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Application of continuous incisional infusion of local anesthetic after major pediatric urological surgery: Prospective randomized controlled trial

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ABSTRACT

Purpose: The aim of the study was to determine efficacy of continuous incisional infusion of local anesthetic, ON-Q® pain relief system (Kimberly-Clark, Georgia), in improving postoperative pain, reducing narcotic requirement, and shortening recovery time after major pediatric urological surgery.
Material and methods: Prospective open-labeled randomized controlled trial comparing the ON-Q® pain relief system to standard of care pain management. Pain was assessed by nurses using the Visual Analog Scale or the Face, Legs, Activity, Cry, Consolability Scale depending on the child's age. Information regarding analgesic consumption and recovery parameters such as temperature, start of oral nutrition, and length of hospitalization were prospectively collected.
Results: Patient's demographic, clinical, and surgical characteristics were similar in both groups. The ON-Q® group experienced significantly lower scores of maximal daily pain episodes compared to the control on the day of surgery (1.9±1.8 vs. 4.2±2.2 p=0.009) and first postoperative day (2.28±3.2 vs. 5.47±2.45 p=0.004). Mean number of narcotic doses was significantly lower in treatment group compared to control [Total (2.21 vs. 4.6 p=0.02), POD0 (0.7 vs. 1.7 p=0.02) and POD1 (1.3 vs. 2.8 p=0.04)].
Conclusion: The ON-Q® system is a viable option for postoperative pain management in children undergoing urological surgeries. This technology significantly decreases the amount of maximal pain, and the need for systemic narcotic consumption.

The management of pain is a critical component of pediatric postoperative care. The current practice for postoperative pain management in children consists of a combination of both opioids and antiinflammatory drug agents. Regional anesthesia with a caudal block is another effective pain management technique. These blocks only last 6–8 hours unless there is an indwelling caudal catheter placed. The downfall of the regional anesthesia is the reduced ability to ambulate and the need for hospitalization in these children. Achieving adequate pain management can improve postoperative recovery and reduce the likelihood of postoperative pulmonary complications [1].

Another effective temporary pain management technique is the use of incisional local anesthetics. This has been shown to diminish patients' pain scores and their use of supplementary analgesics, thus decreasing the incidence of the adverse effects of the medications described above [2,3]. Unfortunately, the analgesic duration of most local anesthetics administrated intraoperatively is short, and therefore continuous infusion has been suggested to increase its duration of effect. Continuous infusion of site-specific analgesia results in fewer side effects and better postoperative recovery as assessed by earlier mobilization and earlier discharge [4–7]. One device that currently provides continuous infusion of analgesia is the ON-Q® pump (Kimberly-Clark, Georgia) (Fig. 1). This device is an elastomeric pump that delivers 0.25% bupivacaine at the incision site via a flexible silver-coated catheter that is tunneled subcutaneously at the completion of a patient's surgery. The catheter is attached to the elastomeric pump, which has a flow-limiting valve [6,7]. The local anesthetic is delivered at a constant flow rate for the entire duration of use that is predetermined according to the patient's weight. The pump functions automatically and does not require any manipulation by the patients or their families. The pump is carried in a small pouch, which does not impede the patient's mobility.

There is an abundance of data in the medical literature supporting the feasibility, safety, and efficacy of the ON-Q® pump system in the adult population [4]. There are currently only two previous pediatric studies of the ON-Q® pump system, which focused only on cardiac surgery with a sternotomy incision [5] and various orthopedic procedures [6].

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We previously showed in a case control retrospective analysis that the ON-Q® system is a viable option for postoperative pain management in children undergoing major urological surgeries [8]. This technology significantly decreases the need for systemic analgesic consumption in this cohort [8]. The favorable results of this study encouraged us to investigate further and perform a prospective randomized controlled trial. We hypothesize that continuous incision infusion of local anesthetic delivered by the ON-Q® pump system will improve pain control in children undergoing major urological procedures. To test this we evaluated the outcomes of highest pain score recorded per postoperative day and the amount of narcotic consumed postoperatively. Secondarily, we hypothesize that the ON-Q® pump system will improve recovery of these children. To test this we evaluated the outcomes of the use of antinausea medication, number of febrile events, time to solid food intake, and length of hospital stay (LOH).

1. Methods

1.1. Patients

After obtaining approval from the Institutional Review Board at CHOC Children Hospital of Orange County, pediatric patients undergoing major urological surgery were offered enrollment from March 2011 through November 2012. Information regarding the study protocol, a letter of introduction, and the informed consent was given to the parents during the preoperative outpatient appointment, as well as mailed to the family for their further review. Parental consent and patient assent were obtained at the day of the surgery before the initiation of the surgical case.

Inclusion criteria included patient's weight being more than 6.25 kg, and American Society of Anesthesiology (ASA) classification I and II. Because of concern for misinterpretation of patient's postoperative pain level, patients with developmental delay or special needs were excluded. Patients with known allergies to bupivacaine were also excluded.

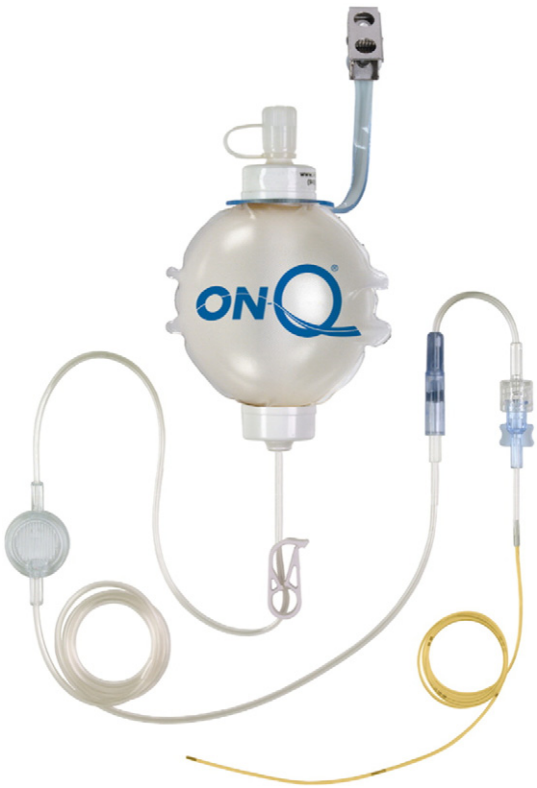

Fig. 1. The ON-Q pump system® (Kimberly-Clark, Georgia).

All surgeries were performed by a single surgeon (AK). Length of incision was similar in all cases (4–5 cm for Pfannenstiel, 3–4 cm for dorsal lumbotomy). All patients stayed in the same hospital ward and were managed by the same registered nurses who were unaware to the existence of the study. Patients were managed with the same postoperative pain control protocol. After ureteral reimplant or pyeloplasty surgeries all patients had an indwelling Foley catheter for 48 hours postoperatively. All hypospadias cases had a Foley catheter in place for one week postoperatively.

1.2. Randomization

The patients were randomized to one of two groups on their day of surgery: the treatment group (received continuous incision infusion of local anesthetic delivered by the ON-Q® pump system), or the control group (received standard of care postoperative pain control consisting of systemic medication as needed).

Randomization was performed in a 1:1 ratio for each type of incision. Randomization was blocked based on the type of incision placement that their surgery required: Pfannenstiel (for lower ureter and bladder surgery), dorsal lumbotomy (for kidney and upper urinary system surgery) or genitals (for penis or clitoris surgery). The surgeons were unaware prior to the time of surgery which group the patient was randomized into.

1.3. Postoperative management: ON-Q® group

Injection of 1 ml/kg of 0.25% bupivacaine along the incision line and placement of the ON-Q® pump system was performed prior to closure of the incision intraoperatively. The ON-Q® pump system catheter introducer was advanced through the skin 1.5 to 2 cm away and parallel to both sides of the incision site and advanced anterior to the fascial sheath. In cases of genital incision the catheters were introduced through the suprapubic area and placed on either side of the penis or clitoris running toward the scrotum or labia. The external portion of the ON-Q® catheter was secured onto the outer layer of the skin using dermal glue and Steri-Strips. An initial 1 ml/kg of 0.25% bupivacaine was injected through each of the two ON-Q® pump catheters as a bolus dose. The pump device administers 0.25% bupivacaine at an infusion rate that is fixed and predetermined according to the patient's weight (0.4 mg/kg range: 1–4 ml/hour). The patient is discharged with the catheters in place and the pump is carried in a small bag with a shoulder strap, or it is attached to the child's clothing. The catheter was removed by the urology team or the patient's parent 3–5 days after the surgery. The patients' incision site (s) and catheter entrance points were examined for signs of infection, edema, hematoma, or delayed healing during their follow-up exam four to seven days after surgery. In the case of a pain episode the patient received a systemic pain control medication at the appropriate dose for their age and weight in the same protocol as the control group below.

1.4. Postoperative management: control group

Standard postoperative pain control protocol in our institution includes intraoperative infiltration of the incision with 1 ml/kg of 0.25% bupivacaine just before the surgical wound is closed. Regional anesthesia with caudal or intercostals block is also administrated as standard of care by some of the anesthesiologists within the institution. Systemic pain control medications are administered by the medical staff dependent on the severity of the patient's pain. Patients with severe pain (pain score >7) were administrated intravenous morphine (0.1 mg/kg); those with moderate pain (pain score >4) received oral ibuprofen (10 mg/kg) or acetaminophen with