Pre-incision local infiltration with levobupivacaine reduces pain and analgesic consumption after laparoscopic cholecystectomy: A new device for day-case procedure

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ABSTRACT

All over the World laparoscopic cholecystectomy is the treatment of choice for symptomatic cholelithiasis; use of local long lasting anesthetics reduces post operative pain. Levobupivacaine is one of the most effective local anesthetics. The aim of our study is to test the effectiveness of local anesthetics comparing pre versus post operative trocar site's infiltration. 50 patients were enrolled in our study and 25 five patients were randomized into pre I group (pre incisional infiltration) and 25 into post I group (post operative infiltration); all the operations were performed with the same technique (Anglo Saxon with 4 accesses) by 4 expert laparoscopic surgeons; our results showed different analgesic consumption between the 2 groups of patients; in the pre I group the mean intravenous dose of Ketorolac post operative used was 124 mg while in the post I group was 339 mg: this difference was statistically significant; the mean VAS was 10.7 in the post I group while in the pre I group was 5.1, also the i VAS score's difference was statistically significant: in fact in the post I group i VAS was 8.8 while in the post I group 14.8. Our study demonstrated that infiltration of the trocar site with long lasting local anesthetic is extremely effective for the treatment of post operative pain after laparoscopic cholecystectomy; pre incisional local infiltration seems to be better in term of pain perception and intravenous post operative analgesic consumption.

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1. Introduction

Laparoscopic cholecystectomy is the treatment of choice for symptomatic cholelithiasis; it is also the most common laparoscopic procedure performed all over the world, and in U.S.A. It has been performed as a day case procedure for over a decade.1

Nevertheless laparoscopic approach, post operative pain still remains the most important patients' complain after cholecystectomy; in fact pain can prolong hospitalization and leads to increase post operative morbidity, for example pulmonary complications. Now, that a lot of this operations are performing as a day case procedure, it is particularly important to prevent and reduce as more as possible post operative pain; local anaesthesia may gain additional benefit.

Use of local anaesthetic, either during or after surgery, has used as a method of reducing post operative pain from several years; In 1993 a randomized study was performed in order to demonstrate the efficacy of intraperitoneal or intramuscular local anaesthesia2; this procedure could facilitate the laparoscopic cholecystectomy as a day case procedure.

We can divide into three components pain after laparoscopic cholecystectomy: visceral pain; parietal pain and shoulder pain3; in the first period of post operative stay, parietal and visceral pain are quite similar in order of importance; shoulder pain occurs in 3rd or 4th post operative day.

Local tissue infiltration seems to be quite effective to prevent and control post operative pain in the first 24 48 h, in fact pain severity decreases after the first 24 h.4

Local tissue infiltration has a lot of advantages: simplicity, safety and low cost; the efficacy of this procedure has been investigated in several study but without reaching a clear conclusion that shows the real benefits of this technique.5

Several studies have also noted the efficacy of local anaesthetics on post operative pain reduction for laparoscopic procedures6,7 but only few studies analyzed the effect of local anaesthesia comparing injection time of levobupivacaine.

Lot of studies showed the utility of local anaesthesia for post operative pain control in day case cholecystectomy and also demonstrated that there was no significant difference between day case and overnight stay with respect to morbidity8,9.
2. Aim of the study

The aim of this study is to evaluate the role of trocar site infiltration by local long lasting anaesthetics for post operative pain control after laparoscopic cholecystectomy comparing pre versus post incision infiltration. With this practice we are able to obtain a better pain control in order to avoid a re admission in patients who underwent a day case cholecystectomy.

3. Methods

50 patients with physical status ASA I were enrolled in this double blind randomized study from October 2004 to March 2005 (32 female and 18 male) with a mean age of 59.12 year. All patient had a symptomatic cholelithiasis (biliary colic, dyspepsia). Patient were excluded if they were operated on because of acute cholecystitis, if the subxifoid incision was ampliated for gallbladder extraction, if patients presented serious cardiovascular, renal, hematologic or hepatic diseases or had an history of drugs or alcohol abuse.

No pre emptive e.v analgesic administration was used. Anaesthesia was induced by Fentanyl (1-2 μg/kg/min i.v.) and Propofol (2 mg/kg, i.v.). All patients underwent a tracheal intubation; anaesthesia was maintained with Sevoflurane (end tidal concentration) 1 1.5%, a intermittent infusion of Fentanyl and oxygen/air. Lungs were mechanically ventilated with end tidal carbon dioxide (PETCO2) maintained at 35 45 mmHg; to prevent peri and post operative vomiting, intravenous metoclopramide was administered to each patient before awakening.

All the operations were performed by four surgeons experienced in laparoscopy; all the operations were performed in the morning between 8.00 a.m. and 1.00 p.m. and were carried out under general anaesthesia performed by the same team. The pneumoperitoneum was established via open laparoscopy; initially slow flow (2 l/m) and then faster flow (maximum 20 L/min) was administrated to avoid a vasovagal reaction. Intra abdominal pressure was maintained at 12 mmHg;

Carbon dioxide was evacuated through the ports by applying a gentle pressure all over the abdomen.

All operations were performed in elective ordinary surgery Unit with the Anglo Saxons’ technique with four trocars: 10 mm infraumbilicaly and subxiphoid in the middle of the epigastrium 5 mm in the right subcostal area on the midclavicular line and another one on the front axillary line (Fig. 1). Skin closure was accomplished subcutaneously by monofilament absorbable suture; only in the two major trocar sites fascia was synthesized with 2/0 absorbable suture. Intra operative complications, such as bleeding or bile spillage didn’t appeared in any of the patients and no surgical drainage was necessary for any patients at the end of the procedures.

The duration of the procedures has a mean of 50 min and bile or blood outflow was registered in both groups without notice any differences between the pre I group and post I group.

Patient received post operative intravenous fluids 6 8 h after the operation (Ringer’s solution).

Levobupivacaine is an S(-) isomer of racemic bupivacaine, has recently been introduced as a promising long acting local anaesthetic with a lower toxicity than bupivacaine: levobupivacaine is assumed to have the same local anaesthetic potency of bupivacaine.

This local anaesthetic induces antinociception by acting on the nerve membranes. It affects membrane associated proteins in tissue and inhibits the release and action of agent (e.g. prosta glandins) that sensitizes or stimulate the nociceptors and contrib uted to inflammation.

The patients were randomly assigned to receive pre incision (pre I) or post incision (post I) local anaesthetic infiltration. In the pre I group local anaesthetic was administered prior skin incision; in the subumbilical site anaesthetic was blindly administered on the muscular facia, while in the other three sites levobupivacaine was infiltrated under visual control. Total dose of local anaesthetic was 100 mg in 10 ml of physiologic solution; the total volume was divided proportionally according to the length of the skin incision (3 ml for the 10 mm trocars and 2 ml for the 5 mm trocars).

In the post I group local anaesthetic was instilled at the end of surgery after trocar removal.

The total volume of infiltrated solution in the two groups was 10 ml divided proportionally according to the length of the skin incisions (3 ml for 10 mm incisions and 2 ml for 5 mm).

Pain assessment was performed by standard as well as “incidental” visual analogue scale (VAS, IVAS) at the awaking at rest and at cough. 3, 6, 24 and 36 h post operatively.

During a pre operative visit the patients were introduced to the concept of the 10 cm visual analogue scale (VAS) which ranged from 0 no pain and 10 worst pain imaginable.

On the day of surgery patients didn’t receive any premedication with oral benzodiazepine.

The nurses in surgical department were trained to monitor the VAS pain scores and to administer analgesic. The nurses were blinded to the patients status concerning peri operative local anaesthetics.

Intravenous Ketorolac was used in case of pain, on patients request.

4. Statistics

Student t test was used to compare the two groups and p < 0.05 was considered significant.

5. Results

From October 2004 and March 2005, 25 patients were enrolled in the pre I group and 25 in the post I group. There were no intra operative complications and no patients suffered from adverse reaction due to local anaesthetic infiltration.
The mean intravenous Ketorolac post operative use was 339 mg versus 124 mg for the post I and pre I group respectively; this difference was statistically significant ($p < 0.04$) (Fig. 2).

The mean VAS was 10.7 versus 5.1 for the post I and pre I group respectively; also in this case the difference was statistically significant ($p < 0.02$); also the IVAS was statistically better in the pre I group versus post I (14.8 versus 8.8 $p < 0.03$) (Fig. 3).

Another important data was that 60% of patients of pre I group was discharged without intravenous analgesia, while only 40% of patients of post I group came back home without analgesic consumption (30 mg per dose) (Fig. 4).

6. Discussion

Post operative pain associated with laparoscopic cholecystectomy is less intense and lasts a shorter time than that seen with open surgery. As there is less functional impairment and pain, patients can be discharged and return to their normal daily activities earlier.\textsuperscript{10,11} Pain reaches a peak within the first few hours following the operation but diminishes during the next 2 or 3 days.\textsuperscript{4,10} Some patients experience a rather painful early post operative period. Dynamic conditions also such as coughing and mobilization particularly aggravate the pain.

A lot of authors keep into focus the different mechanism of pain after laparoscopic cholecystectomy: in this kind of procedures pain can be divided into three component: visceral, parietal and shoulder tip pain, with different intensity and time courses; visceral and parietal pain seem to be the most important during the first 24 48 h after surgery: in fact, in this period the most common location of the pain is the right upper quadrant and the trocar sites and, at the end, the right shoulder.\textsuperscript{12,13} The main sources of pain are: incision sites within the abdominal wall; the pneumoperitoneum in association with both local (peritoneal and diaphragmatic stretching, acidosis and ischemia) and systemic (hypercarbia causing sympathetic nervous system excitation with an amplification of local tissue inflammatory response) changes; and the "postcholecystectomy wound" within the liver (visceral pain). Total abdominal pain after laparoscopic cholecystectomy covers all these aspects: the largest component (50–70%) arising from incisional sites, followed by the pneumoperitoneum (20–30%) and "cholecystectomy wound" (10–20%).\textsuperscript{12,13}

We must also remember that pain is a subjective sensation and its measurement is so difficult; we can also add that pain is not only due to a sensory stimulus but has a motivational and affective components and it must be related with cultural learning, previous experience.\textsuperscript{14}

Although Verma et al. say that pain after laparoscopic cholecystectomy is above all a visceral pain,\textsuperscript{9} several study indicates that the parietal pain plays an important role to determinate post operative pain such as visceral one. Our study, and a lot of others studies, showed the important role of local intrafascial anaesthetic instillation in post operative pain control reduction.\textsuperscript{10,15,16}

So we can say that parietal or somatic pain is important as or more than visceral pain in the first post operative 24 48 h; so the benefit of local anaesthetics is clear.

In our study we didn’t considered shoulder tip pain; in fact it occurred only in one patient who received a great volume of CO\textsubscript{2} due to the duration of procedure.

However, no consensus has been reached concerning effective post operative pain mechanism and relief in patient undergoing laparoscopic cholecystectomy, although a number of study were conducted in an effort to reduce post operative pain after this kind of surgery.

A lot of study took in exams other local anaesthetics such as ropivacaine or bupivacaine without a univocal results; only few studies analyzed the effects of this anaesthetic; in our opinion, according to other few studies, levobupivacaine has a better pain reducing effect than ropivacaine and is more potent than bupivacaine; in fact levobupivacaine produces more vasoconstriction at low concentration and has a longer duration of action.\textsuperscript{8,17}

In our study we find a significant different intravenous dose of Ketorolac between the two groups; in the pre I group the consumption of analgesic drug was inferior than in post I group and pain was less intense during the first 24 48 h at rest (VAS) and at cough (IVAS). It is due to a more efficacy of levobupivacaine to control pain and nociception in the post operative period; and maybe the anaesthetic effect of this drug could begin just after the incision of the skin so its effect could conduce to a less inflammatory response of the organism in the incision sites. In this way we could explain the more efficacy of pre emptive administration of the drug into the trocar sites.

A lot of studies agrees with our findings\textsuperscript{8,9,15,18–20}; in fact these authors recommend to administrate anaesthetic drugs before surgery either in case of intraperitoneal infiltration either in case of local trocar site infiltration.

At the end we must consider the intraperitoneal injection of local anaesthetic There are a lot of studies in literature that...
recommend use of intraperitoneal instillation of local anaesthetic in order to reduce post-operative pain but the most part of them recommend its use in association with incision infiltration of anaesthetic; we also retain that this technique is more expensive and more difficult to perform than the incision infiltration.

7. Conclusion

Our study demonstrated that infiltration of the trocar site with long lasting anaesthetics is extremely effective for the treatment of post-operative pain control after laparoscopic cholecystectomy. Pre-incision infiltration is able to obtain better results than post-incision both in term of patients pain perception and i.v. analgesic requirement. We recommend the use of local long lasting anaesthetics in day-case cholecystectomy, for patients with ASA score I, in order to reach a better post-operative pain control also when patient comes back home.

Conflict of interest
No conflict of interest.

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Ethical approval
None.

References