THE EFFECT OF INTRAPERITONEAL INSTILLATION OFBUPIVACAINE ON POSTOPERATIVE PAIN AFTER SURGICAL LAPAROSCOPY

ID: 0107909

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INTRODUCTION

Laparoscopy is an invasive surgical technique used in both diagnostic and operative procedures ,one benefit of laparoscopy is that it usually takes less time and has a faster recovery than open surgery, [1] postoperative pain as a result of surgical laparoscopy occurs in up to 80% of women, with potential significant morbidity, in form of delayed discharge and readmission. [2]

Pain after surgical laparoscopy is due to various causes, such as : trocar insertion stimulating somatic pain receptors in the skin ,chemical irritation of peritoneal nerves due to abdominal distension by CO2 which is transformed into carbonic acid in nerves,[3] distention secondary to pneumoperitoneum causes mechanical irritation of visceral and parietal nerves of the peritoneum, furthermore the surgical intervention causing injury and inflammation of the tissues, spillage of blood or serous fluid causing more irritation to the visceral and parietal nerves of the peritoneum which leads to visceral dull aching pain referred mainly to the distribution of the nerve dermatomal area.[4]

Unfortunately, pain is the major complaint of the patients, thus making its evaluation a fundamental requisite in the outcome assessment in our practice. Pain intensity, duration and related disability are the aspects that define pain and its effects. For each of these aspects, different assessment tools exist. [5]

Visual Analogue Scale (VAS) consists of a straight line with the endpoints defining extreme limits such as ‘no pain at all’ and ‘pain as bad as it could be’

The patient is asked to mark his pain level on the line between the two endpoints. This tool was first used in psychology by Freud in 1923. [6]

McGill Pain Questionnaire by Melzack, (1975) represented a major evolution in pain research thanks to the MPQ, the qualitative aspect of pain became an important subject in pain research. Pain descriptors were categorized

in three dimensions of pain experience: words that described the **sensory** qualities of the experience in terms of temporal, spatial, pressure, thermal, and other properties, words that described **affective** qualities in terms of tension, fear, and autonomic properties that are part of the pain experience, and evaluative words that subjectively described the overall **intensity** of the total pain experience. [7]

There are numerous interventions that are associated with reduction in the incidence, severity or both of pain or a reduction in analgesia requirements for women having surgical laparoscopy for gynecological purposes.[8] These could be medical or surgical or even technical interventions that has been developed in an attempt to reduce postoperative pain after surgical laparoscopy as an example of those interventions developing a specific technique for releasing pneumoperitoneum; humidification of gas used in pneumoperitoneum reducing the pressure used to inflate the abdomen,[9] also novel techniques regarding intraperitoneal fluid instillation using isotonic saline; an intra-peritoneal drain in an attempt to eliminate any residual fluid or gas; and local anesthetic applied to the peritoneal cavity to reduce nerve irritation of the peritoneal and visceral nerves.[10]

Bupivacaine, is a local anesthetic. In nerve blocks, it is injected around the nerve that supplies a certain area, or into the spinal canal's epidural space, [11] bupivacaine binds to the intracellular portion of voltage-gated sodium channels and blocks sodium influx into nerve cells, which prevents depolarization. Without depolarization, no initiation or conduction of a pain signal can occur. [12-14]

Hence the idea of our study is to instill bupivacaine in a certain concentration in the peritoneal cavity in an attempt to reduce postoperative pain after surgical laparoscopy for gynecological purposes that will inflect certainly on patient’s hospital stay and mobility.

AIM OF THE WORK

The aim of the present study is to:

Primary

1. Evaluate the efficacy of instilling bupivacaine intraperitoneal in reducing postoperative pain after surgical laparoscopy for gynecologic procedures.

Secondary

1. Assessment of the timing passed postoperative, since the patient needs to start the first analgesic dose.
2. Frequency of analgesia requested by the patient in postoperative period.
3. Assessment of the time passed postoperative since the patient start mobility.

PATIENTS

This randomized controlled trial will be conducted for (80) women undergoing laparoscopic procedures at endoscopy unit at El-Shatby Maternity University Hospital, after approval of ethical committee of Alexandria Faculty of Medicine.

Inclusion Criteria:

1- Patients those are indicated for surgical laparoscopy, whatever the gynecological problem.

2- Age between (18-50) years.

3- Cooperative patient that can express pain and score it.

Exclusion criteria:

1- Non-cooperative patients that cannot express and score pain.

2- Drug abusers due to altered pain threshold.

3- Surgical laparoscopy indicated for oncological procedures.

4- Any allergy or reaction to any of the derivatives of bupivacaine drug group.

5- Any cardio-pulmonary condition.

Randomization will be through opaque sealed envelopes.

METHODS

After signing their informed consents, the patients who are included in the study will be divided into two groups each group include (60) patients.

Group A: Patients that will receive intraoperative instillation of bupivacaine.

Group B: (Control group) that will not receive the medication.

The patients in both groups will be subjected to:

Pre-operative:

History taking (gynecological, obstetric, medical any drug reaction and surgical), general examination and abdominal examination.

Intra-operative:

premedication : 1.5 microgram/kg fentanyl IV

induction of anathesia: 2mg/kg Propofol IV , 0.5 mg/kg Atracurium IV , ventilation via face mask 2-3 minutes , then endotracheal intubation

1gm paracetamol IV as intraoperative analgesia which will not interfere with postoperative pain scoring.

Group **(A)** only will receive intra-peritoneal 40 ml bupivacaine 0.2%, after laparoscopic procedure before removing trocars.

Post-operative (Outcome variables):

1- Assessment of the postoperative pain at 2h, 8h ,24h respectively by visual analogue score (VAS).

2- Assessment of the timing -in hours- of analgesia initiation postoperatively -when VAS score is 4 or more-,non-steroidal analgesia ketorolac 30 mg will be used.

3- Assessment of the frequency of analgesic need postoperatively.

4- Assessment of the timing-in hours- of mobility initiation postoperatively.

Every patient will be asked by the data collector, in order to fulfill the following -appendix- sheet postoperative.

ETHICS OF RESEARCH

Research on human or human products:

- [√] Prospective study: Informed consent will be taken from patients. In case of incompetent patients, the informed consent will be taken from the guardians.
- [ ] Retrospective study: Confidentiality of records will be considered.
- [ ] DNA / genomic material: Informed consent for DNA/genomic test and for research will be taken from patients. No further tests will be carried out except with further approval of committee and patients. If the samples will travel outside Egypt the researcher will be responsible for transportation and security approval.
- [ ] All drugs used in the research are approved by the Egyptian Ministry of Health.

Research on animal:

- [ ] The animal species are appropriate for the test.
- [ ] After test, if the animal will suffer, it will be euthanized and properly disposed.
- [ ] After operation, it will have a proper postoperative care.

سأقوم بتسليم الموافقات المبنية على علم المريض الخاصة بالدراسة عند االنتهاء منها أو عند طلبها من اللجنة

RESULTS

The results will be tabulated and statistically analyzed, using the standard statistical methods.

Statistical analysis of the data

Data will be fed to the computer and analyzed using IBM SPSS software package version 20.0**.** **(**Armonk, NY: IBM Corp**)** Qualitative data were described using number and percent. The Kolmogorov-Smirnov test will be used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation, median and interquartile range (IQR). Significance of the obtained results will be judged at the 5% level.

The used tests were

1 - Chi-square test

For categorical variables, to compare between different groups

2 - Fisher's Exact or Monte Carlo correction

Correction for chi-square when more than 20% of the cells have expected count less than 5

3 - Student t-test

For normally distributed quantitative variables, to compare between two studied groups

4 - Mann Whitney test

For abnormally distributed quantitative variables, to compare between two studied groups

5 –Wilcoxon signed ranks test

For abnormally distributed quantitative variables, to compare between two periods

DISCUSSION

The results will be discussed in view of achievement of the aim and will be compared with available literature and published data

REFERENCES

1. Cho M, Kim CJ, Hahm TS, Lee YY, Kim TJ, Lee JW, et al. Combination of a pulmonary recruitment maneuver and intraperitoneal bupivacaine for the reduction of postoperative shoulder pain in gynecologic laparoscopy: a randomized, controlled trial. Obstet Gynecol Sci 2020;63(2):187-94.

2. Cunningham TK, Draper H, Bexhell H, Allgar V, Allen J, Mikl D, et al. Double-blinded randomised controlled study to investigate the effect of intraperitoneal levobupivacaine on post laparoscopic pain. Facts Views Vis Obgyn 2020;12(3):155-61.

3. Haefeli M, Elfering A. Pain assessment. Eur Spine J 2006;15 Suppl 1(Suppl 1):S17-24.

4. Adlan ASA, Azhary JMK, Tarmidzi HZM, Kamarudin M, Lim RCS, Ng DSW. Post Laparoscopy Pain Reduction Project I (POLYPREP I): intraperitoneal normal saline instillation-a randomised controlled trial Women's Health. BMC Womens Health 2022;22(1):116.

5. Sao CH, Chan-Tiopianco M, Chung KC, Chen YJ, Horng HC, Lee WL, et al. Pain after laparoscopic surgery: Focus on shoulder-tip pain after gynecological laparoscopic surgery. Chin Med Assoc 2019;82(11):819826.

6. Kaloo P, Armstrong S, Kaloo C, Jordan V. Interventions to reduce shoulder pain following gynecological laparoscopic procedures. Cochrane Database Syst Rev 2019;1(1):CD011101.

7. Jiménez Cruz J, Diebolder H, Dogan A, Moths A, Rengsberger M, Hartmann M, et al. Combination of pre-emptive port-site and intraoperative intraperitoneal ropivacaine for reduction of postoperative pain: a prospective cohort study. Eur J Obstetric Gynecology Reprod Biol 2014; 179:11-6.

8. Arden D, Seifert E, Donnellan N, Guido R, Lee T, Mansuria S. Intraperitoneal instillation of bupivacaine for reduction of postoperative pain after laparoscopic hysterectomy: a double-blind randomized controlled trial. J Minim Invasive Gynecol 2013;20(5):620-6.

9. Manjunath AP, Chhabra N, Girija S, Nair S. Pain relief in laparoscopic tubal ligation using intraperitoneal lignocaine: a double masked randomized controlled trial. Eur J Obstet Gynecol Reprod Biol 2012; 165(1):110-4.

10. Marks JL, Ata B, Tulandi T. Systematic review and metaanalysis of intraperitoneal instillation of local anesthetics for reduction of pain after gynecologic laparoscopy. J Minim Invasive Gynecol 2012; 19(5):545-53.

11. Malhotra N, Chanana C, Roy KK, Kumar S, Rewari V, Sharma JB. To compare the efficacy of two doses of intraperitoneal bupivacaine for pain relief after operative laparoscopy in gynecology. Arch Gynecol Obstet 2007;276(4):323-6.

12. Chou YJ, Ou YC, Lan KC, Jawan B, Chang SY, Kung FT. Preemptive analgesia installation during gynecologic laparoscopy: a randomized trial Minim Invasive Gynecol 2005;12(4):330-5.

13. Buck L, Varras MN, Miskry T, Ruston J, Magos A. Intraperitoneal bupivacaine for the reduction of postoperative pain following operative laparoscopy: a pilot study and review of the literature. J Obstet Gynaecol 2004;24(4):448-51.

14. National Institute of Health (NIH). Marcaine- bupivacaine hydrochloride injection, solution Marcaine with epinephrine- bupivacaine hydrochloride and epinephrine bitartrate injection, solution. Daily Med; 2021. Available from: https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=67578b56-7540-487e-1fba-481255620e78

APPENDIX

Evaluation sheet of post-operative pain

Patient name: **Date:**

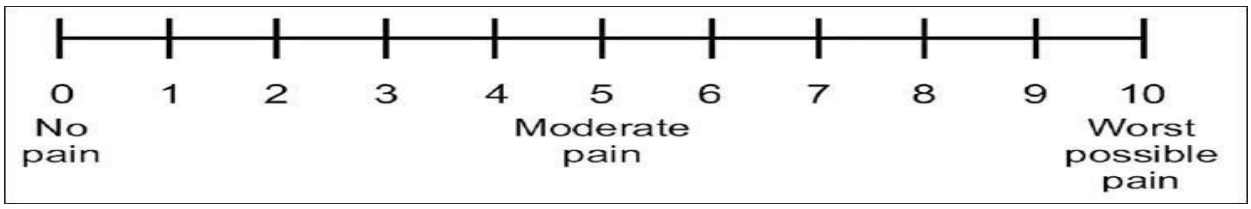
Registration number: **Mobile number:**

Operation undergone: **Time exiting the OR:**

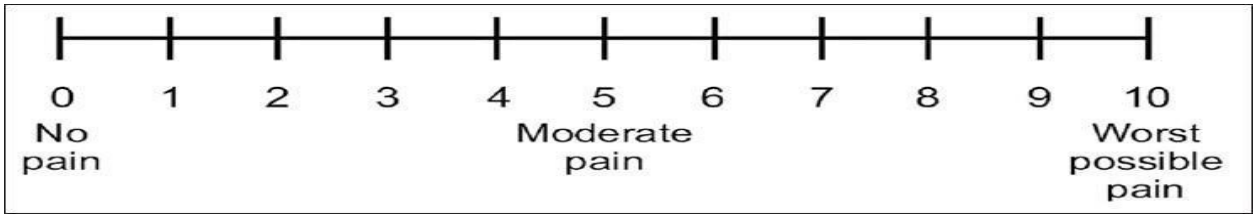
Time of first analgesia: **Frequency of analgesia:**

Time of first mobility:

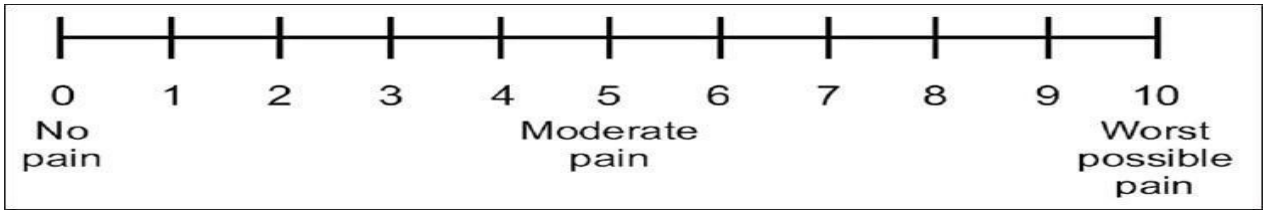
2h. post-operative (.....)



8h. post-operative (.....)



24h. post-operative (.....)



No pain (0), Mild (1-3), moderate (4-6), severe (7-9), worst pain (10), start analgesia at threshold -moderate pain- which is score 4.