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To Compare The Post Operative Analgesic Efficacy Of Dexmedetomidine And Magnesium Sulfate As Adjuncts To Bupivacaine In Ultrasound Guided Bilateral Transversus Abdominus Plane Block In Patients Undergoing Laparocopic Cholecystectomy: A Prospective, Randomized Controlled Trial.

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ABSTRACT:
Background: Even though laparoscopic cholecystectomy is minimally invasive, many patients experience moderate to severe pain in the early postoperative period. Ultrasound-guided transversus abdominis plane (TAP) block for laparoscopic cholecystectomy is effective method for post operative analgesia.Adjuvants like Dexmedetomidine and magnesium sulfate can be added to local anaesthetics to enhance its effectiveness and duration. Thus aim of our study is to compare the effectiveness of Dexmedetomidine and magnesium sulfate when added to Bupivacaine in ultrasound guided bilateral Transverse Abdominus Plane block in patients undergoing laparoscopic cholecystectomy. **Methods and Material:** This is a Prospective ramdomized study of 60 patients who were divided into two groups.At the conclusion of laparoscopic cholecystectomy , bilateral ultrasound guided bilateral Transverse Abdominus Plane block was given. Group D received Dexmedetomidine 1 mcg/kg in addition to 60ml of 0.125 %bupivaine and Group M received magnesium sulfate 5mg/kg in addition to 60ml of 0.125 %bupivaine. The VAS score for pain,time for first rescue analgesic , number of rescue analgesics ,side effects and patient satisfactiob were documented and compared between both the groups. **Results:** VAS score were significantly lower in Group D in early post operative period compared to Group M.Time for first rescue analgesia was significantly longer in Group D compared to Group M. Number of rescue analgesic doses were significantly less in Group D compared to Group M.**Conclusions:** Dexmedetomidine is superior to Magnesiumm Sulfate when used as an adjuvant to Local Anaethetic in ultrasound guided TAP block for post operative analgesia in patients undergoing laparoscopic cholecystectomy under General Anaesthesia.

Keywords: laparoscopic cholecystectomy, Transverse Abdominus Plane block, Bupivaine, Dexmedetomidine and Magnesiumm Sulfate.

I. INTRODUCTION

Laparoscopic cholecystectomy is a minimally invasive, safe and effective procedure performed for various gallbladder diseases. Compared to open cholecystectomy, the laparoscopic approach is associated with reduced postoperative pain, early recovery, lower hospital costs and improved cosmetic and patient satisfaction, which is why it is even performed as day surgery. Although it is minimally invasive, many patients experience moderate to severe pain in the early postoperative period. There are many options for the treatment of acute postoperative pain after laparoscopic cholecystectomy, which mainly consist of systemic analgesia (opioid and non-opioid), portal infiltration of local anesthetics. Opioids may be needed initially to achieve effective analgesia. However, opioids are associated with dose-dependent side effects.

Regional blocks of the anterior abdominal wall can significantly aid in postoperative analgesia. Hemodynamic effects are minimal because the spread of the local anesthetic is limited to the abdominal wall. Nerves supplying the anterior abdominal wall are via the neurofascial plane between the internal oblique and transversus abdominis. The transverse abdominis plane (TAP) is a regional anaesthetic technique that blocks nerve afferents in the abdominal wall by injecting local anesthesia into the internal oblique neurofascial plane and between the transverse abdominis muscle. In TAP blocks, many additives have been added to local anesthetics to improve the effectiveness and duration of the block, reducing the consumption of systemic analgesia and increasing patient satisfaction. Among additives,

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the most popular are alpha-2-adrenergic agonists such as dexmedetomidine, opioids such as tramadol, buprenorphine, and NMDA blockers such as magnesium sulfate.

There are limited studies that compared the effectiveness of TAP block with the use of different adjuvants in laparoscopic cholecystectomy, but none compared the effects of dexmedetomidine and MgSO4 as adjuvants with TAP block. Thus, we conducted a study to compare the efficacy of dexmedetomidine and magnesium sulfate in addition to bupivacaine for postoperative pain relief after laparoscopic cholecystectomy. The primary objective was to compare the time to first rescue analgesic request and the total cumulative requirements of rescue analgesic during 24 hrs postoperative study period between the two groups. The secondary objective included assessment of pain scores (VAS), haemodynamics, side effects and patient satisfaction.

II. METHODS:

We conducted this study after obtaining approval from the institutional ethical committee of the hospital from 01/10/2016 to 24/07/2018.60 patients belonging to "American Society of Anaesthesiology" (ASA) grade I and II physical status, scheduled for laparoscopic cholecystectomy, under general anaesthesia were included in the study. ASA 3 and 4 patients, known allergy to local anaesthetics, surgeries converted to open cholecystectomy, patients with coagulopathy or under medication on anticoagulants within the last one week before surgery and patients not willing to participate in this study were excluded. Written informed consent was obtained from all the patients. The patients were randomized into 2 groups of 30 patients each, using a computer generated random number, Group D-Dexmedetomidine with Bupivacaine and Group M-Magnesium Sulfate with Bupivacaine for TAP block.

Preoperative Period:

After a thorough pre-anaesthetic evaluation, patient was given a detailed explanation of the procedure, intensity of pain normally associated with the surgery and pain relief that could be achieved with the technique employed. Patients were trained to assess pain using visual analogue scale (VAS) during preoperative evaluation. The procedure of TAP block, effects and possible complications were explained to patients of both groups. All patients posted for surgery received oral Alprazolam 0.5 mg the night before surgery and oral Rantidine 150 mg on the morning of the day of surgery.

Intraoperative Period:

In the operating room, a large bore (18G) IV cannula was inserted. All patients were monitored by non invasive blood pressure monitoring, five lead electrocardiogram, pulse oximetry and capnography. All patients were given a premedication of Glycopyrrolate 0.004mg/kg, Midazolam 0.02mg/kg and Fentanyl 0.002mg/kg. They were given general anaesthesia with Propofol 2mg/kg and Vecuronium 0.1mg/kg. After endotracheal intubation, maintenance was done with Vecuronium 0.02mg/kg and inhalational anaesthetic isoflurane. Post-surgery, before extubation, after operative site dressing, an ultrasound guided TAP block was given to the patients. The patients were extubated with Neostigmine 0.05mg/kg and Glycopyrrolate 0.01mg/kg.

Conduct of TAP block:

Ultrasound guided TAP block was given to the patients as described by Hebbard and colleagues[1] after covering the wound with a dressing, the procedure was performed using strict aseptic technique (gown, gloves, facemask and protective sheath for the ultrasound probe). The block was performed using the SONOSITE Portable ultrasound machine. A linear array US probe (12 MHz) was positioned in a transverse plane in the midaxillary line in the axial plane halfway between the iliac crest and the costal margin. Views were considered satisfactory if subcutaneous fat, external oblique muscle, internal oblique muscle, transversus abdominis muscle, peritoneum and intraperitoneal structures were identified.To assist with identifying these structures, the probe was moved anteriorly to the rectus sheath and then the fascial planes are followed back out laterally. The final position of the probe was no further anterior than the anterior axillary line. The TAP block was performed only if the views were satisfactory. A 23G Quinke spinal needle (Spinocan)-B/BRAUN with 10 cm extension tubing was connected and flushed with 2 ml of saline. The needle was introduced anteriorly in plane under real time ultrasound guidance to lie between the internal oblique and the transversus abdominis muscles with the tip in the midaxillary line. 2 ml of study drug was used to separate fascial layers to confirm needle location. In group D-Patients received 60 ml of 0.125% Bupivacaine with 1mcg/kg of Dexmedetomidine and group M-Patients received 60 ml of 0.125% Bupivacaine

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with 5mg/kg of Magnesium Sulfate. A total of 30 ml of study drug was injected on the each side in 5 ml increments after aspiration to avoid intravascular placement. An echolucent lens shaped space between the two muscles was taken as a sign of successful injection. 0 hour was considered immediately after the TAP block was administered. Patients were observed in the Post Anesthesia Care Unit (PACU) by a blinded investigator.

Postoperative Period:

Postoperative pain assessment was done in all patients using visual analogue scale (VAS) score at 0, 2,4,8,10,12 and 24 hours. Whenever visual analogue score was ≥ 6, time to the first rescue analgesic (Tramadol 2mg/kg given by intravenous route) request and supplemental rescue analgesic requirements with respect to 0 hrs were recorded over 24 hrs by the blinded investigator. Haemodynamic parameters (blood pressure and heart rate) and side effects were noted in all patients at time points 0, 2, 4, 8, 10, 12, and 24 hrs postoperatively. Side effects such as nausea, vomiting, hypotension (mean blood pressure ≤ to 70), hypertension (mean blood pressure ≥ 120), bradycardia (heart rate ≤ 50), respiratory depression (respiratory rate ≤ 8 breaths per minute), restlessness, dysphoria, hallucinations, urinary retention or any other if occurred were noted.Twenty four hours after surgery, patients were asked to rate their satisfaction with pain management on a 3 point scale (1= highly satisfied, 2= satisfied, and 3= dissatisfied).

The primary outcome measure in this study was to compare the time to first rescue analgesic request and the total cumulative requirements of rescue analgesic during 24 hrs postoperative study period between the two groups. The secondary outcome measures included assessment of pain scores (VAS), haemodynamics, side effects and patient satisfaction.

Statistical analysis was performed using IBM SPSS software. The demographic data, time to first request for analgesic were analysed using Student's t-test. Normally distributed data were presented as mean ± standard deviation (SD), non-normally distributed data were presented as median (interquartile range). Visual analogue scores were analysed with ANOVA (Analysis of variance) using general linear model for repeated measures (SPSS 9) and by Student's t-test. The complications were analysed using chi-square test. $p<0.05$ was considered statistically significant.

III. RESULTS:

Sixty patients were included in the study with 30 patients in each group. Both groups were comparable in terms of demographical profiles, patient characteristics, mean duration of surgery, heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure.

VAS Score for Pain:

VAS scores were significantly lower in Group D in 0,2,4,8 and 10 hour post operatively compared to Group M. There were no statistical significant changes in VAS scores in the both groups at 12 and 24 hours post operatively (Table 1).

Time for First Rescue Analgesics:

The mean duration of first rescue analgesic was 416.4±132 in group D patients while it was 276±69 minutes in group M patients which was statistically significant ($p<0.005$) (Table 2).

Number of Rescue Analgesics:

The patients in group D required 3±0 number of rescue analgesic in the first 24 hours while patients in group M required 3.5±0.577 number of rescue analgesics, which was statistically significant($p<0.05$)(Table 3).

Side Effects:

One patient in Group D had bradycardia which was treated with atropine 0.6mg IV. None of the patients in either group had hypotension, hypertension, hypoventilation, sedation, urinary retention, restlessness or any other side effects.

Patient Satisfaction:

At the end of 24 hrs, 10 patients in group D were highly satisfied while 8 in group M were highly satisfied, which was not statistically significant.19 in group D were satisfied while 16 in group M were satisfied which was not significant. 1 in group D were dissatisfied while 6 in group M were dissatisfied which was statistically significant (Table 4).

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Time (hours)	Group D	Group M	p value
0	0.5±0.6	1.7±1.1	0.0006
2	1.4 ± 0.9	3 ± 1.0	0.0005
4	2.2 ± 1.0	4.2 ± 0.9	0.0006
8	4.3 ± 0.8	5.2 ± 0.9	0.0005
10	4.4 ± 0.9	5.4 ± 0.9	0.006
12	4.8±0.8	4.5±0.5	0.06
24	4.7±0.4	4.7±0.7	0.86

Table 1: VAS score comparison between two groups

GROUP	N	Mean Time for first rescue in minutes	Std. Deviation	T value	P value
GROUP D	30	416.4000	132.76596	6.731	0.0005
GROUP M	30	276.8571	69.91090		

Table 2: Time for first rescue analgesia between two groups

GROUP	N	Mean Number of rescue analgesics	Std. Deviation	T value	P value
Dexmedetomidne	30	3.0000	0.00000	-4.746	0.0005
Magnesium Group	30	3.5000	0.57735		

Table 3: Number of rescue analgesics between two groups

	Group D N (%)	Group M N (%)	p value
Highly Satisfied	10(33)	8(26)	0.08
Satisfied	19(63)	16(40)	0.07
Dissatisfied	1(3)	6(24)	0.05

Table 4: Patient satisfaction in both groups

IV. DISCUSSION:

Laparoscopic cholecystectomy causes less postoperative pain and requires lesser analgesic treatment as compared with open cholecystectomy. The postoperative pain may be moderate to severe in some patient. The analgesic regimen chosen should provide safe and effective analgesia with minimal side effects in such a manner which can facilitate early ambulation in the postoperative period. This will in turn lead to improved compliance, greater amount of patient satisfaction overall and ultimately early discharge from hospital.

Regional blocks of the anterior abdominal wall can significantly contribute to postoperative analgesia. Haemodynamic effects are minimal as spread of local anaesthetic is limited to the abdominal wall. Intermittent regimens using long acting opioids or patient controlled opioid administration through parenteral route produces analgesia which is often incomplete and also, they are associated with frequent incidence of side effects, particularly nausea, vomiting and pruritus. Randomized controlled trials[2] have successfully demonstrated the efficacy of TAP block. Recently, letters and clinical studies have been published regarding ultrasound-guided blockade of the abdominal wall following open appendectomy, open inguinal hernia repair, laparoscopic cholecystectomy, and caesarean delivery analgesia.[3, 4, 5] Many additives to local anaesthetics are used as adjuvants to prolong the duration of TAP block. Adjuvants like Dexmedetomidine, Clonidine, Buprenorphine, Dexamethasone have been extensively studied in other peripheral nerve blocks but there is scant research on their efficacy in TAP blocks. Furthermore, Magnesium Sulfate, a proven NMDA receptor antagonist, theoretically

has many properties similar to other conventionally used adjuvants to local anaesthetics but there is very few studies available to prove its efficacy in regional blocks including TAP block.

In this context, we conducted a study to compare the efficacy between Dexmedetomidine and Magnesium Sulfate when added to Bupivacaine in ultrasound guided TAP block for post-operative analgesia in patients laparoscopic cholecystectomy.

VAS scores were significantly lower in Group D in 0,2,4,8 and 10 hour post operatively compared to Group M. But no difference in VAS scores in the both groups at 12 and 24 hours post operatively. The mean duration of first rescue analgesic was longer 416.4±132 in group D patients while it was 276±69 minutes in group M patients. The patients in group D required less 2±0 number of rescue analgesic in the first 24 hours while patients in group M required 2.5±0.577 number of rescue analgesics. In Group D, 1 patient had bradycardia which was treated with atropine 0.6mg IV. In Group M, None of the patients in either group had hypotension, hypertension, bradycardia, hypoventilation, sedation, urinary retention, restlessness or any other side effects. In a study conducted by Almarakbi et al [6], there were significantly higher number of patients who experienced nausea and vomiting. Other than that, no other studies reported any adverse events in their studies.

Dexmedetomidine as adjuvant:

In a study conducted by Yurong Xue et al[7], they used Dexmedetomidine at a dose of 1mcg/kg in addition to 20ml 0.375% Ropivacaine for gynecological laparoscopies.In their study, the post op VAS scores were 0.6,0.7,0.8 and 1 at 2,4,8,12 and 24 hours respectively. A study conducted by A.Sinha et al[34], they used Dexmedetomidine at a dose of 0.5mcg/kg with 20ml 0.375% Ropivcaine for laparoscopic hernia repair.In their study, the post op VAS scores were 0,1,1 and 1 at 1,3,6 and 12 hours respectively. We used Dexmedetomidine at a dose of 1mcg/kg added to 30ml of 0.125%Bupivacaine group(Group D) in TAP block after laparoscopic cholecystectomy under GA. Group D patients in our study had mean VAS scores of 0.5, 1.4 ,2.2 , 4.3 , 4.4, 4.8 and 4.7 at 0,2,4,8,12 and 24 hours respectively.There was a significant decrease in VAS scores in other studies when compared to our study. This may be explained by the fact that we used a lower concentration of local anaesthetic.Our rescue analgesic was Tramadol, which is a weak analgesic compared to Fentanyl used in other studies, which may lead to patient experiencing more pain at frequent intervals compared to their study.

In a study conducted by Almarakbi et al[6], where they used Dexmedetomidine at a dose of 0.5mcg/kg with 20ml 0.25% Bupivacaine for abdominal surgeries under GA and in their study, the time for first rescue analgesic was 470minutes. In our study, we used Dexmedetomidine at a dose of 1mcg/kg with 30ml 0.125% Bupivacaine for laparoscopic cholecystectomy under GA and in our study in Group D, the time for first rescue analgesic was 416 minutes.The longer duration for analgesic requirement may be due to the fact that we used lower concentration of local anaesthetic.

Magnesium as adjuvant:

Farhad Imani et al[8] used Magnesium at a dose of 500mg to 0.2% Ropivacaine after open abdominal hysteretctomy under GA. Their post op VAS scores were 5.9, 2.7, 2, 7, 3.4 and 2.8 at 1, 2,6,12 and 24 hours respectively which was significantly lower than the VAS in our study. This may be explained by the fact that they used Magnesium at a higher concentration than our study.

V. CONCLUSION:

Thus we conclude that, Dexmedetomidine is superior to Magnesiumm Sulfate when used as an adjuvant to Local Anaethetic in ultrasound guided TAP block for post operative analgesia in patients undergoing laparoscopic cholecystectomy under General Anaesthesia.

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