Painbuster study

Objective

There is conflicting evidence in the literature about the benefit of the painbuster system of delivering analgesia following major abdominal surgery(1-3). The system involves a rectus shealth “soaker” catheter placed bilaterally in the rectus sheath plane at the end of major abdominal surgery and an elastometric pump which delivers a 2ml/hr infusion of local anaesthetic to each catheter. Physically it seems unlikely that this delivery rate is adequate to anaesthetise the nerves that travel through the rectus sheath. Despite this, anecdotally, our pain service reports good results from use of the pain buster devices. The other advantages of the system include the factor that the elastometric pump is easily portable allowing the patient to mobilise, and that is fully self-contained, not requiring any nursing input for administration following the initial set up.

The price of these devices is around $250 and there has been rapid uptake into our clinical practice, and they are widely used throughout New Zealand. In some ways the conflicting evidence from the literature is not meaningful to our situation as surgical techniques and placements of the catheters vary between the studies and institutions. What we urgently need is evidence from our institution, with our surgeons placing the catheters as to whether or not these devices are useful in our context. Whether these devices are useful will have significant resource implications for our institution, either by confirming their benefit and improving the patient experience and potentially reducing the length of stay, or by saving the DHB the significant cost associated with these devices.

Study design

All patients 18-80 yrs of age having midline laparotomy with pain buster as part of the analgesic plan would be eligible for this study. Exclusions would be patient refusal, plan for epidural analgesia and inability to follow up the patient i.e. not able to communicate for any reason (dementia, not able to speak English) and expected ICU admission following surgery.

Patients would be randomly allocated to either active treatment or control group. In the active treatment group the painbuster infusion device would contain 0.2% ropivacaine (a local anaesthetic) and the control group would have a painbuster infusion device containing normal saline. All patients would have the pain buster catheters placed by the surgeon, and the surgical team and the inpatient pain service (who would be responsible for the follow up) would be blinded to the group allocation. All patients would receive a Patient Controlled Analgesia device (PCA) and other standardized analgesia adjuncts (Paracetamol, Tramadol, and oral opioids at time of discontinuation of the PCA). The primary outcome measures that would be recorded would be the pain scores in PACU, and over the first 4 days of their hospital stay and the amount of PCA opioid used. Length of hospital stay, time to first mobilization, and time to first solid food intake would also be collected as secondary end points. The presence of side effects, sedation, respiratory depression and nausea and vomiting would also be recorded on a daily basis.

Statistics

Using the mean morphine use and the standard deviation from a previous Australian study(1) a power calculation to detect a 30% reduction in pain scores or opioid usage yields a sample size of 35 patients in each group. We aim to recruit 40 patients in each group to account for drop outs and incomplete data collection.

The pain scores, opioid consumption, time to first food intake, time to mobilisation and length of hospital stay will be compared with a two tailed students t test. To test whether there is any difference in side effects between the two groups, a chi squared test will be used.

Reference List

(1) Polglase AL, McMurrick PJ, Simpson PJ, Wale RJ, Carne PW, Johnson W, et al. Continuous wound infusion of local anesthetic for the control of pain after elective abdominal colorectal surgery. Dis Colon Rectum 2007 Dec;50(12):2158-67.

(2) Khorgami Z, Shoar S, Hosseini AN, Mollahosseini F, Nasiri S, Ghaffari MH, et al. Randomized clinical trial of subcutaneous versus interfascial bupivacaine for pain control after midline laparotomy. Br J Surg 2013 May;100(6):743-8.

(3) Baig MK, Zmora O, Derdemezi J, Weiss EG, Nogueras JJ, Wexner SD. Use of the ON-Q pain management system is associated with decreased postoperative analgesic requirement: double blind randomized placebo pilot study. J Am Coll Surg 2006 Feb;202(2):297-305.