the anticoagulant (heparin, LMW heparin or coumadin), the patient should have neurologic exams every hour for the next 4-6 hours for the remote possibility of development of epidural hematoma.

F) Low Molecular Weight Heparins

Low molecular weight (LMW) heparins used for DVT prophylaxis and anticoagulation, have mainly an anti-Xa effect. These drugs do not affect the aPTT. When a patient is receiving LMW heparin, a normal aPTT does not mean that the patient is not anticoagulated .(14)

Protamine zinc neutralizes the anti-thrombic effects but only partially neutralizes the anti-factor Xa effect of the low molecular weight heparins. The dose of protamine sulfate

should be equal to the dose of Lovenox (enoxaparin) injected: One milligram of protamine sulfate should be administered via slow intravenous infusion to neutralize one milligram of Lovenox injection. A second infusion of 0.5 milligram protamine sulfate per one milligram of Lovenox may be administered if the activated PTT measured 2-4 hours after the first infusion remains prolonged. In all cases the anti-factor Xa activity is never completly neutralized (maximum about 60%). Particular care should be taken to avoid overdosage with protamine sulfate. Administration of protamine sulfate can cause severe hypotension and serious anaphylactoid and anaphylactic reactions.

When using LMW heparins (Enoxaprin, Lovenox, Dalteparin, Fragmin) in patients treated with epidural analgesia, we recommend that no other anticoagulant or antiplatelet agent be added to the regimen until the epidural catheter has been removed. Please be advised that these are only guidelines and that the topic remains highly controversial. The management of the individual case, is of course, up to each consultant. ([15])

CONCLUSIONS

1. Postoperative acute pain management is an essential ingredient of quality patient care which hospitals and the government are now emphazising. It should be and is becoming a responsibibilty of the anesthsiologist.

2. The provision of acute postoperative pain services is a time and personnel-intensive endeavor which requires coordination between anesthesiologists, nursing, pharmacy, and hospital administration.

3. In order for the service to function well, standardized protocols, education, and quality improvement programs, as well as ongoing data collection must be instituted.

4. A well managed service will expand and will not become a financial drain.

5. Full time clinical coordinator RN's are essential for smooth operation of the service.

6. Patient data must be analyzed often to detect trends and direct positive changes in policy and procedure.

7. Payors should be presented with data to demonstrate the desirability and cost-effectiveness of the service.There is controversy regarding the use of epidurals in the presence of anticoagulants. However, there are excellent guidelines in the literature which address this issue, permiting the safe use of epidural analgesia in many of these cases.

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