DIFENSIL IMMUNO THERAPY FOR TREATMENT OF UPPER AIRWAYS INFLAMMATION AND OTITIS OF MIDDLE EAR IN CHILDREN: PRELIMINARY RESULTS

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BACKGROUND:
Otitis media can be classified as acute (OMA) or effusive (OME), the first one appears with pain, the second is reliable only as hearing deficit. OMA is acute inflammation of the middle ear and may be caused by bacteria or viruses. OME is a chronic inflammatory condition without acute inflammation. There is an effusion of glue-like fluid behind an intact tympanic membrane in the absence of signs and symptoms of acute inflammation. Normally tympanic membrane (MT) is observed using an otoscopy (see image), when it is necessary to take a picture a rigid endoscope O is used to better investigate the MT. Tympanometry is one of the audiometric test used to evaluate the origin of Hearing Loss, the exam evaluates the elasticity of MT that comes out as a graphic with different shapes. Reduced movement of MT, due to MT inflammation or occlusion in the middle ear, produce a flat curve. The flexible fibro-endoscopy is the elective method to evaluate the occlusion of Eustachian tube- ventilation of middle ear- due to pathology of rhinopharynx. Endoscope allows a perfect view of all structure. Otitis media in both forms is prevalent in children < 6 years old, showing a general incidence of 18% in Europe. The countries from higher to lower are: Germany> Sweden > Spain > UK> Italy. Otitis media in adult has an incidence of 0.25% for year.

Objective: to evaluate the capacity of Difensil Immuno to reduce the frequency of Upper Airways Inflammation (UAI) and Otitis Media with Effusion (OME) in children

Material and Methods: a sample of 42 children affected from Otitis Media with Effusion (OME) in age between 12 and 72 months was divided in 4 groups.
A control group (7) underwent standard treatment (OME)
Group 1 (12), treated with 10 ml of DI for 3 months ( 20 days consecutively, then 10 days stop, repeated 3 times) Group 2 (11)treated with 10 ml of DI for 3 months consecutively
Group 3(12); treated with 15 ml of DI for 45 days consecutively. Tympanometry and fibroscopy at T0, T1 ( 45 days after treatment), T2 (90 days after) were done

Results:
All children treated with DI showed a reduction of UAI episodes and OME when compared with control group. The better results were observed in group 3, that showed completely resolution of symptoms at T3. Group 1 showed a partial resolution of symptoms at T1, with an improvement in the 45% of cases and a complete resolution at T2 in the 70%.
Group 2 showed an improvement of symptoms at T1 in the 65% of cases and complete resolution of it at T2 in the 90% of the observations.

Conclusions: DI should be considered as supporting therapy in children affected from recurrent episodes of UAI associated with OME due to its capacity to reduce the episode of OME and the frequency of UAI.

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