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KONTROLA KVARENJA, PREVENCIJE INFEKCIJA I PRIMENA ANESTETIKA U EGZODONCIJI NATALNIH ZUBA

HEMORRHAGE CONTROL, INFECTION PREVENTION AND APPLICATION ON ANESTHETICS IN EXODONTIA OF NATAL TEETH

Dušan Šurdilović¹, Walid El Sayed^{1,2}, Tatjana Ille³, Mohamed Said Hamed¹, Pooja Narain Adtani¹,
 D Prabhu Manickam Natarajan¹

¹ MEDICINSKI UNIVERZITET GULF, STOMATOLOŠKI FAKULTET, AJMAN, UAE

²UNIVERTZITET SUECKI KANAL, EGIPAT

³MEDICINSKI UNIVERZITET GULF, MEDICINSKI FAKULTET, AJMAN, UAE

¹GULF MEDICAL UNIVERSITY, COLLEGE OF DENTISTRY, AJMAN, UAE

²SUEZ CANAL UNIVERSITY, EGYPT

³GULF MEDICAL UNIVERSITY, COLLEGE OF MEDICINE, AJMAN, UAE

Sažetak

Uvod: Zubi koji se pojavljuju u trenutku rođenja zovu se natalni zubi. Najčešći natalni zubi su donji mlečni sekutići. Tačan uzrok nastanka natalnih zuba nije poznat, ali se kao mogući faktori pominju infekcije, trauma, hormonska stimulacije itd. Imajući u vidu da postoji mogućnost aspiracije kao i otežana ishrana bebe, najčešće su indikovani za ekstrakciju.

Prikaz slučaja: Novorođenče staro jedan dan sa zubima u donjoj vilici poslato je na Odeljenje za dečiju stomatologiju u Thumbay u Dubaiju, u Ujedinjenim Arapskim Emiratima. Konstrukcija krunice bila je pričvršćena za desni sa mobilnošću II stepena (Millerova klasifikacija). Školjkasta gledna struktura natalnih zuba je uklonjena parodontalnom kiretom, obazrivo, da se ne povredi zametak mlečnog sekutića. Vitamin K u dozi od 1 mg dat je IM u anterolateralni predeo butine novorođenčeta dva sata pre hirurškog tretmana. Postoperativni tok protekao je uredno.

Zaključak: Natalni zubi su retka pojava, međutim, nisu nepoznati kod novorođenčadi. Ekstrakcija je prva opcija tretmana, što je pre moguće, uzimajući u obzir sve komplikacije, uz obaveznu administraciju vitamina K.

KLjučne reči: natalni zubi, krvarenja, infekcije

Corresponding author:

Ass. Prof Dušan Šurdilović, DDS, MSD, PhD
 Gulf Medical University
 United Arab Emirate
 E-mail: surdilovic74@gmail.com

Abstract

Introduction: The teeth that appear at the time of birth are called Natal teeth. The exact cause of its appearance is unknown, but possible causes for this condition include infections, trauma, hormonal stimulation etc. There is a possibility to aspirate the tooth and difficulty with feeding.

Case report: A one day old baby born with teeth in the lower jaw was referred to our dental department, Thumbay Hospital, Dubai, UAE. The crown structure was attached to the gums with grade 2 mobility (Millers classification). The shell like crown was removed with a periodontal curette and care was taken not to injure the underlying tooth. Vitamin K injection 1mg IM was given in the anterolateral thigh 2 hours before the procedure.

Conclusion: The appearance of natal teeth is a rare case however it is not uncommon in the newborns. Extraction as the first treatment choice should be performed as soon as possible considering all possible complications. Vitamin K administration is a mandatory step in the treatment.

Key words: natal teeth, hemorage, infection

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Uvod

Razvoj ljudskih zuba je složen proces koji proizilazi iz sekvencijalne i recipročne interakcije između oralnog ektodermalnog i mezenhimalnog tkiva (nalazi se ispod ektodermalnog tkiva). Ova interakcija rezultira različitim putevima u kojima se koriste mnogi specifični medijatori¹. Dokazano je da sekrecija ovih specifičnih medijatora počinje od oralnog epitela, zatim dolazi do difuzije u ektomezenhim, a potom indukuje ekspresiju transkripcionih faktora. Ovaj prelaz između epitela i vezivnog tkiva reguliše i kontroliše razvoj zuba i vreme kada kasnije počnu da niču zubi². Međutim, zubi se ponekad, iz nepoznatih razloga, pojavljuju rano u oralnoj duplji. Zubi koji se pojavljuju u trenutku rođenja zovu se natalni zubi, dok se zubi koji izbijaju u prvih 30 dana nakon rođenja zovu neonatalni zubi. Pored toga, zubi koji niču izvan natalnog perioda od 30 dana obično se nazivaju rani predmlečni zubi³. Natalni zubi se javljaju češće nego neonatalni zubi⁴. Natalni zubi se zovu još i *Dentitia praecox*, *dens connatalis*, kongenitalni zubi, fetalni zubi, zubi novorođenčeta, prethodni zubi i rani zubi^{5,6}. Prevalentni opseg je od 1:11 do 1:30000, u zavisnosti od vrste studije, a najčešći natalni zubi su donji mlečni sekutići^{5,7}. Postoji nekoliko razloga koji uzrokuju ovakvo stanje, uključujući određene vrste infekcije, febrilnost, traumu, nehranjenost, površinski položaj zubne klice, hormonsku stimulaciju i porodičnu anamnezu, ali tačan uzrok nije poznat^{6,8}.

Može se smatrati da je stanje natalnih i neonatalnih zuba od fundamentalnog značaja, jer njihovo prisustvo može dovesti do brojnih komplikacija. Ove komplikacije mogu biti manje komplikacije, kao bolni ugriz ili krvarenje bradavice tokom dojenja. Međutim, mogu se dogoditi ozbiljne komplikacije usled postojanja natalnog/neonatalnog zuba, kao što su inhalacija ovakvog zuba, dehidracija, nehranjenost, mala veličina, koja dovodi do usporavanja napretka. Dakle, veoma je preporučljivo rano otkrivanje i lečenje ovih zuba^{5,6,8}.

Introduction

Human teeth development is a complex process resulting from sequential and reciprocal interaction between oral ectodermal and the underlying mesenchymal tissues. This interaction results in different pathways in which so many signaling mediators are used¹. These signaling mediators have been shown to be secreted first by the oral epithelium, diffuse into the underlying ectomesenchyme and then induce expression of the transcription factors. This cross talk between the epithelium and connective tissue regulates and controls the tooth development and subsequent tooth eruption time². However, the teeth sometimes, due to unknown reasons, appear early in the oral cavity. The teeth that appear at the time of birth are called Natal teeth, while the teeth erupting within first 30 days after birth are called Neonatal teeth. In addition to that, teeth erupting beyond the natal period of 30 days are usually referred to as early infancy teeth³. Natal teeth are most common than neonatal teeth⁴. Natal teeth have other different synonyms such as *Dentitia praecox*, *dens connatalis*, congenital teeth, fetal teeth, infancy teeth, predeciduous teeth, and precocious dentition^{5,6}. Prevalence of natal teeth ranges from 1:11 to 1:30000 depending on the type of the study and the most common natal teeth are lower primary central incisors^{5,7}. Several reasons have been attributed as the cause for this condition including certain types of infection, febrile status, trauma, malnutrition, tooth germ superficial position, hormonal stimulation and family background, however the exact cause is unknown^{6,8}.

It must be considered that natal and neonatal teeth are conditions of fundamental importance since their presence may lead to numerous complications. These complications can be minor complications as painful bite or bleeding nipples in case of breast feeding. However, serious complications can happen due to natal/neonatal teeth such as inhalation of the natal tooth, dehydration, malnutrition leading to low weight, small size that may lead to failure to thrive. So, early detection and treatment of these teeth are highly recommended^{5,6,8}.

Prikaz slučaja

Pedijatar je uputio novorođenče staro jedan dan sa zubima u donjoj vilici na Odeljenje za dečiju stomatologiju u Thumbay bolnici u Dubaiju (Ujedinjeni Arapski Emirati), radi preduzimanja odgovarajućeg medicinskog tretmana. Na pregledu je utvrđeno da je novorođenče imalo dva natalna centralna sekutića (slika 1). Pažljivim kliničkim pregledom ustanovljeno je da zubi zapravo imaju samo gleđnu strukturu. Majka je potvrdila da su zubi prisutni od rođenja, tako da se smatraju natalnim zubima. Takođe, majka se žalila zbog poteškoća tokom dojenja.

Case presentation

A one day old baby born with teeth in the lower jaw was referred to our dental department, Thumbay Hospital, Dubai by the pediatrician for appropriate management. On examination, the baby was found to have two premature central incisors (Figure 1). A careful clinical examination revealed that the teeth have a shell like crown structure. The mother confirmed that the teeth were present at birth so these were considered natal teeth. Furthermore, the mother complained about difficulty during breastfeeding.

Slika 1. Kliničke slike i procedura hirurškog tretmana natalnih zuba; A: centralni i bočni sekutić prisutni su od prvog dana u usnoj duplji (bele strelice); B: još jedna klinička slika koja pokazuje da natalni zubi uzrokuju traumu do gornje vilice (bele strelice); C: slika pokazuje iglu i anesteziju koja se koristi u hirurškom tretmanu; D: korišćenjem parodontalne kirete uklonjeni su natalni zubi

Figure 1. Clinical pictures and surgical extraction procedure of the natal teeth: A) center and lateral incisors are present from day one in the oral cavity (white arrows), B) another clinical picture showing that natal teeth are causing trauma to the upper jaw (white arrows), C) the needle and the anesthesia used in the surgical procedure, D) using periodontal curette to remove the Natal teeth.

Konstrukcija krunice bila je pričvršćena za desni sa mobilnošću II stepena (Millerova klasifikacija). Pošto je krunasta struktura bila dobro pričvršćena za desni, mogućnost aspiracije smatrana je minimalnom. Isto objašnjenje je dato roditeljima novorođenčeta. Oni su bili obavešteni da se natalni zubi moraju ukloniti, ako majka oseća bol ili neugodnost tokom dojenja ili ako postoji povreda jezika ili usana novorođenčeta.

Dva dana nakon otpusta, roditelji novorođenčeta su se vratili u bolnicu sa žalbom da majka ne može da doji zbog bola koji oseća. Nakon razgovora sa roditeljima, odlučeno je da se natalni zube uklone.

The crown structure was attached to the gums with grade 2 mobility (Miller's classification). As the crown structure was well attached to the gums, the possibility of aspiration was considered minimal. The same was explained to the baby's parents. They were informed that the natal teeth had to be removed if the mother felt pain or discomfort while feeding or if there was a self-inflicted injury to tongue or lips.

Two days after discharge, the parents returned back to hospital because of the mother's inability to breastfeed due to pain. After discussion with parents, it was decided

Analiza krvi , uključujući kompletnu krvnu grupu, PT, INR i aPTT, je urađena i svi parametri su bili u granicama normale. Vitamin K u dozi od 1 mg dat je IM u anterolateralni predeo butine novorođenčeta dva sata pre hirurškog tretmana.

Za ekstrakciju natalnih zuba upotrebljena je infiltraciona anestezija lidokainom. Pažnja je bila usmerena ka tome da se ne povredi zametak mlečnog sekutića, a školjkašta gledna struktura natalnog zuba je uklonjena parodontalnom kiretom (slika 1). Zarastanje postekstrakcionih rana je bilo neujednačeno. Propisan je paracetamolni sirup zbog moguće pojave subjektivnih simptoma bola. Nakon dva dana od hirurškog tretmana, novorođenče je pregledano, a praćeno je tokom sledećih mesec dana. Pošto je postignuta postoperativna hemostaza, novorođenče je otpušteno, a roditeljima su data postoperativna uputstva odmah nakon postizanja hemostaze. Na slici 2 je prikazan pacijent opozvan nakon dva dana za pregled (slika 2).

to remove the natal teeth. Blood investigation including complete blood count, PT, INR and aPTT was done and was within normal limits. Vitamin K injection 1mg IM was given in the anterolateral thigh 2hours before the procedure.

The extraction of natal teeth was performed under lidocaine infiltration anesthesia. Care was taken not to injure the underlying tooth bud and the shell like crown was removed with a periodontal curette (Figure 1). Post extraction healing was uneventful. Plain paracetamol syrup was prescribed for possible subjective symptom of pain. Patient was recalled after 2 days for review and followed up for a month. Post-operative hemostasis was achieved and the patient was dismissed after giving the post-operative instructions immediately after the achievement of hemostasis. The patient was recalled after two days for a follow up. (Figure 2).

Slika 2. Praćenje posle hirurškog tretmana; I: neposredna klinička slika nakon hirurškog tretmana; II; praćenje dva dana nakon hirurškog tretmana; III: praćenje nakon četiri nedelje i IV: radiografska slika koja prikazuje zubne zemetke mlečnih sekutića (crna zvezdica)

Figure 2. Follow up after surgical procedure. In this figure: I) Immediate clinical picture after the surgical procedure, II) Follow up after 2 days from the surgical procedure, III) Follow up after 4 weeks and IV) radiographic image showing tooth germ of the deciduous incisors (black asterisk).

Diskusija

Većina novorođenčadi dobija svoje prve zube između 4 i 7. meseca života. Prvi zubi koji se pojavljuju iz gingive alevolarnog grebena su donji centralni sekutići. Dok većina novorođenčadi dobija svoje prve zube nekoliko meseci nakon rođenja, neke bebe su rođene sa jednim ili više zuba. Oni se nazivaju natalni zubi. Pojava natalnih zuba je relativno retka, zastupljena je u jednom od svakih 2000 novorođenčadi³.

Izveštaji o incidenciji natalnih i neonatalnih zuba su objavljeni u brojnim studijama i kreću se u rasponu od jednog u 50 slučajeva (2%) na uzorku od 2000 novorođenčadi pregledanih u Meksiku u prvih 20 sati od rođenja, do odnosa 1:30000, u rezimeima objavljenih istraživanja u periodu od 1976. do 1991. godine. Međutim, mnoge studije pokazuju incidencije u rasponu 1:2000 do 1:3500 slučajeva živorođene dece^{3,6}.

Učestalost verovatno varira u zavisnosti od rase, gde izvesna indijanska plemena u Sjedinjenim Američkim Državama smatraju normalnom pojavom prisustvo natalnih zuba.

Učestalost natalnih zuba je tri puta veća nego pojava neonatalnih zuba. Muško-ženska relacija varira u različitim studijama, u kojima neke od njih ističu predominaciju kod muškog pola, dok druge studije ističu ravnomernu distribuciju ili dominaciju ženskog pola. Natalni i neonatalni zubi se retko mogu javljaju kod prevremeno rođenih beba⁹.

Izgleda da postoji i nasledna tendencija ka razvoju natalnih zuba, jer 60% slučajeva ukazuju na pozitivnu porodičnu anamnezu, sa autozomno dominantnim obrascem nasleđivanja (što znači da se kod oko polovine dece koja imaju porodičnu anamnezu natalnih zuba oni i pojavljuju)¹⁰.

Natalni zubi su često povezni sa slučajevima rascepa usana i nepca: 10% dece rođene sa bilateralnim rascepom usne/nepca imaju natalne zube, dok 25% dece sa unilateralnim rascepom usne/nepca imaju natalne zube¹¹. Rascepi usne/nepca mogu biti zastupljeni u značajnom broju sindroma u kojima se takođe pojavljuju natalni zubi, kao što su Meckel-Gruber sindrom (MIM249000) i Pierre-Robin sindrom (MIM261800). Nastavljajući ovaj niz sindroma u kojima se pojavljuju natalni zubi treba uključiti i: Ellis-Van Creveld sindrom (hondroektodermalna displazija, MIM225500), Jackson-Lawler sindrom (pachynuchia congenita2, MIM1672100), Steatocystoma multiplex sa natalnim zubima (MIM184510) i Hallerman-Streiff (ovulomandibulofacialni sindrom sa hipotrihosom, MIM234100)⁵.

Discussion

Most babies get their first tooth between 4 and 7 months of age. The first teeth that poke through the gums are the central incisors, which are located on the bottom front. While most infants get their first teeth months after birth, some babies are born with one or more teeth. These are called natal teeth. Natal teeth are relatively rare, occurring in about 1 out of every 2000 births³.

The incidence of natal and neonatal teeth has been reported in a number of studies, ranging from 1 in 50 (2%) in a series of over 2000 babies examined within 20 hours of birth in Mexico to 1 in 30000, in a summary of studies published between 1876 and 1991. Most studies however give an incidence between 1 in 2000 to 1 in 3500 live births^{3,6}. The incidence probably varies between different racial groups, with some American Indian tribes reported to commonly present with natal teeth.

Natal teeth are said to be three times more common than neonatal teeth. The male to female ratio varies in different studies with some reporting a male predominance and others no difference or a female predominance. Natal and neonatal teeth are rarely seen in very premature babies⁹.

There appears to be an inherited tendency to developing natal teeth with up to 60% of cases reporting a positive family history with an autosomal dominant pattern (meaning about half the children of an affected individual are affected)¹⁰.

Natal teeth are associated with cleft lip/palate: 10% of children with bilateral cleft lip/palate have natal teeth and 25% of children with unilateral cleft lip/palate have natal teeth¹¹. Cleft lip/palate can be a feature of a number of syndromes in which natal teeth have also been reported such as Meckel-Gruber syndrome (MIM249000) and Pierre Robin sequence (MIM261800). Furthermore, there are some syndromes in which natal teeth are a recognized feature: Ellis-van Creveld syndrome (chondroectodermal dysplasia, MIM225500), Jackson-Lawler (pachyonychia congenita 2, MIM167210), Steatocystoma multiplex with natal teeth (MIM184510) and Hallerman-Streiff (oculo-mandibulofacial syndrome with hypo-trichosis, MIM234100)⁵.

The exact etiology of natal teeth is unknown, however maternal factors reported to be associated with an increased risk of natal teeth include: babies born to mothers exposed to high levels of poly-chlorinated biphenyls and dibenzofurans during the Yusheng environmental accident in Taiwan

Egzaktna etiologija pojave natalnih zuba je nepoznata, međutim, uticaj faktora, koji su posledica stanja majke, uočeni su i povezani sa povećanim rizikom za pojavu natalnih zuba. Ta stanja su uočena kod novorođenčadi čije su majke bile izložene visokim nivoima polihloriniranih bifenila idibenzofurana usled ekološkog incidenta u Yushengu, Tajvan. Tada je uočen 10% veći rizik za pojavu natalnih zuba. Na pojavu ovih zuba utiču i febrilna stanja tokom trudnoće, poremećaji ishrane povezani sa neuhranjenošću, hipovitaminomom i traumom.

Ekstrakcija kao terapijska procedura se razmatra ukoliko su: natalni zubi prekobrojni, veoma pokretljivi, sa slabom vezom sa gingivalnim tkivom ili imaju interakciju sa nazoalveolarnim ortodontskim terapijskim pomagalicama. Ekstarakcija (ili spontano ispadanje) mogu biti iskomplikovani razvojem "rezidualnih neonatalnih zuba", za koje se smatra da se mogu pojaviti u 9% slučajeva, što bi zahtevalo još jednu hiruršku intervenciju.

Vitamin K je važan koagulacioni faktor koji može nedostajati novorođenim bebama^{13,14}. Ovaj nedostatak vitamina K može biti veći usled endogenih faktora, kao što su nedovoljna bakterijska kolonizacija, egzogenih faktora, poput male koncentracije vitamina K u majčinom mleku i slabim placentarnim transportom¹³. Poznato je da nizak nivo vitamina K kod novorođenčadi izaziva krvarenje (VKDB). Zbog toga je 0,5 mg (porođajna težina 1500 g ili manje) ili 1 mg (porođajna težina preko 1500 g) vitamina K preporučena doza za intramuskularnu administraciju za svu novorođenčad u prvih 6 sati posle rođenja, čime se postiže inicijalna stabilizacija koagulacije, odobrena od strane Kanadskog pedijatrijskog udruženja¹⁵.

Prilikom procene rezultata laboratorijskih parametara krvi novorođenčeta, uočen je povećan nivo aPTT (44,7), u poređenju sa normalnim referentnim vrednostima (26,0-40,0). Povećan nivo aPTT ukazuje na nedostatak ili smanjeni nivo faktora koagulacije krvi. Imajući to u vidu, u prikazanom slučaju, pacijentu je intramuskularno bila data dodatna doza od 1 mg vitamina K, dva sata pre hirurške intervencije¹⁴.

Antibiotska terapija nije bila indikovana za ovu hiruršku intervenciju, jer je novorođenče hranjeno majčinim mlekom.

Majčino mleko je rezervoar nutritijenata i biološki aktivnih supstanci. Najpoznatije imuno protektivne komponente majčinog mleka su imunoglobulini, IgA je prisutan u velikim količinama, praćen prisustvom IgM i

were found to have a 10% risk of natal teeth, infection and febrile states, malnutrition including hypovitaminosis, and trauma⁸.

As treatment is considered if teeth are luxate or because of the interference with the nasoalveolar molding appliance. Extraction (or spontaneous loss) can be complicated by the development of 'residual neonatal teeth', said to occur in approximately 9% and necessitating a second surgical procedure¹².

Vitamin K is an important coagulation factor that is found to be deficient in newborns/neonates^{13,14}. This deficiency state arises due to endogenous factors like insufficient bacterial colonization and exogenous factors such as low concentration of vitamin K in breast milk and poor placental transport¹³. Low levels of Vitamin K in neonates is known to cause vitamin K deficiency bleeding (VKDB), therefore 0.5 mg (birthweight 1500 g or less) or 1 mg (birthweight greater than 1500 g) of vitamin K is the recommended dosage administered intramuscularly to all newborns within the first 6 hours after birth for initial stabilization as approved by the Canadian pediatric Society¹⁵.

On evaluating the patient's laboratory report, it was observed that the aPTT was higher (44.7) when compared to the normal reference range (26.0 – 40.0). A higher aPTT refers to lack of or low level of blood clotting factors. Therefore, in the present case the patient was administered an additional dose of 1mg of vitamin K IM, 2 hours prior to the extraction procedure¹⁴.

No antibiotic coverage was suggested prior to the extraction as the child was on breast milk. Human breast milk is a reservoir of nutrients and biologically active compounds. The most recognized immune protective components in human breast milk are immunoglobulins, IgA being present in large quantities followed by IgM and IgG. IgA provides protection against infection by blocking the contact of the pathogen with the intestinal epithelial layers and entrapping the pathogen within the mucin layers. Immune cells in the breast milk produce cytokines such as transforming growth factor beta (TGFβ), interleukin 1 (IL1) and interleukin 13 (IL13) which help in suppressing inflammation¹⁶.

For newborns, the amount of L.A to be administered is calculated based on the child's body weight, medical history, duration of the dental procedure, need for hemorrhage control, it should comply with the American Academy of Pediatric Dentistry (AAPD) recommendations and never exceed the maximum total dosage¹⁷.

IgG. IgA obezbeđuje zaštitu od infekcije blokiranjem kontakata patogena sa intestinalnim epitelom, istovremeno okružujući patogene slojem mucina. Imune ćelije majčinog mleka proizvode citokine, kao što su transformišući faktor rasta beta (TGFβ), interleukin 1 (IL1) i interleukin 13 (IL13), koji pomažu redukciju inflamacije¹⁶.

U slučaju doziranja i davanja lokalne anestezije kod novorođenčadi, količina anestetika se računa na osnovu težine novorođenčeta, medicinske istorije, dužine stomatološke intervencije i potrebe za kontrolom krvarenja, što sve treba da je u saglasnosti sa preporukama Američke akademije za dečiju stomatologiju (AAPD), pri čemu maksimalne preporučene doze nikada ne treba premašiti¹⁷. Preporučena doza je 7 mg/kg telesne mase za pedijatrijske bolesnike. U prikazanom slučaju, težina novorođenčeta je bila 2,5 kg, shodno tome, ukupna doza od 1,5 ml lokalnog anestetika (2% Lidokaina sa adrenalinom, 1:100000) infiltraciono je aplikovana novorođenčetu.

Podaci iz literature ukazuju da je mandibularna bukalna infiltraciona anestezija isto tako efikasna kao i blok anestezija mandibularnog inferiornog nerva¹⁷.

Zaključak

Studija hirurškog tretmana natalnih zuba sa stanovišta kontrole krvarenja, prevencije infekcije i aplikacije anestetika ističe sledeće zaključke:

1. natalni zubi su retka pojava, međutim, nisu nepoznati kod novorođenčadi,
2. ekstrakcija je prva opcija tretmana, što je pre moguće, uzimajući u obzir sve komplikacije,
3. administracija vitamina K je neophodni korak u tretmanu,
4. odgovarajuća količina lokalnog anestetika datog tokom hirurške intervencije, mora biti tačno izračunata u skladu sa telesnom težinom novorođenčeta i
5. u ovom slučaju, primena antibiotske terapije nije bila neophodna.

The recommended dosage is 7 mg/Kg body weight for pediatric patients, in the present case the child weighed 2.5 kg, therefore, a total of 1.5 ml of L.A (2% lidocaine with adrenaline 1:100,000) was administered as infiltration.

Literature studies state that a mandibular buccal infiltration is as effective as an inferior alveolar nerve block¹⁷.

Conclusion

This study is about surgical treatment of natal teeth from the standpoint of hemorrhage control, infection prevention and application on anesthetics that highlights:

1. The occurrence of natal teeth is a rare case however it is not uncommon in the newborns,
2. Extraction as the first treatment choice should be performed as soon as possible considering all possible complications,
3. Vitamin K administration is a mandatory step in the treatment,
4. Proper calculation of the amount of the local anesthesia given during the treatment should be carefully determined according to the body weight of the newborn,
5. Administration of the antibiotic is not necessary in such case.

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Conflict of interest

There is no conflict of interest

Patient consent

All involved patients gave their consent forms

Ethics approval

This study is in accordance with the Helsinki Declaration