بسم الله الرحمن الرحيم

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تم رفع هذه الرسالة بواسطة / مني مغربي أحمد

بقسم التوثيق الإلكتروني بمركز الشبكات وتكنولوجيا المعلومات دون أدنى مسئولية عن محتوى هذه الرسالة.

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Faculty of Medicine
Obstetrics and Gynecology Department

Transversus Abdominis Plane (TAP) Block using Bupivacaine versus Bupivacaine with Magnesium Sulfate for Post-Caesarean Section Pain Control

Thesis

Submitted for partial fulfillment of the Master's Degree in Obstetrics and Gynecology

By

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- Hanan Tarek Hussein

List of Abbreviations

Abbr.	Stands for
%	Percent
AMPA	amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid
CNS	Central Nervous system
CTG	Cardiotocography
CVS	Cardiovascular system
ECG	Electrocardiogram
ed.	Edition
EO	external oblique muscle
et al.	And colleagues
G	Gauge
g	Gram
IM	Intramuscular
IO	internal oblique muscle
IV	Intravenous
J.	Journal
Kg	Kilogram
LA	Local anesthetic
mg	milligram
MHz	Megahertz
min	Minute
ml	Milliliter
mmHg	Millimeters of Mercury
NMDA	N-methyl-D-aspartate
NMDAR	N-methyl-D-aspartate receptor
P	Probability value
PACU	Post-anesthesia care unit
PGE2	prostaglandins E2
pH	Measure acidity and basicity of solution

Abbr.	Stands for
pKa	Acid dissociation constant
PONV	Postoperative nausea and vomiting
SC	Subcutaneous
SD	Standard deviation
TA	transversus abdominis muscle
TAP	Transversus abdominis plane
US	Ultrasound
VAS	Visual analogue scale
VDS	Verbal descriptor scale
VNRS	Verbal numerical rating scales
Vs.	Versus
WHO	World Health Organization
α	Alpha

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ABSTRACT

Background: Caesarean section is a common surgical procedure in the field of obstetrics. Caesarean section rate is increasing worldwide. Postoperative pain is a common undesirable outcome following caesarean section. Proper post-caesarean section patients' management should target management of pain as well as early mobilization, reduction of side effects to the mother and the newborn, rapid functional recovery, and early discharge. Inadequate control of post-caesarean section pain can lead to an increased risk of thromboembolic events, delayed breastfeeding, and post-partum depression.

Aim of the Work: The aim of this study is to assess the efficacy and safety of adding Magnesium Sulfate as an adjuvant to Bupivacaine in ultrasound guided TAP block in reducing post-caesarean section pain in women undergoing elective caesarean section.

Patients and Methods: 92 adult patients undergoing caesarean section under spinal anesthesia were randomly allocated to one of 2 groups (n=46; each). Group A patients received ultrasound-guided transversus abdominis plane (TAP) block using 20 mL of 0.25% Bupivacaine (10 mL Bupivacaine 0.5% + 10 mL normal saline) bilaterally at the end of operation directly after skin closure. Group B patients received ultrasound guided TAP block using 20 mL of 0.25% Bupivacaine with Magnesium Sulfate (10 mL Bupivacaine 0.5% + 2 mL Magnesium Sulfate 10% (200 mg) + 8 mL normal saline) bilaterally.

Conclusion: Addition of Magnesium Sulfate to Bupivacaine used in TAP block following caesarean section enhances its efficacy and prolongs its duration of action which can ultimately lead to reduction in post-operative analgesics consumption, increased patient safety, early patient functional recovery and better surgical outcomes.

Keywords: Transversus Abdominis Plane Block; Bupivacaine; Magnesium Sulfate.

Protocol

Protocol

A. What is already known on this subject? What does this study add?

Ultrasound Guided Transversus Abdominis Plane (TAP) Block is frequently used for post-Caesarean section analgesia. The addition of adjuvant substances to local anesthetics in TAP block have been explored to determine the most efficient combination to achieve long-lasting nerve blockade. This study is designed to compare these two pain-control modalities as regard the analgesic efficacy, duration of analgesia and total need of analgesics and narcotics following caesarean section.

B. Introduction / Review

Caesarean section is one of the commonly performed surgical procedures in the field of obstetrics and accounts for one-fourth of all births worldwide. Postoperative pain is the most common undesirable outcome following caesarean section **(Mohanan et al., 2020)**. Inadequate pain management in the acute postoperative period is associated with persistent pain, greater opioid use, delayed functional recovery, and increased postpartum depression. In addition to pain relief, optimal management of patients after caesarean delivery should address the goals of unrestricted maternal mobility, minimal maternal and neonatal side effects, rapid recovery to baseline functionality, and early discharge home **(Sutton et al., 2016)**.

The most common modality for post-operative pain management has remained the parenteral use of centrally acting opioids such as morphine or its derivatives. However, systemic administration of opioids is associated with side effects including vomiting, sedation and respiratory depression. Several studies have also suggested that systemically administered opioids are ineffective in relieving pain stemming from uterine contractions during labor **(Bozkurt et al., 2009)**.

Transversus abdominis plane block is a compartment block in which a local anesthetic is administered deep to the fascia between the internal oblique and transversus abdominis muscles to block the somatic nerves that pass through the abdominal wall structures that are cut during abdominal incision in caesarean section and cause post-operative pain **(Abd El-Rahman, 2020)**. The technique was first described by Rafi **(Rafi, 2001)** with subsequent introduction of ultrasound guidance by Hebbard **(Hebbard, 2008)**.

To achieve the most efficient analgesia using TAP block technique, different drug combinations have been explored to determine the most efficient analgesic combination. Addition of adjuvant substances to the local anesthetic drugs have been studied and proved to alter the analgesic efficacy and post-operative pain control **(Akkaya et al., 2014)**.

Bupivacaine is frequently used as a local anesthetic in TAP block. Addition of Magnesium Sulfate has been found to enhance the effect of the local anesthetic through regulation of calcium influx into the cell and antagonism of N-methyl-D-aspartate receptors in the central nervous system **(Imani et al., 2018)**.

C. Aim / Objectives:

The aim of this study is to assess the efficacy and safety of adding Magnesium Sulfate as an adjuvant to Bupivacaine in ultrasound guided TAP block in reducing post-caesarean section pain in women undergoing elective caesarean section.

Research Question: For post-caesarean section pain control in women undergoing elective caesarean section, is adding Magnesium Sulfate to Bupivacaine more effective and as safe as using Bupivacaine alone in ultrasound guided TAP block?

Research Hypothesis: Use of Magnesium Sulfate as an adjuvant to Bupivacaine in ultrasound guided TAP block in patients who undergo caesarean section is not superior, regarding efficacy and safety, to using Bupivacaine alone.

D. Methodology:

- **Type of Study:** Randomized, double blinded clinical trial.
- **Study Setting:** Ain-shams University Maternity Hospital, Cairo, Egypt.
- **Expected Study Duration:** May 2021 – November 2021.
- **Study Population:** Women undergoing elective caesarean section.
- **Sample Size:** Using PASS 11 program for sample size calculation, at setting power 99%, significance level 0.05 and by reviewing previous study results **(Rana et al., 2016)**, showed the mean and standard deviation of duration of VAS score for pain among patients taking Ultrasound Guided Transversus Abdominis Plane (TAP) Block using Bupivacaine versus Bupivacaine with Magnesium Sulphate as an Adjuvant after 6 hours were (4.53 ± 2.62 versus 2.40 ± 1.33 respectively) and taking into consideration the dropout rate (15%); based on that, the required sample size will be at least 92 patients undergoing elective Caesarean Section (46 patients in each group) to be sufficient to achieve study objective.
- **Inclusion Criteria:**
    1. Age: Adults from 18 years.
    2. Women subjected to elective caesarean section under spinal anesthesia after 8 hours fasting.
    3. Physical Status: No medical illness.
- **Exclusion Criteria:**
    1. Refusal of procedure or participation in the study by patients.
    2. Patients unable to consent.

3. Physical status: Patients with severe systemic disease.
4. Infection at site of injection because it may introduce and spread infection into the body.
5. Daily use of opioids which may affect VAS score.
6. History or evidence of coagulopathy due to risk of hematoma.
7. Allergies to drugs used.
8. Extensive pelvic adhesions necessitating vigorous dissection because it may cause intestinal injury.

- **Sampling Method:** Randomized.
- **Ethical Considerations:**
    1. Ethical approval will be obtained from Research Ethics Committee of Ain Shams University.
    2. Informed consent will be obtained from the participants prior to the study that a substance will be used to enhance the effect of TAP block.
    3. The protection of the privacy and anonymity of research participants will be ensured.
- **Randomization:** Randomization will be achieved by computer generated random number table.
- Allocation Concealment: Random groups will be enclosed in sealed opaque envelopes to ensure concealment of allocation sequence. The outside of the envelopes will be labeled with the sequence number. After a patient has been enrolled into the study and consented, the next sequence numbered envelope on the stack will be assigned to the patient. The sealed envelope will be opened by an anesthesiologist who is neither involved nor interested by any means in the study, to prepare and administer the drug solution according to randomization.

- **Blinding:** The drugs will be prepared and administered by an anesthesiologist with expertise in TAP block administration who is not involved or interested in the research in any way. The patient and the observer who collects the pre-operative and post-operative data will be blinded to the patient's group assignment and the drug solution administered.
- **Study Procedures:**

1. Pre-operative Setting:

All patients will be subjected to a thorough medical history, physical examination, and laboratory investigations (fasting blood sugar, kidney, liver function tests, serum electrolytes, coagulation profile) pre-operatively. They will be counselled about the anesthetic management and potential complications of both surgery and anesthesia, and the explanation of visual analogue scale (VAS) from 0 – 10. Age, and weight will be recorded. The patient will be fasting for 8 hours preoperatively.

2. Groups and Anesthesia Technique:

Patients will be assigned randomly into two equal groups. Randomization will be done with the help of computer-generated list of numbers. A total of 92 full term pregnant women will be randomly divided into the following groups:

- **Group A:** 46 patients will receive spinal anesthesia followed by TAP block using Bupivacaine alone directly after skin closure.

  Bilateral TAP block will be performed using the following technique:

  The patient will have 20 mL of 0.25% Bupivacaine (10 mL Bupivacaine 0.5% + 10 mL normal saline) administered on each side by midaxillary approach under ultrasound guidance using Mindray