

MATERIAL AND METHODS

Clinical investigations and observations were carried out in two groups of patients treated in the years 1991–1997 in the Lublin Otolaryngology Department and in the Laryngologic Research–Consulting Centre of the University School of Medicine in Iwonicz Zdrój. The study group comprised 450 people aged 21–76 years. Because of incomplete follow-up observations 93 of them were excluded from study groups.

The clinical group (I) of 194 patients aged 21–76 years, mean age 45.2 years operated on with the Kleinsasser's method for primarily chronic inflammation of laryngeal mucosa with hyperplastic reaction, especially within the vocal folds in the form of limited foci of pachydermia, leukoplakia, hyperkeratosis, granulomas or laryngeal nodules.

The control group (II) of 165 subjects aged 28–76 years, mean age 47.5 years, suffering from primarily chronic simple inflammation of nasal, pharyngeal or laryngeal mucosa without morphologic features of mucosal hyperplasia.

In both groups (I and II) the following subjects were excluded from the study: those with diagnosed other coexisting diseases, e.g. in neighbouring organs or general internal diseases, which could negatively affect the clinical condition of patients and especially their general immunity, subjects with rudimentary inflammations with a specific bacterial aetiology.

The performed clinical investigations and observations and stages of treatment of the examined groups of patients comprised subsequently: 1) Planning of the technique and carrying out (in patients of group I) microsurgery of the larynx with the Kleinsasser's method (5, 6, 7, 14), 2) Referring patients from both groups examined at the same time for treatment in Iwonicz Zdrój in order to compare the effect of balneotherapy in identical conditions,

3) Performing follow-up examinations in patients after sanatorium treatment at the following time intervals: up to 2–4 weeks (1st examination), 2–4 months (2nd examination), 6–7 month (3rd exam.) and 10–12 months after balneotherapy (4th exam.), 4) Performing foniatric examinations and possibly carrying out foniatric rehabilitation both before and after balneotherapy in some patients (especially in group I) in whom disturbances of voice emission persisted.

Balneotherapy in the Iwonicz Center was carried out in patients from both groups in identical conditions. Every day individual inhalations with mineral water Elin 7 at 36°C were used without dilutions for 20 days. Ultrasound apparatus by Thomex L–2 were used which produced thick fog of 1–4 u break-up.

The used mineral water came from the spring Elin 7 in Iwonicz Zdrój. This is an 0.87% chloride–sodium–bicarbonate–iodide water. It contains anions of Cl (3543.3 mg/l), HCO₃ (2024.10 mg/l), Na (2950 mg/l), J (3.27 mg/l), Br (4.20 mg/l). Besides the above mentioned ones the water also contains, in smaller quantities, ions of calcium, potassium and sulphates. The general mineralisation of the water amounts to 8729.39 mg/l. This is isotonic water with pH 7.45 and temperature 12°C. Its effect is mainly manifested by dissolution of mucous microplugs in the eductive ducts of mucosal glands, liquefaction of secretion which affects the decrease or subsidence of the sensation of dryness.

In the clinical assessment of the local therapeutic effect there was taken into account persistence, decrease or complete subsidence of morphologic features of mucosal, catarrhal inflammation. Attention was also paid to the character and intensity of subjective complaints from the pharynx and larynx as well as the speech function. As a very good therapeutic result there was assumed complete regression of subjective complaints, hoarseness and subsidence or considerable decrease of morphologic

features of mucosal inflammation. As a good result there was assumed a considerable decrease of subjective complaints and morphologic features of local tissue inflammation as well as subsidence of permanent hoarseness of voice. A very good and good therapeutic effects were classified as favourable results compared with unfavourable (unsatisfactory) results. As an unsatisfactory result there was regarded persistence without changes of the above mentioned subjective complaints, hoarseness and objective features of mucosal inflammation during and after treatment, and in patients from group I also a relapse of hypertrophic changes within laryngeal mucosa found in follow-up examinations after surgery.

The obtained results were statistically analysed (11). Statistical significance of differences between the frequency of favourable and unfavourable results was tested with chi square test. 5% was assumed as the risk of conclusion error.

RESULTS AND DISCUSSION

The frequency of favourable and unfavourable treatment results in patients from the experimental (clinical) (I) and control group (II) in the consecutive periods of observation is listed in Table 1.

Table 1. The frequency of occurrence of favourable and unfavourable treatment results in the clinical group (I) and control group (II) in consecutive observation periods

Examined group	Assessment of clinical effect	Consecutive follow-up examinations							
		I b.k		II b.k.		III b.k.		IV b.k.	
		L	%	L	%	L	%	L	%
Clinical (I) 194 patients (100%)	Favourable	166	85.6	172	88.7	149	76.8	131	67.5
	Unfavourable	28	14.4	22	11.3	45	23.2	63	32.5
Significance of differences	(p)	< 0.01		< 0.01		< 0.01		< 0.01	
Control (II) 165 patients (100%)	Favourable	151	91.5	145	87.9	117	70.9	89	53.9
	Unfavourable	14	8.5	20	12.1	48	29.1	76	46.1
Significance of differences	(p)	< 0.01		< 0.01		< 0.01		< 0.01	

Favourable treatment results in group I in all follow-ups during observation were statistically highly significantly more frequent than unfavourable ones ($p < 0.01$). In group II favourable results were statistically highly significantly more frequent than unfavourable ones in the 1st, 2nd and 3rd follow-up examination ($p < 0.01$) and significantly more frequent in the 4th examination ($p < 0.05$).

The dynamics of changes in the assessment of local therapeutic effect as for favourable results (F) and unfavourable ones (UF) in the examined groups of patients in subsequent periods of observation as well as depending on the clinical group of patients can be seen in Table 2.

Table 2. The dynamics of changes in the assessment of the local therapeutic effect for favourable and unfavourable results in the examined patients

Results	Examined group	Consecutive follow-up examinations					
		II b.k.		III b.k.		IV b.k.	
		L	%	L	%	L	%
Favourable	Clinical (I) 194 patients	+6	.1	-17	8.8	-35	18.0
	significance (p)					< 0.01	
	Control (II) 165 patients	-6	.6	-34	20.6	-62	37.6
	significance (p)			< 0.01		< 0.01	
Unfavourable	Clinical (I) 194 patients	-6	.1	+17	8.8	+35	18.0
	Control (II) 165 patients	+6	3.6	+34	20.6	+62	37.6
	significance (p)			< 0.01		< 0.01	

A considerable decrease of favourable results in group I was only observed in the 4th follow-up examination ($p < 0.01$). However, in group II a significant decrease of such results was found even in the 3rd and then 4th examination ($p < 0.01$). The subjects examined after treatment also revealed, starting from the 3rd follow-up and the next one, a statistically significantly greater decrease of favourable results in group II than in group I (3rd examination $p < 0.01$; 4th examination $p < 0.01$).

Both compared groups of patients: group I – clinical and group II – control comprised a similar composition of patients as for the sex and age, percentage of smokers and persons exposed to negative factors in their working environment (selection of material). Considering the above remarks the groups should be assumed as comparable in the performed studies assessing the clinical effect obtained in identical balneotherapeutic conditions.

In group I significantly better results of treating laryngeal inflammations were obtained than in group II (control), which indicates a considerably greater efficacy of the combined therapeutic method – microsurgery and balneotherapy – used in patients from group I.

The applied operative technique (microsurgical) lets precisely remove pathological foci of mucosal lesions without damage to the neighbouring tissue structures which remarkably shortens the period of local healing and facilitates the regeneration of the respiratory epithelium from the neighbouring surrounding.

Own clinical observations (14) and findings of other authors (1, 12, 15, 16, 18) however, have shown that in patients operated on for chronic, hyperplastic laryngeal inflammation, inflammation of the mucosa often persists in the postoperative period and the recurrence of hyperplastic reactions is not an infrequent phenomenon and usually occurs within the first year after surgery. While using

inhalation treatment in these patients it was observed that Na⁺ and Cl⁻ ions contained in Elin 7 water affect the increase of secretion from mucosal microglands favouring dilution and liquefaction of pathologic secretions. Iodine content in the mineral water used, apart from systemic therapeutic properties of this element, exhibits a local effect by increasing the secretory function of mucous glands which is clinically manifested by a decrease or subsidence of the sensation of dryness. A favourable effect on the condition of the mucosa of the used saline inhalations was also observed by other authors (8, 9, 10, 13). Rafiński et al. (13) emphasise that they observed a favourable effect of the used saline inhalations on the condition of bacterial and *Candida* flora in the pharynx – a decrease in the number of pathogenic strains and increase in saprophytic micrococci which helped normalise bacterial flora on the mucous membrane.

In the auxillary treatment administered to patients from both clinical groups in the Iwonicz Center, apart from inhalations, there was very often used physical treatment with radiotherapy. From among definite indications general irradiations with a sun lamp or quartz lamp were applied.

CONCLUSIONS

1. The performed observations have confirmed the clinical therapeutic value of the Iwonicz mineral water Elin 7 used in the inhalation treatment of chronic inflammatory conditions of nasal, pharyngeal and laryngeal mucosa.

2. The observations have shown that the combined procedure – microsurgery and balneotherapy – can be an effective method of treatment of some hyperplastic inflammatory diseases of the larynx after their operative treatment with the Kleinsasser's method, especially in obtaining favourable distant effects.

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STRESZCZENIE

Celem przeprowadzonych badań była ocena klinicznej wartości zastosowania skojarzonej metody mikrochirurgii i balneoterapii krtani w leczeniu i zapobieganiu nawrotom ograniczonych zmian hyperplastycznych w błonie śluzowej krtani.

Przebadano dwie grupy chorych diagnozowanych i leczonych w latach 1991–1997 w Lubelskiej Klinice Laryngologii i Laryngologicznym Ośrodku Badawczo-Konsultacyjnym w Iwoniczu Zdroju. Badania przeprowadzono w I grupie klinicznej – 194 chorych, u których z określonych wskazań wykonano operacje mikrochirurgiczne w krtani, oraz w II grupie kontrolnej – 165 osób, chorujących na przewlekły prosty nieżyt błon śluzowych gardła i krtani bez cech przerostu, nieoperowanych. Obie grupy leczono balneoklimatycznie.

Leczenie inhalacyjne przeprowadzono metodą indywidualną, stosując aparaty inhalacyjne firmy Thomex L-2. Wykonywano mgłę o dużej gęstości i rozdrobnieniu rzędu 1–4, inhalując chorych izotoniczną solanką iwonicką Elin 7.

Przyjęto i stosowano ujednoczone kryteria oceny bezpośredniego i odległego efektu (w badaniach kontrolnych) leczniczego dla całej grupy chorych w okresie badanym. Uzyskane wyniki badań poddano analizie statystycznej.