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Vrijednost pH-a, kiselost titracije i ukupan udjel čvrste topljive tvari u pedijatrijskim lijekovima protiv kašlja

pH, Titratable Acidity and Total Soluble Solid Content of Pediatric Antitussive Medicines

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Sažetak

Svrha: U ovoj su se eksperimentalnoj studiji in vitro procijenili endogeni pH, kiselost titracije i ukupan udjel čvrste topljive tvari (UUTČT) u pedijatrijskim antitusivnim lijekovima u obliku sirupa. **Ispitanici i metode:** sedam lijekova procijenjeno je u pokusu prema načelu slučajnog odabira i svaka je analiza bila ponovljena tri puta. Procjena pH-a obavljena je potenciometrijom, a ocijenjen je bio i puferski kapacitet nakon što se razrijedio svaki lijek. Inkrementi od 0,1 N KOH-a titrirani su dok nije dosegnuta neutralnost. Mjerenje UUTČT-a obavljeno je Brixovom refraktometrijom uz pomoć Abbéova refraktometra. **Rezultati:** vrijednosti pH-a kretale su se od 2,65 (Mucolin®) do 6,56 (Fluimucil®), a kod četiriju lijekova bile su niže od kritičnih 5,5. Vrijednosti titracijske kiselosti za te lijekove bile su od 0,061 (Fluimucil®) do 0,467 (Ambroxmel®). Fluimucil® je pokazao najnižu vrijednost UUTČT-a (4,33%), a Mucofan® je imao najveću (53,41%). **Zaključak:** mnogobrojni pedijatrijski antitusici imali su pH ispod kritične vrijednosti, visoke titracijske vrijednosti te veliku koncentraciju šećera, što može povećati njihov kariogeni i erozivni učinak u slučaju neodgovarajuće primjene kod djece.

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Uvod

Djeca oboljela od kroničnih bolesti često dugo moraju uzimati lijekove. Njih nekoliko može promijeniti sastav plaka i oralnoga pH, što može štetiti zubima. Tradicionalno se smatra "kritičnim" za razgradnju cakline pH od 5,5, iako gubitak minerala može početi već kod viših vrijednosti (1).

Introduction

Children with chronic diseases often require long-term drug regimens. Several medicines can alter plaque composition and oral pH being potentially harmful to the teeth. A pH of 5.5 is traditionally considered to be the ‘critical pH’ for enamel dissolution, although mineral loss may begin at higher pH (1).

Kako bi poboljšali okus i možda suradnju malih pacijenata, farmaceutske tvrtke proizvode tekuće lijekove zaslađene sukrozom (2). Visok udjel šećera u tim proizvodima može završiti sklonošću prema karijesu. Svoj kariogeni učinak sirupi za djecu duguju velikoj koncentraciji fermentibilnih ugljikohidrata i njihovoj acidogenosti – sposobnosti da proizvode kiseline (3, 4). Ipak, količina šećera u određenim lijekovima nije jedina odgovorna za štetan učinak na zube i sve češći karijes. Tome pridonosi i to koliko se često medikamenti uzimaju, jesu li potrebni i noću, koliko im je visoka viskoznost te nizak endogeni pH (5).

Kiselost sadžaja može se izraziti u kiselosti titracije, što je mjera postotka težine kiseline u otopini, a računa se iz volumena natrijeva hidroksida (NaOH-a) ili kalijeva hidroksida (KOH-a) potrebnog za neutralizaciju kisele tvari. U praksi se mjeri potenciometrijom iz standardizirane otopine NaOH-a ili KOH-a s poznatom koncentracijom na temperaturi od 20°C.

Brixova ljestvica, numerički jednaka postotku šećera i drugih čvrstih otopljenih tvari u otopini, sada se spominje u Brixovim stupnjevima (ukupan udjel čvrstih topljivih tvari – UUTČT-a). U velikom broju slučajeva pretpostavlja se da su sve otopljene tvari šećer (6).

Svrha je studije evaluirati endogeni pH, kiselost titracije i UUTČT antitusika za djecu u obliku sirupa.

Materijali i metode

Određivanje razina pH-a, kiselosti titracije (KT-a) i ukupnog udjela čvrste topljive tvari (UUTČT-a) obavljeno je za sedam najčešćih komercijalnih pedijatrijskih antitusika u brazilskome gradu Campini Grande. Ti su proizvodi slučajno odabrani prema njihovoj tržišnoj dostupnosti (Tabl. 1.). Procijenjeni su eksperimentom prema slučajnom uzorku, pokusi su za svaki uzorak bili ponovljeni tri puta, a zatim im je zabilježe-

In order to improve palatability and perhaps patient compliance, pharmaceutical companies supply liquid medicines sweetened with sucrose (2). The high sugar content of these pediatric products can lead to a higher susceptibility to caries disease. The cariogenic potential of pediatric syrups is due to a high concentration of fermentable carbohydrates and their acidogenicity (3,4). However, the sugar content of certain medicines is not the only factor responsible for potential harmful effects on the teeth. Frequency of consumption, nocturnal ingestion, high viscosity, and low endogenous pH also contribute to increase caries experience (5).

The acidity of a composition may be expressed in terms of titratable acidity, which is a measure of the percent weight of acid present in a solution as calculated from the volume of sodium hydroxide (NaOH) or potassium hydroxide (KOH) required to neutralize the acidic species. In practice, titratable acidity is measured potentiometrically with a standardized NaOH or KOH solution of a known concentration at a temperature of 20°C.

The Brix scale, which is numerically equal to the percent of sugar and other dissolved solids in the solution, is now referred to as degrees Brix (total soluble solids content - TSSC). In many cases, it is assumed that all of the dissolved solute is sugar (6).

The objective of this study was to evaluate the endogenous pH, titratable acidity and TSSC of antitussives of pediatric use presented as syrups.

Material and methods

The determination of pH, titratable acidity (TA) and total soluble solids content (TSSC) levels was carried out in the seven most frequently prescribed commercial pediatric antitussive medicines in the city of Campina Grande, PB, Brazil. The products were randomly selected according to their availability in the market (Table 1). They were evaluated by a random experiment with 3 repetitions for each sample, and the

Tablica 1. Komercijalni naziv, farmaceutski naziv i proizvođači pedijatrijskih lijekova analiziranih u ovom istraživanju
Table 1 Commercial name, pharmaceutical name and manufacturers of the pediatric medicines used in this study

Komercijalni naziv • Commercial Name	Farmaceutski naziv • Pharmaceutical Name	Proizvođač • Manufacturer
Mucolin	Ambroxol	Abbot Lab. do Brazil Ltda.
Mucolitic	Carbocysteine	Altana Pharma Ltda.
Mucofan	Carbocysteine	União Química Farm. Nac. S/A
Fluibron	Ambroxol	Farmalab Ind. Quím. e Farm. Ltda.
Fluimucil	N-acetilcisteina	Zambon Labs. Farms. Ltda.
Ambroxmel	Ambroxol	Cimed Ind. Med. Ltda.
Fluitoss	Carbocysteine	Lab. Teuto Brasileiro S/A

na srednja vrijednost. Podaci su prikupljeni kalibriranim ispitivačem (Kappa = 0,81) te su nakon toga upisani u tablice pripremljene samo za ovu studiju.

Mjerenje pH vrijednosti

Endogeni pH svakog lijeka bio je određen pH-metrom na sobnoj temperaturi od 20°C (TEC-2 pH meter; Tecnal, Sion Paulo, SP, Brazil) te postavljen izravno u svaku otopinu. Točnost pH-metra iznosila je 0,1, bila je kalibrirana prema uputama proizvođača, a koristili su se puferski standardi od pH 7 i pH 4. Najprije je 10 mL svakog antitusika bilo stavljeno u posudu, a pH-metar je bio imerziran u sirup, te su nakon toga zabilježene vrijednosti.

Kiselost titracije (KT)

Kiselost titracije bila je izmjerena prema metodi preuzetoj od Udruženja službenih analitičkih kemičara - Association of Official Analytical Chemists (7), a zahtijeva količinu otopine od 0,1 N KOH-a kako bi proizvod dosegnuo neutralni pH ili pH iznad toga. Alikvot otopljenog proizvoda od 10 mL (10% otopine uzorka) bio je titriran s 0,1 N otopine KOH-a, dok tvar nije dosegnula pH vrijednost između 8,2 i 8,4, što odgovara završnoj točki fenolftaleina. Rezultati su očitani pH-metrom (TEC-2R; Tecnal, São Paulo, SP, Brazil). Kada je bila postignuta vrijednost pH-a, zabilježio se potrošeni volumen KOH-a, te izračunao postotak kiselosti tvari uz pomoć jednadžbe koja slijedi, a rezultat je bio izražen u postotku citrične kiseline.

$$\text{Kiselost (\% citrične kiseline)} = \frac{V \times Nap \times F \times \text{meq-g(citrična kiselina)} \times 100}{}$$

Uzorak

V = volumen KOH-a; Nap = normalna koncentracija KOH-ove baze; F = čimbenik korekcije normaliteta; meq-g = miliekvivalent *po* gramu citrične kiseline; Uzorak = volumen ispitanog lijeka.

Briksovi stupnjevi (°Bx)

Očitavanje °Bx-a obavljeno je refraktometrijom uz pomoć Abbéova refraktomera (PZO-RL1, Varšava, Poljska). Kako refraktivni indeks otopine koja sadržava šećer ovisi i o temperaturi, uređaje se obično kalibrira na 20°C. Oprema je kalibrirana deioniziranom vodom (indeks refrakcije= 1,3330 i 0° Brixa kod 20°C), a zatim su očitani uzorci (8).

Rezultati

U Tabl. 2. prikazana je distribucija pH-a i srednje vrijednosti KT-a i UUTČT-a za ispitivanje antitusika za djecu.

mean of the three values was recorded. Data were collected by a single calibrated examiner (Kappa = 0.81) and were recorded in study-specific charts.

pH Measurement

The endogenous pH of each medicine was determined at room temperature (20°C) using a pH meter (TEC-2 pH meter; Tecnal, Sion Paulo, SP, Brazil) placed directly into each solution. The pH meter accurate to 0.1 was first calibrated according to the manufacturer's instructions, using buffer standards of pH 7 and pH 4. As much as 10 mL of each antitussive medicine was placed in a beaker, the pH meter was immersed into the syrup and the value was recorded.

Titratable Acidity (TA)

Titratable acidity was measured according to the method adopted by the Association of Official Analytical Chemists (7), that is, the amount of 0.1 N KOH solution needed for the product to reach a neutral pH or a pH value above it. A 10 mL aliquot of the diluted product was titrated (10% solution of the sample) with the 0.1 N KOH solution until the substance reached a pH value between 8.2-8.4, corresponding to the end-point of the phenolphthalein. Readings were done with a pH meter (TEC-2R; Tecnal, São Paulo, SP, Brazil). When this value was reached, the spent KOH volume was recorded and the acid percentage of the substance was calculated using the following equation, with the result being expressed as percentage of citric acid.

$$\text{Acidity (\%citric acid)} = \frac{V \times Nap \times F \times \text{meq-g(citric acid)} \times 100}{}$$

Sample

Where: V = KOH volume; Nap = Normal concentration of the KOH base; F = Normality correction factor; meq-g = miliequivalent *per* gram of citric acid; Sample= volume of the medicine.

Degrees Brix (°Bx)

°Bx readings were made by refractometry using an Abbé refractometer (PZO-RL1, Warszawa, Poland). As the refractive index of a sugar-containing solution is also temperature-dependent, refractometers are typically calibrated at 20°C. The equipment was calibrated with deionized water (refraction index= 1.3330 and 0° Brix at 20°C) and the readings of the samples were performed (8).

Results

Table 2 displays the distribution of pH, TA and TSCC mean values for the tested pediatric antitussive medicines.

Tablica 2. pH, kiselost titracije i ukupan udjel čvrste topljive tvari (UUTČT-a), vrijednosti za svaki pedijatrijski lijek
Table 2 pH, titratable acidity mean and total soluble solids (TSS) values for each pediatric medication

Lijek • Medication	pH		Kiselost titracije • Titratable Acidity		UUTČT • TSS	
	Srednja • Mean	SD	Srednja • Mean	SD	Srednja • Mean	SD
Mucolin	2,65	0,09	0,255	0,021	41,50	0,66
Mucolitic	5,43	0,25	0,134	0,044	44,25	0,25
Mucofan	6,18	0,07	0,197	0,029	53,41	0,28
Fluibron	4,80	0,53	0,075	0,011	45,08	0,38
Fluimucil	6,56	0,04	0,061	0,018	4,33	0,14
Ambroxmel	3,36	0,01	0,467	0,008	33,25	2,61
Fluitoss	6,00	0,20	0,117	0,025	39,91	0,87

SD = Standardna devijacija • Standard Deviation

S obzirom na pH, vrijednosti su bile u rasponu od 2 ,65 (Mucolin®) do 6,56 (Fluimucil®). Kod četiriju lijekova ustanovljene su pH vrijednosti ispod kritične točke od 5,5. Usporedbom sirupa došli smo do najniže vrijednosti KT-a kod Fluimucila® (0,061), a najviša je ustanovljena kod Ambroxmela® (0,467). Fluimucil® je imao najniži udjel UUTČT-a (4,33%), a Mucofan® najveći (53,41%).

Rasprava

U našem smo se pokusu odlučili za mali uzorak, jer je svrha studije bila upozoriti liječnike da ti lijekovi kod djece možda pridonose zubnom karijesu i caklinskoj eroziji.

Redovito korištenje tekućih lijekova s visokim udjelom šećera često kod djece potiče razvoj zubnog karijesa (2, 3, 9). Ipak, to je višečimbenična bolest te dugotrajno oralno uzimanje tekućih lijekova mora biti spojeno s drugim čimbenicima da bi nastao karijes (9). Antibiotici i antitusici koje djeca najčešće piju, sadržavaju šećer (10).

Što se češće na dan uzimaju zaslađeni lijekovi, to je više kariogenih izazova (11). Bolesna su djeca prisiljena piti lijekove prema liječnikovu odabiru, a razmaci ovise o vrsti bolesti i propisanom lijeku. Također im se često daju medikamenti prije spavanja. Tada noću dolazi do ingestije zaslađenih lijekova ili hrane, što posebice šteti zubima jer je smanjen salivarni protok, a to ograničava prirodnu zadaću sline – čišćenje. To znači da lijek ili hrana koji sadržavaju šećer dulje ostaju u doticaju sa zubnim površinama (12). Tekući oralni lijekovi često su viskozni sirupi te prodiru u fisure i interproksimalna područja nedostupna zubnoj četkici. Djecu bi isto tako trebalo podsjećati da vodom moraju isprati usta nakon što popiju tekuće lijekove.

With regard to pH, values ranged from 2.65 (Mucolin®) to 6.56 (Fluimucil®). Four medicines showed pH below the critical value of 5.5. Comparing the syrups, the lowest TA value was recorded for Fluimucil® (0.061) and the highest TA value was recorded for Ambroxmel® (0.467). Fluimucil® presented the lowest TSSC content (4.33%), while Mucofan® presented the highest TSSC content (53.41%).

Discussion

The small sample size of this experiment was due to the fact that the study purpose was to just warn health professionals to the potential contribution of these medicines to dental caries and enamel erosion in children.

Regular use of sugar-containing liquid medicines is often implicated in the development of dental caries in children (2,3,9). However, caries is a multifactorial disease and long-term use of liquid oral medicines must be associated with other factors for caries onset (9). Antibiotics and antitussives are the most common sugar-containing medicines regularly used by young children (10).

The larger the number of daily ingestions of a sweetened medicine, the larger the number of cariogenic challenges (11). Sick children must take medicines in accordance to the physician's prescription and the frequency or intervals depend on the type of disease and the prescribed medication. Children are often given medicines just before bedtime. Ingestion of sweetened medicines or foods by children at bedtime or during the night is especially harmful to the teeth because the reduced salivary flow during sleep limits the natural cleansing action of saliva. This means that the sugar-containing medicine or food remains in contact with tooth surfac-

Nizak endogeni pH tekućih lijekova mogao bi znatno pridonijeti erozivnom učinku tih otopina. U ovoj je studiji četiri od sedam ispitanih lijekova pokazalo dosta niske pH vrijednosti, čak ispod kritičnih 5,5. Jedan od njih (Mucolin®) imao je izrazito nizak pH (2,65). Prijašnje studije iz Brazila pokazale su da nekoliko sirupa za pedijatrijsku primjenu sadržava endogeni pH ispod kritične pH vrijednosti od 5,5, i to u rasponu od 2,64 do 5,4 (11,13). Dakle, zbog njihove niske pH vrijednosti, ti lijekovi mogu prouzročiti zubnu eroziju, posebice ako dugo djeluju na caklinu (11).

S obzirom na kiselost titracije, Fluimucil® i Ambroxmel® imali su najnižu (0,061) i najvišu vrijednost (0,467). Fenolftaleinski oblik određivanja kiselosti titracije ovisi o promjeni boje iz bezbojne u ružičastu/crvenu. Tu se teško uočava kod jako obojenih proizvoda. Zato što su oralni lijekovi ispitivani u ovoj studiji sadržavali kolorante (boje), bilo bi teško vizualizirati promjenu boje te je kiselost titracije izmjerene pH-metrom.

U nekim istraživanjima pedijatrijskim je sirupima bio dokazan udjel šećera od 12,00 do 54,87 posto (13,14). U ovoj je studiji raspon UUTČT-a bio između 4,33 i 53,4 posto. Udjel šećera u lijekovima Mucolanu, Fluibronu, Mucolitu i Mucolinu bio je, prema Brixovoj ljestvici, iznad 40 posto. Redovita i dugotrajna primjena lijekova s produženim oralnim klirensom može povećati rizik od zubnog karijesa ako sadržavaju šećer, ili čak dentalne erozije imaju li u sastavu kiseline (15).

Redukcija kariogenog učinka u pedijatrijskim tekućim oralnim lijekovima trebala bi biti vrlo važna svim stomatolozima i ostalim liječnicima (16). Zbog toga su napisane i preporuke kako bi se utjecalo na farmaceutske tvornice da proizvode tekuće oralne lijekove bez fruktoze, glukoze ili sukroze. Sirupi s hidrogeniranom glukozom, likasinom, maltitolom, sorbitolom ili ksilitolom također se navode kao proizvodi "bez šećera", jer postoje dokazi da nemaju kariogeni učinak. U dugotrajnoj terapiji trebaju se birati lijekovi bez šećera. Osim toga djecu i roditelje/skrbnike treba podučiti da je potrebno četkati zube svaki put kada se uzme lijek, da ga je bolje popiti tijekom obroka a ne prije ili poslije, da se treba izbjegavati uzimanje lijekova prije spavanja, te koliko je važna primjena topikalnih fluorida i redovita preventivna dentalna skrb (16). Roditelji djece koja uzimaju tekuće oralne lijekove, farmaceuti koji daju preporuke kupcima i liječnici koji propisuju pedijatrijske sirupe, čine ciljne skupine za edukativne akcije o promjeni i odabiru lijekova bez šećera (17).

es for a long period (12). The liquid oral medicines are usually viscous syrups that penetrate into the fissures and proximal areas, which are inaccessible to the toothbrush. Children should also be encouraged to rinse their mouths with water after taking liquid medicines.

Low endogenous pH of liquid medicines could markedly contribute to the erosive potential of these solutions. In the present study, four out of seven medicines showed quite low pH values, being even below the critical value of 5.5. One of the medicines (Mucolin®) presented an extremely low pH (2.65). Previous Brazilian studies have demonstrated that several pediatric syrups present endogenous pH below the critical pH of 5.5, ranging from 2.64 to 5.4 (11, 13). Therefore, due to their low pH, these medicines may cause dental erosion, especially after long-term contact with enamel surface (11).

Regarding the titratable acidity, Fluimucil® and Ambroxmel® presented, respectively, the lowest (0.061) and the highest (0.467) values. The phenolphthalein method of titratable acidity method is dependent on a color change from colorless to pink/red. This pink/red color can be difficult to see with highly colored products. Therefore, as the liquid oral medicines evaluated in this study have colorants in their composition, it would be difficult to visualize color alteration and hence titratable acidity was measured using a ph meter.

Some studies have shown that the sugar content in pediatric syrups ranged from 12.0% to 54.87% (13, 14). In the present study, TSSC varied between 4.33% and 53.41%. The amount of sugar present in Mucolan, Fluibron, Mucolit and Mucolin, as determined by the Brix scale was above 40%. Regular and long-term use of medications with prolonged oral clearance may increase the risk of dental caries if they contain sugars or dental erosion if they contain acids (15).

Reducing the cariogenic potential of pediatric oral liquid medicines should be matter of concern to all health professionals (16). Recommendations have been made to try to influence pharmaceutical industries to produce oral liquid medicines that do not contain fructose, glucose or sucrose. Preparations containing hydrogenated glucose syrup, lycasin, maltitol, sorbitol or xylitol are also listed as sugar free since there is evidence that they do not have cariogenic potential. Sugar-free medicines should be preferred for long-term treatment. In addition, children and parents/caregivers should be instructed on the need to brush the teeth after taking each dose,

Izobrazba pacijenata kako bi se osigurali dostatni oralni klirensi nakon svake doze lijeka, primaran je potez u smanjivanju opasnosti od nastanka zubnog karijesa vezanog za dugotrajnu primjenu tekućih lijekova (14). Ipak, skupoća lijekova koji u sastavu imaju non-fermentabilne ugljikohidrate mogla bi biti ozbiljan problem u populaciji niskoga društveno-ekonomskog statusa, posebice u zemljama u razvoju. Zamjenski proizvodi, poput biljnih pripravaka, mogli bi biti prikladan izbor. Potrebna su daljnja istraživanja kako bi se proširile spoznaje o tom problemu.

Zaključak

Iako su tekući pripravci vrlo prikladni za djecu, oni mogu sadržavati šećer, što može povećati opasnost od karijesa. Zato bi liječnici, posebice stomatolozi, trebali biti svjesni kariogenog učinka pedijatrijskih lijekova.

to take medicines at meal times rather than between meals, to avoid taking medicines at bedtime, and the importance of topical fluoride applications and regular preventive dental care (16). Parents of young children who consume liquid oral medicines, pharmacists who guide the consumers and physicians that prescribe pediatric syrups would be the obvious targets for campaigns to encourage the change to sugar-free medicines (17).

Patient education to ensure adequate oral clearance after each dose of medication is a primary step for minimizing the risk of dental caries related to long-term regimens with liquid medicines (14). However, the high cost of medicines containing non-fermentable carbohydrates could be a serious problem for low-socioeconomic level populations, mainly in developing countries. Alternative products, such as herbal medicines, may be a viable option. Further research is required to elaborate more on this subject.

Conclusion

Although liquid preparations are particularly suitable for children, they may contain sugar, which may increase the susceptibility to caries disease. Therefore, health professionals, especially dentists, should know the cariogenic potential of pediatric medicines.

Abstract

Objectives: This *in vitro* experimental study evaluated the endogenous pH, titratable acidity and total soluble solids content (TSSC) of pediatric antitussive medicines presented as syrups. **Materials and Methods:** Seven medicines were evaluated by a random experiment with 3 repetitions for each sample. pH analysis was performed by potentiometry and buffering capacity was assessed by dilution of each medicine. Increments of 0.1 N KOH were titrated until neutrality was reached. TSSC readings were performed by Brix refractometry using the Abbé refractometer. **Results:** pH values ranged from 2.65 (Mucolin®) to 6.56 (Fluimucil®) and four medicines showed pH below the critical value of 5.5. The titratable acidity values ranged from 0.061 (Fluimucil®) to 0.467 (Ambroxmel®). Fluimucil® presented the lowest TSSC content (4.33%) and Mucofan® presented the highest TSSC content (53.41%). **Conclusions:** Many pediatric antitussives showed pH below the critical value, high titratable values and high sugar concentration, which may increase their cariogenic and erosive potentials in case of inadequate administration of these products to children.

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