

# Psychodiagnostics as a Mandatory Element of Patient Protocols in Dentistry

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## ABSTRACT

**Objectives:** This study aims at performing psychodiagnostics of the patients' condition with removable and fixed dentures both before and after dental treatment. **Materials and Methods:** The first group included 200 patients with fixed-type dentures, and the second group consisted of 200 patients with removable dental devices. The control group included 200 patients with healthy teeth. All patients were subjected to Fere's skin-galvanic reaction procedure. Patients also filled out the Dental Status Questionnaire and were then tested following the Spielberger-Hanin Scale. For a comparison of differences, a two-sample t-test for independent samples was used. The Pearson correlation between features was calculated considering their distribution as normal. **Results:** In the control group, the hemispheric activity index increased 1.1 times after treatment. In Group 2, following the dental status questionnaire, the index of hemispheric activity increased 1.3 times in males with a positive emotional mood ( $P \leq 0.01$ ). A 2.2-fold and 2.1-fold ( $P \leq 0.01$ ) increase was observed among female and male patients with a negative emotional mood in Group 2, respectively. After the treatment, the hemispheric activity index in Group 1 increased by 1.1 times for males with a positive mood ( $P \leq 0.01$ ) and by 1.2 times for male and female patients with a negative mood ( $P \leq 0.05$ ). Direct correlation was recorded between the increase in the number of scores and emotional mood among males and females from Group 1 (0.72 and 0.73, respectively). After the survey, a correlation was established between the values of the hemispheric activity index and the increase in scores among males (0.82) and females (0.81). There was also a connection between the increase in scores and the level of personal anxiety in both male (0.57) and female (0.66) patients, as well as between the increase in scores and the level of reactive anxiety (0.56 and 0.57, respectively). **Conclusions:** Changes in the hemispheric activity index were shown to be related to the patient's dental condition questionnaire. Besides, there is a relationship with the type of dental service. The practical application of this study implies that more reliable information about the patient's satisfaction with the quality of dental care provided can be obtained using not only standard psychodiagnostic methods but also questionnaires on the patient's dental status. Once the survey is completed and the data obtained analyzed, it is possible to define the correct strategy to restore the patient's physical and mental health after dental treatment.

**KEYWORDS:** Dental status, dentures, personality anxiety, psychodiagnostics, reactive anxiety

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## INTRODUCTION

The psycho-emotional status of patients requiring dental treatment is severely affected by constant stress.<sup>[1]</sup> Stress is associated with visible or perceived defects that disrupt the patient's image: difficulties in articulating words during chewing or communicating with other people. The severity of such a stressful condition depends on several factors. Among these are the type of nervous activity, characteristics of the patient's perception of their image, social environment and social reaction to the patient's appearance, patient's assessment of their own condition, and the dentist's attitude toward the patient's psycho-emotional state.<sup>[2]</sup>

Many unsuccessful dental interventions occur primarily due to the negative emotional mood of patients; however, they also deal with the discomfort that they experience both during and after the dental procedure. That is exacerbated by increasing stress, anxiety, and psycho-emotional tension or exhaustion, diminishing the positive effect of dental treatment.<sup>[3]</sup> Further, numerous research works observed possible changes in the normal functioning of the patient's body, namely, in pulse, blood pressure, and heart rate values.<sup>[4-6]</sup> These are visible in the results of studies when the ECG was performed during dental surgery.<sup>[7]</sup> Such deviations might also have the opposite effect. Thus, psycho-emotional stress leads to a delay in the grafting process. Changes in the nervous and endocrine systems can cause certain disturbances in the hemostatic system.<sup>[8]</sup> High emotional tension is also known to cause a specific contraction of the skeletal musculature of the face, which results in a manifestation of a local vascular response.<sup>[9]</sup> Another psycho-emotional trait that characterizes patients with dental problems is the anticipation of pain far before the start of the surgery. Some particularly sensitive patients can experience serious emotional trauma, even during simple dental procedures such as dental extraction. Fear can occur at the anesthesia stage, and the patient's body is then characterized by an increase in energy expenditure, which exceeds energy production. Psycho-emotional stress results in a 17% increase in oxygen consumption on average, triggering anaerobic glycolysis. This process, in turn, is a precursor to acidosis, leading to tissue hypoxia and a delayed reparation process. Increased anxiety is the cause of maladaptation and the appearance of neuropsychic disorders, as well as a slower recovery rate after surgery.<sup>[10]</sup>

Psychodiagnosis is, thus, a necessary element of dental treatment. The use of dental questionnaires contributes to the selection of appropriate tactics for interaction between the physician and the patient. In this case, the

questionnaires both before and after patients' dental treatment appear necessary. Comparing the results of the pretreatment and posttreatment questionnaire provides good insights into the effectiveness of dental treatment. As there are relatively few studies of this type to date, it appears necessary and relevant to conduct them.

In order to adequately assess patient satisfaction with the quality of dental care provided, specialized questionnaires may be helpful, in addition to traditional methods of psycho-emotional analysis.<sup>[11]</sup> They contain dental questions that are relevant to both the dentist and the patient.<sup>[12]</sup> Once these questionnaires have been analyzed, the right tactics for patient rehabilitation can be selected.<sup>[13]</sup> A logical construction of such an analysis is the study of changes in the values of indicators of the patient's psychological state both before and after dental intervention.<sup>[14]</sup> Such an analysis is a reliable measure of the effectiveness and quality of dental care provided.<sup>[15,16]</sup> Further, these studies appear necessary as they may contribute to the improvement of dental service quality.

This study aims at performing a comparative analysis of the psycho-emotional condition of patients both before and after dental surgery.

The objectives of the study were: (a) to examine the psycho-emotional state of patients with removable constructions; (b) similarly, to examine the state of patients with fixed constructions.

## MATERIALS AND METHODS

### MATERIALS

The study was conducted in the Russian Federation in 2019–2020; it addressed data on patients from three dental clinics (two clinics from the Moscow city [Dental Clinic No. 62 of the Moscow City Health Department and Dental Clinic No. 12 of the Moscow City Health Department] and one clinic from the Perm city [City Dental Clinic No. 1]). The study involved a total of 600 patients divided into three groups. The patients' age ranged from 22 to 63 years, with a mean age of  $42.0 \pm 5.5$  years. The average age and the number of men and women in each group are shown in Table 1.

The number of men and women in each group was similar ( $P \geq 0.05$ ; Table 1). The age of patients within each group and between groups also had no significant differences.

The first group consisted of 200 patients with fixed dentures (metal-ceramic, used up to 3 years); the second group included patients with removable devices (200 patients); and the control group comprised 200

patients with healthy teeth. The dental procedures were provided under local anesthesia.

#### STUDY DESIGN

The Fere method was applied to estimate the predominant activity of the hemispheres. A scheme included three components: a current source and its amplifier (15 mA) + silver electrodes ( $S = 2\text{ cm}^2$ ) + ohmmeter. Parameters of this skin-galvanic reaction were taken from two fingers of the right and left hands. Parameters on different hands were measured separately, first on the left hand and then on the right hand.

Low resistance values at the moment of data acquisition allowed concluding the right hemisphere dominance in the patient's mental and emotional spheres and the corresponding emotional manifestations, namely, aggression, negative emotions, and increased anxiety. On the left side, the same data indicated the dominance of the left hemisphere with the corresponding emotions—satisfaction and positive emotions. Afterward, a bilateral asymmetry of hemispheric activity was calculated, when the left-hand indicators were divided by the right-hand indicators. The index value equaling to one was considered to be a physiological norm. Thus, the activity of the hemispheres was balanced.

This study was conducted following international ethical and moral standards (the Helsinki Declaration of 1975). When working with patients, their written consent to data processing was obtained. Anonymity and confidentiality of information were preserved.

#### RESEARCH METHODS

Levels of anxiety and pain were determined by using a questionnaire. For this purpose, a generally accepted scale of patients' self-assessment of anxiety by Spielberger and Hanin and a Universal Pain Assessment Tool were applied. This test adequately reflects personal and reactive anxiety, estimating it as a constant characteristic of a personality. The advantage of the test is its validity and informativeness in the self-assessment of anxiety levels. The test includes two

blocks corresponding to the level of reactive (questions 1 to 20) and personal (questions 21 to 40) anxiety.

Reactive anxiety was calculated following the formula  $P = (A1 - A2) + 50$ , where A1 is the sum of 3–4, 6–7, 9, 12–14, and 18 items of the anxiety level scale, and A2 is the sum of items 1–2, 5, 8, 10, 15, and 19–20. Similarly, the level of personal anxiety was calculated using the formula  $L = (A1 - A2) + 35$ , in which A1 corresponds to the sum of items from questions 22 to 25 inclusive, questions 28 and 29, 31 and 32, also questions 34 and 35, questions 37 to 39 inclusive, and A2 is the sum of items from the remaining questions.

Pain level was interpreted on a scale from 0 to 10 or by monitoring the patient's behavior.

Each patient also filled out a questionnaire designed to express their opinion about the quality of dental treatment received. The questionnaire included questions on the patient's assessment of their teeth condition and their opinion on how the treatment affected their health and various aspects of life. The list of questions also included social aspects of the patient's life and, from the patient's point of view, the necessity and obligation of visiting the dentist.

#### RESEARCH ALGORITHM

The study was performed in the following way. First, a testing of Fere's skin-galvanic reaction was performed. Then, each of the patients filled out a quality-of-life questionnaire developed by the authors. Pain assessment was performed during the dental procedure under local anesthesia. Afterward, the skin-galvanic reaction readings were taken again, and the Spielberger-Hanin Scale questionnaire was administered. The Anxiety Scale questionnaire was offered once since in case of repeated completion, the patient may deliberately change the answers following his/her momentum opinion that the wrong answer was chosen at the beginning. The aim was to capture the possible relationship between questions about dental health and changes in anxiety levels. The algorithm allows establishing a clear psychodiagnostic of the patient's psychic state after the dental procedure, in particular, to reveal any changes in anxiety scores after the received therapy.

#### STATISTICAL ANALYSIS

The data were processed using Statistica v. 6.0. A two-sample t-test for independent samples was used to detect the significance of differences. Differences were considered significant at  $P \leq 0.05$ . The distribution of features corresponded to normal, allowing for the establishment of Pearson's correlations. Tables 1–3

**Table 1: Gender composition and average age of patients in the three groups**

Group	Gender	Number of patients	Age (years)
Group 1	Men	107	44.0 ± 6.5
	Women	93	42.0 ± 5.5
Group 2	Men	101	42.0 ± 7.0
	Women	99	43.0 ± 3.0
Group 3	Men	93	41.0 ± 6.5
	Women	107	42.0 ± 4.5

show arithmetic mean values for each parameter and the error of the mean.

**RESULTS**

For the control group, the asymmetry hemispheric activity index in 81 patients was within unity, which corresponded to a state of equilibrium. For another 69 patients, this index was less than unity, which corresponded to positive mood and the dominance of the left hemisphere. Finally, in 60 patients, the coefficient exceeded unity, which corresponded to dominance of the right hemisphere and negative emotional mood [Table 2].

In the control group, significant differences were established only for female patients. In both groups, with equilibrium and negative hemispheric activity index, the differences between the values before and after treatment were significant toward a 1.1-fold increase [Table 2].

The other indicators, particularly in the male group, did not differ from those in the control one. A direct correlation was established between the score in the dental status questionnaire and the emotions with

which the patient filled out the questionnaire. This correlation was more pronounced in women (0.72;  $P \leq 0.05$ ) compared with men, namely, 0.72 vs. 0.57 at  $P \leq 0.05$ , respectively. Consequently, the emotional state of the patients can influence the answers in the dental status questionnaire.

There was also a direct correlation between the score growth in the questionnaire and the values of the hemispheric activity index after the survey, namely, 0.75 ( $P \leq 0.05$ ) for women and 0.64 ( $P \leq 0.05$ ) for men. Thus, the questions of the survey itself can have a significant influence on the patients' emotional state.

At the same time, no statistically significant correlation between anxiety scores and the results of the dental status questionnaire were recorded for the control group.

For patients from the second group with removable dentures, the hemispheric activity index corresponded to unity in 83 patients, that is, was equilibrium; in 48 patients, it was less than unity, that is, the left hemisphere and positive emotions dominated; and in the remaining 69 patients, the index exceeded unity, that is, the right hemisphere and negative emotions

**Table 2: Psychodiagnostics results of patients with healthy teeth (control group) before and after the survey about the condition of teeth**

Gender	Type of emotion	Hemispheric activity factor before treatment	Points, average value	Hemispheric activity factor after treatment	Personal anxiety index	Reactive anxiety index
Women	Equilibrium (n = 44)	0.960 ± 0.07	7.60 ± 0.10	1.070 ± 0.101	32.97 ± 0.47	38.30 ± 0.76
	Positive (n = 36)	0.780 ± 0.05	7.10 ± 0.10	0.810 ± 0.07	29.88 ± 0.44	36.45 ± 0.66
	Negative (n = 27)	1.155 ± 0.08	8.80 ± 0.15	1.310 ± 0.091	40.03 ± 1.26	38.55 ± 1.44
Men	Equilibrium (n = 37)	0.970 ± 0.06	6.25 ± 0.05	1.050 ± 0.10	31.76 ± 0.35	37.43 ± 0.55
	Positive (n = 33)	0.760 ± 0.05	6.10 ± 0.03	0.810 ± 0.10	27.78 ± 0.56	35.54 ± 0.44
	Negative (n = 23)	1.210 ± 0.05	8.45 ± 0.06	1.280 ± 0.09	38.99 ± 0.59	37.87 ± 0.67

Differences between hemispheric activity factors before and after treatment are significant at  $P \leq 0.05$

**Table 3: Characteristics of psycho-emotional condition in patients from Group 1 (fixed metal-ceramic dentures) before and after evaluation of dental status**

Gender	Type of emotion	Hemispheric activity factor before treatment	Hemispheric activity factor after treatment	Type of emotion	Points	Personal anxiety index	Reactive anxiety index
Women	Equilibrium (n = 40)	0.995 ± 0.08	1.110 ± 0.05	Equilibrium (n = 36)	12.35 ± 0.35	40.67 ± 0.51	41.55 ± 0.66
	Positive (n = 33)	0.795 ± 0.07	0.890 ± 0.04	Positive (n = 30)	8.17 ± 0.44	38.90 ± 0.51	38.99 ± 0.55
	Negative (n = 20)	1.210 ± 0.10	1.480 ± 1	Negative (n = 27)	27.35 ± 0.87	44.24 ± 1.24	45.95 ± 1.22
Men	Equilibrium (n = 47)	1.005 ± 0.08	1.117 ± 0.05	Equilibrium (n = 44)	10.34 ± 0.55	38.81 ± 0.55	40.73 ± 0.66
	Positive (n = 35)	0.795 ± 0.07	0.911 ± 1	Positive (n = 33)	7.91 ± 0.33	39.22 ± 0.55	39.94 ± 0.61
	Negative (n = 23)	1.205 ± 0.06	1.465 ± 1	Negative (n = 28)	25.30 ± 0.80	42.31 ± 0.77	45.77 ± 0.89

Differences are significant at  $P \leq 0.05$

dominated. However, after a survey about dental health, the following changes were observed: 55 patients reported a state of equilibrium, 37 patients had positive emotional disposition, and the remaining 108 had a negative empathy. Significant changes were also obtained for the hemispheric activity index after the dental status survey, namely a 1.3-fold in men with the positive emotional disposition ( $P \leq 0.01$ ), a 2.2-fold in women with the negative emotional disposition ( $P \leq 0.01$ ), and a 2.1-fold in men from the same group ( $P \leq 0.01$ ). Also, a direct correlation between the increase of patients' questionnaire scores and their emotional state was recorded: 0.70 for women ( $P \leq 0.05$ ) and 0.79 for men ( $P \leq 0.05$ ). These results indicate the influence of the patient's emotional state on the questionnaire results.

After the survey, however, this relationship intensified in Group 2, and the correlation between the scores and hemispheric activity factor was 0.88 for women ( $P \leq 0.05$ ) and 0.91 for men ( $P \leq 0.05$ ). In contrast to the control group, there was also a correlation between the anxiety level and score growth rates. Thus, for personal anxiety in men, the Pearson's correlation was 0.84 for both genders ( $P \leq 0.05$ ), whereas the reactive anxiety index amounted to 0.78 for women and 0.81 for men ( $P \leq 0.05$ ). The increasing level of anxiety indicates a negative influence of responses about dental treatment, which is also illustrated by the increasing number of patients with a negative emotional empathy in Group 2.

Patients in Group 1 had a similar emotional state distribution compared with Group 2 before completing the dental status questionnaire. Thus, 87 had an equilibrium status with index values around unity, 68 were positive, and 43 were negative [Table 3].

After the patients answered the questions about dental health, the ratio of subgroups with different emotional moods changed in favor of the negative one. Hence, there were 80 people in an equilibrium state, 63 were positively inclined, and 57 had a negative emotional disposition [Table 3]. This indicates a tendency for the negative emotional mood to increase after the survey on dental status.

Significant changes in the hemispheric activity coefficient both before and after treatment were noted for men with positive mood (a 1.1-fold increase,  $P \leq 0.01$ ), for women with negative mood (a 1.2-fold increase,  $P \leq 0.05$ ), and for men from the same group (a 1.2-fold increase,  $P \leq 0.05$ ). There was a direct correlation between the increased scores and emotional disposition among men and women in Group 1, namely 0.72 and 0.73, respectively ( $P \leq 0.05$ ). Also, a correlation

was established between the value of the hemispheric activity factor and the increased scores after the survey was recorded, namely, 0.82 for men and 0.81 for women ( $P \leq 0.05$ ). A correlation between an increase in the scores and the values of personal anxiety for men and women was 0.57 and 0.66, respectively ( $P \leq 0.05$ ). For reactive anxiety, these indices were 0.56 and 0.57 for men and women, respectively ( $P \leq 0.05$ ).

As a result, patients in Groups 1 and 2 with removable and fixed dentures differ in anxiety levels. This confirms the hypothesis that the results of the dental health survey generally have a negative impact on the psycho-emotional status of the patient, especially when the local type of anesthesia is used.

## DISCUSSION

This study showed that after the survey on dental status and quality of life was conducted, a significant increase in the hemispheric activity index values was noted among patients in the groups with removable and fixed dentures demonstrated. Hence, the emotional state of the patients changed toward the negative in both groups in general.

These changes affected most patients with negative emotional mood prior to the administration of the questionnaire. There was also a dependence on the type of dentures. In Group 2 (with removable dentures), the increase in negative emotions was more pronounced, with the indices of anxiety varying more in male patients.

Thus, the survey results can be used to perform a psychodiagnostic of the patient's emotional condition. If the patient scored up to 18 points on the survey, it can be stated that he or she is satisfied with the dental treatment provided. When the number of points ranges from 18.0 to 29.0, the patient can be considered as only partially satisfied with the quality of dental care provided. If a patient scores more than 29 points based on the test results, it can be assumed that they are not satisfied with the dental treatment performed. The behavioral response of patients under local anesthesia in the first group suggested a moderate level of pain. According to the results on the hemispheric activity index, the indicators of negative emotional mood worsened 1.2 times ( $P \leq 0.05$ ) for men and women in the group with fixed dentures; however, in the group with removable dentures, this tendency was stronger with 2.2 and 2.1 times, accordingly ( $P \leq 0.01$ ). These results are supported by the increased level of anxiety in patients with removable and fixed dentures. No emotional changes were found in any

of the controls. The significance of differences between the groups according to the survey results was confirmed by statistical tests and established correlations between the emotional mood and the increase in scores. Among the study limitations, the factor of gender belonging (significant differences obtained for men and women) and the state of the patient's psyche should be particularly considered. In cases where the patient's mental condition may deviate from generally accepted norms (i.e., phobias), the test results may not adequately correspond to the patient's real psycho-emotional state.

This was demonstrated in a study that evaluated the stress level of patients with epilepsy during dental procedures.<sup>[17]</sup> Data from questionnaires administered to 85 patients with epilepsy before elective dental surgery were considered. Dental anxiety was found in 17.6% of patients ( $n = 15$ ). At the same time, dental anxiety did not correspond to factors such as age, level of education, type of epilepsy, frequency of attacks, use of antiepileptics, and many others. However, a significant correlation was found between gender ( $P < 0.01$ ) and the type of oral surgery (removal of a retained third molar;  $P < 0.05$ ) on the one hand and the level of dental anxiety on the other. Similar results were reported in other studies.<sup>[18,19]</sup> A relationship to the gender factor was also established in this study.

Results from this study are generally consistent with similar research. Thus, using data on 105 patients (aged 18–23 years) of dental clinics, it was found that different groups demonstrated various anxiety levels expressed in dentophobia and salivary pH changes.<sup>[20]</sup> Group 1 demonstrated a low level of anxiety and consisted of 33 patients (31.4%). Group 2 included 32 patients (30.5%) with moderate anxiety levels; however, in Group 2 with 40 patients (38.1%), a high anxiety level was recorded.<sup>[20]</sup> Of the 105 study participants, 85% showed low levels of dentophobia, 27% demonstrated low levels of anxiety, 29% showed moderate anxiety levels, and 28% showed high levels of anxiety. The mean salivary pH of all participants was 6.79 at rest and 6.43 in anxiety.<sup>[20]</sup> Thus, saliva pH may also be a factor worth considering in such studies.

Another study showed that microcirculatory changes can indicate psycho-emotional stress development.<sup>[21]</sup> The study included 30 patients. The control group consisted of patients without psycho-emotional disorders but with postprosthetic complications after dental implantation. The results obtained showed that the capillary blood flow during stress changes at both oscillatory and nonoscillatory levels.

At vasodilatation, an intensification of blood flow and disruption of venous flow was established. Analysis of high- and low-frequency oscillations by wavelet transformations revealed an increase in endothelium activity and a decrease in sympathetic adrenergic vasomotor and precapillary tone. Psycho-emotional stress is, therefore, mostly caused by a physiological factor. The patient's consciousness in dental clinic is a comprehensive relationship with the stimuli received from external and internal receptors. Through the interaction of these receptors, the consciousness forms a kind of emotional background, reflecting the patient's perception of the physical condition.<sup>[22-25]</sup> Besides, all of the patient's perceptions or experiences about their condition are reflected in the way they relate to their health.<sup>[26]</sup> In general, such patients can be divided into three groups: with a dismissive attitude, with an adequate attitude, and finally, the group with increased attention to their health.<sup>[16]</sup> Other data indicate that a negative emotional background is influenced by factors, such as the patient's intelligence, the intensity of pain, and the severity of the ongoing disease or upcoming dental procedure.<sup>[27,28]</sup> Thus, research into the patient's emotional activity type plays an important role in subsequent dental treatment. The predominance of negative emotions, such as irritability, demandingness, and the frustration of their physical sensations, constitute a significant proportion among character traits, which also affect the patient's social life.<sup>[29]</sup> It is known that among the patients who have agreed to treatment, feelings of fear and pain may increase even before the dental treatment starts. Fear may take different, and often opposing, forms, such as worry, euphoria, and anxiety. Of the techniques used, two approaches are dominant.<sup>[22]</sup> The first approach is clinical, consisting of analytical conversations with the patient and observing behavioral patterns. The second approach is a laboratory one, which is less costly in time and resources and implies the use of questionnaires.

The most commonly used questionnaires are the Eysenck questionnaire, the MMPI, and the MMPI 2. Further, the Eysenck questionnaire links types of temperament, extraversion and introversion, as well as stability and instability. However, most of the questionnaires show different deficiencies. Some of them diagnose a small number of psychotypes, others are too cumbersome, and many do not include psychometric properties.

## CONCLUSION

This study showed that changes in the hemispheric activity index and indicators of personal and reactive anxiety are related to the survey results on the dental status and the

type of dental service provided. By the quality-of-life criteria, the values obtained were different according to the emotional mood of the patient. It follows that obtaining reliable information about the patient's satisfaction with the dental care provided, questionnaires on the patient's dental health status are required in addition to the standard psychodiagnostic techniques. The study and analysis of the data obtained allow for the right choice to restore the patient's physical and mental health after receiving dental care. Such a multicomponent approach can greatly enhance the quality of dental treatments and establish the most efficient methods.

These results are confirmed by the heightened level of anxiety in patients in groups with removable and fixed prostheses. No change of emotional mood was noted in controls.

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#### CONFLICTS OF INTEREST

There are no conflicts of interest.

#### AUTHORS CONTRIBUTIONS

OB, EI, and AY contributed equally to the experimentation. OB wrote and edited the article. EI designed and conducted the experiment. AY studied scientific literature about the topic. All the authors read and approved the final manuscript.

#### ETHICAL POLICY AND INSTITUTIONAL REVIEW BOARD STATEMENT

The study was approved by the scientific committee of Peoples' Friendship University of Russia and Perm State University.

#### PATIENT DECLARATION OF CONSENT

The participants were informed of the purpose of the study. Their consent was required in writing in order to participate to the study.

#### DATA AVAILABILITY STATEMENT

Data will be available on request.

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