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Original Research Article

Immunofan in the Comprehensive Treatment of Patients with Phlegmon of the Floor of the Mouth

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Abstract

In recent years, an increased incidence of patients with phlegmon of the floor of the mouth has been observed in outpatient dental clinics and maxillofacial surgical departments. According to the literature, secondary immunodeficiency frequently contributes to the development of purulent-septic complications of various diseases, including dental pathologies.A total of 75 patients with phlegmon of the floor of the mouth admitted for inpatient treatment were examined. The patients were divided into two groups. Group 1 (n = 53) received conventional comprehensive therapy. Group 2 patients, as part of comprehensive treatment, additionally received the immunomodulatory agent Imunofan at a dose of 50 µg administered intramuscularly once daily for 5 days.Comparative analysis of treatment outcomes between the conventional and proposed therapeutic regimens revealed significant differences in efficacy and clinical results. The inclusion of the modern immunomodulator Imunofan in the complex therapy of patients with phlegmon of the floor of the mouth resulted in immunological correction, improvement of clinical and laboratory parameters, and a reduction in treatment duration.

Keywords: *odontogenic purulent-inflammatory diseases, Imunofan, immune correction.*

Introduction

In recent years, an increased number of patients with phlegmon of the floor of the mouth has been reported in outpatient dental institutions and maxillofacial surgical hospitals. There is also a tendency toward a more severe clinical course, a higher propensity for generalization of purulent infection, and the development of more severe inflammatory complications. Immunological mechanisms involved in the pathogenesis of both somatic diseases and dental disorders have been intensively investigated. According to published data, secondary immunodeficiency frequently underlies purulent-septic complications, including those of odontogenic origin, and may be associated with insufficient effectiveness of conventional therapy. Therefore, investigation of pathogenetic mechanisms underlying inflammatory diseases of the maxillofacial region, as well as the development of pathogenetically substantiated treatment modalities, remains a major challenge in surgical dentistry.

Materials and Methods

A comprehensive immunological assessment of patients with phlegmon of the floor of the mouth was performed during the course of treatment using the immunomodulatory agent Imunofan, approved for clinical use.Twenty-two patients received Imunofan as part of complex therapy at a dose of 50 µg intramuscularly once daily for 5 consecutive days. Clinical examination and treatment were carried out at the Department of Maxillofacial Surgery of the Emergency Hospital in Tashkent.Clinical evaluation followed a standard protocol and included patient interview, medical history assessment, physical examination (inspection, palpation, percussion), and additional diagnostic investigations (orthopantomography, complete blood count, urinalysis, and biochemical blood analysis when indicated).

Immunological investigations included:

- Immunophenotyping of lymphocyte subsets (CD3+, CD4+, CD8+, CD19+, CD95+, CD16+) using monoclonal antibodies;
- Determination of the immunoregulatory index (IRI; CD4/CD8 ratio);
- Measurement of serum immunoglobulin classes A, M, and G concentrations.

Results and Discussion

Comprehensive immunological evaluation of patients with phlegmon of the floor of the mouth revealed secondary cellular immunodeficiency. Specifically, patients demonstrated decreased absolute counts of CD3+ and CD4+ lymphocytes, increased levels of CD8+ and CD16+ cells, and a significant imbalance in the immunoregulatory index (CD4/CD8 ratio) due to a statistically significant reduction in T-helper cell populations (Fig. 1).

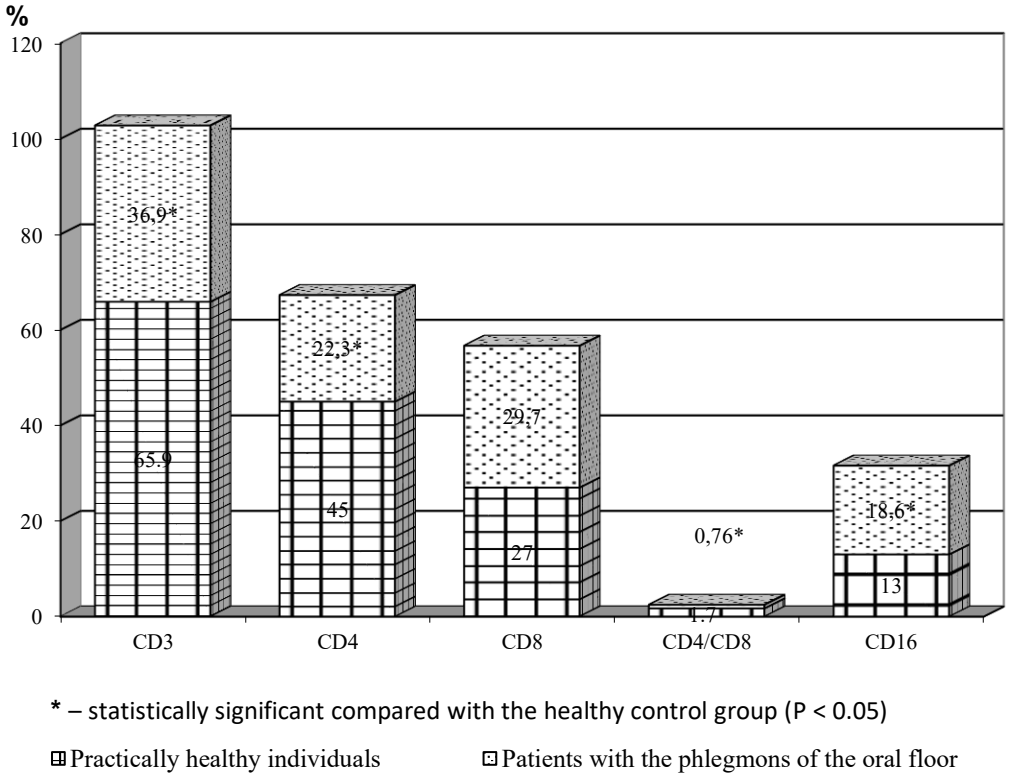

Figure 1. Cellular immunity status in patients with phlegmon of the floor of the mouth.

Evaluation of the humoral immune response in patients with phlegmon of the floor of the mouth revealed decreased serum levels of IgA and IgG, while IgM concentrations remained within reference values (Table 1).

Parameter	Patients	Healthy Controls	p
$CD19^+$, %	23,0± 1,8	10±2	0,01
$CD19^+$,10^9/L	750 ± 54,2	170±34	0,05
IgA mg%	1,45±0,13	1,9±0,15	0,05
IgG mg%	8,8±1,5	12,0±1,5	0,01
IgM mg%	1,2±0,06	1,2±0,1	ns

Table 1. Humoral immunity status in patients with phlegmons of the oral floor

Thus, characteristic patterns of the immune response were identified, manifested by deficiencies in both T-cell–mediated and humoral immunity, as well as progressive impairment of neurohumoral regulatory mechanisms. These findings provided the scientific rationale for the development of an immune correction strategy incorporating **Imunofan** into the conventional therapeutic regimen for patients with phlegmon of the floor of the mouth.

Comparative analysis of outcomes between the conventional treatment protocol and the proposed regimen demonstrated significant differences in efficacy. As early as the second postoperative day following surgical intervention and administration of Imunofan, patients in Group II reported marked clinical improvement compared with patients receiving standard therapy alone. They reported minimal postoperative pain, demonstrated greater physical activity, improved emotional status and communication, and noted overall improvement in well-being, mood, and appetite.

Statistical analysis revealed that normalization of body temperature occurred significantly earlier in the immunomodulatory treatment group (1.92 ± 0.10 days) compared with the conventional treatment group (3.88 ± 0.22 days) ($p < 0.001$).

The inclusion of Imunofan in the basic therapeutic regimen significantly reduced treatment duration in Group II patients. The mean duration of exudation was 2.66 ± 0.42 days in the immunomodulatory treatment group versus 4.11 ± 0.31 days in the conventional treatment group ($p < 0.05$) (Table 2).

In patients with phlegmon of the floor of the mouth receiving immunotherapy, resolution of pain and facial soft tissue edema was observed on average at 2.88 ± 0.39 and 3.67 ± 0.50 days, respectively, compared with 4.32 ± 0.37 and 4.89 ± 0.30 days in patients treated with conventional therapy ($p < 0.05$).

Parameter (days)	**Study Groups**	
	Group 1 (Conventional Therapy, n=53)	**Group 2 (Conventional Therapy + Immunofan, n=22)**
Pain syndrome	4,32±0,37	2,88±0,39*
Time to resolution of collateral edema	4,89±0,30	3,67±0,50*
Time to cessation of exudation	4,11±0,31	2,66±0,42*
Time to resolution of infiltrate	5,20±0,30	3,26±0,11*
Duration of disease	7,84±0,44	4,85±0,60**

Note: *p<0.05 – between groups, **p<0.001 – between groups.

Table 2. Comparative characteristics of reparative processes in purulent wounds in patients of the study groups.

Immunocorrection in combination with conventional therapy allowed for a relatively rapid and effective correction of secondary immunodeficiency. This was achieved through a quantitative increase in T-lymphocytes, primarily T-helper cells, with a corresponding rise in the immunoregulatory index in the study group, as well as through normalization of natural killer cell counts (see Table 3).

Regarding the subpopulations of immunoregulatory T-lymphocytes, the applied treatment method was characterized by a significant increase in the relative proportion of CD4+ cells. Specifically, the CD4+ lymphocyte count increased from 22.3 ± 3.2% to 34.1 ± 3.2% ($p<0.01$).

Parameter		**Patients with FOM Phlegmon Receiving Conventional Therapy + Immunofan (n=22)**		Control Group (n=25)
		Before treatment	After treatment with Immunofan	
T-lymphocytes (CD3+)	%	36,9±4,3*	49,7±4,2**	65,9±7,0
T-helper cells (CD4+)	%	22,3±3,2*	34,1±32**	45±6
Cytotoxic T-lymphocytes (CD8+)	%	29,7±2,7	22,7±3,1**	27±4,0
CD4/CD8 ratio (IRI)		0,76±0,01*	1,5±0,1*	1,7±0,1
NK cells (CD16)	%	18,6±2,4*	12,9±1,2*	13±6
B-lymphocytes (CD19+)	%	23±1,8*	19,7±10,8*	10,0±2

Note: *p<0.05 – compared to control, *p<0.05 – compared to pre-treatment values.

Table 3. Comparative characteristics of cellular immunity in patients with phlegmons of the oral floor receiving immunocorrection.

The immunomodulatory effect of Immunofan was manifested in its influence on the levels of major immunoglobulin classes. The amounts of IgA and IgG in patients with phlegmons of the oral floor after immunocorrection therapy reached normal values (see Table 4). Inclusion of Immunofan in the comprehensive therapy was associated with a significant increase in IgA concentration, which is one of the key factors of antimicrobial and antitoxic defense (from 1.45 ± 0.13% to 1.9 ± 0.17%, $p<0.05$), as well as a trend toward an increase in IgM and IgG levels, though these changes were not statistically significant.

Parameter	Patients with FOM Phlegmon (n=22)		Control (n=25)	P
	Before treatment	After treatment		
IgA g/L	1,45±0,13	1,9±0,17	1,9±0,15	P_{1-3}<0,05 P_{2-3} - ns P_{1-2}<0,05
IgM g/L	1,2±0,06	1,2±0,03	1,2±0,1	P_{1-3}- ns P_{2-3}- ns P_{1-2}- ns
IgG g/L	8,8±0,3	9,5±0,1	10,0±2	P_{1-3}<0,05 P_{2-3}- ns P_{1-2}<0,05

Table 4. Humoral immunity parameters in patients with phlegmons of the oral floor treated with Immunofan in combination with conventional therapy.

Assessment of neutrophil phagocytic activity in the groups of treated patients revealed reduced values of this immune factor at the beginning of therapy. Our results indicate that patients with phlegmons of the oral floor who received Immunofan as part of their treatment regimen demonstrated a significantly more pronounced improvement in neutrophil phagocytic activity compared to conventional therapy alone.

Conclusions

Thus, inclusion of the modern immunomodulator Immunofan in the standard treatment regimen for patients with phlegmons of the oral floor led to correction of immune function, which was accompanied by improvements in clinical and laboratory parameters and a reduction in disease duration. The effectiveness of Immunofan as part of combination therapy, along with its safety, accessibility, and absence of complications or adverse reactions, supports its broad use as part of comprehensive treatment strategies.

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CITATION

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