Pre-Emptive Topical 2% Lignocaine Gel Soaked Pledget Improves Postoperative Analgesia After Endoscopic Nasal Surgery

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Abstract: Objective: The primary objective of this randomized double-blind controlled trial was to determine whether pre-emptive intranasal 2% lignocaine gel decreases postoperative pain and lessens the use of rescue analgesics. **Methods:** Forty ASA I-II patients (aged 18-65yr) underwent Endoscopic nasal surgery under general anesthesia, were randomly assigned to one of two groups, either pre-emptive topical intranasal saline (Placebo group, n=20) or pre-emptive intranasal 2% lignocaine gel soaked pledgets (lignocaine group, n=20). The postoperative pain assessed by the verbal rating pain scale, time to first postoperative analgesic request, total analgesic consumption during 1st 24hrs postoperative, surgeon and patient satisfaction and adverse effects were recorded. **Results:** Topical lignocaine gel significantly reduced pain scores in the 1st 4hrs postoperative (P<0.001) and at the 24th hr postoperative (P<0.02). Pain scores at the 6th and 12th hrs postoperative were lower but failed to reach a statistical significance. Patients in the lignocaine group had prolonged time to first request for rescue analgesia (239.50±36.45 min. *vs.* 92.40±38.02 min., P<0.000) and lower diclofenac consumption in the 1st 24hrs postoperative (107.14±26.73mg *vs.* 178.94±41.89mg, P<0.000). A higher surgeon and patient satisfaction were recorded in lignocaine group (P<0.000). No significant side effects were recorded in either groups. **Conclusion:** Pre-emptive lignocaine gel soaked pledgets applied in the nasal cavity is a simple and effective method that enhanced intraoperative surgical conditions and accentuated postoperative analgesia.

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1. Introduction

Several endoscopic ear-nose and throat (ENT) procedures such as functional endoscopic sinus surgery (FESS) and endoscopic turbinectomy have been recently developed with the aim of minimizing surgical invasiveness [(1)]. They are associated with mild to moderate postoperative pain related to both surgical trauma and nasal packing [(2)]. Local anesthetics are sometimes used to decrease pain resulting from nasal packs and surgery itself [(3, 4)].

Topical anesthetics work by reversibly blocking sodium channels and preventing propagation of painful nerve impulses. This reduces postoperative pain, improves patient comfort and diminishes the necessity for further parenteral medications such as opioids and nonsteroidal anti-inflammatory drugs [(5, 6)].

Gel formulations of topical anesthetics have been in use in the fields of urology and otolaryngology for many years. Due to their viscous qualities, they are favored for anesthesia of mucous membranes and other areas where high flow of saliva and secretions may dilute an aqueous anesthetic and reduce its effectiveness.

The primary objective of this randomized double- blind controlled trial was to determine whether, pre-emptive topical application of 2% lignocaine gel soaked pledgets in the nasal cavity reduces postoperative pain and lessens consumption of rescue analgesics following endoscopic nasal surgery. We also investigated the patient and surgeon satisfaction, and postoperative side effects as secondary outcomes.

2. Methods:

After obtaining written informed consent and hospital ethics committee approval, a prospective double blind randomized controlled study was conducted on 40 patients of either sex, aged 18-65 yrs, belonging to American Society of Anesthesiologists (ASA) physical status classification I-II and undergoing endoscopic nasal surgery.

The exclusion criteria were hepatic or renal insufficiency, cardiac conduction problems (second or third degree atrio-ventricular block with or without pace maker), concurrent treatment with class I anti-arrhythmic agents e.g. quinidine, history of recent local or systemic infection, reported allergy to

lidocaine or amide local anesthetics, porphyria, psychological disorders, and the use of analgesic medications in the three days before surgery.

The patients were randomly allocated using computer generated numbers into two groups of 20 patients each:

Placebo group: intranasal saline soaked pledget.
Lignocaine group: intranasal 2% lignocaine gel soaked pledget (Xylocaine Jelly 2%, AstraZenaca, Södertälje, Sweden, 100g/2g). A xylocaine Jelly tube (30g containing 600mg lidocaine hydrochloride) was evacuated by a syringe to measure its contents in milliliters and it approximately contained 30ml. So, one millitre xylocaine Jelly contains 20mg lidocaine hydrochloride.

Ten minutes prior to induction of general anesthesia, In the lignocaine group patients, each nostril was packed with a lignocaine gel soaked pledget. Using a syringe, each pledget was heavily soaked with 3ml (60mg) 2% lignocaine gel before its application. Patients in the placebo group were packed with saline soaked nasal pledgets.

In all patients standard general anesthesia with controlled ventilation was used. Anesthesia was induced with thiopentone sodium 5mg/kg and fentanyl citrate 1.5µg/kg. The trachea was intubated with atracurium besylate 0.5mg/kg. Anesthesia was maintained with atracurium besylate 0.5mg/kg/hr and isoflurane 1-2% in oxygen/air mixture to maintain muscle relaxation and depth of anesthesia, respectively. Additional propofol infusion (4-6mg/kg./hr) was administered when there were signs of inadequate anesthesia as determined by a 20% increase in systolic blood pressure and/or heart rate above respective base line values for >60s. One of four surgeons performed endoscopic nasal surgery using a standardized technique. Afterwards, the surgeon graded his satisfaction with the technique (very satisfied, mildly satisfied, or not satisfied) based on surgical conditions and bleeding during surgery, and bilateral nasal packing was performed.

After end of the procedure and reversal of residual neuromuscular blockade with neostigmine methylsulphate 50µg/kg and atropine 20µg/kg, patients were shifted to the post-anesthesia care unit (PACU) where they were discharged to the ward after attaining an Aldrete& Kroulik [(7)] score > 9.

Pain intensity was assessed postoperatively by using the Verbal Rating scale (VRS) (0 = no pain, 1 = mild pain, 2 = moderate pain, 3 = severe pain, and lastly 4 = excruciating pain). VRS assessments were performed at rest at 30, 60, 90min., and at 2, 4, 6, 12, and 24 hrs postoperative. Diclofenac sodium 75 mg iv was given if requested and if VRS scores were ≥2, and the total consumption of rescue analgesics in the first 24 hrs postoperative was calculated.

The attending anesthesiologist, surgeon and data collection personell were blinded to patient group assignment and to the nature of the study medication.

Any adverse effects in the 1st 24 hrs postoperative were treated and recorded including nausea and vomiting, bleeding, central nervous system or cardiovascular lidocaine adverse effects such as tinnitus, tremors, circumoral paraesthesia, dizziness, blurred vision, hypotension, bradycardia, or arrhythmias. The patients graded their satisfaction regarding analgesia (very satisfied, mildly satisfied, or not satisfied) at the end of the 24-hrs study period.

Statistical analysis:

To achieve power of 0.9 and an alpha coefficient of 0.5, it was determined that at least 15 patients in each group would be required to detect a difference of 2 in the verbal rating pain score. The data were analyzed using SPSS version 17. The continuous independent samples were analyzed using Student's t-test, while continuous non-numerical variables were evaluated using the rank sum test. For categorical variables, Fisher's exact test was applied. The VRS scores at the various time points were analyzed using generalized estimating equations. Paired t-test was used to compare VRS scores in each group. A *P* value <0.05 was considered significant.

3. Results:

The demographic profile in both groups was comparable [Table. 1]. In the lignocaine group, 8/20 (40%) of the patients required intraoperative additional propofol infusion, compared with 14/20 (70%) of the patients in the placebo group ($P<0.01$). The mean time to first request for rescue analgesia was significantly prolonged in lignocaine group (239.50±36.45 min., $p<0.000$), compared with placebo group (92.40±38.02min.). The mean diclofenac consumption in lignocaine group was 107.14±26.73mg *vs.* 178.94±41.89 mg in placebo group [$P< 0.000$, Table.2]. Postoperative pain scores at rest were significantly lower ($P<0.05$) in lignocaine group compared to placebo group at 60, 90min., 2, 4 and 24hrs postoperative [Table.3 and Figure.1]. The VRS scores in lignocaine group in the 6th and 12th hrs postoperative were lower than in the placebo controls but failed to reach a statistical significance. There were significant differences between the two groups regarding surgeon and patient satisfaction [$P< 0.000$, Table.4]. Two patients in placebo group and one in lignocaine group reported PONV single episode. One patient in placebo group had mild postoperative bleeding that didn't require surgical intervention. No systemic complications were observed in either group.

Table.1: Patient demographic data.

	Placebo group	Lignocaine group	*P*- value
Age(yr)	28.45±9.83	29.75±10.49	NS
Weight(kg)	72.20±14.27	72.95±13.62	NS
Height(cm)	152.67±10.83	150.94±9.78	NS

Data are expressed as mean ±SD.

Table.2: Time to first analgesic request and Diclofenac consumption in 1st 24hrs postoperative.

	Placebo group	Lignocaine group	*P*- value
Time to first analgesic request (min.)	92.40±38.02	239.50±36.45	0.000
Diclofenac consumption in 1st 24hrs postoperative (mg).	178.94±41.89	107.14±26.73	0.000

Data are expressed as mean ±SD.

Table.3: Pain scores in the placebo and lignocaine groups.

	Placebo group	Lignocaine group	Difference in pain scores	95% confidence interval	*P*-value
VRS30min.	0.85±0.24	0.4±0.13	-0.45	-0.11-1.01	NS
VRS60min.	1.7±0.34	0.5±0.15	-1.2	0.44-1.96	0.003
VRS90min.	1.7±0.37*	0.5±0.17	-1.2	0.37-2.03	0.006
VRS2h	2.05±0.30*	0.85±0.15*	-1.2	0.52-1.88	0.001
VRS4h	1.7±0.27*	0.9±0.19*	-0.8	0.13-1.47	0.02
VRS6h	1.6±0.24	1.10±0.18*	-0.5	-0.11-1.11	NS
VRS12h	2.1±0.18*	1.7±0.15*	-0.4	-0.06-0.86	NS
VRS24h	2.15±0.13*	1.75±0.9*	-0.4	0.07-0.73	0.02

Data are expressed as mean ±SE. * means statistically significant versus the VRS30min of the same group. VRS: Verbal Rating Scale pain score.

Table. 4: Surgeon and patient satisfaction.

	Very satisfied	Mildly satisfied	Not satisfied
Surgeon satisfaction index: Placebo group	-------	16 (80%)	4 (20%)
Lignocaine group	12 (60%)	8 (40%)	----------
***P* value**	*0.000*		
Patient satisfaction index: Placebo group	---------	12 (60%)	8 (40%)
Lignocaine group	15 (75%)	5 (25%)	-------
***P* value**	*0.000*		

Data are expressed as number and percentages.

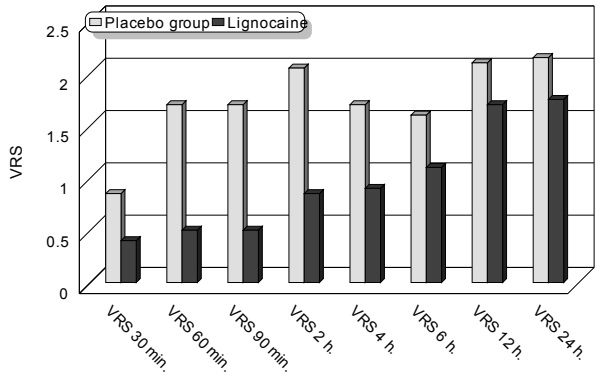

Figure.1: The Verbal rating scale (VRS) Pain score in the placebo and lignocaine groups.

4. Discussion:

Topically applied 2% lignocaine gel significantly improved postoperative analgesia in the 1st 24 hrs after endoscopic nasal surgery. A pre-emptive lignocaine gel soaked pledgets applied in the nasal cavity is a simple and effective method that enhanced intraoperative surgical conditions and reduced the requirements for postoperative rescue analgesia.

Kuo *et al.* Have found that the postoperatively applied lignocaine ointement Vaseline gauze packs caused less pain in septoplasty patients compared to

gauze packs alone [8]. Pain scores were significantly lower in the 1st 3hrs postoperative and this was attributed to the lidocaine's short duration of action. Compared with intranasal saline, pre-emptive topical lignocaine gel significantly reduced pain scores in the 1st 4hrs postoperative and at the 24th hrs postoperative. Pain scores at the 6th and 12th hrs postoperative were lower but failed to reach a statistical significance. The observed pain profile of topical lignocaine in this study may be attributed to the pre-emptive timing of its administration. Several experimental studies demonstrated that various antinociceptive techniques applied before injuries are more effective in reducing the post injury central sensitization phenomena compared to administration after injury [9].

We used lidocaine in a gel formulation aiming for a long lasting effect. The dose of lidocaine was not adjusted for weight or body mass index (BMI) because we wanted to evaluate a simple one-dose regimen for adults. A dose of 3ml 2% lignocaine gel applied in each nostril with a total of 120 mg is far below the toxic dose. Absorption of lidocaine varies according to both the site and the mode of delivery and fluctuates with the use of vasoconstrictors or cholinergic drugs [10, 11]. Serum levels to determine total plasma lidocaine concentrations if present would have confirmed the safety of such technique.

Our study can be criticized for a small sample size. Further studies with larger patient groups should be conducted and the effect of lignocaine gel further investigated. A combination of pre-emptive and postoperative topical lignocaine gel would accentuate and prolong its analgesic effect.

In conclusion, pre-emptive lignocaine gel soaked pledgets applied in the nasal cavity is a simple and effective method that enhanced intraoperative surgical conditions and accentuated postoperative analgesia.

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Conflict of interest:

There were no conflicts of interest.

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References:

1. Mark M, Barry S. Erasorama surgery. Nose and paranasal sinuses. Curr Opin Otolaryngol Neck Surg., 2002; 10:19-2.
2. Friedman M, Venkatesan TK, Lang D, Caldarelli DD. Bupivacaine for postoperative analgesia following endoscopic sinus surgery. Laryngoscope, 1996; 106:1382:5.
3. Bonaparte JP, Javidnia H, Kilty S. A double-blind randomised controlled trial assessing the efficacy of topical lidocaine in extended flexible endoscopic nasal examinations. Clin Otolaryngol., 2011 Dec; 36(6):550-7.
4. Mishra P, Kaushik M, Dehadaray A, Qadri H, Raichurkar A, Seth T. Preparation of nose for nasal endoscopy: cotton pledget packing versus topical spray. A prospective randomized blinded study. Eur Arch Otorhinolaryngol., 2012 Mar 17. [Epub ahead of print]
5. Granier M, Dadure C, Bringuier S, Bonnet-Boyer MC, Ryckwaert Y, Loriaux E, Capdevila X. Intranasal lidocaine plus naphazoline nitrate improves surgical conditions and perioperative analgesia in septorhinoplasty surgery. Can J Anaesth. 2009 Feb; 56(2):102-8. Epub 2009 Jan 7.
6. Karman E, Gunger G, Alimoglu Y, Kilic E, Tarakci E, Bozkurt P, Enver O. The effect of lidocaine, bupivacaine and ropivacaine in nasal packs on pain and hemorrhage after septoplasty. Eur Arch Otorhinolaryngol. 2011 May; 268(5):685-9. Epub 2010 Dec 1.
7. Aldrete JA, Kroulik D. A postanesthetic recovery score. Anesth Analg., 1970; 49:924-934.
8. Kuo MJ, Zeitoun H, Macnamara M, Wagstaff K, Carlin WV, Turner N. The use of topical 5% lignocaine ointment for the relief of pain associated with post-operative nasal packing. Clin Otolaryngol Allied Sci., 1995 Aug; 20(4):357-9.
9. Katz J, Kavanagh BP, Sandler AN, *et al.* Preemptive analgesia. Clinical evidence of neuroplasticity contributing to postoperative pain. Anesthesiology 1992; 77(3):439-46.
10. Watanabe H, Lindgren L, Rosenberg P, Randell T. Glycopyrronium prolonges topical anaesthesia of the oral mucosa and enhances absorbtion of lignocaine. Br J Anaesth. 1993; 70:94-5.
11. Williams KA, Barker GL, Harwood RJ, Woodall NM. Combined nebulization and spray –as-you-go topical local anaesthesia of the airway. Br J Anaesth. 2005; 95:549-53.

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