

# Comparison of Quality of Recovery (QoR-15) following the administration of intravenous lignocaine and fentanyl in patients undergoing septoplasty under general anaesthesia: A double-blinded, randomised, controlled trial

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## ABSTRACT

**Background and Aims:** Recovery from surgery and anaesthesia is usually observed through conventional indicators. The Quality of Recovery (QoR-15) score was specially designed to measure psychometric and functional recovery from the patient's perspective. This study aimed to evaluate QoR-15 following the administration of intravenous (IV) lignocaine or IV fentanyl in patients undergoing septoplasty surgery. **Methods:** This randomised, controlled trial was conducted on 64 patients of American Society of Anesthesiologists (ASA) physical status I and II, of either sex, of ages between 18 and 60 years, and who were scheduled for septoplasty. The primary end point was to compare the quality of recovery following the administration of IV lignocaine (group L) and IV fentanyl (group F) using the QoR-15 score in patients undergoing septoplasty. Secondary end points were to compare postoperative analgesia, recovery characteristics, and adverse effects in both groups. Statistical analysis was done using the Shapiro–Wilk test, paired *t* test/ Wilcoxon signed-rank test, and unpaired *t* test/Mann–Whitney *U* test. A *P*-value <0.05 was considered statistically significant. **Results:** There was a significant improvement in the postoperative QoR-15 score than in the preoperative score in both groups (*P* < 0.000). However, the postoperative QoR-15 score was significantly higher in group L compared to group F (*P* < 0.001). Total consumption of analgesic doses were reduced in group L (*P*=0.000). Time taken to achieve an Aldrete score >9 and gastrointestinal recovery was shorter in group L compared to group F. **Conclusion:** Both IV lignocaine and IV fentanyl improved postoperative QoR-15 score; however, lignocaine had a higher postoperative QoR-15 score than fentanyl, in addition to showing early discharge readiness, better analgesia, and better recovery profile in patients following septoplasty surgery.

**Key words:** Anaesthesia, fentanyl, lignocaine, quality of recovery, septoplasty

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## INTRODUCTION

The health status or quality of life of patients after surgery and anaesthesia has become an important endpoint in clinical studies as it influence the outcome of care, such as relative state of normality, well-being, and independence from the patient's perception.<sup>[1–3]</sup> Recently, the patient-reported outcome measurement (PROM) of postoperative quality of recovery tool

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developed a 15-item Quality of Recovery (QoR-15) score tool that measures psychometric properties and that is more feasible to use.<sup>[4]</sup>

A nasal surgery like septoplasty is usually associated with mild-to-moderate postoperative pain, and the use of opioids for postoperative pain is associated with several complications that may affect the patient's recovery profile. There has been a surge of interest in the use of intravenous (IV) lignocaine in various surgeries due to its analgesic, anti-hyperalgesic, and anti-inflammatory effects and opioid properties. Thus, perioperative administration of IV lignocaine reduces postoperative pain and opioid consumption and its side effects in the post-anaesthesia care unit (PACU), thereby facilitating early recovery and decreased hospital stay.<sup>[5,6]</sup> Our primary objective was to compare the quality of recovery following the administration of IV lignocaine with that of IV fentanyl using the QoR-15 score in patients undergoing septoplasty; our secondary objective was to compare the postoperative analgesia, recovery characteristics, and adverse effects of lignocaine and fentanyl in both the groups.

## METHODS

After obtaining approval from the Institutional Research Ethical board (GU/HREC/EC/2019/1571) dated 1 February 2019) and written, informed consent from the patients, this randomised, and double-blinded clinical study was conducted as per the principles of the Declaration of Helsinki at a tertiary care institute from January 2019 to June 2020. Sixty-four patients with ASA physical status I and II, of either sex, of the ages between 18 and 60 years, and who were scheduled for septoplasty were included in the study. Patients with known hypersensitivity to local anaesthetics, alcoholic or drug abuse, a body mass index (BMI) > 30 kg/m<sup>2</sup>, with clinically significant neurologic, psychiatric, cardiovascular, renal, and hepatic diseases, and those who received an opioid analgesic medication within a 24-hour period before surgery were excluded from the study. A pre-tested and pre-validated QoR-15 questionnaire was used for the postoperative quality analysis, and on the day of surgery patients were asked to complete the QoR-15 questionnaire in the pre-anaesthetic room. Pre-loading was done with 10–15 ml/kg Ringer's lactate solution and all subjects were pre-medicated with intravenous 0.005 mg/kg glycopyrrolate and 0.1 mg/kg ondansetron. Sampling was done based on computer-generated randomisation, and allocation concealment

was done using a sealed, opaque envelope that had only one number on the outer side. Study medications were prepared by anaesthesiologists who were not involved in further patient care or data collection. The anaesthesiologist and post-anaesthesia care unit (PACU) nurse involved in data collection were not aware of the groups. Patients were randomised into two groups: group L received IV lignocaine (1.5 mg/kg bolus diluted to 10 ml 0.9% normal saline [NS] followed by a 2 mg/kg/h infusion till the end of surgery), and group F received IV fentanyl (2 µg/kg bolus diluted to 10ml 0.9% normal saline [NS] followed by an infusion of 0.5 µg/kg/h till the end of the surgery). For infusion, both the drugs were diluted in a 20-ml syringe at a concentration of 5 µg/ml for fentanyl (100 µg fentanyl diluted in 20 ml of 0.9% NS) and 5 mg/ml for lignocaine (100mg lignocaine diluted in 20 ml of 0.9% NS), thereby having similar volume (ml/h) to maintain blinding for intraoperative infusion of both the study drugs. All patients were induced with 2 mg/kg propofol followed by tracheal intubation using 1.5 mg/kg IV suxamethonium as a muscle relaxant. Maintenance of anaesthesia was achieved by oxygen in air, sevoflurane, and intermittent doses of atracurium throughout the surgery. Intraoperatively, haemodynamics, peripheral capillary oxygen saturation (SPO<sub>2</sub>), and end tidal CO<sub>2</sub> (EtCO<sub>2</sub>) were continuously monitored throughout the surgery. Intraoperative adverse effects like bradycardia, hypotension, and arrhythmias were noted and managed accordingly. At the end of the surgery, all anaesthetics were discontinued, neuromuscular blockade was reversed with 0.05 mg/kg IV neostigmine combined with 10 µg/kg glycopyrrolate; the patient was allowed to emerge from anaesthesia while breathing spontaneously, and endotracheal tube was removed. The patients were then transferred to the post-anaesthesia care unit (PACU) and monitored for pain at regular time intervals using an 11-point Numerical Rating Scale (NRS) of 0–10 where 0 indicated “no pain” and 10 indicated “worst pain”. If the patient had NRS score >4, then a rescue dose of 1 g IV paracetamol was administered and time to first rescue analgesia with total number of analgesic doses was recorded. Discharge readiness was assessed by using Modified Aldrete Score and a score more than or equal to 9 was considered as ready for discharge to ward. Time taken to achieve an Aldrete score ≥9 was also recorded. Postoperative adverse effects like drowsiness, light-headedness, metallic taste, nausea and vomiting, hypotension, visual disturbance, and

seizure-like movement were also noted. The patients were contacted 24 hours after the surgery by an investigator unaware of the group allocation to assess the quality of postoperative functional recovery using the QoR-15 score. The questionnaire consisted of 15 items: each item was graded on an 11-point NRS, and the total sum of the scores ranged from 15 to 150.<sup>[7]</sup> Gastrointestinal recovery was noted by resumption of bowel function and time for oral intake from 6 to 12 h.

The primary outcome was the global QoR-15 score recorded 24 hours after surgery. Considering the paucity of similar studies using the QoR-15 score, a sample size calculation was based on the pilot study with the assumption of a 10-point difference in global QoR-15 score and overall standard deviation of 14 for the two study groups. Sample size calculation revealed that 32 patients in each group were required to achieve a power of 80% with a type 1 error of 0.05. Data was entered in Microsoft Excel software and analysed using IBM SPSS Statistics version 21. Quality of data was analysed using the chi-squared test/ Fisher's exact test. Quantitative data analysis was done by using a normality test called the Shapiro-Wilk test, paired *t* test/ Wilcoxon signed-rank test, and unpaired *t* test/ Mann–Witney *U* test. A *P*-value <0.05 was considered statistically significant.

## RESULTS

A total of 72 patients were screened for eligibility to participate in this study. Eight patients did not meet the inclusion criteria and the remaining 64 patients were allocated to one of the two study groups [Figure 1].

There was no statistically significant difference in demographic characteristics like age, sex, BMI, duration of surgery, duration of infusion of study drugs, and duration of anaesthesia (*P* > 0.05) [Table 1].

The preoperative QoR-15 score were comparable in both the groups (Table 2). There was a significant improvement in the postoperative QoR-15 score compared to the preoperative score in both the groups (*P* < 0.001). However, postoperative QoR-15 score was significantly higher in group L compared to group F (*P* < 0.001).

Mean NRS for severity of pain was comparable in both the groups till 30min in PACU, but it was significantly lower in group L compared to group F

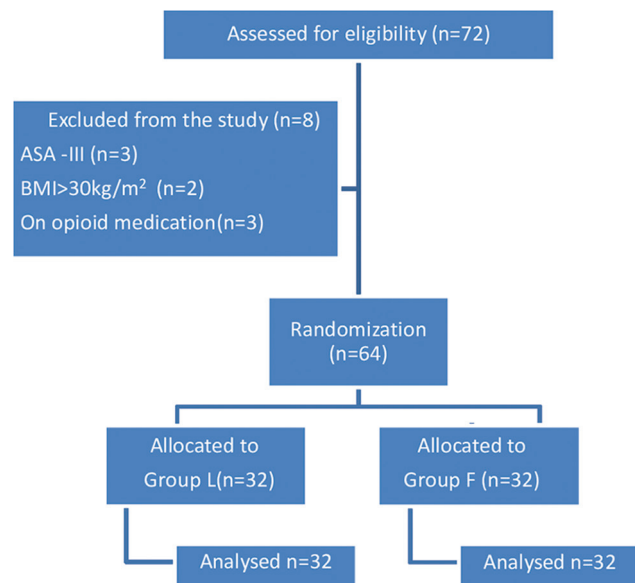


Figure 1: CONSORT diagram

at 60 min and postoperatively at 2–4 h [Figure 2]. Thus, the time to first rescue analgesic dose was significantly prolonged in group L compared to group F (*P* = 0.039). Similarly, total consumption and total number of analgesic doses were lower in group L than in group F and were highly statistically significant [Table 3]. There was no significant difference in the Aldrete score between the groups (*P* > 0.05) in PACU, but the time taken to achieve an Aldrete score >9 was shorter in group L ( $7.41 \pm 1.80$  min) than in group F ( $13.13 \pm 2.09$  min) and was highly significant statistically (*P* = 0.000). Figure 3 shows that gastrointestinal recovery was found in <6h in all patients in group L compared to group F, in which it was within 6 to 12 h. Seventy-five percent of patients (*n* = 24) had metallic taste in group L, and in group F 31.25% of patients (*n* = 10) were drowsy and 62.50% of patients (*n* = 20) suffered from nausea and vomiting, postoperatively.

## DISCUSSION

Traditionally, several parameters including pain, postoperative nausea and vomiting (PONV), length of stay in recovery room, and length of hospital stay are used to estimate postoperative recovery status and are major concerns for many patients. The Visual Analogue Scale (VAS) can be used as an alternate assessment of recovery, but it is prone to overrating and is an imperfect scale without psychometric evaluation, in which the individual components of recovery are overlooked.

Quality of recovery (QoR-40) has been used to measure functional recovery of the patient in the postoperative period, but when the acceptability and feasibility of QoR-15 versus QoR-40 was assessed using the recruitment rate, successful completion rate, and time taken to complete the questionnaire, there was higher rate of participation and completion of questionnaire (in less than three minutes) when employing the QoR-15 score.<sup>[8]</sup>

In our study, patients receiving IV lignocaine had a significantly higher emotional quotient (EQ); they were more communicable and more comfortable, and a subjective sensation of feeling of general well-being was significantly better in these patients compared to patients who received IV fentanyl. Objective parameters like pain, nausea and vomiting, anxiety, and depression were significantly less in patients who were given lignocaine compared to those who received fentanyl. In accordance to our study, Oliveira *et al.*,<sup>[8]</sup> who compared systemic lidocaine and saline to improve postoperative quality

of recovery after laparoscopic surgery, found that the median difference (99% CI) in global QoR-40 scores at 24 hours after surgery was 16 (2–28) between the lidocaine and saline groups. Subjects in the lidocaine group also scored better in the subcomponents of the QoR-40 score that specifically examined pain ( $P=0.001$ ), physical comfort ( $P=0.003$ ), and physical independence ( $P=0.008$ ). Similarly, Kim *et al.*<sup>[9]</sup> who compared QoR-40 score following administration of lidocaine and magnesium during thyroid surgery in female patients, found that intravenous lidocaine led to significantly better quality of recovery (QoR-40 scores) by preventing physiological deterioration related to anaesthesia and surgery. Opioid medications are given systemically to reduce postoperative pain, and fentanyl is the most commonly used opioid for perioperative pain management; however, it causes supraspinal analgesia, respiratory depression, physical independence, and muscle rigidity. Lignocaine is an amide local anaesthetic; apart from it being anti-arrhythmic, it also has analgesic, anti-hyperalgesic, and anti-inflammatory properties without it producing

**Table 1: Comparison of demographic data and study characteristics between the groups**

Variables	Group L (n=32)		Group F (n=32)		P
	Mean±SD		Mean±SD		
Age (years)	31.19±11.37		30.78±9.68		0.878
Sex (male/female)	23/9		24/8		0.777
Height (cm)	167.69±7.94		167.87±11.30		0.939
Weight (kg)	61.34±10.92		59.56±12.23		0.541
BMI (kg/m <sup>2</sup> )	21.70±2.64		21.09±3.79		0.431
Duration of surgery (min)	90±0		88.125±15.748		0.503
Duration of anaesthesia (min)	99.84±0.88		100.62±2.46		0.096
Duration of infusion of study drug (min)	92.22±2.41		92.47±4.46		0.781

**Table 2: Comparison of total QoR-15 scores between each group**

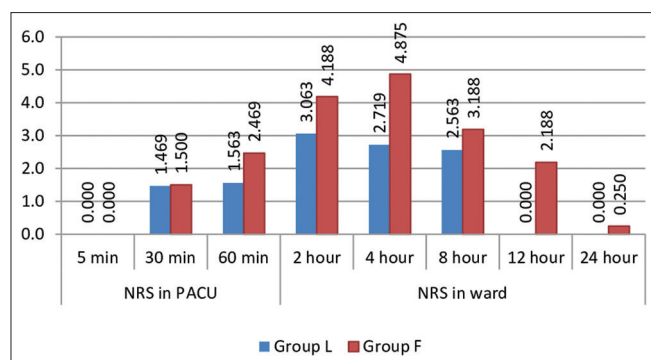
Total QoR-15 Score	Group L (n=32)		Group F (n=32)		Shapiro–Wilk Test/P	Mean Difference	U	P
	Mean±SD	SE Mean	Mean±SD	SE Mean				
Preoperative	127.19±12.10	2.14	128.94±11.58	2.046	0.632/0.0001	1.750	419	0.557
Postoperative	149.19±1.447	0.256	140.50±3.78	0.669	0.409/0.001	8.688	120	0.001
Mean difference	22.00		11.56					
Shapiro–Wilk test/P	0.63/0.001		0.25/0.01					
Z	101		271					
P	0.0001		0.0001					

SE=Standard error. Z=Wilcoxon signed-rank test value; U=Mann–Whitney U test value

**Table 3: Comparison of rescue analgesics between the groups**

Variables	Rescue Analgesia Data				Mean Difference	t test'	P
	Group L (n=32)		Group F (n=32)				
	Mean±SD	SE Mean	Mean±SD	SE Mean			
Time to first rescue dose (h)	2.37±1.79	0.412	1.28±2.33	0.317	1.094	2.104	0.039
Total no. of doses	0.375±0.492	0.087	1.375±0.707	0.125	1.000	6.567	<0.001
Total dose (g)	0.438±0.504	0.089	1.375±0.707	0.125	0.938	6.107	<0.001

SE=Standard error

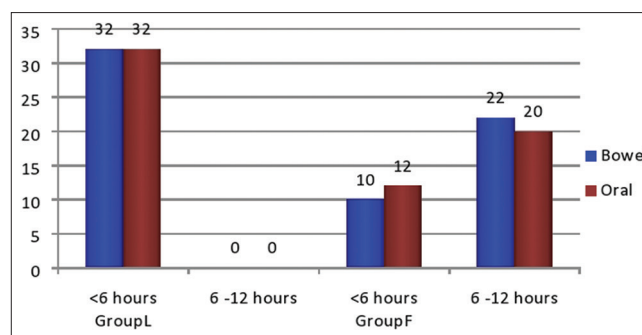


**Figure 2:** Graphic representation of the NRS from 5 to 60 min in PACU and till 24 h in ward in both the groups

toxic side effects or significant cardiovascular changes. A selective depression of pain transmission in the spinal cord and reduction in tonic neural discharge of active peripheral nerve fibres that mediate pain (A-delta and C fibres) are uniquely sensitive to effects of lignocaine for its analgesic efficacy.<sup>[10,11]</sup>

Our study depicts that postoperative pain was significantly lower in patients receiving lignocaine compared to those receiving fentanyl. Thus, total consumption and total number of analgesic doses were reduced in patients receiving lignocaine infusion. These results were comparable to the study conducted by Oliveira *et al.*<sup>[8]</sup> wherein they found that patients in the lidocaine group had lower pain scores and improved postoperative quality of recovery after laparoscopic surgery. Furthermore, McKay *et al.*<sup>[12]</sup> evaluated the effect of systemic lidocaine on perioperative opioid analgesic requirements and discharge time after ambulatory surgery and found that in PACU, patients in the lidocaine group reported less pain at rest.

The cause of postoperative gastrointestinal dysfunction is multifactorial. The most common feature of postoperative ileus is due to activation of spinal reflex arc and sympathetic hyperactivity inhibiting intestinal motility and peristalsis. Another important cause of said dysfunction is the administration of anaesthetics and opioids, both of which can prolong hospital stay. Lignocaine stimulates the postoperative colonic motility by blocking the afferent and efferent link of inhibitory spinal and prevertebral reflexes. It also shortens the duration of ileus by reducing opioid consumption.<sup>[13–15]</sup> Similar to our study, Choi *et al.*<sup>[16]</sup> who studied the effect of intraoperative lidocaine on anaesthetic consumption, bowel function, pain intensity, analgesic consumption, and hospital stay after breast surgery, found that the time to first flatus



**Figure 3:** Graphic representation of gastrointestinal recovery in both the groups

and defecation occurred approximately five and six hours, respectively, faster in the lidocaine group than in the control group; however, no statistically significant difference was found ( $P > 0.05$ ). In a systematic review conducted by Weibel *et al.*<sup>[17]</sup> to evaluate the effects of perioperative IV lignocaine infusion on postoperative pain and recovery in patients undergoing various surgical procedures, the authors found that administration of IV lidocaine did not significantly reduce time to first defecation but significantly shortened the time to first flatus and time to first bowel movements or sounds when compared to the control group.

Use of opioids that are given systemically to reduce postoperative pain are associated with several postoperative complications such as sedation, nausea and vomiting, ileus, respiratory depression, and urinary retention. Lignocaine, on the other hand, decreases the incidence of PONV, by 10%, to 20%; this benefit is likely due to its opioid-sparing effect.<sup>[18,19]</sup>

In the present study, we did not find any intraoperative adverse effects like bradycardia, hypotension, and arrhythmia in both the groups, whereas postoperative adverse effects were comparable in the two groups. Metallic taste was more common with lignocaine, and drowsiness and nausea and vomiting were observed in fentanyl, both postoperatively. Goyal *et al.*<sup>[20]</sup> compared the efficacy of IV fentanyl versus dexmedetomidine for evaluation in breast cancer surgery and found that four patients receiving fentanyl experienced nausea as opposed to none receiving dexmedetomidine. Similarly, many studies reported frequent PONV during intraoperative fentanyl infusion.<sup>[21,22]</sup> In contrast to the present study, Weibel *et al.*<sup>[17]</sup> evaluated the efficacy and safety of IV lidocaine for postoperative analgesia and recovery after surgery and found that three trials reported neuropsychological disturbance (light headedness,

dizziness, and visual disturbance) in the lidocaine group of patients.

Our study has few limitations. Firstly, the QoR-15 score was not measured using different anaesthetic drugs to study stress of anaesthesia and surgery on postoperative recovery in patients. Thus, further research focusing on a larger sample size should be carried out to assess patient recovery. Furthermore, continuous infusion of lignocaine doses used in various studies may cause lignocaine toxicity. We did not investigate plasma concentration to measure the toxic levels of lignocaine; however, in our study we used lignocaine infusion that did not exceed more than two hours. Additionally, there is a scarcity of studies that have systemically assessed the safety of lignocaine as an alternative to opioid medications, particularly because of the beneficial impact on the patient-relevant outcomes such as gastrointestinal recovery, PONV, lesser analgesic consumption, faster discharge readiness time, and lower pain during postoperative recovery in patients undergoing nasal surgeries.

## CONCLUSION

In conclusion, both IV lignocaine and IV fentanyl improved the quality of postoperative recovery, as measured by the QoR-15 score. However, lignocaine had higher postoperative QoR-15 scores than fentanyl, in addition to early discharge readiness, better analgesia, and better recovery profile in patients following septoplasty surgery.

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Nil.

## Conflicts of interest

There are no conflicts of interest.

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