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COMPARISON OF THE EFFECTIVENESS OF THE USE OF SUBMENTAL ISLET FLAP AND RADIAL FOREARM FREE FLAP FOR TONGUE RECONSTRUCTION AFTER HEMIGLOSSECTOMY

Abstract. The paper presents a comparative analysis of the effectiveness of the use of local submental island flap (SIF) and radial forearm free flap (RFFF) to replace hemiglossectomy defects in cancer patients. It has been shown that RFFF remains the first option of choice for tongue reconstruction after hemiglossectomy. Although the use of RFFF to replace hemiglossectomy defects significantly improves the functional outcome and the quality of life of patients, it can increase the duration of surgery and the incidence of complications in the donor site compared with the use of SIF. There were no statistically significant differences in terms of inpatient treatment, incidence of complications after flap transplantation, complications in the recipient area in patients who underwent surgery to replace hemiglossectomy defects with SIF and RFFF. The 5-year overall and 5-year relapse-free survival rates of patients who underwent surgery to replace hemiglossectomy defects with SIF and RFFF were comparable, which indicates the oncological safety of using local SIF.

Keywords: hemiglossectomy defects, submental island flap, radial forearm free flap.

Introduction. Squamous cell carcinoma of the oral tongue is the most common subsite of all oral malignancies [1]. The patients with early oral tongue cancer require only surgery, while the patients with advanced cancer should complement surgery with subsequent radiation or concomitant chemoradiation therapy [2]. With the development of reconstructive surgery, the approaches to the surgical treatment of tongue malignancies have significantly changed. The primary closure of the tongue defect after hemiglossectomy was modified by reconstruction using local, regional, or free flaps. The restoration of the shape, volume, mobility of the tongue is of crucial importance for achieving the most optimal speech, swallowing, chewing functions and oral hygiene [3, 4].

For many years, radial forearm free flap (RFFF) has been considered as the best choice for plastic replacement of hemiglossectomy defects [3]. In recent years, anterolateral thigh flap for tongue reconstruction has been promoted. However, only a few studies have compared differences in the quality of life of patients with RFFF and anterolateral thigh flap. Thus, the results remain open to objection [5–7]. The use of local and regional flaps, as an alternative to free ones, has recently become more common for the plastic replacement of oral defects after oncologic resections. This is due to a deeper understanding of the features of blood supply to the flaps, the possibilities of preoperative and intraoperative imaging of the vascular pedicle and skin perforators, improvement of the flap harvest [8, 9].

The submental islet flap (SIF) was described by D. Martin et all in 1993 [10]. It has been recognized as a useful local flap for the reconstruction of the floor of mouth, tongue, cheeks, palate and soft facial tissues. The advantages of SIF inherent in RFFF include its reliability, fineness and pliability. It also allows a large surface area to be harvested. In addition, the use of SIF to replace postoperative oral defects avoids the microsurgical stage, and therefore shortens the duration of surgical intervention and achieves functional rehabilitation results comparable to RFFF [11–13].

In general, most studies have evaluated postoperative oral defects as a whole, rather than a specific hemiglossectomy defect, which makes it impossible to determine the benefits of a particular reconstructive technique. In addition, there were usually compared such parameters as the duration of surgery, the duration of hospitalization, postoperative complications, cost of treatment, functional outcome, but there is very few data on comparing the quality of life of patients.

Aim of study: comparison of the effectiveness of the use of SIF and RFFF for plastic replacement of hemiglossectomy defects.

Materials and methods. A retrospective comparative analysis of surgical interventions was performed in 62 patients with oral tongue cancer who underwent treatment at the Head and Neck Oncology Department of the National Cancer Institute between 2008 and 2013. The activities were carried out in accordance with the principles of the Declaration of

Helsinki. The study protocol was approved by the Ethics Committee of the National Cancer Institute.

The criteria by which patients were included in the study were oral tongue squamous cell carcinoma without prior radiotherapy or chemoradiation therapy; tongue reconstruction after hemiglossectomy using SIF or RFFF. The exclusion criteria included oral tongue non-squamous cell carcinoma; relapse of the disease after surgical treatment or radiation therapy; squamous cell carcinoma of the root of the tongue; previously performed segmental mandibulectomy.

All the patients underwent surgical treatment, which included hemiglossectomy, neck dissection and tongue reconstruction. Depending on the type of the flap used to replace the hemiglossectomy defect, the patients were divided into two groups. The SIF group included 32 patients, whereas the RFFF group was comprised of 30 patients. The tumor resection was performed with a margin of 1 cm from the visible borders of the tumor. All patients underwent supraomohyoid or comprehensive neck dissection - unilateral or bilateral, depending on the clinical status of the cervical lymph nodes. The SIF was used for the tongue reconstruction in the case of absence of clinical and radiological signs of extranodal spread in level I metastatic lymph nodes. Tumors were staged according to the International Union against Cancer (UICC) 2009 tumor, node, metastasis (TNM) classification. Adjuvant chemoradiation therapy was prescribed for histologically confirmed factors of high risk of recurrence (positive surgical margin where re-resection is not achievable or extracapsular extension in metastatic nodes). The patients with intermediate risk factors for relapse (pT3, pT4, lymphovascular invasion, perineural invasion, metastatic lesion of the cervical lymph nodes, which corresponds to pN2–3, metastatic lesion of the cervical lymph nodes of IV or V level) underwent adjuvant radiotherapy.

Socio-demographic characteristics (age, sex), clinical data (TNM, stage of the disease, type of neck dissection, marginal mandibulectomy, adjuvant treatment) were retrospectively collected from medical records and analyzed. There were compared such factors as duration of a surgical procedure, duration of the inpatient treatment, postoperative complications, functional status and quality of life of patients. The functional status assessment was conducted according to the Performance Status Scale for Head and Neck Cancer Patients (PSS-HN) in 6 months and 12 months after surgical treatment. The quality of life was assessed by the University of Washington Quality of Life questionnaire, version 4 (UW-QOL v4) in 6 months and 12 months after surgical treatment. The 5-year overall and the 5-year relapse-free survival rates between the groups were compared as well.

The statistical analysis of the results of the study was performed in the package MedCalc v. 18.11 (MedCalc Software bvba, Belgium, 1993-2018).

To represent the quantitative traits, mean value ($\overline{X}$) and its root-mean-square deviation (± SD) were calculated, whereas the representation of qualitative traits was achieved via the calculation of their frequency (%). The quantitative trait comparison involved the use of either Student's t-test (in the case of a normal distribution law) or the Wilcoxon signed-rank test (in the case of an abnormal distribution law). The Shapiro-Wilk test was used to check the appropriateness of distribution. The chi-squared test (with Yates's correction) was used to compare qualitative indicators. The Kaplan-Meier estimator served to analyze patient survival rate. To evaluate the clinical effect, its magnitude and 95% probable interval (95% CI) were calculated. The critical level of significance is assumed to be $\alpha_{кр.}$=0,05.

Results. A total of 62 patients participated in the study. 32 patients underwent tongue reconstruction using SIF, while 30 patients had reconstruction using RFFF. All 62 (100%) patients started adjuvant radiation or chemoradiation therapy within 6 weeks after the surgical stage of treatment. The characteristics of patients are presented in Table 1. There were no statistically significant differences in age, sex, TNM, stage of the disease, type of neck dissection, previously performed marginal mandibulectomy (p> 0.05 for all comparisons; Table 1).

Table 1

CHARACTERISTICS OF PATIENTS

Index		Submental flap (n=32)	Free radial flap (n=30)	Significance level of difference, *p*
Age, $\overline{X}$ ±SD, years		58.6±11.1	55.9±9.3	0.31
Sex, n (%)	F	5 (15.6)	3 (10)	0.78
	M	27 (84.4)	27 (90)	
T, n (%)	T2	6 (18.8)	6 (20)	0.85
	T3	26 (81.2)	24 (80)	
	T4	–	–	
N, n (%)	N0	13 (40.6)	10 (33.3)	0.44
	N1	7 (21.9)	11 (36.7)	
	N2	12 (37.5)	9 (30)	
	N3	–	–	
Stage, n (%)	III	20 (62.5)	21 (70)	0.72
	IV	12 (37.5)	9 (30)	
Neck dissection, n (%)	Supraomohyoid	13 (40.6)	10 (33.3)	0.74
	Comprehensive	19 (59.4)	20 (66.7)	

	Unilateral	17 (53.1)	13 (43.4)	0.61
	Bilateral	15 (46.9)	17 (56.6)	
Marginal mandibulectomy, n (%)	Yes	4 (12.5)	5 (16.7)	0.92
	No	28 (87.5)	25 (83.3)	
Adjuvant treatment, n (%)	Radiotherapy	24 (75)	21 (70)	0.88
	Chemoradiotherapy	8 (25)	9 (30)	

Having analyzed the duration of surgery, we determined that the average duration of surgery in patients of the SIF group was (6.17 ± 0.30) hours, whereas the average duration of surgery in patients of the RFFF group was (9.14 ± 0.54) hours, (p <0.001). The use of SIF compared to RFFF to replace hemiglossectomy defects reduced the duration of surgery by an average of 3.5 hours (95% BI 3.3 hours - 3.7 hours).

There were no statistically significant differences between the groups in terms of inpatient treatment. The average duration of inpatient treatment of patients in the SIF group was (12.7 ± 1.5) days, while the average duration of inpatient treatment in RFFF group was (13.2 ± 1.7) days (p = 0.24).

The analysis of complications after flap transplantation showed the following data. Only one patient of the SIF group developed total skin flap necrosis (3.1%) and two patients of the group had partial skin flap necrosis (6.3%). The patients of this group did not have any marginal flap necrosis. One patient (3.3%) of the RFFF group developed total skin flap necrosis, but no one of the patients in this group had partial or marginal skin flap necrosis. Thus, the incidence of complications after flap transplantation in the SIF group of patients was 9.4%, while the same indicator in patients of the RFFF group was 3.3%, (p = 0.65).

The complications in the recipient area are as follows. Both groups of patients did not have any postoperative wound dehiscence and the formation of orostomas. Two (6.3%) patients of the SIF group developed salivary fistula, one (3.1%) had a hematoma in the area of the postoperative wound and one (3.1%) had infectious complications. In the RFFF group, three (10%) patients developed a hematoma in the area of the postoperative wound and one (3.3%) had infectious complications. The patients of this group did not have any salivary fistula. In general, the incidence of complications in the recipient area in patients of the SIF group was 12.5%, while the same indicator in patients of the RFFF group was 13.3%, (p = 0.78).

The complications in the donor site are listed below. Two patients (6,3%) of the SIF group had wound dehiscence that did not require additional surgery. The patients did not have any other complications, including lesions of the marginal mandibular branch of the facial nerve. Three patients (10%) of the RFFF group developed partial skin graft necrosis, which was replaced by a defect of the donor area. Moreover, seven patients (23.3%) felt numbness of the fingers and tissues of the dorsal surface of the wrist, two patients (6.7%) had hypertrophic scars. Thus, the incidence of complications in the donor site in patients of the SIF group was 6.3%, while the same indicator in patients of the RFFF group reached 40%, (p = 0.004).

Functional status assessment was completed according to the PSS-HN scale. The indicator of the normalcy of diet in patients of the RFFF group in 6 months and in 12 months (p = 0.03 and p = 0.04, respectively) was significantly increased. There were not found any statistically significant differences in other indicators of the scale between the groups of patients in 6 months and 12 months after surgical treatment (p> 0.05 for all comparisons; Table 2).

Table 2

FUNCTIONAL STATUS OF PATIENTS IN 6 AND 12 MONTHS AFTER SURGICAL INTERVENTION.

Functional status according to the PSS-HN scale, %	$\overline{X}$ ±SD				Significance level of difference between groups, *p*	
	SIF group		RFFF group			
	in 6 months, (n=32)	in 12 months, (n=27)	in 6 months, (n=30)	in 12 months, (n=27)	in 6 months	in 12 months
Normalcy of diet	78.8±9.4	80.4±8.1	83.7±9.6	85.6±9.3	0.04	0.03
Public eating	77.3±14.7	77.8±16	80.8±14.2	81.5±13.1	0.35	0.36
Understandability of Speech	85.2±12.5	86.1±12.7	87.5±12.7	88.9±12.7	0.46	0.42

The quality of life of patients was evaluated using the UW-QOL v4 questionnaire. The RFFF group showed significantly higher indices of swallowing and chewing in 6 and 12 months (p = 0.045 and p = 0.04, respectively). There were not found any statistically significant differences in other indicators of the questionnaire between the groups of patients in 6 and 12 months after surgical treatment (p> 0.05 for all comparisons; Table 3).

Table 3

THE QUALITY OF LIFE OF PATIENTS IN 6 AND 12 MONTHS FOLLOWING THE SURGICAL INTERVENTION.

Quality of life according to the questionnaire UW-QOL v4, %	$\overline{X}$ ±SD				Significance level of difference between groups, p	
	SIF group		FRFF group			
	in 6 months, (n=32)	in 12 months, (n=27)	in 6 months, (n=30)	in 6 months, (n=27)	in 6 months	in 12 months.
Pain	89.1±12.6	89.8±12.5	90.8±12.3	92.6±11.6	0.57	0.4
Appearance	86.7±14.2	86.1±14.4	83.3±13.7	82.4±13.5	0.34	0.34
Activity	75.8±17.4	80.6±16	79.2±14.8	81.5±11.2	0.41	0.95
Recreation	80.5±16.5	85.2±14.3	82.5±13.4	81.5±11.2	0.6	0.24
Swallowing	72.5±18.3	69.6±23.6	81.7±11.2	83.3±12	0.04	0.03
Chewing	61.8±31.5	62.2±30.2	77.5±24.9	78.7±24.7	0.045	0.04
Speech	76.6±12.6	80±14.4	82±14.9	85.6±15.3	0.12	0.17
Shoulder function	72.2±22.7	70.7±21.3	75±20.5	69.6±20.5	0.61	0.81
Taste	65.9±14.8	72.6±17	62±16.3	74.4±10.9	0.31	0.81
Saliva production	53.8±20	61.1±16.9	50.3±22	64.1±14.5	0.56	0.49
Mood	72.8±20.1	76.9±16.9	70.8±21.9	75.9±17.7	0.71	0.84
Anxiety	75.6±20.3	78.5±17.3	74±19.9	76.3±16.2	0.75	0.63
Global Questions A	61.7±14.2	63±12.7	63.3±14.3	64.8±12.5	0.66	0.59
B	66.9±20.1	68.1±20.2	68.7±18.7	69.6±18.7	0.72	0.78
C	68.8±17.6	69.6±17.9	70.7±18	71.1±17.8	0.67	0.76

Note:
A – Health-related QOL compared to month before you had cancer?
B – Health-related QOL during the past 7 days?
C – Overall QOL during the past 7 days?

The 5-year overall survival rate of patients in the SIF group was 70.1 ± 8.2%, while the same indicator in the RFFF group was 70.0 ± 8.4%; 5-year relapse-free survival rate of patients in the SIF group was 67.5 ± 8.5%, while the same indicator in the RFFF group was 66.7 ± 8.6%. The comparison of the curves of overall and relapse-free survival rates between the groups did not show any statistically significant differences ($p = 0.83$ and $p = 0.93$, respectively). The curves of overall and relapse-free survival rates for groups of patients are presented in Figures 1, 2. (Fig.1,2)

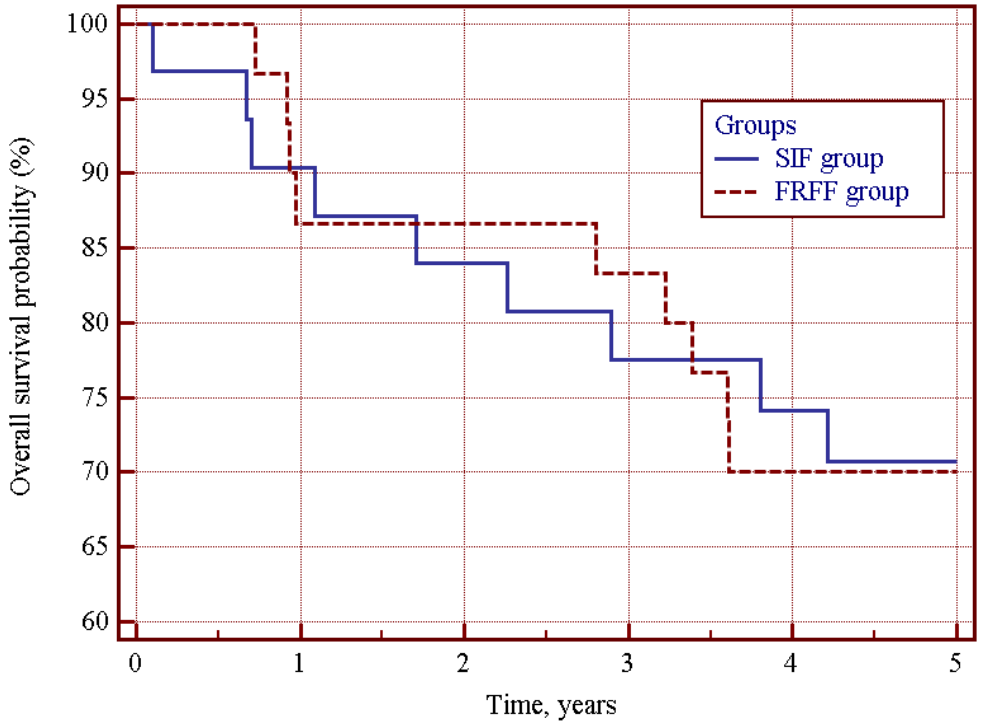

Fig. 1. Overall survival curves of SIF and RFFF patient groups

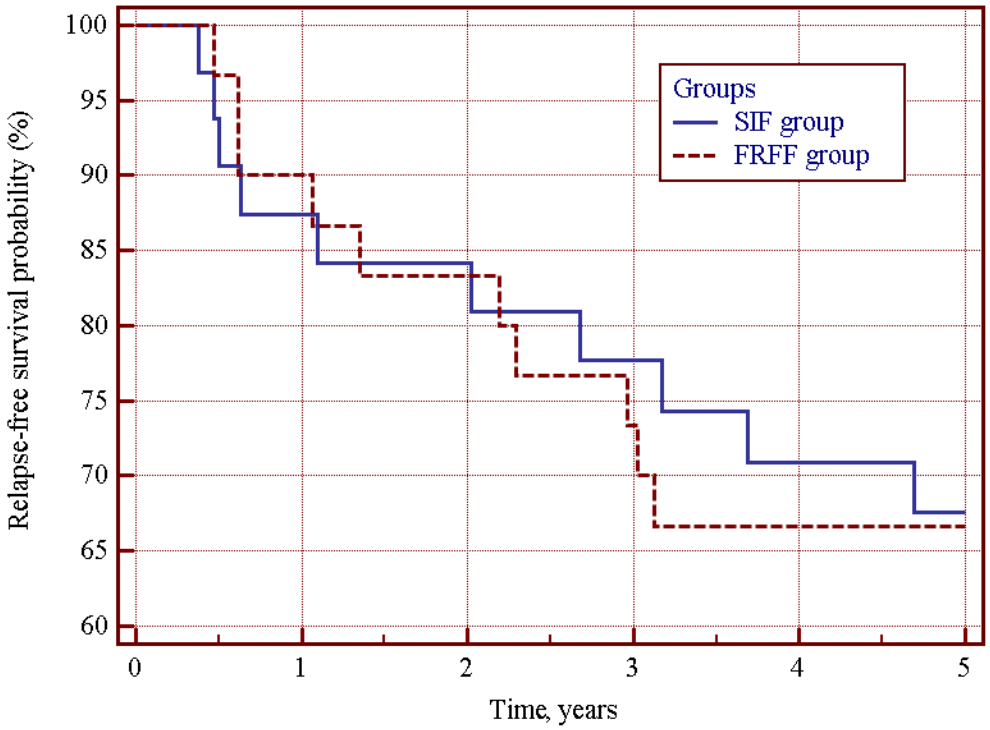

Fig. 2. Relapse-free survival curves of SIF and RFFF patient groups

Discussion. In recent years, there has been a renewed interest in local and regional flaps for the replacement of postoperative oral defects. J. Paydarfar and co-authors conducted the first direct comparison of the results of the use of SIF and RFFF to replace defects of the floor of the mouth and tongue. The authors note that the use of SIF provides a reduction in the duration of surgery and the duration of inpatient treatment with comparable functional speech and swallowing results [12]. D. Forner and co-authors conducted a comparative analysis of the results of the use of SIF against RFFF when replacing only hemiglossectomy defects, which showed that the use of SIF reduces the duration of surgery and reduces the cost of treatment at comparable terms of inpatient treatment [14]. P. Sittitrai and co-authors compared the complications

and functional outcome in patients with tongue cancer after reconstruction using SIF and RFFF. The study included patients with hemiglossectomy, subtotal glossectomy and near-total glossectomy defects. The reconstruction using RFFF resulted in a significantly higher incidence of donor site complications. The SIF group was characterized by a significantly shorter duration of surgery and duration of inpatient treatment. Speech and swallowing function, frequency of complications after flap transplantation, frequency of complications in the recipient area and locoregional control were comparable between the groups [15].

In our study we made a comparative analysis of the effectiveness of the use of SIF and RFFF for plastic replacement of only hemiglossectomy defects. It was found that the use of SIF contributes to the shorter duration of surgery. In addition, our analysis showed a significantly lower incidence of donor site complications when using SIF compared to RFFF. There were no statistically significant differences in terms of inpatient treatment, incidence of complications after flap transplantation, complications in the recipient site. Also, there were not found any statistically significant differences between the 5-year overall and the 5-year relapse-free survival rates between the groups, which indicates the oncological safety of SIF use. However, our study found that the use of RFFF to replace hemiglossectomy defects significantly improves the functional outcome of the normalcy of diet and the quality of life of patients in terms of swallowing and chewing compared to the use of SIF. As no comparisons of quality of patients' life with SIF and RFFF use have been made before, we are unable to compare our findings with other studies, so further accumulation of experience is needed to understand the benefits of a particular flap after hemiglossectomy.

Many studies have already noted partial or total skin graft necrosis, affected sensitivity of the tissues of the forearm and hand, tendon ruptures and cosmetic deformation of the donor site [16]. The techniques for the replacement of the defect of the donor site of the forearm aimed at reducing the frequency of complications and improving the cosmetic result require further improvement. Therefore, in our opinion, local SIF can be considered to replace hemiglossectomy defects in patients who are not candidates for microsurgical reconstruction using RFFF.

Conclusions. RFFF remains the first choice of option for tongue reconstruction after hemiglossectomy. The local SIF can be used to replace hemiglossectomy defects in patients who are not candidates for microsurgical reconstruction.

The use of RFFF to replace hemiglossectomy defects significantly improves the functional outcome and the quality of life of patients, but increases the duration of surgery and the incidence of complications in the donor site compared with the use of SIF.

There were not found any statistically significant differences in terms of inpatient treatment, incidence of complications after flap transplantation, complications in the recipient area in patients who had hemiglossectomy defects replaced by SIF and RFFF.

There were not found any significant differences between the 5-year overall and 5-year relapse-free survival rates of patients with hemiglossectomy defects replaced by SIF and RFFF, which indicates the oncologic safety of using local SIF.

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К ВОПРОСУ ОБ УТОЧНЕНИИ ТЕРМИНОВ "СИНДРОМ", "СИМПТОМОКОМПЛЕКС" И ДРУГИХ БАЗОВЫХ ТЕРМИНОВ В ПСИХИАТРИИ

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TO THE QUESTION OF REFINING THE TERMS "SYNDROME", "SYMPTOMOCOMPLEX" AND OTHER BASIC TERMS IN PSYCHIATRY

Annotation. The fuzziness of many definitions of basic medical terms and the ambiguity of their understanding in their practical mass use are considered. The next attempt was made to determine the basic terms of the symptom, phenomenon, syndrome and symptomatic complex as clearly and unambiguously as possible. One of the overly broad definitions of the symptomatic complex is replaced by the concept of “set of symptoms”. For the purpose of creating a one-to-one correspondence between the clinical diagnosis and its symptomatic justification, the concepts of the diagnostic complex of symptoms (diacomplex) and the preliminary diagnostic complex of symptoms (prediacomplex) are introduced and defined. The "extra" terms of the presindroma and presymptomatic complex are also proposed and explained.

Аннотация. Рассмотрена нечеткость множества определений базовых медицинских терминов и неоднозначность их понимания при их практическом массовом использовании. Выполнена очередная попытка как можно четче и однозначней определить базовые термины симптома, феномена, синдрома и симптомокомплекса. Одно из излишне широких определений симптомокомплекса заменено понятием "комплект симптомов". Для целей создания взаимно-однозначного соответствия между клиническим диагнозом и его симптоматическим обоснованием введены и определены понятия диагностического комплекса симптомов (диакомплекса) и предварительного диагностического комплекса симптомов (предиакомплекса). Также предложены и объяснены "лишние" термины пресиндрома и пресимптомокомплекса.

Key words: symptom, phenomenon, syndrome, symptomatic complex, set of symptoms, diacomplex, prediacomplex, predisyndrome, presymptomatic complex.

Ключевые слова: симптом, феномен, синдром, симптомокомплекс, комплект симптомов, диакомплекс, предиакомплекс, предисиндром, пресимптомокомплекс.

Введение

Занимаясь терминами, сначала воспользуемся приведенным в Википедии определением самого понятия "термин" (статья "Термин", URL: https://ru.wikipedia.org/wiki/Термин (дата обращения 30.08.2019)): "Те́рмин (греч. ὅρος, лат. *terminus* - предел, граница) - слово или словосочетание, являющееся названием некоторого понятия какой-нибудь области науки, техники, искусства и так далее. Термины служат специализирующими, точными [подчеркнуто нами – И.Д.] обозначениями, характерными для этой сферы предметов, явлений, их свойств и взаимодействий. В отличие от слов общей лексики, которые зачастую многозначны и несут эмоциональную окраску, термины в пределах сферы применения однозначны [подчеркнуто нами – И.Д.] и лишены экспрессии". Термин одним-двумя словами фиксирует явление или понятие, описываемое многими словами.

В медицинской и общей литературе содержатся десятки достаточно различных определений базовых медицинских терминов, таких как симптом, феномен, синдром и подобные медицинские термины. Именно множественность определений привела к тому, что во многих случаях