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Elastomeric pumps for ambulatory patient controlled regional analgesia.

Purpose: To report our experience with the use of the (Eclipse®) elastomeric pump for ambulatory Patient Controlled Regional Analgesia (PCRA)

Method: After a pilot study using this device in patients admitted to the hospital, seven patients received PCRA at home using the elastomeric pump. Patients with a variety of continuous regional anesthetic blocks were sent home with written and verbal instructions regarding the use of this device, boluses, side effects of local anesthetics and removal of block catheters. Patients were contacted daily to collect data with regards to the efficacy of the block, problems associated with the use of this device and their satisfaction with the method of analgesia.

Results: During the pilot study there were two catheter disconnections requiring rescue analgesics. Two patients had the entire contents of the bulb delivered over several minutes. Among the seven patients receiving PCRA at home, one patient had to be admitted to the hospital. One patient had block catheter slip out during transit. The volume delivered could not be measured. Patients found it difficult to know if the drug had been delivered. Three patients noted that the pumps were empty earlier than expected. One patient found it difficult to change the bulb. No patient had difficulty with catheter removal or with bolusing.

Conclusions: PCRA offers excellent postoperative analgesia at home. Elastomeric pumps facilitate PCRA but are imprecise with drug delivery and may not be safe for epidural infusions. The safety of this device for peripheral nerve blocks should be evaluated further.

Objectif : Décrire l'expérience de l'usage de la pompe en élastomère (Eclipse®) pour l'analgésie régionale contrôlée par le patient (ARCP) ambulatoire.

Méthode : Après avoir utilisé l'appareil lors d'une étude pilote avec des patients admis à l'hôpital, sept patients ont reçu l'ARCP à domicile au moyen de la pompe en élastomère. Des patients ayant besoin de différents blocs anesthésiques régionaux ont quitté l'hôpital avec des directives écrites et verbales sur l'usage du dispositif, sur les bolus, les effets secondaires des anesthésiques locaux et le retrait de cathéters. À chaque jour, on prenait contact avec les patients pour recueillir les données au sujet de l'efficacité du bloc, des difficultés associées à l'usage de l'appareil et de leur appréciation de cette méthode d'analgésie.

Résultats : Pendant l'étude pilote, il y a eu deux débranchements de cathéters qui ont nécessité des analgésiques de rattrapage. Deux patients ont vu le contenu entier du réservoir se vider en quelques minutes. Parmi les sept patients qui ont reçu l'ARCP à domicile, l'un d'eux a dû être admis à l'hôpital. Le cathéter d'un patient s'est retiré pendant le retour. Le volume de médicament administré n'a pu être mesuré. Les patients ne pouvaient savoir exactement si le médicament avait été administré. Trois patients ont noté que la pompe s'était vidée plus vite que prévu. Un patient a eu de la difficulté à changer le réservoir. Le retrait du cathéter ou l'administration des bolus n'a présenté de problème pour aucun patient.

Conclusion : L'ARCP offre une excellente analgésie postopératoire à domicile. Les pompes en élastomère facilitent l'ARCP, mais sont imprécises sur la quantité de médicament administré et ne sont peut-être pas sécuritaires pour les perfusions péridurales. La sécurité de ce dispositif pour le bloc des nerfs périphériques exige une évaluation supplémentaire.

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PATIENTS experience considerable pain after major orthopedic surgery. Often active physiotherapy or continuous passive motion (CPM) is started soon after surgery increasing the need for good analgesia. Regional anesthesia offers excellent analgesia during activity but the duration of postoperative pain outlasts the duration of single injection regional blocks. We have been using continuous catheter regional blocks to provide extended pain relief in the hospital setting. Elastomeric pumps are devices that have a distendable bulb inside a protective bulb with a built in filling port, a delivery tubing and a bacterial filter (Figure). Rawal *et al.* have used the elastomeric home pump (I-Flow®, Lake Forest, CA) to allow patient controlled regional analgesia (PCRA) at home.¹ Klein *et al.* have reported its use in two ambulatory surgical patients.² We have been using the elastomeric pump (Eclipse®, Block Medical, San Diego, CA) at the London Health Sciences Centre for the last 24 mo. We wish to report our early experience with this home pump used for both acute and chronic pain.

Clinical data

Pilot Study: We evaluated the pump in a pilot study in 11 patients admitted to the hospital following elective major ankle and foot surgery. Patients received preoperative instructions about the elastomeric pump, administration of boluses, bulb changes and block catheter removal. All patients had a popliteal sciatic block catheter inserted using the posterior approach prior to surgery. Using sterile precautions and skin infiltration with lidocaine 1%, an 18G canula over 20G sproutte needle (Pajunk®, Geisingen, Germany) with a stimulating cable was used to identify the sciatic nerve using a peripheral nerve stimulator. Plantar flexion with <0.4mA current was accepted as the end point. A two ml injection of local anesthetic was used to rule out intraneuronal injection. The potential perineural space was distended with 20 ml of ropivacaine 0.5% with 5 mcg·ml⁻¹ of epinephrine. The canula was advanced an additional 1 cm. A 20G, 40 cm long styleted catheter was inserted via the canula so that 3-5 cm of the catheter was in the perineural area. The catheter was fixed with steristrips® (3M, Canada) at the skin and an occlusive bandage (Tegaderm® 3M, Canada) was applied enclosing a loop of the catheter. The edges were fixed with additional tape (Mefix® 3M, Canada) to prevent them from rolling up. An additional 10 mL of ropivacaine 0.5% was injected via this catheter both to ensure patency and to complete total dosage requirement. All patients received a spinal anesthetic for the surgical procedure to facilitate use of thigh tourniquet.

FIGURE The 50 ml elastomeric (Block Medical, San Diego, Ca) pump with inline filter and infusion tubing with delivery rate of 50 ml per hour.

If patients had incision on the medial side of ankle, the skin incision was infiltrated with bupivacaine 0.5% with epinephrine at the end of the procedure and an epidural catheter was inserted under the incision for infusion of ropivacaine 0.3% at 2 mL·hr⁻¹ using another elastomeric pump capable of delivering continuous infusion at 2 mL·hr⁻¹. The popliteal catheter was connected to an elastomeric pump containing 50 ml of ropivacaine 0.3%. Patients were given written instructions to bolus the catheter if they felt some discomfort in the foot by opening the clamp for 10-15 min or until the pain disappeared. They were allowed boluses every two hours if needed. They were given a alarm stopclock to time the boluses. They were requested to keep a diary of bolus-

es, pain scores where 0=no pain and 100=worst pain possible, number of emesis, rescue medications and if they needed nursing intervention. One of the patients had bilateral popliteal catheters and she was instructed to time boluses one hour apart between the two catheters and was discharged home with the catheters (narrated in the next section).

Results of the pilot study: The number of boluses required were 0-6 with a mean of 3.2 on the day of surgery and 1-9 with a mean of 5.3 on postoperative day 1, 0-6 with a mean of 3 on the 2nd postoperative day. Half of the boluses were given between 2000 and 0800 hr. There were two catheter disconnections at the hub and one catheter slipped out of position resulting in inadequate block necessitating rescue morphine. The pain scores before bolus ranged from 60-100 and post bolus were 0-45. Two patients had mild nausea, six patients required Tylenol #3 (2-8 tablets/48hr) for headache or mild surgical pain. All patients except one could remove their catheters by themselves. Two patients fell asleep after opening the clamp resulting in delivery of the contents of the bulb (<200 mg ropivacaine) over several minutes early in the study with no untoward effect. One patient receiving 10 min boluses felt that the device did not meet his expectations. After his bolus time was increased to 15 min, he was very satisfied with the device. The rest of the patients scored their satisfaction "very satisfied" with the technique and indicated that they would certainly use the technique again. One patient developed metallic taste in the mouth on the 3rd postoperative day during the bolus and discontinued the catheter. She also noted that the bulbs did not last as long as they were expected to last. After this pilot study, the catheter fixation at the hub was reinforced using a wooden tongue depressor and waterproof tapes to stabilize the junction.

Main Study: Seven patients including one from the pilot study were sent home with the elastomeric pump for continuous PCRA. The principal author took the responsibility of primary contact for the patients, as education of home care nurses had not been established. All patients had her contact telephone and pager number both with the instructional material and attached to the device. Specific instructions were given regarding the presence of responsible adult in the room during boluses and being in bed during boluses.

Case #1

A 39-yr-old healthy woman had arthroscopic debridement of the shoulder joint with manipulation under anesthesia for idiopathic adhesive capsulitis as an outpatient. A continuous interscalene block (ISB) was initiated under sedation using a peripheral nerve stimulator

and the Pajunk® catheter. A dense motor sensory block was established within 15 min using 200 mg ropivacaine 0.75%. She had a light general anesthesia with propofol infusion for surgery as per surgical request. She required no opioid during or after surgery. She was to undergo aggressive physiotherapy to maintain range of motion. The catheter was connected to an elastomeric pump (50 mL volume, 50 mL·hr⁻¹) (Figure) containing 50 mL ropivacaine 0.4% in the post anesthesia care unit (PACU) and discharged home with instructions to give herself twice daily boluses over 30 min each in the presence of her husband. Symptoms of local anesthetic toxicity were reiterated. She was instructed to clamp and remove the catheter if symptoms should develop. She could move her fingers slightly eight hours after the initial block. Self-bolusing at this time over 24 min resulted in reestablishment of dense motor sensory block. Through the night, she developed numbness in her jaw and ears and was bothered by the dense motor block as well. She wished to try bolusing when needed for short intervals. A bolus over five minutes (20 mg) 15 hr later for mild shoulder discomfort resulted in good analgesia for 3.5 hr. The subsequent bolus over six minutes when the pressure sensation returned in the shoulder was inadequate for the planned physiotherapy. Additional bolus at this time over five minutes resulted in motor block that lasted four hours. She gave herself a few titrated boluses for 48 hr and removed the catheter as it started to leak around insertion site. She had further four hours of analgesia from the last bolus. She noted that 17-34 mg doses gave her pain relief for 3-5 hr. The first bulb was completed after opening the clamp for only 41 min instead of the expected 50 min. She required no opioid during this period. She felt that dense block necessitated use of sling which on one occasion was noted to cause pressure on the upper arm. The lower dose allowed more mobility with her arm. During one of the follow-up calls, on direct questioning she reported reduced hearing in the right ear compared to the left ear, a known side effect of ISB, which gradually improved over three weeks. She had two areas of persisting sensory deficit over the areas supplied by the cervical plexus that have since improved. She was very satisfied with the technique and the pump.

Case #2

A 37-yr-old healthy woman had lateral release of ankle with excision of fibula under continuous popliteal sciatic block. Postoperatively, she was discharged home from the PACU with an elastomeric pump containing 50 mL of ropivacaine 0.3%. She self-administered a bolus over 15 min prior to her flight and had no pain

or nausea during travel. An anesthesiologist gave her a refill with bupivacaine but unfortunately the catheter had dislodged during transit. She was able to remove the catheter without a problem. Her pain was controlled well with oral NSAIDS and codeine after removal of the catheter.

Case #3

A 23-yr-old woman with complex regional pain syndrome (CRPS) of her left foot had four sympathetic blocks offering her only temporary relief. Ambulatory continuous lumbar epidural was planned using the elastomeric pump after detailed discussions. A lumbar epidural was started at L2-3 space and she was sent home with the bulb containing 50 ml ropivacaine 0.1% delivering the drug at 2 ml·hr⁻¹. Her foot remained warm and pink during the infusion. She had minimal numbness in the front of thigh but no motor weakness. As we were short on a similar bulb, she was changed to 50 mL·hr⁻¹ bulb containing 50 mL of ropivacaine 0.1% and instructed to dose herself over five minutes using a stop watch four times during the day. Forty-eight hours later the catheter at the hub started to leak and therefore was discontinued. Home care was instructed to inspect the site everyday and supervise her changing the bulb. The foot remained warm for two weeks. She received a continuous popliteal block for recrudescence of CRPS and sent home with written instructions to bolus her catheter four times during the day with 0.15% ropivacaine over 10 min each time. She was warned about protecting her desensitized foot. She developed motor block even with this small volume of low concentration local anesthetic and reduced her bolus time to five minutes and could continue her sympathetic block for six days. Her foot improved for three weeks and worsened slightly over the next one week. She expressed desire to try the epidural home infusion while awaiting consult for spinal cord stimulation. An epidural catheter was inserted at L₂₋₃ and she used the elastomeric pump for four days with good effect. She developed a viral fever on the fifth day and therefore the epidural catheter was removed and the tip sent for culture. The insertion site had no local tenderness or signs of infection. A neurologist was consulted who did not find any clinical evidence of epidural abscess and did not feel there was need for further investigations. The catheter tip grew scanty skin contaminants. Her foot remained pink but somewhat cold. A lumbar paravertebral catheter was inserted two weeks later and she was sent home with the elastomeric device and instructions to bolus her catheter every 12 hr over 10 min. Her foot remained warm but after 48 hr the bulb

failed to discharge due to distal occlusion in the catheter. She found it difficult to determine if the drug had been delivered. She returned to the hospital and the catheter was adjusted and tested and she continued it for an additional 48 hr with good effect. She has since undergone insertion of spinal cord stimulator and has shown improvement with pain and other symptoms of CRPS.

Case #4

A 40-yr-old wife of a physician had bilateral forefoot reconstruction under bilateral popliteal sciatic blocks. She remained in hospital for 48 hr and used the pump containing ropivacaine 0.3% as needed every two to four hours. On trial of discontinuing the block prior to discharging her home on oral medications, she experienced significant pain. She expressed desire to use the device to make herself comfortable during travel to her home in another province and to avoid nausea with opioids. She was given written instructions to bolus each catheter over 10 min one hour apart prior to departure while at the hospital and while on transit at the airport. She traveled comfortably and pulled out the catheters without problem on reaching her destination. On follow up the surgeon was informed that she had no problem with her block and had excellent pain relief.

Case #5

A 38-yr-old dentist had reconstruction of her anterior cruciate ligament as an outpatient under total intravenous anesthesia. She agreed to try patient controlled fascia iliaca block with a catheter for management of postoperative pain using the elastomeric pump. After initiating the block with 35 mL ropivacaine 0.5%, the catheter was connected to the pump containing 50 mL ropivacaine 0.4%. She was given written instructions to bolus herself while supine over 30 min at 0700 hr and 2200 hr for the next 48 hr. Specific instruction was given with regards to weakness of quadriceps and problem with weight-bearing. She had excellent pain relief, no nausea and required no narcotics for 48 hr. Her husband pulled out the catheter and she had no complications from the block.

Case #6

A 34-yr-old nurse with severe shoulder pain and muscle spasms following a remote motor vehicle accident was referred for continuous interscalene block to see the effect of pain relief and muscle weakness on her shoulder movement and stability. This was tried as an in-patient initially but she agreed to try the same at home using the elastomeric pump. She was discharged

home with two elastomeric pumps containing ropivacaine 0.3% with instructions to bolus the catheter while in bed every two to four hours as needed over 10-15 min. She managed doing it for 48 hr but eventually had to be admitted to a peripheral hospital and was continued on a computerized ambulatory drug delivery device (CADD) as we could not provide her with more elastomeric pumps nor refill it. Even ropivacaine 0.3% gave her considerable motor block that changing the bulb had to be done by home care.

Case #7

A 20-yr-old student had reconstruction of her ACL under spinal anesthesia and had fascia iliaca catheter inserted at the end of the procedure. She was managed in a similar fashion to case #5. She had no problems removing the catheter or handling the elastomeric pump. Her pain management was labeled good and she has indicated that she most certainly would use the technique again.

Discussion

With the health care reform, more surgery is done as ambulatory surgery. In a recent survey conducted at our hospital, a significant number of ambulatory surgical patients felt that they were sent out of hospital when they were still nauseous, in pain and "were not physically ready to leave". Postoperative pain management could be improved with regional anesthetic techniques but for major surgery the pain outlasts the duration of conventional single injection regional blocks. Continuous catheter blocks give excellent pain relief but are mainly used in the hospital setting. Ambulatory PCRA using elastomeric pump similar to the Eclipse® device that we have used is a good bridge to continued pain management at home.

Rawal *et al.*¹ using this device document excellent analgesia following a variety of surgical procedures without major problems. Recently Klein *et al.*² reported its use in two patients for ambulatory PCRA. There are no randomized trials comparing PCRA to conventional oral analgesics. Our study is the first to report the use of this device for the management of a variety of chronic pain problems. Attention to a few details is needed to optimize delivery of ambulatory PCRA with elastomeric pump.

Patient selection is very important. Certain educational level is necessary for the patient to comprehend use of such a device, removal of indwelling block catheters and sterile precautions. Self-administration of local anesthetic in these block catheters as well as removal of these catheters should be done in the presence of a responsible adult. Patients living alone are

not ideal candidates for such analgesic techniques such as the case #6 in our series.

Local anesthetic toxicity with accidental intravascular injection or due to cumulative dosing is a possibility. Seizures occur rarely (1 in 1,000 blocks) mainly during initiation.³ Although there are rare reports of intravascular migration of epidural catheters, migration of peripheral block catheters has not been reported. Patients should be adequately educated about signs and symptoms of local anesthetic toxicity and the importance of administering the bolus via these catheters in the presence of another responsible adult in the room while seated or supine.

Instruction should be clear and should include details of emergency contacts. Patient education should include care of a desensitized flaccid limb and sterile precautions during bulb change. Rawal *et al.*¹ report one of their patients having a vasovagal episode during removal of an interscalene catheter standing in front of a mirror. Ropivacaine may have a specific role with ambulatory PCRA as it has a better cardiovascular toxic profile as well as better motor sensory separation.⁴ To date there are no deaths directly attributable to accidental intravascular injection of even 200 mg ropivacaine.

We note that with continuous peripheral catheter blocks even ropivacaine 0.15%, which we consider equivalent to bupivacaine 0.075%, can produce motor blockade. Patients do not like dense motor block nor is it safe to have a totally flaccid limb. We currently have no data on the local anesthetic concentration/dose that will provide purely sensory block in the peripheral nerves. Rawal *et al.*¹ used much shorter bolus times or bolused until pain disappeared. Optimal concentration of local anesthetic, bolus time and interval need to be determined. Some of our patients during the pilot study did not like waking up during the night to bolus the catheter.

Infection in catheter sites is rare (0.12%) but can pose significant risk of permanent neurological deficit in the epidural space. Apart from educating patient, arrangements should be made for monitoring these patients at home to identify such complications early. Our case #2 had home care look after her epidural site and supervise bulb changes. The cost involved is approximately \$80 compared with \$950 per night of admission to the hospital. The patient had become so well educated after using the device on two previous occasions that she contacted us immediately when she developed fever.

Accidental discharge of the entire contents of the bulb is a reality and happened in two of our pilot study patients. Limiting the dose per bulb may offer some safety with peripheral nerve blocks but still will not be

safe with epidural infusions. Use of a stopwatch to indicate the end of bolus may help avoid such a complication. Elastomeric pumps are unsafe to use for epidural infusion.

There are a few problems with these bulbs.

1. The rate of drug delivery seems variable and depends on a number of factors. According to the product information brochure, delivery rates may be 20% higher if the bulb was used within four hours of filling. Storage temperature and conditions can affect the flow rate. At 25°C, flow rate can increase by 14% and at 15°C, it can decrease by 12% below nominal rate. Dextrose as diluent reduces flow rate by 8%. Overfilled bulbs empty slower and underfilled bulbs empty faster.

2. There is no means of measuring the amount of drug delivered and the amount left over in these bulbs making this device unsafe for epidural use. There is no way the patient can ensure that the drug is getting delivered.

3. The clamp is difficult to open and close and may need to be redesigned.

4. Restricting total dose per bulb necessitates bulb changes. Allowing patients to change bulbs may increase risk of infection but this could be potentially avoided by using home care facility. The bulbs are available in a variety of sizes and flow rates. Home care organizations are familiar with the device for delivery of antibiotics to cancer patients.^{5,6} We still need to educate home care personnel with regards to the use of this device for delivery of local anesthetics, signs and symptoms of local anesthetic toxicity as well as safety monitoring during various regional blocks before we can safely introduce ambulatory PCRA. Fixation of catheter should prevent dislodging without making it unduly difficult for patients to remove them.

Conclusion

PCRA with elastomeric pumps is an exciting development in the ambulatory pain management. Elastomeric pumps allow delivery of excellent of pain relief at home at a low cost. The additional advantage is disposability of the device. Lack of precision is a disadvantage and certainly makes this device unsuitable for epidural use.

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