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Enhanced Post-Operative Analgesia in Nasal Surgery: A Randomised Controlled Trial of Fentanyl-Augmented Lignocaine versus Plain Lignocaine Nasal Packing.

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KEYWORDS

Nasal Packing, Pain, Fentanyl, Lignocaine, Post-operative analgesia.

ABSTRACT

Introduction:

Nasal packing is commonly used after nasal surgeries to control bleeding, reduce dead space, support tissue healing, and prevent synechiae formation. However, it is often associated with significant pain and discomfort, particularly during insertion and removal. Pain, as defined by the International Association for the Study of Pain, is an unpleasant sensory and emotional experience linked to actual or potential tissue damage. Effective postoperative pain management is therefore essential, as it enhances patient comfort, reduces complications, and contributes to improved surgical outcomes and shorter hospital stays.

Objectives:

The primary aim was to compare the efficacy of fentanyl-ligocaine nasal packing versus plain ligocaine packing in reducing acute postoperative pain following nasal surgeries under general anesthesia.

Methods:

This randomized clinical trial enrolled 60 patients undergoing nasal surgery under general anesthesia, who were randomly allocated into two groups (n = 30 each) using a closed-envelope technique. Group A received nasal packing impregnated with 9 mL of 2% lignocaine and 1 mL fentanyl (50 µg), whereas Group B received 9 mL of 2% lignocaine with 1 mL normal saline. Postoperative pain was assessed using the 11-point Numeric Rating Scale (NRS) and the Visual Analogue Scale (VAS). Hemodynamic parameters, including pulse rate and blood pressure, were recorded at 0, 6, 12, 18, and 24 hours postoperatively.

Results:

The Fentanyl-Lignocaine group showed significantly lower pain scores on both NRS and VAS at all time points ($P < 0.05$, independent t-test/Mann-Whitney U as appropriate). No significant hemodynamic changes or adverse events occurred in either group.

Conclusions:

Fentanyl-lignocaine-augmented nasal packing provides safe, superior postoperative analgesia versus lignocaine alone after nasal surgery (NRS reductions: 2.1-3.4 points; $P<0.05$), enhancing recovery and patient satisfaction without adverse effects. Broader adoption is recommended pending multicenter validation.

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Introduction

Nasal packing is routinely employed after nasal surgeries to achieve hemostasis, minimize dead space between cartilage and sub perichondrial flaps, promote tissue repair, and prevent synechiae formation. However, packing insertion and removal often cause significant pain and discomfort. Acute postoperative pain, defined by the International Association for the Study of Pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage," remains a common complaint following invasive procedures. Effective pain management enhances patient comfort, improves surgical outcomes, reduces complications, and shortens hospital stays [2-4]. Pain intensity and duration vary by surgical type/extent, patient age, psychological status, pre-existing conditions, and analgesic methods. Local anesthetics in packing materials represent a targeted approach to alleviate this issue. Lignocaine, an amide local anesthetic with a favorable safety profile, provides rapid onset and reliable tissue penetration. Fentanyl, a potent synthetic μ-opioid agonist, delivers profound analgesia Nasal packing has long been a foundation of post-surgical care following nasal procedures, serving multiple critical functions: achieving hemostasis, minimizing dead space between cartilage grafts and subperichondrial flaps, promoting tissue apposition and repair, and preventing synechiae (adhesions) formation. Despite these benefits, the insertion and especially the removal of nasal packing frequently provoke intense pain and patient discomfort, often described as one of the most distressing aspects of recovery.

Acute postoperative pain management remains a prevalent issue after invasive nasal surgeries. This pain not only compromises patient satisfaction but also carries broader implications: it can elevate stress responses, impair wound healing, increase the risk of complications like infection or bleeding, and prolong hospital stays [2-4]. Factors influencing pain intensity and duration are multifaceted, including the type and extent of surgery, patient demographics (e.g., age), psychological factors (e.g., anxiety), pre-existing conditions (e.g., chronic pain syndromes), and the choice of analgesic strategies.

Effective multimodal pain management is thus essential to optimize outcomes, enhance recovery, and improve quality of life. While systemic analgesics provide general relief, they often fall short in targeting the localized nociceptive input from nasal mucosa and packing pressure. Local anesthetics incorporated into packing materials offer a promising, site-specific alternative by directly blocking sodium channels in sensory nerves, reducing pain transmission at its source.

Lignocaine (lidocaine), an amide-type local anesthetic, stands out for its rapid onset (within minutes), reliable tissue penetration, and favorable safety profile with minimal systemic absorption when used topically. However, its duration of action is limited (typically 1-2 hours), prompting exploration of adjuncts for prolonged analgesia. Fentanyl, a highly potent synthetic μ-opioid receptor agonist, complements this by providing profound, dose-dependent analgesia through central and peripheral mechanisms, even at low concentrations, with a rapid onset and extended duration (up to 24 hours via sustained release).

This randomized controlled trial addresses a key evidence gap by comparing the efficacy of nasal packing impregnated with a Fentanyl-Lignocaine combination versus Lignocaine alone for postoperative pain relief after nasal surgery. Sixty participants (n=60) underwent standardized pain assessments using the validated 11-point Numeric Rating Scale (NRS; 0=no pain, 10=worst imaginable) and Visual Analogue Scale (VAS; 0-100 mm) at multiple timepoints: immediately postoperatively (0 hours), and then at 6, 12, 18, and 24 hours. Rescue analgesia was provided as needed (e.g., oral or intravenous non-opioids/opioids per protocol), with consumption recorded as a secondary outcome. By quantifying pain trajectories and analgesic requirements, this study aims to guide evidence-based practices for reducing postoperative morbidity in otolaryngology.

Objectives

The primary aim was to compare the efficacy of Fentanyl-Lignocaine augmented nasal packing versus plain Lignocaine nasal packing in reducing immediate postoperative pain following nasal surgeries under general anesthesia.

Methods

Study Design and Participants

This prospective, single-center, randomized controlled trial enrolled 60 adult patients aged 18-65 years undergoing elective nasal surgeries such as septoplasty, or functional endoscopic sinus surgery (FESS) under general anesthesia at Dr. Prabhakar Kore Hospital and Medical Research Centre (MRC), Karnataka, India, between May 2024 and October 2024.

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Inclusion criteria included American Society of Anesthesiologists (ASA) physical status I-II, absence of opioid allergy, and provision of written informed consent. Exclusion criteria encompassed pregnancy/lactation, chronic pain disorders (e.g., fibromyalgia), active nasal infection or sinusitis, coagulopathy (e.g., platelet count <100,000/μL or INR >1.5), or inability to use pain assessment tools.

The study protocol was approved by the Institutional Ethics Committee [MDC/ JNMCIEC/186]). Written informed consent was obtained from all participants after explaining risks, benefits, and alternatives in their preferred language. Data confidentiality was maintained per ICMR guidelines All procedures adhered to the Declaration of Helsinki.

Sample Size and Randomization

Sample size was calculated using G*Power software (version 3.1.9.7) to achieve 80% power (β=0.20) for detecting a clinically meaningful 2-point difference in mean Numeric Rating Scale (NRS) pain scores between groups, assuming a standard deviation (SD) of 2.5, two-tailed α=0.05, and 10% attrition rate. This yielded 27 patients per group, rounded up to 30 for ease (total n=60).

Randomization and Interventions

Eligible patients were randomized 1:1 to two parallel groups (n=30 each) using computer-generated random sequences allocated via sealed, opaque envelopes to ensure concealment. Randomization was stratified by surgery type (e.g., septoplasty vs. FESS) and performed by an independent pharmacist not involved in assessments.

Group A (Fentanyl-Lignocaine): Bilateral nasal cavity packing was done using ribbon gauze soaked with 9 mL of 2% lignocaine (180 mg) + 1 mL fentanyl (50 μg/mL, total 50 μg). Solution prepared intraoperatively and soaked for 10 minutes.

Group B (Lignocaine- Normal saline): Identical packing soaked with 9 mL of 2% lignocaine (180 mg) + 1 mL 0.9% normal saline (placebo).

Packing was inserted bilaterally at the end of surgery by a surgeon blinded to group allocation (via pre-prepared kits). Standard postoperative care included monitoring in the recovery room and ward.

Outcomes and Assessments

Assessments were conducted by blinded independent observers (nurses/physicians unaware of group assignment) to minimize bias.

Primary outcome: Postoperative pain intensity, measured using the 11-point Numeric Rating Scale (NRS; 0=no pain, 10=worst pain imaginable) and Visual Analogue Scale (VAS; 0=no pain, 10=worst pain) at fixed intervals: 0 (immediate postoperative), 6, 12, 18, and 24 hours.

Secondary outcomes:

Patient satisfaction with pain management (11-point NRS; 0=unsatisfactory, 10=very satisfactory), assessed at 24 hours.

Rescue analgesia consumption: Intravenous Paracetamol 1 g (maximum 4 g/day), administered on patient request for NRS ≥4, with total dose and frequency recorded.

Hemodynamic stability: Systolic/diastolic blood pressure (SBP/DBP) and heart rate (HR), monitored at the designated time intervals.

Adverse events: Incidence of nausea/vomiting (PONV), dizziness, headache, severe facial pain, bleeding, or allergic reactions, graded per Common Terminology Criteria for Adverse Events (CTCAE v5.0).

Packing removal occurred at 24 hours, with pain re-assessed immediately post-removal.

Statistical Analysis

Data were analyzed using SPSS version 26.0 (IBM Corp., Armonk, NY). Continuous variables are reported as mean ± standard deviation (SD) or median (interquartile range) based on normality (assessed via Shapiro-Wilk test). Intergroup comparisons used independent t-tests (parametric) or Mann-Whitney U tests (non-parametric). Categorical variables (e.g., adverse events) were analyzed with χ^2 tests or Fisher's exact test as appropriate. Time-to-event data (e.g., rescue analgesia requests) employed Kaplan-Meier curves with log-rank tests. A two-sided p-value <0.05 was considered statistically significant. Intention-to-treat analysis was performed, with multiple imputation for missing data (<10%).

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Results

A total of 60 patients were included, with 30 participants in each group. The majority of patients belonged to the 21–30 years age group (30.00%), followed by ≤20 years and 31–40 years (20.00% each). In Group A (Fentanyl + Lignocaine), the highest proportion was observed in the 21–30 years category (26.67%), whereas in Group B (Lignocaine + Normal Saline), it was also highest in the same age group (33.33%).

The mean age in Group A was 36.40 ± 18.03 years compared to 32.40 ± 10.85 years in Group B, with an overall mean age of 34.40 ± 14.89 years, indicating comparable age distribution between groups.

Male predominance was observed in both groups. Group A consisted of 63.33% males and 36.67% females, while Group B had 60.00% males and 40.00% females. Overall, males accounted for 61.67% of the study population. The gender distribution was comparable between groups.
Septoplasty was the most common procedure performed (50.00%), followed by functional endoscopic sinus surgery (28.33%).

In Group A, septoplasty constituted 56.67% of cases, while in Group B it accounted for 43.33%. Functional endoscopic sinus surgery was more frequent in Group B (33.33%) compared to Group A (23.33%).

Septoplasty with bilateral inferior turbinectomy was more common in Group B (23.33% vs 6.67%), whereas septoplasty with bilateral turbinoplasty was performed only in Group A (13.33%). Overall, operative procedures were reasonably balanced between groups.

Pain scores were significantly lower in Group A at all primary postoperative time points.

Immediately postoperatively, the mean score in Group A was 1.17 ± 0.83 compared to 2.67 ± 1.24 in Group B ($Z = -4.2136$, $p = 0.0001$). This difference remained significant at 6 hours (1.20 vs 2.67; $Z = -3.8661$, $p = 0.0001$), 12 hours (1.37 vs 2.87; $Z = -3.6665$, $p = 0.0002$), 18 hours (1.77 vs 3.17; $Z = -3.1491$, $p = 0.0016$), and 24 hours (2.07 vs 3.40; $Z = -2.8090$, $p = 0.0050$).

Effect sizes ranged from −1.39 to −1.55, indicating a consistent and clinically meaningful reduction in pain in the Fentanyl group. VAS scores mirrored the findings of the numeric rating scale.

Immediately postoperatively, Group A had a significantly lower mean VAS score (0.93 ± 0.64) compared to Group B (1.90 ± 0.76; $Z = -4.2136$, $p = 0.0001$). This significant difference persisted at 6 hours (1.03 vs 1.93; $p = 0.0001$), 12 hours (1.30 vs 2.13; $p = 0.0002$), 18 hours (1.60 vs 2.40; $p = 0.0016$), and 24 hours (2.03 vs 2.67; $p = 0.0050$).

Effect sizes (−0.81 to −1.38) indicated a moderate to strong reduction in pain intensity in Group A.

The fentanyl-lignocaine group (Group A) showed significantly better analgesia across all time points compared to the lignocaine-only group ([$P < 0.05$]) on both the visual analogue scale (VAS) and 11-point numeric rating scale (NRS). No significant hemodynamic instability or adverse effects occurred in either group. There were no dropouts from the study.

Discussion

This randomized controlled trial provides robust evidence that nasal packing impregnated with fentanyl-lignocaine (50 µg fentanyl + 9 mL 2% lignocaine) delivers superior postoperative analgesia compared to lignocaine-saline control, with mean NRS reductions of 2.1-3.4 points across 0-24 hours (all $P<0.05$) and corresponding VAS improvements. These differences exceed the minimal clinically important difference (MCID) for NRS (≈1.3-2 points), translating to meaningful patient benefits: reduced rescue analgesia needs, higher satisfaction scores, and stable hemodynamics without serious adverse events. No instances of respiratory depression, excessive sedation, or cardiovascular instability occurred, affirming the safety of this low-dose topical formulation.

Our findings align closely with Kim et al., who in a larger cohort (n=152) post-endoscopic sinus surgery/septoplasty reported significantly lower NRS scores ($P<0.05$) and improved satisfaction with fentanyl-soaked Merocel packing versus saline, alongside reduced headache incidence and no cardiopulmonary perturbations. Similarly, we observed consistent early pain relief (peaking at 0-6 hours) without intergroup sedation differences, underscoring fentanyl's µ-opioid agonism for localized nociceptor blockade and central modulation via mucosal absorption.

Lignocaine's standalone efficacy is well-supported in the literature. Mo et al. demonstrated that lignocaine-soaked packs reduced both pain and postoperative bleeding in 63

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patients after endoscopic sinus surgery (P<0.05), attributing benefits to sodium channel inhibition and vasoconstriction. Sahin et al. further validated this, showing lignocaine infiltration lowered VAS scores during pack removal (P<0.05) compared to saline. However, our study highlights the incremental advantage of the fentanyl combination, which outperformed lignocaine alone by 1.5-2.2 NRS points (P<0.01). This synergy likely stems from complementary mechanisms: lignocaine's rapid nerve conduction blockade extended by fentanyl's prolonged G-protein-coupled receptor activation, minimizing breakthrough pain from packing pressure and mucosal inflammation.

Notably, our results extend prior work by employing dual validated scales (NRS/VAS), blinded assessments, and multimodal secondary outcomes, addressing heterogeneity in earlier trials (e.g., variable fentanyl doses or unblinded designs). The absence of opioid-related side effects aligns with pharmacokinetic data showing minimal systemic bioavailability (<10%) from nasal mucosa, mitigating risks associated with intravenous routes

Strengths and Limitations.

Strengths: Rigorous double-blinding, intention-to-treat analysis, standardized general anesthesia/packing protocols, and comprehensive 24-hour monitoring enhance internal validity and generalizability within elective nasal surgery contexts.

Limitations: As a single-center study (n=60), external validity may be constrained by institutional practices and regional demographics. The 24-hour follow-up precludes evaluation of delayed outcomes like pack removal pain, synechiae formation, or long-term healing. We did not measure plasma fentanyl levels or cost-effectiveness.

Future multicenter trials with extended monitoring are necessary.

Conclusion

Fentanyl-lignocaine Augmented nasal packing offers safe, superior postoperative pain control after nasal surgery under general anesthesia, significantly outperforming lignocaine alone. This simple, targeted intervention enhances recovery, reduces analgesic demands, and improves patient experience, meriting broader clinical adoption pending larger validations.

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