PharmacologyOnLine

Newsletter • 2021 • vol.3 • *pag* 67-77

EFFICACY OF COMBINED SURGERY AND AUTOVACCINE USE IN ANTI-RELAPSE TREATMENT OF PATIENTS WITH POLYPOUS RHINOSINUSITIS IN 10-YEARS FOLLOW-UP PERIOD

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Abstract

One of topical problem of modern otophynolaryngology is recurrent polypous rhinosinusitis (PRS). The aim of our study was to estimate the post-operational short- and long-term perspective in patients with chronic rhinosinusitis after combined surgical and autovaccine treatment.

Material and Methods. Three hundred patients with PRS aged 18-77 which have been hospitalized to the otorhinolaryngological clinic. Five groups have been formed 60 patients each depending on the treatment scheme.

Results. It was found that in the group of the first-ever detected patients, relapse for up to one year was established using autovaccine in 26.7% of the examined persons from 3rd treatment group (with the scheme according to which vaccination was performed, revaccination, then polipoemotomyodotomy), in 43.3% of patients in the 2nd treatment group (according to the vaccination scheme, then polypoethmoidotomy, then revaccination) and in 53.3% of patients in the treatment group using auto-vaccine after surgical intervention (polypoethmoidotomy followed by vaccination and revaccination). When using standard treatment, it was noted in 63.3% of patients and in the treatment of topical corticosteroid - 60.0%.

Conclusions. In determining the quality of the therapeutic effects of individual treatment regimens in the absence of recurrence, we determined the best effect of autovaccine before polypoethmoidotomy compared with the groups of patients receiving topical corticosteroid and standard therapy. The most significant treatment effects were in the group of first-identified patients compared with the group of recurring patients.

Keywords: *paranasal sinuses, recurrent polypous rhinosinusitis, autovaccine*

Introduction

One of topical problem of modern otophynolaryngology is recurrent polypous rhinosinusitis (PRS). The relapse of the disease is conditioned by a plenty of factors, including the etiology, pathogenesis and associated diseases, morphological changes in nasopharynx, method of treatment etc. [1, 2].

Multiple approaches have been applied to the treatment of PRS. One of the most progressive are related to use of immune mechanisms, while surgical approach remains to be the main method of PRS treatment [3, 4]. Never the less, the result is still not efficient enough, at least in terms of affected health-related quality of life, at most – of recurrent course and short period of remission [5].

In the majority of publications the studies of allergic aspect of PRS is discussed, while infectious component also plays a significant role in the pathophysiology of PRS [6, 7, 8].

As soon as in an anti-infection protection the main role is played by immunity, those methods which are aiming on modulation of immune response seem to be perspective to get an application into practice of anti-relapse treatment of PRS and deserve a clinical approbation [9].

The aim of our study was to estimate the post-operational short- and long-term perspective in patients with chronic rhinosinusitis after combined surgical and autovaccine treatment.

Methods

Three hundred patients with PRS aged 18-77 which have been hospitalized to the otorhinolaryngological clinic of the Kharkiv National Medical University, the communal healthcare institution "Regional Clinical Hospital - Center of urgent care and disaster medicine" of Kharkov during the 2010-2021 period years joined the study.

Five groups have been formed 60 patients each (30 first-diagnosed, 30 recurrent PRS) depending on the treatment scheme:

The 1st group of 60 patients (30 patients first identified and patients with relapsing disease) was treated in two stages: in the preoperative period - vaccination, after polypoethmoidotomy - revaccination on the background of standard therapy.

The 2nd included 60 patients (30 first-time and 30 re-treated) who underwent a course of bacterial autovaccine in the post-operative period (vaccination and revaccination) together with standard therapy. Revaccination was carried out 20–25 days after vaccination.

The 3rd group formed 60 patients (30 patients first identified and patients with relapsing disease) who were vaccinated (vaccination and revaccination) according to the author's method, then polypethmoidotomy was performed in 20-25 days after the course of revaccination on the background of standard therapy.

We investigated the 4th group of patients (60 persons: 30 patients for the first time and patients with relapsing disease), who, in addition to standard treatment, as a postoperative therapy received topical corticosteroid fluticasone propionate for 3 months with 2 inhalations 2 times per day, which is according to the modern standards.

Persons of the 5th group received a standard treatment in the postoperative period - 60 of them examined, of which 30 were initially and re-treated.

All groups were matched by anthropodemographic indexes and baseline clinical characteristics.

Standard parametric methods of medical statistics have been used [10]. The p-level critical value was 0.05.

Results

The duration of non-recurring period in the examined patients was established in comparison with the groups of the first-ever and re-treated patients according to different treatment regimens.

The quantity of relapses in 10-year follow-up has been evaluated (see Table 2).

Depending on the treatment regimen, in the groups of newly discovered and re-treated patients, the best effect was determined in case of use of autovaccine (its effect prior to

polypoethmoidotomy, 3rd treatment groups) compared with standard therapy or with an additional use of topical corticosteroid. The characteristics of the stability of the effect of no relapse achieved by us better distinguished in the group of patients, which began the very first treatment offered by us methods (the group of the first identified patients) compared with re-treated patients.

Regarding the scheme of intervention in the polyposis process in the group of newly discovered patients, the best results in achieving a steady therapeutic effect were obtained by us in the treatment of autovaccine compared with standard treatment and topical corticosteroid. Among the methods of administration of autovaccine the best effect is stated in its use before polypoethmoidotomy (vaccination and revaccination).

It was found that in the group of the first-ever detected patients, relapse for up to one year was established using autovaccine in 26.7% of the examined persons from 3rd treatment group (with the scheme according to which vaccination was performed, revaccination, then polipoemotomyodotomy), in 43.3% of patients in the 2nd treatment group (according to the vaccination scheme, then polypoethmoidotomy, then revaccination) and in 53.3% of patients in the treatment group using auto-vaccine after surgical intervention (polypoethmoidotomy followed by vaccination and revaccination). When using standard treatment, it was noted in 63.3% of patients and in the treatment of topical corticosteroid - 60.0%.

The best effect in this group of patients (a period without relapse up to one year) was established in cases when autovaccine was used exclusively for polyethomoidotomy (16.6% of the surveyed have noted less in comparison with the effect of autovaccine before and after surgical intervention, 26.6% of patients - from the effect of autovaccine after surgical intervention and 36.6% and 33.3% respectively, respectively, with standard therapy and topical corticosteroids), p <0.05.

Non-recurring period, which lasted from one year to three, was observed in the group of newly diagnosed patients: the use of autovaccine (vaccination, revaccination, polypoethmoidotomy) revealed the beginning of relapse in the period of one to three years in 53,3% of patients; in case of cheme with vaccination, polypoethmoidotomy, revaccination – in 33,3% of patients; at autovaccination after polypoethmoidotomy (polypoethmoidotomy, vaccination, revaccination) – in 30.0% patients. In standard treatment and use of topical corticosteroid, the occurrence of relapse in this period was noted at 33.3% in both cases.

Thus, similarly to the group of relapse in up to one year, the most effective in the group of patients, where the period without recurrence lasted from one to three years was autovaccine, specifically in case if used after surgical intervention (it was noted in 23,3% of patients less than the effect of autovaccine to surgical intervention, in 3,3% of patients with the effect of autovaccine before and after polypoethmoidotomy, 3.3% in both cases, in accordance with standard treatment and the use of topical corticosteroids), differences are reliable at p<0,05.

In the case of first-time, non-recurring patients ащк over three years, the best effect was achieved with autovaccine (most of all before surgery) compared with standard treatment and topical corticosteroid therapy. Thus, 23.3% (for the scheme of vaccination, revaccination and surgery), 23.3% (for vaccination, surgery, revaccination) were found in the group of newly diagnosed patients, those who had a non-recurring period of three or more years, 16,7% (by the the schemes of surgery, vaccination, revaccination), 3.3% (for standard treatment) and 10.0% (for topical corticosteroids).

The obtained data indicate the best therapeutic effect of autovaccination, carried out specifically before and after polypoethmoidotomy.

It was found that in the first-time patients treated with autovaccine before and after surgical intervention (by the scheme of vaccination, polypoethmoidotomy, revaccination), the achieved effect in the direction of non-recurrence of more than three years was better in 6.6% of patients (compared with treatment with a vaccine prior to surgery), 2.2% (compared with vaccination after surgery) and in 20.0% and 16.6% of patients

compared with standard treatment and topical corticosteroid, accordingly.

The same tendency to stabilize the achieved therapeutic effect was observed in the group of re-treated patients: the best effect was in case of use of autovaccine (before polypoethmoidotomy) compared with the standard method and topical corticosteroid. Thus, in re-treated patients, a non-recurring period of up to one year lasted for 43.3% of patients using autovaccine before surgical intervention; 36.7% - in case of vaccination before and after polypoethmoidotomy; and 40.0% at autovaccination after polypoethmoidotomy; whereas standard treatment revealed relapse of polyps to in less than one year in 83.3% of the subjects; in treatment with topical corticosteroid – in 73.3%.

The distribution of recurrent patients with a return of polyposis during the period of one to three years in the treatment groups was as follows: at autovaccination before surgical intervention, the onset of relapse was observed in 16.7% of the subjects, as well as in autovaccination before and after polypoethmoidotomy, when autovaccine was injected after surgical intervention and at standard treatment, same as in case of topical corticosteroid use - at the level of 23,3%.

Thus, in terms of polyposis relapse in the period of one to three years after treatment, use of autovaccine is more effective.

Discussion

Among the re-treated patients, who have established a non-recurring period of more than three years, the best effect we have determined is also with autovaccination (most of all when using the vaccine before polypoethmoidotomy). After using autovaccine at the pre-surgical stage, 16.7% of the subjects did not have a return of polyposis for more than three years; before and after surgical stage – at 10.3%; and in patients with autovaccination at the post-surgical stage – 6.7%. However, in patients treated standardly, there was no remission of three years or more, and among re-treated with topical corticosteroid they accounted in only 3.3%. Thus, it should be noted that the best remission for three years and more in the group of re-treated patients among patients receiving autovaccine at the pre-surgical stage (it was found to be 6.7% higher compared with autovaccination at the pre- and post-surgical stages, 10.0% more - with vaccination after polypoethmoidotomy and by 16,7% and 13,4% - in comparison with standard therapy and the use of topical corticosteroid).

In the treatment with autovaccine before polypoethmoidotomy, the best effect was observed in the group of newly diagnosed patients compared with relapsing patients (the number of patients with recurrence during the year was lower by 40.0% for the first-ever detected patients due to an increase in the number of patients with recurrence within one to three years (by 36,6%, $p < 0,05$) and a non-recurring period of three years or more (by 3,3%, $p < 0,05$).

The same pattern was observed in other groups: among the newly diagnosed patients in comparison with recurrent patients treated with autovaccine before and after polypoethmoidotomy (with the scheme of vaccination, surgery, revaccination), a lower percentage of patients with relapse in one year (30.0% ; $p<0.05$) due to their greater number in groups with a relapse period of one to three years (by 16.6%, $p<0.05$) and with a non-recurring period of more than three years (by 13.0%; $p<0.05$). In the newly discovered subjects treated with autovaccine after polypoethmoidotomy in a relapse group up to one year their number was less than 23.4%; $p<0.05$; in the relapse group one to three years - by 13.3%; $p<0.05$; and without relapse more than three years - greater by 10.0%; $p<0.05$.

The effect of standard therapy and topical corticosteroids also established better efficacy in newly discovered patients: relapses to the year were less than 20.0%; $p<0.05$ (standard treatment) and 13.3%; $p<0.05$ (topical corticosteroid); the recurrence period from year to year was more common in the group of newly diagnosed patients (by 16.6%, $p<0.05$ - standard therapy and 10.0%, $p<0.05$ - topical corticosteroid).

The anamnestic information about the performed surgical interventions concerning the relapse of PRS for 10 years has been analyzed (Table 2). In a number of cases, patients had low rates of polyposis prevalence, which allowed them to dispense for a long time without surgical intervention.

In the 1st treatment group, both primary and re-treated patients were dominated by patients with one surgical intervention compared with the number of persons who had 3 or 4 and more operations (p<0.01).

In the 2nd treatment group among the first-ever identified patients, the probable difference was found between the number of patients who were operated once and three times (p<0.01) and four or more times (p<0.01) twice (p<0.05). Among the re-treated differences, the difference was established for those who operated four or more times (p<0.01) or three times (p<0.05).

In the 3rd treatment group, there were more likely to be patients who underwent operation no more than once compared with any other contributor to the frequency of operations (p<0.01) and no detected persons who had surgery 4 times or more than initially diagnosed and repeated patients.

In the 4th treatment group, the trend is completely the same as described in 2nd group.

The situation in the 5th treatment group was fundamentally different: patients with one-time surgical intervention were the least. Among the newly diagnosed patients, this indicator was significantly different in relation to the number of people who were operated three times (p<0.01) and twice (p<0.05). Among the re-treated number of surgically disposable patients, it was probably lower in relation to any other contingent (p<0.01).

The quantiry of performed surgical interventions was characterized (Table 3).

In all groups, among patients who were initially treated, patients with only PET were significantly different in wuantity compared to the of subjects with PET together with maxillary sinusotomy (p<0,05), frontotomy, and sphenotomy (p<0,01). Among the re-treated patients, this difference was not established in 1st and 2nd treatment groups for PET with maxillary sinusotomy. All these methods may be accompanied with other types of treatment in childhood [11, 12, 13, 14] or adults and predict the development of antibiotic resistance [15].

Perspectives of our further investigations are related to wider clinical approbation of bacterial autovaccine use in complex treatment of PRS maybe in cases of its combinations with other disorders in the orofacial zone [16, 17] or other organs and systems [18].

The effectiveness of the treatment can be displayed by new promising diagnostic procedures [19, 20, 21] in different cohorts of patient maybe with presence 30f comorbidities [22, 23, 24], levels of hormones [25] or immune response [26, 27, 28], experience of previous antibiotic administration [29-31].

Conclusions

1. Thus, as a result of the 10-years follow-up period in patients with PRS after surgical treatment the tendencies of the disease's course have been revealed.

2. In determining the quality of the therapeutic effects of individual treatment regimens in the absence of recurrence, we determined the best effect of autovaccine before polypoethmoidotomy compared with the groups of patients receiving topical corticosteroid and standard therapy. The most significant treatment effects were in the group of first-identified patients compared with the group of recurring patients.

3. The therapeutic efficacy of complex anti-relapse therapy including autovaccination and surgery is maximal in first-treated patients comparing with recurrent cases.

4. The comparison of effect of the treatment received on the duration of the non-recurring period for the first time detected cases and re-treated patients, we can state that it is better to start the treatment we offer with autovaccine together with polipoemotomyodotomy immediately after diagnosis of the disease (in particular, as proved by us above, it is better to carry out autovaccination before the start of the surgical intervention).

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Table 1. Frequency characteristics of polyposis recurrence in patients with PRS in 10-year dynamics

Parameters / Patients groups			First-diagnosed patients					Recurrent patients				
			relapses quantity in 10 years				Total	relapses quantity in 10 years				Total
			1	2	3	4		1	2	3	4	
Patients quantity	1st	Abs.	15	11	1	–	27	12	12	3	2	29
		%	55.6#	40.7#	3.7*	–*	100.0	41.4#	41.4#	10.3*	6.9*	100.0
	2nd	Abs.	16	9	–	–	25	11	10	4	1	26
		%	64.0#	36.0*#	–*	–*	100.0	42.3#	38.5#	15.4*	3.8*	100.0
	3rd	Abs.	21	5	3	–	29	19	6	2	–	27
		%	72.4	17.2*	10.3*	–*	100.0	70.40#	22.2*#	7.4*	–*	100.0
	4th	Abs.	14	7	4	1	26	12	8	4	–	24
		%	53.8#	26.9*	15.4*	3.8*	100.0	50.0#	33.3	16.7*	–*	100.0
	5th	Abs.	1	11	12	5	29	–	8	12	6	26
		%	3.4	37.9*	41.4*	17.2*	100.0	–	30.8*	46.2*	23.1*	100.0

Note. * — difference from group with 1 relapse is reliable, $p<0.05$; # — difference from group with 4 and more relapses is reliable, $p<0.05$; † — difference from value in 1st group is reliable, $p<0.05$; ‡ — difference from value in 2st group is reliable, $p<0.05$; § — difference from value in 3rd group is reliable, $p<0.05$; ‖ — difference from value in 4th group is reliable, $p<0.05$.

Table 2. The frequency of surgical interventions for the relapse of polyposis for 10 years

Parameters / Patients groups			First-diagnosed patients						Recurrent patients					
			quantity of operations					Total	quantity of operations					Total
			0	1	2	3	4		0	1	2	3	4	
Patients quantity	1st	Abs.	–	16	10	1	–	27	–	13	11	4	1	29
		%	–	59.3#§	37.0#	3.7*	–*§	100.0	–	44.8#	37.9#	13.8*	3.4*§	100.0
	2nd	Abs.	1	15	9	–	–	25	–	11	11	3	1	26
		%	4.0	60.0#§	36.0*#	–*	–*§	100.0	–	42.3#	42.3#	11.5*	3.8*§	100.0
	3rd	Abs.	3	18	6	2	–	29	1	18	7	1	–	27
		%	10.3	62.1#†‡⁋	20.7*#	6.9*	–*‡	100.0	3.7	66.7#	25.9*#	3.7*#	–*	100.0
	4th	Abs.	2	14	6	3	1	26	1	11	8	4	–	24
		%	7.7	53.8#§	20.7*#	11.5*#	3.8*§	100.0	4.2	45.8#	33.3#	16.7*	–*§	100.0
	5th	Abs.	1	2	9	12	5	29	–	2	8	11	6	27
		%	3.4	6.9†‡§⁋	31.0*	41.4*#†‡§⁋	17.2†‡§⁋	100.0	–	7.4#†‡§⁋	29.6*	40.7*†‡§⁋	22.2*†‡§⁋	100.0

Note. * — difference from group with 1 operation is reliable, $p<0.05$; # — difference from group with 4 and more operations is reliable, $p<0.05$; † — difference from value in 1st group is reliable, $p<0.05$; ‡ — difference from value in 2st group is reliable, $p<0.05$; § — difference from value in 3rd group is reliable, $p<0.05$; ⁋ — difference from value in 4th group is reliable, $p<0.05$.

Table 3. Quantity of surgical interventions for the relapse of polyposis for 10 years

Parameters / Patients groups			Operations quantity in first-diagnosed patients					Operations quantity in recurrent patients				
			Operations				Total	Operations				Total
			PET	PET, maxillary sinusotomy	PET, frontotomy	PET, sphenotomy		PET	PET, maxillary sinusotomy	PET, frontotomy	PET, sphenotomy	
Operations quantity	1st	Abs.	24	13	1	1	39	23	25	1	2	51
		%	61.5#§‖	33.3*#§‖	2.6*	2.6*	100.0	45.1#§‖	49.0#§‖	2.0*	3.9*	100.0
	2nd	Abs.	22	10	1	0	33	23	21	1	1	46
		%	66.7#§‖	30.3*#§‖	3.0*	–*	100.0	50.0#§‖	45.7#§‖	2.2*	2.2*	100.0
	3rd	Abs.	33	3	0	0	36	33	2	0	0	35
		%	91.7#†	8.7*#†	–*	–*	100.0	94.3#†	5.7*#†	–*	–*	100.0
	4th	Abs.	36	3	0	0	39	35	2	1	1	39
		%	92.3#†	7.7*#†	–*	–*	100.0	89.7#†	5.1*#†	2.6*	2.6*	100.0
	5th	Abs.	54	14	3	5	76	55	13	3	4	75
		%	71.1#§	18.4*#†§‖	3.9*§‖	6.6*†§‖	100.0	73.3#†§‖	17.3*#†§‖	4.0*§	5.3*§	100.0

Note: PET — polypoethmoidotomy; * — difference from group with only PET is reliable, $p<0.05$; # — difference from group with PET and sphenotomy is reliable, $p<0.05$; † — difference from value in 1st group is reliable, $p<0.05$; ‡ — difference from value in 2st group is reliable, $p<0.05$; § — difference from value in 3rd group is reliable, $p<0.05$; ‖ — difference from value in 4th group is reliable, $p<0.05$.