Simple. Smart. Solutions

Xilonibsa® Spray 10%

Topical anaesthetic

Product file

Contents

Xilonibsa® Spray 10%

1

Xilonibsa® Spray 10%

Description & indications

Xilonibsa Spray 10% is a lidocaine cutaneous spray solution. Every pulse of the dispenser releases a dose of 10 mg of lidocaine and it comes in a 50 ml bottle.

Xilonibsa Spray 10% is a topical anaesthetic for mucous membranes in surgery, obstetrics, dentistry and otorhinolaryngology.

Posology: general information

The dosage can be adjusted **depending on the patient's response** and the site to be anaesthetised, evaluating the extent of tissue vascularisation and the anaesthetic technique to be applied. It should be administered at the **lowest dose possible that provides the anaesthetic effect** required, avoiding the use of excessive doses (see "Special warnings and precautions for use").

The administration of lidocaine should be **adjusted when used concomitantly with other drugs** that reduce its clearance (see "Interaction with other **medicinal** products and other forms of interaction").

No more than 20 pulses should be applied to **produce** the desired anaesthesia in adults.

Adults (Table 1)

In dentistry
1 to 5 applications are recommended for administration on the mucous membranes.

In otorhinolaryngology
When used for maxillary sinus puncture, **3 sprays** are recommended.

In gynaecology and obstetrics
Applying 20 sprays (equivalent to 200 mg) is recommended.

Bear in mind that **the maximum 24-hour dose for an adult weighing 70 kg is 200 mg** (corresponding to 20 applications with the dosing valve).

Table 1. Dosing of Xilonibsa Spray 10% considering each speciality

SPECIALITY	ADMINISTRATION DOSE
Dentistry	1 to 5 sprays
Otorhinolaryngology	3 sprays
Gynaecology and obstetrics	20 sprays (maximum dose)

Note: If dosing according to patient´s weight, this dose **must not exceed 3 mg/kg of body weight per day**.

Special population

Weakened or elderly patients
They may be more sensitive to the standard dose, so it is recommended to **reduce the dose in this group of patients**.

Patients with impaired cardiovascular function
In patients with cardiovascular alterations and cardiovascular insufficiency, it is recommended to **reduce the dose**, taking into account that their **volume of distribution is low**.

Patients with impaired renal function
In patients with nephrotic syndrome, it is recommended to **reduce the dose**, taking into

account the low capacity of plasma proteins to bind to lidocaine and its metabolites.

Patients with impaired liver function
It is recommended to **reduce the dose**, taking into account that it is **metabolised in the liver** and there is a greater likelihood of occurrence of adverse reactions.

Patients with epilepsy
In patients who suffer from epilepsy, treated over a long period of time with **phenytoin or barbiturates**, it is recommended to **adjust the dose**.

Paeditric population

The dose of lidocaine in children **should be adjusted** according to the nature of the procedure and the patient's characteristics.

In children **over 6 years of age**, the dose shall be calculated according to body weight, using the dose of **3 mg/kg of body weight per day as the maximum recommended daily dose**.

The use of **Xilonibsa Spray 10%** in **children under 6 years of age is not recommended** (see "Special warnings and precautions for use").

Contraindications

Hypersensitivity to lidocaine, amide-type anaesthetics or any of its excipients.

Special warnings and precautions for use

Lidocaine should be used with caution in the elderly and debilitated person as well

as in patients with epilepsy, hypovolemia, atrioventricular block, or other conduction disturbances, bradycardia, or impaired respiratory function.

Lidocaine is metabolized in the liver and should be used with caution in patients with impaired liver function.

The **plasma half-life** of lidocaine may be extended under conditions that **reduce hepatic blood** flow, such as cardiac and circulatory insufficiency. In addition, lidocaine **metabolites** may accumulate in patients with renal impairment.

The administration of excessive doses should be avoided, as well as the application of the drug in **tissues infected or inflamed** since in these cases the absorption of lidocaine is very fast, and systemic adverse reactions may occur.

In addition to this, it should be noted that **anaesthetic absorption is very quick** in the trachea and **bronchial tree**, which could lead to systemic adverse reactions.

After any **oropharyngeal anaesthesia** application, the ingestion of **solid or liquid food must be avoided for at least two hours** to avoid false routing of the alimentary bolus, as well as lingual lesions due to bites.

Avoid Xilonibsa Spray 10% contact with the **eyes**.
In case of eye contact, remove contact lenses if necessary, rinse immediately and flush with water for 15 minutes, keeping eyelids apart. Do not let water flow towards the unaffected eye.
Immediately seek further ophthalmologist care.

Patients treated with **class III anti-arrhythmic drugs** (e.g. amiodarone) should be **closely monitored**. Monitoring via electrocardiogram (ECG) should be considered, as cardiac effects may be additive.

Xilonibsa 10 mg/pulse **contains ethanol**. This medicine contains 241 mg of alcohol (ethanol) in each ml. May cause burning sensation in the injured skin.

Paeditric population

The use of **Xilonibsa Spray 10%** is **not recommended** in children under 6 years of age due to the risk of very rapid absorption of the anaesthetic and the **risk of laryngospasm** in newborns.

Xilonibsa Spray 10% should be **used with caution** in children **over 6 years** of age, never exceeding the maximum recommended dose.

Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Drugs that affect the use of lidocaine

- **ß-adrenergic receptors antagonists** (propranolol) and H2-antagonists (cimetidine) reduce hepatic clearance of lidocaine.
    - **Propranolol**-induced hepatic reduction seems to be mainly due to a **direct inhibition** of lidocaine metabolism.
    - **Cimetidine**-induced hepatic reduction is due to a reduction in **liver metabolism** of lidocaine and a decrease in **hepatic blood flow**.

Although clinical relevance of these interactions has not been established, it is recommended to **reduce the dose** of Xilonibsa Spray 10% when administered concomitantly with these drugs, especially when lidocaine is used at **high doses repeatedly**.

- **Halothane** reduces hepatic blood flow, leading to a reduction in lidocaine clearance.
- **Phenytoin** and other enzymatic inducers in long-term treatments, could make necessary to increase the dose of lidocaine as a result of an enhanced liver metabolic effect.
- **Antiretroviral drugs** used in AIDS treatment (atazanavir, darunavir), increase plasma concentrations of lidocaine.
- **Hypokalaemia** caused by **acetazolamide**, **loop diuretics** and **thiazides**, antagonize the effect of lidocaine.

Drugs affected by the use of lidocaine (Table 2)

- Lidocaine may enhance the effect of **muscular blockers**: high doses of lidocaine may reduce the release of **acetylcholine** and act directly on the muscular membrane.
- Specific interaction studies on the interaction between **lidocaine/prilocaine** and **class III anti-arrhythmic drugs** (e.g. amiodarone) have not been conducted; therefore, **caution is advised** (see "Special warnings and precautions for use").
- Lidocaine should be **used with caution** in patients who receive **other local anaesthetics** or **amide-type drugs**, as the toxic effects are additive.
- The simultaneous administration with **anti-psychotic drugs** that extend the QT interval **increases the risk** of ventricular arrhythmias.

Table 2. Effects of Xilonibsa Spray 10% over different drugs

DRUGS	EFFECT OF LIDOCAINE	REASON
Muscular blockers	May enhance their effect	High doses of lidocaine may reduce the release of acetylcholine and act directly on the muscular membrane.
Class III anti-arrhythmic drugs	Caution is advised	Specific interaction studies have not been conducted.
Other local anaesthetics or amide-type drugs	Caution is advised	Toxic effects are additive.
Anti-psychotic drugs (that extend the QT Interval)	Caution is advised	Risk of ventricular arrhythmias is increased.

Fertility, pregnancy and Breast-feeding

Pregnancy

Using **Xilonibsa Spray 10%** during pregnancy is **not recommended** as lidocaine crosses the placental barrier.

Data in a limited number of pregnant women did not show evidence of congenital anomalies.

The use of **Xilonibsa Spray 10%** during this stage should be **reserved** exclusively for those cases in which the **potential benefit justifies possible risks** to the foetus.

Breast-feeding

Lidocaine is excreted in breast milk, but at the therapeutic doses of **Xilonibsa Spray 10%**, **effects** on nursing newborns/infants are **not expected**.

Fertility

Although there are no systematic studies in humans regarding lidocaine influence on fertility, since its introduction to the market many years ago, there have been **no unfavourable effects** reported **on fertility** to date.

Effects on ability to drive and use machines

Xilonibsa 10 mg/pulse has minor influence on the ability to drive and machines use.

Depending on the dose and site of administration, local anesthetics can affect mental function and temporarily impair locomotion and coordination. When this medicine is administered, the doctor must assess in each particular case if the patient ability to react is compromised and if the patient can drive or use machines.

Normally, a single application of lidocaine does not cause systemic adverse effects. However, lidocaine can cause lightheadedness, sedation, blurred vision, and dizziness. If any of these side effects occur after the application of lidocaine, patient should wait until these symptoms subside before driving or using machinery.

Undesirable effects

Xilonibsa Spray 10% may cause local irritation (coughing, sneezing) at the time of the application or immediately after.

Product administration route excludes any risks in inadvertent intravascular administration.

Adverse reactions by group

Other adverse reactions that may occur with the use of lidocaine are (Table 3):

Paediatric population

Children are more prone than adults to experiment adverse effects from local anaesthetics such as lidocaine.

Reporting of suspected adverse reactions

When an adverse reactions arises after authorization of the medicinal product, it is important to report it. This allows to continue monitoring benefit/risk balance of the drug.

Healthcare professionals are asked to report any suspected adverse reactions via the Spanish Pharmacovigilance System for Medicinal Products for Human Use website: www.notificaram.es (or the Pharmacovigilance System recommended in your country).

Overdose

As with other local anesthetics, due to an excessive dosage or rapid absorption, especially by the trachea and bronchial tree which it can simulate a slow intravenous injection, systemic reactions may occur affectting the CNS and the cardiovascular system. In these cases, treatment should consist of monitoring vital signs and, in the event of seizures, intravenous

Table 3. Xilonibsa Spray 10% low frequency side effects

FREQUENCY	DISORDERS	EFFECTS
Rare (≥1/10000 to <1/1000)	Cardiac disorders	Hypotension, arrhytmias, bradycardia, cardiac arrest.
	Nervous system disorders	Metallic taste, tinnitus, felt faint, nausea, vomiting, anxiety, tremors, nystagmus, headaches, increased respiratory rhytm.
		Paresthesia (sensory loss accompained by a burning sensation) of the lip and/or tongue.
		Unconciousness and convulsions, coma and respiratory arrest (in the event of overdose).
	Respiratory disorders	Tachypnoea followed by bradypnoea, possibly causing apnoea.
Very rare (<1/10000)	General disorders and administration site conditions	Allergic reactions, skin eruption, erythema, pruritus, oedema of the tongue, mouth, lips or throat and, inthe most severe cases, anaphylactic shock.

administration of short-acting barbiturates (thiopental) or benzodiazepines (diazepam).

Pharmacological properties: Mechanism of action

Like the rest of local anesthetics, lidocaine blocks nerve impulse transmission preventing Na^+ ions entry through nerve membrane.

Pharmacokinetic properties

Absorption

Lidocaine is rapidly absorbed from gastrointestinal tract, mucous membranes and damaged skin, while lidocaine absorption through healthy skin is low. After topical application of Xilonibsa Spray 10% on the mucous membranes, the analgesic **effect begins between 1 and 3 minutes later and lasts approximately 15 minutes**.

Distribution

After intravenous infusion, lidocaine spreads widely and quickly through highly perfused tissues, subsequently redistributing in muscle and adipose tissue.

Lidocaine **binds to plasma proteins**, including α-1-acid glycoprotein. Its degree of protein binding is **variable** and **66%** approximately. This binding depends on the **lidocaine and glycoprotein concentrations**. For this reason, any change in α-1 acid glycoprotein concentration can significantly affect lidocaine plasma concentration.

Lidocaine crosses placenta and blood-brain barrier and passes into breast milk.

Metabolism

Lidocaine is **metabolised widely in liver**. Any change in hepatic function or hepatic blood flow can significantly affect its pharmacokinetics and dosage.

First-pass metabolism is extensive. Approximately 90% of lidocaine administered is **transformed** into monoethylglycinexylidine and glycinexylidine. Both metabolites may contribute to therapeutic and toxic effects of lidocaine.

Half-life of these **metabolites** are **greater than** that of **lidocaine**.

Elimination

Plasma concentrations of lidocaine **decline rapidly after intravenous infusion**.
Elimination half-life is 1 to 2 hours, though it may be longer if infusions are administered for more than 24 hours or if hepatic blood flow is decreased.

Its metabolites are **excreted in urine**, with **less than 10% excreted as lidocaine**.

Lidocaine **clearance is reduced** in patients with cardiovascular insufficiency, viral or chronic hepatitis and alcohol-related liver diseases.

Drugs that alter hepatic blood flow or induce the enzymatic metabolism of lidocaine may affect its clearance.

In addition, lidocaine clearance may be affected when kidney damage exists, as this could result in an accumulation of metabolites.

Preclinical safety data

Local tolerance

Local tolerance studies in cats with current formulation of **Xilonibsa Spray 10%** showed clinical signs of **irritation in respiratory tract** (coughing, sneezing), which appeared at the time of administration or immediately after.

Reproduction toxicology

Rat and rabbit models have been used in **fertility studies** to evaluate lidocaine effects.

In rat models, administration of 30 mg/kg (180 mg/m^2 body surface) on reproductive organ did not produce **alterations to fertilisation capacity or fertility**.

In rabbit models, there was **no evidence of foetal damage** at doses of 5 mg/kg (60 mg/m^2 body surface). At much **higher doses** than 25 mg/kg (300 mg/m^2), signs of **toxicity appeared** in progenitor rabbit as well as signs of delayed foetal development, regarding a non-significant reduction in weight (7%) and an increase in minor skeletal development defects and skull, sternum and phalanges ossification abnormalities.

Use of **Xilonibsa Spray 10%** **is not contraindicated during childbirth**.

Mutagenesis, genotoxicity and carcinogenesis

- The **mutagenic potential** of lidocaine has been assessed using the **Ames test on Salmonella**, ***"in vitro"* trials on chromosomal aberrations** in human lymphocytes and ***"in vivo"* estimations** of its effects using the rat micronucleus test. No mutagenic effects were observed from the results of all of these test.
- In **genotoxic effects** research of lidocaine administered topically, no alterations appeared. However, one of its metabolites, 2,6-xylidine, has demonstrated potential uterine genotoxicity under *"in vitro"* conditions.
- In a **carcinogenic study** in rats exposed to 2,6-xylidine metabolite in the uterus over a long period and at very high doses, tumours in the nasal cavity, liver and subcutaneous tissue did appear.

The clinical relevance of this lidocaine metabolite effect after its intermittent use as a local anaesthetic, has not been established.

There are no animal studies that have evaluated the carcinogenic potential of lidocaine given as

a spray, nor is there evidence of foetal damage from subcutaneous administration of lidocaine at doses of 50 mg/kg (300 mg/m^2 body surface).

In conclusion, there are no properly formalised studies on the effects of lidocaine on pregnant women.

Given that studies on the effects on reproduction in animals are not always predictive of the response in humans, lidocaine should be used in pregnancy **only when clearly needed**.

List of excipients

- Ethanol 96%
- Menthol
- Saccharin
- Macrogol 400
- Fragance of banana
- Purified water

Shelf life & Special precautions for storage

3 years.

Do not store above 25ºC.
Store in the original package in order to protect it from light.

Incompatibilities: Not applicable.

Marketing authorisation holder

Inibsa Dental, S.L.U.
Ctra. Sabadell a Granollers, km 14.5
08185 Lliçà de Vall
e-mail: info_medica@inibsa.com

Xilonibsa® Spray 10%, the anesthesia enabler.

Clinical data support.

2

Otorhinolaryngology

Indian Journal of Medical Research and Pharmaceutical Sciences

August 2020;7(8)
DOI: https://doi.org/10.29121/ijmrps.v7.i8.2020.3

ISSN: ISSN: 2349-5340
Impact Factor: 4.054

The effect of 10 % lidocaine sprayed to nasal packs on pain after elective septoplasty

Sadeq M. Da'meh MD*, Khaled S El Share MD, Zaidoun H. Al-Rawashdeh MD, Motasem M Al- Krymeen MD & Wardeh A Alhusban MD

Department of anesthesiology, intensive care and pain management, RMS, KHMC, Amman, Jordan

Objective

To study analgesic effect of lidocaine 10% sprayed to 10 cm x 10 cm gauze swabs with neomycin and bacitracin ointment nasal packing using visual analog scale (VAS) in postoperative period for patients underwent septoplasty operation.

Materials and methods

Patients between 17 and 50 years (n=100) scheduled for septoplasty between Jan 2018 and Jan 2019, were divided into two equal groups: lidocaine 10% (Group L) was sprayed to gauze swabs with neomycin and bacitracin ointment nasal packing and group S (saline; 0.9% NaCl) applied to same nasal packing.

Table 1. Visual analog score (VAS) at post-operative 2, 6, 12,18 and 24 h

Post-operative period	10% Lidocaine group	0.9% NaCl group	t value	P value
	Mean ± SD	Mean ± SD		
2 H	3.65 ± 2.21	5.21 ± 2.30	3.4583	<0.001*
6 H	2.96 ± 2.05	5.08 ± 1.98	5.2598	<0.001*
12 H	2.01 ± 1.95	4.18 ± 1.88	5.6649	<0.001*
18 H	1.91 ± 1.17	3.77 ± 1.23	7.7476	<0.001*
24 H	1.05 ± 1.01	2.67 ± 1.16	7.4477	<0.001*

* statistically significance at ($\alpha \leq 0.05$)

Outcomes: pain (VAS scale), side effects and analgesic (paracetamol or nonsteroidal anti-inflammatory analgesic) requirements were recorded.

Exclusion criteria: nasal concha bullosa, polyposis or any para-nasal pathology.

Forms were collected at end of 24th hour's period. Mean pain scores for each group were calculated (except those from patients whom needed rescue drugs) (Table 1).

Results

- There were no differences between the number of female and male patients.
- Postoperative pain was less in group L than group S ($p < 0.05$).
- Patients in the S group needed more rescue drug.
- L group had significantly better pain score versus S group at all intervals (2, 6, 12, 18, and 24) postoperative period (Figure 1).

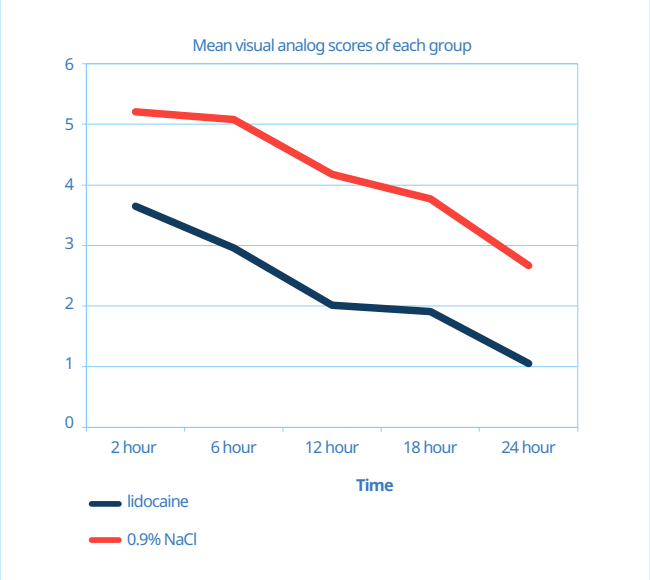


Figure 1. Mean VAS of 10% lidocaine and 0.9% NaCl group.
Figure 1 shows the 0.9% NaCl group pain score were remained stable at the first 6 hours then dropped steadily, while the pain score of the lidocaine group were dropped rapidly at the first 12 hours after that they were remained relatively stable at 18th hours then dropped at end of the 24th hour postoperatively.

Conclusion

"Our study showed that application of 10% lidocaine spray to 10 cm x 10 cm gauze swabs with neomycin and bacitracin ointment nasal packs provides better analgesia than the 0.9% NaCl group.

As a result, ***we recommend using 10% lidocaine spray to nasal packs to decrease additional analgesics drugs uses in postoperative period and increases patient satisfaction and comfort****."*

Bibliography

Sadeq M. Da'meh MD, Khaled S El Share MD, Zaidoun H. Al-Rawashdeh MD, et al. The effect of 10% lidocaine strayed to nasal packs on pain after elective septoplasty. Indian JMedResPharmSci; 2020August;7(8).

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

European Journal of Pain

Epub 2019 Nov 25
DOI: 10.1002/ejp.1503

Analgesic efficacy of 10% lidocaine spray during nasoenteral catheterization: Randomized tripleblind trial

Amanda Santos Oliveira[1], Caíque Jordan Nunes Ribeiro[1], Aline Láyra Carvalho Oliveira[2], Viviane Oliveira de Sousa Correia[2], Jonas Santana Pinto[2], Evando Santos-Júnior[3], Maria do Carmo de Oliveira Ribeiro[1-2]

[1]Postgraduate Program in Health Sciences, Federal University of Sergipe, Aracaju, Brazil
[2]Department of Nursing, Federal University of Sergipe, Aracaju, Brazil
[3]Department of Medicine, Federal University of Sergipe, Aracaju, Brazil

Objective

To evaluate the analgesic efficacy of the use of 10% lidocaine spray during nasoenteral catheterization (NEC).

Materials and methods

Randomized, triple-blind trial (n=50) with two groups: an intervention group (IG), in which 10% lidocaine spray combined with 2% lidocaine gel was used, and a control group (CG), in which a saline solution spray combined with 2% lidocaine gel was used.

- **Exclusion criteria:** Participants with allergy to components of 10% lidocaine spray or 2% lidocaine gel
- **Measurements:** Pain and discomfort during and after nasoenteral catheterization using numerical rating scale (NRS) and the visual analogue scale (VAS), respectively.
- Statistical analysis was performed using the Chi-square and Fisher's exact tests and to examine differences between the groups the Mann-Whitney test.

In addition, the magnitude of the effect was calculated using the Cliff Delta statistic (|***d***|). This measure can be understood as a useful complementary analysis to the corresponding hypothesis test since the p-values alone do not actually provide information about the magnitude of a difference between two groups of observations. Values of |***d***| (ranges from -1 to 1): |***d***| < 0.147 - insignificant difference; |***d***| < 0.33 - small difference; |***d***| < 0.474 - moderate difference; other values indicate large differences.

Results/Efficacy

Intervention group participants reported lower pain scores **during** (0.20 ± 0.71 vs. 5.00 ± 2.84, $p < .001$; |d| = -0.677) and **after** (0.00 ± 0.00 vs. 2.80 ± 2.83, $p < .001$; |d| = -0.718) nasoenteral catheterization compared to the CG.

- We observed a large difference between the IG and CG treatments in the reported intensity of discomfort during and after catheterization and the reported intensity of pain during and after the procedure (Table 1 and 2).
- Most CG patients had complications during and after the procedure, with no significant differences between groups (Table 3).

Table 1. Characteristics of pain and discomfort related to NEC.

VARIABLES	GROUP				OR (95%IC)	P VALUE
	IG		CG			
	n	%	n	%		
Presence of pain						
During catheterization	22	88	21	84	0.02 (0.00, 0.10)	0.000[b]
After catheterization	-	-	15	60	-	0.000[b]
Location of pain during catheterization						
Nostril	22	88	10	40	0.13 (0.03-0.68)	0.018[b]
Nasopharynx	-	-	10	40	-	0.001[b]
Pharynx	-	-	1	4	-	1.000[b]
Location of pain after catheterization Nostril						
Nasopharynx	-	-	8	32	-	0.004[b]
Pharynx	-	-	6	24	-	0.022[b]
Presence of discomfort	-	-	1	4	-	1.000[b]
During catheterization	14	56	24	96	0.03 (0.00-0.28)	0.000[b]
After catheterization	19	76	21	84	0.11 (0.03-0.41)	0.001[b]
Location of discomfort during catheterization						
Nostril	25	20	12	48	0.27 (0.08-0.95)	0.073[a]
Nasopharynx	25	20	11	44	0.32 (0.09-1.12)	0.129[a]
Pharynx	1	4	1	4	1.00 (0.06-16.93)	1.000[b]
Stomach	-	-	1	4		1.000[b]
Location of discomfort after catheterization						
Nostril	25	20	10	40	0.38 (0.11-1.33)	0.217[a]
Nasopharynx	14	16	9	36	0.34 (0.09-1.30)	0.196[b]
Pharynx	-	-	2	8	-	0.489[b]

[a]Chi-square test, [b]Fisher's exact test.

Table 2. Analgesic efficacy analysis of 10% lidocaine spray.

VARIABLES	GROUP				P VALUE	|d|
	IG		CG			IG vs. CG
	Mean	SD[a]	Mean	SD[a]		
Intensity of disco mfort[b]						
During catheterization	1.84	2.54	5.48	2.60	0.000	-0.677[d]
After catheterization	0.92	1.32	4.0	2.55	0.000	-0.718[d]
Intensity of pain[c]						
During catheterization	0.2	0.71	5.0	2.84	0.000	-0.822[d]
After catheterization	0.0	0.0	2.80	2.83	0.000	-0.600[d]
Ease of catheterization	1.76	1.87	1.88	0.83	0.538	-0.096[e]
Catheterization time (min)	4.08	1.53	4.08	1.68	0.842	0.032[e]

[a]Standart deviaton, [b]VAS, [c]NRS, [d]large difference, [e]insignificant difference.

- Regarding the type of complication recorded during the survey, nausea was most frequent in patients in both groups, and the most frequent complications after the procedure were coughing and nausea (Table 3).

Table 3. Complications during and after NEC.

VARIABLES	GROUP				OR (95%IC)	P VALUE
	IG		CG			
	n	%	n	%		
Complications during catheterization	12	48	23	92	0.08 (0.02-0.42)	0.001[b]
Cough	6	24	13	52	0.29 (0.09-0.98)	0.080[a]
Nausea	9	36	21	84	0.11 (0.03-0.41)	0.001[b]
Vomiting	-	-	3	12	-	0.235[b]
Dyspnea	1	4	4	16	0.22 (0.02-2.11)	1.000[b]
Nasal bleeding	-	-	1	4	-	1.000[b]
Hypertensive peak	-	-	1	4	-	1.000[b]
Complications after catheterization	6	24	21	84	0.06 (0.01-0.25)	0.000[b]
Cough	4	16	13	52	0.18 (0.05-0.66)	0.015[b]
Nausea	3	12	15	60	0.09 (0.02-0.39)	0.000[b]
Vomiting	-	-	2	8	-	0.489[b]
Nasal bleeding	-	-	1	4	-	1.000[b]
Dyspnea	-	-	1	4	-	1.000[b]
Sneezing	-	-	1	4	-	1.000[b]

[a]Chi-square test, [b]Fisher's exact test.

Conclusion

"Spraying 10% lidocaine spray before nasoenteral catheterization was most effective for relieving discomfort and pain, with lower pain and discomfort recorded in NRS and VAS. ***Topical administration of 10% lidocaine spray is therefore a suggested measure for procedural pain relief related to nasoenteral catheterization****.*

Significance: The use of 10% lidocaine spray was more effective in relieving procedural pain and discomfort during nasoenteral catheterization. Patients who received 10% lidocaine spray registered lower discomfort and pain scores than those from 2% lidocaine gel group; there were less complications among patients in the IG."

Bibliography

de Oliveira AS, Ribeiro CJN, Oliveira ALC, Correia VOS, Pinto JS, Santos-Júnior E, Ribeiro MDCO. Analgesic efficacy of 10% lidocaine spray during nasoenteral catheterization: Randomized triple-blind trial. Eur J Pain. 2020 Mar;24(3):536-543.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Clinical and Experimental Otorhinolaryngology

Vol. 10, No. 2: 158-163, June 2017
http://dx.doi.org/10.21053/ceo.2016.00563

pISSN 1976-8710 eISSN 2005-0720
Original Article

Premedication Methods in Nasal Endoscopy: A Prospective, Randomized, Double-Blind Study

Mehmet İlhan Şahin[1], Kerem Kökoğlu[1], Şafak Güleç[2], İbrahim Ketenci[1], Yaşar Ünlü[1]

[1]*Department of Otolaryngology, Erciyes University Medical School, Kayseri*
[2]*Department of Otolaryngology, Akdağmadeni State Hospital, Yozgat, Turkey*

Objective

To identify the optimal pharmacological method of preparing patients for nasal endoscopy (NE) while considering both the clinicians' needs and the patients' comfort and physiological stability.

Materials and methods

Prospective, randomized, double-blind study (n=20; healthy volunteers). Exclusion criteria: were asthma, cardiovascular disease, rhinitis, severe septal deviation, and a history of nasal endoscopic examination.

- Blinding: 4 spray bottles were prepared and numbered; two of the bottles contained normal saline (NS; 0.9% sodium chloride), one contained 0.05% oxymetazoline; and one contained 10% lidocaine.
- 4 binary combinations of sprays (placebo) (normal saline [NS]+NS), decongestant (NS+oxymetazoline),anesthetic(NS+lidocaine), and decongestant plus anesthetic (oxymetazoline+lidocaine), were applied in each subject's nostrils in a random order on four different days. In each day, two puffs (one puff per bottle; 0.1 mg oxymetazoline and 20 mg lidocaine) were applied to both nostrils to each subject to reduce the bias of subjective evaluation and eliminate individual differences.
- The application and evaluation processes were identical for each combination (Figure 1).

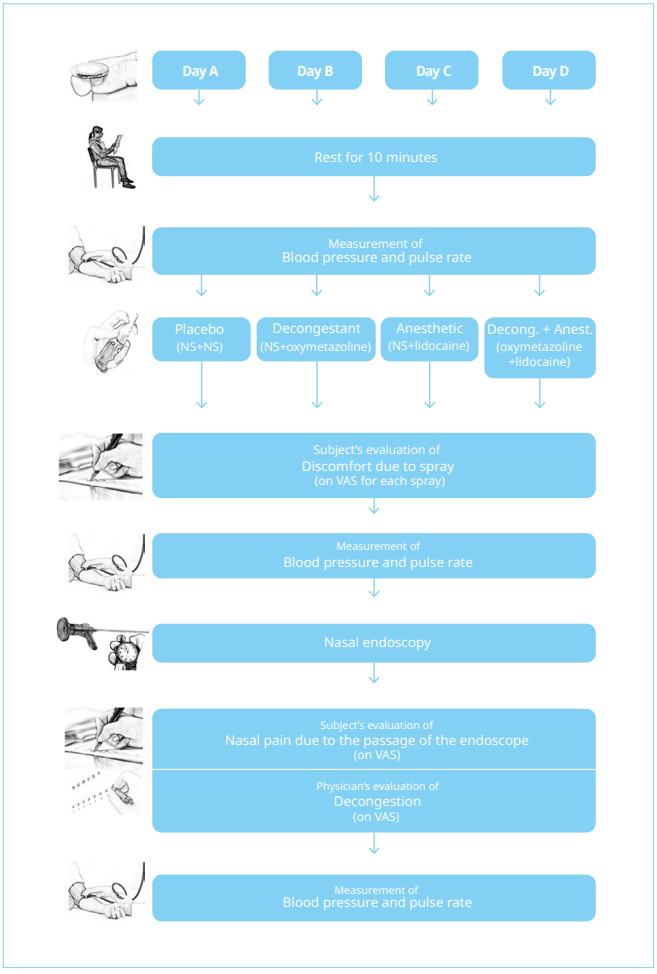


Figure 1. Flowchart of the method. NS, normal saline; Decong., decongestant; Anest., anesthetic; VAS, visual analog scale.

Results

Four parameters were evaluated:

1. Evaluation of discomfort due to the sprays.
2. Evaluation of nasal pain due to the passage of the endoscope.
3. Evaluation of decongestion (field of view).
4. Measurement of blood pressure and pulse.

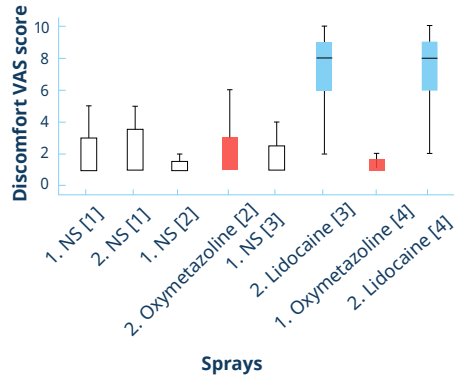


Figure 2. Distribution of visual analog scale (VAS) scores of discomfort due to the spray. Numbers in brackets show the type of the spray combination. [1] placebo; [2] decongestant; [3] anesthetic; [4] decongestant plus anesthetic. Numbers before the names of the sprays show the order in that combination. NS, normal saline.

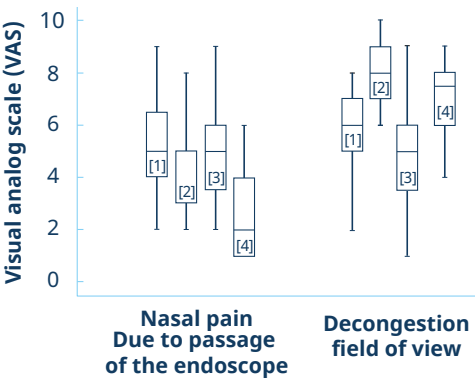


Figure 3. Distribution of visual analog scale (VAS) scores of nasal pain and decongestion. Numbers in brackets show the type of the spray combination. [1] placebo (NS+NS); [2] decongestant (NS+oxymetazoline); [3] anesthetic (NS+lidocaine); [4] decongestant plus anesthetic (oxymetazoline+lidocaine). NS, normal saline.

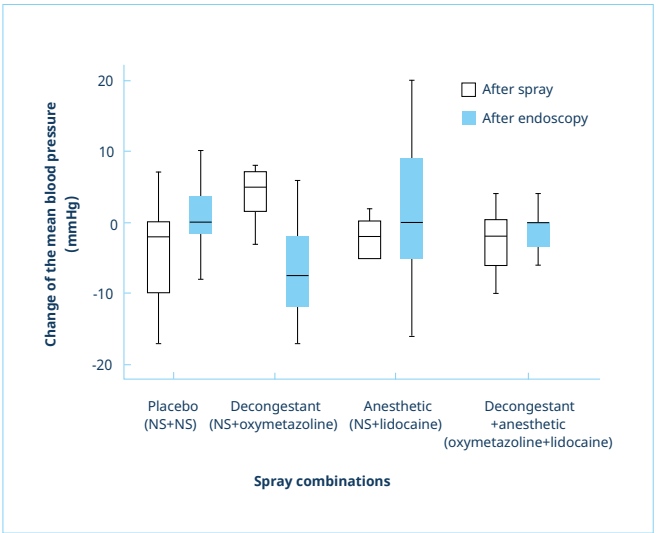


Figure 4. Distribution of changes of the mean blood pressure from the beginning to 10 minutes after spray application and from that point to just after endoscopy. NS, normal saline.

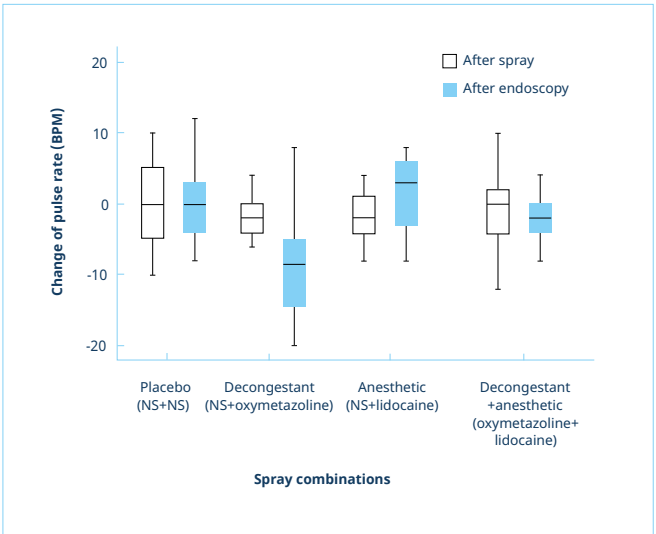


Figure 5. Distribution of changes of the pulse rate from the beginning to 10 minutes after spray application and from that point to just after endoscopy. NS, normal saline; BPM, beats per minute.

The discomfort caused by lidocaine was significantly higher than that caused by the other sprays ($p<0.001$). The lowest pain score related to endoscopy (Figure 2) was obtained for oxymetazoline + lidocaine ($p<0.001$) (Figure 3). Nasal decongestion was best achieved with NS + oxymetazoline ($p<0.001$) (Figure 3). Endoscopy duration was the shortest for oxymetazoline + lidocaine ($p<0.05$). Statistically significant Median Blood Pressure (MBP)

changes were only seen with the application of NS + oxymetazoline ($p<0.05$) (Figure 4).

However, neither MBP nor pulse rate change was significant clinically (Figure 5).

Conclusion

"The combined use of a decongestant and an anesthetic spray provided better field of view, reduced pain significantly, and decreased the duration of endoscopy. For these reasons, ***we considered decongestant plus anesthetic the best premedication method for nasal endoscopy****. Because anesthetic sprays have bad taste and smell, we recommend using a decongestant spray alone in patients who refuse to use an anesthetic spray, while considering its side effects."*

Bibliography

Şahin Mİ, Kökoğlu K, Güleç Ş, Ketenci İ, Ünlü Y. Premedication Methods in Nasal Endoscopy: A Prospective, Randomized, Double-Blind Study. Clin Exp Otorhinolaryngol. 2017 Jun;10(2):158-163.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Gastroenterology

Surgical Laparoscopy Endoscopy & Percutaneous Techniques

Volume 29, Number 5, October 2019 (383–388)
https://journals.lww.com/surgical-laparoscopy/pages/default.aspx

ISSN: 1534-4908

Unsedated Outpatient PEG in Stroke Patients: Is It Feasible and Safe?

Georgia Tsaousi, MD, PhD, George Stavrou, MD, PhD, Konstantinos Kapanidis, MD, Antonios Michalopoulos, MD, PhD, and Katerina Kotzampassi, MD, PhD

Objective

This study sought to determine the feasibility and safety of outpatient, unsedated Percutaneous Endoscopic Gastrostomy (PEG) implementation in stroke patients.

Materials and methods

Retrospective, cohort, descriptive, singlecenter study involved stroke victims (n=127) who underwent unsedated outpatient PEG insertion from 2014 to 2017 at our Surgical Endoscopy Unit. Patients were given pharyngeal anesthesia with lidocaine 10% spray, while the PEG tube was placed under local anesthesia.

Primary outcome: incidence of cardiorespiratory complications occurring during and immediately after the PEG.

Secondary outcome: development of all other procedure related complications and mortality within a 30-day timeframe.

Results

The procedures were performed with minor, transient complications, which resolved after rescue maneuvers. No intraprocedural and postprocedural major complications or death were observed.

Table 1. List of Observed Complications

Immediate(Cardiorespiratory) Complications	No.Patients
Hypoxia	11
Hypertension	13
Tachycardia	5
Bradycardia	4
PEG-related complications at 30 d	
Local inflammation	5
Abscess	3
Accidental removal	1

PEG indicates percutaneous endoscopic gastrostomy.

Primary outcomes

Hypoxia: In 8 of 11 cases was immediately reverted after the insertion of an oropharyngeal airway device.

Hypertension: Common finding (10.2%) mainly during the second phase of blood pressure measurement (procedural manipulations of performance of PEG).

Tachycardia: was experienced at the beginning of the endoscopy procedure (3.9%) immediately after the application of lidocaine spray for local anesthesia purposes.

Bradycardia: in 3.1% (obese patients) experienced a subtle attributed to overdistention of the stomach to achieve transillumination; no medication was needed.

Secondary outcomes

During the 30-day follow-up, the most important complication involved a single case of accidental PEG removal that was successfully resolved surgically (Table 1).

Conclusion

*"The findings of the present analysis suggest that **unsedated PEG placement** on an outpatient basis **constitutes a feasible, safe, well-tolerated, and acceptable alternative to standard practice for a selected group of stroke patients, in whom advanced neurological impairment, serious co-comorbidities, and poor general status, strictly prohibit from PEG insertion under sedation**.*

Potential candidates need to be carefully chosen and prepared for the procedure in advance using a multidisciplinary approach.

Unsedated PEG placement needs to be performed by a highly skilled and experienced endoscopy team.

Future and well-designed studies are needed to establish the applicability and cost-effectiveness of this practice, with a view to develop a care path–driven team approach for this unique subgroup of patients."

Bibliography

Tsaousi G, Stavrou G, Kapanidis K, et al. Unsedated Outpatient Percutaneous Endoscopic Gastrostomy in Stroke Patients: Is It Feasible and Safe? Surg Laparosc Endosc Percutan Tech. 2019 Oct;29(5):383-388.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Pediatric Gastroenterology, Hepatology & Nutrition

Pediatr Gastroenterol Hepatol Nutr 2017 June 20(2):87-93
http://dx.doi.org/10.5223/pghn.2017.20.2.87

pISSN 2234-8646 eISSN 2234-8840
Original Article

Investigation of Efficacy of Lidocaine Spray for Sedated Esophagogastroduodenoscopy in Children

Ahmet Basturk, Reha Artan, and Aygen Yılmaz

Department of Pediatric Gastroenterology, Faculty of Medicine, Akdeniz University, Antalya, Turkeyn

Objective

Our aim in this study is to investigate efficacy of topical lidocaine spray for sedated esophagogastroduodenoscopy (EGD) in children.

Materials and methods

Randomized double-blind trial included patients (n=195) 3-18 years who underwent EGD in our endoscopy unit.

Sedation was performed by intravenous (IV) midazolam and ketamine. Prior to sedation, endoscopy nurse applied topical lidocaine 10% with pump spray at 1 mg/kg dose in group 1 (LS group), and distilled water via identically scaled pump spray in group 2 (DS group).

Effectiveness of sedation was assessed by the endoscopist using modified Ramsay sedation scale (RSS).

Primary outcome: efficacy of topical lidocaine in sedated children who have undergone an EGD procedure.

Secondary outcome: reduction of side effects that occur due to IV midazolam and ketamine, such as apnea, hypoxia, vomiting, agitation and allergic reactions, with the use of topical lidocaine.

Results

Efficacy results (Primary outcome)

Sedation was not applied in 24.1% of the cases in LS group and in 5.7% of the cases in DS group, showed that a lesser extent of IV sedation was needed in the LS group compared to the DS group.

Regarding patients who received sedation, 27% in LS group and 11% in DS group received low-dose sedation and the difference was statistically significant (p=0.027).

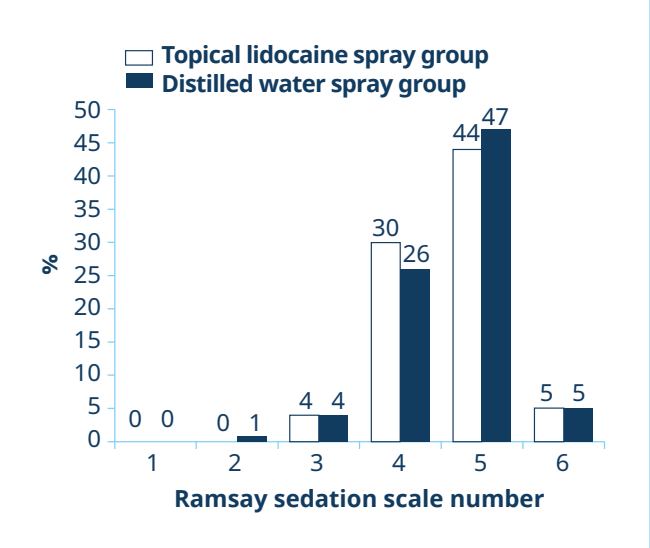


Figure 1. Comparison (distribution) of groups according to Ramsay sedation scale (p=0.982).

Safety results (Secondary outcome)

During the procedure: gag reflex was observed in 6.5% of cases in LS group and 33.3% of cases in DS group (p=0.024), increased oral secretion was observed in 9.3% of cases in LS group and 51.7% of cases in DS group (p=0.038) (Table 1).

After the procedure: sore throat was observed in 3.7% of cases in LS group and 35.6% of cases in DS group (p=0.019) and the difference was statistically significant (Table 2).

Table 1. Comparison of Groups for Complications. Observed during the Procedure

Complication	LS group (n=108)	DS group (n=87)	p-value
Hypoxia	3 (2.8)	4 (4.6)	1.000*
Hypertension	18 (16.7)	19 (21.8)	0.960†
Hypotension	1 (0.9)	5 (5.7)	1.000*
Tachycardia	21 (19.4)	23 (26.4)	0.267†
Bradycardia	3 (2.8)	3 (3.4)	1.000*
Increased oralsecretion	10 (9.3)	45 (51.7)	0.038†
Gag reflex	7 (6.5)	29 (33.3)	0.024*
Flushing-Urticeria	0	5 (5.7)	0.029†
Ketamine volume (average, mg)	7	13	-
Midazolam volume (average, mg)	1.5	2.6	0.031†
Sedation duration (average, min)	12	23	0.068†
Non-sedated	28 (25.9)	5 (5.7)	0.047*

Values are presented as number (%) or number only.
LS group: topical lidocaine spray group, DS group: distilled water spray group, -: do not be calculated.
*Fisher's exact test, †Chi-square test

Table 2. Comparison of Groups for Complications Observed after the Procedure

Complication	LS group (n=108)	DS group (n=87)	p-value
Sore throat	4 (3.7)	31 (35.6)	0.019*
Vomiting	10 (9.3)	14 (16.1)	0.264*
Vertigo	13 (12.0)	20 (23.0)	0.298†
Diplopia	26 (24.1)	31 (35.6)	0.371*
Euphoria	0	3 (3.5)	-
Dysphoria	3 (2.8)	4 (4.6)	0.251†
Hallucination	5 (4.6)	8 (9.2)	1.000†
Emergent situatio			
O2 with mask	1 (0.9)	3 (3.5)	0.137†
Convulsion	0	0	-
Apnea	0	0	-
Arrhythmia	0	0	-

Values are presented as number (%).
LS group: topical lidocaine spray group, DS group: distilled water spray group, -: do not be calculated.
*Chi-square test, †Fisher's exact test.

Conclusion

"The study showed that ***topical pharyngeal lidocaine reduces requirement and amount of IV sedation before EGD in children as well as sore throat, gag reflex and decreased oral secretion increase****."*

Bibliography

Basturk A, Artan R, Yılmaz A. Investigation of Efficacy of Lidocaine Spray for Sedated Esophagogastroduodenoscopy in Children. Pediatr Gastroenterol Hepatol Nutr. 2017 Jun;20(2):87-93.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Digestive Endoscopy 2021

Doi: 10.1111/den.14168 Original Article

Evaluation of pharyngeal lidocaine anesthesia for esophagogastroduodenoscopy: Double-blind randomized control trial

Irene Martín-Marcos[1,2], Nuria Fernández-Morte[1,2], María Balsategui-Martín[1,2], Alexandra Ortiz-Cantero[1,2], Cristina Bermúdez-Ampudia[2,3], Amanda López-Picado[5], Pilar Pérez-Vaquero[2,4], Marta Salvador-Pérez[2,4], and Estíbaliz Cristóbal-Domínguez[1,2]

[1]*Bioaraba, Nursing and Health Care Research Group, Vitoria-Gasteiz, Spain*
[2]*Osakidetza Basque Health Service, Araba University Hospital, Vitoria-Gasteiz, Spain*
[3]*Bioaraba, Epidemiology and Public Health Research Group, Vitoria-Gasteiz, Spain*
[4]*Bioaraba, Vitoria-Gasteiz, Spain*
[5]*Clinical Research and Clinical Trials Unit, Hospital Cl ınico San Carlos, IdISSC, Madrid, Spain*

Objective

The aim of this study was to assess whether the use of topical pharyngeal anesthesia improves endoscopist -and patient- reported tolerance and satisfaction, the total dose of propofol used and the rate of adverse effects associated with this procedure.

Materials and methods

Double-blind randomized clinical trial conducted in patients who met the inclusion criteria and underwent elective oesophagogastroduodenoscopy (n=586).

Table 1. Tolerance reported by endoscopist and patient scales

Endoscopist Tolerance Scale
1. Well tolerated, easy intubation, procedure completed
2. Well tolerated, difficult intubation, procedure completed
3. Poorly tolerated, procedure completed
4. Poorly tolerated, procedure incomplete or unsuccessful
Patient Tolerance Scale
1. Well tolerated, willing to repeat the procedure
2. Well tolerated, would not repeat the procedure
3. Poorly tolerated, but would repeat the procedure
4. Poorly tolerated, would not repeat the procedure

Patients were assigned to receive five squirts of lidocaine 10% spray (LG) (50 mg, n=268) or placebo (PG) (n=271) 3 min before starting the procedure or sedation.

A specific protocol was drawn up in order that the same steps were followed in all cases.

Primary outcome: patient -and endoscopist-reported tolerance, and satisfaction with the procedure, adverse events and supplementary propofol used (Table 1).

Secondary outcome: total amount of propofol used, and number and type of adverse events observed during the procedure*.

Results

Primary outcome

LG: was twice (odds ratio [OR] 2.136, 95% confidence interval [CI] 1.228–3.715) or three times (OR 3.311, 95% CI 1.623–6.757) more likely that the endoscopist rated the procedure as "well tolerated and easy to intubate" than as "well tolerated but the patient difficult to intubate" or as "poorly tolerated", respectively (Table 2).

Secondary outcome

With respect to the secondary outcomes, the dose of propofol used in each group for carrying out the procedure was lower in the LG (80 vs. 100 mg, OR 1.008, 95% CI 1.003–1.013; P=0.001).

Regarding adverse events, we only found significant differences for coughing during the intubation and procedure as reported by health professionals and for retching (Table 3). Patients assigned to the placebo group were more likely to cough during the intubation (OR 2.172, 95% CI 1.378–3.423) and procedure (OR 1.989, 95% CI 1.325–2.984) and to retch (OR 3.582, 95% CI 1.667–7.7) (Table 3).

Patients with any of these three adverse events were more likely to be in the PG (Table 4).

Table 2. Primary endpoint by study group (n=539)

	Lidocaine, n (%) (n=268)	Placebo, n (%) (n=271)	OR	CI	p-value
Well tolerated, easy intubation, procedure completed (reference category)	235 (87.7)	200 (73.8)			
Well tolerated, difficult intubation, procedure completed	22 (8.2)	40 (14.8)	2.13	1.22–3.71	0.007
Poorly tolerated, procedure completed	11 (4.1)	31 (11.4)	3.31	1.62–6.75	0.001

CI, confidence interval (95%); OR, odds ratio.

Table 3. Comparison of secondary endpoints by study group (n=539)

	Lidocaine (n=268)	Placebo (n=271)	p-value
Tolerance as reported by the patient, n (%)			0.187
• Well tolerated, would repeat the procedure	260 (97)	260 (98.5)	
• Well tolerated, would not repeat the procedure	8 (3)	3 (1.1)	
• Poorly tolerated but would repeat the procedure	0	1 (0.4)	
Endoscopist-reported satisfaction with the procedure, median (IQR)	10 (9-10)	9 (7-10)	<0.001
Patient-reported satisfaction with the procedure, median (IQR)	10 (9.75-10)	10 (10-10)	0.760
Total dose of propofol, median (IQR), mg	80 (60–112)	100 (80–120)	0.001
Cases with deeper sedation, n (%)	20 (7.5)	54 (19.9)	<0.001
Deterioration of vital signs†, median (IQR)			
• Cardiac frequency	1 (-6 to 7)	1 (-3 to 7.75)	0.394
• Systolic blood pressure	-20 (-32 to -10.8)	-20 (-31.8 to -10)	0.629
• Diastolic blood pressure	-11 (-19 to -4)	-13 (-18.8 to -4)	0.480
• Oxygen saturation	-1 (-2 to 0)	-1 (-3 to 0)	0.619
Adverse events observed during the procedure, n (%)	34 (12.7)	65 (24)	0.001
• Coughing observed during the intubation	48 (17.9)	82 (30.3)	0.001
• Coughing observed during the procedure	0	1 (0.4)	-
• Bronchospasm or airway spasm	-	-	-
• Bronchoaspiration	-	-	-
• Laryngospasm or spasm of the larynx	9 (3.4)	30 (11.1)	0.001
• Retching	-	-	-
• Sickness or vomiting	1 (0.4)	1 (0.4)	-
• Bradycardia	-	-	-
• Perforation	-	-	-
• Methemoglobinemia			
Adverse events after the procedure, n (%)	46 (17.2)	24 (8.9)	0.004
• Observed coughing	21 (7.8)	31 (11.4)	0.157
• Pain	1 (0.4)	-	-
• Nervousness	13 (4.9)	7 (2.6)	0.164
• Abdominal pain	252 (94)	259 (94)	0.604
Retrograde amnesia, n (%)			

† Difference of vital signs between the beginning and the end of the endoscopy.
IQR, interquartile range.

Table 4. Multivariate analysis of the adverse events

	OR	95% CI	p-value
Coughing during intubation	1.71	1.05-2.77	0.03
Coughing during the procedure	1.57	1.02-2.42	0.04
Retching	2.88	1.31-6.30	0.008

CI, confidence interval; OR, odds ratio.

Conclusion

The results of our study show that the **topical lidocaine as an adjuvant** to sedation can improve endoscopists' ratings of the procedure, being associated with **higher levels of tolerance and satisfaction**, though it seems not to have such an effect on patients, probably because of sedation.

Additionally, the use of **topical lidocaine** blocks the gag reflex and **reduces the amount of propofol required**.

For all this, we believe the use of **topical pharyngeal anesthesia is highly recommended to improve EGDs**.

> *"**Topical lidocaine may improve the procedure** as rated by the endoscopist, **as well as reduce the requirement for propofol and rate of adverse events such as retching and coughing**. No adverse events associated with lidocaine administration were observed."*

Bibliography

Martín-Marcos I, Fernández-Morte N, Balsategui-Martín M., et al. Evaluation of pharyngeal lidocaine anesthesia for esophagogastroduodenoscopy: Double-blind randomized control trial. Dig Endosc. 2021 Oct 13.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Anesthesia

Korean Journal of Anesthesiology

DOI: 10.4097/kjae.2011.60.6.422

Korean J Anesthesiol 2011 June 60(6): 422-427
www.ekja.org

Effects of 10% lidocaine spray on arterial pressure increase due to suspension laryngoscopy and cough during extubation

Deok Hee Lee, and Sang-Jin Park

Department of Anesthesiology and Pain Medicine, College of Medicine, Yeungnam University, Daegu, Korea

Objective

To investigate whether 10% lidocaine spray could attenuate hemodynamic changes and coughing responses during suspension laryngoscopy (SL) and extubation under general anesthesia.

Materials and methods

Randomize control trial (n=60) where patients were divided and intubated into a control group (n=30) without 10% lidocaine and a 10% lidocaine group (n=30) given 1.5 mg/kg of 10% lidocaine, sprayed onto laryngeal and intratracheal sites 2 minutes prior to intubation.

No statistically significant differences were found between the two study groups with respect to demographic data, time of operation and anesthesia, or number of smokers.

Primary outcomes: Mean arterial pressure (MAP) and heart rates (HR) during SL and coughing incidence during extubation.

Results

Mean arterial pressure (MAP) and heart rates (HR) – During SL

During SL: MAP at 2.5 and 5 min ($p<0.05$) and HR at 2.5 min ($p<0.01$) were greater in the

Table 1. Mean Arterial Pressures and Heart Rates during Application of Suspension Laryngoscope

	T1	T2	T3	T4	T5
MAP (mmHg)					
Control group	88.9 ± 2.9	92.1 ± 11.6	117.7 ± 16.9‖	109.8 ± 10.1‖	95.8 ± 10.2
10% lidocaine group	89.2 ± 3.1	88.8 ± 8.9	105.7 ± 15.6*,‖	100.9 ± 15.1*,§	89.5 ± 6.7
HR (beats/min)					
Control group	76.6 ± 10.3	84.4 ± 13.9	105.3 ± 16.7‖	90.1 ± 13.1§	77.6 ± 10.5
10% lidocaine group	75.5 ± 7.4	78.0 ± 14.0	91.0 ± 16.4†,‖	83.4 ± 15.2‡	81.3 ± 14.9

Values were expressed as mean ± SD. T1: pre-induction, T2: pre-application of suspension laryngoscope, T3: 2.5 min after suspension laryngoscope, T4: 5 min after suspension laryngoscope, T5: 10 min after suspension laryngoscope, MAP: mean arterial pressure, HR: heart rate. *$p<0.05$, †$p<0.01$ as compared with the control group and ‡$p<0.05$, §$p<0.01$, ‖$p<0.001$ as compared with pre-induction.

control group than in the 10% lidocaine group (Table 1).

During extubation:

- MAP at 2.5 min before ($p<0.05$), immediately before ($p<0.001$), and immediately after extubation ($p<0.05$) in the control group were significantly higher than in the 10% lidocaine group.
- Heart rate in the control group was higher than in the 10% lidocaine group 2.5 min before extubation ($p<0.05$), immediately before extubation ($p<0.01$), and 2.5 min after extubation ($p<0.05$) (Table 2).

Number of coughs

Was decreased in the 10% lidocaine group compared to the control group during pre- (6.8 ± 3.2 vs 10.3 ± 4.4, $p<0.01$) and post-extubation period of 5 min (4.0 ± 2.3 vs 6.2 ± 4.2, $p<0.05$) and during the entire study period (10.8 ± 3.9 vs 16.5 ± 5.6, $p<0.001$) (Table 3).

Table 2. Mean Arterial Pressures and Heart Rates during Extubation

	T1	T2	T3	T4	T5	T6
MAP (mmHg)						
Control group	101.5 ± 9.5	114.7 ± 10.2¶	117.3 ± 8.2¶	118.2 ± 9.4¶	111.0 ± 7.7¶	95.8 ± 10.2
10% lidocaine group	96.8 ± 11.5	107.9 ± 11.7*,¶	108.8 ± 7.3‡,¶	111.6 ± 11.4*,¶	106.9 ± 10.0¶	89.5 ± 6.7
HR (beats/min)						
Control group	90.3 ± 15.0	107.9 ± 11.7*,¶	108.9 ± 16.8¶	103.8 ± 14.4‖	100.4 ± 14.9§	94.9 ± 14.0
10% lidocaine group	83.6 ± 15.8	91.4 ± 16.4*,¶	91.1 ± 18.7†,‖	96.0 ± 14.1¶	90.3 ± 15.4*,§	81.3 ± 14.9

Values were expressed as mean ± SD. T1: 5 min before extubation, T2: 2.5 min before extubation, T3: immediately before extubation, T4: immediately after extubation, T5: 2.5 min after extubation, T6: 5 min after extubation, MAP: mean arterial pressure, HR: heart rate. *p<0.05, †p<0.01, ‡p<0.001 as compared with the control group and §p<0.05, ‖p<0.01, ¶p<0.001 as compared with T1.

Table 3. Number of Coughs and Incidence of Coughing during Extubation

	Control group (n=27)	10% lidocaine group (n=28)
Pre-extubation period of 5 min		
Number of coughs	10.3 ± 4.4	6.8 ± 3.2†
Incidence of coughing (%)	27/27 (100)	23/28 (82.1)
Post-extubation period of 5 min		
Number of coughs	6.2 ± 4.2	4.0 ± 2.3*
Incidence of coughing (%)§	25/27 (92.6)	19/28 (67.9)
Period of I + II		
Number of coughs	16.5 ± 5.6	10.8 ± 3.9‡
Incidence of coughing (%)	27/27 (100)	23/28 (82.1)

Values were expressed as mean ± SD or number. *p<0.05, †p<0.01, ‡p<0.001 as compared with the control group. §p<0.05 between the control and 10% lidocaine groups.

Conclusion

*"Preoperative laryngeal and intratracheal spraying with 1.5 mg/kg of **10% lidocaine spray is effective for attenuation of arterial pressure increase to SL and suppression of coughing during extubation**."*

Bibliography

Lee DH, Park SJ. Effects of 10% lidocaine spray on arterial pressure increase due to suspension laryngoscopy and cough during extubation. Korean J Anesthesiol. 2011 Jun;60(6):422-7.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Chest Journal

DOI: https://doi.org/10.1016/j.chest.2019.06.018

CHEST 2020; 157(1):198-204
THORACIC ONCOLOGY: ORIGINAL RESEARCH

A Randomized Trial of Nebulized Lignocaine, Lignocaine Spray, or Their Combination for Topical Anesthesia During Diagnostic Flexible Bronchoscopy

Sahajal Dhooria, MD, DM; Shivani Chaudhary, MSc; Babu Ram, MSc; Inderpaul Singh Sehgal, MD, DM; Valliappan Muthu, MD, DM; Kuruswamy Thurai Prasad, MD, DM; Ashutosh N. Aggarwal, MD, DM, FCCP; and Ritesh Agarwal, MD, DM, FCCP

Objective

To compare the efficacy and safety of nebulized lignocaine, lignocaine oropharyngeal spray, or their combination during during flexible bronchoscopy procedure.

Materials and methods

Patients (n=1.050; median age, 51 years; 64.8% men) were randomized 1:1:1 to receive nebulized lignocaine (2.5 mL of 4% solution, group A), oropharyngeal spray (10 actuations of 10% lignocaine, group B), or nebulization (2.5 mL, 4% lignocaine) and two actuations of 10% lignocaine spray (group C).

Primary outcome: subject-rated severity of cough according to a visual analog scale.

Secondary outcomes: bronchoscopist-rated severity of cough and overall procedural satisfaction on a visual analog scale, total lignocaine dose, subject's willingness to undergo a repeat procedure, adverse reactions to lignocaine, and others.

Results

Subject-rated cough severity

The median (interquartile range) score was significantly lower in group B vs group C and group A (4 [1-10] vs 11 [4-24] and 13 [5-30], respectively; p<.001).

Bronchoscopist-rated severity of cough and overall satisfaction

In group B was also the least (p<.001) and in overall satisfaction was highest in group B (p<.001).

Lignocaine dose

The cumulative dose administered was the least in group B (p<.001).

Willingness of patients

A significantly higher proportion of subjects (p<.001) were willing to undergo a repeat bronchoscopy in group B (73.7%) than in groups A (49.1%) and C (59.4%).

No lignocaine-related adverse events were observed (Table 1).

Table 1. Primary, Secondary, and Exploratory Outcomes of the Study

Outcome	Group A (n = 350)	Group B (n = 350)	Group C (n = 350)	p Value
Primary outcome				
Patient-rated VAS score for cough	13 (5-30)	4 (1-10)	11 (4-24)	<.001[a]
Secondary outcomes				
Operator-rated VAS score for cough	16 (7-34)	7 (2-20)	13 (6-27)	<.001[a,b]
Faces Pain Rating Scale	0 (0-0)	0 (0-0)	0 (0-0)	.0
Operator-rated VAS score for overall satisfaction	79 (63-92)	88 (74-96)	82 (68-90)	<.001[a]
Lignocaine				
Cumulative administered dose, mg	292 (292-292)	285 (285-285)	312 (312-312)	<.001[a,b]
Range, mg	292-420	285-349	312-376	
Heart rate during procedure, beats/minute	120 (112-125)	120 (108-124)	118 (108-124)	.09
Heart rate after procedure, beats/min	94 (92-98)	92 (90-98)	92 (90-98)	.29
Oxygen saturation during procedure, beats/min	96 (95-97)	96 (95-97)	96 (95-97)	.37
Oxygen saturation following the procedure, beats/min	96 (95-97)	97 (95-97)	96 (95-97)	.15
Procedure duration, min	5 (4-7)	5 (4-7)	5 (4-7)	.18
Time to cross the vocal cords, s	25 (21-34)	20 (17-26)	24 (20-32)	<.001[a]
Willingness to repeat the procedure, No. (%)	172 (49.1)	258 (73.7)	208 (59.4)	<.001[a,b]
Exploratory outcomes				
Diagnostic yield, n/N (%)				
Endobronchial biopsy	57/74 (77.0)	75/81 (92.6)	61/70 (87.1)	.02
Transbronchial biopsy	18/34 (52.9)	15/29 (51.7)	20/35 (57.1)	.89

Data are presented as median (interquartile range), unless otherwise indicated. VAS ¼ visual analog scale. [a]Significant difference between groups A and B, and groups B and C. [b]Significant difference between groups A and C.

Conclusion

"The results of this study suggest that the use of 10 actuations of ***10% lignocaine spray delivered to the oropharynx resulted in superior topical anesthesia compared with nebulized lignocaine or their combination during diagnostic*** *FB."*

Bibliography

Dhooria S, Chaudhary S, Ram B., et. A Randomized Trial of Nebulized Lignocaine, Lignocaine Spray, or Their Combination for Topical Anesthesia During Diagnostic Flexible Bronchoscopy. Chest. 2020 Jan;157(1):198-204.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Chest

DOI: 10.21470/1678-9741-2019-0112 Braz J Cardiovasc Surg 2020;35(3):291-8

Effects of Lidocaine Oropharyngeal Spray Applied Before Endotracheal Intubation on QT Dispersion in Patients Undergoing Coronary Artery Bypass Grafting: a Prospective Randomized Controlled Study

Murat Bilgi[1], MD; Yusuf Velioglu[1], MD; Hamit Yoldas[1], MD; Mehmet Cosgun[1], MD; Ahmet Yuksel[1], MD; Ibrahim Karagoz[1], MD; Isa Yildiz[1], MD; Abdulhamit Es[2], MD; Duygu Caliskan[1], MD; Kemalettin Erdem[1], MD; Abdullah Demirhan[1], MD

[1]*Abant Izzet Baysal University Medical School, Bolu, Turkey*

[2]*Abant Izzet Baysal University Faculty of Economics and Administrative Sciences, Bolu, Turkey*

Objective

To investigate the effects of lidocaine oropharyngeal spray applied before endotracheal intubation on hemodynamic responses and electrocardiographic parameters in patients undergoing coronary artery bypass grafting.

Materials and methods

60 patients underwent coronary artery bypass grafting surgery were included in this prospective randomized controlled study and randomly divided into two groups, the topical lidocaine group (Group L) (administration of 10% lidocaine oropharyngeal spray, five minutes before laryngoscopy and endotracheal intubation) and the control group (Group C).

Groups were similar in terms of age, gender, and other demographics and basic clinical characteristics.

Both groups were compared with each other in terms of main hemodynamic parameters including mean arterial pressure (MAP) and heart rate, as well as P and QT wave dispersion durations (Pd) (QTd), before and after endotracheal intubation.

Results

QT dispersion durations

There was a statistically significant difference between the groups after laryngoscopy and endotracheal intubation.

The increase in QTd duration was not statistically significant in the topical LG, whereas the increase in QdT duration was statistically significant in the CG (Table 1).

P dispersion durations

When the groups were compared in terms of Pd durations, there were significant decreases in both groups, but there was no significant difference between the groups (Table 1).

Mean arterial pressure

GC values: were statistically significantly decreased at the 1st minute of the induction, and the 3rd, 4th, and 5th minutes of the

Table 1. Electrocardiographic data of the groups.

		T0	T1	T2	T3
QTd (ms)	Group C (n=30)	52.8(±10.1)	48.1 (±8.5)+	63.2 (±19.6)+	57.4 (±13.5)+
	Group L (n=30)	48.6 (±9.2)	46.6 (±8.8)	51.5 (±12.8)*	47.4 (±16.2)*
Pwd (ms)	Group C (n=30)	44.6(±9.1)	36.6. (±9.2)++	41.4 (±12.7)	37.7(±10.5)++
	Group L (n=30)	46.8 (±10.8)	37.4 (±9.3)&	43.4 (±15.1)&	36.2 (±12.5)&

T0=basal; T1=1st min of induction; T2=1st min of intubation; T3=3rd minute of intubation
ms=millisecond; Pwd=*P* wave dispersion; QTd=QT dispersion
*There was a statistically significant difference between Group C and Group L (p<0.05)
+There was a statistically significant difference between Group C QTd basal and the 1st min of induction,1st min of intubation, and 3rd min of intubation (p<0.05)
++There was a statistically significant difference between Group C Pwd duration basal and the 1st min of induction and 3rd min of intubation (p<0.05)
&There was a statistically significant difference between Group L basal and the 1st min of induction,1st min of intubation, and 3rd min of intubation (p<0.05)

intubation (p=0.000, p=0.032, p=0.015, and p=0.030; respectively).

GL values: statistically significant differences between baseline values and at the 30th second up to 5th minutes, and 10th minutes of the intubation (p=0.000, p=0.006, p=0.003, p=0.002, p=0.007, p=0.007, p=0.029, and p=0.03; respectively).

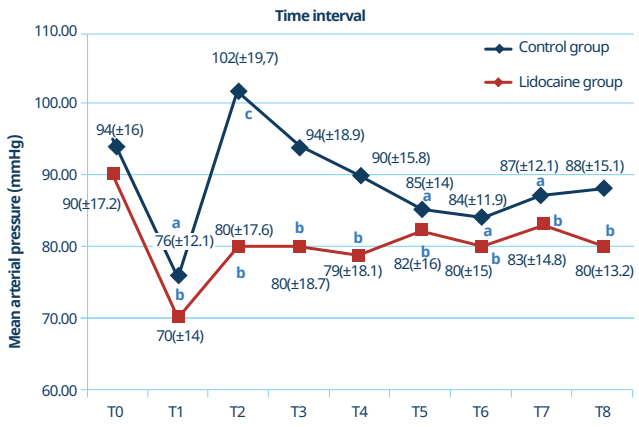
Comparison between groups: values were statistically significantly increased in GC vs GL at the 30th second and the 1st and 2nd minutes of the intubation (p=0.000, p=0.006, p=0.021; respectively) (Figure 1).

Heart rate

GC values: was significantly increased at the 1st minute after the intubation (p<0.05)

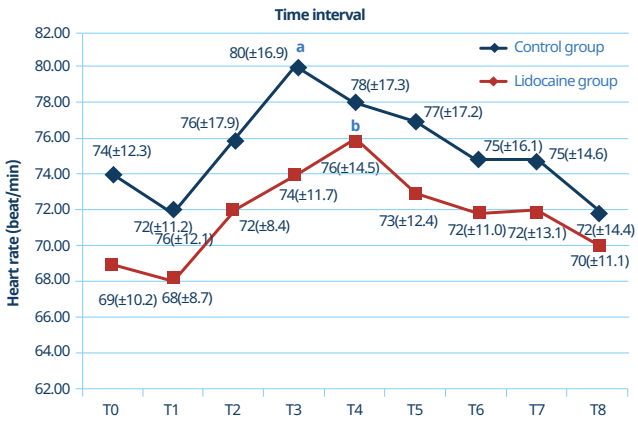
GL values: was significantly increased at the 2nd minute after the intubation (p<0.05).

Comparison between groups: no significant difference was found between the groups (p>0.05) (Figure 2).



T0, basal; **T1**, 1nd min of induction; **T2**, 30 sec of intubation; **T3**, 1nd min of intubation; **T4**, 2nd of intubation; **T5**, 3rd minute of intubation; **T6**, 4th min of intubation; **T7**, 5th minute of intubation; **T8**, 10th min of intubation.
[a] There was statistically significant difference between Group C basal and 1nd min of induction, 3rd, 4th, 5th min of intubation (p<0.05).
[b] There was statistically significant difference between Group L basal and 1nd min of induction, 30 sec. of intubation, 1nd, 2nd, 3rd, 4th, 5th , 10th min of intubation (p<0.05).
[c] There was statistically significant difference between two group (p<0.05).

Figure 1. Comparison of mean arterial pressure between control group and lidocaine group.



T0, basal; **T1**, 1nd min of induction; **T2**, 30 sec of intubation; **T3**, 1nd min of intubation; **T4**, 2nd of intubation; **T5**, 3rd minute of intubation; **T6**, 4th min of intubation; **T7**, 5th minute of intubation; **T8**, 10th min of intubation.

[a] There was statistically significant difference between Group C basal and 1nd min of induction ($p<0.05$).

[b] There was statistically significant difference between Group L basal and 2nd min of induction ($p<0.05$).

Figure 2. Comparison of heart rate between control group and lidocaine group.

Conclusion

We suggest that topical lidocaine administration before laryngoscopy and endotracheal intubation can be useful in **patients undergoing CABG since it has hemodynamically beneficial effects and reduces the prolongation of QTd**.

> *"Our study revealed that the **topical lidocaine administration before endotracheal intubation prevented increase of QT dispersion duration in patients undergoing coronary artery bypass grafting**."*

Bibliography

Bilgi M, Velioglu Y, Yoldas H., et al. Effects of Lidocaine Oropharyngeal Spray Applied Before Endotracheal Intubation on QT Dispersion in Patients Undergoing Coronary Artery Bypass Grafting: A Prospective Randomized Controlled Study. Braz J Cardiovasc Surg. 2020 Jun 1;35(3):291-298.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Gynaecology

THE JOURNAL OF Obstetrics and Gynaecology Research

Doi:10.1111/jog.13308 J. Obstet. Gynaecol. Res. 2017

Lidocaine for pain control during intrauterine device insertion

Yetkin Karasu[1], Duygu Kavak Cömert[1], Burak Karadağ[2] and Yusuf Ergün[1]

[1]*Department of Obstetrics and Gynecology, Ankara Training and Research Hospital, Ankara*

[2]*Department of Obstetrics and Gynecology, Antalya Training and Research Hospital, Antalya, Turkey*

Objective

The aim of this study was to compare the effects of topical lidocaine spray, cream and injection on pain perception during intrauterine device (IUD) insertion.

Materials and methods

Multiparous women of reproductive age (n=200) were randomized into control, lidocaine cream, spray and injection groups. The groups were similar in terms of demographic characteristics.

A visual analog scale (Figure 1) was used for all patients to evaluate pain during the three steps of the IUD insertion procedure. Assessments:

- Baseline pain immediately after the administration of analgesics.
- Immediately after use of the tenaculum.
- After IUD insertion.

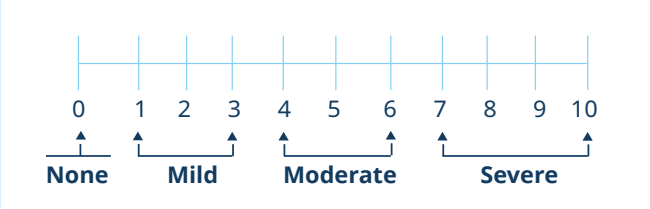


Figure 1. Visual analog scale.

Results

Baseline pain scores: lidocaine injection group exhibited higher baseline pain scores (p<0.001).

Tenaculum use: pain associated was lower in the lidocaine spray group.

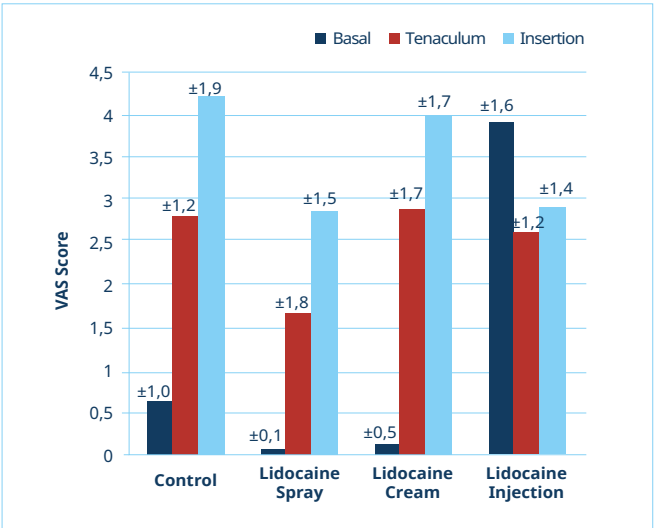


Figure 2. Visual analog scale (VAS) scores for pain in the groups during the procedure (± standard deviation).

IUD insertion: pain was lower in the lidocaine spray and injection groups (p<0.001); however, lidocaine spray was superior to injection for the reduction of IUD insertion related pain (p=0.001) (Table 1).

Table 1. Comparison of the VAS scores

	Control *n* = 49	Lidocaine Spray *n* = 51	Lidocaine Cream *n* = 53	Lidocaine injection *n* = 47	p
Baseline					
0 (none)	44 (89.8 %)	49 (96.1 %)	49 (92.5 %)	1 (2.1 %)	
1-3 (mild)	4 (8.2 %)	2 (3.9 %)	4 (7.5 %)	12 (25.5 %)	< 0.001*
4-6 (moderate)	1 (2.0 %)	0 (0 %)	0 (0 %)	33 (70.2 %)	
7-10 (severe)	0 (0 %)	0 (0 %)	0 (0 %)	1 (2.1 %)	
Tenaculum					
0 (none)	2 (4.1 %)	20 (39.2 %)	4 (7.5 %)	3 (6.4 %)	
1-3 (mild)	26 (53.1 %)	22 (43.1 %)	28 (52.8 %)	26 (55.3 %)	< 0.001*
4-6 (moderate)	21 (42.9 %)	8 (15.7 %)	20 (37.7 %)	18 (38.3 %)	
7-10 (severe)	0 (0 %)	1 (2.0 %)	1 (1.9 %)	0 (0 %)	
Insertion					
0 (none)	1 (2.0 %)	13 (25.5 %)	1 (1.9 %)	1 (2.1 %)	
1-3 (mild)	14 (28.6 %)	16 (31.4 %)	13 (24.5 %)	28 (59.6 %)	< 0.001*
4-6 (moderate)	31 (63.3 %)	19 (37.3 %)	37 (69.8 %)	18 (38.3 %)	
7-10 (severe)	3 (6. %)	3 (5.9 %)	2 (3.8 %)	0 (0 %)	

*Chi-square test.

Conclusion

*"To conclude, **we believe that lidocaine spray is a good option for reducing pain during IUD insertion, which is a common method of contraception around the world**.*

Spray application is both easy and rapid. While paracervical lidocaine injection also reduces pain during IUD insertion, the injection itself is painful. Therefore, this option is not seen as a plausiblemethod for reducing pain during IUD insertion."

Bibliography

Karasu Y, Cömert DK, Karadağ B, Ergün Y. Lidocaine for pain control during intrauterine device insertion. J Obstet Gynaecol Res. 2017 Jun;43(6):1061-1066.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

THE JOURNAL OF Obstetrics and Gynaecology Research

Doi:10.1111/jog.13308 J Low Genit Tract Dis. 2018 Jan;22(1):38-41

Lidocaine Spray Versus Paracervical Block During Loop Electrosurgical Excision Procedure: A Randomized Trial

Nopporn Limwatanapan MD[1]; Wadwilai Chalapati MD[1]; Srisuda Songthamwat MD[1]; Surapong Saenpoch MD[1]; Kuanoon Buapaichit MD[2] and Metha Songthamwat MD[1]

[1]*Department of Obstetrics and Gynecology, Udonthani Hospital, Udonthani, Thailand*

[2]*Department of Obstetrics and Gynecology, Sakonnakhon Hospital, Sakonnakhon, Thailand*

Objective

The aim of the study was to compare the effectiveness of pain control between lidocaine spray (LS) and paracervical block (PB) with lidocaine during the loop electrosurgical excision procedure (LEEP).

Materials and methods

A single-blinded randomized controlled trial was conducted on women who underwent LEEP of the cervix (n=132) who were allocated to either a PB group (n=66) or a LS group (n=66).

PB group: anesthetized using 10 mL of 2% lidocaine with 1:100,000 of epinephrine.

LS group: locally anesthetized with four puffs (40 mg) of 10% LS, which was applied thoroughly to the cervix.

Pain scores, using 10-cm visual analog scales, were obtained and compared during excision and 30 minutes after procedure.

Results

Pain scores during excision (mean (SD))

LS group: 5.2 (2.4) vs. PB group: 4.2 (3.3)
Mean difference = 1.1 (95% CI = 0.8 to 2.1, p=.033), which was within the nonclinically significant margin of this study.

Adverse effect
There were any in the LS group compared with eight cases in the PB group (tinnitus, numbness, palpitation or tachycardia, and hypertension). (Table 1).

Pain score after speculum examination
At the baseline was not significantly different in both groups (Table 2).

Table 1. Adverse Effect

Characteristic	LS group, %	PB group, %
Tinnitus	0 (0.0)	4 (6.1)
Palpitation or tachycardia	0 (0.0)	2 (3.0)
Hypertension	0 (0.0)	1 (1.5)
Numbness	0 (0.0)	1 (1.5)
Dizziness	0 (0.0)	1 (1.5)

Total 8 case had adverse effect (1 case had both palpitation and hypertension).
LS indicates lidocaine spray; PB, paracervical block.

Table 2. Pain Scores

Characteristic	LS group	Paracervical group	Mean difference	95% CI of mean difference	p value
Baseline*	2.0 (2.2)	1.9 (1.9)	0.06	-0.65 to 0.77	.87
During anesthesia	2.0 (2.3)	3.1 (2.5)	−1.11	-1.94 to -0.28	.008
During excision	5.2 (2.4)	4.2 (3.3)	1.07	0.08 to 2.06	.033
30 min after excision	1.1 (1.6)	0.8 (1.2)	0.35	-1.13 to 0.84	.15

Data are mean (SD).
LS indicates lidocaine spray; PB, paracervical block.
*After speculum insertion.

Conclusion

*"The local 40 mg of **10% LS can be used to substitute for PB for pain control during LEEP of the cervix. It also resulted in fewer adverse effects**."*

Bibliography

Limwatanapan N, Chalapati W, Songthamwat S, et al. Lidocaine Spray Versus Paracervical Block During Loop Electrosurgical Excision Procedure: A Randomized Trial. J Low Genit Tract Dis. 2018 Jan;22(1):38-41.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Journal of Obstetrics and Gynaecology

https://doi.org/10.1080/01443615.2018.1538329

ISSN: 0144-3615 (Print) 1364-6893 (Online)
http://www.tandfonline.com/loi/ijog20

Comparison of topical lidocaine spray with forced coughing in pain relief during colposcopic biopsy procedure: a randomised trial

Erbil Karaman[a], Ali Kolusarı[a], İsmet Alkış[a] & Orkun Çetin[b]

[a]*Department of Obstetrics and Gynecology, Division of Gynecologic Oncology, Medical Faculty, Yuzuncu Yil University, Van, Turkey*

[b]*Department of Obstetrics and Gynecology, Medical Faculty, Yuzuncu Yil University, Van, Turkey*

Objective

Our objective was to compare the effectiveness of local lidocaine spray (LS) compared to forced coughing (FC) for relieving the pain during colposcopically guided cervical biopsies (CGBs).

Materials and methods

Randomised study which included patients (n=96) with abnormal cervical cytologic results requiring a colposcopic biopsy procedure. Patients were randomly assigned to either the 10% LS (n=44) or the FC (n=42) groups before the biopsy procedure.

The age, parity, body mass index, history of previous curettage and vaginal delivery, smoking status and the number of biopsies were similar in both groups.

Primary outcome: pain assessed by using a 10 cm visual analogue scale at the different steps during the procedure.

Results

Mean (± SD) pain scores

Speculum insertion: 1.4 (± 0.8) and 1.2 (± 0.9) in the LS and FC groups, respectively (p<.89).

Table 1. Visual analogue pain scores for patients receiving topical lidocaine spray or forced cough during colposcopy.

	Lidocaine spray	Forced coughing	p-value
Speculum insertion	1.4 ± 0.8	1.2 ± 0.9	.89
Cervical biopsy	3.25 ± 1.4	4.4 ± 1.3	.02*
5 min after the procedure	1.9 ± 0.4	2.1 ± 0.6	.46
Patients with ECC at 5 min after colposcopy	2.4 ± 1.2	2.6 ± 1.8	.78
Time needed (min)	7.6 ± 1.4	5.2 ± 0.8	.004*

ECC: endocervical curettage. Pain scores in centimetres are given as the mean±SD. *p< .05 indicates statistical significance.

After cervical biopsy: 3.25 (± 1.4) and 4.4 (± 1.3) respectively (p<.05).
5 min after the procedure: 1.9 (± 0.4) and 2.1 (± 0.6) respectively (p< .46).
Patients with ECC at 5 min after colposcopy: 2.4 (± 1.2) and 2.6 (± 1.8) respectively (p<.78) (Table 1).

Operative time

Longer in the LS than in the FC group (7.6 ± 1.4 vs. 5.2 ± 0.8, p: .004).
No **complication or adverse effect** was observed in both groups (Table 1).

Conclusion

*"The present study showed that LS **lidocaine spray use can be recommended for pain relief during colposcopically directed cervical biopsy procedure with a superiority to the forced coughing in the terms of pain and absence of any adverse reactions**."*

Bibliography

Karaman E, Kolusarı A, Alkış İ, Çetin O. Comparison of topical lidocaine spray with forced coughing in pain relief during colposcopic biopsy procedure: a randomised trial. J Obstet Gynaecol. 2019 May;39(4):534-538.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Paediatrics

Pediatric Drugs

https://doi.org/10.1007/s40272-018-0320-2 Paediatr Drugs. 2019 Feb;21(1):25-31

Topical Pharyngeal Lidocaine Reduces Respiratory Adverse Events During Upper Gastrointestinal Endoscopies Under Ketamine Sedation in Children

Jose Carlos Flores-González[1,4], Ana Estalella-Mendoza[1,4], Patricia Rodríguez-Campoy[1,4], Mónica Saldaña-Valderas[2,4], Alfonso M. Lechuga-Sancho[3,4]

[1]Pediatric Intensive Care Unit, Puerta del Mar University Hospital, Avda Ana de Viya 21, 11009 Cádiz, Spain

[2]Clinical Farmacology Unit, Puerta del Mar University Hospital, Cadiz, Spain

[3]Mother and Child Health, and Radiology Department, Cádiz University, Cadiz, Spain

[4]Institute of Research and Innovation in Biomedical Sciences (INIBiCA), Cadiz, Spain

Objective

To investigate if the administration of topical lidocaine would reduce the incidence of laryngospasm caused by the introduction of an endoscope through the larynx, as well as reducing the incidence of RAEs associated with UGEs (Upper gastrointestinal endoscopies) under ketamine sedation.

Materials and methods

Single-center prospective study was performed including every patient (n=88; 52.3% boys) admitted for an elective diagnostic UGE under ketamine sedation who received lidocaine prior to the technique (1 month to 14 years; Median age 7 years [interquartile range (IQR) 3–11]) (Table 1).

Patients requiring any other medication were excluded.

Primary outcome: number of desaturation episodes subsequently compared with those obtained in an historic group who did not receive topical lidocaine, in which we registered a total of 54 desaturation episodes (n=88)

Results

The mean duration of the procedure was 6.5 ± 2.4 min, and the median initial ketamine dose was 1.76 mg/kg (IQR 1.56–2.03).

Primary outcome: The total number of desaturation episodes was 3 (3.4%), and two of these occurred prior to the introduction of the endoscope.

This result represents a lower incidence than in previously reported series, and a significant decrease ($p < 0.0001$) compared to the 54 RAEs registered in the historic group (Table 2).

Table 1. Demographic and clinical variables in study and historic control groups.

Variable	No lidocaine	Lidocaine	p value
Age (years)	7.2 ± 3.96	7 ± 3.98	0.517
Sex (% boys)	56.8	52.3	
ASA risk class			
ASA 1	72 (81.8)	75 (85.2)	0.752
ASA 2	16 (18.2)	13 (14.8)	0.345
Ketamine initial dose (mg/kg)	1.88 ± 0.22	1.76 ± 0.63	0.68
Extra bolus (*n*)	20	32	
Duration of endoscope (min)	6.5 ± 2	6.4 ± 2.59	
Baseline heart rate (bpm)	100 ± 21.2	106 ± 22.4	0.91
Baseline respiratory rate (bpm)	24.4 ± 6.9	26.7 ± 8	0.075
Baseline $SatO_2$ (%)	98.7 ± 1.3	99.2 ± 0.98	0.004
Baseline FiO_2 (%)	21 ± 0.0	21 ± 0.0	1
Pre-endoscopy heart rate, bpm	100.91 ± 20.9	109 ± 22.6	0.952
Pre-endoscopy respiratory rate, bpm	24.52 ± 6.8	27.5 ± 7.7	0.027
Pre-endoscopy $SatO_2$ (%)	99.7 ± 1.3	98.2 ± 4.2	0.000
Pre-endoscopy FiO_2 (%)	21.0 ± 0	21.14 ± 0.9	0.050
Endoscopy min 1 heart rate, bpm	110.6 ± 20.7	112 ± 18.2	0.776
Endoscopy min 1 respiratory rate, bpm	25.2 ± 6.4	26.9 ± 6.5	0.071
Endoscopy min 1 $SatO_2$ (%)	95.9 ± 2.2	98.25 ± 2.2	0.000
Endoscopy min 1 FiO_2 (%)	21.5 ± 1.8	21.08 ± 0.7	0.000

Data are presented as *N* (%) or mean ± standard deviation unless otherwise indicated.
ASA American Society of Anesthesiologists, *baseline* vital signs before the procedure, *bpm* beats per minute, *endoscopy* min 1 vital signs at min-ute 1 after introduction of endoscope, *FiO_2* fraction of inspired oxygen, *pre-endoscopy* vital signs after ketamine administration, *$SatO_2$* oxygen saturation.

Table 2. Desaturation episodes and necessary interventions in the historic control group with no lidocaine use versus the study group.

Variable	No lidocaine	Lidocaine
Desaturations	55 (62.5)	3 (3.4)
Severity		
Mild	26 (29.6)	2 (2.2)
Moderate	13 (14.7)	1 (1.1)
Severe	16 (18)	0 (0)
Intervention		
None	18 (32.1)	1 (33.3)
O2	33 (58.9)	2 (66.6)
IPPV	4 (8.9)	0 (0)
ET	0 (0)	0 (0)
Duration		
Short	11 (28.9)	2 (66.6)
Mean	4 (10.5)	0 (0)
Prolonged	23 (60.5)	1 (33.3)

Data are presented as *N* (%) unless otherwise indicated.
ET endotracheal intubation, *IPPV* intermittent positive pressure ventilation, O_2 oxygen.

Conclusion

To our knowledge, **this is the first study** to evaluate premedication with topical lidocaine in children undergoing UGE under ketamine sedation outside the operating room.

"Topical lidocaine premedication significantly reduced the incidence of RAEs in children during UGEs under ketamine sedation. Our findings should be confirmed by a double-blind randomized controlled trial."

Bibliography

Flores-González JC, Estalella-Mendoza A, Rodríguez-Campoy P, et al. Topical Pharyngeal Lidocaine Reduces Respiratory Adverse Events During Upper Gastrointestinal Endoscopies Under Ketamine Sedation in Children. Paediatr Drugs. 2019 Feb;21(1):25-31.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Archives of Disease in Childhood (ADC), from BMJ and RCPCH

Doi:10.1136/160 adc.2010.188433 Arch Dis Child 2011;96:160–163

Intranasal lidocaine and midazolam for procedural sedation in children

Antonio Chiaretti[1], Giuseppe Barone[2], Donato Rigante[1], Antonio Ruggiero[2], Filomena Pierri[2], Egidio Barbi[3], Giovanni Barone[1], Riccardo Riccardi[2]

[1]*Department of Pediatric Sciences, Catholic University Medical School, Rome, Italy*
[2]*Pediatric Oncology, Catholic University Medical School, Rome, Italy*
[3]*Department of Pediatrics, Burlo Garofolo Hospital, Trieste, Italy*

Objective

To evaluate the efficacy and safety of a sedation protocol based on intranasal lidocaine spray and midazolam (INM) in anxious and uncooperative children who undergoing minor painful or diagnostic procedures.

Materials and methods

Prospective observational clinical study (n=46), with patients aged 5–50 months, who received INM (0.5 mg/kg) via a mucosal atomizer device. To avoid any nasal discomfort a puff of lidocaine spray (10 mg/puff) was administered before INM.

Primary outcome: Child's degree of sedation, scored using a modified Ramsay sedation scale. A questionnaire was designed to evaluate the parents' and doctors' opinions on the efficacy of the sedation (Table 1).

Statistical analysis was used to compare sedation times with children's age and weight.

Table 1. Sedation and reactivity scores

Score	Description
Sedation	
5	Not arousable
4	Arousable if stimulated powerfully
3	Arousable if stimulated moderately
2	Opens eyes spontaneously/on command
1	Patient awake but mildly sedated
0	Not sedated
Reactivity	
4	No reaction
3	Mild reactions that do not disturb the procedure
2	Reactions that disturb the procedure
1	Marked movements that make the procedure impossible
0	Procedure not in progress

Results

Degree of sedation: achieved by INM, enabling all procedures to be completed without additional drugs. The mean duration of sedation was 23.1 min and the depth of sedation was 1 on the modified Ramsay scale. Premedication with lidocaine spray prevented any nasal discomfort related to the INM (Table 2).

Parents' and doctors satisfaction: the questionnaire revealed high levels satisfaction of by both. Sedation start and end times were significantly correlated with age only. No side effects were recorded in the cohort of children studied (Table 3).

Table 2. Age, weight, start times, end times and duration of the sedation effect in children undergoing procedural sedation by intranasal lidocaine and midazolam.

Parameter	Mean	95% CI	Median	95% CI	SD	Minimum	Maximum
Age	26 months	19.1 to 33.2	18 months	16 to 21.9	21.6 months	5 months	50 months
Weight	13.4 kg	11.65 to 15.1	12 kg	10 to 14	8.4 kg	7 kg	18 kg
Start time of sedation effect	6.9 min	6.1 to 7.7	7 min	6 to 8	2.4 min	3 min	15 min
End time of sedation effect	29 min	26.2 to 33.6	26 min	24 to 29.3	11.2 min	18 min	65 min
Duration of sedation effect	23.1 min	19.7 to 26.4	20 min	17 to 23.9	10.3 min	10 min	50 min

Table 3. Parents' and medical doctors' responses to the questionnaire on the administration of intranasal lidocaine and midazolam via a mucosal atomiser device.

	Parents (n)	Score (median)	Range	Doctors (n)	Score (median)	Range
Helped	46	10	10–0	13*	10	10–10
Level of child's outlook	42	9.1	8–10	11*	8.5	7–10
Level of parents' outlook	41	8.9	7–10	10*	7.6	6–9
Level of doctors' outlook	–	–		12*	9.2	8–10
Level of child's tolerance of procedures	43	9.3	8–10	12*	9.2	8–10
Judgement on child's behaviour prior to procedure	45	9.8	9–10	10*	7.7	6–9
Judgement on child's behaviour during/after procedure	46	10	10–10	11*	8.5	7–10
Would recommend to other parents	45	9.8	9–10	–	–	
Would recommend to other doctors	–	–		12*	9.2	8–10
Would like to see MAD used routinely	46	10	10–10	12*	9.2	8–10

*13 medical doctors were involved in the painful or diagnostic procedures carried out in the study.
MAD, mucosal atomiser device.

Conclusion

*"This study has shown that the combined use of **lidocaine spray and atomised INM appears to be a safe and effective method to achieve short-term sedation in children** to facilitate medical care and procedures."*

Bibliography

Chiaretti A, Barone G, Rigante D, et al. Intranasal lidocaine and midazolam for procedural sedation in children. Arch Dis Child. 2011 Feb;96(2):160-3.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Pediatric Gastroenterology, Hepatology & Nutrition

pISSN: 2234-8646 eISSN: 2234-8840
https://doi.org/10.5223/pghn.2017.20.2.87

Pediatr Gastroenterol Hepatol Nutr 2017 June 20(2):87-93

Investigation of Efficacy of Lidocaine Spray for Sedated Esophagogastroduodenoscopy in Children

Ahmet Basturk, Reha Artan, and Aygen Yılmaz

Department of Pediatric Gastroenterology, Faculty of Medicine, Akdeniz University, Antalya, Turkey

Objective

To investigate efficacy of topical lidocaine spray for sedated esophagogastroduodenoscopy (EGD) in children.

Materials and methods

Double blinded study was performed with patients aged between 3-18 years who underwent EGD in our endoscopy unit (n=195).

Intravenous (IV) midazolam and ketamine were used for sedation.

Prior to sedation, endoscopy nurse applied topical lidocaine 10% with pump spray at 1 mg/kg dose in group 1 (Lidocaine Spray; LS group), and distilled water (DS group) via identically scaled pump spray in group 2.

Primary outcome: to measure the efficacy of topical lidocaine in sedated children who have undergone an EGD procedure.

Secondary outcome: to measure the reduction of side effects that occur due to IV midazolam and ketamine, such as apnea, hypoxia, vomiting, agitation and allergic reactions, with the use of topical lidocaine.

Results

Efficacy

Sedation was not applied in 24.1% of LS group and in 5.7% of DS group. Regarding the patients who received sedation 27% in LS group and 11% in DS group received low-dose sedation and the difference was statistically significant (p=0.027) (Figure 1).

Safety

Gag reflex was observed in 6.5% of cases in LS group and 33.3% of cases in DS group (p=0.024),

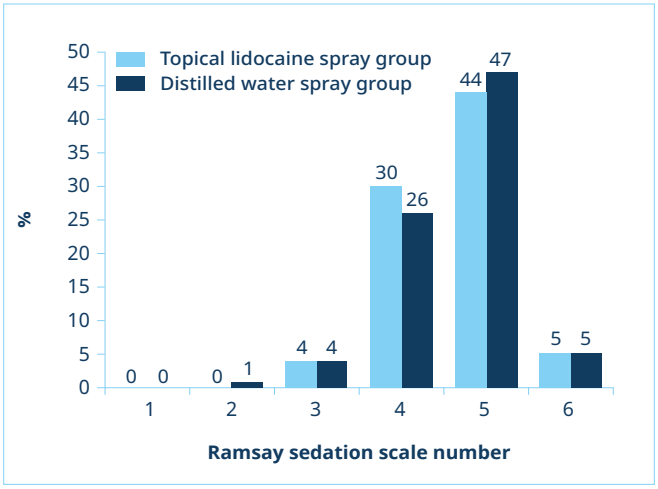


Figure 1. Comparison sedation scale (p=0.982).

increased oral secretion was observed in 9.3% of cases in LS group and 51.7% of cases in DS group (p=0.038), sore throat was observed in 3.7% of cases in LS group and 35.6% of cases in DS group (p=0.019) and the difference was statistically significant (Table 1 and 2).

Table 1. Comparison of Groups for Complications Observed during the Procedure.

Complication	LS group (n=108)	DS group (n=87)	p-value
Hypoxia	3 (2.8)	4 (4.6)	1.000*
Hypertension	18 (16.7)	19 (21.8)	0.960†
Hypotension	1 (0.9)	5 (5.7)	1.000*
Tachycardia	21 (19.4)	23 (26.4)	0.267†
Bradycardia	3 (2.8)	3 (3.4)	1.000*
Increased oralsecretion	10 (9.3)	45 (51.7)	0.038†
Gag reflex	7 (6.5)	29 (33.3)	0.024*
Flushing-Urticeria	0	5 (5.7)	-
Ketamine volume (average, mg)	7	13	0.029†
Midazolam volume (average, mg)	1.5	2.6	0.031†
Sedation duration (average, min)	12	23	0.068†
Non-sedated	28 (25.9)	5 (5.7)	0.047*

Values are presented as number (%) or number only.
LS group: topical lidocaine spray group, DS group: distilled water spray group, -: do not be calculated.
*Fisher's exact test, †Chi-square test.

Table 2. Comparison of Groups for Complications Observed after the Procedure.

Complication	LS group (n=108)	DS group (n=87)	p-value
Sore throat	4 (3.7)	31 (35.6)	0.019*
Vomiting	10 (9.3)	14 (16.1)	0.264*
Vertigo	13 (12.0)	20 (23.0)	0.298†
Diplopia	26 (24.1)	31 (35.6)	0.371*
Euphoria	0	3 (3.5)	-
Dysphoria	3 (2.8)	4 (4.6)	0.251†
Hallucination	5 (4.6)	8 (9.2)	1.000†
Emergent situations			
O2 with mask	1 (0.9)	3 (3.5)	0.137†
Convulsion	0	0	-
Apnea	0	0	-
Arrhythmia	0	0	-

Values are presented as number (%).
LS group: topical lidocaine spray group, DS group: distilled water spray group, -: do not be calculated.
*Chi-square test, †Fisher's exact test.

Conclusion

"The study showed that topical pharyngeal ***lidocaine reduces both requirement and amount of IV sedation before EGD in children and sore throat, gag reflex and decreased oral secretion increase****."*

Bibliography

Basturk A, Artan R, Yılmaz A. Investigation of Efficacy of Lidocaine Spray for Sedated Esophagogastroduodenoscopy in Children. Pediatr Gastroenterol Hepatol Nutr. 2017 Jun;20(2):87-93.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Neurology

Journal of Research in Medical Sciences

J Res Med Sci. 2014 Apr;19(4):331-5

Evaluation of efficacy of intra-nasal lidocaine for headache relief in patients refer to emergency department

Naser Mohammadkarimi, Mohammadali Jafari, Ali Mellat[1], Ehsan Kazemi[2], Amir Shirali[2]

[1]*Department of Emergency Medicine, Neurology, Shahid Sadoughi University of Medical Sciences, Yazd, Iran*

[2]*Department of Emergency Medicine, General Practitioner, Shahid Sadoughi University of Medical Sciences, Yazd, Iran*

Objective

To evaluate the efficacy of intranasal lidocaine on different types of headache regarding the importance of headache in medical practice and lack of appropriate medications or serious side effects of drugs as well aa lack of previous studies investigating it.

Materials and methods

Double blind randomized clinical trial (n=90) performed with adult patients (n=45 in 10% lidocaine spray group and n=45 in normal saline (placebo) group) with acute headache. One puff of 10% lidocaine or normal saline (placebo) was sprayed into each nostril.

The mean age of patients was 35.32 years. According to sex and age, there was no significant difference between groups (p-values were 0.83 and 0.21; respectively).

Exclusion criteria: history of epilepsy, allergy to lidocaine, signs of skull base fracture, Glasgow Coma Scale (GCS) <15, <14 years and patients who had received any medication in previous 2 h.

Primary outcome: Patients' headache severity measured by visual analog scale (VAS) before drug administration and after intervention (1, 5, 15, and 30 min).

Statistical analysis: statistical tests including t-test, ANOVA, Fisher's exact test, and Mann-Whitney test were performed. Descriptive variables expressed by mean ± standard deviation (SD) and quantitative variables reported by frequency and percentages.

Results

Mean VAS score before intervention

Lidocaine group: 6.97 ± 1.94.

Placebo group: 6.42 ± 1.82 with not significantly different (p-value = 0.198) (Table 1, Figure 1).

Mean VAS score after intervention

Mean scores were significantly lower in lidocaine group than placebo group in all mentioned times (p-value <0.001) (Table 1, Figure 1).

Repeated measures analysis of variance (ANOVA) test revealed no significant difference in VAS score between the four subtypes (primary and secondary) of headache in the mentioned times in case and control groups (p=0.87 and 0.602, respectively) (Table 2).

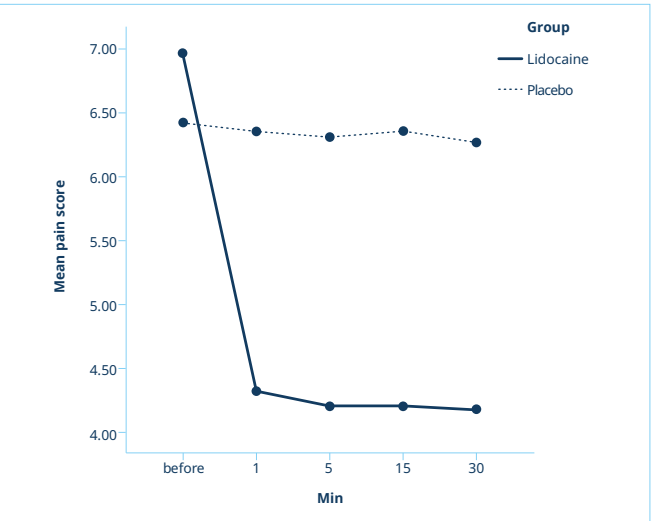


Figure 1. Comparison of VAS score changes between the two groups.

Table 1. Comparison of pain (VAS) score before and 1, 5, 15, and 30 min after intervention between the two groups

Variable	Control group	Case group	p value
VAS before intervention	6.42±1.82	6.97±1.94	0.198
VAS in 1st min	6.35±1.93	4.31±2.6	<0.001
VAS in 5th min	6.1±1.95	4.2±2.67	<0.001
VAS in 15th min	6.35±1.93	4.2±2.68	<0.001
VAS in 30th min	6.26±1.93	4.17±2.72	<0.001

VAS = Visual analog score.

Table 2. Comparison of VAS score changes in four types of headache in case and control groups

Types of headache	VAS in 1st min	VAS in 5th min	VAS in 15th min	VAS in 30th min	
Migraine headache	5.13±2.89	5.13±2.97	4.73±2.91	4.73±2.91	Case group
Tension headache	4.18±2.99	3.81±2.99	4.18±2.06	4.18±2.06	
Traumatic headache	4.07±1.54	4±1.7	4.14±1.99	4.14±2.24	
Nontraumatic headache	4.1±2.6	2.8±3.11	2.8±3.11	2.6±2.79	
Migraine headache	6.33±2.31	6.2±2.36	6.33±2.31	6.06±2.31	Control group
Tension headache	6.71±2.56	6.71±2.56	6.71±2.56	6.71±2.56	
Traumatic headache	6.63±1.28	6.63±1.28	6.63±1.28	6.63±1.28	
Nontraumatic headache	5.91±1.62	5.91±1.62	5.91±1.62	5.91±1.62	

VAS = Visual analog score.

Conclusion

*"Intranasal **10% lidocaine spray is an efficient method for pain reduction in patients with headache any type of headache**.*

Regarding easy administration and little side effects, we recommend this method in patients referred to emergency department (ED) with headache."

Bibliography

Mohammadkarimi N, Jafari M, Mellat A, Kazemi E, Shirali A. Evaluation of efficacy of intra-nasal lidocaine for headache relief in patients refer to emergency department. J Res Med Sci. 2014 Apr;19(4):331-5.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

La Prensa Médica Argentina

Pren. Méd. Argent. Marzo 2016 Vol.102 - Nº 1; 24-33

Lidocaina intranasal vs ketorolaco intravenoso en pacientes con cefalea migrañosa atendidos en un servicio de urgencias

Intranasal lidocaine vs intravenous ketorolac in patients with migraine headache treated in an emergency department

Luis Vicente Gómez Bañuelos[1], Jorge Loria Castellanos[1,2], Carlos Alberto Rodarte González[3]

[1]*Especialista en Urgencias Médico Quirúrgicas*
[2]*Doctor en Educación, División de Proyectos Especiales en Salud*
[3]*Inmunología y Biología Molecular. Genética Forense. UNITEC*
[1-2]*Instituto Mexicano del Seguro Social*

Objective

To evaluate the usefulness of intranasal lidocaine in migraine headache treatment, as well as its correlation of serotonin levels, which are related to the intensity of pain due to a decreased secretion of calcitonin gene-related peptide.

Materials and methods

Experimental study (n=16; age range= 16-73 years (X=35.88 ± 14.22), 87.5% were female).

Patients were divided by simple randomization into two groups of 8 subjects each whith different treatments administered:

Group 1: 30mg of Ketorolac IV.
Group 2: 2 shots of 10% intranasal lidocaine (20mg) in the nostril ipsilateral.

Inclusion criteria: patients older than 15 years of both sexes, with migraine, who agreeded to participate in the study and who underwent VAS assessments and serotonin levels measuresat admission and 15 minutes later.

Exclusion criteria: patients with systemic diseases, previous immunotherapy treatments, psychological disorders and use of psychotropic drugs. Headache lasting more than 15 days or with inadequate collaboration for the study.

Primary outcome: VAS rating at admission and at 15 minutes for pain, serum serotonin levels at admission and at 15 minutes, as well as adjuvant treatment used.

Serotonin levels were measured 15 minutes prior treatment using:

a. A 5ml blood sample based on ELISA technique which uses monoclonal antibodies against human serotonin.
b. Visual Analogue Scale for pain (VAS).

Results

VAS scale measurements

A statistically significant difference was observed in the pain analog scale (VAS) in the intranasal Lidocaine group at 5 minutes (p=<0.05), which increased at 15 minutes (p=<0.01). (Figure 1).

A statistically significant difference was found between the groups regarding the pain analog scale (VAS) at 15 minutes after treatment: ketorolac group (p=<0.05) vs intranasal lidocaine (p=<0.01). (Figure 2).

Serotonine measurements

No statistically significant difference was found in serotonin levels in the group treated with Ketorolac (p=0.22), mean 243.80, standard deviation 153.21.

A statistically significant difference is observed in serotonin levels in the group treated with intranasal lidocaine, finding (p=<0.05), mean 213.51, standard deviation 165.46. (Figure 3).

We made a comparison according to serum serotonin levels, not observing significant differences in the ketorolac group (p=0.22), however, in the lidocaine group we found a significant difference (p=<0.05), mean 213.51, standard deviation 165.46. (Figure 4).

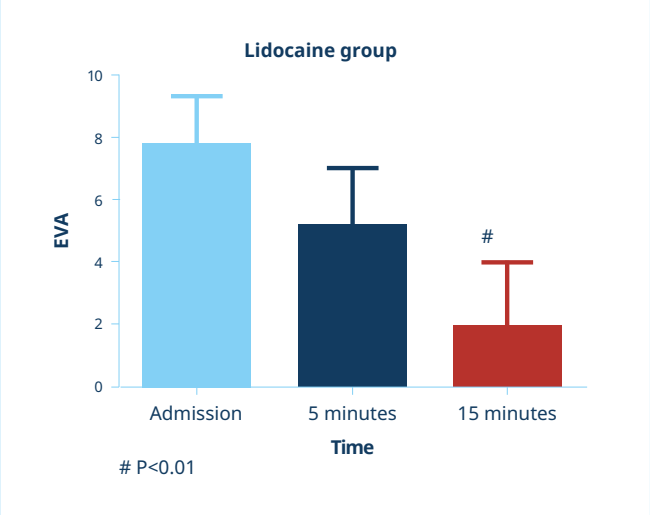


Figure 1. n=8, Median=1.66 (2.1)

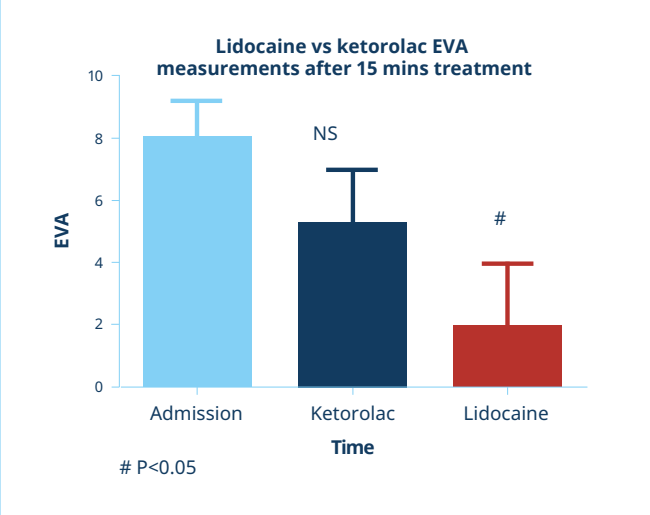


Figure 2. n=8, Median=1.88 (2.1)

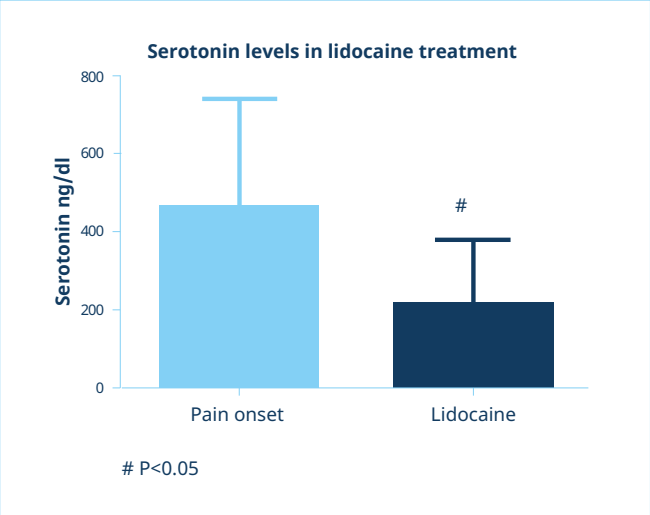


Figure 3. Overage n=5; Median=213.51 (165.46)

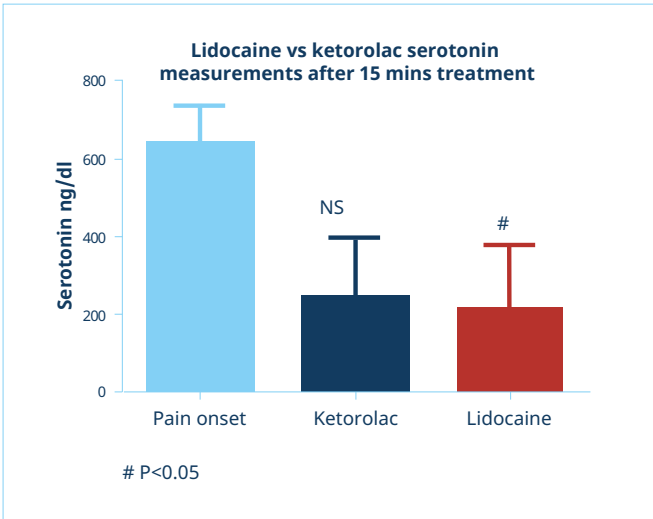


Figure 4. Overage n=5; Median=213.51 (165.46)

Conclusion

*"**Intranasal 10% lidocaine decreases migraine headache and its associated symptoms more rapidly and effectively**.*

***Serotonin levels** are related to the intensity of pain, they **decrease in greater quantity with the Lidocaine application compared to Ketorolac**.*

Studies with a larger number of patients are needed to determine the effect of intranasal lidocaine on the decrease in serum serotonin as it is responsible for the initial vasoconstriction in migraine headaches, as should treatment be taken into account in acute migraine attacks, since it can eliminate its entire pain and symptomatology generated, is easily accessible and easy to apply in health services with minimal adverse effects, mainly in emergency areas, avoiding hospital stay and spending on supplies."

Bibliography

Gómez Bañuelos L.V., Loria Castellanos J., Rodarte González C.A., et al. Lidocaina intranasal vs ketorolaco intravenoso en pacientes con cefalea migrañosa atendidos en un servicio de urgencias. Pren. Méd. Argent. Marzo 2016, 102 (1), p. 24-33.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Diagnostic and procedural purposes

Prenatal Diagnosis

DOI: 10.1002/pd.5559 Prenat Diagn. 2019 Dec;39(13):1179-1183.

Effect of Xylocaine spray for analgesia during amniocentesis: A randomized controlled trial

Panupun Homkrun, Theera Tongsong, Kasemsri Srisupundit

Department of Obstetrics and Gynecology, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand

Objective

To compare the effect of Xylocaine spray on pain score during amniocentesis.

Materials and methods

Randomized controlled trial was conducted with singleton pregnant women undergoing amniocentesis (n=570) and assigned to one study group:

- Group 1 (Xylocaine spray; n=191): 1 min before the procedure, 8 puffs (80mg) of 10% Lidocaine spray on abdominal wall.
- Group 2 (placebo; n=193): 8 puffs of sterile normal saline.
- Group 3 (control): no spray was used.

Primary outcome: difference in pain score among three groups. A 10□cm visual analog scale before, during, and 30 min after amniocentesis was used to rate the pain.

Results

Baseline pain was not different. The median procedural pain score was significantly different (2.3, 3.3, and 2.8 respectively; p 0.001). Post□hoc analysis showed that the procedural pain score in Xylocaine group was significantly lower than placebo or control group (p value <0.001 and 0.02, respectively) (Table 1).

Table 1. Pain score from 10-cm visual analog scale among three groups of participants. Median ± interquartile range (min□max) (Kruskal–Wallis test)

Pain score	Group 1: Xylocaine (191 cases)	Group 2: Saline (193 cases)	Group 3: Control (186 cases)	p-value
Baseline pain	0 ± 0 (0–1.2)	0 ± 0 (0–3.6)	0 ± 0 (0–1.3)	0.495
Procedural pain	2.3 ± 2.9 (0–10)	3.3 ± 3.3 (0–10)	2.8 ± 3.7 (0–10)	0.001
Post procedural pain	0.1 ± 1.5 (0–10)	0.2 ± 1.1 (0.3–5.2)	0.1 ± 1.03 (0.2–7.4)	0.893

Conclusion

*"**Xylocaine spray significantly reduces pain score during amniocentesis, when compared to placebo and conventional method**, but its clinical significance is modest given that the procedure-related discomfort is mild and short-lived.*

*Nevertheless, **Xylocaine spray has its own favorable properties: rapid onset, simplicity, and convenience in use, safety, low cost, non-invasiveness, and wide availability**. Accordingly, it may be an attractive option for clinical practice in some selected pregnant women."*

Bibliography

Homkrun P, Tongsong T, Srisupundit K. Effect of Xylocaine spray for analgesia during amniocentesis: a randomized controlled trial. Prenat Diagn. 2019 Dec;39(13):1179-1183.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Archives of Italian Urology and Andrology

Arch Ital Urol Androl. 2010 Jun;82(2):125-7 ORIGINAL PAPER

Lidocaine spray administration during transrectal ultrasound guided prostate biopsy modified the discomfort and pain of the procedure: Results of a randomized clinical trial

Lucio Dell' Atti, Carlo Daniele

Urology Unit, Arcispedale "S. Anna", Ferrara, Italy

Objective

To assess the efficacy of lidocaine spray application for local anesthetic during prostate biopsy in comparison with customary method with intrarectal lidocaine gel and lidocaine/prilocaine (EMLA R) anesthetic cream.

Materials and methods

Randomized clinical trial performed with consecutive male patients with elevate PSA and (or) abnormal digital rectal and (or) suspect who underwent a prostate biopsy and divided in 3 groups (n=372):

- Group 1 (n=98) intrarectal instillation of a lidocaine/prilocaine cream (EMLA R).
- Group 2 (n=126) application of 2,5% lidocaine gel.
- Group 3 (n=148) administration of a lidocaine spray (10 gr/100 ml) before the procedure.

Primary outcome: efficacy of lidocaine spray in terms of pain relieve. Pain was self evaluated by patiens with the use of a simple rating scale of pain called Verbal Numerical Scale (VNS).

Biopsied patients were asked to evaluate separately the degree of pain associated with the insertion of the probe and the manoeuvres associated with it and the degree of pain associated with the biopsy (from = 0 no discomfort to 10 = severe pain).

Results

Efficacy: Mean value of pain VNS in patients was:

- Group 1 (cream group): 5.3 (2-8) for the insertion of the probe (first question) and 3.2 (2-7) for the biopsy by itself (second question).
- Group 2 (gel group): 6.2 (4-9) and 3.8 (3-8) for the same questions.
- Group 3 (spray group) 3.1 (1-6) and 2.8 (0-6), respectively.

A statistically significant difference was observed in the tolerability of the procedure according to the first questionnaire, not to the second questionnaire ($p<0.001$).

Conclusion

"Pain score results showed that the use of ***intrarectal lidocaine spray provided significantly better pain control than cream and anaesthetic gel****.*

Our pain score data suggests that ***lidocaine spray provides efficient patient comfort during prostate biopsy by reducing pain*** *both during probe insertion and insertion of the needle through the prostate gland.*

The use of lidocaine spray makes an ***excellent alternative****, causing a reduction of anal sphincter tone with better patient compliance and tolerability to the ultrasound probe during biopsies with an optimization in terms of cost-effectiveness of the procedure."*

Bibliography

Dell'Atti L, Daniele C. Lidocaine spray administration during transrectal ultrasound guided prostate biopsy modified the discomfort and pain of the procedure: results of a randomized clinical trial. Arch Ital Urol Androl. 2010 Jun;82(2):125-7.

Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Journal of Obstetrics and Gynaecology

ISSN 0144-3615 print/ISSN 1364-6893 online
DOI: 10.3109/01443615.2015.1060201

ISSN 0144-3615 print/ISSN 1364-6893 online

Effect of lidocaine spray in pain management during office-based endometrial sampling: A randomised placebo-controlled trial

H. Aksoy[1], U. Aksoy[2], S. Ozyurt[2], G. Acmaz[2], M. A. Babayigit[3], B. Yücel[4] & T. Aydin[4]

[1] *Kayseri Military Hospital, Department of Obstetrics and Gynaecology, Kayseri, Turkey*
[2] *Kayseri Education and Training Hospital, Department of Obstetrics and Gynaecology, Kayseri, Turkey*
[3] *Gulhane Military Medical Academy, Department of Public Health, Kayseri, Turkey*
[4] *Acibadem Hospital, Department of Obstetrics and Gynaecology, Kayseri, Turkey*

Objective

The objective of our study was to investigate the analgesic efficacy of lidocaine spray and placebo on the patients who perceived pain during endometrial biopsy.

Materials and methods

A prospective, randomised, double-blind, placebo-controlled trial was designed (n=120).

Participants were randomly assigned into two treatment groups:

- Lidocaine spray (n=60) receiving 4 pumps (40 mg 4 pumps) of 10% lidocaine spray.
- Placebo (n=60) receiving 4 pumps of placebo (isotonic saline solution) spray.

There was no statistically significant difference among the 2 study groups in terms of mean age, BMI, gravidity, parity, total number of previous vaginal deliveries and menopausal status.

Primary outcome: endometrial biopsy-related pain score as measured by the 10-cm VAS and performed at 3 different time points: immediately before the procedure, during the procedure (immediately following the endometrial aspiration and 15 minutes after the procedure.

Results

Baseline

All participants reported their pain level as 0 on a continuous 10-cm VAS before the study.

The mean pain score during procedure was 3.51 ± 1.51 in the lidocaine spray group and 5.11 ± 1.66 in the placebo group.

Lidocaine spray treatment significantly lowered the pain scores compared with placebo ($p<0.001$) (Table 1).

After procedure

The mean pain score at 15 minutes after the procedure was 0.83 ± 0.92 in the lidocaine spray group and 2.05 ± 1.07 in the placebo group ($p<0.001$).

The pain scores after the procedure were significantly lower in the lidocaine spray group (Table 1).

Table 1. Comparison of pain scores during and after the procedure in treatment groups.

	Lidocaine group (n= 60) (Mean ± SD)	Placebo group (n=59) (Mean ± SD)	p-value
VAS intraop (cm)	3.51 ± 1.51	5.11 ± 1.66	<0.001 *
VAS postop (cm)	0.83 ± 0.92	2.05 ± 1.07	<0.001 *
VAS difference (cm) (Intraop-postop)	2.68 ± 1.47	3.06 ± 1.32	0.068 **

Values are expressed as mean ± standard deviation. The variables were compared with Student's t-test and Mann – Whitney U test. p<0.05 probability value was considered as statistically significant.
* Student's t-test.
** Mann Whitney U Test.

Conclusion

*"Lidocaine spray can be accepted as a **non-invasive, easy to apply and more comfortable anaesthetic method for office-based endometrial sampling**."*

Bibliography

Aksoy H, Aksoy U, Ozyurt S, et al. Effect of lidocaine spray in pain management during office-based endometrial sampling: A randomised placebo-controlled trial. J Obstet Gynaecol. 2016;36(2):246-50.

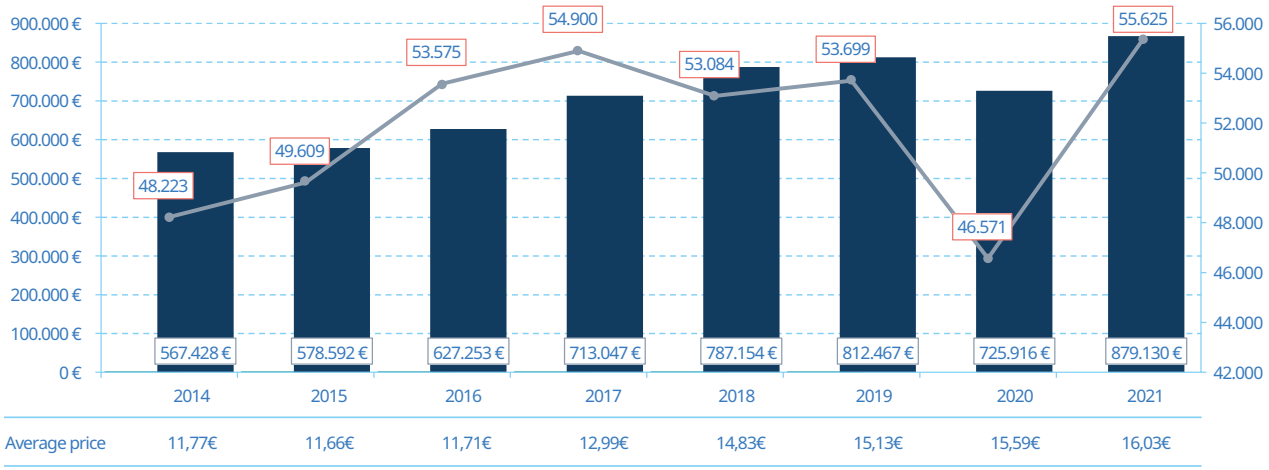
Numbering of tables and figures may not coincide with that of the source articles as only those useful to elaborate the content of this material have been extracted.

Spanish market overview.

3

Spanish market overview

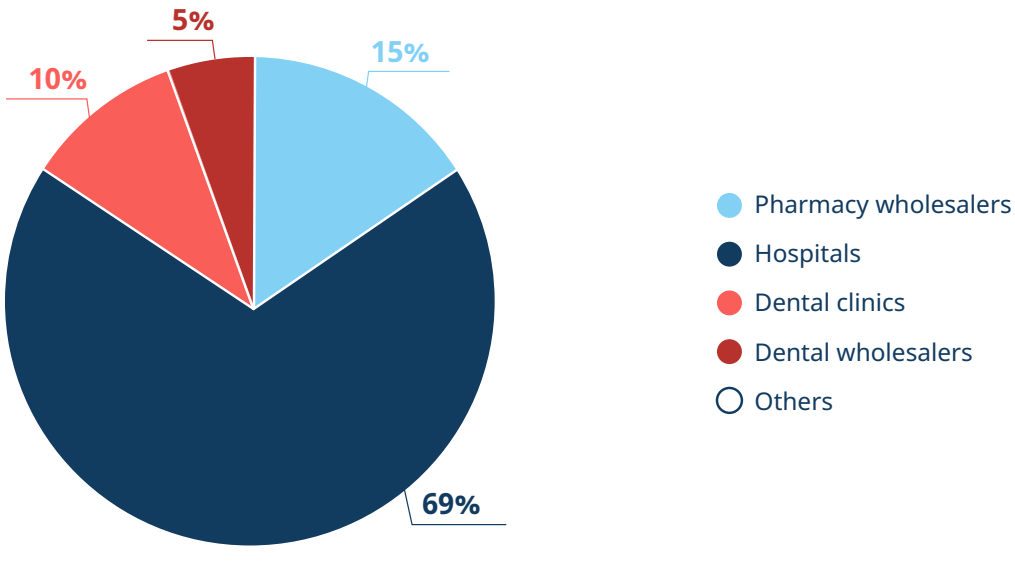
Sales evolution



	2014	2015	2016	2017	2018	2019	2020	2021
Average price	11,77€	11,66€	11,71€	12,99€	14,83€	15,13€	15,59€	16,03€

*2020 sales decrease: pandemic effect

Market distribution

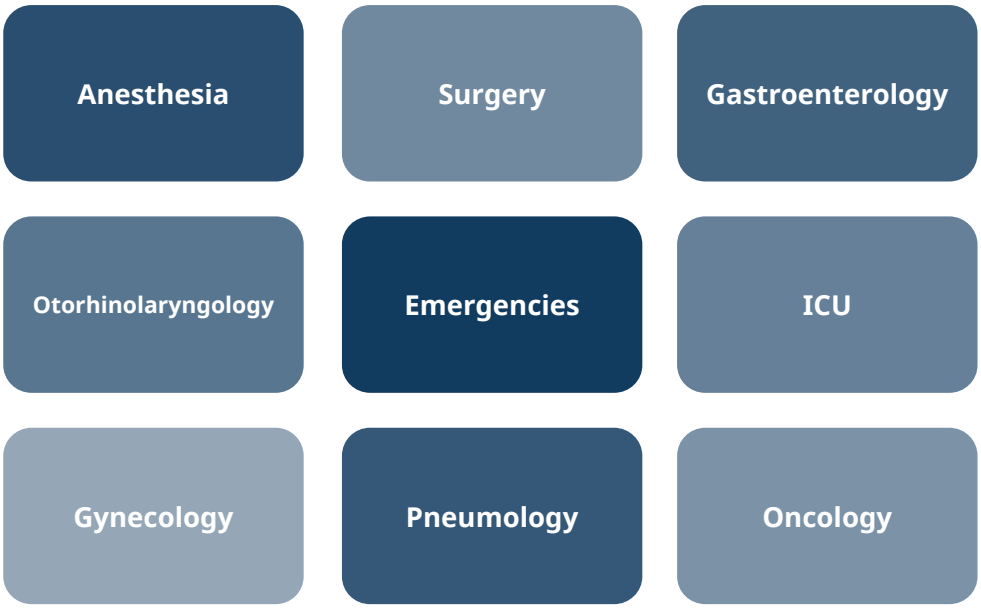


Main applications*

To facilitate invasive tests: Bronchoscopies, intubations, biopsies.	To reduce discomfort before punctures or small incisions in painful localized areas.	To desensitize the mucosa before anesthesia infiltration.	To suppress pharingeal reflex.

*Market research report elaborated by Nueva Investigación S.L. for Inibsa, April 2021.

Main hospital services targets



Ctra. Sabadell a Granollers, Km. 14,5
Lliçà de Vall, 08185. Barcelona (Spain)

Email: export@inibsa.com
Tel.: +34 938 609 500
Fax: +34 938 437 389

Junio 2022