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Efficacy of Injection Ketamine and Injection Dexmedetomidine for Relief of Shoulder Pain in Laparoscopic Appendectomy Under Spinal Anaesthesia.

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ABSTRACT

Background: Laparoscopic appendectomy is preferred because of increasing popularity and certain benefits over open method. Laparoscopic surgeries are conventionally done under general anaesthesia with positive pressure ventilation to avoid shoulder pain, respiratory embarrassment and abdominal discomfort caused by pneumoperitoneum. The data regarding use of spinal anaesthesia for laparoscopic appendectomy is limited. This study was designed to evaluate laparoscopic appendectomy under spinal anaesthesia along with the use of intravenous injection ketamine and intravenous injection dexmedetomidine. Objectives of this study were to observe efficacy of both drugs in reducing shoulder pain, need of rescue analgesia, need of conversion to open method due patient discomfort, changes in hemodynamic parameters, postoperative nausea and vomiting. **Methods:** After approval of ethical committee of institute , 100 patients of age group between 18-60 years with ASA grade I or II undergoing laparoscopic appendectomy with written informed consent were included in this study .All patients were informed about standard spinal anaesthesia technique in detail and also about the risk of conversion to general anaesthesia.Spinal anaesthesia procedure was carried out with hyperbaric injection bupivacaine 0.5% . Patients were randomized in two groups. One is Group K (n=50) patients who received injection Ketamine and other is Group D (n=50) patients who received injection Dexmedetomidine intravenously.Intraoperative hemodynamic parameters,shoulder pain,abdominal discomfort,need of rescue analgesia ,postoperative recovery were monitored and recorded. **Results:** No patients during study required conversion to general anaesthesia or open method. VDS(verbal descriptive scale) score for referred shoulder pain was statistically lower in group K compared to group D.Group D was associated with statistically significant lower heart rate and blood pressure than Group K. **Conclusion:** Injection ketamine and injection dexmedetomidine, both drugs are efficacious for reduction of referred shoulder pain with more hemodynamic stability in ketamine group during laparoscopic appendectomy.

Keywords: Dexmedetomidine, Laparoscopic appendectomy, Ketamine, Referred shoulder pain, hemodynamic stability.

INTRODUCTION

Acute appendicitis is one of the most common causes of acute abdominal pain and open appendectomy was the standard treatment for acute appendicitis.[1-3] The introduction of laparoscopic technique has revolutionized surgical field.[4] Open appendectomy has been gradually replaced by laparoscopic appendectomy because of its certain benefits such as reduced bleeding, better cosmetic outcome, less postoperative complications, early recovery, reduced hospital stay and overall reduction in medical costs.[5] Conventionally, laparoscopic surgeries are done under general anaesthesia with endotracheal intubation to avoid respiratory embarrassment due to pneumoperitoneum.[6] As general anaesthesia is associated with certain side effects like stress response, postoperative nausea and vomiting, inadequate analgesia,[7] its conventional use for laparoscopic surgeries needs a relook.

Recently, regional anaesthesia has been documented to be equally favorable in laparoscopic surgeries. Many studies showed that laparoscopic surgery can be done safely under spinal anaesthesia Main advantages of spinal anaesthesia are awake,[8,9] spontaneously breathing patient with no need of airway manipulation, profound muscle relaxation, less incidence of postoperative nausea vomiting, effective postoperative analgesia and shorter recovery time.[10] Shoulder pain and abdominal discomfort are common complications of the laparoscopic surgeries that can be alleviated by adding various adjuvants to local anesthetics or by

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giving sedative analgesics during spinal anaesthesia.[11-13]

Ketamine, a NMDA receptor blocker, is a well-known anesthetic agent for its property of providing profound analgesia and sedation.[13-15] Dexmedetomidine is a newer alpha-2 adrenergic agonist which provides sympatholysis, conscious sedation, anxiolysis and analgesia without respiratory depression. There are studies showing the use of intravenous as well as intrathecal dexmedetomidine as an adjuvant to hyperbaric bupivacaine for shoulder pain during laparoscopic surgery.[12,16] But there are very few studies regarding use of sedative and analgesics for shoulder pain in laparoscopic appendectomies under spinal anaesthesia. So, considering above references this study was designed to evaluate the efficacy of injection ketamine and injection dexmedetomidine intravenously in laparoscopic appendectomy under spinal anaesthesia.

This study was designed to evaluate efficacy of injection ketamine and injection dexmedetomidine intravenously in laparoscopic surgeries under spinal anaesthesia. The primary objectives were to study the efficacy for relief of shoulder pain, conversion to general anaesthesia due to unrelieved discomfort and need for rescue analgesia after 2 hours surgery .The secondary objectives were to study the effects on hemodynamic parameters intraoperatively, postoperative nausea vomiting and side effects if any in both groups.

MATERIALS AND METHODS

After receiving approval from the ethical committee of Government Medical College Miraj Institute,100 patients of either sex in the age group of 18-60 years, belonging to American Society of Anesthesiologists (ASA) physical status I or II scheduled for laparoscopic appendectomy during March 2016 to March 2018 with written informed consent were enrolled in this study. The Exclusion criteria for this study were 1] patient refusal for spinal anaesthesia 2] contraindications to spinal anaesthesia 3] known allergy or hypersensitivity to local anesthetics 4] ASA grade > II 5] duration of surgery >120min 6] patients on medication causing bradycardia 7] patients with major cardiac, respiratory, liver and renal disease.

A thorough preanasthesia examination along with all routine blood investigations and other investigations as per need were carried out. Standard spinal anaesthesia technique and visual analogue scale for pain (VAS) [0=no pain 2 = mild pain 4=moderate pain 6=severe pain 8=extreme pain 10=worst pain] were explained in detail in language that patients could understand. Also, all patients were informed about the possibility of conversion to general anesthesia at any point of time intraoperatively due to any cause like persistent pain even after sedation, adequate analgesia, patients' request or surgical factors.

In the operating room, written informed consent for surgery and anaesthesia were checked. All the standard monitors like non-invasive blood pressure (NIBP), electrocardiography (ECG) and pulse oximetry (SpO2)] were attached to patients and baseline parameters were recorded. Ringer's lactate solution was started after securing 20 G intravenous (IV) catheter. Premedication was given with Injection Ranitidine 1mg/kg, Injection Ondansetron 0.1mg/kg as antiemetic regimen, Injection Glycopyrrolate 4mcg/kg as antisialogouge regimen, Injection Midazolam 0.02mg/kg as anxiolytic agent intravenously, injection pentazocine 0.3mg/kg intravenously.

Standard spinal anesthesia technique was carried out under all aseptic precautions with 25 gauge quincke's spinal needle with 0.5% hyperbaric bupivacaine in right lateral position. The dosage to be injected intrathecally was determined considering patients' height, weight, and age and target sensory level of anaesthesia (T4). Then patient's position was immediately changed to supine. The sensory block was assessed by pinprick test using 24 gauge hypodermic needle and the motor blockade was assessed by bromage scale(0=no motor blockade,1=unable to raise extended legs,2=unable to flex knees,3=unable to flex ankle) in consideration of our target sensory level of anaesthesia (T4) and complete abdominal muscle relaxation.

Group D (n=50): After properly assessing and fixing spinal anaesthesia level, infusion of injection dexmedetomidine 1mcg/kg over 10 min started and followed by maintenance dose 0.4 mcg/kg/hr.

Group K (n=50): After properly assessing and fixing spinal anaesthesia level, before the start of pneumoperitonium, injection ketamine 0.5 mg/kg was given intravenously. If any patient experienced pain or discomfort according to VAS score additional dose of injection ketamine was repeated.

All patients were provided with supplemental oxygen via a face mask at a rate of 2-4 L.min−1 to keep saturation more than 95%.Surgeons were requested to apply minimum possible intra-abdominal carbon dioxide pressure for pneumoperitoneum around 12 mmHg. All patients were monitored for blood pressure, heart rate, ECG, oxygen saturation, CO2 level changes, shoulder pain and recorded every 15 min till the end of surgery.

Bradycardia was defined as a heart rate of less than 60 beats/minute and was treated with 0.6 mg of intravenous atropine. Hypotension was defined as systolic blood pressure < 90 mmHg or less than 20% of baseline record and was treated with 50-100 ml bolus of intravenous crystalloid fluid or injection mephentermine 6 mg in bolus doses. Rescue analgesia was given with injection diclofenac 75 mg intravenously to the patients experiencing shoulder pain postoperatively with VDS ≥4.

RESULTS

Statistical analysis:

Statistical software MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyze data. Graphical representation of data: MS Excel and MS word was used to obtain various types of graphs such as bar diagram. P value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Table 1: Age distribution comparison between two groups

		Age		P value
		Mean	SD	
Group	Group K	26.88	12.52	0.625
	Group D	25.82	8.80	

In Group K, mean age of subjects was 26.88 ± 12.52 years and in Group D, mean age of subjects was 25.82 ± 8.80 years. There was no significant difference in age distribution between two groups.

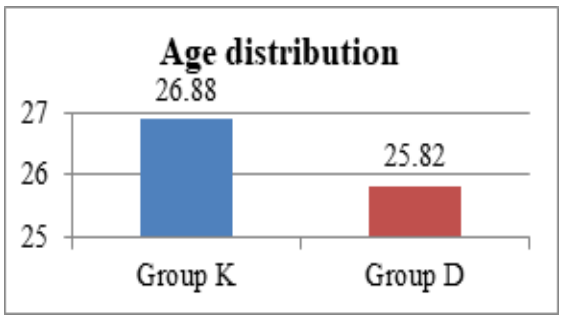

Figure 1: Bar diagram showing Age distribution comparison between two groups

Table 2: Sex distribution comparison between two groups

		Group				P value
		Group K		Group D		
		Count	%	Count	%	
Sex	Female	30	60.0%	32	64.0%	0.680
	Male	20	40.0%	18	36.0%	

In Group K, 60% were females and 40% were males and in Group D, 64% were females and 36% were males.

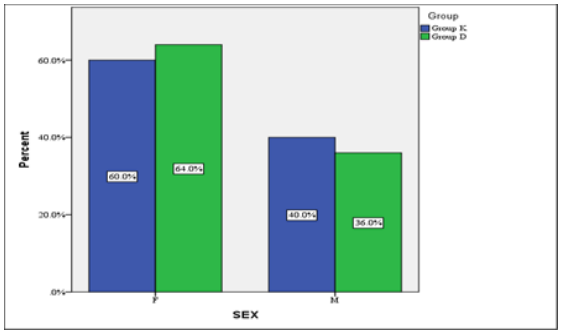

Figure 2: Bar diagram showing Sex distribution comparison between two groups

Table 3: GA requirement and Conversion to open comparison between two groups

		Group				P value
		Group K		Group D		
		Count	%	Count	%	
Requiring GA	No	50	100.0 %	50	100.0 %	-
Conversion to open	No	49	98.0%	45	90.0%	0.092
	Yes	1	2.0%	5	10.0%	

In both groups, none of them required GA. In Group K, 2% were converted to open surgery and in Group D, 10% converted to open surgery due to surgical factors. There was no significant difference in conversion to open between two groups.

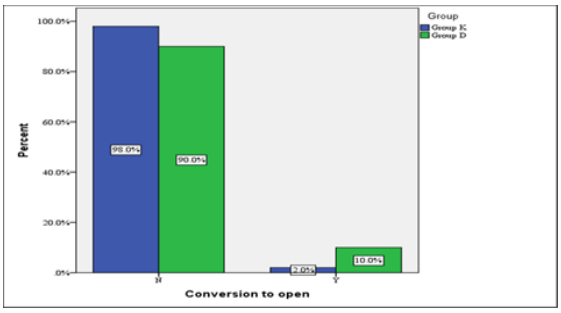

Figure 3: Bar diagram showing Conversion to open comparison between two groups

Table 4: SBP and DBP comparison between two groups

	Group				P value
	Group K		Group D		
	Mean	SD	Mean	SD	
Systolic	113.18	10.76	106.04	13.50	0.004*
Diastolic	73.98	7.68	69.32	10.75	0.014*

Mean SBP in Group K was 113.18 ± 10.76 and in Group D was 106.04 ± 13.50 mmHg. Mean DBP in Group K was 73.98 ± 7.68 and in Group D was 69.32 ± 10.75 mmHg. There was significant difference in SBP and DBP between two groups.

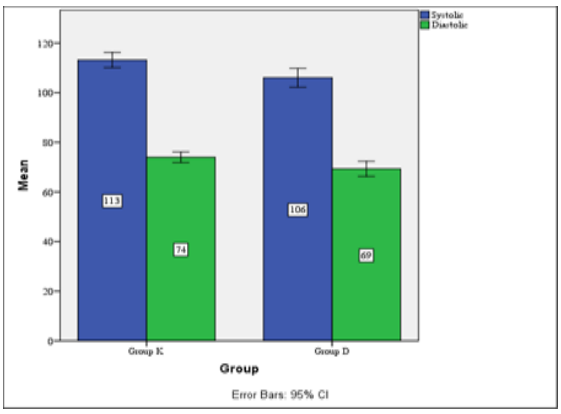

Figure 4a: Bar diagram showing SBP and DBP comparison between two groups

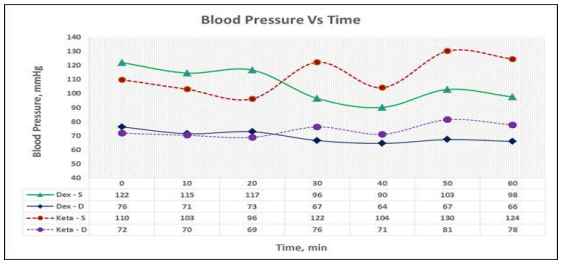

Figure 4b: Graphical presentation of variation of SBP and DBP with time in two groups

Table 5: Pulse rate comparison between two groups

	Group				P value
	Group K		Group D		
	Mean	SD	Mean	SD	
Pulse rate	77.52	8.27	75.42	13.15	0.342

In Group K, mean PR was 77.52 ± 8.27 and in Group D, mean PR was 75.42 ± 13.15. There was no significant difference in Pulse rate between two groups.

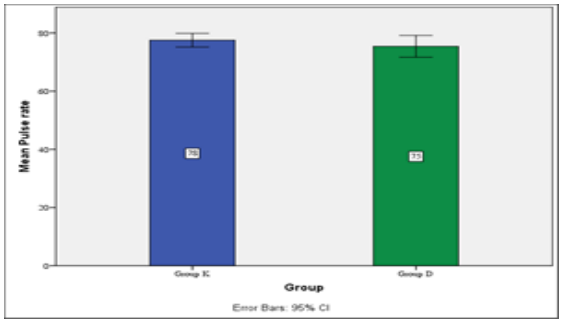

Figure 5: Bar diagram showing Pulse rate comparison between two groups

Table 6: Shoulder pain comparison between two groups

		Group				P value
		Group K		Group D		
		Count	%	Count	%	
Shoulder Pain	No	45	90.0 %	42	84.0 %	0.372
	Yes	5	10.0 %	8	16.0 %	

In Group K, 10% had shoulder pain and in Group D, 16% had Shoulder pain. There was no significant difference in shoulder pain between two groups.

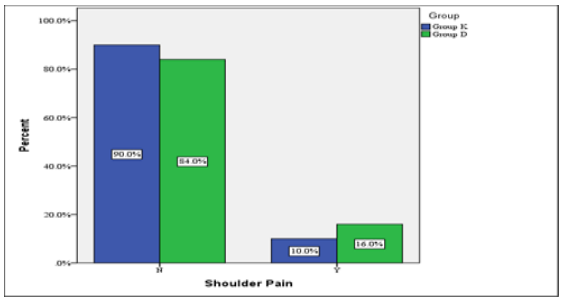

Figure 6: Bar diagram showing Shoulder pain comparison between two groups

Table 7: Nausea/Vomiting and Rescue analgesia between two groups

		Group				P value
		Group K		Group D		
		Count	%	Count	%	
Nausea/Vomiting	No	50	100.0 %	50	100.0 %	-
Rescue Analgesia	No	45	90.0 %	42	84.0 %	0.372
	Yes	5	10.0 %	8	16.0 %	

In Both groups, none of them had nausea and vomiting. In Group K, 10% required Rescue Analgesia and in Group D, 16% required Rescue Analgesia after 2 hours of surgery. There was no significant difference in Rescue Analgesia between two groups.

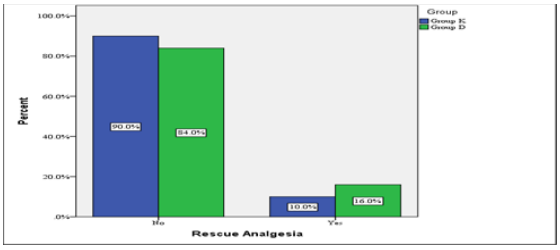

Figure 7: Bar diagram showing Rescue analgesia between two groups

Table 8: Repeat dose of Ketamine among Group K

		Group	
		Group K	
		Count	%
Repeat dose of Ketamine	No	45	90.0%
	Yes	5	10.0%

In Group K, 10% required Repeat dose of Ketamine.

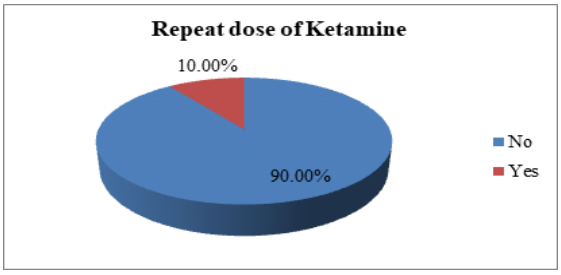

Figure 8: Pie diagram showing Repeat dose of Ketamine among Group K

DISCUSSION

Laparoscopic surgeries are conventionally performed under general anaesthesia with endotracheal intubation.[6] During laparoscopic surgeries, pneumoperitoneum is created with insufflation of carbon dioxide and trendelenburg position is given for better visualization of operative field. This may cause upward displacement of diaphragm and respiratory embarrassment. General anaesthesia has its own disadvantages such as pressor response to intubation, sore throat, increased release of stress hormones, postoperative nausea and vomiting, inadequate postoperative analgesia.[6,7]

Some reports and studies of regional anaesthesia being used for laparoscopic surgeries are documented.[8-10] There are studies supporting growing evidences that patients of ASA grade1 and 2 without any preexisting respiratory disease can tolerate laparoscopic procedures very well without any complications under regional anaesthesia.[10]

Stretching of peritoneum and collection of blood or CO2 under diaphragm cause diaphragmatic irritation and discomfort. As the diaphragm is supplied by phrenic nerve, pain is referred to shoulder due to common root value C3,C4,C5.[11,12] Major concerns during the use of regional anesthesia for any laparoscopic surgery are proper management of shoulder pain, discomfort and anxiety along with hemodynamic stability. Shoulder pain is very common troublesome problem during laparoscopic surgeries under regional anaesthesia. Overall, reported rate of conversion of regional anaesthesia to general anaesthesia due to shoulder pain has been 0-37.1%for laparoscopic cholecystectomies.[17,18] Several studies have been conducted for relief of shoulder pain during laparoscopic surgery under spinal anaesthesia.[9,10] However, very few studies are there on use of injection ketamine and injection dexmedetomidine infusion for shoulder pain relief in laparoscopic appendectomy.[12-14]

In this study, we enrolled 100 patients of ASA grade 1 and 2 posted for laparoscopic appendectomy under spinal anaesthesia with either intravenous injection ketamine or intravenous dexmedetomidine infusion.

Ketamine is structural analogue of phencyclidine having multiple effects throughout the central nervous system, inhibiting polysynaptic reflexes in spinal cord and selected areas of brain. It acts as an antagonist at NMDA (N-methyl D-aspartate) receptor.[13,15] Dexmedetomidine acts on alpha-2 adrenergic receptors which results in mainly two pharmacological mechanisms: 1)Efflux of potassium ions causes hyperpolarization of the excitable cell membrane which in turn decrease neuronal firing 2) Suppression of calcium ion entry causing decrease in release of neurotransmitter and terminating pain signals. Analgesic and sedative properties of dexmedetomidine are expected to resolve the shoulder pain and abdominal discomfort during laparoscopic surgery under spinal anaesthesia.

There are two studies reporting 24 out of 60 patients and 8 out of 26 patients complaining of referred shoulder pain while using intravenous dexmedetomidine.[16,17] Even in our study, we also observed in group D, 8 patients out of 50 complaining of shoulder pain. In Group K, 5 out of 50 had shoulder pain. There was no significant difference in shoulder pain between two groups. These were managed with additional dose of injection ketamine and infusion of dexmedetomidine according to severity of shoulder pain.

Hypotension and bradycardia are common adverse effects associated with dexmedetomidine as well as with spinal anesthesia. The incidence of dexmedetomidine-related hypotension and bradycardia were 30% and 9%, respectively, in a phase-III study of 401 patients.[18] In another study as the dose of dexmedetomidine increases ,the incidence of hypotension, but not of bradycardia, increases.[19] In contrast, a meta-analysis study showed that dexmedetomidine use during spinal anesthesia is associated with more frequent bradycardia but did not increase the incidence of hypotension.[20] In another study too there was a higher incidence of bradycardia than hypotension.[17]

In our study, we observed 15 out of 50 patients developed hypotension and 8 out of 50 patients had bradycardia in dexmedetomidine group i.e. incidence of hypotension was higher than bradycardia. While in ketamine group 5 out of 50 patients developed hypotension and in 2 patient's bradycardia was noticed. Mean SBP in Group K was 113.18 ± 10.76 and in Group D was 106.04 ± 13.50 mmHg. There was significant difference in SBP between two groups. Mean DBP in Group K was 73.98 ± 7.68 and in Group D was 69.32 ± 10.75 mmHg. There was significant difference in DBP between two groups there was significant difference in evidence of Hypotension but not in bradycardia between two groups. Hypotension was treated with fluid boluses and injection mephentermine 6 mg and bradycardia responded well to injection atropine 0.6mg.

In our study none of patients complained of nausea and vomiting postoperatively which is a commonly observed complication in case of general anaesthesia. This study result correlates with the another study in which patients receiving spinal anaesthesia, there was 11 fold decreased risk for nausea and vomiting compared to general anaesthesia.[21] All laparoscopic appendectomies enrolled in this study were completed under spinal anaesthesia. None of the procedure required conversion to general anaesthesia due to any reason.

There was no significant difference in conversion to open between two groups. 5 patients in dexmedetomidine group (10%) and 1 patient in ketamine group(2%) were converted to open technique due to surgical factors but procedure was completed under spinal anaesthesia only. In Group K, 10% required Rescue Analgesia and in Group D, 16% required Rescue Analgesia after 2 hours. There was no significant difference in Rescue Analgesia requirement between two groups.

CONCLUSION

Our study concluded that both injection ketamine and injection dexmedetomidine are feasible for relief of shoulder pain during laparoscopic appendectomy under spinal anaesthesia. Injection Ketamine is more effective than dexmedetomidine infusion for relief of

shoulder pain during laparoscopic appendectomy under spinal anaesthesia although statistically it is not significant. Injection Dexmedetomidine infusion was associated with more hemodynamic alteration with more incidence of hypotension. However careful monitoring and adequate dose adjustment overcame these problems. There was no significant difference in Rescue Analgesia requirement between two groups.

There were several limitations to this study. This observational study was done in very small population. There was no control group or placebo for comparison. We did not evaluate effects of various maintenance doses of dexmedetomidine (0.2-0.7mcg/kg/hr).

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