Does preperitoneal local anesthesia in laparoscopic gastric bypass surgery reduce postoperative pain and opioid consumption?

Published: 24-07-2013
Last updated: 26-04-2024

Primary objective:To evaluate the postoperative opioid consumption and pain after laparoscopic bariatric surgery. Our hypothesis is that less opioids will be consumed by patients in the group receiving local anesthetics compared to normal saline....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON37220

Source
ToetsingOnline

Brief title
Preperitoneal local anesthesia in laparoscopic gastric bypass surgery.

Condition

- Gastrointestinal therapeutic procedures

Synonym
postoperative pain

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: eigen onderzoeksfonds

Intervention

Keyword: Gastric bypass surgery, Local anesthetics, Opioid consumption

Outcome measures

Primary outcome

- Opioid consumption

- Painscores

Secondary outcome

- Side effects of opioids

- Mobilisation possible within 2 hours after surgery

- Length of hospitalstay

- Patientsatisfaction with pain treatment

Study description

Background summary

Bariatric surgery for morbid obesity is a fast growing area of surgery in western counties (1). In our hospital bariatric surgery is performed 800-900 times a year. Laparoscopic bariatric surgery induces less postoperative pain than open bariatric surgery (2), but opioids are still necessary for optimal analgesia. The reduction of opioid consumption and quick mobilisation is especially important in obese patients. Obstructive sleep apnea syndrome is often found in these patients and this is an important riskfactor for hypoventilation after use of opioids (3).
Recently we have changed our protocol for bariatric surgery from our *common practice* (CP) anesthesia to the modified Fast-track (FT) protocol. This protocol is based on the Fast-track protocol, as described by Bergland et al(1). We expected this protocol would lead to a reduction in postoperative pain and opioid consumption.
In a retrospective study (unpublished data) we compared 100 patients of our CP protocol with 60 patients from the FT protocol. The main changes made in the analgesic part of the protocol were the change from long-acting analgesics,

morfine and during surgery sufentanil, to short- and ultrashort-acting analgesics, sufentanil at induction and remifentanil during surgery, combined with preperitoneal infiltration of bupivacaine 0.5%. Both groups were given paracetamol 1 gram during surgery, which was continued after surgery 4 times a day. After surgery the CP-group was given patient controlled analgesia (PCA) with morfine. The FT-group got subcutanous morfine on demand.
We compared these two groups on opioid consumption and numeric rating scale (NRS) for pain after surgery. This evaluation shows a significant reduction in opioid consumption of 19mg (SD+/-15mg) to 7.3mg (SD+/- 7,5mg) of morfine in the first 24 hours after surgery. In the CP-group 95% of the patients needed opioids after surgery compared to 65% of the patients in the FT-group. NRS-scores in both groups are similar. Our hypothesis is that this effect comes from preperitoneal infiltration with bupivacaine, since our short- and ultrashort working analgesics will be completely eliminated from the body within approximately 10 minutes after surgery.
However, we can not conclude from this retrospective study that preperitoneal infiltration with local anesthetics have an opioid-sparing effect. Also several other factors have changed. Surgical technique has changed leading to less tissue damage. Also we now have a very dedicated team of doctors and nurses taking care of this specific group of patients. Another very important change is our change from PCA-analgesia to on demand analgesia, which may affect opioid consumption as well(4).
No studies have been done researching preperitoneal infiltration with a local anesthetic in morbidly obese patients undergoing laparoscopic gastric bypass surgery. One study has researched a combined preemptive and preventive analgesia in open gastric bypass surgeries. This study shows a combination of preoperative intravenous ketorolac, subcutaneous bupivacaine along the planned incision and bupivacaine in the rectus fascia before closing leads to a reduction in postoperative analgesics.(5)
Several studies have been done in other surgeries researching preperitoneal local anesthetics. These studies show oppsite results. Bar-Dayan et al found preperitoneal bupivacaine attenuates pain following laparoscopic inguinal hernia repair, while Dean et al found no significant effect on pain. (6,7)
Studies researching continuous infusion of local anesthetics after abdominal surgery show a reduction in pain, use of other analgesics and an accelerated postoperative recovery. (8,9)
Three studies have been done researching intraperitoneal local anesthetics.(10,11,12) A meta-analysis of these studies shows evidence in favour of intraperitoneal local anesthetics for reduction of pain and opioid consumption.(13)
Because no studies about this subject have been done and our retrospective study shows inconclusive but promising results, a double-blind randomized clinical trial is needed to compare the effect of preperitoneal infiltration with bupivacaine with a placebo.

Study objective

Primary objective:
To evaluate the postoperative opioid consumption and pain after laparoscopic bariatric surgery. Our hypothesis is that less opioids will be consumed by patients in the group receiving local anesthetics compared to normal saline.

Secondary objectives:
To evaluate side-effects from opioids, mobilisation, length of hospitalstay and patientsatisfaction with pain treatment. Our hypothosis is that in our treatment group we will less side-effect from opioids. We expect to see that mobilisation within two hours after surgery will be possible for more patients in our treatment group, length of hospitalstay will be shorter and patientsatisfaction with pain treatment will improve.

Study design

This is a double-blind, randomized controlled clinical trial.

This study will have two groups:
1) Preperitoneal infiltration with bupivacaine 0.5%
2) Preperitoneal infiltration with normal saline 0.9%

Postoperatively, the groups will be followed, pain scores are recorded and opioidconsumptie will be checked.

Intervention

Local infiltration with bupivacaine 0.5% 30-40 ml or normal saline 0.9%

Study burden and risks

Additional risks are minor. Bupivacaine is a local anesthetic used in daily practice and complications are rarely seen.
The burden of this study is minimal. No extra visits or blood samples need to taken. Patients will have to fill in the use of postoperative analgesics and their painscores will be asked every 6 hours. The day after surgery patients will be asked if they were satisfied with paintreatment.

Contacts

Public
Rijnstate Ziekenhuis

Wagnerlaan 55
6815AD Arnhem

NL
Scientific
Rijnstate Ziekenhuis

Wagnerlaan 55
6815AD Arnhem
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients > 18 years old
- Planned laparoscopic gastric bypass surgery
- Body mass index > 35

Exclusion criteria

- No informed consent possible or obtained.
- Major abdominal surgery in the past
- Known side effects or allergies to morfine or bupivacaine
- Use of opioids or benzodiazepines in the past 3 months
- History of alcohol- or drugabuse
- Indication for premedication with a benzodiazepine

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-05-2014
Enrollment:	84
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bupivacaine
Generic name:	Bupivacaine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	24-07-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-10-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2012-002618-38-NL
CCMO	NL40740.091.12

Study results

Date completed:	01-12-2014
Actual enrolment:	100