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THE EFFECT OF IPRIFLAVON (YAMBOLAP) ON THE OTOSCLEROTIC PROCESS

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According to statistics otosclerosis is a disease effecting millions. The essence of the pathological process is in the reconstruction taking place in the labyrinthine capsule. Through the process the footplate of the stapes becomes fixed in the oval window and as a result of this conductive hearing loss occurs which is continually increasing and in its advanced stage perceptual disorder, the damage of the Corti-organ develops. Vestibular disorders may be present, too and the only symptom is perceptive hearing damage in the cochlear appearance of the disease.

The aetiology of otosclerosis is not exactly known yet. The results of the latest examinations suggest that the pathogenetic base for the disease is the imbalance in the different enzymatic processes.

Presently, according to examinations the 7-isopropoxy-isoflavon, or by its manufacturing name Yambolap, /produced by Chinoïn/ has a favourable effect on the mitochondrial metabolism at the subcellular level. The cell metabolism requires lower oxygen consumption due to Ipriflavon treatment and because of this remineralization becomes more effective.

Based on the present knowledge of biology, biochemistry and pharmacology, it may be supposed that Ipriflavon has a favourable effect /beside its other effects/ on every osteopathy which is in some way connected with disorders of mineralization or remodelling.

We have tested the preparation in the treatment of otosclerosis at the Ear-, Nose- and Throat Clinic of Szeged University of Medical Sciences.

Case record and method

Examinations were carried out on 53 otosclerotic patients of both sexes who were otherwise found healthy.

Forty-three patients were treated by Yambolap with the dosage of 3x200 mg per day.

Stapedectomy was performed on the patients within 3 months, as a general rule, following the treatment.

We have examined the stapes of 20 patients histologically.

Atomic absorption tests were done on auditory ossicles of 23 patients for Ca-, Zn-, and Cu-contents. For the purpose of comparison we determined components of the cortical bone-samples for the same patient.

Ten patients received placebo.

All patients had thorough otorhinolaryngological and audiological examinations, complete blood-counts, and urinalysis.

These examinations were repeated after a period of 1 week, 1 month, 3 months and 6 months following the beginning of treatment.

Results were compared to findings of untreated otosclerotic patients who were given placebo.

Results - Discussion

We found Schwartz-phenomenon in 11 cases which disappeared in 6 cases after 3 months of treatment by Yambolap.

At the evaluation of the subjective complaints the most remarkable observation was the effectiveness of Yambolap upon tinnitus.

From the 43 patients treated with Yambolap 40 reported on a certain degree of tinnitus. After 3 months of treatment by Yambolap tinnitus in 12 patients /30%/ disappeared, tinnitus in 16 patients /40%/ decreased, complaints of 12 patients /30%/ were unchanged.

From the 10 patients taking placebo, the originally slight tinnitus in 1 patient disappeared, tinnitus in 1 patient decreased, complaints of 8 patients were unchanged.

Changes in clear-tone hearing threshold

After 3 months of the treatment the hearing of 28 patients /65%/ did not change or improvement was shown only within the 5 dB limit of error, 12 patients /28%/ had a 10 dB or more improvement in hearing. The hearing of 3 patients /7%/ deteriorated under the course of treatment.

The hearing of patients belonging to the control group had not improved, in fact, the hearing of 3 patients became worse under the time of examinations.

Operative findings

Operations were performed more easily on treated than on untreated patients. Bleeding has remained under the usual level during operations. In most of the treated cases the stapes could be removed intact while in cases of untreated patients the superstructure was generally broken off and the footplate of the stapes could be lifted out only in fragments.

Histological examinations

Compared to untreated cases it seemed that the number of osteoclasts decreased in the otosclerotic focuses. The mesenchymal cells became osteoblasts, then osteocytes. Calcification occurred at the perivascular regions and at the perimeter /edge/ of the focuses. Therefore, Ipriflavon /Yambolap/ promotes the deposition of lime salts in the fibrous interstitial tissue of the focuses. Probably, the healing of the otosclerotic focuses was induced by a primary metaplastic osteogenesis, also preventing the progress of the disease.

Atomic absorption tests

The Ca-content of the cortical bone has not changed by the treatment.

The Ca-content of the untreated otosclerotic stapes was usually lower than in the cortical bones serving as standard control. The Ca-content of the auditory ossicles became definitely higher, often by more than 50 per cent, as a result of Ipriflavon treatment.

The Zn-content of the stapes was also higher than in the cortical bone, and approximately a 6 per cent, and a 16 per cent increase could be detected in the cortical bone and auditory ossicles, respectively, in the cases of treated patients.

The Cu-content of the stapes was also higher than the Cu-content measured in the cortical bone. For the effect of treatment Cu-content increased by 32 per cent while increase in the cortical bone was only 7 per cent.

We may conclude that there is a relation between the changes of Ca-, Zn- and Cu-contents in cases treated by Yambolap. The process taking place may be explained so that for the effect of Yambolap the activity of enzymes necessary to Ca-incorporation increases /increase in Cu- and Zn-contents/ which is resulting in a rise of the Ca-level observed by us.

Summary

We have studied the effect of Ipriflavon /Yambolap/ in 43 patients who had suffered from otosclerosis.

It is evident that tinnitus, one of the most tormenting symptoms of the disease, disappears or becomes moderated in the majority of cases. Also hearing impairment may be arrested at an early stage, in fact, hearing may even improve. Considering the improvement of clinical symptoms /e.g. the disappearing of Schwartze-phenomenon, and tinnitus, improvement of hearing/, less bleeding at the operations, the easy removal of the footplate of the stapes, the results of histologic examinations and atomic absorption tests, we may come to the conclusion that the activity of the otosclerotic focuses decreases, and the process of remineralization increases in the bone.

We have not found any harmful side effect of the drug beside the employed dosages.