Optimization of examination methods in the diagnosis of precancerous and malignant oral mucosal lesions

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ABSTRACT

Relevance. The prevalence of oral mucosal diseases among the Russian population varies from 3% to 20% [7]. Precancerous and malignant diseases are a particular problem. More than nine thousand new cases of malignant oral mucosal lesions are registered annually in the Russian Federation, and yearly mortality rates reach 34%. Unfortunately, despite being externally located, the rate of late-diagnosed malignant oral mucosal neoplasms reaches 60%-70% in various regions of the Russian Federation [2]. Thus, one of the most urgent problems in dentistry and oncology is the early diagnosis of precancerous and malignant oral mucosal lesions. As a rule, precancerous lesions are not diagnosed at an early stage since there are no visible clinical signs, and therefore patients do not seek medical attention [8]. An accurate diagnosis requires both basic and additional examination methods. In turn, the conventional methods include traditional inspection, which largely depends on the clinician's experience. Besides the clinical examination, additional techniques are used, namely, fluorescence examination and biopsy [9-11].
Subsequently, optimizing the diagnosis of oral mucosal lesions is the most promising direction in practical healthcare, both in the dental and oncology practice, for early detection and reduction of advanced stages of malignant oral mucosal lesions.
Thus, the study confirmed that the development and application of modern approaches are necessary for the early diagnosis of oral mucosal lesions.
Purpose. The study aimed to improve the outcome of oral mucosal precancerous and malignant lesion diagnosis by upgrading examination methods.
Material and methods. The study included 147 patients with oral mucosal lesions, referred to the oncologists of Samara regional clinical oncology centre by the city polyclinics. The patients were divided into two groups according to the examination methods. The control group patients, 63 people, had a conventional examination by a dentist (patient interview, inspection, palpation) and an incisional biopsy by an oncologist. The main group consisted of 84 patients, who, besides conventional dental examination, were evaluated by a new – developed and put into practice – technique with point and index score and subsequent incisional biopsy performed by an oncologist. The studied patients were comparable by gender, age and localization. The study assessed the effectiveness of the new method for the diagnosis of precancerous lesions (PL) and malignant lesions (ML) by matching the Need for Histology Verification Index (NHVI) value equal to 5 points or more and histopathology results.
Results. In the main group, 71 out of 84 patients scored 5 or more according to the new method, and 13 patients scored less than 5. Patients with a low score had a non-surgical treatment, 11 patients reached remission, and two patients were referred to an oncologist for a biopsy, which confirmed oral mucosa PL and ML. The patient complaints in both groups demonstrated that pain and bleeding were more frequent in the control group compared to the main one. The evaluation of clinical examination data revealed more erosions in the control group and non-removable plaque and hyperplasia in the main group. The incisional biopsy detected more PL and ML in the main group ($p = 0.001$), and early malignant lesions were in 23% versus 5% in the control group. The new method specificity in oral mucosal PL and ML diagnosis was 55%, sensitivity – 97%, accuracy – 87%, whereas the conventional examination specificity was 28%, sensitivity – 84%, and accuracy – 60%.
Conclusion. The administered improved method for examination of patients with oral mucosal lesions and the compulsory use of autofluorescence examination and risk factor score assessment allowed us to identify PL and ML in 88% and to diagnose more PL and ML at early stages, which explains the need to use this method in the clinical practice for the early diagnosis of lesions.

Key words: oral mucosa (OM), precancerous lesion (PL), malignant lesion (ML), Need for Histological Verification Index (NHVI)
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INTRODUCTION

According to the statistical data, over 354 thousand new cases of malignant oral mucosal lesions are registered annually worldwide [1]. In 2018, over 9 thousand people in Russia, and 199 people in the Samara region, were diagnosed with oral mucosa cancer. Oral mucosal cancer occupies 18th place in the structure of oncological morbidity and was confirmed morphologically in 97% of patients in the Russian Federation [2]. Despite the external localization of oral mucosa lesions, the rate of advanced stage cases is still sufficiently high. It reaches up to 62 % in Russia and 63% in the Samara region. Thus, the lack of screening programs, proper oncological alertness among doctors and population awareness are the principal causes of OMML neglect. Primary care doctors currently work in the secondary prevention system, which allows the detection of oral mucosal lesions only upon patient presentation to a specialist. In turn, clinicians, who closely work with oral mucosa pathology, do not have an accurate and necessary patient examination algorithm and mainly rely on patient questioning and inspection, which often leads to a diagnostic error [3, 4, 5]. According to the modern literature, clinical examination remains the principal method for suspected malignant process evaluation [8, 9]. Though this method does not allow an accurate diagnosis, most patients with suspected OMML are referred to an oncologist for a biopsy, which, in turn, can lead to overdiagnosis [10, 11, 14]. Oral mucosal lesion biopsy is an invasive method of collecting tissue for histological examination for further differential and final diagnosis [5-7]. This procedure may lead to undesirable events, so it should be carried out strictly if indicated and, firstly, if a malignant oral mucosal lesion is suspected. The obtained histopathology result determines the correct diagnosis, further treatment and prognosis of the disease [4-6]. Thus, oral mucosal lesion biopsy is exclusively applied for differential diagnosis, and its indications must be justified. Therefore, non-invasive additional diagnostic methods in a dental practice deserve special attention and should be widely used. One of the available methods which confirmed the effectiveness is autofluorescence examination. It is popular in the diagnosis of oral mucosa lesions and has been known for a long time. There are a lot of publications on this method in international and national literature, but no connection is shown with patient questioning and clinical examination, and even more so with risk factors for ML development [11, 12, 14]. In this context, in 2017, the authors developed and implemented a new method for diagnosing oral mucosal lesions at a dental appointment [13].

MATERIAL AND METHODS

A planned prospective study took biopsies and diagnosed 147 patients referred by Samara city polyclinic dentists with oral mucosal lesions and examined at the Samara Regional Clinical Oncological Center from 2014 to 2019. The patients were divided into two groups based on the examination methods used at the dental appointment. The control group included 63 patients referred to an oncologist by dentists from 2014 to 2016 with a diagnosis of oral mucosal lesion after a conventional examination, including patient questioning, inspection and palpation. In 2017, a new diagnostic method was developed and applied for the early diagnosis of precancerous and malignant oral mucosa lesions – "a method for determining indications for histological verification of vermillion and oral mucosal lesions at a dental appointment" (RF patent No. 2738855). Thus, the main group included 84 patients with oral mucosal lesions, in which a new method was administered additionally to the conventional examination (patient interview, inspection, palpation) in a dental office. The new examination technique is presented in a protocol, which identifies patient history data, includes inspection data, evaluates palpation results, and assesses examination with an AFS D 400 autofluorescence lamp (Polyronic, Moscow) and glasses with a green light filter. There was a score for each section the protocol. The Need for Histological Verification Index (NHVI) allowed us to facilitate and fix the obtained score and the table column with the letter mark of the lesion location included the index value. We filled in a separate protocol and calculated an index for each identified lesion. The selection of random numbers determined the point value and their sum. An index of fewer than 5 points required observation and treatment by a dentist, followed by a second examination, whereas an index of 5 or more points indicated the need for an oral mucosal lesion biopsy. The main group included patients with an index of 5 and more. Criteria for inclusion in the study were as follows: patients were initially referred to an oncologist by a dentist with superficial oral mucosal lesions. The exclusion criterion comprised the patients referred by other specialists or who presented to an oncologist themselves and those who refused the examination. The studied patients were comparable by gender M/F 3:1 ($p = 0.858$), age: 63 ± 2.8 years in the control group, 71 ± 2.8 years in the main group, and localization (Table 1). Incisional biopsy in both groups was performed using ENT conchotomes under local anaesthesia with the subsequent morphological examination (Fig. 2). The new method's effectiveness for PL and ML diagnosis was assessed by matching NHVI equal to

Table 1. Distribution of patients in comparison groups by oral mucosal lesion location

Location	Groups			
	Control n = 63		Main n = 84	
	n	%	n	%
Tongue	29	46	39	46
Maxillary Alveolar Ridge	1	2	-	0
Mandibular Alveolar Ridge	3	5	1	1
Oral cavity floor	14	22	17	20
Hard Palate	2	3	4	5
Soft Palate	1	2	3	4
Cheek	13	20	20	24
Total	63	100	84	100

Note: Pearson's Test 2.7567; p = 0.8386

Date: **Initial / Follow-up** (Underline as applicable)	**Score**	**Sequence of inspection, palpation and autofluorescence examination of vermillion and oral mucosa**
Name and Family Name		
DOB		**a) Lip** vermillion / mucosa, corner upper / lower / right / left **b) Vestibulum** upper / lower / right / left **c) Buccal alveolar ridge mucosa** maxillary/ mandibular, right /left / anterior **d) Buccal mucosa** right / left **e) Lingual (Palatal) alveolar ridge mucosa** maxillary / mandibular, right / left / anterior **f) Retromolar space** right / left **g) Mouth floor mucosa** anterior / posterior / right / left **h) Ventral surface of the tongue** right / left **i) Lateral border of the tongue** right / left **j) Tongue tip** **k) Dorsal surface of the tongue** right / left **l) Root of the tongue** right / left **m) Hard palate mucosa** right / left **n) Soft palate mucosa** right / left **o) Anterior palatine arches** right / left **Note:** Underline as applicable
Patient Interview Complaints: Yes – 0.25 points, No – 0 points; Complaints are present for: 14 days or longer – 0.25 points, under 14 days – 0 points; Bad Habits (except smoking) – 0.25 points; Smoking – 0.5 points; No Bad Habits – 0 points; Episodic Industrial Health Hazards – 0.25 points, No Industrial Health Hazards – 0 points **Note:** Underline as applicable	0.25 0.25 0 0	
Inspection Visually detected erosions, aphta, crack, scab, scar, hyperkeratosis – 2 points, Spot, node, nodule, papule, vesicle, bulla, pustule, cyst – 1 point, No lesions – 0 points; No dental treatment is required – 0 points, Dental treatment is required – 0.25 points **Note:** Underline as applicable	2 0.25	
Palpation No palpable lesions – 0 points; Palpable lesion – 1 point; Periphery lymph nodes are palpable – 0.5 points; Periphery lymph nodes are not palpable – 0 points **Note:** Underline as applicable	 1 0	
"AFS" autofluorescence lamp examination Dark-brown glow – 2 points; Pink-red – 1 point; Green glow – 0 points **Note:** Underline as applicable	 2	
NHVI (Need for Histology Verification Index)	**NHVI = 5.75j**	

Fig. 1. Method for determining indications for histological verification of the vermillion and oral mucosal lesion at a dental appointment

5 points or more, and the histology results. There is an example of a tongue lesion examination in natural light in Fig. 3 and with an autofluorescence lamp according to the new method with the subsequent NHVI calculation in the main group patient in Fig. 1 and Fig. 4.

STATISTICAL ANALYSIS

The work used multivariable logistic regression models in patients with oral mucosa lesions. The p-value was significant at $p < 0.05$. All data were statistically analysed using Statistica 10.0.

RESULTS

The new-method examination of the main-group patients showed that 13 out of 84 patients scored less than 5 points and therefore were observed and treated by the city polyclinics dentists. Eleven out of thirteen people reached remission, their oral mucosa inflammation was confirmed after the non-surgical treatment provided by the dentist during 14-20 days, and two patients were referred to an oncologist for a consultation after the conservative treatment without changes. Those two patients had an incisional biopsy and were diagnosed with oral mucosa PL and ML, re-

Fig. 2. Incisional biopsy of buccal mucosa lesion

Fig. 3. Clinical examination of tongue mucosa lesion

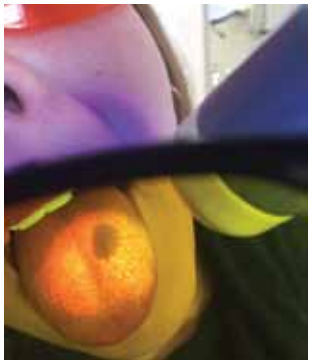

Fig. 4. Brown glow of the tongue lesion in the light of "AFS400"

spectively. The assessment of patient complaints showed the difference between the main and control groups. The main-group patients marked the presence of the lesion less frequently than the control group (0.54 and 1.17 times, respectively). 23.9% of patients in the main group noted pain, and 47.6% – in the control group (p = 0.001). Burning and itching manifested equally in both groups, and complaints of lesion bleeding were more frequent in the control group. The significant pain in patients of the control group is associated with an inflammatory process and/ or the presence of a locally-spread malignant disease.

Clinical examination revealed the following signs of the disease. A change in the oral mucosa colour was 0.82 times more frequent in the main group than in the control group (54.9% of cases compared to 28.4% of cases, p = 0.001). The plaque was equally present in 62.0% and 60.3% of cases, and lesion elements with hyperkeratosis were in 45.1% and 58.7%. After biopsies, the control group demonstrated significant prevalence of erosions – 55.6%, compared to 36.6% in the main group (which characterized inflammatory diseases). Hyperplasia and atrophy were found from 11.1% to 31.0% (Table 3).

Thus, complaints of pain, burning, discomfort, and erosions were more significant in the control group, and the main group more often revealed non-removable plaque and tissue hyperplasia. According to our observations, oral mucosa lesions were more frequently present on the tongue in the control and main groups (46%), which does not contradict the data of modern studies [2, 4, 14]. After the incisional biopsies in 63 control group patients and 73 main group patients, the diagnoses were as follows: precancerous lesions – 23 people and in 37 cases of the main group, malignant lesions – 15 control-group patients and 27 main-group patients (p = 0.046), inflammatory diseases – 20 patients in the control group and one patient in the comparison group (p = 0.001) and benign lesions – 5 patients in the control group and 8 patients in the main group (Fig. 5). After the incisional biopsy, early oral mucosal cancer was diagnosed in 17 patients of the main group and 3 patients of the control group (p = 0.001). There were no significant differences between the comparison groups in the diagnosis of advanced lesions, which corresponded to 11 controls and 10 main-group patients (Fig. 6). Thus, patients with oral mucosal inflammatory diseases were often and unreasonably referred to an oncologist for invasive examination after a conventional dental examination. In general, the new method in the diagnosis allowed identification of precancerous and malignant oral mucosal lesions in 88% in the main group, whereas the conventional examination detected 60% in the comparison group (p = 0.001). According to modern literature, the inspection cannot be a diagnostic test in the differential diagnosis of oral mucosal lesions. Therefore, an additional fluorescence method should be used, which, in our study, also confirmed its effectiveness along with a conventional patient interview, inspection and palpation [12, 14]. The specificity of the new method in oral mucosal PL and ML diagnosis was 55%, sensitivity was 97%, accuracy was 87%, and the conventional examination demonstrated the specificity of 28%, sensitivity of 84%, and accuracy of 60%.

CONCLUSION

The new method, used in the examination of patients with oral mucosal lesions, includes a compulsory autofluorescence examination and a risk factor score assessment and allows clinicians to identify PL and ML with a high percentage in 87% of cases and to diagnose more initial oral mucosal malignant lesions compared to the conventional examination methods (23% and 5%, respectively), and perform invasive examination (biopsy) only if strictly indicated. The new method's high sensitivity and accuracy compared to the conventional evaluation methods indicate its wide application in practice for oral mucosal precancerous and malignant lesion early diagnosis.

Table 2. Distribution of complaints identified during the clinical examination of main and control group patients, %

Complaints Groups		Lesion Presence	Pain	Discomfort	Burning sensation	Itching	Bleeding
Main	Detected	35.2%	23.9%	64.8%	40.8%	29.6%	7.04%
	Not Detected	64.8%	76.1%	35.2%	59.2%	70.4%	92.96%
	Difference	->0.54	->3.17 раза	+>1.84 раза	->1.45 раза	->0.98 раза	->13.2 раза
Control	Detected	53.9%	47.6%	80.9%	42.9%	39.7%	22.2%
	Not Detected	46.1%	52.4%	19.1%	57.1%	60.3%	77.8%
	Difference	+>1.17 times	->1.1 times	+>4.25 times	->1.33 times	->1.52 times	->3.5 times

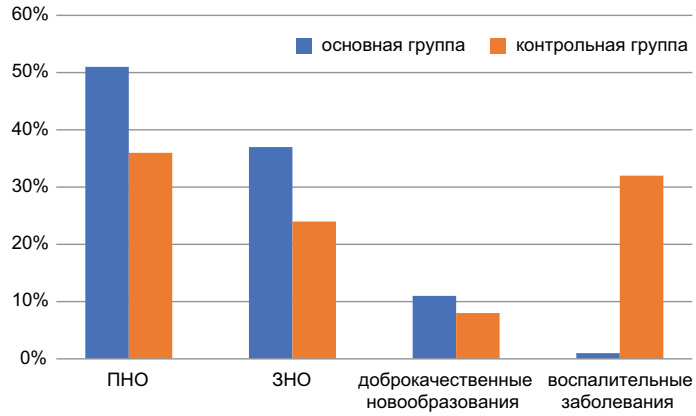

Fig. 5. Comparison group distribution by diagnoses

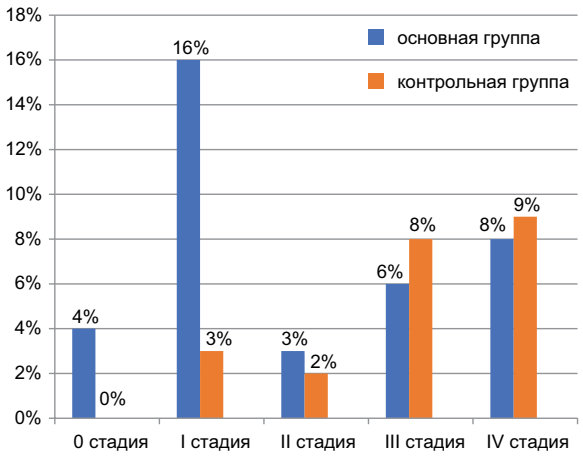

Fig. 6. Distribution by malignant oral mucosal lesion stages in comparison groups

Table 3. Comparative characteristics of disease signs detected during the clinical examination of the main and control group patients, %

Oral mucosa examination		Change in mucosal colour	Moist (shiny) mucosa	Plaque			Lesion elements			
				Present	Removable	Non-removable	Hyper-keratosis	Hyper-plasia	Atrophy	Erosion / Ulcer
Main	Detected	54.9%	43.7%	62.0%	31.0%	28.2%	45.1%	31.0%	12.7%	36.6%
	Not Detected	45.1%	56.3%	38.0%	69.0%	71.8%	54.9%	69.0%	87.3%	63.4%
	Difference	+>0.82 times	->1.29 times	+>1.63 times	->2.23 times	->2.55 times	->1.22 times	->2.23 times	->6.9 times	->1.73 times
Control	Detected	28.4%	53.9%	60.3%	33.8%	36.5%	58.7%	17.5%	11.1%	55.6%
	Not Detected	71.4%	46.1%	39.7%	66.2%	63.5%	41.3%	82.5%	88.9%	44.4%
	Difference	->2.5 times	+>1.17 times	+>1.52 times	->3.2 times	->1.7 times	+>1.42 times	->4.7 times	->8.0 times	+>1.25 times

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