Systemic analysis of clinical data in dry eye syndrome: a model for supporting medical decision-making

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Abstract— **This paper considers the issue of constructing a mathematical model to support decision-making by ophthalmologists in cases of dry eye syndrome associated with meibomian gland dysfunction, based on standard clinical and diagnostic parameters used during outpatient consultations. The initial diagnostic indicators were normalized and their acceptable ranges were checked. To ensure the comparability of indicators in subsequent modeling, the parameter values were reduced to a single formalized form. An early control point (T_1) corresponding to the assessment of the patient's condition after the first stage of therapy was selected as the key time reference in the study, which was due to clinical expediency and the need to decide whether to continue the previously selected tactics or to enhance them by adding IPL therapy and eyelid massage. The predicted outcome within the model was an early clinical response, defined as a consistent improvement in subjective and objective indicators of the condition of the ocular surface. The probability of achieving an early clinical response in each individual patient was described by a logistic regression model. To ensure the clinical interpretability of the results of prognostic modeling and the possibility of practical application of the conclusions obtained in outpatient settings, a score model was developed, which is a simplified form of the basic logistic prognostic model. The score model is designed for the integrated assessment of the severity of the patient's initial condition and to justify the need for early IPL therapy and eyelid massage without performing complex probability calculations.**

Keywords: binary indicator of early clinical response, ocular surface, diagnostic indicators, mathematical modeling, medical decision support.

I. INTRODUCTION

One of the most common ophthalmic diseases in the population [1], [2] with a chronic course, manifested by a pronounced negative impact on the quality of life of patients, is dry eye syndrome (DES) [3], [4]. In real clinical practice, the management of patients with DES associated with meibomian gland dysfunction (MGD) requires a comprehensive assessment to decide on further treatment tactics, including the need for early involvement of hardware techniques [5]. At the same time, the effectiveness of initial conservative therapy varies significantly among different patients, and clinical improvement may occur either early or later. The lack of formalized criteria for predicting response to treatment at the initial stage of therapy makes it important to develop a mathematical model focused on supporting medical decision-making. The lack of formalized criteria for predicting response to treatment at the initial stage of therapy makes it relevant to develop a mathematical model focused on supporting medical decisions.

This paper presents a mathematical model for assessing the probability of achieving clinically significant improvement in the condition of the ocular surface in the early stages of observation based on the patient's initial diagnostic parameters and the construction of a personalized prognosis of clinical response based on these data, which is of practical importance for the choice of further treatment tactics.

II. CLINICAL BASE

The initial basis for constructing the prognostic model was a clinical database formed on the basis of the medical histories of 116 patients with DES associated with MGD. The database is retrospective in nature and reflects the results of examination and treatment of patients in real clinical practice. For each patient in the database, diagnostic indicators were recorded at the initial visit: T_0 – initial visit to the clinic; then – data from the early follow-up assessment T_1 – one week after standard conservative therapy and a visit after completion of the course of treatment (T_2).

The unit of analysis in this study was the patient, which was determined by the clinical logic of deciding on treatment tactics and the lack of statistical independence between the indicators of the right and left eyes of the same patient. Thus, the principle of aggregation “two eyes → one patient” was implemented. For the purposes of mathematical modeling at the data preparation stage, the method of aggregating interocular indicators was used, aimed at bringing the data to the format “one patient — one set of characteristics.”

At the same time, in the initial database, diagnostic parameters were recorded separately for the right and left eyes, which made it possible to preserve complete clinical information at the data collection stage. Then, the indicators were normalized (at T_0, T_1, T_2) according to the tests studied for the convenience of constructing the score function.

III. DIAGNOSTIC INDICATORS

Diagnostic examination of patients was performed according to a standardized algorithm with a fixed sequence of tests, which was aimed at minimizing the mutual influence of individual diagnostic procedures and increasing the reproducibility of the results obtained. The sequence of tests was determined by their physiological characteristics and the potential impact of manipulations on tear film and eye surface parameters.

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The following indicators were used as objective criteria for assessing the patient's condition as input variables for the prognostic model:

1. To assess the aqueous component of the tear film, the Schirmer test (Sch. mm/5 min) was used, which allows quantitative determination of tear production. This test was performed as the first stage of the examination, before any manipulations were performed on the eye surface. This step was chosen in the diagnostic algorithm because contact with the eyelid, instillation of vital dyes, and mechanical impact during subsequent examinations can cause a reflexive change in tear production and thus distort the test results. Despite the predominance of the evaporative mechanism in meibomian gland dysfunction, the inclusion of this indicator in the analysis is due to the clinical heterogeneity of patients and the possible combination of disorders of the lipid and aqueous components of the tear film, which is important for the personalized selection of treatment tactics. Performing the Schirmer test at the initial stage allowed for the most reliable assessment of the aqueous component of the tear film.

2. The tear film breakup time was determined using the Norn test (TBUT, sec.), which reflects the time from the last blink to the appearance of the first tear film breakup on the surface of the cornea. This indicator is one of the main clinical markers of the evaporative component of the tear film and directly characterizes the functional state of the lipid layer of the tear film.

3. The degree of damage to the epithelial surface of the eye was assessed using the Oxford scale (Oxford; 0–5), based on an analysis of the intensity of sodium fluorescein staining. The condition of the epithelium was assessed using the Oxford scale on a 5-point system in three areas: across the entire cornea and in two areas (nasal and temporal) of the bulbar conjunctiva. Score values: 0 — no staining; 1 — minimal staining; 2 — insignificant; 3 — moderate; 4 — pronounced; 5 — total. This indicator reflects the severity of epithelial damage and serves as an integral marker of the involvement of the ocular surface in the pathological process, as well as an objective criterion for the dynamics of the condition against the background of ongoing therapy.

4. The final stage of the examination was to determine the severity of subjective symptoms by having the patient independently complete the OSDI-6 questionnaire, followed by calculation of the total score (0–24 points). Placing the questionnaire at the end of the diagnostic algorithm made it possible to record a subjective assessment of OSDI symptoms without the influence of prior discussion of the results of objective tests with the doctor and without distortion of responses due to diagnostic manipulations. In this study, the results of the OSDI-6 questionnaire were converted to an ordinal severity scale (0–4), where 0 corresponded to the absence of subjective manifestations of DES, 1 to mild severity, 2 to moderate severity, and 3–4 to severe forms of the disease. This transformation of data made it possible to compare the patient's subjective complaints with objective clinical and functional indicators of the condition of the ocular surface and to use the questionnaire results as an input parameter for a mathematical model.

Let us further assume that during the patient's visits to the doctor at times $t \in \{T_0, T_1, T_2\}$ measurements are taken for the right (OD) and left (OS) eyes:

$TBUT_t^{OD}, TBUT_t^{OS}$ (sec)

Sch_t^{OD}, Sch_t^{OS} (mm/5min)

Ox_t^{OD}, Ox_t^{OS} (0-5)

$OSDI_t$ (0–4)

Thus, the following target structures were selected: tear production level (Schirmer test), tear film stability (TBUT), staining of the corneal epithelium and conjunctiva (Oxford scale), subjective symptoms (OSDI-6). The unit of analysis was the indicators that were taken into account at the patient level with aggregation by eye: TBUT — minimum (worst eye), Schirmer — minimum, Oxford — maximum; OSDI-6 — maximum (0-4).

The inclusion criteria for the baseline model were selected as follows: OSDI-6 ≥ 1, TBUT <10 sec, Schirmer <15 mm/5 min; presence of epithelial staining according to the Oxford scale at baseline and at week 1 $t \in \{T_0, T_1\}$. Exclusion criteria: severe water deficiency (Schirmer <5 mm), keratitis/corneal erosion, recent eye surgery.

These parameters were selected due to their reproducibility, availability in routine practice, and compliance with current recommendations for the diagnosis and monitoring of DES [1], [5], [6]. The proposed indicators are independent to ensure the reliability of conclusions.

IV. Normalization of Indicators

In the first stage, the initial diagnostic indicators obtained during the T_0 visit were normalized. Normalization was performed in such a way that an increase in the value of each normalized indicator corresponded to a worsening of the condition of the ocular surface and an increased risk of no early clinical response. For each patient, a vector of indicators was formed, including normalized values of diagnostic indicators:

$$\bar{x} = (Z_{OSDI}, Z_{TBUT}, Z_{SCHIRMER}, Z_{Oxford})$$

$Z_{OSDI}, Z_{TBUT}, Z_{SCHIRMER}, Z_{Oxford}$ -

standardized indicators of the severity of subjective symptoms, tear film stability, tear production, and corneal epithelial damage, respectively. The indicators were standardized so that an increase in the value of each component of the vector corresponded to a deterioration in the functional state of the ocular surface [7].

The normalized indicators were calculated using the following formulas:

$Z_{OSDI} = \frac{OSDI}{4}$ - the severity of subjective symptoms of DES, presented as an ordinal scale from 0 to 4.

$Z_{TBUT} = \max\left(0, \frac{10 - TBUT_0}{10}\right)$ - tear film breakup time in seconds; a value of 10 is accepted as the reference threshold for tear film stability.

$Z_{SCHIRMER} = \max\left(0, \frac{15 - Schirmer_0}{15}\right)$ - tear production (mm/5 min) corresponds to the lower limit of normal.

$Z_{Oxford} = \frac{Oxford}{5}$ - degree of corneal staining on a scale of (0-5) points.

In our case: 10 seconds and 15 mm/5 min are reference values that were previously used in the criteria normalization logic. During the data preparation stage, the acceptable ranges of indicator values were checked, the logical consistency of observation time points was verified, and omissions were systematized.

Table 1 shows an example of standardization of the indicators studied at control points. T_0, T_1 and T_0, where OD is the patient's right eye and OS is the left eye of the same patient.

The sample prepared in this way was used for the subsequent construction and evaluation of predictive mathematical models.

Table 1. Example of normalization of the studied indicators at three control time points.

	OSDI-6	Oxford (OD/OS)
T_0	0,5	0,4/0,4
T_1	0,5	0,4/0,2
T_2	0,25	0/0
	TBUT (OD/OS)	Schirmer (OD/OS)
T_0	0,875/0,875	0,8/0,74
T_1	0,875/0,875	0,74/0,74
T_2	0,375/0,375	0,6/0,6

To ensure comparability of indicators in subsequent modeling, parameter values were converted to a uniform formalized form, taking into account the direction of interpretation (deterioration of the situation — increase in the indicator's contribution to the model).

V. Aggregation of Indicators

The aggregation of indicators between the eyes was carried out according to predefined rules. For parameters reflecting the functional state of the tear film (tear film breakup time and tear production level), the analytical set included the minimum value from both eyes, corresponding to the worst functional state. To assess corneal epithelial damage on a scale in the summary database, the maximum indicator from both eyes, reflecting the greatest degree of epithelial damage, was recorded.

The results of the OSDI-6 questionnaire were recorded at the patient level and did not require interocular aggregation. This approach made it possible to avoid underestimating the severity of the disease and to ensure a clinically conservative interpretation of the initial condition.

An early control point (T_1) corresponding to the assessment of the patient's condition after the first stage of therapy was selected as a key time reference in the study. All patients underwent standardized basic conservative therapy, including the use of preservative-free moisturizing (tear replacement) drops, a short course of local anti-inflammatory therapy with glucocorticosteroids on a tapering regimen, and regular eyelid hygiene at home [8], [9].

These measures were considered background treatment, mandatory for all patients, and were not subject to comparative analysis in this study. Specific dosage forms and regimens may have varied slightly within standard clinical recommendations, but the fact of prescription and the class of drugs were uniform for the entire study sample and were considered a constant component of therapy. The choice of the early stage (T_1) is due to clinical expediency: it is at this stage that the doctor is faced with the need to decide whether to continue with the previously chosen tactics or to intensify them by adding IPL (Intense Pulsed Light) therapy and eyelid massage.

The model we are considering is intended for use until the completion of the full course of treatment (duration 3-4 months). Table 2 shows the standardization of the indicators under study as an example.

Table 2. Example of interocular aggregation of the studied indicators at three control time points.

	OSDI-6	Oxford
T_0	0,4	0,4
T_1	0,4	0,4
T_2	0,2	0
	TBUT	Schirmer
T_0	0,875	0,8
T_1	0,875	0,74
T_2	0,375	0,6

VI. Score Function Model

To ensure the clinical interpretability of the results of prognostic modeling and the possibility of practical application of the conclusions obtained in outpatient settings, a score model was developed, which is a simplified form of the basic logistic prognostic model [10], [11]. The score model is designed for an integrated assessment of the severity of the patient's initial condition and to justify the need for early IPL therapy and eyelid massage without performing complex probability calculations.

Based on the normalized indicators presented in table 1, a linear integral score function was formed:

$$S = \beta_0 + \sum_{i=1}^{4} \beta_i Z_i$$

The following symbols are used here:

$Z_1 = Z_{OSDI}$; $Z_2 = Z_{TBUT}$; $Z_3 = Z_{SCHIRMER}$; $Z_4 = Z_{Oxford}$

S — integral score of the severity of the eye surface condition, and the coefficients reflect the relative contribution of the corresponding diagnostic parameters and are determined at the stage of training the prognostic model using expert assessments.

The predicted outcome within the model is early clinical response, defined as a consistent improvement in subjective and objective indicators of the condition of the ocular surface. The score function is a linear convolution of four indicators and allows us to move from a multi-criteria analysis task to a single-criteria one. Let us represent this $S = S(\bar{x})$ in the form:

$$S = \beta_0 + \beta \bar{x}^T$$

where $\beta = (\beta_1, \beta_2, \beta_3, \beta_4)$.

Table 3 shows the values of the score function. Analysis of the data obtained allows us to say with confidence that the function takes into account the main indicators of the severity of subjective symptoms, tear film stability, tear production, and corneal epithelial damage, respectively, and avoids a one-sided interpretation of the disease based on a single test. The same dynamics can be observed in other patients.

Analysis of individual score functions obtained during the study in patients at the stages T_0, T_1, T_2 confirms the need for early initiation of IPL therapy. So, when visiting the clinic (stage T_0) S-function>2, respectively, the patient receives

basic pharmacological therapy. A repeat visit to the clinic (stage T_1) shows some positive dynamics, however, the S-function remains above the "2" mark, which is a signal for the doctor to introduce a physiotherapy component into the treatment protocol. The results obtained (less than "2") at stage T_2 indicate the undoubted success of complex treatment with the introduction of IPL therapy into the protocol. The data are presented for several patients in table 3.

Table 3. Indicators of the integral assessment of the patient's condition severity

№ patient	S-function	
1	T_0	2,475
	T_1	2,415
	T_2	1,245
2	T_0	2,365
	T_1	2,115
	T_2	1,645
3	T_0	2,625
	T_1	2,025
	T_2	1,32
4	T_0	2,42
	T_1	2,165
	T_2	1,115
5	T_0	2,175
	T_1	2,1
	T_2	1,725

Thus, the model is used not for retrospective assessment of treatment effectiveness, but as a tool for predicting clinical response before the end of the course of therapy, which is consistent with the principles of personalized and prognostic medicine.

The study also examined the binary indicator of early clinical response (BIRCO) at visit T_1. Early clinical response allows decisions to be made about continuing the previously selected treatment strategy or intensifying it by adding IPL therapy and eyelid massage. It was determined using a composite criterion that took into account both subjective and objective dynamic indicators of the condition of the ocular surface. Formally, the target variable was set as follows:

$$Y = I(I(\Delta OSDI_1) + I(\Delta TBUT) + I(\Delta Oxford) + I(\Delta SCHIRMER)$$

The dynamics of the indicators under study are determined using the following formulas:

$$\Delta TBUT = TBUT_1 - TBUT_0$$
$$\Delta Oxford = Oxford_1 - Oxford_0$$
$$\Delta SCHIRMER = SCHIRMER_1 - SCHIRMER_0$$
$$\Delta OSDI = OSDI_1 - OSDI_0$$

$I(.)$ - a binary indicator function that takes the value 1 when the conditions are met and 0 otherwise.

Thus, early clinical response (BIRCO) was recorded when at least three of the four conditions were met. This approach allows for the multicomponent nature of DES to be taken into account and avoids a one-sided interpretation of disease dynamics based on a single test. Formalizing the clinical response criterion and using it as a target variable model provides a link between mathematical prediction and clinically significant changes in the patient's condition. Table 4 shows the values for patients with DES and MGD.

Table 4. Binary indicator values for achieving early clinical response.

№ patient	Therapy dynamics	Y
1	$\Delta T_1 - T_0$	0
	$\Delta T_2 - T_1$	1
2	$\Delta T_1 - T_0$	0
	$\Delta T_2 - T_1$	1
3	$\Delta T_1 - T_0$	0
	$\Delta T_2 - T_1$	1
4	$\Delta T_1 - T_0$	0
	$\Delta T_2 - T_1$	1
5	$\Delta T_1 - T_0$	0
	$\Delta T_2 - T_1$	1

Analysis of the data obtained shows that the comprehensive criterion (BIRKO) allows predicting the correction of therapy tactics in the second stage of treatment by adding IPL therapy and eyelid massage.

VII. LOGISTIC FORECASTING MODEL

The resulting linear models predict a continuous value, preventing the classification of patients according to the severity of the disease. The score model is not an alternative to the logistic prognostic model, but rather a clinically interpretable form of it. The value of the integral score S is associated with the probability of achieving an early clinical response, calculated within the framework of logistic regression, which ensures consistency between the mathematical prognosis and the clinical decision-making algorithm.

To solve the classification problem, let us consider a logistic predictive model, which is a classifier that predicts the probability of a patient belonging to a certain class. The logistic model is based on a statistical machine learning algorithm that allows predicting the probability of achieving an early clinical response in a specific patient at all stages of treatment based on diagnostic indicators. The logistic regression model can be represented as follows:

$$P(Y = 1(X) = \frac{1}{1 + e^{-(\beta_0 + \beta_1 ZOSDI + \beta_2 ZTBUT + \beta_3 ZSCHIRMER + \beta_3 ZOxford)}}$$

Let's transform this expression to the following form:

$$P(Y = 1(X) = \frac{1}{1 + e^{-S}}$$

The value obtained based on independent indicators (predictors) predicts the probability of a patient belonging to one of two classes and is considered a quantitative assessment of the expected effectiveness of the initial treatment strategy for a specific patient.

VIII. ALGORITHM FOR MAKING MEDICAL DECISIONS

The result of the logistical predictive model was used to support the decision on the advisability of early initiation of IPL therapy + eyelid massage. To this end, a threshold probability value was introduced ε, determining the boundary between a favorable and unfavorable prognosis for response to conservative therapy.

Formally, the decision rule can be written as follows:

$$P(Y = 1(X) \le \varepsilon$$

For probability values exceeding the threshold $\varepsilon = 0{,}5$, the patient was considered a candidate for continuing the initial conservative therapy without immediate intensification.

Thus, the algorithm for making a medical decision can be represented as follows:

1. Survey of patients with DES+MGD.
2. Initial diagnosis: OSDI, TBUT, Schirmer, Oxford.
3. Standardization of diagnostic indicators (Z_{OSDI}, Z_{TBUT}, $Z_{SCHIRMER}$, Z_{Oxford}).
4. Aggregation of indicators.
5. Calculation of the integral score S.
6. Calculation of indicator dynamics.
7. Definition of a binary indicator of early clinical response Y.
8. Logistical predictive model, probability calculation P.
9. Classification. Comparison with threshold ε.
10. Making a medical decision.

Table 5. Classification of clinical response.

№ patient	CR T_0	CR T_1	CR T_2
1	0	1	-
2	0	0	1
3	0	0	0
4	0	0	1
5	0	0	1

Table 5 shows the distribution of patients at control points T_0, T_1, and T_2 depending on the patient's clinical response (CR) class, where 0 is the condition of a patient who needs therapy (let us conditionally designate this as "sick"); 1 is the condition of a patient who does not require further therapy (let us conditionally designate this as "healthy").

Based on the CR data obtained, the doctor decides on the need to prescribe a course of treatment (control point T_0) if the indicator is 0, which is the case for all patients at the initial appointment. At control point T_1, depending on the CR value, a decision is made to add physiotherapy procedures if CR = 0, which corresponds to the absence of effect from the prescribed basic therapy or if this effect is insufficient. If CR = 1, then the effect of therapy has already been achieved. Analysis of the clinical response in patients in the study sample shows a low percentage of CR = 1 at T_1. At the same time, CR = 0 at T_2 prevails.

IX. Conclusion

Thus, the task of mathematical modeling was to develop a predictive model that, based on the patient's initial clinical and functional parameters, would allow assessing the probability of achieving an early clinical response and, based on this prediction, justify the inclusion of IPL therapy in the treatment regimen.

The developed model is considered as an element of a medical decision support system focused on practical application in outpatient ophthalmological practice. The output variable of the model was a binary indicator of achieving an early clinical response at visit T_1, determined in accordance with a composite criterion that included the dynamics of subjective and objective indicators of the condition of the ocular surface. The proposed choice of the target variable allows us to consider the modeling task as a binary classification task focused on predicting the effectiveness of the initial treatment strategy in the early stages.

Given the binary nature of the target variable—achievement or non-achievement of an early clinical response—the modeling task was formulated as a binary classification task. A multivariate logistic regression model was chosen as the mathematical apparatus, ensuring clinical interpretability, reproducibility, and the possibility of direct use of the result in the form of a probabilistic estimate.

This approach was consistent with the goal of developing a simple and clinically applicable tool to support medical decision-making.

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