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The use of a disposable auriculo-nerve stimulator as an alternative to opioids in cancer patients undergoing abdominal surgery

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Introduction

Reducing postoperative opioid requirements is a constant concern in patients undergoing abdominal surgery for cancer. In the past few years, Enhanced Recovery After Surgery (ERAS) protocols have been developed which include a multimodal approach to perioperative pain management including the use of regional anesthesia (1). Although such an approach has been proven to reduce pain and opioid use, postoperative pain and opioid requirement remain a concern.

Recently, an auricular percutaneous electrical nerve field stimulator (APENFS), a small, battery-operated, disposable device, that stimulates nerves present in the ear for 5 days was approved by the FDA for the treatment of withdrawal symptoms which include abdominal pain (2). This made APENFS potentially interesting to control postoperative pain following abdominal surgery (3).

Since the survival of cancer patients is constantly increasing, and since it is established that perioperative exposure to opioids is a risk for development of opioid use disorder (OUD), being able to minimize the exposure to opioids using a non-pharmacologic approach may be interesting (4).

The study was designed to assess the role that APENFS may have in minimizing postoperative opioid requirement and the factors affecting its response in patients with cancer undergoing abdominal surgery.

Materials and Methods

This was a single-center, prospective, randomized, double-blind, placebo-controlled trial conducted at the University of Pittsburgh Medical Center (UPMC). The protocol was approved by the Institutional Review Board for the University of Pittsburgh Human Resources Protection Office and was registered to Clinicaltrials.gov before any eligible patients were approached and consented (STUDY19040260, NCT03555266). After obtaining a signed informed consent each patient was randomized to either an active or a placebo APENFS. The randomization sequence was generated from a computer-generated random number.
Inclusion Criteria:

Over 18 years of age undergoing elective abdominal surgery performed by a member of the surgical oncology group under general anesthesia.
Exclusion Criteria:
Active depression, anxiety or catastrophizing, active alcoholism or opioid use disorder, or severe chronic pain requiring daily opioids. In addition, subjects that required admission to an intensive care unit or required to go back to the operating room because of surgical complications and whose opioid use was above 3 SD were not included in the final analysis. The specific exclusion for APENFS included a history of hemophilia and patients with cardiac pacemakers.
Statistics
Primary endpoint was the total postoperative opioid consumption over the 5-day study period or prior to discharge from the hospital. Secondary endpoints included pain and opioid consumption, non-opioid consumption and episodes of nausea and vomiting (PONV) on postoperative day 1 to 5, time to ambulation, oral intake, first bowel movement, as well as overall patient satisfaction using a scale 0-10 (0 = least satisfied and 10 = most satisfied), the device tolerance using a scale 0-10 (0 = excellent, 1-4 = good satisfaction, 5-7 = acceptable and 8-10 = unacceptable) and, at 3 months, the functional recovery of each subject was assessed using SF12.
Data are reported as mean ± SD. Differences between groups were assessed using a one-tail unpaired t-test. Alpha was set up as 0.1.

Results/Case Report

The use of APENFS resulted in a 26% overall reduction in OME in the absence of a difference in pain (14 ± 7.03 vs 14 ± 7.66 in the active APENFS group vs placebo group, respectively). This was the result of a 6% reduction in OME in the laparoscopic procedure group and a 39% reduction in the open surgical procedure group in the presence of a 25% reduction in pain.
The effect of APENFS on the overall opioid requirement was 56% greater in the elderly (n=12) compared to younger patients (n=14). The effect of APENFS on opioid requirement was similar in males (n=16) vs females (n=10): 92 ± 112 OME mg vs 102 ± 85 OME mg, respectively (p=0.4313).
The time to oral intake and the time for ambulation were similar in both the APENFS and placebo group as was the time to discharge from the hospital.
The tolerability of the device was reported to be excellent.

Discussion

It seems that the effectiveness of APENFS is greater in patients undergoing open vs laparoscopic surgery, and in elderly vs young patients. This confirms data reported by Blank et al (5) in patients undergoing colorectal surgery .
Conclusion:
Our study suggests that the use of APENFS may represent an effective alternative to control postoperative pain and opioid consumption in patients undergoing abdominal surgical oncology procedures, especially when it involves elderlies undergoing an open surgical approach. However, additional randomized placebo-controlled studies are required to confirm the role that NBD® may play in patients undergoing surgery.

References

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Disclosures

No

Tables / Images