

Role of bilateral suprazygomatic maxillary nerve block in primary surgery for soft palate cleft and soft-hard palate cleft

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Key points

Using a monocenter retrospective study to evaluate the using bilateral suprazygomatic maxillary nerve block vs. general and morphine-based anesthesia in the global care management for primary surgery of cleft palates, we found that local nerve blocks have improved the anesthetic care management as well as the perioperative and postoperative follow-up, with a significant decreased use of morphine agents and thus absence of related side effects

Abstract

Introduction

Bilateral suprazygomatic maxillary nerve block seems to play an important role in clinical tolerance and postoperative management of primary cleft palate surgery.

Objective

Study the use of bilateral suprazygomatic maxillary nerve block in the global management of primary closing surgery of cleft palates.

Materials and methods

Monocenter, retrospective study evaluating general anesthesia (GA) vs. bilateral suprazygomatic maxillary nerve block under sedation in primary surgery of cleft palate. Postoperative management, anesthetic parameters and hospital analgesia were analyzed.

Results

49 patients (23 GA vs. 26 LRA) were included (mean age = 13.5 months). The postoperative anesthetic time is significantly reduced, just like the use of morphine dur-

ing surgery and Step II analgesics post-surgery in the LRA group.

Conclusion

Anesthetic management associating sedation and bilateral suprazygomatic maxillary nerve block is highly relevant in the care management of cleft palates.

Keywords: Cleft palate, analgesia, nerve block, maxillofacial surgery, anesthesia, morphine.

Introduction

Primary surgery of cleft palates varies according to the different surgical teams. Its peculiarity lies in the numerous care management protocols proposed (1) according to the surgical techniques used, operating time (between M3 and M18 of life), anesthetic technique and postoperative management.

This surgery must be associated to a specific care management because of potential associated complications, especially the risk of obstruction of the upper respiratory tract and respiratory distress majored by the use of

morphine anesthetics during and after surgery (2-5). In fact, respiratory distress can be majored according to the clinical picture (type of cleft, syndromic type) (6). Anesthesia and pain-relief management post-surgery play an important role in clinical tolerance and postoperative follow-up. This surgery has been labeled as painful by most teams and benefited these past years from the use of locoregional nerve blocks (7, 8).

The objective of this work was to do a comparative study of our practices using bilateral suprazygomatic maxillary nerve block vs. general and morphine-based anesthesia in the global care management for primary surgery of cleft palates.

Materials and Methods

Patients

This is a monocenter retrospective study over a 2-year period before and after the introduction in our service of the locoregional anesthesia via bilateral suprazygomatic maxillary nerve block.

The inclusion criteria were: all patients requiring primary surgery for soft palate cleft or soft and hard palate clefts. The clefts could be isolated palate clefts or associated to a previously operated cleft lip; syndromic or not. Exclusion criteria: patients whose parents refused to participate in the study or managed for secondary cleft surgery or any other subsequent surgery for soft palate cleft or soft-hard palate cleft.

Care management / Anesthetic protocol

According to the chronology, two types of anesthetic care management were applied, defining two types of successive surgical populations.

The first population (25/49 – GA group), before bilateral suprazygomatic maxillary nerve block became available, benefited from general anesthesia.

The second population (24/49 – LRA group) benefited from a bilateral suprazygomatic maxillary nerve block under sedation. In both groups, patients were monitored in a similar manner with continuous monitoring (pulse oximetry, cardiac monitor, capnometry, continuous non-invasive arterial pressure (CNAP)). Inhaled inductions

of anesthesia were performed with a facial mask using a halogenated agent (Sevoflurane®) with a 6% fraction of inspired oxygen and implementation of a peripheral intravenous catheter, orotracheal intubation using a preformed tube. Finally, an antibiotic prophylaxis was initiated (amoxicillin + clavulanic acid).

- For the GA group, during surgery the anesthesia consisted in Sevoflurane® 3% and sufentanil dosed from 0.2 to 0.5 gamma/kg under mechanical ventilation.

- For the LRA group, before surgery a suprazygomatic maxillary nerve block was performed with Chirocaine® (2.5 mg/mL – 0.2 mL/kg per side). In certain cases a locoregional analgesic-dedicated catheter was placed bilaterally to ensure continuous diffusion (0.5 to 1 ml/h) of the local anesthetic agent (Levobupivacaine 0.625 to 1.25 mg/mL). Patients had surgery under mechanical ventilation (MAC 1). If the sedation was found insufficient (CNAP) or increased heart rate > 10%), some sufentanil was administered intravenously on demand.

Patients from both groups received additional local anesthesia using lidocaine with epinephrine 0.1%, 0.5 mL/kg, infiltrated by the surgeon before the incision, to reduce bleeding and facilitate the dissection.

The surgical management was done by two junior surgeons specialized in the care management of cleft lip-palate. The choice of the technique used depended on the cleft's clinical type.

Postoperative management

Extubation was done in the operating room before moving to the recovery ward.

Postoperative follow-up and management were identical in both groups.

Pain was managed in several manners, in immediate postoperative right in the recovery room with step 1 analgesics (acetaminophen 15 mg/kg every 6 hours systematically) and step 3 (Nabulphine 0.2 mg/kg every 4 hours) via IV when the Face, Legs, Activity, Cry, Consolability (FLACC) scale was above 6/10.

Oral administration of analgesics was started as soon as possible and late postoperative analgesic management

associated acetaminophen 15 mg/kg every 6 hours systematically and codeine with a dose of 0.5 mg/kg every 6 hours. When the latter became contraindicated, we replaced it by ketoprofen 0.5 mg/kg every 6 hours.

The IV perfusion was stopped when the patient was able to eat. Hospital discharge was authorized as soon as the patient was pain free and had resumed feeding.

Comparative study between the two groups

Postoperative management during hospitalization were studied via a retrospective study of the patients' charts. Data collected were: duration of the surgery, time necessary for the child to wake up and time to extubation, time when the patient left the recovery room, time to resume feeding, use of step 2 analgesics as well as delay in removing IV infusions.

The former collected data were described by means and standard deviations for quantitative variables, and numbers and percentages for qualitative variables. Inter-group comparison was performed with a Student t-test for quantitative data or with a Mann-Whitney non-parametric test for temporal data, finally qualitative data were analyzed by a Pearson's chi-squared test. Systat 11.0 software was used for all analyses. The significance threshold was set at 0.05.

Results

Epidemiology

49 patients (25 boys and 24 girls) met the inclusion criteria and were included in this study, i.e. 28 cleft lip and palate cases, 21 cleft palate cases, including 14 soft palate clefts, 9 Pierre Robin sequences (7 stage I and 2 stage II) and 8 syndromic types (Table 1).

Mean age at the time of surgery was 13.5 ± 10.7 months (Table 2), without any significant difference between the GA and LRA groups ($p=0.5$).

No complications were noted for bilateral suprazygomatic maxillary nerve blocks during the preoperative, perioperative and postoperative periods.

In all, 44 surgeries were performed with the Veau-Wardill-Kilner technique and 5 with the Furlow double-opposing z-plasty technique of palate repair. There was

no significant difference between both groups regarding the type of intervention done and duration of surgery ($p=0.823$).

Perioperative data

In the GA group, 100% of children had at least one morphine injection during the surgical procedure, vs. 41% of children in the LRA group. In fact, 59% of patients who had a bilateral suprazygomatic maxillary nerve block did not require morphine during surgery to complete the locoregional anesthesia. We observed a significant difference between the GA and LRA groups regarding perioperative morphine use ($p<0.001$).

Mean use of sufentanil during surgery in the GA group was 4.13 ± 1.41 μg vs. 0.91 ± 1.59 μg in the LRA, with a significant difference between these two groups ($p<0.001$).

Mean time to extubation and transfer to the recovery room were respectively 09 ± 05 minutes in the LRA group vs. 25 ± 11 minutes in the GA group, with a significant difference between these two groups ($p=0.05$).

Postoperative data

All patients in both groups received step II analgesics during postoperative management. However, there was a significant difference ($p<0.01$) in terms of mean postoperative use of Nalpbuphine with 9.02 ± 6.44 mg for the GA group vs. 4.83 ± 3.41 mg for the LRA group. Thus in the postoperative period, 6 patients received one dose and 1 patient had two doses in the LRA group (Table 3).

The mean postoperative hospitalization duration was 1.6 night (1-4) with a mean total stay duration of 2.1 nights (1-6). Details according to groups are listed in table 4. No significant difference ($p=0.85$) was evidenced between both groups regarding the postoperative delay to return to the pediatric unit and the first postoperative feeding.

Furthermore, the mean time to remove the IV infusion was similar in both groups without any significant difference, i.e. 22.5 hours (± 4.75 hours) after leaving the

operating room in the LRA group vs. 23 hours (\pm 5 hours) for the GA group alone ($p=0.82$).

Finally, mean hospitalization duration was 40 ± 17 hours in the GA group vs. 37 ± 25 hours in the LRA group. There was no significant difference between both groups regarding hospitalization duration ($p=0.163$).

	Cleft lip-palate cases	Soft/ hard palate cleft cases	Soft palate cleft cases	Total
LRA*	13 non syndromic clefts	3 non syndromic	2 non syndromic	18 patients
	2 syndromic clefts (Pulmonary valve stenosis)	4 syndromic clefts (Pierre Robin sequence)	2 syndromic cases (Pierre Robin sequence, Hypospadias, polycystic degeneration, Ventricular Septal Defect, psychomotor delay)	8 patients
GA†	12 non syndromic cases	0 non syndromic case	6 non syndromic cases	18 patients
	1 syndromic case (pyelic dilation, bilateral hexadactylia)	1 syndromic case (Pierre Robin sequence, congenital vertical talus)	3 syndromic cases (Pierre Robin sequence)	5 patients
Total	28 patients	8 patients	13 patients	49 patients

Table 1. Epidemiologic summary of the different clinical cases (type of cleft, syndromic type) according to the type of anesthesia management during surgery (GA vs. LRA). *LRA: locoregional anesthesia (bilateral suprazygomatic maxillary nerve block), †General anesthesia (Sunfentani)

	N=49	GA=24	LRA=25	p
Age (months)	13,47 +/- 10,71	14,54 +/- 13,50	12,52 +/- 7,56	0.5 (1)*
Weight (kg)	9,02 +/- 1,88	9,23 +/- 2,04	8,83 +/- 1,74	0.5 (1)
Surgical technique :				0.8 (2) †
Veau-Wardill-Kilner	44	20	24	NS ‡ (2)
Furlow	5	3	2	NS (2)
Surgery duration (min)	53 ± 21	49 ± 23	57 ± 20	NS (3)

Table 2. Summary of patients' demographics and perioperative detail. *(1): Student's t-test; †(2): Pearson Chi-Square test; ‡ NS: Not significant; §(3): Mann-Whitney U test

	GA*	LRA†	P (t-test)
Step 1: Acetaminophen (mg)	773.54 ± 398.10	594.07 ± 224.01	0.06
Step 2: Codeine (mg)	2.87 ± 4.03	1.33 ± 3.27	0.1
Step 3: Nalbuphine (mg)	9.02 ± 6.44	4.83 ± 3.41	0.5

Table 3. Postoperative mean analgesic use according to the WHO analgesic ladder.

*GA=General anesthesia

†LRA= Locoregional anesthesia

	GA*	LRA†	P (Mann-Whitney U test)
Time to extubation (minutes)	25 ± 11	9 ± 5	0.05
Time to resuming feeding (hours)	7 ± 5	7 ± 5	0.85
Hospitalization duration (hours)	40 ± 17	37 ± 25	0.163
Time to removing the intravenous infusion (hours)	23 ± 5	22.5 ± 4.75	0.82

Table 4. Mean times to extubation, resuming feeding, removing the intravenous infusion and mean hospitalization duration.

*GA=General anesthesia

†LRA= Locoregional anesthesia

Discussion

Analgesia and perioperative management

Cleft palate surgery is known to be painful in the 24 to 48 hours post-surgery (9). The analgesic and hospital care management varies according to the different teams. Local nerve blocks have improved the anesthetic care management as well as the perioperative and postoperative follow-up, with a significant decreased use of morphine agents and thus absence of related side effects (10) such as nausea and vomiting with a quick postoperative wake-up (on-off effect).

Our study puts forward this decreased perioperative use of morphine agents thanks to bilateral suprazygomatic maxillary nerve blocks. In fact only 41% of children who had never blocks received morphine during surgery and the quantity of morphine was 4 times lower vs. the group who had general anesthesia alone.

A significant difference was noted regarding the use of Step II analgesics post-surgery with a decreased use in the LRA group. This decreased use seemed to be related to the use of the suprazygomatic maxillary nerve block. Using acetaminophen decreases significantly the use of morphine agents during the postoperative period in cleft palate surgery (11). Early feeding has not been related to pain; in fact Hugues et al unveiled the absence of significant difference in the use of morphine agents between groups who resumed feeding orally vs. parenteral nutrition after surgery (12).

As described by Dadure et al when surgery affects the middle or posterior palate it is preferable to proceed with truncal maxillary nerve blocks. The suprazygomatic approach should be used since it presents a lower rate of complications vs. other surgical approaches (13, 14). This way one can reach the nerve as it exits the skull at the foramen rotundum within the pterygopalatine fossa, before the location where its nervous branches innervate the palate (15). This simple, reliable and almost risk-free approach can yield an effective and prolonged anesthesia with a clear decreased use of morphine agents during and after cleft lip-palate surgery in small children (16). The nerve block must be bilateral. The local anesthetic is directly injected in the middle part of the fossa at a distance from the foramen rotundum to avoid any trauma to the nerve or vascular injury, as soon as the tip of the needle has crossed the temporal muscle.

In our study we evidenced a significant difference regarding time to extubation between the GA and LRA groups. Children wake up faster and more alerts with locoregional nerve blocks thus promoting a higher quality of care and faster return to the surgical pediatrics unit.

In our practice locoregional nerve blocks are performed in pre-anesthesia rooms. Of course this system enables to condition the patient with a locoregional block requiring more anesthetic time than simple general anesthesia without interfering with the occupation time of the operating rooms. However, children are systematically

awakened in the operating room. Thus, with the nerve block children awake faster leading to maximizing the operating room occupation time.

Analgesia and postoperative care

The analgesia quality provided by LRA decreases the duration of the hospital stay (9). These same results were evidenced in the article by Jonnavithula et al who evaluated the efficacy of greater palatine nerve block in the care management of cleft palate, postoperative analgesia and parent satisfaction. They reported significantly lower pain rates in the nerve block group, less requests for additional analgesia in the operating room and good parental satisfaction for the nerve block group vs. poor parental satisfaction for the GA group.

No significant difference was highlighted regarding hospital duration or resuming feeding. In fact, in our department with our protocol, feeding was resumed 6 hours post-surgery in average, whereas in the recent study by Chiono (7), feeding was not resumed before 13 to 15 hours post-surgery. This could be explained on one hand by the palatal infiltration with lidocaine with epinephrine performed by the surgical team at the beginning of the surgery and on the other hand by the analgesic efficacy of the palatal block as evidenced in the study by Jonnavithula (10), who used a local anesthetic with an extended duration of action (bupivacaine).

Finally, the effectiveness of the analgesia can be explained by the local anesthetic agent used to perform the maxillary nerve block, levobupivacaine. This new local anesthetic agent has been recommended by the ADARPEF (French-speaking association of anesthesiologists) for LRA in pediatrics because of its longer duration of action and its lesser systemic toxicity. To date, no study has been conducted in this domain with levobupivacaine, Chiono et al (7) used ropivacaine 2mg/ml just like Mesnil et al (16). A study would be relevant to compare the effectiveness and duration of action of these two local anesthetics in cleft surgery. The duration of action of local anesthetics can also be prolonged by adding adjuvants such as clonidine (1 to 2 µg/kg). No study

has been conducted, using a new local anesthetic with a long duration of action and prolonged with an adjuvant. In our practice, in addition to general or locoregional anesthesia, at the beginning of the surgical procedure the surgeon proceeds with an infiltration of lidocaine with epinephrine 1%. The objective is a triple one: achieving hydrodissection, vasoconstriction to reduce bleeding during and after surgery and analgesia. The role of lidocaine in analgesia is difficult to evaluate but it must certainly contribute to this multifactorial pain management. It would be relevant to conduct a study to compare a group with epinephrine infiltration alone vs. a group receiving lidocaine and epinephrine. However, the use of lidocaine must be well controlled in order to avoid any risk of overdose.

At the beginning of this study, Codenfan® (codeine phosphate hemihydrate) still had its Marketing Authorization Application from the French health authority. We did not report any complication with this product and we observed its effectiveness in analgesic procedures.

Recently in February 2013, the FDA (Food and Drug Administration) published a contraindication to using codeine in postoperative for tonsillectomy, and recommended only to use codeine in children when the benefit was definitely higher than the potential risk. In Europe the European Medicines Agency (EMA) followed FDA guidelines with a notice from the ANSM (National Agency for the Safety of Medicines and Health Products), dated April 12th, 2013. Thus, the Marketing Authorization Application (MAA) restricted the indications to use codeine for an acute of moderate-intensity pain for adolescents from the age of 12 years old after the analgesic failure of acetaminophen and/or NSAIDs. Nowadays, recommendations in pediatric surgery propose to use NSAIDs instead of codeine as an alternative solution.

A recent study conducted by Mireskandari et al unveiled the analgesic efficacy of the combined use of ketoprofen and acetaminophen (17). Several teams substitute the use of codeine in favor of ketoprofen. However the results

of the available analgesic efficacy studies remain inconclusive. Adarsh et al proposed to use NSAIDs rectally before surgery and observed a significant reduction of the pain and a lesser use of morphine agents during the postoperative period (18).

Conducting a similar study could help evaluate the quality of home discharge with the use of ketoprofen, a NSAID, which is available in injections or drops, which is really easy to administer in small children. The results might be similar according to poor medication adherence, as previously reported (19).

Conclusions

The anesthetic management associating sedation and bilateral suprazygomatic maxillary nerve block, to reduce the use of morphine, is highly relevant in the care management of cleft palate.

Using simple and non-invasive postoperative protocols also guarantee less postoperative complications.

In parallel, it seems useful to refine the exact role played by an infiltration of lidocaine with epinephrine during surgery.

Will the next step be to stop using lidocaine in infiltration during surgery or rather to promote its essential role in perioperative analgesia?

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