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THE CRITICAL VISION OF SAFETY AND INTRAPERITONEAL ANALGESIA IN VIDEOLAPAROSCOPIC SURGERY

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Abstract: Videolaparoscopic cholecystectomy (CVL) is a surgical procedure where the resection of the gallbladder is performed by videolaparoscopy, which has advantages such as a reduction in surgery and hospitalization time and less surgical trauma, but it can also be associated with a high incidence of immediate postoperative pain. Therefore, effective pain control is crucial at this time. In the present study, we aimed to continue the assessment of analgesia with intraperitoneal ropivacaine as part of patient management in this procedure. To make it viable, approval was obtained from the Research Ethics Committee of the University of Vassouras, consent of the volunteers by signing the Informed Consent Term and, in addition, it will, in the future, obtain registration in the Clinical Trials Registration Platform. The study was divided into two stages: first, a controlled clinical trial, prospective, randomized blind study with a sample of volunteers, randomized through the group: Cholecystectomy Group, which will have a sample of 100 volunteer patients in the surgical ward of the University Hospital of Vassouras, Rio de Janeiro, Brazil. In the draw, it is being randomized between conventional and intraperitoneal analgesia. The second stage comprises a study with a qualitative, exploratory, descriptive and transversal approach. The data collection scheduled for the period from October 2020 to September 2021, resulted, so far, in only 7 patients for the intervention group due to the worldwide pandemic, therefore, it is not possible to observe significant results. However, in the studied sample, it was observed that intraperitoneal injection of ropivacaine during the procedure significantly reduced postoperative pain in these patients compared to the control group. The dose used was 75 mg, which is considered non-toxic, but future studies should explore the ideal duration for different doses, as well as the relationship

between dosage and plasma concentration.

Keywords: laparoscopic cholecystectomy, analgesia, postoperative, ropivacaine, intraperitoneal.

INTRODUCTION

Videolaparoscopic cholecystectomy (CVL) is the surgery where the resection of the gallbladder is performed by videolaparoscopy and is the most performed laparoscopic procedure worldwide (VACCARI et al. 2020; PRASAD et al. 2019; AMIN et al. 2019). Furthermore, historically, the first published laparoscopic cholecystectomy (LC) took place in 1987 by Phillipe Mouret, year of publication of the same procedure in France by Dubois and Perissat (LITYNSKI et al. 1999). The success was so great that it soon gained worldwide acceptance, being reproduced in several countries. In Brazil, LC was performed for the first time at Hospital Albert Einstein, in São Paulo, by Thomas Szego in 1990 (PINTO et al. 2015).

Due to its multiple advantages, in addition to being considered the gold standard for cholecystopathies, SVC is currently the most common gastrointestinal surgical procedure performed worldwide; with 700,000 procedures performed per year in the United States of America alone. In Brazil, in Curitiba, cholelithiasis has a prevalence of 9.3% in individuals aged > 20 years, and LCV is the indicated surgical treatment (IRIGONHÊ et al. 2020). According to Datasus, 93,732 surgeries were performed in Brazil in 2019 (DATASUS 2020). For this reason, the surgical training of residents in General Surgery is essential for them to consolidate, in practice, theoretical studies, but the reduced number of cases and qualified tutors to perform such procedure makes the training more difficult and prolonged.

Despite being considered a minimally invasive surgery, the postoperative period is often extremely painful, especially the immediate one, and that is why effective analgesia is crucial at this initial moment, but studies have shown that traditional pain management with opioids usually causes side effects such as postoperative nausea, vomiting and respiratory depression (LIANG et al. 2020; IMAM et al. 2018; MISHRA et al. 2016), thus demonstrating a possible advantage of intraperitoneal ropivacaine infiltration during surgery.

In addition, previously, some researches have shown that multimodal analgesic strategies with local infiltration not only provide strong analgesic effects, but also reduce the incidence of side effects related to opioids, resulting in faster recovery and shorter hospital stay (DE SOUZA FRANCO et al . 2017; UCHIYAMA et al. 2006) and, also, there are clinical studies showing that local infiltration with ropivacaine effectively controls postoperative pain, being a viable, easy-to-use resource and, therefore, it has been widely adopted in recent years, at doses of 0.75%, 0.5% or 0.2% (ATHANASIOU et al. 2019; KAUSHAL-DEEP et al. 2018; SUN et al. 2017, DE ALBUQUERQUE et al. 2016), thus reducing, the indices of discomfort and post-operative physiological repercussions, such as respiratory restriction, tachycardia and hypertension, pain delays early ambulation and hospital discharge (DE MENEZES COUCEIRO et al. 2009). Collaborating for a shorter hospital stay and, consequently, for a reduction in the cost for the institution.

In order for the management of the patient in the postoperative period of laparoscopic surgery to be effective, it is necessary to create a protocol based on preexisting literary evidence added to the results of this study, for further training of the multidisciplinary team in which it will apply it in a way satisfactory in service. In addition, the surgical training of residents in General Surgery is essential for

them to consolidate, in practice, theoretical studies, but the reduced number of cases and qualified tutors to perform such procedure makes the training more difficult and prolonged.

JUSTIFICATION

Cholecystectomy is the most frequent abdominal operation (RÊGO et al. 2003), therefore, it is imperative that a clear protocol for conducting the patient who performs this type of procedure is created, including, mainly, effective analgesia. For this, the present work aims to demonstrate the most adequate type of pain control for the patient, so that, subsequently, the evidence-based protocol is carried out and, then, the training of the multidisciplinary team of the hospital, including residents in General Surgery that, in addition to dealing directly with the patient and acting as an intermediary between the team, must learn to master not only the surgical technique, but also the correct and effective management of the patient in the postoperative period.

GOALS

MAIN GOAL

Identify the best type of analgesia in lapaloscopic cholecystectomy.

SPECIFIC OBJECTIVES

- Conduct a literature review on laparoscopic cholecystectomy.
- Contribute to the implementation of a postoperative management protocol for patients who underwent laparoscopic cholecystectomy.
- Contribute to obtaining effective results that improve analgesia and, consequently, patient adherence to treatment.

MATERIAL AND METHODS

The present study was divided into two stages. The first corresponds to a non-systematic, qualitative, exploratory, descriptive and cross-sectional literature review study, carried out until November 24, 2021. The terms were searched: "Videolaparoscopic Cholecystectomy"; "ropivacaine"; "analgesia" in the following databases: PubMed, Scielo, LILACS. Articles originally published in English were considered eligible. Articles published in 2020 or late 2019 with a focus on elucidating or discussing the action, clinical outcomes, doses, adverse effects, drug combination, pharmacokinetic and pharmacodynamic parameters of ropivacaine in videolaparoscopic cholecystectomy were included. Among the exclusion criteria, the following were considered: publications in which ropivacaine is not related to analgesia, publications related to advances in diagnostic methods, non-pharmacological therapies, vaccines, clinical picture; publications related to the use of drugs that only superficially mentioned ropivacaine. Alternatively, other studies selected jointly by the authors to reference additional review data were included. These studies, in turn, were not necessarily listed in previously consulted databases and publication dates prior to 2019 were considered suitable.

The second phase comprises a controlled clinical trial study, prospective, randomized double-blind study through a sample of 100 volunteer patients, through the group: Cholecystectomy Group (CG). This was a convenience sample, considering the approximate number of patients available in the service in a unit of time. It was decided to use a minimum of 50 patients per group to allow for the use of parametric tests. Data collection was scheduled for the period from October 2020 to October 2021 for organizational purposes.

The first phase draw is being randomized between intraperitoneal analgesia and a placebo group. All will undergo videolaparoscopic cholecystectomy, with a total of 50 patients undergoing intraperitoneal analgesia during surgery (intervention group) and 50 patients will receive saline as a placebo (control group).

The intervention group will use 10 ml of 0.5% ropivacaine in the hepatic bed, 10 ml in the left cupola and 10 ml diluted in 10 ml of distilled water in the right diaphragmatic hemi-dome of the phrenic nerve right after the pneumoperitoneum. The control group will receive 30 ml of 0.9% saline solution divided into 10 ml in the right diaphragmatic dome, 10 ml in the left diaphragmatic dome and 10 ml in the liver bed. Patients in both groups will receive multimodal analgesia.

In the postoperative period, abdominal and shoulder pain scores by waking upem and after 1, 2, 4, 6, 12 and 24 hours will be chosen, in addition to the need for rescue analgesia, opioid consumption and adverse events. Pain intensity was assessed with the visual analogue scale (VAS) in anesthetic emergency, where zero meant no pain and 10 "worst pain" felt by the patient. A value of $p < 0.05$ was considered statistically significant.

To carry out this study, it was submitted to the Research Ethics Committee (CEP) of the University of Vassouras seeking the approval, consent of the volunteers by signing the Informed Consent Form (TCLE) and will obtain, in the future, registration on the Clinical Trial Registration Platform. Furthermore, to preserve anonymity, the letter E is being assigned as an identification code, followed by Arabic numerals.

SAMPLE SIZE

One hundred volunteer patients from the surgical ward of the University Hospital of Vassouras.

INCLUSION CRITERIA

Being in the surgical ward and being a patient at the University Hospital in the city of Vassouras - RJ, of both genders, aged 18 years or over, physical status ASA I, II and III, according to the American Society of Anesthesiology (ASA) submitted elective SVC surgery under balanced general anesthesia.

EXCLUSION CRITERIA

The participant who refuses to sign the Informed Consent Form (FICF), minors, lactating women, physically disabled and those using parenteral nutrition, patients weighing less than 50 kg, with acute pancreatitis, preoperative abdominal or shoulder pain, being treated for chronic pain, in antiepileptic therapy, addicted to alcohol or drugs, with liver or kidney dysfunction, allergy or sensitivity to the drugs used in this study, active cognitive impairment, pregnant or breastfeeding women and when the surgical technique had to be changed to conventional. Patient in need of additional surgery, cancer patients and patients with pyloric stenosis. In addition, patients who were not present on the day the survey was carried out.

RISKS

There were no physical risks for participants in this research project; given that there is no danger, according to scientific evidence. However, participants may feel embarrassed about answering a question while carrying out the survey. Furthermore, during the period of application, collection and analysis of data, some of the documents may be lost and, therefore, there is a negligible possibility of exposure.

NECESSARY RESOURCES

The research requires a videolaparoscopy SET and basic boxes of videolaparoscopic materials to carry out the main procedures

described in the study and maintenance of the equipment.

RESULTADS

So far, only 12 patients were operated by videolaparoscopy in the stipulated period for data collection, 7 belonging to the intervention group and 5 to the placebo group. The simplified methodology for conducting the study to date is presented as a consort diagram (Figure 1).

All survey participants are female. And there is no statistically significant difference ($p > 0.05$) between mean ages in the control and intervention groups (Table 1). That is, the two groups are homogeneous with each other.

The intensity of pain in the abdomen in the postoperative period was higher in patients in the control group compared to patients in the intervention group (Figure 2). However, this result was not statistically significant (Table 1). Thus, the benefit of decreasing postoperative pain through intraperitoneal injection of ropivacaine during SVC cannot be affirmed as having multiple clinical benefits over conventional analgesia.

With the exception of 1 patient, all research participants reported mild shoulder pain postoperatively (Table 1). It was not possible to perform statistical tests for this variable.

DISCUSSION

The statistical results of the present study were demonstrated by Student's t-Test and Fisher's Exact Test, showing significant results, even with a small sample of patients. Importantly, as the COVID-19 pandemic shifted epicenters from Asia to Europe and the US, surgical societies issued guidelines recommending postponing elective procedures and advising non-operative management of emergency conditions (PRYOR et al. 2020). This was then deemed necessary as many health systems were overwhelmed by the scale of the pandemic and all resources were redirected to deal with it. In addition, many were concerned about the possibility of viral transmission from affected or undiagnosed individuals to healthcare professionals and secondary nosocomial infection from other patients (CHEW et al. 2020).

Certain surgical procedures, both laparoscopic and open approach, have been labeled aerosol-generating medical procedures, which are those that result in the production of airborne particles that can remain suspended in air or travel a distance (WHO, 2014). However, the risk of aerosolization in laparoscopy is not yet clear, but is often related to reports of metastases at the laparoscopic port site during previous experiences, hypothesized to be related to the state of pneumoperitoneum with associated pressure-related air currents in the abdomen (EMOTO et al. 2017). Although the surgeon's risk of viral infection is well documented in open surgery, there is no such literature in laparoscopic surgery. However, studies comparing the quantity and quality of surgical smoke produced by various instruments found that the main determinant of aerosolization was the instrument used, supporting the notion that surgical plumes are produced in both laparoscopic and open surgery (WELD et al. . 2007).

Today, as communities gradually relax blockade measures and health systems plan to restart, the surgical community must anticipate an increase in emergency and elective procedures. Cholecystectomy is one of the most performed abdominal surgeries in the world. To date, there are several reports of patients with COVID-19 undergoing cholecystectomy (FLEMMING et al. 2020; GIULIO et al. 2020; NAHSHON et al. 2020; KABIR et al. 2020).

From the perspective of results, pain is the most direct feeling for postoperative

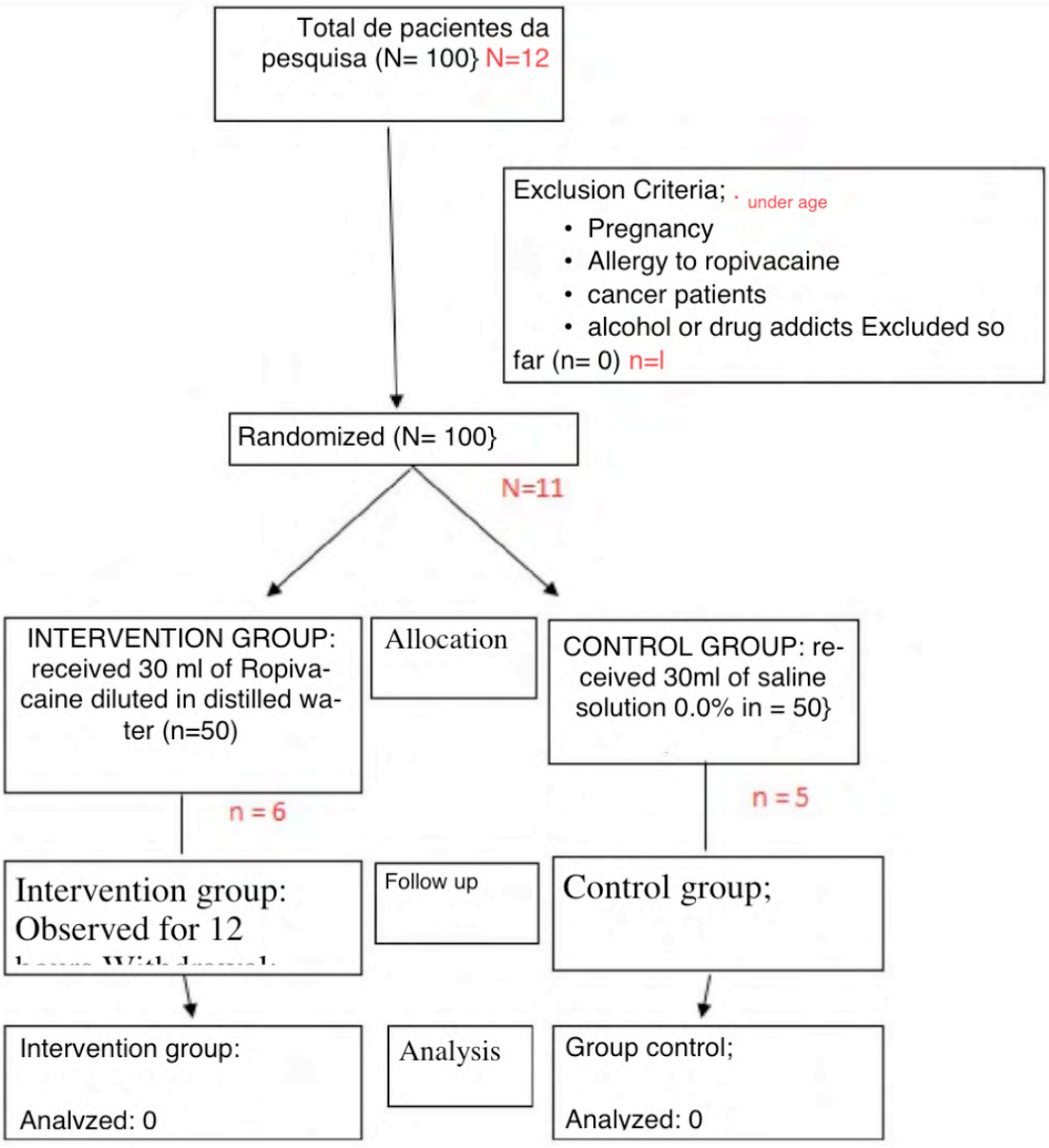
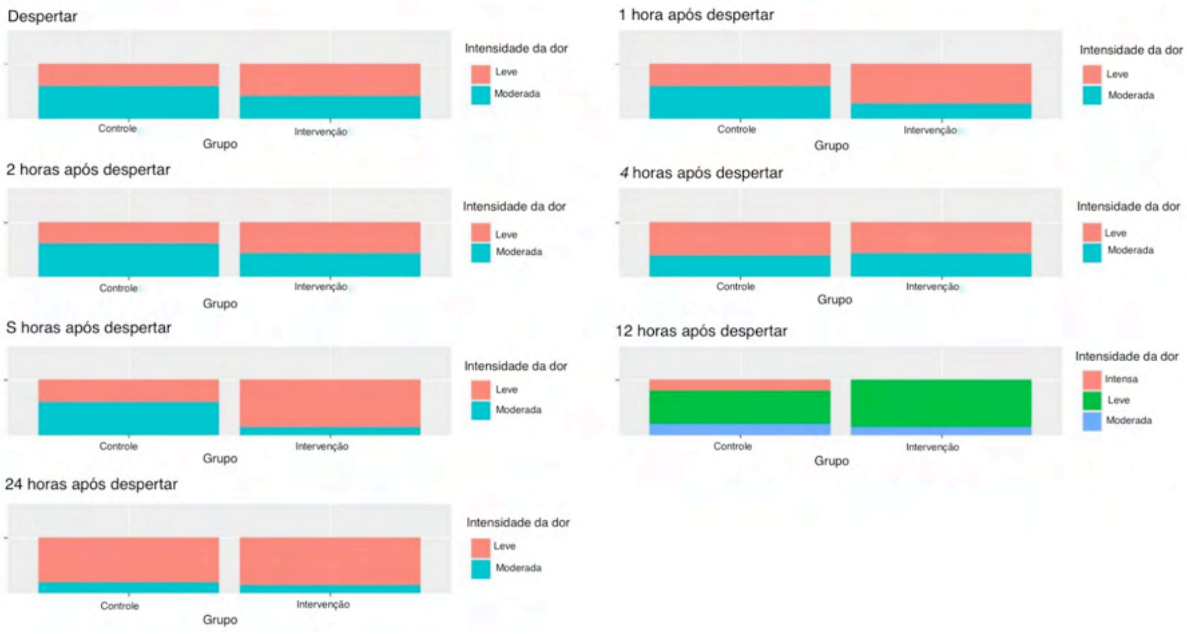


Figure 1: Diagram CONSORT.

	Group		
	Control (N=5)	Intervention (N=6)	
Age			Student's t-Test
mín – máx	20 - 60	28 - 65	p-value = 0.4738
Average ± dp	34 ± 16.01	43 ± 12.01	
Moderate/severe pain in the abdomen			Fisher's Exact Test
By waking up	60%	33.33%	p-value = 0.5671
1 hour after waking up	60%	16.67%	p-value = 0.2424
2 hours after waking up	60%	33.33%	p-value = 0.5671
4 hours after waking up	40%	33.33%	p-value > 0.9999
8 hours after waking up	60%	16.67%	p-value = 0.2424
12 hours after waking up	40%	16.67%	p-value = 0.6970
24 hours after waking up	20%	16.67%	p-value > 0.9999
Moderate/severe pain in the shoulder			
By waking up	-	-	-
1 hour after waking up	-	-	-
2 hours after waking up	-	-	-
4 hours after waking up	-	n =1 (16.67%)	-
8 hours after waking up	-	n =1 (16.67%)	-
12 hours after waking up	-	-	-
24 hours after waking up	-	-	-

Table 1.



Intensidade da dor = pain intensity

Leve = light

Moderado = moderate

Grupo = group

Intervenção = intervention

1 hora após acordar = 1 hour after waking up

2 horas após acordar =2 hours after waking up

4 horas após acordar = 4 hours after waking up

12 horas após acordar = 12 hours after waking up

24 horas após acordar = 24 hours after waking up

Figure 2. Percentage distribution (%) of pain intensity in the patient‘s shoulder after surgery according to the group (control/intervention).

patients, often leading them to not want or be afraid to move, considering that it results in increased postoperative complications (ZHU et al . 2019). Furthermore, nausea and vomiting are common complaints in patients under anesthesia, which come from several factors, including the excessive use of common analgesia. Previous studies demonstrate that wound infiltration can reduce opioid consumption, as well as the side effects associated with the traditional analgesia strategy based on them, although the incidence of postoperative nausea and vomiting, pruritus and respiratory depression was not significantly different between the group, although more morphine and tramadol were used (Kumari et al. 2020). This result can be attributed to the small sample size of the study.

Given the critical analysis of the data obtained in comparison with the literature on the subject, the results tend to confirm the findings in the literature on the analgesic effect of intraperitoneal ropivacaine on SVC, including in the immediate postoperative period (SHREY et al. 2020; MEENA et al. . 2019; DE ALBUQUERQUE et al. 2016; YEH et al. 2014; LABAILLE et al. 2002).

Local anesthetics used at the incision site trigger analgesia, blocking peripheral afferents, thus inhibiting the transmission of harmful impulses to spinal dorsal horn neurons and the local inflammatory reaction, as well as hyperalgesia at the incision site (JEONG et al. 2019). Ropivacaine and bupivacaine are long-acting local anesthetics widely used worldwide for the management of postoperative pain. However, although ropivacaine has the same analgesic effects as bupivacaine, it results in fewer side effects, such as motor block, central nervous system and cardiovascular toxicity (LIANG et al. 2020; KHANNA et al. 2017). Therefore, ropivacaine seems to be the most suitable local and postoperative analgesic to be used. However, the side effects of using high concentrations remain unknown. (WULF et al. 1999).

Furthermore, it is necessary to emphasize that the present study has some limitations such as a very short observation period to reveal potential differences between the analgesic infiltration group under the dose of ropivacaine and the control group. In addition, we are experiencing a moment of global pandemic, which reduces the number of elective CVLs, which makes it difficult and, consequently, reduces the number of samples for research. Second, taking blood samples after surgery makes patients bored and therefore can increase complaints and make compliance difficult. Therefore, only the systematic blood concentration of ropivacaine at a time point is observed, and it is not feasible to assess the relationship between dosage and blood concentration. There is also the issue of depth of anesthesia monitoring that was not used in this study, which may affect its results. Finally, other factors that affect pain intensity were not considered, such as psychological factors, age, sex and education, for example.

CONCLUSION

The 75 mg of intraperitoneal ropivacaine injected during SVC decreases postoperative pain in patients compared to the control group, however this result was not statistically significant. Therefore, it is possible to conclude that the research needs a longer time interval and a higher number of elective CVL for better results to be obtained, thus justifying its continuity. In fact, the battle against this pandemic will be a long one. However, we expect the three components of the "new" critical security view: knowledge that SARS-CoV-2-RNA is not present in bile; evidence of safe laparoscopic surgery in patients infected with COVID-19 and the implementation of rigorous preoperative screening measures

will help to allay the concerns of surgeons who find themselves having to perform cholecystectomy even though we do not recommend starting the minimally invasive practice during it. unprecedented period.

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