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RESEARCH ARTICLE
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"EFFECTIVENESS OF LOCAL ANAESTHESIA (CLONIDINE AND FENTANYL) INFILTRATION FOR POST - NASAL SURGERIES."

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Abstract

Background: Postoperative pain management following nasal surgeries is crucial for improving patient comfort and minimizing analgesic requirements. This study aimed to evaluate the effectiveness of local infiltration anesthesia combining clonidine and fentanyl in improving postoperative pain relief and overall comfort levels in patients undergoing nasal surgeries. The study compared this combination with standard infiltration anesthesia using lignocaine with adrenaline.

Methods: A total of 60 patients undergoing nasal surgeries such as Functional Endoscopic Sinus Surgery (FESS), septoplasty, dacryocystorhinostomy, and nasal bone fracture reduction were enrolled in the study. Patients were randomized into two groups: the study group (n=30) received block anesthesia consisting of Inj. Lignocaine 2% (3ml), Inj. Lignocaine with Adrenaline 2% (3ml), Inj. Sensorcaine 0.5% (3ml), Inj. Fentanyl 50 µg/ml (0.5ml), and Inj. Clonidine 100 µg/ml (0.5ml); the control group (n=30) received infiltration anesthesia with Inj. Lignocaine with Adrenaline 2% (10ml). Discomfort levels were evaluated at 6 hours, 12 hours, Day 1, Day 2, and Day 7 postoperatively using predefined criteria: no discomfort, tolerable discomfort, and intolerable discomfort. Statistical analysis was performed using the Chi-square test.

Results: Patients in the study group consistently experienced lower discomfort levels across all postoperative time points. At 6 hours, 30% of the study group reported no discomfort compared to only 15% in the control group ($p<0.05$). At 12 hours, 33.33% of the study group reported no discomfort versus 16.67% in the control group ($p<0.05$). By Day 2, no patients in the study group experienced intolerable discomfort compared to 6.67% in the control group ($p<0.01$). On Day 7, 48.33% of patients in the study group experienced no discomfort compared to 36.67% in the control group ($p<0.05$). The improved outcomes in the study group demonstrate the enhanced analgesic effect of clonidine and fentanyl infiltration.

Conclusion: The combination of clonidine and fentanyl in block anesthesia effectively reduced postoperative discomfort and improved overall patient comfort compared to infiltration anesthesia using lignocaine with adrenaline alone. The significant reduction in intolerable discomfort and prolonged analgesic effect supports the use of this combination as an effective postoperative pain management strategy in nasal surgeries.

Keywords: Clonidine, Fentanyl, Nasal Surgeries, Local Anesthesia, Postoperative Pain, Block Anesthesia

Introduction

Local anaesthesia refers to the technique of inducing a temporary loss of sensation in a specific body area to enable surgical procedures without causing unconsciousness. Among various agents, clonidine and fentanyl have emerged as effective adjuvants to enhance the efficacy of local anaesthetics. Clonidine, an α2-adrenergic agonist, is known for its analgesic, sedative, and hemodynamic-stabilizing properties, while fentanyl, a potent opioid analgesic, is commonly used to manage acute pain and improve postoperative comfort.

Post-nasal surgeries, such as septoplasty, turbinectomy, and functional endoscopic sinus surgery (FESS), are often associated with moderate to severe postoperative pain. Effective pain control is crucial to reduce discomfort, minimize opioid consumption, and expedite recovery.

Clonidine's analgesic action stems from its ability to activate α2-adrenoceptors in the central nervous system, which inhibits the release of norepinephrine, reducing sympathetic outflow and enhancing pain modulation[1]. When combined with local anesthetics like bupivacaine, clonidine has been shown to prolong the duration of sensory blockade and improve postoperative analgesia[2].

Fentanyl, acting on μ-opioid receptors, provides potent analgesia and is widely recognized for its rapid onset and effective pain control. Infiltration of fentanyl with a local anesthetic has demonstrated significant reductions in postoperative pain, reduced analgesic requirements, and improved hemodynamic stability[3].

The combination of clonidine and fentanyl for local infiltration anaesthesia in post-nasal surgeries represents a promising alternative to traditional methods. While each agent demonstrates effective pain control independently, their combined effect may provide superior analgesia, reduced side effects, and improved patient outcomes. Previous research indicates that clonidine infiltration reduces intraoperative blood loss and enhances postoperative comfort compared to fentanyl alone[4]. Similarly, clonidine has been found to provide longer-lasting analgesia than fentanyl when used in regional anaesthesia techniques[5]. Investigating this combination is essential to explore its potential benefits in nasal surgeries, where precise pain management is crucial for minimizing complications and expediting recovery. This study aims to assess the effectiveness of clonidine and fentanyl infiltration for post-nasal surgery pain management by comparing outcomes such as pain scores, complications, and patient acceptability.

Methodology

The present study was conducted on 60 patients diagnosed with various nasal pathologies such as fracture of the nasal bone, sinusitis, epiphora, recurrent rhinitis, and nasal blockade. These patients underwent surgical procedures that included Functional Endoscopic Sinus Surgery (FESS), Septoplasty, reduction of nasal bone fractures, and Dacryocystorhinostomy. The selection of patients was performed in a randomized manner from the ENT Outpatient Department (OPD) of a teaching institute in Pune. The study was carried out over a period ranging from August 2007 to January 2009. Informed written consent was obtained from all the patients prior to their inclusion in the study. Each participant was thoroughly informed about the procedure, the risks involved, and the potential outcomes. This ensured that every patient provided informed consent before undergoing surgery.

The data for this study was collected from patients presenting to the ENT OPD with various nasal complaints that required surgical intervention. These complaints included nasal obstruction, recurrent rhinitis, epiphora, headache, and external nasal deformity. Patients were selected for surgery based on the underlying nasal pathology.

For the purpose of comparison, patients were randomly divided into two groups. The study group received block anaesthesia containing a combination of Inj. Lignocaine 2% (3ml), Inj. Lignocaine with Adrenaline 2% (3ml), Inj. Sensorcaine 0.5% (3ml), Inj. Fentanyl 50 μg/ml (0.5ml), and Inj. Clonidine 100 μg/ml (0.5ml). The control group received only infiltration anaesthesia with Inj. Lignocaine with Adrenaline 2% (10ml).

Inclusion criteria for the study included patients requiring surgical procedures such as Septoplasty, Functional Endoscopic Sinus Surgery, Dacryocystorhinostomy, and nasal bone fracture reduction. Patients who were below 18 years of age, had suspected malignancy, bleeding disorders, or reported

allergic reactions to local anesthetics were excluded from the study. To ensure patient safety, sensitivity tests were conducted for all injectable drugs used in the study prior to the surgical procedure.

Prior to surgery, all patients underwent a series of investigations to assess their suitability for anaesthesia and surgery. These investigations included a hemogram, urine examination, bleeding time, clotting time, prothrombin time, platelet count, blood sugar levels, blood urea levels, and serum electrolyte analysis. These assessments ensured the patients' medical stability and fitness for the planned surgical intervention. To evaluate the efficacy of block anaesthesia, patient comfort levels were assessed based on the presence of nasal pain, headache, sleep quality, and mouth breathing. The comfort levels were categorized into three groups: no discomfort, tolerable discomfort, and intolerable discomfort. Tolerable discomfort was managed with oral analgesics such as Tab. Voveron, while intolerable discomfort was addressed with injectable analgesics such as Inj. Voveron.

Postoperative discomfort was assessed at multiple intervals — initially at 6 hours and 12 hours after surgery, followed by Day 1 while the nasal pack remained in situ, on Day 2, and finally on Day 7 after the nasal pack was removed. Patients were discharged on Day 2 and were advised to return for a follow-up visit on Day 7.

The infiltration technique was carefully standardized. Following the induction of general anaesthesia (GA) or administration of local anaesthesia (LA), and after proper skin preparation, the block technique was performed. The prepared anesthetic solution was injected at specific anatomical points bilaterally: the supra-trochlear area (to relieve headache), infra-orbital area, medial to the medial canthus, nasal sill, and anterior septum. Each nasal cavity was then packed for five minutes with a cotton pledget soaked in the same anesthetic solution to ensure adequate mucosal sensation blockade. The block infiltration mixture was prepared in a 10ml syringe. This solution contained 3ml of 2% Lignocaine, 3ml of 2% Lignocaine with Adrenaline (1:200,000), 3ml of 0.5% Sensorcaine, 0.5ml of Fentanyl (50µg/ml), and 0.5ml of Clonidine (100µg/ml). This consistent method ensured uniform administration, accurate patient selection, and precise evaluation of outcomes, ensuring the study's reliability and validity.

Results

The study included a total of 60 patients, with 30 patients in the study group and 30 patients in the control group. The mean age of patients in the study group was 30.73 years, while the mean age in the control group was 30.16 years. The age distribution across both groups was comparable, ensuring uniformity in the study population.

Table 1: Sex wise distribution of cases in study and control group

Sex	Study group (%)	Control group (%)	Total (%)
Male	20 (33.33)	16 (26.67)	36 (60)
Female	10 (16.67)	14 (23.33)	24 (40)
P Total	30 (50)	30 (50)	60 (100)

Among the 60 patients, 36 (60%) were males and 24 (40%) were females. In the study group, there were 20 males (33.33%) and 10 females (16.67%). In the control group, there were 16 males (26.67%) and 14 females (23.33%). The distribution of male and female patients was fairly balanced across both groups, supporting unbiased group comparisons.

Table 2: Surgeries undergone General and local anaesthesia in study and control group

Surgery	Study group (%)	Control group (%)	Total (%)
GA (General Anaesthesia)	21 (35)	23 (38.33)	44 (73.33)
LA (Local Anaesthesia)	9 (15)	7 (11.67)	16 (26.67)
Total	30 (50)	30 (50)	60 (100)

The majority of patients underwent surgeries under general anaesthesia. In the study group, 21 patients (35%) received general anaesthesia, while 9 patients (15%) underwent surgery under local anaesthesia. In the control group, 23 patients (38.33%) were given general anaesthesia, and 7 patients (11.67%) received local anaesthesia. The similarity in anaesthesia distribution ensured the results were not significantly influenced by the type of anaesthesia administered.

Table 2: Various Nasal Surgeries performed in study and control group

Surgery	Study group (%)	Control group (%)	Total (%)
Functional endoscopic sinus surgery	7 (11.67)	11 (18.33)	18 (30)
Septoplasty	12 (20)	10 (16.67)	22 (36.67)
Dacro-cysto-rhinostomy	7 (11.67)	5 (8.33)	12 (20)
Reduction of fracture nasal bone	4 (6.67)	4 (6.67)	8 (13.33)

The distribution of surgical procedures across the study and control groups was as follows: Functional Endoscopic Sinus Surgery (FESS): Performed in 7 patients (11.67%) in the study group and 11 patients (18.33%) in the control group, totaling 18 patients (30%). Septoplasty: Conducted in 12 patients (20%) in the study group and 10 patients (16.67%) in the control group, making a total of 22 patients (36.67%). Dacryocystorhinostomy: Performed in 7 patients (11.67%) in the study group and 5 patients (8.33%) in the control group, with a total of 12 patients (20%). Reduction of Nasal Bone Fracture: Equally distributed in both groups, with 4 patients (6.67%) each in the study and control groups, totaling 8 patients (13.33%).

Table 5: Measurement of discomfort level in study and control group

	Discomfort level	**Study group (%)**	**Control group (%)**	**Total (%)**	**Chi square, P value**
6 hours	No	18 (30)	9 (15)	27 (45)	**χ^2 = 6.52, P < 0.05**
	Tolerable	5 (8.33)	5 (8.33)	10 (16.66)	
	Intolerable	7 (11.67)	16 (26.67)	23 (38.34)	
	Total	**30 (50)**	**30 (50)**	**60 (100)**	
12 hours	No	20 (33.33)	10 (16.67)	30 (50)	**χ^2 = 6.92, P < 0.05**
	Tolerable	7 (11.67)	12 (20)	19 (31.67)	
	Intolerable	3 (5)	8 (13.33)	11 (18.33)	
	Total	**30 (50)**	**30 (50)**	**60 (100)**	
Day 1	No	21 (35)	12 (20)	33 (55)	**χ^2 = 6.82, P < 0.05**
	Tolerable	8 (13.33)	12 (20)	20 (33.33)	
	Intolerable	1 (1.67)	6 (10)	7 (11.67)	
	Total	**30 (50)**	**30 (50)**	**60 (100)**	
Day 2	No	25 (41.67)	16 (26.66)	41 (68.33)	**χ^2 = 7.64, P < 0.01**
	Tolerable	5 (8.33)	10 (16.67)	15 (25)	
	Intolerable	0 (0)	4 (6.67)	4 (6.67)	
	Total	30 (50)	30 (50)	60 (100)	
Day 7	No	29 (48.33)	22 (36.67)	51 (85)	**χ^2 = 4.01, P < 0.05**
	Tolerable	1 (1.67)	8 (13.33)	9 (15)	
	Intolerable	0 (0)	0 (0)	0 (0)	
	Total	30 (50)	30 (50)	60 (100)	

Postoperative discomfort levels were assessed at multiple intervals: 6 hours, 12 hours, Day 1, Day 2, and Day 7.

At 6 Hours: In the study group, 18 patients (30%) reported no discomfort, 5 patients (8.33%) reported tolerable discomfort, and 7 patients (11.67%) experienced intolerable discomfort. In contrast, the

control group had fewer patients with no discomfort (9 patients, 15%) and more patients with intolerable discomfort (16 patients, 26.67%). The difference was statistically significant ($\chi^2 = 6.52$, $P < 0.05$).

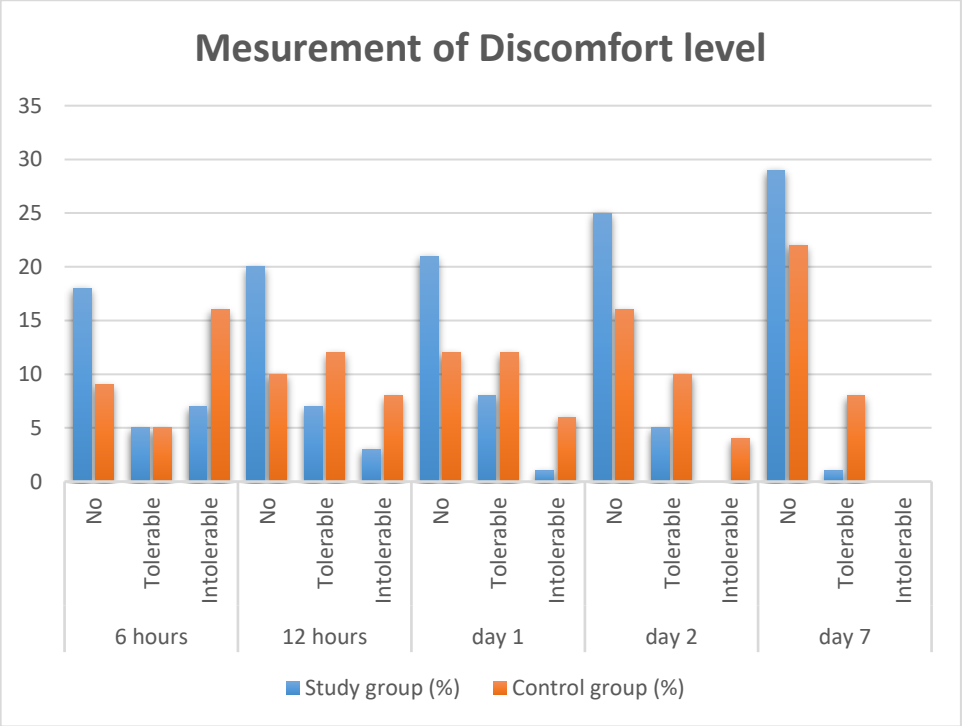
At 12 Hours: In the study group, 20 patients (33.33%) had no discomfort, 7 patients (11.67%) reported tolerable discomfort, and 3 patients (5%) experienced intolerable discomfort. The control group had 10 patients (16.67%) with no discomfort, 12 patients (20%) with tolerable discomfort, and 8 patients (13.33%) with intolerable discomfort. The results showed a significant difference ($\chi^2 = 6.92$, $P < 0.05$).

On Day 1: On the first postoperative day, 21 patients (35%) in the study group reported no discomfort, while 8 patients (13.33%) reported tolerable discomfort and 1 patient (1.67%) experienced intolerable discomfort. The control group had 12 patients (20%) reporting no discomfort, 12 patients (20%) with tolerable discomfort, and 6 patients (10%) experiencing intolerable discomfort. The difference remained statistically significant ($\chi^2 = 6.82$, $P < 0.05$).

On Day 2: By the second postoperative day, 25 patients (41.67%) in the study group experienced no discomfort, while 5 patients (8.33%) reported tolerable discomfort and none reported intolerable discomfort. The control group had 16 patients (26.66%) with no discomfort, 10 patients (16.67%) with tolerable discomfort, and 4 patients (6.67%) experiencing intolerable discomfort. The difference between the two groups was highly significant ($\chi^2 = 7.64$, $P < 0.01$).

On Day 7: By the seventh postoperative day, 29 patients (48.33%) in the study group reported no discomfort, with only 1 patient (1.67%) experiencing tolerable discomfort and none reporting intolerable discomfort. In contrast, the control group had 22 patients (36.67%) with no discomfort, 8 patients (13.33%) with tolerable discomfort, and none reporting intolerable discomfort. The results showed significant improvement in the study group ($\chi^2 = 4.01$, $P < 0.05$).

Figure 1. Measurement of discomfort level in study and control group



Discussion

The results of this study highlight the effectiveness of block anaesthesia combining clonidine and fentanyl in providing improved postoperative comfort and reduced discomfort compared to infiltration anaesthesia alone. The findings align with existing literature on the efficacy of clonidine and fentanyl in postoperative pain management.

The demographic distribution of patients was balanced between the study and control groups. The mean age was comparable (30.73 years in the study group vs. 30.16 years in the control group),

ensuring no significant influence of age on pain perception or recovery outcomes. Similarly, the distribution of male and female patients in the two groups was fairly even. Previous studies have shown that factors such as age and gender have minimal influence on the efficacy of clonidine and fentanyl in anaesthesia when administered in appropriate doses[1].

A comparable distribution of patients receiving general anaesthesia (GA) and local anaesthesia (LA) in both groups ensured that outcomes were not significantly influenced by the anaesthesia technique itself. Similar studies have demonstrated that the addition of clonidine and fentanyl in both GA and LA settings enhances postoperative analgesia. For instance, the study by Kumari et al. demonstrated that clonidine provided superior sedation and reduced intraoperative bleeding in ENT surgeries when added to conventional anaesthesia techniques[2].

The distribution of surgeries, including Functional Endoscopic Sinus Surgery (FESS), septoplasty, dacryocystorhinostomy, and nasal fracture reduction, was well-matched across the two groups. The improved outcomes in the study group across these surgeries highlight the versatility of clonidine and fentanyl in providing effective pain control. Naja et al. also reported that clonidine and fentanyl significantly reduced pain scores and improved patient comfort in nasal surgeries compared to general anaesthesia alone[3].

The study group consistently reported significantly lower discomfort levels across all time points — at 6 hours, 12 hours, Day 1, Day 2, and Day 7. The improved outcomes align with existing research emphasizing the superior analgesic properties of clonidine when combined with fentanyl.

At 6 and 12 Hours: The proportion of patients reporting no discomfort was significantly higher in the study group. This aligns with the findings of Rai et al., where clonidine combined with fentanyl prolonged sensory blockade and improved postoperative analgesia in spinal anaesthesia cases[4].

On Day 1: The study group had a lower proportion of patients experiencing intolerable discomfort, reinforcing the prolonged analgesic effect of clonidine. Similar results were reported by Ahuja et al., who observed that caudal clonidine significantly reduced postoperative pain and minimized analgesic requirements compared to fentanyl alone[5].

On Day 2 and Day 7: By Day 2, no patient in the study group experienced intolerable discomfort, while several patients in the control group still reported discomfort. By Day 7, almost all patients in the study group had no discomfort. This extended pain relief has been consistently observed in other trials, such as Samantaray et al., where clonidine significantly reduced VAS scores and minimized the need for additional opioids in the postoperative period[6].

The observed outcomes demonstrate that clonidine combined with fentanyl effectively reduced postoperative pain, discomfort, and analgesic requirements compared to lignocaine with adrenaline alone. Clonidine's action as an α2-adrenergic agonist leads to enhanced analgesia through reduced norepinephrine release, thereby improving pain modulation. Additionally, clonidine's sedative properties contribute to better comfort levels during the recovery period.

The findings are well-supported by prior research. Kumie et al. reported that clonidine provides longer-lasting postoperative analgesia than fentanyl when used with bupivacaine[7]. Similarly, Vinayak et al. demonstrated that adding clonidine to fentanyl premedication significantly improved postoperative pain control in spine surgeries[8].

Conclusion

Conflict of interest

No conflict of interest

References

1. Naja M, El-Rajab M, Kabalan W, Itani M, Kharma K, Al Tannir MA, Ziade MF. Effectiveness of local anaesthesia (clonidine and fentanyl) infiltration for post-submucosal resection pain relief: a randomized, double-blinded clinical trial. *J Laryngol Otol*. 2006;121:19-24.

2. Kumari I, Naithani U, Harsha, Singhal Y, Meena K, Mohan M. Clonidine as an adjuvant in monitored anaesthesia care for ENT surgeries: A prospective, randomized, double blind placebo controlled study. *[Unpublished Journal]*. 2019;260-268.
3. Naja M, El-Rajab M, Kabalan W, Itani M, Kharma K, Al Tannir MA, Ziade MF. Effectiveness of local anaesthesia (clonidine and fentanyl) infiltration for post-submucosal resection pain relief: a randomized, double-blinded clinical trial. *J Laryngol Otol*. 2006;121:19-24.
4. Rai N, Mathew ME, Gogna RL. Comparative Study Intrathecal Clonidine versus Intrathecal Fentanyl in Hyperbaric Bupivacaine for Spinal Anaesthesia and Postoperative Analgesia in Patients Undergoing Lower Limb Surgeries. *[Unpublished Journal]*. 2021.
5. Ahuja S, Aggarwal M, Joshi N, Chaudhry S, Madhu S. Efficacy of Caudal Clonidine and Fentanyl on Analgesia, Neuroendocrine Stress Response and Emergence Agitation in Children Undergoing Lower Abdominal Surgeries Under General Anaesthesia with Sevoflurane. *J Clin Diagn Res*. 2015;9(9):UC01-5.
6. Samantaray A, Rao M, Chandra A. The effect on post-operative pain of intravenous clonidine given before induction of anaesthesia. *Indian J Anaesth*. 2012;56:359-364.
7. Kumie FT, Hailekiros A, Eshetie S. Comparison of the postoperative analgesic effects of intrathecal Clonidine and Fentanyl as adjuvants: Meta Analysis of randomized control trials. *J Anesth Crit Care*. 2018;11.
8. Vinayak A, Rajarathna K, Raghavendra BS. Effect of clonidine as an add-on to fentanyl premedication on post-operative pain in patients undergoing spine surgeries: A randomized study. *Natl J Physiol Pharm Pharmacol*. 2019.