

A Web-Based System for Automated Assessment of Therapeutic Outcomes Using Hemato-logical Data

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ABSTRACT

The study is devoted to the automation of assessing the effectiveness and individual tolerability of therapeutic interventions based on hematological parameters. The aim of the study is to develop an algorithm for processing histograms of blood cell size distributions to assist in the interpretation of cellular changes arising as a result of therapy. An algorithm for histogram analysis is proposed, enabling the identification of characteristic cellular phenomena. A specialized web-based application for the processing, storage, and systematization of patients' hematological data has been developed. It is shown that the implementation of standardized and automated approaches contributes to increased speed and quality of hematological research.

Keywords: Hematological Data, Cell Distribution Analysis, Spline Approximation, Web Application, Data Processing Automation, Medical Information Systems, Hematological, Algorithm, Automation, Histogram, Therapy Monitoring.

Introduction

A pressing issue in modern medicine is the development of objective methods for evaluating the effectiveness and individual tolerability of various therapeutic methods, such as chemotherapy, photodynamic therapy, ozone therapy, and intravenous administration of antibiotics and immunotropic drugs. To solve this problem, the cellular composition of blood is analyzed using automatic hematology analyzers that operate on the impedance principle. This principle is based on measuring the change in resistance as blood cells pass between two electrodes [1]. These devices construct histograms of the distribution of blood cells by size, with the analysis of the histogram of leukocyte distribution being of greatest interest for diagnosis.

Problem Statement

In accordance with the methodology developed by Dr. M.E. Bogdanov, blood samples are taken from the patient before and after therapeutic intervention. A comparative analysis of the

histograms obtained allows the key cellular phenomena arising in response to therapy to be identified and quantitatively described. Currently, this analysis is performed manually in the customer's laboratory using Excel and Access programs, which is a labor-intensive process prone to subjective errors. Therefore, there was a need to develop a software package that automates patient records and performs an objective analysis of leukocyte distribution histograms to identify and quantitatively assess diagnostically significant phenomena.

The blood tests obtained are compared in terms of the absolute content of leukocytes, erythrocytes, and thrombocytes. Measurements of their quantities can have direct diagnostic value. For example, studies by the National Specialized Hospital for Active Treatment of Hematological Diseases in Sofia, Bulgaria, demonstrate how therapy has contributed to a significant reduction in the number of large erythrocyte aggregates in patients with chronic lymphocytic leukemia [2].

Comparing histograms of leukocyte size distribution allows us to identify and quantitatively describe the changes occurring in the blood during therapeutic exposure. The following physiological phenomena can be distinguished

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- Aggregation of erythrocytes with the formation of “coin stacks” as a result of the release of antigens into the blood that irritate the patient’s B-lymphocytes. This phenomenon manifests itself in the appearance of additional “cells” in the fraction of small and medium-sized lymphocytes. The severity of erythrocyte aggregation can serve as an indicator of the degree of damage to cells in the bloodstream [3].
- Destruction of certain fractions of leukocytes (lymphocytes, monocytes, granulocytes). This phenomenon is characterized by a decrease in cells in the corresponding leukocyte fractions. Since defective and pathologically altered cells are destroyed first, this phenomenon allows us to clarify the type of pathological process occurring in the patient’s body [4].
- Neutrophil degranulation. This is an indicator of the functional activity of innate immune cells. It manifests itself in the form of a decrease in granulocyte volume. Changes in the mechanisms of neutrophil destruction are associated with pathologies such as cancer and autoimmune diseases [5].
- Release of additional leukocytes from the depot into the bloodstream. This indicates the presence of functional reserves in the patient’s immune system [6]. It manifests itself as an increase in the concentration of granulocytes in a blood sample obtained after therapeutic intervention.

Description of the Algorithm

The initial data obtained from the device is a discrete set of points (x_i, y_i) , where x_i is the cell volume, and y_i is the number of cells of the i -th volume. Two types of histograms are studied: a control sample obtained from the analysis of the patient’s blood before therapeutic intervention and an experimental sample obtained after therapeutic intervention. As the practice of some clinical laboratories and veterinary clinics shows, histograms allow you to quickly see abnormalities and are an important visual tool [7, 8]. The initial data are presented in Figure-1.

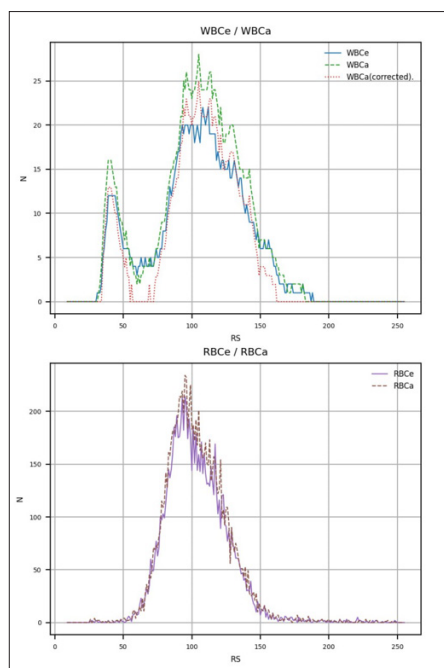


Figure 1: Leukocyte (WBCe/WBCa) and erythrocyte histograms (RBCe/RBCa) before and after therapeutic intervention

Each analysis is divided into two classes: erythrocyte histogram and leukocyte histogram. To account for differences in the volume of blood collected, each analysis is normalized by volume. The leukocyte histogram is used for direct interpretation of the effect of therapeutic exposure.

At first glance at the leukocyte histogram, two clearly defined maxima and minima can be seen. The first maximum, in the area of smaller cells, is the peak of the lymphocyte fraction. The global minimum corresponds to the monocyte fraction and aggregated lymphocytes. The second maximum, in the area of larger cells, is the peak of the granulocyte fraction.

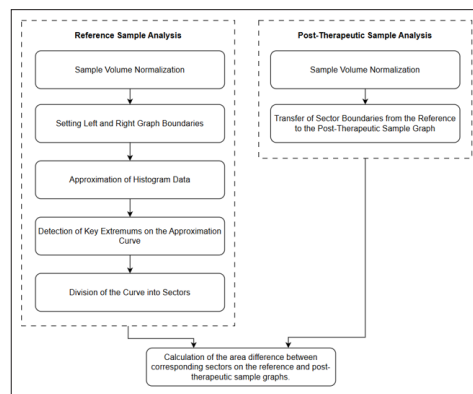


Figure 2: Block diagram of the hematological data processing algorithm

The algorithm underlying the calculation module is shown in Figure 2. The task of the calculation module is to generate two difference diagrams: the first, step-by-step, shows the difference between the experimental and control samples for cells of each individual size; the second, a segmental diagram, shows the difference in blood segments. The method of dividing the histogram into sectors is described below. Differential diagrams are designed to help recognize and interpret the blood’s response to therapeutic intervention.

Since blood samples vary in mass, appropriate adjustments must be made. The leukocyte histogram data is converted so that the area under the graph equals the calculated area based on the reference leukocyte, reference erythrocyte, and experimental erythrocyte histogram data. The Simpson method `scipy.integrate.simpson` is used to calculate the area under the curves.

Next, the original data is approximated. The approximation of experimental data using various functions was investigated, including spline interpolation and polynomials of various orders, including Chebyshev polynomials. Figure 3. shows the approximation of data using various methods. As a result, Chebyshev polynomials of the 11th degree were selected, since they significantly smooth out data fluctuations and allow the extraction of extrema close to the parameters of normal distributions of fractions [9, 10]. This was implemented using the `chebfit` and `chebval` functions of the `numpy.polynomial.chebyshev` library.

The resulting smooth continuous function (Figure 4.) allows us to use a simple and effective algorithm for finding extrema by comparing the values of the function at neighboring points. Local

extrema were searched for using the argrextrema function from the scipy.signal library. The function allows finding both local minima and local maxima with flexible parameter settings. The specified methods from the SciPy and Numpy libraries of the Python programming language were used because they have proven themselves to be powerful and high-performance computational tools [11].

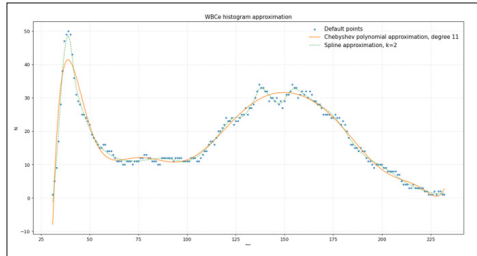


Figure 3: Comparison of approximation methods using the example of a “spiked” leukocyte histogram

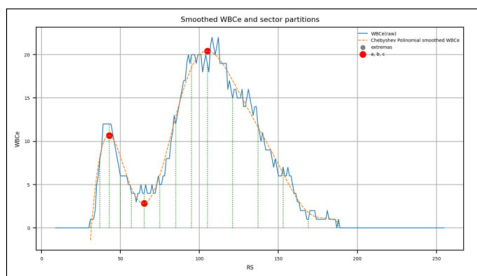


Figure 4: Approximation of the original data with an 11th-order Chebyshev polynomial

Two maxima and one minimum between them are then selected from the obtained extrema. The selection of specific points is left to the discretion of the expert; the selection interface is shown in Figure 5. The obtained points are the boundaries separating the leukocyte fractions.

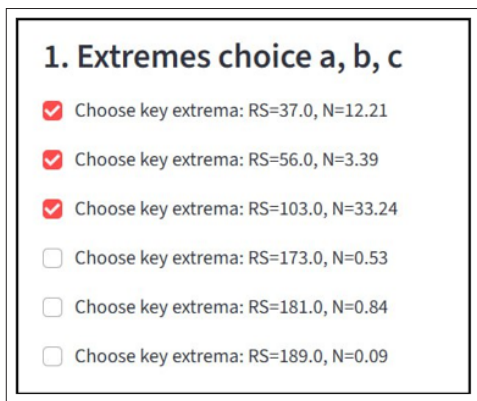


Figure 5: Interface for selecting key extrema

Each fraction is then divided into a certain number of equal intervals, the number of which can also be varied by the expert; the interface is shown in Figure 6. An example of such a division is shown in Figure 7.



Figure 6: Interface for Selecting the Number of Divisions for Each Interval

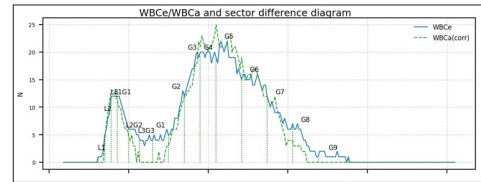


Figure 7: Example of Selecting key Extremes and Dividing Fractions into Intervals

The final stage of the algorithm is the construction of two types of difference diagrams: a general step-by-step difference diagram and a sector difference diagram. The general step-by-step difference diagram represents the difference between the leukocyte histograms before and after therapeutic intervention at each point in terms of cell size:

$$\Delta_d = WBC_d^a - WBC_d^e$$

where WBC_d^a is the number of leukocytes in the post-therapeutic sample at point d, and WBC_d^e is the number of leukocytes in the reference sample.

The sector difference diagram is calculated using the following formula:

$$\Delta_i^s = \frac{\sum_{j=d_i}^{d_{i+1}} (WBC_d^a - WBC_d^e)}{\sum_{d=1}^D WBC_d^e} * 100\%$$

The resulting histograms, shown in Figure-8, are intended to assist in studying the effect of therapeutic exposure on the patient’s body and adjusting the treatment strategy.

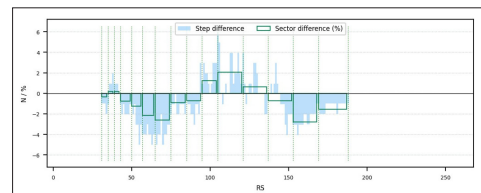


Figure 8: Stepwise and Sectoral Difference Diagrams

The numerical values of the differences by sector are presented in the table (Figure 9). Red color indicates negative values; green color indicates positive values. The color is more intense, the higher the absolute value of the difference by sector.

antigen	WBCtotal	L	H	L1	G	G1	G2	G3	G4	G5	G6	G7	G8	G9
0	150208	-0.4	0.5	0.4	0.0	0.3	0.5	0.3	0.4	-1.3	2.9	-2.9	-1.3	1.2
1	150213	-0.5	0.0	0.0	1.8	0.7	0.5	0.0	-0.4	0.1	2.0	1.5	3.4	4.0
2	150204	-0.0	0.4	0.0	0.3	0.0	0.0	0.0	0.0	0.1	2.5	2.1	-0.9	-0.7
3	150205	-0.5	0.5	0.0	0.1	2.9	0.1	0.5	-0.5	-0.3	0.0	1.4	3.0	3.1

Figure 9: Table of Sector Differences

Technical Implementation

Web architecture was chosen for the implementation of the complex, ensuring cross-platform compatibility and easy access from any workstation in the laboratory. This approach is widely used for the transition from paper-based accounting to an automated system [12]. Figure 10 shows a diagram of the interaction between the system components.

The software complex for laboratory diagnostics is built on a client-server model and is divided into two large interconnected parts: an internal application for the laboratory and a public application for patients. The internal application provides a complete data processing cycle. It includes the following modules:

- The patient accounting module is designed to maintain a centralized electronic file. It allows you to register, search, and manage patient data.
- The cytometer data download module provides direct integration with laboratory equipment.
- The analytical module performs primary analysis, curve smoothing, peak search and identification, and statistical evaluation of results.
- The visualization module displays distribution histograms, allows you to manage the division of histograms into sectors, and is responsible for generating reports.

The public application provides patients with secure access to test results and helps maintain feedback with doctors. It includes the following modules:

- The authorization module provides secure user login to the system.
- The data exchange model provides patients with access to their medical history, test results, and doctors' conclusions. It also allows them to send information about their well-being and the results of additional tests.

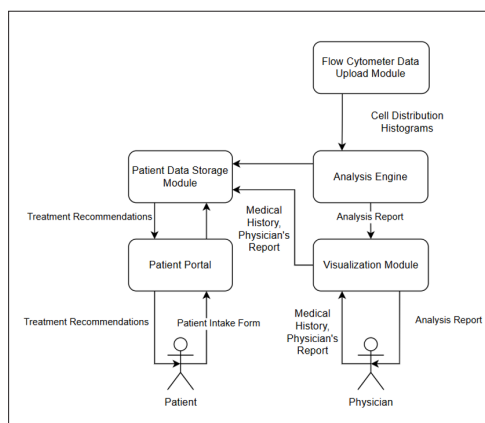


Figure 10: Diagram of the Interaction Between the Components of the Software Complex

The backend of both applications is implemented on ASP.NET Core, provides a REST API for the client, contains business logic, and implements the described mathematical methods.

The frontend for the internal application was created using Blazor WebAssembly, which allows for a minimalistic and functional interface.

For the frontend of the public application, it was decided to use the Vue.js framework. It provides a wide range of functionality and supports a modular structure. This is especially important for projects that require constant updating and expansion of functionality [13]. Although the JavaScript programming language can lead to data type issues during execution, it greatly speeds up development and provides greater flexibility [14].

Data storage is implemented using Entity Framework Core as an ORM for working with the PostgreSQL relational database.

The software complex is deployed in the cloud on a Nginx server. It was chosen because it has open-source code and a wide range of capabilities, including reverse proxying, load balancing, and proxy caching [15].

Designing a New Database and Migrating Data

The laboratory, which is the customer for this development, uses a Microsoft Access database to store analysis data. This database cannot cope with the current volume of data, is poorly structured, and is not suitable for use in the software complex. It was decided to design a new data-base for PostgreSQL, taking into account the new requirements, and to migrate the existing data.

The new model includes all the necessary entities and demonstrates a clearer division of responsibilities. Separating patient personal data and specific examination data, as well as moving microscopic/cytometric measurements to a separate table, improves normalization, reduces duplication, and simplifies the expansion of the schema for new types of studies [16].

Data obtained from cytometers and laboratory blood tests are characterized by a large number of quantitative indicators and parameters, which requires strict normalization and maintenance of integrity [17]. In the new scheme, such data is grouped by thematic entities (general patient information, visit information, specific test results), which facilitates the use of standardized encodings, reuse of results, and construction of complex samples for statistics and machine learning [18].

In practice, data migration was performed using Python scripts, which is consistent with current recommendations for programmable data transfer from Access to PostgreSQL [19]. This approach allows you to sequentially: read data from the original Access tables, transform it according to the new schema: distribute fields across normalized tables, convert types and values to uniform formats, and safely load them into PostgreSQL with error checking [20].

The following algorithm has been developed to ensure seamless migration of the existing data-base.

- Analyze the existing MS Access schema. Create a schema for the PostgreSQL database based on existing and new requirements.
- Performing the initial data transfer. During this operation, the Access database is switched to read-only mode to ensure data consistency. All changes made in Access during the transfer are recorded.
- Setting up a process for regular synchronization of changes. Applications are switched to parallel mode with both databases, ensuring that new data is written only to PostgreSQL, while maintaining read access from both DBMSs.
- Performing data integrity checks. Testing query performance. Implementing backup.
- Switching all modules to use the new DBMS. Short-term support for parallel access for a smooth transition.
- Final synchronization and data verification. Complete cessation of work with the Access data-base.

Results

A working prototype of the system has now been developed. It has been tested on historical laboratory data. It has been confirmed that the algorithm correctly performs approximation, peak identification, and calculation of differences between samples. A database is being developed to support the new system requirements. An algorithm has been developed to migrate data from the existing database to the new one.

Practical benefits:

- Reduced labor costs for data processing and analysis.
- Improved accuracy of research results and their analysis.
- Standardization of data processing and analysis.
- Centralized storage of test results and patient data.

Project development prospects:

- Implementation of machine learning methods for classifying types of immune response based on accumulated data.
- Development of a module for statistical evaluation of the significance of differences obtained by sector.

Conclusion

The described software complex successfully solves the problem of automating the labor-intensive process of analyzing hematological data. The use of mathematical methods of approximation and function analysis made it possible to formalize and make reproducible a key stage of the study – the quantitative assessment of the effect of various therapeutic methods on the cellular composition of blood. The introduction of the web application into the practice of this immunological laboratory and similar ones will not only speed up research, but also increase the reliability and standardization of the results obtained, adjust individual patient treatment trajectories, and increase its effectiveness. This is an important contribution to the development of modern digital medicine and personalized treatment methods.

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Conflicts of interest

No conflicts of interests of any sort beyond.

Informed Consent

none to declare

Data Availability

None to declare

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