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The late effect of intraoperative wound infiltration with local anaesthetic in surgical patients; is there any? A randomized control trial



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HIGHLIGHTS

- Intraoperative wound infiltration (IOWI) with local anaesthetic (LA) is commonly in clinical practice.
- Apart from the immediate action it has been supported that a down regulation of pain receptors may lead to longer effects.
- This RCT aimed to answer this question: i.e whether there is a late effect of the wound infiltration with local anaesthetic.
- IOWI with LA offers no further benefit apart from that of the immediate PO period. There is no late effect for pain control.

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ABSTRACT

Introduction: Intraoperative wound infiltration with local anaesthetic is commonly used. Apart from the obvious immediate action it has been supported that a possible down regulation of pain receptors may lead to longer effects. Our aim was to compare the use of local anaesthetic versus placebo in order to assess if indeed there is a late beneficial effect.

Methods: We conducted an RCT involving 400 consecutive general surgery patients randomized in 2 groups: Group A = placebo, Group B = wound infiltration with 15 ml of ropivacaine 10%. We recorded the preoperative and postoperative pain for the 1st week as well as the type and quantity of the analgesia used during the study period.

Results: No significant difference was found between the groups in all known confounding factors recorded. No significant difference was found in the intensity of postoperative pain. More people of group A required NSAIDs during the first 3 PO days while more people of Group B required stronger painkillers. For those patients who underwent a non urgent operation and especially laparoscopic surgery higher pain score was recorded in the group B from the 3rd PO day onwards.

Discussion: Intraoperative local infiltration of the wound with local anaesthetic offers no further benefit for the general surgery apart from that of the immediate PO period. There is no late effect for pain control. Considering that during the immediate postoperative period stronger systematic painkillers are given the intraoperative, infiltration of the wound with the local anaesthetic under study offers no obvious benefit.

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1. Introduction

Pain is a subjective and multidimensional experience that is often inadequately managed in clinical practice. The International

Association for the Study of Pain defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” [1].

In surgery, pain is important because it is the most frequent symptom of patients after an operation. Pain has a significant impact on the postoperative course of the patients since it influences and affects multiple systems. Suboptimal treatment of

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pain might lead to chronicity of the symptom, need for longer and expensive treatment and further future complications [2–5]. Inadequate management of pain not only compromises the quality of life but can lead to a considerable financial burden on the health care system [6,7]. For the aforementioned reasons, the effective control of postoperative pain is important after anesthesia and surgery [8]. National health organizations throughout the world recognize pain relief as a primordial medical objective [9].

Effective control of postoperative pain facilitates the mobilization and rehabilitation of the patients, and shortens the length of hospital stay [10]. As postoperative pain is highly subjective, the existence and intensity as well as the need for treatment is determined by the person who is experiencing it and varies significantly among individuals. The published studies on the postoperative acute pain highlight the necessity to develop an effective strategy for pain management by identifying the high-risk patients and the optimal methods for prevention and relief [10–13].

Infiltration of the surgical wound with local anaesthetics is a simple, secure, and low-cost technique for postoperative analgesia and has been widely used by the surgeons in an attempt to partially control pain and minimize the need for systemic analgesia. Due to the local application, transmission of pain from the wound is reduced, and the local inflammatory response to the injury is suppressed [14,15].

There is evidence derived from some studies that the intraoperative wound infiltration with local anaesthetic provide short-term pain relief after the operation [15]. What has not yet been adequately studied is the possible late effect of this practice and whether there is a down regulation of the pain receptors leading to a more extended beneficial effect for the surgical patients.

Since there are no randomized control studies addressing the issue of the late effect of the infiltration of the surgical wound with local anesthetic we designed and conducted this comparative study in order to see if indeed there is a late effect apart from the obvious early effect of this practice.

2. Materials and methods

After the approval of the study by the ethical committee of the hospital (“Korgialleneio –Benakeio”, Athens General Hospital) we prospectively enrolled 400 consecutive eligible general surgery patients who were managed by the same surgical team applying the same predetermined principals. Patients who could not comprehend well or who remained intubated even for one postoperative day were excluded from the study. On admission the patients were informed about the purpose and the method of the study and they were asked if they wanted to participate in it. If they agreed, they were informed about their medical condition and the necessary operation and they were interviewed by a trained surgical resident. The interview was predesigned based on the known factors related to postoperative pain and included apart from the demographics, questions about the educational level, the level of preoperative pain, the use of analgesics or other medications related to pain or mood control, the smoking history, the previous experience with surgery, the psychological state, the type of operation and if the operation was emergency or routine [8].

The psychological state was assessed with the Hospital Anxiety and Depression Scale (HADS) [16] which is a fourteen item scale with a score ranging from 0 to 21 for each. Seven of the items relate to anxiety and seven relate to depression. It is a self-assessment scale for detecting symptoms of anxiety and depression in non-psychiatric patients from a medical department. Based on the score we can classify the psychological status of the patients (anxiety, depression) as: normal (0–7), borderline (8–10), and probable presence of mood disorder (severe anxiety, depression) (11 or

higher). Scores for the entire scale (emotional distress) range from 0 to 42, with higher scores indicating more distress. For the purpose of the study we used the cut-off point of 7 to further classify the patients in two categories (normal and with anxiety/depression). The educational level was classified as “Low” (up to junior school), and “High” (high school and university).

The patients were randomized (using computer software for randomization) either not to receive (Group A) or to receive (Group B) intraoperatively local infiltration of the wound and the drain site with 15 ml of ropivacaine 10%. Both the patients and the study group doctors who interviewed the patients were unaware to which group each patient was allocated.

The primary outcome was the postoperative pain intensity and the secondary the quality and quantity of the analgesia required.

For the assessment of pain we used two methods: (a)The visual analogue scale (VAS) which is a psychometric response scale and the patient has to indicate a position along a continuous line between two end-points (no pain and maximum pain) [17] and (b) the numeric rating scale (NRS) which is a segmented numeric version of the visual analog scale (VAS) in which the patient indicates the number (0–10) that best reflects the intensity of their pain. Both tests are easy to obtain, reliable, valid and can detect changes of over time [17]. The patients were visit by the responsible doctors 3 times a day during the ward rounds and they were asked about the pain intensity and the need of analgesia. The highest pain intensity score of the day was eventually recorded. The pain intensity was assessed preoperatively and for the first 7 postoperative days (PO). The type and amount of analgesia required was also recorded from the 1st to the 7th postoperative day.

On purpose, we did not record the pain on the day of the operation and we further did not record the analgesia given since this was highly dependent on the anesthesiologist preferences and was impossible to control all the confounding factors. Nevertheless, from the postoperative day 1 onwards the analgesia was given on demand from the patient and was recorded in the medical records. The patients were trained before the operation about the way the analgesia should be requested and a member of the team was assisting the patients in their decision during the first days of the study. They all followed the same post operative pain management protocol.

In this way we recorded the type and the quantity of the pain killers given and we classified them in 3 major groups: 1.NSAIDs (1–2/24h), 2.Tramadole HCL 100 mg/pethidine 50 mg (1–2/24h), 3.Tramadole HCL 100 mg/pethidine 50 mg (>3/24h). We further classified the patients in 2 groups: 1.NSAIDs and 2.Opioids/Stronger painkillers, to facilitate the interpretation of the results since there were no significant differences between analgesia group 2 and 3.

The equivalent dose in morphine for the group 2 and 3 is 20 mg (i.e 100 mg Tramandole = 20 mg of morphine and 50 mg Pethidine = 20 mg of morphine).

The hypothesis under investigation was that intraoperative wound infiltration with local anaesthetic leads to better outcomes in terms of the postoperative pain during the 1st PO week.

3. Statistical analysis

The statistical analysis was carried out using SPSS for Windows version 17 software package (Statistical Package for Social sciences; Inc, Chicago, IL).

For categorical variables we used Pearson Chi-square test and Fisher's exact test.

For continuous variable we used independent sample t-test for equality of means to assess if there were any statistically significant differences between the means of the outcome values.

For comparisons involving more than 2 groups we used analysis

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