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Review. The averaged anthropometric data for the groups are given in Table1 and significant differences in the power of spectral characteristics for all indicators of the frequency spectrum were established by us (Table 2).

Table 2
General indicators of spectral characteristics of the Heart Rate Variability

	•			
	Group n₁=60		Group n ₂ =23	
	Background	Orthostatic test	Background	Orthostatic test
	recording		recording	
TP (MC ²)	24173±71872	7333±11772	2918±2042*	2614±1955**
VLF (MC ²)	8442±32908	3269±8946	935,5±858,2*	880,4±818,3**
LF (MC ²)	7369±29211	2918±3429	1080±808,7*	1413±1218**
HF (MC ²)	8362±14530	1146±2326	902,4±759,2*	320±251,7**
LF/HF ratio	1,024±1,071	6,656±5,078	1,433±0,925	6,003±5,591

Note *- the difference is reliable at p<0,0001 between the indicators Background recording, ** the difference is reliable at p<0,0001 between the indicators Orthostatic test.

Conclusions: Indicators of spectral analysis of HRV and body composition (BFP, SMP) differ significantly at different levels of physical activity. This confirms the clinical value and objectivity of methods in examining the human body as screening markers of health and metabolic/energy status.

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TETRANEXT IN THE TOPICAL TREATMENT OF MINOR RECURRENT APHTHOUS STOMATITIS

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Recurrent aphthous stomatitis (RAS) is a very common oral mucosal diseases characterized by solitary or multiple small, round, recurrent oral ulcers surrounded by an erythematous halo. It causes not only pain but could also decrease the quality of life by interfering with swallowing, drinking, eating and even speaking.

RAS affects approximately 20% of the general population. It is more common in patients between 10-40 years of age, and predominantly affects women and individuals of higher socioeconomic levels [1].

Up to now, the definitive etiology and pathogenesis of RAS is not entirely understood. The potential factors are known to predispose to the appearance of oral aphthae, including genetic factors, some viral and bacterial infections, vitamin

and microelement deficiencies, AIDS, gastrointestinal disorders (e.g., celiac disease, Crohn's disease, ulcerative colitis), food allergies, hormonal imbalance, endocrine alterations (menstrual cycle), cyclic neutropenia, mechanical injuries, stress and anxiety, smoking cessation and certain chemical products [2].

The effect of trigger factors initiates the cascade of proinflammatory cytokines, directed against selected regions of the movable and nonkeratinized oral mucosae.

The management of RAS poses a complicated problem for both clinicians and patients, and seeks to reduce inflammation of the aphthae, afford pain relief, to promote ulcer healing as well as the reduction of the frequency of recurrences and an increase in disease-free period. The current therapeutic approaches including antimicrobial mouth-washes, topical corticosteroids, local analgesics, astringents, and laser therapy have been showed to be partially effective in alleviating patients symptoms and disease length [3].

Given the inflammatory nature of RAS, topical tetracyclines can be considered for the optimal management of oral ulcers. One of the important positive properties of these agents in addition to the known antibiotic action is the inhibitory effect on matrix metalloproteinases (collagenases) that form part of the inflammatory response and contribute to tissue destruction and ulcer formation. Moreover, tetracyclines increase the adhesion of fibroblasts which contributes to the regeneration of damaged tissues, and this property is other possible mechanism suggesting its potential curative benefits. The anti-inflammatory properties of tetracyclines and its efficacy in RAS have been shown in several previously conducted studies. Yarom N. et al. [4] reported significant reduction or even suppression the pain and shortening the aphthae healing time using tetracycline mouthwashes four times a day. As pointed out by other authors [5, 3], it is advisable to apply the medication directly onto the lesions, keeping it in direct contact for as long as possible.

Clinical trials on new agents with tetracycline as an active ingredient are still ongoing. Therefore, using a similar local drug to assess efficacy could be relevant.

The **aim** of this study was to assess a potential benefit of TetraNext in the treatment of RAS.

Fifty-seven patients (33 women and 24 men) who visited the Department of Therapeutic Dentistry of the Dnipropetrovsk Medical Academy with complaints of oral ulcers participated in the study. All patients agreed to participate in the study and therefore they did sign the consent form.

To decrease the number of variables affecting the RAS pathophysiology and pharmacology, we narrowed the patients' age range between 18 and 35 years. The average subjects age was 27,3±13,03 years. The patients with minor recurrent ulcer singular lesions in an easily accessible area of the mouth without any other medical complications who had noticed oral lesions during the last two days were included in this study. Patients with systemic diseases, iron, vitamin B12 and/or folic acid deficiency, pregnant mothers and smokers were excluded from the study.

The patients were allocated into two groups: test group (n=28) and control group (n=29). The groups were not significantly different in the female to male ratios and their mean age, ulcer histories.

The participants were instructed to rinse their mouth with 0,05% chlorhexidine and apply TetraNext (test group) or Aecol (control group) on the lesions four-times a day (after meals and before bed time) for as long as the lesions persist. Participants it was recommended not to eat or drink anything for 30 minutes after application of the agents in all groups. All patients were strictly warned not to use any other products for the treatment of ulcers while participating in this study. At the

end of therapy, all patients were also asked to report any adverse effects of the agents.

Assessment of the effectiveness of topical management of RAS was made according to three criteria: pain intensity, RAS lesions' diameters and inflammation zone on the third and seventh days of the RAS therapy.

The quantify pain intensity was recorded using a paper visual analog scale /VAS/ (ranging from 0 /no pain/ to 10 /unbearable pain/). Scores from 0 to 10 were noted on the vertical line, and participants had to circle the level of their pain. Using a calibrated periodontal probe, the ulcer size and their inflammatory zone were calculated.

Patients with lesion diameter less than 1mm and pain score of 1 were considered healed.

TetraNext (Balkanpharma-Razgrad AD, Bulgaria) which recently appeared on the Ukrainian pharmaceutical market is a topical agent that contains tetracycline hydrochloride as an active ingredient and mineral oil gel base as an inactive substances. TetraNext is supplied in the form of an ophthalmic ointment at a concentration of 0.1%. Aecol is a solution containing an oil solution of retinol acetate, alpha-tocopherol acetate and vikasol. Both agents form a lipid film on the ulcer surface that protects against mechanical injury and can help reduce oral moisture loss and inflammation.

All of the data was analyzed using statistical tests (unpaired students t-test) and p value of less than 0,05 was considered to be statistically significant.

Two out of fifty-seven participants enrolled in the study stopped their treatment course for no specific reason therefore 27 subjects in control group and 28 subjects in test group completed the study (total 55).

At study entry the high pain level (ranging from 8 to 10) which patients indicated was found in 19 patients; almost half of all participants (41.8%) reported a mean pain level (ranging from 5 to 7); smaller percentages (23.6%) are related to low VAS scores (ranging from 0 to 4). The total mean VAS score in our study was 5.82 associated with the highest perception of pain as a symptom of RAS.

Pain relief in the days following treatment was recorded in both groups. However, significant differences were showed in pain evaluation when comparing the results of local use of TetraNext and standard local therapy of RAS. Overall, the mean pain scores were all higher in patient controls than mean pain scores in patients treated TetraNext for the same period suggesting that the tetracycline is able to pain relief.

On the third day high pain levels were more often found in control group than in patient TetraNext-treated (18.5% vs 7.14% respectively). Symptomatology improved by at least 50% (good response) in 11 (39.3%) patients of the test group and only 8 (29.6%) patients in the control group for a given period of assessment (P <0.001). Seven (25%) patients in the test group did not complain of pain while in the control group only 4 (14.8%) reported complete cessation of pain (P <0.001). The mean VAS scores decreased by 46.9% in the test group and by 32.6% in the control group when compared with the baseline data.

The pain scores in the test group were found statistically lower on the seventh day as well. Efficacy of TetraNext in treatment protocol of RAS, regarding pain score, was higher than the control group which is confirmed by a 5.3-fold decrease in mean VAS scores relative to the baseline data. When compared with test group the mean pain dimensions in patients controls decreased by 3.6 times. In contrast to 66.7% of the patients in the control group, 75% of the patients treated TetraNext in the present study noted the absence of pain on the seventh day of treatment.

Regarding the RAS lesions' diameters at study entry, their mean size in the control group was 2.73 ± 0.66 mm, while 2.69 ± 0.71 mm in the TetraNext treatment

group. The mean values of the inflammation zone (erythema diameter) in the test group were 4.19 ± 1.01 , in the controls -4.11 ± 1.05 (p>0.05).

Although the baseline ulcer size was similar in groups at the beginning of the study (p> 0,05), significant differences were detected after 3 days.

The prevalence of healing episodes confirms the therapeutic benefits of TetraNext.On the third day 10.71% patients with complete epithelialization of the oral mucosa and 21.4% patients with reduction more than half lesion diameter in the test group was observed. These data were 3.7% and 11.1% in the control group, respectively. Furthermore, more than half (55.6%) of patients in the control group did not change of lesion diameter, on third day of treatment. While only 10 (35.71%) patient in the test group had a baseline ulcer size.

The RAS lesions' diameters in the test group became significantly smaller than in the control group after third day - 2.07mm±0.44 and 2.19mm±0.63mm respectively.

Significant group differences were also found at the later visit.

The advantage of the wound-healing properties of TetraNext over standard therapy of RAS on the seventh day of observation was more clearly manifested. The mean ulcer size of the test group was almost two times higher than in patients of the control (0.69±0.62 vs 1.34±0.58 respectively). Sixteen of 28 patients treated with TetraNext application had the complete regeneration of damaged oral tissues, while 11 of 27 patients in control had a similar response (P<0.001).

The reduction in erythema diameter of the test group was found much greater at the third day and the seventh day when compared with control group (2.96±0.71 and 1.16±1.05 vs 3.53±0.69 and 2.18±0.88 respectively). Our interpretation of these results is that the clinical beneficial effects of TetraNext could be attributed to the ability to decrease inflammation by blocking matrix metalloproteinases.

The pain and lesion in both groups on the tenth day were considered healed based on the patients' self-reports.

TetraNext is safe when used in treatment of RAS. No side-effects were found in both groups.

Conclusions. The present study revealed that TetraNext to be effective in accelerating the healing of ulcer and in lessening the pain, erythema and size of the lesions.

In summary, the topical application of TetraNext is statistically significantly more effective than standart therapy in inducing clinical and symptomatological improvement of RAS. TetraNext can be considered a safe therapeutic option for patients with RAS.

To the best of our knowledge, this is the first study to examine the efficacy of TetraNext in the topical management of RAS, and further studies with a larger sample size are required to validate our results.

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