

# Multimodal versus Conventional Approach for Postoperative Pain Relief in Oral Cancer Patients

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## ABSTRACT

**Introduction:** Multimodal analgesia includes regional anaesthesia in the form of nerve block may improve recovery along with optimal rehabilitation and early resumption of day-to-day activity following major surgery. Conventional general anaesthesia consists of premedication, induction, intubation and maintenance.

**Aim:** The aim of the study is to compare the multimodal versus conventional approach in oral cancer surgery.

**Materials and Methods:** The patients were randomly allocated into three groups, 30 patients in each group using the computer generated random table to one of the following groups: Group A: Fentanyl 1 µg/kg, Group B: Fentanyl 1 µg/kg + bupivacaine local infiltration, Group C: Fentanyl 1 µg/kg + bupivacaine local infiltration + Dexmedetomidine infusion (Loading 0.5 µg/kg, Maintenance 0.2µg/kg/hr).

**Results:** No significant ( $p>0.05$ ) difference was found in mean arterial pressure and heart rate at different time intervals among the groups. The VAS was lower in Group C than Group B and A. The Ramsay sedation scale was higher in Group C than Group B and A. The rescue analgesic for 24 hour was lower in Group C than Group B and A. The time of first time analgesia requirement was significantly ( $p=0.001$ ) higher in Group C than Group B and A. The rescue analgesic was significantly ( $p=0.001$ ) lower in Group C ( $39.29\pm 19.67$ ) than Group B ( $68.33\pm 18.49$ ) and A ( $160.83\pm 35.16$ ).

**Conclusion:** Multimodal analgesia has beneficial haemodynamic effects during oral cancer surgery with reliable postoperative analgesia and sedation and less postoperative complication. Dose of drugs used in our study is not associated with any major adverse effect.

**Keywords:** General anaesthesia, Haemodynamic effects, Multimodal analgesia

## INTRODUCTION

Despite advances in radiotherapy and chemotherapy, surgery remains the mainstay of treatment for cancer. Now-a-days, more conservative approach is used in removal of tumours and efforts are made to preserve as much normal oral cavity structure and function as possible. Multimodal analgesia is recommended for the treatment of pain in cancer and postsurgical patients. It is achieved by different analgesics that act through different mechanisms and at different sites in the nervous system. It results in synergistic analgesia with minimal adverse effects [1]. It also refers to concurrent application of analgesic in combination with regional analgesia [2]. Multiple drugs which act on different sites of pain pathway with different mechanism of action leads to better haemodynamic control, good quality of analgesia intra operatively and postoperatively, minimising dose of analgesic, reduced side effects, early mobilisation and recovery, shortened hospital stay, reduced hospital costs.

Multimodal analgesia, which involves nerve block for regional anaesthesia, hastens recovery and rehabilitation, enabling the patient to return back to his daily life after a major surgery [3]. It also reduces health care resources, minimizes cost, improve outcome by reducing opioid use for optimal pain control. Use of preemptive analgesia and multimodal technique, results in better pain management [4,5].

Conventional general anaesthesia comprises premedication by iv fentanyl, induction by iv propofol, intubation is facilitated by iv succinylcholine, and maintained by oxygen, nitrous, oxide isoflurane and iv vecuron, with the use of iv paracetamol and tramadol for postoperative pain.

General anaesthesia is accompanied by regional anaesthesia which is administered once the patient is induced, so the patient does not experience the pain of the local anaesthesia administration. Once the procedure is completed and the general anaesthesia is discontinued, the patient is awake and experiences no pain of surgery. This gives time to an analgesic to start working, before the pain begins [6].

Dexmedetomidine is a drug commonly used in multimodal analgesia. It is a new generation highly selective  $\alpha_2$  adrenoreceptor agonist that dose-dependently reduces blood pressure and heart rate, produces an anaesthetic-sparing effect, decreases the total amount of intraoperative fentanyl and propofol and has a sedative and analgesic effect without the unwanted vascular effects from activation of  $\alpha_1$  receptors [7-9]. The present study was designed to compare the multimodal approach versus conventional general anaesthesia in oral cancer surgery.

## MATERIALS AND METHODS

### Study Design and Patients

This was a randomised, prospective, clinical trial conducted in a King George's Medical University, Lucknow, India from January 2014 to November 2015. The study was approved by the ethical committee of the institute and consent was taken from each patient/ attendant before enrolling in the study. Patients aged 18-70 years, either sex, ASA physical status I or II and planned for oral cancer surgeries under general anaesthesia were included in the study. The patients recently given chemotherapy, cardiovascular diseases, use of  $\beta$  blocker & ACE inhibitor, ASA III and IV, severe pulmonary diseases, chronic pain syndrome and inability to communicate with the patient due to any reason were excluded from the study.

### Study Groups

The patients were randomly allocated into three groups, 30 patients in each group using the computer generated random table to one of the following groups.

Group A: Fentanyl 1 µg/kg.

Group B: Fentanyl 1 µg/kg + bupivacaine local infiltration.

Group C: Fentanyl 1 µg/kg + bupivacaine local infiltration + Dexmedetomidine infusion (Loading 0.5 µg/kg, Maintenance 0.2µg/kg/hr).

All patients scheduled for surgery were given tablet ranitidine 150 mg and alprazolam 0.5 mg per orally in the night before surgery.

All patients were fasted for six hours. After arrival in the operating room, standard monitoring like pulse oximetry, non invasive blood pressure, electrocardiography and temperature was started and baseline cardio-respiratory parameters were noted.

All the patients were catheterised per urethrally for monitoring output. Baseline heart rate, mean arterial pressure and oxygen saturation were recorded. An 18 gauze intravenous access was secured and patients were preloaded with lactated ringer solution 10 ml/kg of body weight. Dexmedetomidine was prepared in concentration of 2µg/ml by taking 1 ml (100µg/ml) in 50 ml normal saline. Patients were pre-medicated with intravenous ondansetron 4 mg, glycopyrrolate 0.2 mg and fentanyl 1µg/kg.

In all groups, after preoxygenation general anaesthesia was induced with propofol 2 mg/kg intravenous. Endotracheal intubation was facilitated by succinylcholine 2 mg/kg intravenously. After intubation anaesthesia was maintained with oxygen and nitrous oxide in ratio of 40:60, isoflurane was given at 0.2-1.16 Vol% and muscle relaxation was maintained by vecuronium bromide 0.1 mg/kg loading and 0.02 mg/kg intermittently there after. Controlled mechanical ventilation was done to maintain end tidal CO<sub>2</sub> between 30-40 mmHg by using anaesthesia ventilator. The following parameters were monitored intraoperatively: non invasive arterial blood pressure, electrocardiography, capnography, pulse oximetry, temperature and urine output. Blood pressure and heart rate was kept within 20% of base line value by using isoflurane upto 0.2- 1.16 vol % and fentanyl repeat doses 1µg/kg hourly. In group B after aseptic preparation of skin, C-ARM guided nerve blocks (Maxillary, Mandibular, Glossopharyngeal.) were performed in anaesthetised patient with 5 ml 0.5% bupivacaine before initiating surgery.

In group C, dexmedetomidine in dose of 0.5 µg/kg (loading dose) diluted in 50ml normal saline was given slow intravenous infusion over 15 min before induction and 0.2µg/kg/hr in 50 ml saline (maintenance dose) intraoperatively and stopped just before skin suturing, while giving dexmedetomidine, simultaneously after aseptic preparation of skin, nerve blocks were performed in anaesthetised patient before surgery with the help of C-ARM by giving five ml, 0.05% bupivacaine. Patients were monitored while premedicated with dexmedetomidine over 15 min. Patient were observed at specific end point (after premedication, at induction, at intubation, 5 minutes after intubation, while giving skin incision, at the point of extubation).

At the end of surgery, residual neuromuscular block was reversed by neostigmine in dose of 0.04-0.08mg/kg and glycopyrrolate in dose of 0.2mg per mg of neostigmine intravenously in all groups. Extubation was done after adequate reversal of neuromuscular blockade. Patients were shifted to recovery room.

Patient sedation score were noted according to Ramsay sedation score at the end of surgery at 1, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24 hour. Pain was assessed on 10 point Visual Analogue Score (VAS) at the end of surgery at 1, 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24 hour. Incidence of postoperative nausea and vomiting and use of any drug for pain, vomiting and any other side effects were noted.

Rescue medication in postoperative room for pain was paracetamol 1 gm infusion, and it was repeated when needed, while for nausea and vomiting injection ondansetron was given. Patients were observed in the postoperative room for 24 hour, if a patient still complained of pain, inj., tramadol 1mg/kg body weight was given as second line of analgesic and study was terminated. The amount of tramadol administered, paracetamol administered after surgery, time to first analgesic dose, total requirement of paracetamol in 24 hour and incidence of any intra operative or postoperative adverse events were documented and treated accordingly.

Degree of surgeon's and patient's satisfaction for postoperative analgesia and incidence of side effects were assessed by using a 7 point Likert verbal rating scale.

## STATISTICAL ANALYSIS

The results are presented in mean±SD and percentages. The Chi-square test was used to compare the categorical/dichotomous variables. The one-way analysis of variance (ANOVA) was used to compare the parameters among the groups followed by Tukey's post-hoc comparison test. The p-value<0.05 was considered significant. All the analysis was carried out by using SPSS 16.0 version (Chicago, Inc., USA).

## RESULTS

The mean age of the patients of Group A, Group B and Group C were 50.53±12.45, 44.67±12.09 and 49.77±13.14 years. Majority in all the groups were males. The weight of the patients and duration of surgery among the groups were similar (p>0.05). Thus, all the groups were comparable in terms of age, gender, weight and duration of surgery [Table/Fig-1].

	Group A (n=30)	Group B (n=30)	Group C (n=30)	p-value
Age (years)	50.53±12.45	44.67±12.09	49.77±13.14	0.15 <sup>1</sup>
Gender				
Male	21 (70.0%)	23 (76.7%)	25 (83.3%)	0.47 <sup>2</sup>
Female	9 (30.0%)	7 (23.3%)	5 (16.7%)	
Weight (kgs)	56.57±7.26	57.90±6.79	60.63±6.15	0.07 <sup>1</sup>
Duration of surgery (hrs)	3.51±0.59	3.43±0.55	3.62±0.58	0.47 <sup>1</sup>

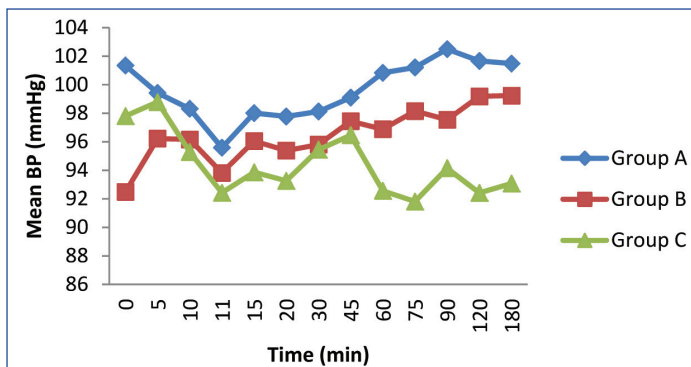
**[Table/Fig-1]:** Basic characteristics of the patients.  
<sup>1</sup>ANOVA test, <sup>2</sup>Chi-square test

The analysis of variance revealed that there was significant difference in rescue analgesic (Tramadol) for 24 hour among the groups. The post-hoc comparison test revealed that the rescue analgesic for 24 hour was lower among the patients of Group C than Group B and A. There was significant (p=0.0001) difference in the first time requirement of analgesia among the groups. The time of first time analgesia requirement was significantly (p=0.001) higher in Group C than Group B and A. The rescue analgesic was significantly (p=0.001) lower among the patients of Group C (39.29±19.67) than Group B (68.33±18.49) and A (160.83±35.16). The total top up doses of fentanyl intraoperatively was significantly (p=0.0001) lower among the patients of Group C (0.10±0.30) than Group B (2.10±0.66) and A (2.50±0.50). The mean isoflurane concentration use intraoperatively was significantly (p=0.001) lower among the patients of in Group C (0.15±0.05) than Group B (0.57±0.16) and A (0.65±0.15). The mean satisfaction score was significantly (p=0.0001) higher among the patients of Group C than Group B and A in both surgeon and patients [Table/Fig-2].

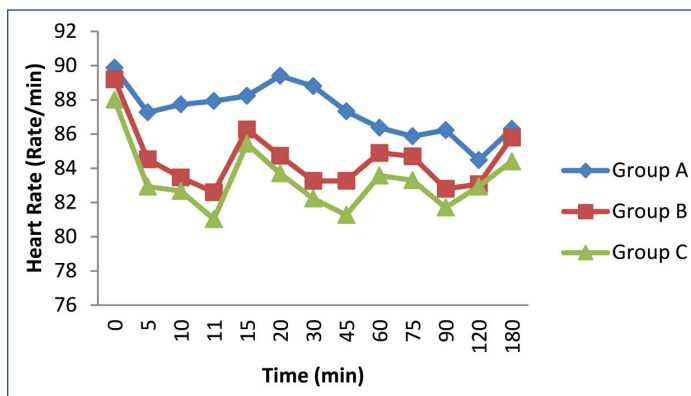
	Group A (n=30)	Group B (n=30)	Group C (n=30)	p-value <sup>1</sup>
Rescue analgesic for 24 h	2.33±0.71 <sup>b</sup>	1.97±0.44 <sup>a</sup>	1.12±0.35 <sup>ab</sup>	0.001 <sup>1</sup>
First time requirement of analgesic (h)	2.10±0.75 <sup>a</sup>	4.97±0.55	6.47±0.57 <sup>a</sup>	0.001 <sup>1</sup>
Rescue analgesic (Tramadol in mg) for 24 h	160.83±35.16 <sup>a</sup>	68.33±18.49 <sup>b</sup>	39.29±19.67 <sup>ab</sup>	0.001 <sup>1</sup>
Top up doses of fentanyl intraoperatively	2.50±0.50 <sup>a</sup>	2.10±0.66 <sup>b</sup>	0.10±0.30 <sup>ab</sup>	0.001 <sup>1</sup>
Mean isofluraneconc use intraoperatively (vol%)	0.65±0.15 <sup>a</sup>	0.57±0.16 <sup>b</sup>	0.15±0.05 <sup>ab</sup>	0.001 <sup>1</sup>
Surgeon's Satisfaction	3.30±0.46 <sup>a</sup>	5.23±0.43 <sup>a</sup>	6.43±0.50 <sup>a</sup>	0.001 <sup>1</sup>
Patient's Satisfaction	3.20±0.40 <sup>a</sup>	5.17±0.37 <sup>a</sup>	6.57±0.50 <sup>a</sup>	0.001 <sup>1</sup>

**[Table/Fig-2]:** Comparison of study parameters among the groups.  
<sup>1</sup>ANOVA test, <sup>a,b</sup>Post hoc comparison test in between group  
<sup>\*</sup> significant

The Mean arterial pressure (MAP) was comparable at the baseline (p>0.05). There was no significant (p>0.05) difference in MAP at 5



[Table/Fig-3]: Mean Blood Pressure Summary



[Table/Fig-4]: Heart rate Summary

min, 10 min, 15 min, 30 min and 45 min among the groups. However, there was significant ( $p < 0.05$ ) difference in MAP (intraoperative) among the groups at 15 min, 20 min, 60 min, 75 min to 180 min. The MAP (postoperative) was observed to lower in Group C than Group B and A [Table/Fig-3]. The heart rate was comparable at the baseline ( $p > 0.05$ ). There was no significant ( $p > 0.05$ ) difference in heart rate at 5, 10, 15, 20, 60, 75, 120 minutes among the groups. However, there was significant ( $p < 0.05$ ) difference in heart rate among the groups at 11, 30, 45 and 90 minutes. The heart rate was observed to lower in Group C than Group B and A [Table/Fig-4]. There was no significant difference in  $SPO_2$  among the groups at baseline and subsequent time intervals. The VAS was comparable at the baseline among the groups. There was significant difference in VAS among the groups at two hours to 24 hours. The VAS was lower among the patients of Group C than Group B and A [Table/Fig-5]. The Ramsay Sedation Score (RSS) was comparable at the baseline among the groups. There was significant difference in RSS among the groups at two hours to 24 hours. The RSS was higher among the patients of Group C than Group B and A [Table/Fig-6].

The nausea/vomiting were lower among the patients of Group C (6.7%) than Group B (23.3%) and Group A (70%). The shivering was present in 40% patients in Group A, 33.3% in Group B and 6.7% in Group C. The hypotension was seen only in Group C of 3.3% patients. Bradycardia was in 3.3% of Group B and in 6.7% of Group C [Table/Fig-7].

## DISCUSSION

In the present study, there was no significant difference in MAP at 5, 10, 11, 30 and 45 minutes among the groups. However, there was significant difference in MAP among the groups at 15, 20, 60, 75 to 180 minutes. The MAP was observed to be lowest in Group C and highest in Group A. However, a significant difference was found in heart rate among the groups at 11, 30, 45 and 90 minutes. The HR was observed to be lowest in Group C and highest in Group A. The findings of the present study are similar to other studies [10-12].

In this study, the mean requirement of intraoperative isoflurane and fentanyl to maintain blood pressure and heart rate within 20%

Time interval	Group A (n=30)		Group B (n=30)		Group C (n=30)		p-value <sup>1</sup>
	Mean	SD	Mean	SD	Mean	SD	
1 h	1.83	1.289	1.34	.450	1.33	.547	0.13
2 h	3.70	2.070	1.54	.861	1.53	.571	0.001*
4 h	5.73	0.691	3.13	.860	1.57	.504	0.001*
6 h	5.33	0.547	3.67	1.093	3.20	1.495	0.001*
8 h	4.97	0.718	4.03	1.245	1.73	.785	0.001*
10 h	5.90	.803	2.80	.997	2.57	1.431	0.001*
12 h	3.70	1.022	3.57	.679	2.77	1.251	0.001*
14 h	4.47	.507	4.07	.828	2.17	.986	0.001*
16 h	4.13	.681	1.97	.626	1.87	.860	0.001*
18 h	5.40	.968	2.60	.498	1.80	.805	0.001*
20 hrs	4.53	.973	4.13	.730	1.60	.724	0.001*
22 h	2.33	.844	2.13	.629	1.60	.675	0.001*
24 h	5.07	.944	4.40	.621	1.80	.761	0.001*

[Table/Fig-5]: Comparison of VAS among the group at different time intervals in postoperative period  
<sup>1</sup>ANOVA test, \*Significant

Time interval	Group A (n=30)		Group B (n=30)		Group C (n=30)		p-value <sup>1</sup>
	Mean	SD	Mean	SD	Mean	SD	
1 h	2.40	0.498	2.47	0.681	2.60	0.968	0.13
2 h	1.70	0.466	2.37	0.490	3.47	0.937	0.01*
4 h	1.50	0.509	2.50	0.509	3.60	0.855	0.01*
6 h	1.77	0.430	2.37	0.556	3.17	10.206	0.01*
8 h	1.93	0.583	2.50	0.509	3.17	0.699	0.01*
10 h	2.00	0.587	2.90	0.548	3.33	0.802	0.01*
12 h	2.00	0.455	2.70	0.596	3.10	0.885	0.01*
14 h	2.13	0.346	3.37	0.556	3.27	0.828	0.01*
16 h	2.10	0.305	3.00	0.743	3.43	0.898	0.01*
18 h	2.13	0.346	2.87	0.681	3.00	0.788	0.01*
20 h	2.00	0.000	3.10	0.712	3.43	0.817	0.01*
22 h	2.13	0.346	2.73	0.640	3.40	0.724	0.01*
24 h	2.20	0.484	3.00	0.695	3.50	0.974	0.01*

[Table/Fig-6]: Comparison of Ramsay sedation score among the group at different time intervals  
<sup>1</sup>ANOVA test, \*Significant

Complications	Group A n (%)	Group B n (%)	Group C n (%)
Nausea/vomiting	7 (70)	7 (23.3)	2 (6.7)
Shivering	12 (40)	10 (33.3)	2 (6.7)
Hypotension	0 (0.0)	0 (0.0)	1 (3.3)
Bradycardia	0 (0.0)	1 (3.3)	2 (6.7)

[Table/Fig-7]: Adverse effects

of base line was significantly low among the patients in which multimodal approach was given in the form of dexmedetomidine, nerve block along with fentanyl i.e. Group C, in comparison to nerve block with fentanyl i.e. Group B and fentanyl alone Group A. There was no significant difference in  $SPO_2$  among the groups at baseline and subsequent time intervals in the present study and remained same & within normal limit in postoperative period for 24 hr as well as did not require any ventilator support. Liu et al. have reported that dexmedetomidine offers a unique ability of providing both sedation and analgesia without respiratory depression [13]. It is a new agent with a wide safety margin, excellent sedative capacity and moderate analgesic properties.

In the present study, there was significant difference in VAS among the groups at two hours to 24 hours. The VAS was significantly low among the patients of Group C than Group B and highest in Group

A. There was significant difference in the first time requirement of analgesia among the groups. The time of first time analgesia requirement was significantly high in Group C than Group B and earliest in Group A. The analysis of variance revealed that there was significant difference in rescue analgesic for 24 hour among the groups. The dose of rescue analgesic for 24 hour postoperatively was lowest among the patients of Group C and highest in Group A. Similar findings were reported by Park et al., in which VAS scores of dexmedetomidine group were lower than that of placebo group during the 1<sup>st</sup> hour after operation [14]. The 24 hours tramadol requirement after the operation was significantly lower in dexmedetomidine group compared to placebo group. McCleane studied that regional anaesthesia with a local anaesthetic such as lidocaine and bupivacaine is mostly preferred and is associated with significantly lower pain scores than seen with systemic opioids [15].

In this study, Ramsay Sedation Score (RSS) did not affect oxygen saturation, and need for ventilatory support which was similar to the other studies [16-18].

In this study, the intraoperative use of dexmedetomidine caused postoperative sedation, but not associated with respiratory depression and no ventilator support were required. We found that the complications were lowest among the patients of Group C and highest in Group A. Nausea and vomiting in Group C was 6.7%, shivering was 6.7%, in group 23.3% and 33.3%, and in group A 70% and 40% respectively. Lazo et al., reported that single analgesic were not able to provide effective pain relief for most moderate to severe pain, and associated with opioid related side effects mainly sedation, nausea, vomiting, pruritus and constipation [2].

In this study, mean satisfaction score for postoperative sedation and analgesia for both patient and surgeon was significantly high among the patients of Group C than Group B and lowest in Group A. Badner et al., studied that the patients receiving dexmedetomidine reported being happier with pain relief during the first 90 minutes they remained in PACU [19]. Patients receiving dexmedetomidine remained more comfortable in the PACU according to the nursing team evaluation. Tufanogullari et al., found that intraoperative dexmedetomidine infusion decreases severity of pain, analgesic requirements, opioid use, antiemetic therapy, length of stay in ICU, and more patient satisfaction with pain management, quality of recovery, as well as resumption of dietary intake and recovery of bowel function [20].

## LIMITATIONS

One of the limitations of the present study was that we have not included patients of ASA III-IV, therefore results of this study cannot be applied completely on them especially patients with respiratory and cardiovascular disease. Decision should be taken on individual basis. The patients involved in the study were mainly resident of

northern India and there may be differences in the effect of drug in residents of other areas and other ethnic groups. The sample size of the study was not adequate to reflect the pharmacological properties of study drugs in general population and person to person variation may exist.

## CONCLUSION

Multimodal analgesia has beneficial haemodynamic effects during oral cancer surgery with reliable postoperative analgesia and sedation and less postoperative complications.

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