Safety in Regional Anesthesia

What does it mean in daily practice?

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Introduction

Including lectures presented by:
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Already published:

No. I Continuous Regional post-operative Analgesia: Breaking up some Taboos
XVII. ESRA Congress, Geneva, September 1998

No. II Plexus Anaesthesia and Today’s Challenges in Surgery and post-operative Pain Management
German Congress of Anaesthesiology, Wiesbaden, May 1999

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No. IX Safety in Regional Anesthesia: What does it mean in daily practise?
XXIV. ESRA Congress, Berlin, September 2005
Patients with multiple medical problems who undergo surgery are at high risk for perioperative morbidity and even mortality. However, the use of regional anesthesia and analgesia can reduce pathophysiology and the incidence of adverse outcomes including mortality and major morbidity.[1-4]

In general, the use of regional anesthesia and analgesia (versus general anesthesia followed by systemic opioids for postoperative pain control), especially utilizing a local anesthetic-based solution, will provide superior analgesia and attenuate adverse pathophysiology, particularly the neuroendocrine stress response. However, not all of the available trials consistently show an improvement in these outcomes with the perioperative use of regional anesthesia. Although there are some data supporting the use of perioperative epidural anesthesia and analgesia in decreasing postoperative pulmonary, gastrointestinal and cardiovascular complications [2-6], whether regional anesthesia is superior to general anesthesia in decreasing mortality is still controversial with recent trials providing both supporting [1] and refuting [2,7] evidence. One of the main reasons that this issue has not been resolved is the presence of significant methodological issues present in every available trial which may influence the interpretation of the trial results.[8]

**Intraoperative Benefits of Regional Anesthesia**

A variety of physiological effects, such as hypercoagulability, immunosuppression, the neuroendocrine stress response, and impaired gastrointestinal and pulmonary function, occur as a result of surgery and may contribute to morbidity and mortality. Many pathophysiologic responses begin intraoperatively and continue into the postoperative period. In a sense, these divisions (intraoperative versus postoperative) are artificial as most of these pathophysiologies follow a continuum from the intraoperative to postoperative period. For instance, the perioperative hypercoagulable state begins in the intraoperative period [9] but the vast majority of thromboembolic events occur well into the postoperative period. Likewise, the incidence of other complications, such as myocardial infarction and delirium, often peak in the postoperative period (e.g., second or third postoperative day).[10-12]

A meta-analysis of randomized data (up to 1997) examining the effect of intraoperative neuraxial versus general anesthesia on mortality included a total of 141 trials with 9,559 subjects and demonstrated that use of perioperative neuraxial anesthesia reduced overall mortality (primarily in orthopedic patients) by approximately 30%.[1] Subgroup analysis also showed that perioperative neuraxial anesthesia and analgesia decreased the odds of development of deep venous thrombosis by 44%, pulmonary embolism by 55%, pneumonia by 39%, respiratory depression by 59% and need for transfusion by 55%. The majority of trials used in the meta-analysis evaluated primarily on comparing intraoperative neuraxial versus general anesthesia followed by only a few examining intraoperative epidural anesthesia followed by postoperative epidural analgesia.[1]

**Postoperative Benefits of Regional Analgesia**

Postoperative epidural analgesia may improve patient outcomes including a decrease in mortality.[2-6,13]. A database analysis of the Medicare claims from 1997 through 2001 noted that the presence of postoperative epidural analgesia was associated with a significant decrease in 7-day (odds ratio = 0.52 [95% confidence interval: 0.38-0.73], p = 0.0001) and 30-day (odds ratio = 0.74 [95% confidence interval: 0.63-0.89], p = 0.0005) mortality after a variety of surgical procedures.[13]

Clinically, the effect of epidurals on the incidence of myocardial ischemia or infarction in randomized trials has been equivocal [14-18], although a meta-analysis revealed that the use of thoracic, but not lumbar, epidural analgesia significantly decreases the incidence of postoperative myocardial infarction.[3]

A large number of randomized indicate that use of perioperative regional anesthesia will decrease the incidence of postoperative hypercoagulable-related events such as deep venous thrombosis, pulmonary embolism and vascular graft thrombosis.[1,19-20] However, it should be noted that many of these trials did not utilize concurrent systemic thromboprophylaxis. The effect of postoperative epidural on the incidence of thromboembolic events is not clear as some data demonstrate a lower incidence of deep venous thrombosis with use of postoperative epidural analgesia.[21-22] This has to be balanced against the risks of epidural hematoma associated with thromboprophylaxis.

Gastrointestinal ileus results in increased postoperative pain, prolonged hospital stays, pulmonary complications, septic complications, and decreased wound healing. The cause of postoperative ileus is multifactorial including postoperative use of opioids, increases in sympathetic output (from the stress response and pain), the systemic inflammatory response, and spinally mediated reflex arcs.[5,26-31]

A systematic review of all randomized trials demonstrated that epidural administration of local anesthetics in patients undergoing abdominal surgery facilitates return of gastrointestinal function compared to systemic or epidural opioids.[28] In addition, thoracic epidural analgesia with local anesthetics may provide earlier fulfillment of discharge criteria [29,30]; however, use of epidural opioids, whether alone or in combination with local anesthetics, will delay return of gastrointestinal motility compared to patients who receive epidural local anesthetics alone.[31-35]
Two meta-analyses demonstrated a decrease in the incidence of atelectasis, respiratory complications, and respiratory depression with perioperative use of regional anesthetic and analgesic techniques.[1,4] Use of epidural anesthesia-analgesia was superior to intercostal blocks, wound infiltration or intrapleural analgesia in decreasing the incidence of pulmonary complications.[4] A recent large randomized controlled trial corroborated findings of these meta-analyses as high-risk patients undergoing abdominal surgery who had perioperative epidural analgesia and analgesia (versus those without perioperative epidural analgesia) had a significantly lower incidence of respiratory failure.[3] Perioperative use of epidural analgesia has also been shown to decrease pulmonary complications, decrease the incidence of dysrhythmias, and facilitate postoperative extubation with a resultant shorter length of intensive care unit stay in thoracic and cardiac bypass surgical patients.[36-38]

The perioperative use of regional anesthesia-analgesia (versus general anesthesia followed by systemic opioids) offers many advantages that may translate into improvements in many patient-oriented outcomes including satisfaction, quality of recovery and quality of life.[39]

When compared to systemic opioids, epidural analgesia provides superior postoperative pain control. A systematic review including nonrandomized trials revealed that intramuscular (IM) analgesia and intravenous patient-controlled analgesia (IV PCA) resulted in a higher incidence of moderate-severe and severe pain versus epidural analgesia (moderate-severe pain: 67.2% for IM, 35.8% for IV PCA, and 20.9% for epidural analgesia; severe pain: 29.1% for IM, 10.4% for IV PCA, and 7.8% for epidural analgesia).[40] These results were similar to a meta-analysis of randomized trials comparing epidural analgesia to systemic opioids which found that epidural analgesia provided better overall postoperative analgesia compared with systemic opioids and on each postoperative day up to 4 days after surgery.[41] When analyzed by types of surgery and pain assessments, all forms of epidural analgesia provided significantly better postoperative analgesia compared with systemic opioids, with the exception of thoracic epidural analgesia versus opioids for rest pain after thoracic surgery. Thus it appears that epidural analgesia, regardless of analgesic agent, location of catheter placement, and type and time of pain assessment, provides superior postoperative analgesia compared with systemic opioids.

The superior analgesia conferred by epidural (and presumably peripheral) analgesia may result in an improvement in patient-oriented outcomes. A systematic review examining the issue of patient satisfaction indicated that use of both neuraxial and peripheral regional anesthetic techniques will result in higher patient satisfaction compared to systemic opioids.[39] Despite the fact that patient satisfaction and quality of life are complex and difficult to measure properly, it appears that perioperative regional analgesia, in part to the superior analgesia provided, improves patient-oriented outcomes such as patient satisfaction[39] and health-related quality of life.[40-41]

The incorporation of perioperative regional analgesia into a multimodal approach to patient convalescence appears to maximize the analgesic and physiologic benefits of the regional technique. By attenuation of the neuroendocrine stress response, providing effective pain control, mobilizing patients earlier, and facilitating return of gastrointestinal function to allow early enteral feeding, perioperative regional anesthetic and analgesic techniques are an important and integral part of a multimodal approach to patient convalescence.[42]


Introduction

Peripheral nerve blockade is now practiced widely for both surgery and postoperative analgesia and offers several advantages compared to opioid-based analgesic techniques – superior quality analgesia, reduced nursing workload, fast-tracking bypass of the postoperative recovery unit, less postoperative nausea and vomiting and cost – effective benefits for both in-patient and ambulatory care surgery [1,2,3]. In combination, these benefits reduce lengths of stay, promote earlier discharge times and improve the cost-effectiveness of healthcare [4]. Peripheral nerve blocks have also been shown to reduce blood loss and improve outcome from major joint surgery [5,6].

Peripheral nerve blocks have a low risk of serious morbidity, in particular, permanent nerve damage. Auroy recorded an incidence of 0.019% for nerve damage in a large prospective survey [7]. The published data for paediatric injury is even lower [8] Smaller studies of nerve injury following peripheral nerve block reveal a range of up to 5% depending on the type of peripheral block studied although there is usually no distinction between temporary and permanent symptoms.

However, the sustained increase in the use of peripheral nerve blocks has been associated with an increase in the reported complications of peripheral nerve blocks [9,10]. There is a debate about whether this rise is just a reflection of the increased use of these techniques or due to a general increase in reporting rates and a decreased threshold for resorting to medico-legal action. There remains a lack of objective data of both the numerator (the number of complications) and denominator (the total number of blocks performed). If peripheral nerve blocks are to retain their current popularity, it is important to ensure that peripheral nerve blockade is practiced to the highest standards of safety and best practice. There are a number of complications and risk factors associated with peripheral nerve blockade including:

- Failure of technique
  - primary (multiple attempts)
  - secondary (apparent successful location of nerve but no clinical effect)

- Poor patient management
  - Failure to manage side effects may convert them to complications

- Direct nerve trauma
  - needle damage to major peripheral nerve or plexus
  - intraneural injection

- Infection
  - perineural
  - Risk of central spread (paravertebral/psoas compartment)

- Haematoma
  - Psoas sheath
  - Brachial plexus

- Drug toxicity
  - Drug error
  - Systemic overdose
  - Intravascular injection

- Miscellaneous
  - Thermal, mechanical or ischaemic damage to insensate limb/joint

There are three elements to developing safe practice for peripheral nerve blockade.

1. The Patient

Patients expect to be involved more closely in their medical care than in previous years and this particularly applies to their anaesthesia and analgesia. Detailed but easy to understand patient information leaflets about regional anaesthesia, including the risks, are now available [11] to ensure that the patient has sufficient information to enable balanced preoperative discussions which result in properly informed consent. Informed consent is an essential prerequisite to safe practice; the amount of detail of risk and benefit that patients expect will vary between individuals but each must have the opportunity, time and relevant information to be able to make a rational decision. Similarly, different peripheral blocks will have an individual profile of essential and optional information to impart to each individual patient who is considered for that block.
The issue of whether to perform the peripheral nerve block before or after induction of general anaesthesia is complex and generates strong views amongst both its critics and supporters [12]. With peripheral nerve blocks, there is insufficient data to draw any objective conclusions about the safety of the “asleep or awake” argument but this topic should be part of any preoperative discussions with the patient so that their views can be taken into account during the planning process for the intended procedure.

2. Performing and documenting the block

The doctor performing the block must possess the requisite theoretical and practical knowledge and competence if safety and effectiveness are to be maintained.

- Sound anatomical knowledge
- Proper supervised training
- Regular practice
- Careful, subtle technique
- Familiarity with equipment and needles
- High index of suspicion with difficulties and a readiness to avoid repeated attempts
- Careful patient selection and assessment of preexisting neurological, endocrine or microvascular co-morbidity

Recommendations for safe peripheral block techniques include:-

- Use a peripheral nerve stimulator for all motor or mixed nerve blocks but remain vigilant
- Avoid paraesthesia and pain when inserting the needle; remove the needle if they occur!
- Heavy sedation/light GA will prevent patient feedback – be aware
- Avoid stimulus threshold of < 0.3mA
- Do not inject against resistance (ensure needle is patent and understand what low resistance injection feels like)
- Slow incremental injection with regular aspiration
- Respect maximum recommended doses

3. Risk Management Issues

Safe practice requires a formal, systematic approach to managing clinical risk; the care and management of the patient for the entire duration of the block must also be planned to ensure safety. A properly organized, integrated care pathway should ensure that patients will be safely managed in hospital, in a step down unit or at home for the duration of the block (up to 48 – 72 hours, if a catheter infusion is used). (Fig. 1) All staff involved in caring for this group of patients should be aware of the importance of:-

- Management of the insensate limb [13]
- Provision of adequate sequential analgesia as the block wears off.
- Risk awareness of potential complications of the block (nerve damage)
- Risk awareness of potential surgical complications (ischaemia, compartment syndrome, infection)

Permanent serious morbidity is extremely rare and it is difficult to make general assumptions about the factors involved and how they can be reduced even further. One of the features of nerve damage from regional anaesthesia is that it is usually impossible to determine the mechanism of damage in the majority of cases.

- Ensure that there is system for involving an experienced anaesthetist in the review of any potential nerve injuries.
- Take a careful history especially looking for any pre-existing neurological problems
- Obtain an early, formal neurological examination by a neurologist who understands the practice of regional anaesthesia
- Exclude other causes (Surgical injury, Ischaemia, Compression)
- Define the character of the deficit
- Define the anatomical basis of the damage
- Electrophysiological testing and Imaging

Ensure that colleagues know what you are looking for

- Be patient, the great majority resolve in time.
- Treatment options are limited
References

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The concept of continuous spinal anaesthesia (CSA) was first described by the British surgeon Dean in 1907 (1) who left the spinal needle in place during an operation. In 1939, Lemmon (2) introduced the malleable needle and the split mattress technique to overcome the problems of needle trauma and breakage. Tuo-hy (3) introduced the catheter technique – he used a no.4 ureteral catheter inserted through a 15 gauge needle. Throughout the following years, the fear of CSA resulting in high incidence rates of postdural puncture headache (PDPH) and neurological complications, along with the development of the epidural technique, discouraged the frequent use of CSA. Since the incidence of PDPH depending on cerebrospinal fluid loss is due to needle size and tip configuration (4), Hurley and Lambert introduced micro catheter systems in an effort to reduce frequency of PDPH associated with spinal anaesthesia (5). Thus, CSA technique became suitable also for the use in younger patients without incurring an unacceptable risk of PDPH.

However, serious neurological complications such as cauda equina syndrome after CSA performed with microcatheters using 5 % hyperbaric lidocaine were described by Rigler et al. in 1991 (6); additional cases after CSA administered through microcatheters resulted in a safety alert of the Food and Drug Administration in 1992. Spinal micro catheters thinner than 24 gauge intended for the use in CSA were banned from the US-market. Furthermore, manufacturers of local anaesthetics declared that their products were not indicated for the use with CSA. In all, approximately 12 cases of cauda equina syndrome after CSA with microcatheters have been reported (7).

This reinforced the misconception that CSA was a dangerous technique. However, with experiences gained from more than 3000 patients in the course of the recent five years, CSA appears in a totally different light to me – namely as an effective and safe technique when performed correctly using the Spinocath over the needle system (Fig. 1).

Therefore, I give a brief update on the present status and possible future directions for CSA.

CSA offers the attractive possibility of extending the block during surgery when needed. It provides an easy technique to reach an adequate level and duration of anaesthesia with small intermittent doses of local anaesthetic, which also minimizes the risk of possible cardiovascular and respiratory disturbances.

Several studies have shown that haemodynamic stability is greater with CSA than with continuous epidural anaesthesia (CEA). For example, Sutter et al. (8) retrospectively compared more than 700 patients who underwent lower limb orthopaedic surgery either with CSA or with CEA. Although the patients in the CSA group were at a higher anaesthetic risk, the incidence of failures was lower and fewer patients showed a decrease in the mean arterial pressure. CSA thus was more reliable and provided better cardiovascular stability for elderly and high-risk patients.

Such results can be attributed to the fact that CSA allows administration of small incremental doses of local anaesthetics at different concentrations and baricity according to the need of the individual patient, whatever surgical procedure and position are required. The better cardiovascular stability observed in CSA patients seems to be a result of the more easily controlled sympathetic blockade (9). Other advantages of CSA compared with CEA are a more complete muscular blockade and smaller dosage of local anaesthetic to obtain adequate anaesthesia, without any risks of systemic toxic effects due to absorption. The large dose of local anaesthetics administered with epidural anaesthesia means that elderly patients are at greater risk of intoxication because of their reduced clearance for local anaesthetics and their reduced cardiac output and liver blood flow (10). Since the elderly population is increasing, and since these patients often have concomitant medical problems and reduced physiologic adaptation capacities, CSA might be the anaesthetic technique of choice for such patients, especially when haemodynamic stability is critical (11, 12, 13, 14).

By contrast to the question of intraoperative anaesthesia with CSA, there are only few studies published on the use of spinal catheters for postoperative analgesia (15, 16, 17). There is general agreement about the major goals of postoperative pain treatment such as minimizing the patient’s discomfort, facilitating the recovery process and avoiding side effects. Nevertheless, unrelieved postoperative pain is still reported to be a rather common clinical problem (18, 19). There is increasing evidence in the literature that especially for major orthopaedic surgery techniques using regional anaesthesia provide a pronounced inhibitory effect.
on the stress response and have beneficial effects on outcome variables (20). Finally, the fact that morbidity and hospital stay decrease with the use of such techniques implies economic aspects that should not be underrated nowadays (21, 22).

Postoperative pain relief using CSA was first described by Ansbro et al. (23). Concerning the question whether to prefer CSA or CEA for postoperative pain control, Niemi et al. (24) randomized 55 patients who underwent hip arthroplasty under spinal anaesthesia to receive postoperative analgesia either using an intrathecal or an epidural catheter. Spinal catheter failures were found to present a significant disadvantage of CSA. However, Standl et al. (25) presented 100 patients undergoing lower limb orthopaedic surgery who received CSA using a 28 gauge catheter inserted through a 22 gauge needle and 0.25% bupivacaine titrated as bolus injections in the postoperative period. Their data suggest that CSA provides good postoperative analgesia, associated with a low incidence of complications and a high acceptance of CSA reported from the patients.

In our research group, we found in two randomized, prospective studies with more than 200 patients that both techniques result in adequate postoperative pain relief (26, 27). In all groups, the level of pain was gauged from verbal rating score and from a visual analogue scale. In the CSA-group 90.2% reported complete analgesia on the verbal rating score, but only 21.6% of the CEA-group did so. (Fig. 2)

Throughout the study period of 72 postoperative hours, the visual analogue scores given by the CSA-group were significantly lower than those of the CEA-group. (Fig. 3)

It can be concluded that CSA and CEA proved to be effective and safe, but CSA provided faster onset of pain relief, ensured better analgesia and produced more satisfied patients. As the incidence of side effects such as motor blockade, nausea and vomiting was comparable in both groups, CSA should be regarded as an attractive technique for a flexible postoperative pain therapy.

Asking about their main point of fear, most critics of CSA mention two complications: neurological damage and cerebrospinal fluid infection.

Unfortunately, only few prospective studies have formally investigated the real incidence of neurological complications (28). That is why we tried in our research group to evaluate the frequency of permanent neurologic sequelae after CSA in a standardized pre- and postoperative investigation (29). A preoperative neurological status was gained from 150 patients who underwent hip arthroplasty with CSA technique, and the same neurological status was gained by the same anaesthetist ten days after surgery. At the occasion of this examination, no patient had noticed any remarkable difference on his own; nevertheless, in four patients who suffered from Diabetes mellitus II a decrease of the quadriceps-femoris reflex was found. No differences in physical power were found and no cauda equina syndrome arose. All patients reported complete satisfaction with anaesthesia and postoperative shape and no serious complications were found – thus CSA should no longer be just condemned as a „risky technique”, but more prospective clinical studies on this question are mandatory in the future.

In order to research on the risk of infection when performing CSA in the postoperative period, in 144 patients, who successfully underwent CSA for surgery, CSF was sampled both immediately after positioning and before removing the catheter (30). Leukocytes, proteins and glucose concentration were determined, meningeal and infection parameters were compared preoperatively and by removal. The catheter was removed under aseptic conditions, the tip was cut and washed with saline. CSF, tip and saline were cultured to find microbiological contamination. In five cases bacteria were found in CSF, the catheter tip was contaminated in eight cases and saline in one case. Statistically significant positive correlation with the indwelling catheter time was found. Signs of local infection at the insertion side appeared in three cases with CSA lasting longer than 90 hours. However, no patient showed evidence of local or systemic infection with CSA for up to 200 hours. Taking into consideration that a meticulous technique of insertion and handling the catheter is mandatory, as well as a daily inspection of the insertion site, we conclude from our results that fear of infection should no longer lead to restrictions in the use of CSA in the postoperative period, even when performed for 200 hours.

In conclusion, CSA is an established anaesthetic technique that has advantages over CEA especially in elderly or high-risk patients. Correctly used, CSA is an effective and safe technique – not only for intraoperative anaesthesia but also for an up-to-date postoperative pain treatment. Former doubts about its safety can be regarded as eliminated by clinical studies published over the last years that should encourage the more frequent use of this technique in the future.
References


