A new approach using high volume blood patch for prevention of post-dural puncture headache following intrathecal catheter pump exchange

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ABSTRACT

Background: In an observational study, complications of intrathecal catheter pumps necessitating surgical exchange were analyzed. Also the use of a high-volume prophylactic epidural blood patch (EBP) during surgery for preventing post-dural puncture headache (PDPH) with a follow-up for 1 year is described.

Materials and Methods: In 22 patients with refractory chronic pain of cancer/noncancer origin or severe spasticity, who were receiving intrathecal morphine including adjuvants or baclofen for symptom relief, catheter exchange with or without pump was performed. In patients with documented symptoms of PDPH following initial intrathecal catheter implantation, a prophylactic EBP with a high blood volume was used for PDPH prevention during surgery. Catheters were replaced using 40 mL EBP before entering dural space at a speed of 5mL/min into the epidural space. Patients were asked to quantify pain experience and functional ability.

Results: From a sample of 72 patients admitted for catheter exchange with or without pump, 22 patients (33%) (12 male, 10 female) had a history of PDPH following initial implantation. Diagnostic and therapeutic measures occurring with malfunction of intrathecal catheter pump systems were described. Twenty-one patients were successfully treated with prophylactic EBP, while one patient could not be properly evaluated because of intracranial bleeding as the underlying disease.

Conclusions: A new approach using a high-volume prophylactic EBP for preventing PDPH following catheter exchange is presented. The efficacy and safety of this technique for 1 year follow-up have been evaluated and was found to be safe and potentially effective.

Key Words: Epidural blood patch, intrathecal pump, intrathecal catheter, post-dural puncture headache

INTRODUCTION

In 1995, we started to implant battery-powered, programmable, and gas driven constant infusion rate pumps for long-term delivery of drugs to the intrathecal space in patients with refractory chronic pain and severe spasticity in various neurological conditions. During the first 3 years of pump implantation, we observed the common symptoms of post-dural puncture headache (PDPH). Especially patients with spinal catheter were at highest risk for developing PDPH; in two cases with difficult anatomic conditions due to severe ossifications and obesity neurosurgical repair of dural tear was required.[1] In a recently published study over a 20-year time period, 23% of the cases developed PDPH symptoms after surgical implantation of an intrathecal catheter.[2] During pump implantation, the space of CSF is accessed with a 14-gauge Tuohy needle followed by the placement of a smaller diameter catheter. When the needle is removed, a CSF leak is likely to occur; and a persistent CSF leak can lead to PDPH.[3] In case of catheter exchange, the dura mater is penetrated at two sites,
the old one after catheter removal and the second one caused by inserting a new catheter for exchange. The clinical hallmark of PDPH is the presence of orthostatic headache which may be associated with neck pain, nausea, vomiting, diplopia, blurred vision, and distorted hearing.\cite{1}

The success rate of therapeutic epidural blood patch (EBP) is variable and depends on the size of the dural hole, timing of the EBP, and possibly the volume of blood used.\cite{4} Taking into account the variable therapeutic efficacy of EBP in the treatment of PDPH as well as the high incidence and severity of PDPH, it is reasonable to investigate the applicability of prophylactic EBP\cite{5} to prevent headache after dural puncture during pump catheter exchange. Since PDPH can be severe enough for suffering and can increase the cost of healthcare by lengthening hospital stay, it might be more justified to take a proactive approach by administering preventative measures rather than waiting to begin treatment once the symptoms appear provided that the prophylactic procedure itself is not associated with significant risks.\cite{6} Unfortunately, the overall quality of the literature related to PDPH is poor.\cite{7} Most experienced clinicians have observed that there is a large and unpredictable variation in the volume of injected blood that elicits symptoms; thus, the risk of a large volume injectate, which is essentially creating a temporary epidural hematoma, must be balanced with the risk of inadequate volume possibly failing to patch the leak.\cite{4,8} Keeping in mind the absence of controlled studies to guide the clinical practice of this approach and based on the refractory nature of PDPH to conservative treatment as well as the possibility of infection by postoperatively repeated EBP, a high-volume prophylactic EBP during the exchange of the intrathecal catheter for prevention of PDPH seems reasonable to optimize the spread of the blood in the epidural space at the same puncture spot.

In a retrospective observational study, we used a high-volume prophylactic EBP during exchange of intrathecal catheters for preventing PDPH in patients with a history of PDPH according to medical records and observed its efficacy and safety in a 1 year follow-up. In addition, complications of intrathecal catheter pumps necessitating surgical exchange were analyzed.

**MATERIALS AND METHODS**

After obtaining approval from our institutional review board, patients with severe chronic pain or spasticity, who had an intrathecal pump in place and experienced inadequate symptom relief between January 1998 and August 2010 were identified and included in the retrospective analysis. Twenty-two patients who had already suffered from symptoms of PDPH following catheter pump implantation were considered for a prophylactic EBP with a high blood volume during exchange. Prior to admission to surgery, the battery-powered or gas driven pump with its catheter was checked separately for proper function in each patient. Replacement due to battery exhaustion was not considered to be a pump failure. A catheter pump check algorithm was followed sequentially. A normal functioning pump was assumed in the battery-powered pump with normal movement of the rotor by bolus injection during fluoroscopy and in the gas pump with pressure measured in the mean chamber above 2,000 mbar. Beside the pump reservoir port, the side port for bypassing the pump with a self-sealing septum for percutaneous access to the catheter was used for aspiration and injection, and for evaluating its function with and without imaging. The patient under intubation anesthesia was placed in a lateral decubitus position, after which the back was flexed, prepped, and draped, in sterile fashion. Antibiotic prophylaxis was given 30 min prior to incision. Using electrocautery, meticulous attention to hemostasis was necessary during surgery. A posterior midline incision approximately 6 cm long was made from the skin to the supraspinous fascia at the level of L2–3 or L3–4. The defective catheter was first carefully removed, while a new one was prepared for placement. The 14-gauge Tuohy needle supplied by the manufacturer in the implant kit was advanced through the incision into the epidural space, using “loss of resistance” technique while a 10 mL syringe filled with normal saline was attached. Once the needle tip was in adequate position with its slightly curved tip directed superiorly, autologous venous blood was drawn by a second operator from the antecubital vein into a 10 mL plastic syringe attached to an extension tube under sterile technique. A total of 40 mL blood was injected slowly through the Tuohy needle at a speed of 5 mL/min into the epidural space to spread both cephalad and caudal. Then, the needle was advanced through the dura into the CSF fluid space and the catheter was introduced 15 cm intrathecally to the T11-level with the tip oriented cephalad while clear CSF was flowing [Figure 1]. At this point, it is preferable to check fluoroscopically the correct catheter movement into cranial direction without any looping on itself. The insight guide wire catheter with its small metallic bead at the tip could make fluoroscopic tracking relatively easy. After removing the needle and subsequently the guide wire, the spinal catheter was anchored to the lumbar fascia using a silastic anchor provided by the manufacturer. The anchor was placed around the catheter and sutured. The spinal catheter was checked for free flowing CSF by aspiration with a 2 mL plastic syringe. Once the tunnel needle was firmly attached, the spinal catheter was pulled by the tunnel subcutaneously from the lumbar side to the patient’s flank site using a facilitating flank incision. Then, the spinal catheter was clamped with a rubber
shod mosquito at the flank incision to prevent excessive CSF loss. After careful review of the manufacturer’s procedural guidelines for pump exchange, a lunar incision around the pump pocket was made along the course of the proposed position in the right or left lower quadrant of the abdomen at the umbilical level. The malfunctioning pump was explanted and replaced with a new one implanted under the subcutaneous tissue of the abdomen or at the rectus fascia for secure attachment. The pump was placed into the pocket reservoir side up. The pump-sided catheter was measured, trimmed if needed, and connected to the pump. The connection was manually tested for leak using a saline injection in the catheter access port while occluding the catheter distally. Gentle subcutaneous guidance of the pump catheter tip attached firmly to the tunnel needle ensured safe tunneling to the flank incision. Prior to connecting both spinal and pump catheters at the flank incision, it is important to verify the free flow of CSF from the spinal catheter. Both catheter parts were attached using a metal pin connector secured with silk sutures. Before implantation, the pump was filled for 14 postoperative days and the catheter was filled with predetermined drug solution by a bridge bolus to clear the dead space and deliver the prescribed medication dose. The follow-up visits for 1 year were carried out on postoperative day 1 by the attending physician, then by telephone interview on day 2, later at weekly intervals during the 1st month, and finally at refilling requirements after surgery. Pumps were refilled only by trained staff of our pain clinic, using sterile refill kits offered by the pump manufacturer. The patients were asked to quantify their pain experience on a visual analog scale (VAS). Likewise, pain was assessed on a 0–3 verbal categorical rating scale (VRS) (0 = none, 1 = mild, 2 = moderate, and 3 = severe). Oswestry Activity Scale[9,10] which is a well-validated international outcome measure in the management of spinal disorders or Modified Ashworth Scale[11] for examining the efficacy of baclofen by grading muscle spasticity and clinical interview were obtained by neurology staff specialists experienced in pain and spasticity management. Patient satisfaction with the effectiveness of pain relief was recorded by using a 4-point scale which shows the verbal expressed satisfaction of assigned numerical values: 1 = worse, 2 = moderate, 3 = good, 4 = very good. Results were predominantly descriptive and expressed as means and standard deviations or medians plus minimum and maximum.

**RESULTS**

PDPH is a common complication following implantation of intrathecal catheters with or without pump for drug delivery. From a sample of 72 patients admitted for catheter exchange with or without pump, 22 patients (33%) (12 male, 10 female) had a history of PDPH following initial implantation. The symptoms of PDPH in these patients had been mostly self-limited and had resolved with conservative medical management. The mean age of the patients in the study group was 51.5 ± 9.5 years ranging from 34 to 72 years. The mean pump refill interval before surgical intervention for exchange was 35.5 days (range: 14–45 days). The duration of intrathecal drug therapy before catheter-pump exchange was 6.25 ± 0.55 years. Twenty-two catheters were exchanged and eight pumps were replaced, six of them by gas driven pumps and two by battery-powered programmable pumps with a reservoir volume of 18 mL for baclofen infusion in muscle spasticity. Baseline patient characteristics, along with the medical indication for device replacement are listed in Table 1.

**Complications of intrathecal catheter pumps necessitating surgical exchange**

Substantial complications prior or during surgery for each patient, that is relevant to discuss, were recorded. Based on a distinct increase of predominantly excitatory symptoms (hyperexcitability or increased muscle spasticity) due to reduced drug infusion suggesting pump malfunctioning and/or catheter defect, the preoperative check program was started. In six patients, the battery-powered pump had neared the manufacturer’s recommended exchange interval; thus the device was electively scheduled for replacement which was necessary after 5.7 ± 0.3 years. In two cases, the pumps were defective. One pump was battery-powered, while the other was gas driven. In both cases, withdrawal symptoms appeared within 1–3 days after interruption of intrathecal therapy. One patient treated with baclofen using a battery-powered pump for muscle spasticity on upper and predominantly lower extremities presented with more stiffness which completely disappeared after two boluses of 25 µg (maximum 50 µg) into the side port. The other patient treated with morphine showed withdrawal symptoms, such as stomach cramps,
diarrhea, rhinorrhea, sweating, elevated heart rate and increased blood pressure, irritability, hyperalgesia, and insomnia. The symptoms also disappeared completely after the injection of 1–2 mg morphine diluted in 5 mL normal saline within 15 min into the side port. The malfunctioning pumps were also explanted and replaced. Catheter complications were the most common cause of malfunctioning in our patients. While the catheters were checked with fluoroscopy, we found slight leaking at different sites in the catheter system [Figure 2a and b]. During surgical exploration at the site of spinal entry, we observed catheter obstruction and fracture caused by fibrous sheath [Figure 3a and b]. The catheter was fractured close to the site of spinal entry [Figure 3b]. Catheter obstruction was confirmed in four cases by lack of CSF aspiration with the needle inserted into the side port bypassing the pump. Normal saline was also unable to enter the port. In seven cases, leakage of CSF with perforating tear was found in close proximity to the vertebral spinous process and spine catheter entry site.

EBP
Information concerning technical difficulties encountered when performing peridural puncture could be ascertained in only three out of 22 patients. They were managed by fluoroscopy. All patients received 40 mL EBP before entering the dural space. For exchange, battery-powered pumps were preferably replaced by gas driven pumps, so that the mean pump refill interval changed to 42 days (range, 32–50 days). The postoperatively administered intrathecal infusion rate was kept similar to that dosage being administered preoperatively for intrathecal management of intractable pain or severe muscle spasms. Additional boluses of either morphine 0.1–0.5 mg or baclofen 25–50 µg diluted in 5 mL normal saline were given on the day of surgery as required. Most patients were discharged from the hospital on the day of surgery. After surgical intervention, 21 patients were successfully treated with a prophylactic EBP and had a satisfactory outcome, while one patient remained in coma and could not be properly evaluated because of intracranial bleeding as the underlying disease. Seventeen patients reported substantial symptom relief and four other patients reported moderate symptom relief. Results from the Oswestry Disability Index revealed that 19 patients were able to walk longer distances and sit for longer periods of time. In both patients with muscle spasticity, the Modified Ashworth Scale showed a decrease in muscle tone predominantly in the lower extremities. Catheter defect, pump failure, or discrepancies of pump volume at the time of refill as well as adverse events were not reported.

DISCUSSION

Patients with back pain using morphine with/without clonidine and bupivacaine were strongly represented in our study.[12,13] Intrathecal baclofen was used for the treatment of patients with severe muscle spasticity associated with intracranial bleeding or intramedullary ependymoma as underlying neurological diseases who were unresponsive to conservative pharmacotherapy or developed intolerable side effects at therapeutic doses of oral baclofen.[14,15]

Most clinicians implant battery-powered, programmable pumps when frequent dosage changes are likely to occur. At our facility we used to implant gas driven constant infusion rate pumps because of economic aspects and variable volume capacity (35–50 mL). Exchange of intrathecal catheters was required in 22 patients; in eight of them also the pump was replaced. The explantation technique was described in detail; the presented malfunctions were found by checking the pump and the catheter preoperatively and under surgery. The most important outcome measures were symptom reduction and improvement in level of activity. We therefore intended to keep the preoperative intrathecal infusion rate during surgery, while utilizing a drug bolus for the early postoperative symptom control. The expertise of a skilled physician with good understanding of diagnostic and therapeutic challenges faced with a possible device malfunction was essential to minimize the risks during surgical exchange.[12,16,17]

The patients who had already suffered from PDPH after initial implantation were found to be completely free of headache in both sitting and standing position with no apparent complications from the surgical procedure using a prophylactic EBP. They reported no symptoms of headache during the follow-up period. The PDPH has been the most common significant morbidity of dural puncture and an important source of litigation against anesthesiologists.[18] PDPH with its high incidence also in our study is not only

| Table 1: Characteristics of patients (n = 22) with underlying disease, concomitant intrathecal drug with or without adjuvants (plus: Either clonidine or bupivacaine) |
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| Patients (n) | Underlying disease | Drugs | Type of pump | Exchange |
| 2 | Intracranial bleeding, intramedullary ependymoma | Baclofen | Battery-powered | 2 catheters, 2 pumps |
| 3 | Malignant disease | Morphine | Replaced by gas driven | 3 catheters, 2 pumps |
| 9 | Post-discectomy syndrome | Morphine | Replaced by gas driven | 9 catheters, 2 pumps |
| 5 | Failed back surgery syndrome | Morphine | Replaced by gas driven | 5 catheters, 1 pump |
| 2 | Spondylodesis surgically treated | Morphine plus | Gas driven | 2 catheters, 1 pump |
| 1 | Chronic coccydynia after resection | Morphine plus | Gas driven | 1 catheter |
a disabling condition but, if left untreated, can also lead to complications such as cranial nerve palsies, subdural hematoma, and cortical venous thrombosis. The mechanism of relieving PDPH by a blood patch is thought to be related to a dual mode of action, namely compression of the thecal space as well as clotting and occluding the dural perforation by preventing further CSF leak.\[20\] The success rate for an EBP is variable and depends on the size of the dural hole, timing of the EBP, and possibly the volume of blood used.\[21,22\] Studies regarding prophylactic EBP are limited by small patient numbers.\[23\] A survey of anesthesiologists in the USA regarding PDPH, unintentional dural puncture, and related issues showed that 10–31% applied an EBP as a prophylactic measure.\[24\] Without controlled studies to guide clinical practice, we postulate that a high blood volume patch during catheter exchange is a reasonable procedure that will optimize the spread of blood in the epidural space and prevent PDPH.

However, in the present study, the small number of reported cases who received this uncommon preventive measure for PDPH after catheter exchange leaves questions still open for the optimal management approach. Without prophylactic EBP the mainstay of specific therapy for PDPH is a therapeutic EBP,\[25\] which may be repeated postoperatively in case PDPH should occur after surgical catheter exchange. This approach may be associated with the risk of infection. However, the safety and effectiveness of prophylactic EBP in combination with pump exchange have not been investigated so far. Complete symptomatic relief without side effects postoperatively during the follow-up period, even among a limited number of cases may suggest that treatment of the causative pathology and application of a prophylactic EBP during surgery may be adequate for preventing PDPH. Our preventive approach during catheter exchange is certainly less invasive than the neurosurgical exposure with repair of the dural defect. Successful treatment outcomes may give the patient the opportunity to return to activities of daily living, thus improving quality of life.

**Limitations**

The study has some limitations due to its design with a limited number of patients and the lack of a control group for PDPH outcome. Nevertheless, the results are valuable because complications are most commonly evaluated in observational or small sample studies.

**CONCLUSIONS**

PDPH is a common complication following implantation of spinal catheter with or without pump for drug delivery. A new approach using a high-volume prophylactic EBP for preventing PDPH following spinal catheter exchange with or without pump is presented. The efficacy and safety of this technique for 1 year follow-up have been evaluated and was found to be safe and potentially effective. However, prospective controlled clinical trials are needed.

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