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A comparative study of intraperitoneal Bupivacaine with Dexmedetomidine versus intraperitoneal Bupivacaine with Fentanyl for post operative analgesia following laparoscopic cholecystectomy

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ABSTRACT

INTRODUCTION: Maximum open surgeries are being replaced with laparoscopic surgeries. Laparoscopic cholecystectomy is being more commonly practiced than open surgery. Many parenteral or oral medications are used to control post operative pain following laparoscopic cholecystectomy do have their own side effects. So, local instillation will be beneficial with lesser or negligible side effects. The present study was conducted to compare the effect of intraperitoneal instillation of 0.25% Bupivacaine with Dexmedetomidine and 0.25% Bupivacaine with Fentanyl to know which combination has better efficacy in patients of Laparoscopic Cholecystectomy.

METHODOLOGY: The present comparative study was carried on patients posted for Laparoscopic Cholecystectomy in a tertiary care hospital during 2019 to 2022, The patients were divided in two equal groups of 40 each with Group D - Patients receiving 0.25% bupivacaine with Dexmedetomidine and were instilled with 30ml of 0.25% bupivacaine with 1 μ g/kg Dexmedetomidine (diluted in 2 ml Normal Saline). Also, Group F - Patients receiving 0.25% bupivacaine with Fentanyl where patients were instilled with 30ml of 0.25% bupivacaine with 1 μ g/kg Fentanyl (diluted with 2 ml Normal saline NS). Degree of postoperative pain was assessed using Visual Analogue Scale (VAS).

RESULTS: Overall VAS in 24 hrs was significantly lower in the D group compared to F group. The time required for the first dose of rescue analgesia was longer in the D group than in F group, indicating better and longer pain relief in the D group compared to that of F group. The difference was also statistically significant among the two groups. Total analgesic consumption was high in F group than in the D group.

CONCLUSION: We concluded that intraperitoneal instillation of dexmedetomidine 1 μ g/kg in combination with 0.25% Bupivacaine in elective laparoscopic cholecystectomy significantly reduces the post operative pain and analgesic requirement in postoperative period.

KEYWORDS: Dexmedetomidine, Fentanyl, Laprascopic

INTRODUCTION:

Laparoscopic surgery is a modern surgical technique used for cholecystectomy, appendectomy, hernia repair and other surgeries with advantages of reduced pain and bleeding, shorter recovery time and hospital stay, and thus over all reduced healthcare costs. $^{[1]}$ The type of pain after laparoscopic surgery differs from that which occurs after laparotomy. Postoperative pain is the most common undesirable outcome for patients who undergo surgical procedures. [2] The aim of day care surgeries especially laparoscopy is the reduced number of days of disability and hospitalization which is sometimes influenced by the postoperative pain. The adequacy of postoperative pain control is one of the most important factors in determining when a patient can be safely discharged from the outpatient facility. [3] Following laparoscopy, pain may occur in the upper abdomen, lower abdomen, back or shoulders and is at times transient or persists for at least 3 days. Shoulder pain may occur in as many as 63% or as few as 35% of the patients. [4] Post surgical chronic pain may be either a result of ongoing inflammation or probably an expression of neuropathic pain which may result from peripheral nerve injury during surgery. Pain after laparoscopic surgery results from the stretching of the intra-abdominal cavity also due to peritoneal inflammation and phrenic nerve irritation caused by residual carbon dioxide (CO2) in the peritoneal cavity. Intraperitoneal injections

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of local anaesthetic have been proposed to minimize postoperative pain after laparoscopic surgeries. [5] Adjuvants are often added to Bupivacaine for nerve blocks to prolong its anaesthetic effects. Alpha 2 agonists such as clonidine or dexmedetomidine and opioids like fentanyl combined with Bupivacaine has shown to increase the duration of anaesthesia significantly. Dexmedetomidine has become one of the commonly used drugs in anaesthesia due to its hemodynamic, sedative, anxiolytic, analgesic, neuroprotective and anaesthetic sparing effect. [6] There is also evidence that dexmedetomidine decreases postoperative pain, postoperative opioid usage and nausea. [7] Fentanyl is a strong synthetic opioid, similar to morphine but produces analgesia to a greater extent. [8] The Present study was carried out to compare the effect of intraperitoneal instillation of 0.25% bupivacaine with dexmedetomidine and 0.25% bupivacaine with fentanyl to know which combination has better efficacy for post operative analgesia in patients of Laparoscopic Cholecystectomy.

OBJECTIVES:

The objectives of the study were Comparison of VAS Scores of both the groups D (Dexmedetomidine) & F (Fentanyl), note haemodynamic variations in both combinations, study adverse effects if any in both groups and Comparison of Rescue analgesia requirement in both groups

MATERIAL AND METHODS:

After obtaining permission from the Institutional Ethics Committee a total of 80 patients posted for laparoscopic cholecystectomy surgery for the period from 2019 to 2022 in the Department of Anaesthesiology at a tertiary care hospital. The present randomized prospective observational study was conducted on 80 patients selected using Purposive Sampling method Inclusion criteria: All patients of any gender of age group 18-60 years undergoing laparoscopic cholecystectomy under general anaesthesia with ASA grade I and II and giving informed consent.

Exclusion criteria were All patients less than 18 years and more than 60 years of age, patients of ASA grade more than III, patients having allergy to the study drugs, patients on active treatment for major illness or co-morbidities, pregnant and lactating females and patients who are not willing to give consent.

The total 80 number of patients were randomly divided into two groups Group D-Patients receiving 0.25% bupivacaine with dexmeditomedine-Group and F-Patients receiving 0.25% bupivacaine with fentanyl.After taking written informed consent and confirming Nil by mouth status patients were taken into operation theatres and attached with all the necessary monitors.The patients were induced with, Premedication: Inj Midazolam 0.02 mg/kg ,Inj Glycopyrrolate 0.004 mg/kg , Inj Fentanyl 2 μ cg/kg.Induction was done with Inj Propofol 2mg/kg, Muscle Relaxant was Inj Atracurium 0.5 mg/kg. After long-acting muscle relax-

ant, Surgeons were then allowed to start with their procedure and told to instruct us after dissection and removal Gall bladder so that local drug can be instilled before removal of trocar. Group D patients were instilled with 30ml of 0.25% bupivacaine with 1microgram/kg dexmeditomedine (Diluted in 2ml NS). Group F patients were instilled with 30ml of 0.25%bupivacaine with 1microgram/kg fentanyl (diluted with 2mlNS). Both the groups were given drugs through trocar before its removal on gall bladder bed.

Degree of postoperative pain was assessed using Visual Analogue Scale (VAS)at the end of 0,4,8.12 and 24 hours postoperatively on scale of 10cms showing varying intensity of pain from 0cm to 10cm with 0cm showing no pain and 10 cms showing worst pain. Rescue analgesia was given for patients showing VAS score >/= 3.

RESULTS:

A total 80 patients were included in study. The distribution of age of patients is as shown in Table ${\bf 1}$

Age in years	Group D	Group F	Total
<40	18 (45.00%)	15 (37.5%)	33 (41.25%)
40-50	17 (42.5%)	19 (47.5%)	36 (45.00%)
>50	5 (12.5%)	6 (15.00%)	11 (13.75%)
Total	40	40	80
Mean + SD	42.95+7.2	44.95+6.96	P value=0.83

Table 1: Distribution of patients according to age

Rescue analgesia time in group D and Group F is as shown in Table 2 The data shows more patients in Group D were pain free at 150 minutes.

Rescue Analge- sia time minutes	Group D	Group F	Total
<150	1	35	36
>150	39	5	44
Total	40	40	80
Mean +SD	176.2+16.3	142.65+10.6	50.009*

^{*} statistically significant

Table 2: Requirement of rescue analgesia time in minutes

More patients in Group F required diclofenac as rescue analgesic as shown in Table 3

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Diclo mg	Group D	Group F	Total
75	30	17	47
150	10	22	32
175	0	1	1
Total	40	40	80

Table 3: Distribution of patients according to Injection Diclo requirement[mg] post-operatively.

Visual analog scale of both groups is as shown in Table 4 The data shows VAS scores are significantly low in Group D

VAS	Group D		Group F		P value
VAS	SD	Mean	SD	Mean	
Baseline	0.27	0.55	0.9	0.84	0.009*
30 min	0.65	0.66	1.2	0.61	0.002*
1 hour	1.6	0.49	2.4	0.98	<0.0001*
2 hours	3.2	1.06	4.8	1.33	<0.0001*
4 hours	1.5	0.96	2.3	0.57	<0.0001*
8 hours	1.5	1.06	2.6	0.74	<0.0001*
12 hours	1.15	0.76	2.97	0.73	<0.0001*
16 hours	2.17	0.63	3.12	0.9	<0.0001*
24 hours	1.05	0.78	2.92	0.72	<0.0001*

^{*} statistically significant

Table 4: VAS scoring

Postoperative complications were similar in both groups, with vomitting and sedation more common in Group F while bradycardia common in Group D as shown in Table 5

Complication	Group D	Group F
Nausea	6	6
Vomiting	2	4
Sedation	1	6
Pruritus	0	1
Bradycardia	3	0

Table 5: Post operative complications

DISCUSSION:

During laparoscopic surgery, postoperative pain is multifactorial in origin, and therefore, multimodal therapy may be needed to optimize pain relief. In the present study, a total of 80 cases were studied. Intraperitoneal local anaesthetics were instilled at the end of the procedure before removal of trocar.Post operative analgesia was assessed.In the present study majority of the patients were in the age group of 40-50years. The mean age in our study was 42.95+7.2 years and 44.95+6.96 years in Group D and F respectively.The demographic data was comparable to that in the literature of Ibemhal Heisnam ^[9]had a mean age of 41.7+15:97(SD); range (19-70) years which is comparable. Rajkumar Reddy Inugala et al ^[10] had patients with mean age group of 39.23+6.51 in test and 38.35+7.48 in control group respectively that is comparable to our study. Overall this study showed a female preponderance with a total of 41 females.

In a study by Novacek [11] showed that female gender is the most important risk factors which correlates with our study. Similar conclusions were obtained in various studies by IbemhalHeisnam Sheikh Ahmad [9] and co-workers. No statistically significant differences were noted in the vital parameters between the two study groups. However, it was statistically insignificant (p value >0.5). In our study the mean duration of surgery was 85.2+13.73 and 81.9+13.2 minutes in Group D and F respectively as compared to a study [12] who showed that most cases of laparoscopic cholecystectomy were between the time duration 60 - 90 minutes.Study by B.Lakshmi Praveena et al [13] showed duration of surgery between range of 60-80 minutes. In the present study we found out that the difference in the VAS scores of the two Treatment Groups at the four time points across the 12-hour time period was significant(p value <0.05). Our study noted a relatively lesser VAS scores in Group D Than in Group F. All VAS scores had P values < 0.05 that showed statistical significance.

Chundrigar [14] noted pain relief upto 2 hours post op with the intraperitoneal administration of 0.25% Bupivacaine, although in the present study we could note pain relief upto 12 hours post op. This may be due to the fact that we instilled the local anaesthetic in the Trendelenburg position at the end of surgery which may have resulted in better dispersion of the drug also we have used additives in combination. Narchi et al [15] found intraperitoneal local anaesthetics to be more effective in reducing pain upto 48 hours postoperatively in patients undergoing diagnostic laparoscopy. Also, instillation of local anaesthetics in the supine position prevented its flow over the coeliac plexus and phernic nerve endings. Using 20 ml of 0.5% Bupivacaine, Pasqulucci et al [16] noted a decrease in pain probably due to a complete block of afferents using higher concentrations and volumes than used by other authors. In the present study we used 20ml of 0.25% Bupivacaine along with Dexmedetomidine and fentanyl as additives and we Found significant pain relief upto 24 hours which is similar when compared to Pasqulucci et al. [16] The study of B.Lakshmi Praveena et al [13] used 0.2 % Ropivacaine along with additives of Fentanyl vs Dexmedetomidine intraperitoneally in patients undergoing laparoscopic cholecystectomy. Conclusion of this study Pawar et al www.pimr.org.in

was similar to our study that patients receiving Dexmedetomidine as additive along with Ropivacaine showed better post operative pain relief and lesser Vas scores than that of Ropivacaine with Fentanyl group. In the present study we found that there was a significant difference in the study groups with respect to the time for intake of rescue analgesic consumption. Mean Rescue analgesia time was more in Group D [176.2 + 16.3 minutes] than that of Group F [142.65 + 10.65 minutes].P value was 0.009 that showed statistical significance. Study by Usha Shukla et al [17] had greater rescue analgesia time in group of bupivacaine plus dexmedetomidine [BD] [128 + 20 minutes] than bupivacaine [B] group alone [55+18 minutes] and bupivacaine plus tramadol group [118+22 minutes] that supports our study by proving dexmedetomidine is better additive.

Study by B.Lakshmi Praveena et al [13] had rescue analgesia time of 122+24.5 minutes in group of Ropivacaine plus dexmedetomidine [RD] which was greater than group of Ropivacaine plus Fentanyl [RF] 89.3+13.2 minutes. Conclusion of this study was similar to our study. Over all consumption of analgesics in our study was more in Group D than in Group F.30 patients in Group D required one dose of Diclofenac injection & remaining 10 needed two doses. However, in Group F 1 patient needed 3 doses 22 of them needed 2 doses and 17 required 1 dose. Thus, over proving that Group D had better effect of intraperitoneal analgesia. P value calculated using chi square test was <0.05 that showed statistical significance. lucci et al [16] noted a decrease consumption of analgesics up to 24 hours post operative period.Our results correlate with the study done by Ahmed et al. [18] has shown that intraperitoneal instillation of Meperidine or dexmedetomidine in combination with bupivacaine 0.25% significantly decreases the post‑operative analgesic requirements and decreased incidence of shoulder pain in patients undergoing laparoscopic gynaecological surgeries.

MaharjanSk et al [19] and Rajkumar Reddy Inugala et al study [10] found that the test group of patients receiving Bupivacaine required lesser doses of analgesics than the control group who didn't receive anything which shows that Bupivacaine given intraperitoneally in patients undergoing laparoscopic cholecystectomy is effective in preventing post operative pain which supports our study. Similar results were obtained by B.Lakshmi et al [13] that combination of Ropivacine plus dexmedetomidine [RD] required lesser analgesia [95.3+15.6mg] than Ropivacaine plus Fentanyl [RF] Group [135+75.1mg] which is just like that of our study that combination with Dexmedetomidine is better. Local anaesthetic techniques are part of the multimodal approach to postoperative pain management. The main advantage of using local anaesthetics is that they do not have the adverse effects of opioids, which may delay recovery and discharge from hospital. These effects include post- operative nausea, sedation, impairment of return of gastrointestinal motility, and pruritus. In addition, time to return of bowel function in the postoperative period may be reduced when the use of opioids is obviated by administering local anaesthetics. There was equal incidence of nausea in both groups. However, vomiting, sedation and pruritus had higher incidences in group F though P value [>0.05] showed no statistical significance.

CONCLUSION:

Intraperitoneal instillation of dexmedetomidine 1 $\mu g/kg$ in combination with Bupivacaine 0.25% in elective laparoscopic cholecystectomy significantly reduces the postoperative pain and significantly reduces the analgesic requirement in postoperative period as compared to fentanyl 1 $\mu g/kg$ in combination with Bupivacaine.

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