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Titolo articolo/sezione: Clinical efficacy of a solution composed by sodium bicarbonate and alginate, aloevera, propoli, chamomile, calendula and honey, in the treatment

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and China classical galactosemia is a rarest disease than that found in this study.[5]

In a previous study estimation of GALK deficiency prevalence ranged from 1:20,000 to 50,000. Balkan population, Romanians, Bosnians and Bulgarians are the most affected from the disease. In our previous report,[3] we found no GALK-deficient infant of Greek origin among 200,000 tested newborns. In this study we identified 7 neonates with GALK deficiency. All these affected infants belonged to moving populations of Roma families living in Greece, in whom consanguineous marriages are very common. The absence of the discovery in any neonate with the disease previously [3] and the identification of 7 cases with GALK deficiency in this study could be due to the larger number of tested infants for galactosemia and/or the presence of the above mentioned population group in our country.

GALE deficiency was diagnosed in 4 infants among 713,057 newborns tested for the disease. The incidence of this galactose metabolic disorder was estimated 1:147,537. Similar to this incidence of the disease was reported in Germany. In this study, the newborns with GALE deficiency were of Greek origin. As expected, the infants were asymptomatic since they suffered from the peripheral type of GALE deficiency and were put on a low lactose/galactose milk diet. Interestingly, the presence of mild hyperbilirubinemia and high liver enzyme blood levels in a newborn homozygous GALE deficiency and heterozygous Duarte 2 (DG) galactosemia may explain the presence of both galactosemia disorders in the infant.[6]

High incidence of partial galactose-uridyl-transferase deficiency such as DG galactosemia has been reported in this study. We found 15 infants (1:47,537) with the disease. The neonates had been put on a lactose/galactose free diet for 6-8 months and thereafter on natural milk. All patients have been asymptomatic until now. The absence of appearance of any symptom is in agreement with the reports of other authors who have followed up children with the same galactose metabolic disorder for a long time.[7]

Further studies on GALT deficiency mutation analysis in neighbor countries, Italy and Turkey as well as in North European countries, Germany and Austria, the enzyme deficiency incidence was found similar. Additionally, the incidence of GALK deficiencies in North Europeans was found also similar.[8]

In conclusion, the incidences of classical galactosemia and Epimerase deficiency galactosemia are similar to those reported in other European countries. In contrast, galactokinase deficiency incidence is higher, but it is not referred to infants of Greek origin. These cases belong to moving people (Roma) in whom consanguineous marriages are very common.

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Clinical efficacy of a solution composed by sodium bicarbonate and alginate, aloe vera, propoli, chamomile, calendula and honey, in the treatment of minor recurrent aphthous stomatitis in children

Dear Editor:

Recurrent aphthous stomatitis (RAS), with its frequency of 5-25%, is one of the most common oral mucosal disorders.[1] A variety of treatment has been pro-

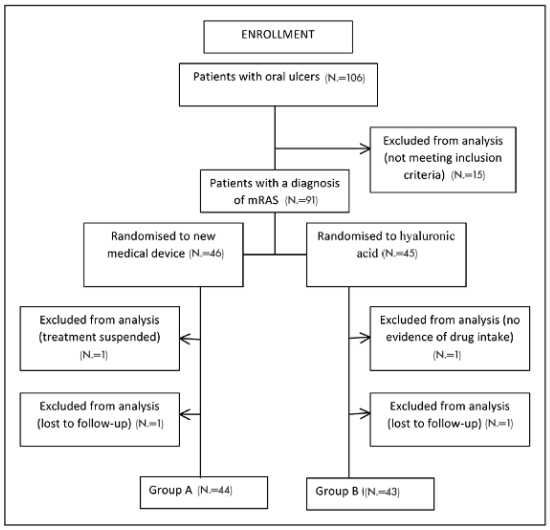

Figure 1.—Diagram demonstrating the flow of participants during enrolment stage.

TABLE I.—*Demographic characteristics of the patients.*

	Group A (N.=44)	Group B (N.=43)	P value
Male-female	12:32	15:28	0.59 °
Age (years)	9.1±3.2	8.2±2.6	0.15^
N. aphthous ulcers (mean/patient)	2.5±0.9 (N.=103)	2.4±1.2 (N.=109)	0.49^
Site			
Upper lip	21	28	0.15°
Lower lip	22	29	0.15°
Buccal mucosa	40	32	0.053°
Soft palate	20	20	0.90°

Significant value P<0.05; Mean±SD.
Tests: °Exact Fisher' Test, ^*t*-Student Test.

posed but many of the therapies have not specifically been studied in children. The aim of this study was to assess the efficacy of a new medical solution (Faringel®) containing sodium bicarbonate and alginate with the addition of herbal components (honey, chamomile or *Matricaria recutita L*, *Calendula officinalis*, *Aloe vera*, Propolis gel) — compared to conventional treatment (hyaluronic acid) — in the management of minor RAS (mRAS) in children.

This prospective study was carried out on a group of consecutive children with clinical diagnosis of mRAS ulcers referred to the Pediatric Dentistry Department of the Dental Clinic of Brescia (Italy) from October 2013 to October 2014. Exclusion criteria were chronic diseases (*e.g.* celiac disease, IgA deficit, diabetes, etc.) and drug intake (*e.g.* antibiotic, antifungal, corticosteroid, hormone therapies, etc.).

Patients were randomized into two groups by a computer code: group A which included patients treated

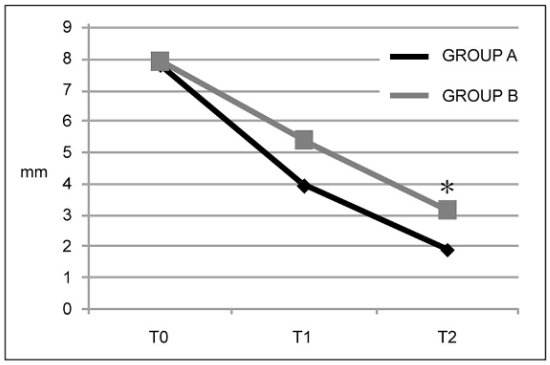

Figure 2.—Decline in ulcers extension at T1 and T2.

TABLE II.—*VAS medians at T0, T1, T2.*

	Group A	Group B	P value
T0	5±1.86	5±2.07	0.58
T1	2±1.89	1±1.68	0.02*
T2	1±0.82	2±1.46	0.14

P value (*t*-Student Test)
*statistically significant

with Faringel® and group B which included patients treated with 0.2% hyaluronic acid (HA) gel. Both the devices were used three times per day for seven days.

Oral aphthous lesions were measured through a ruler to score the diameter length (mm).

Length: on day 1 (immediately before the beginning of treatment) (T0), after three days of treatment (T1), on day 7 (T2) and on day 10 (T3) as follow-up by three calibrated clinicians. Pain was evaluated through the Visual Analogue Scale (VAS) with the same timing of lesion measurement. Patients were asked to select a number from 1 to 10 on a ruler with drawn faces to express the intensity of their pain.

Statistical analysis was descriptive, including mean, medians, standard deviation and percentiles for variables such as age, localization, and number of lesions. Concordance or differences between the two groups were tested using Student *t*-Test. A level of significance of 5% was used and data were analysed using Stata® software for Mac.

All patients' parents or caregivers were informed about the research and signed an informed consent to take part. The study protocol was approved by the local Ethics Committee and performed according to the Declaration of Helsinki.

A total of 87 patients (aged 5-14 years) were finally included in the study (Figure 1). Group A (Faringel®), was composed of 44 patients (mean age 9.1±3.2) while group B (HA gel) of 43 patients (mean age 8.2±2.6). A total of 212 ulcers (103 for group A and 109 for group B) were analysed. The involved oral sites were: upper and lower lip, buccal mucosa and soft palate. Demographic and clinical features

are summarized in Table I. The number of lesions and baseline soreness scores were similar for the two treatment groups (P>0.05).

At T0, the mean of lesion extension was 7.85±2.52 mm for group A and 7.92±1.77 mm for group B at T1 the extension mean was 6.82±1.81 mm for group A and 6.94±1.81 mm for group B; at T2 the mean resulted 1.87±0.94 mm in group A and 3.2±1.22 mm in group B (P=0.0038) (Figure 2). In both groups, there was a progressive reduction in ulcer extension, with a complete healing in both groups on day 10 (T3). The medians of VAS at the three intervals and P values are displayed in Table II. A statistically significative difference in pain reduction between two groups resulted just at T1 (P<0.05). No pain was reported after 10 days from the beginning of the treatment.

The results showed that the use of Faringel® allows a faster reduction of the ulcerative lesions and of the pain level in comparison to patients treated with HA. Faringel® is a viscous oral suspension that can be used as a mouth rinse or can be ingested. The higher healing rates in the group treated by the new medical solution could be explained by the properties of the solution itself. Sodium alginate and bicarbonate, in the oral cavity, precipitate and create a viscous gel, which forms a physical barrier to protect mucosal damage. The protection possibly prevents the superinfections of oral mucosal ulcers fostering the healing process. *Aloe vera* has a proven anti-inflammatory effect related to the inhibition of the cyclooxygenase pathway of arachidonic acid and reduction of prostaglandin E2.[2] Propoli has antibacterial, antifungal and antiviral activity.[3] The other component, *calendula officinalis*, contains triterpinoids and flavonoids that stimulate granulation and increase glycoprotein and collagen metabolism in the wound site and, as essential oils, have an antifungal and antibacterial activity. Moreover, it contains carotenoids that accelerate the epithelialization process, and polysacacharides as immunostimulator.[4] Honey promotes wound healing through osmotic properties that serve to moisturize the wound bed and to reduce the risk of maceration. *Chamomile* explicates an anti-inflammatory effect through the inhibition of interleukin-6 and cycloossygenase-2 production.[5]

While a study with a larger sample size is necessary, the present trial demonstrated its efficacy on the healing of mRAS ulcers in pediatric patients.

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