

Research Article

Is Recurrent Acute Otitis Media (RAOM) a Consequence of Fundamental Changes to the Traditional Mediterranean Diet?

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Abstract

Introduction: Acute Otitis Media (AOM) is the most commonly-occurring bacterial complication in childhood. After making certain corrections to the patients' dietary habits, we observed a significant reduction in recurrent colds and their bacterial complications. The purpose of the study was to assess the effects of the Traditional Mediterranean Diet (TMD) on patients diagnosed with Recurring Acute Otitis Media (RAOM). **Methods:** Prospective before-after comparison study with 48 girls and 42 boys aged 1-5 years were included on the programme “Learning to eat the Mediterranean Way”, designed to encourage the adoption of the TMD. We studied clinical and therapeutic variables and various anthropometric parameters. **Results:** All the symptomatic indicators studied (number and intensity of episodes of otitis and emergency admissions) showed a positive and statistically significant evolution in RAOM. By the end of the study, none of the patients met the criteria for classification as RAOM, and 60% percent of patients did not present any further episodes of AOM. In line with the above, the use of anti-microbial drugs and symptomatic treatments reduced considerably; the use of antibiotics dropped from 4.30±1.45 occasions/patient/year, to 0.66±0.98 ($p<0.001$), and the used of symptomatic treatments dropped from 7.63±2.65 to 2.75±1.90 ($p<0.001$). The level of family satisfaction was very high. **Conclusions:** The adoption of the Traditional Mediterranean Diet may make a major contribution to the curing of patients diagnosed with RAOM.

Keywords: Acute otitis media, Recurring acute otitis media, Chronic suppurative otitis media, Mediterranean diet, Dietary intervention, Nutritional therapy

Introduction

Acute Otitis Media (AOM) is the most commonly-occurring bacterial complication in childhood, generally presenting alongside Upper Respiratory Infections (URIs) [1]. It occurs most frequently in children under 2 years of age, and is one of the most common cause of consultation with primary care paediatricians (25-40%) [2,3]. It is estimated that 2 out of every 3 children suffer an episode before their first birthday, and over 90% do so before reaching the age of 5 [4]. It is the leading reason for the prescription of antibiotics for children [5]. The pathogens most commonly involved in AOM are: *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Moraxella catarrhalis* [6,7]. Viruses are a contributing factor in AOM, but no direct role as the cause of inflammation of the middle ear has been proven [8]. One study concluded that AOM has a major impact on health, given the high number of consultations, use of antibiotics, related surgery and the need for auditory rehabilitation [9].

There is a high rate of relapse, leading to Recurrent Acute Otitis Media (RAOM). Thirty-three percent of children under 3 years of age have suffered 3 or more episodes and 10-20% of all children present repeat episodes of AOM [10]. A significant connection has been established between the appearance of Chronic Suppurative Otitis Media (CSOM) and conductive hearing loss [11]. Multiple preventative measures have been proposed for RAOM, such as not attending nursery, avoiding passive smoking and allergen exposure, inoculation against influenza, limiting the use of pacifiers [12,13], the administration of probiotics [14] and vaccination against pneumococcus, with insignificant results [15]. Prophylactic antibiotics have also been proposed during the

colder months of the years, in 3-6months cycles; no satisfactory results have been obtained [16]. Finally, adenoidectomy and the insertion of grommets has also been recommended, with contradicting results [17].

There is little available literature linking diet to the development of RAOM. Breastfeeding has been highlighted as a highly effective protection factor during early infancy. Unfortunately, the protective effect disappears shortly after the end of breastfeeding [18], at the time when weaning starts. Studies performed by our group on the role of the Mediterranean Diet in repeat inflammatory processes during childhood, have revealed a significant reduction in URIs and its most common bacterial complications, after modifying certain feeding errors in the patients' diet. We have also observed a drop in asthma in children fed on the Mediterranean diet. In line with our main line of argument in which we link recurrent inflammatory episodes in childhood with cessation of the Mediterranean diet, we considered completing this study on the effects of the Traditional Mediterranean Diet (TMD) [19-21] in patients diagnosed with RAOM.

Material and Methods

Study design

The study was approved by the Ethics and Research Committees at Ciudad Real University Hospital. The design was for a prospective before-after comparison study. The study consecutively included patients aged 1 to 5 attending a primary attention paediatrics office between May 2010 and June 2017, diagnosed with RAOM, and with the informed consent of parents or legal guardians. Students who had undergone surgical treatment were excluded from the study. The study focused on dietary re-education based on the TMD, using the nutritional education programme “Learning to Eat the Mediterranean Way” [22-24]. This programme is based on a number of consultations with the nutritionist and the paediatrician, which all members of the family are advised to attend. These visits are held monthly for the first 4 months and then every two months until the year is complete. The first visit includes an assessment of each child's eating habits and

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those of his/her family, and dietary changes are proposed based on any problems observed, with schedules, recipes, sample menus, etc. An anthropometric study is completed and fundamental health topics are discussed, such as “breakfast ideas”, variability of daily menus, the energy ingestion/consumption balance, quality of fats, proteins and carbohydrates, how to read food labels, grocery shopping, etc. Patients were monitored over the course of a year, assessing pondered height growth, clinical evolution, treatment requirements, adherence to the TMD and the level of family satisfaction, using the variables described below.

Study variables

Parameters for clinical evolution and treatment: The main variable was the number of episodes of AOM per patient, per year. All patients who had suffered 3 or more episodes of AOM in a maximum period of 6 months, or 4 or more episodes in a maximum of 12 months were included in the study [25]. We considered any further episodes occurring in the first month after diagnosis to be a relapse and these were not counted as new episodes of AOM [26]. The presence of trans-tympanic fluid was assessed using a portable tympanometric instrument (MicroTymp`3) Cases of bilateral exudate or leakage lasting more than 3 months, or unilaterally for more than 6 months were considered to be Chronic Suppurative Otitis Media (CSOM) [27]. The following secondary variables were considered: Number of Upper Respiratory Infections (URIs), emergency consultations, other bacterial complications, number of symptomatic treatments prescribed, and number of antibiotics prescribed, all per patient per year. A basic ear, nose and throat examination was performed, including rhinoscopy, otoscopy, tympanometry, audiometry in cooperative children using a portable audiometer (Audioscope), careful examination of the face (Adenoid facies) and cervical adenopathy, and finally, a clinical assessment of the degree of AOM (Mild, moderate or severe).

URI episodes were defined using two or more of the following criteria: fever over 38°C (Measured with an ear thermometer), nasal congestion or breathing through the mouth, nasal secretion, difficulty swallowing and coughing. AOM was defined using the criteria listed in the Spanish Paediatric Association (*Asociación Española de Pediatría - AEP*) [28], which, to quote the American Academy of Pediatrics guideline [29], are: 1. Acute onset; 2. Presence of middle ear effusion seen in the bulging of the tympanic membrane, pathological pneumatoscopy or otorrhea; 3. Signs of symptoms of inflammation such as otalgia or evident tympanic membrane erythema. Once a diagnosis of AOM was confirmed, expectant therapy was followed in mild cases, and antibiotics were used in higher risk cases, such as children under 2, bilateral AOM and where overall well-being was more gravely affected [30-33]. “Probable” cases of AOM were not taken into account. “Confirmed” cases of AOM were those where the above criteria were accompanied by an URI [26,34].

Clinical and therapeutic assessment performed on parents or guardians: In order to assess the patients’ clinical evolution, we designed a questionnaire for parents or guardians, to assess AOM-related symptoms and subsequent evolution, the intensity of clinical conditions, emergency medical visits, treatment requirements, difficulties with the diet undertaken, and level of satisfaction with the process. Each question can be answered in terms of the improvement

observed, using the following scale: 3: a lot, 2: quite a lot, 1: a little, 0: none (Table 1). Ten questions are posed about the clinical situation and treatment over the past four weeks, scored between 0 (Poor control) and 30 (Good control). A patient is considered to be under control with a score of 20 or over.

Pondered height growth parameters: By limiting certain foods forming part of Western culture, we have assessed the correct height growth in the patients included in the study. This was done by collecting anthropometric data, such as weight, height, skin folds, arm, abdomen and waist measurements, to calculate body mass index, lean mass and body fat, following the procedures habitually used by our group [19-21].

TMD adherence parameters: The Traditional Mediterranean Diet [35,36] has been proclaimed Intangible Heritage by UNESCO. It is characterised by being high in fresh plant-based food such as fruit and vegetables, whole grains, legumes, olive oil and dried fruits, low to moderate in animal-based foods such as fermented dairy products, fish, eggs and lean meat, and low in sugars, refined flour and pre-prepared foods. To assess the new dietary habits of patients and their families, we used the KidMed [36] test, which evaluates adherence to the Mediterranean diet, and the TMD test, developed by our group to include aspects not covered by the KidMed test, and described in previous papers [19-21].

Sample size and statistical analysis

In order to calculate the sample size, a significance level of 0.05 and a potency of 80% were used, with a reduction in the average number of AOM episodes per patient per year to 1 unit, with a typical deviation of 3.5 units, adjusted for 25% losses, resulting in a sample size of 80 patients.

The statistics package SPSS 15.0 was used to analyse the results. A descriptive analysis was performed using centrally-trending statistics and dispersion for quantitative variables, and absolute and relative frequency for qualitative variables. The results of the different variables before and after the process were compared using the Student’s t-test for paired data in the case of variables with normal distribution, or using the Wilcoxon test in the case of abnormal variables, after checking using the Shapiro-Wilk test. The significance level was set at $\alpha=0.05$.

Results

According to the sample size calculation, the programme “Learning to eat the Mediterranean Way” was proposed for the families of 104 patients meeting the inclusion criteria, of which, 4 opted not to take part. Of the 100 patients initially included, 5 abandoned the programme after the first session and a further 2 after the fourth session. Five left for social or personal difficulties in adopting the diet, while the other two did not agree with the limitation of certain foods. Three patients were excluded after surgical intervention by ENT specialists, not coordinated with our team. The study was therefore completed by a total of 90 patients, of which 48 were female and 42 males, with an average age of 2.9 years (Table 1). All the patients included in the study were assessed after 4 months and 12 months. The results obtained were similar in both sexes, and so they are treated jointly hereafter.

At the end of the study (One years’ monitoring), there was a marked drop in the number and intensity of AOM episodes, reducing from a profile of mild-moderate to none-mild. Sixty percent of patients had no episodes of AOM during the period of nutritional therapy; 28% had only one during the year and 11% had two, compared to an average of almost 4 episodes in the previous year.

The number of episodes of AOM dropped by 87.5% overall. From 3.84 ± 0.73 in the previous year, compared to 0.48 ± 0.65 ($p < 0.001$) during the year of treatment. The level of intensity of AOM dropped from 1.6 ± 0.65 (mild-moderate) to 0.09 ± 0.18 ($p < 0.001$) (none-moderate). The

Table 1: Sample characteristics. average age 2.9 years.

	Boys (n=42)	Girls (n=48)
Weight (Kg)	15.38 ± 4.67	13.31 ± 3.27
Height (m)	0.96 ± 0.11	0.91 ± 0.09
BMI (kg/m ²)	16.44 ± 1.28	15.89 ± 1.49
Fat mass (%)	15.23 ± 2.95	16.38 ± 2.98
Lean mass (%)	13.01 ± 4.32	11.08 ± 2.43

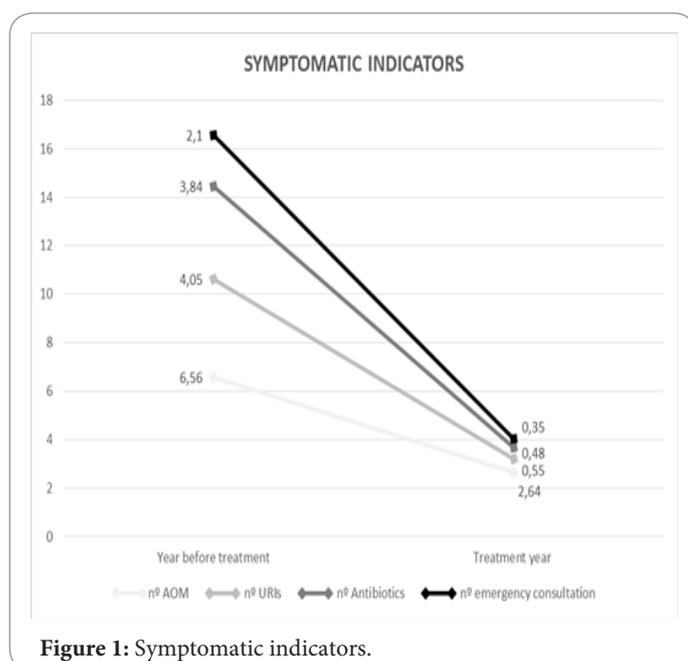
Table 2: Evolution during the previous year and during the year of treatment.

	Previous year to treatment	Year of treatment	P
Number of otitis	3.84 ± 0.73	0.48 ± 0.65	0.001
Intensity of episodes	1.60 ± 0.40	0.09 ± 0.12	0.001
Number of UTIs (Upper respiratory infections)	6.56 ± 1.45	2.64 ± 1.45	0.001
Other complications	1.53 ± 1.22	0.56 ± 0.63	
Number of emergency treatments	2.1 ± 0.89	0.35 ± 0.21	0.001
Antibiotics	4.05 ± 1.37	0.55 ± 0.88	0.001
Symptomatic treatment	7.19 ± 1.96	2.65 ± 1.76	0.001
CSOM	0.67 ± 0.52	0.07 ± 0.12	0.001

Table 3: Response of parents or guardians regarding the improvement observed in recurrent otitis. A lot (3), quite a lot (2), a little (1), none (0).

Clinical and therapeutic assessment in recurrent acute otitis media	4 th month	12 th month
Has the number of otitis episodes decreased?	2.29	2.55
Have you noticed that the infectious process is less intense?	2.70	2.95
Has the need for emergency medical attention decreased?	2.96	2.95
Have the complications decreased?	2.91	2.95
Have you noticed an improvement in recovery?	2.36	2.95
Has there been a decrease in the use of antibiotics?	2.50	2.95
Has there been a decrease in the use of symptomatic medicine?	2.95	2.95
Has the diet been well tolerated by the patient?	2.95	2.95
Has there been cooperation in these dietary changes?	2.96	2.96
Are you satisfied with the results?	2.50	2.96
Total Score	27.08	29.12

average number of URIs dropped by 60% on the previous year. From 6.56±1.45 to 2.64±1.45 ($p<0.001$). All this indicates fewer episodes of URIs, with a significant drop in AOM during the study period. The need for emergency medical treatment also dropped 83.3%, from 2.1±0.89 occasions per year, to 0.35±0.21 ($p<0.001$). Table 2 shows the data from the previous year and at the end of the study year. The use of antibiotics reduced by 86.4%, and the use of symptomatic medicine dropped by 63.2% (Figure 1). The level of family satisfaction was high, as shown on the questionnaire, in terms of the improvement observed (Table 3).

**Figure 1:** Symptomatic indicators.

The anthropometric variables before the study, at 4 months and after the process, are shown in Table 4. The determining growth and development parameters such as height and lean mass, showed appropriate and statistically significant increases. The increase in average weight compared to the previous year was 2.11 kg, compared to 2.60 kg at present, and the increase in average height was 8.7 cm, compared to 9.20 cm. There was a slight reduction in Body Mass Index (BMI). The lean mass on the arm increased slightly, while the amount of fat mass showed a tiny decrease.

The patients' eating habits had also improved across the sample at the end of the programme. So, there was an increase in the number of patients eating fruit, vegetables, whole grains and fermented dairy produce; similarly, there was a drop in the number of patients who did not have breakfast or who would eat factory-baked goods, as well as the proportion of patients eating sweets on a daily basis. According to this data, the average score on the KidMed scale showed a positive evolution, from a mid-high rating at the start of the process to an optimum rating at the end. The TMD test also showed a satisfactory evolution, from low quality levels, to optimum levels (Tables 5 and 6 and Figure 2).

It must be stressed that over the course of the study there was a notable decrease in children diagnosed with recurrent AOM-thus explaining the delay in obtaining our sample, partly due to extending the TMD to a large part of the population (Families, patients with other recurrent conditions, and infants aged under two). At present, recurrent AOM is an uncommon pathology presented in our paediatrician's office. Table 7 shows the inclusion periods for patients with recurrent AOM and other inflammatory conditions after the gradual introduction of the TMD in children. Table 8 shows the changes in percentage of scheduled and requested appointments in our paediatrician's office.

Table 4: Anthropometric assessment at the start, after 4 months and after one year.

	At the start of treatment	4 months of treatment	Year of treatment	P
BMI (Body Mass Index)	16.15 ± 1.38	16.01 ± 1.32	15.94 ± 2.33	0.16
Fat mass (%)	15.85 ± 2.98	15.56 ± 3.12	15.18 ± 2.91	0.24
Lean mass (%)	11.98 ± 2.94	12.89 ± 3.83	14.29 ± 3.20	0.011

Table 5: KidMed Test (percentage).

	At the start of the study	After 4 months of study	After one year of study
1 piece of fruit per day	65	82	100
1+ piece of fruit per day	37	68	96
1 vegetable per day	61	72	93
Vegetables more than once per day	7	33	63
Regularly eats fresh fish (2-3 times/week)	63	77	96
Visits fast food rest. once or more per week	25	5	4
Legumes 1-2 times/week	75	82	98
Pasta and rice every week	81	82	100
Cereal or deriv. for breakfast	79	81	96
Regularly eats dried fruit and nuts	2	12	37
Olive oil used at home	82	82	98
No breakfast	5	0	0
Dairy at breakfast	79	81	98
Factory-baked goods for breakfast	28	5	0
Two yoghurts or 40g cheese / day	82	82	100
Sweets and snacks every day	26	5	4

Table 6: TMD Test (%).

	Start	4 Months	Year
Minimum 2 pieces of fruit every day.	53.3	82.2	93.3
Fresh vegetables at every meal, as a first course or as part of the main course	34.4	71.1	75.6
Limited sugar intake (sweetened breakfast cereal, sweetened yoghurts or milkshakes, cakes, soft drinks, sugary biscuits, sweets, ice-cream, etc).	10.0	70.0	83.3
Sporadic use of potatoes (1-2 times/week) and preferably not fried.	24.4	78.9	82.2
Legumes twice or more per week, not always with meat.	36.7	81.1	86.7
Regular intake of white fish, oily fish and seafood (1-3 times/week).	66.7	75.6	90.0
Preferably eats whole grains (whole wheat pasta, brown rice, brown bread, etc., limiting the intake of refined flour such as white bread to less than 40 g per day)	15.6	76.7	85.6
Intake of seasonal, natural, fresh food.	21.1	70.0	87.8
Moderate to low intake of dairy produce: Preferably in the form of natural yoghurt and goat's or sheep's cheese.	15.6	65.6	85.6
Only lean processed meats, less than twice per week.	15.6	70.0	86.7
Preferably white meat, less than 3 times per week (lean).	20.0	73.3	85.6
30- 50 % of the daily intake consists of raw food (fruit, vegetables, virgin extra olive oil, freshly-squeezed fruit juice, nuts, etc.) and semi-raw food (green vegetables)	10.0	36.7	67.8
Frequent intake of broths, soups, natural smoothies and water	35.6	66.7	70.0
Intake of fats mainly from virgin extra olive oil and raw nuts. Avoiding low quality industrial fats.	38.9	76.7	91.1
Good quality breakfast and mid-morning meal	25.6	63.3	81.1
No snacking between meals, and a reasonable portion size at meals	23.3	53.3	83.3
Adapts to the food made at home (family) and alternatives not offered.	32.2	74.4	91.1
Limits intake of additives, avoiding "junk" food (<1/week)	68.9	81.1	84.4
Regular physical exercise (running, playing, walking, climbing, etc) or sport.	71.1	75.6	81.1
Mealtimes together, avoiding the television or other technology	67.8	83.3	95.6

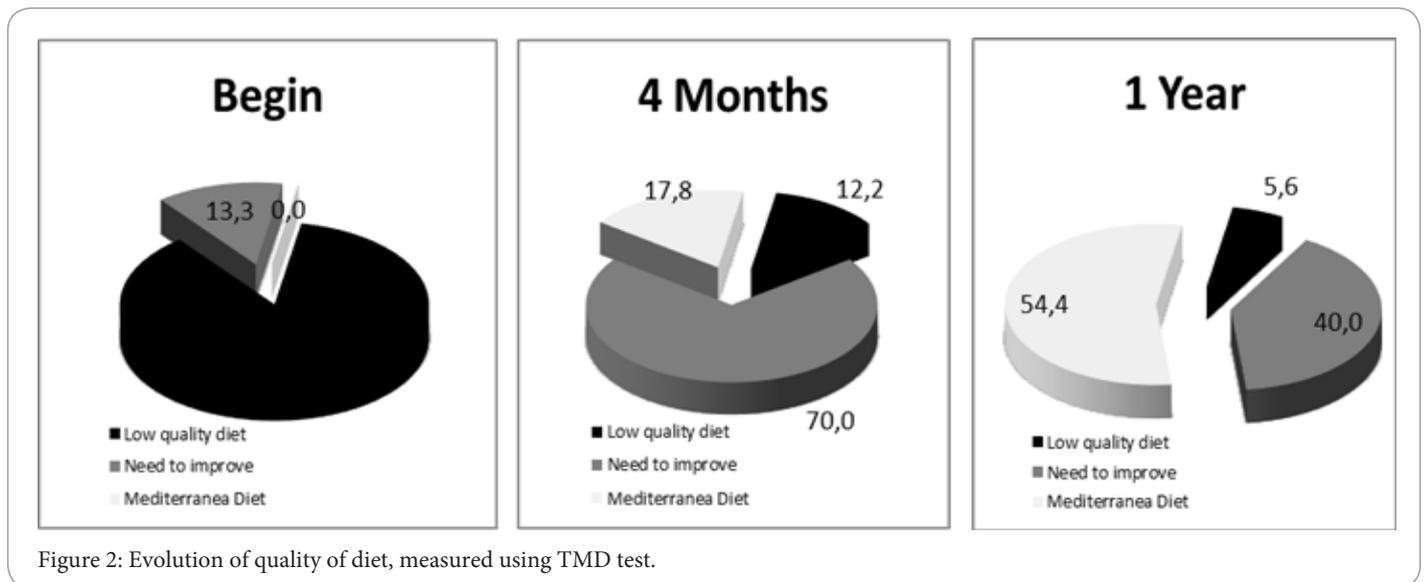


Figure 2: Evolution of quality of diet, measured using TMD test.

Table 7: No of children with RAOM and other recurrent inflammatory diseases/year. After progressive introduction of TMD in the paediatric population.

No of children/year	2010	2011	2012	2013	2014	2015	2016	2017
Excess weight and obesity	20	19	13	12	11	9	4	3
RAOM	15	27	12	10	9	9	4	2
URI with = or >3 bacterial Compl.	25	46	36	19	18	16	6	5
CSOM	12	24	16	10	9	0	0	1
Recur. Rhinosinusitis	16	40	24	12	11	10	5	3
Pers. Nasal Obstr.	20	27	12	11	11	5	2	1
Child Asthma	22	41	25	20	18	17	7	2
Total	130	244	138	94	87	66	28	22

RAOM: Recurrent Acute Otitis Media; URI: Upper Respiratory Infections with 3 or more bacterial complication in <6 months; CSOM: Chronic Suppurative Otitis Media

Table 8: Percentage of scheduled and requested appointments at our office.

	2010	2011	2012	2013	2014	2015	2016	2017
% Requested appointments	72	71	65	61	59	56	52	50
% Scheduled appointments	28	29	35	39	41	44	48	50
Total No appts/day	32	31	30	28	25	20	18	16

Discussion

Given the results obtained, we consider that a high nutritional quality diet such as the Traditional Mediterranean Diet can significantly reduce the prevalence of recurrent AOM and prevent pharmacological and surgical intervention. After a year of nutritional therapy, there was a significant reduction in UTIs, with much milder effects on overall well-being, and with much more positivity in patients regarding the condition, which has undoubtedly influenced the near disappearance of AOM, to such an extent that at the end of the study, none of the patients treated met the criteria for classification as recurrent AOM, and most of the patients presenting with middle ear effusion (CSOM) progressed positively. There was an important reduction in the use of antibiotics, symptomatic drugs and emergency treatment. The level of satisfaction indicated by parents on the clinical evolution test was very high, with high overall scores showing good therapeutic and clinical progress. In the first four months, notable improvements were observed compared with the situations in the previous year, thus considerably increasing adherence to the programme and making it easier to monitor

the process. The proposed diet was well tolerated, easy to adapt to, with few culinary issues. The patients showed satisfactory pondered growth rates. Their weight, height and BMI percentile evolved as expected. A positive result was the slight decrease in BMI and fat mass levels and a small increase in height and lean body mass.

Although this data suggests that the intake of healthy food and/or avoiding poor quality food may play a key role in the control of AOM, there are almost no bibliographical references in scientific literature. The bibliography highlights that there are 4 factors contributing to RAOM: age under 5, attending childcare, suffering upper respiratory infections and previous episodes of AOM.

Some children have a disproportionate inflammatory response to infectious agents, while others barely show any discomfort. Could there be a hyper-inflammatory response to small antigen stimulants, due to alterations in the inflammatory mechanisms? Or, in other words, is it possible that a minor infection is not the cause of the illness, but the trigger for the hyper-inflammatory response? What is going on to make these children have such poor defences? Their adenoid tissue is

extremely hyperplastic, and yet their immune response is inefficient. Many children have a marked tendency to URI complications with excess bacterial infection such as AOM, rhinosinusitis or middle ear effusion (CSOM), while this does not happen in other children with similar circumstances and common colds. How might a healthy diet influence the body's defences against the factors described above? In the light of the results of our study, we could say that it does have a consistent effect on achieving better immune responses.

The children we studied reached early immune maturity in clinical terms. The IDEFICS study [37] has shown that children consuming excess refined flours and processed animal-based products and a diet poor in fruit and vegetables have high inflammatory markers. This means that overall they can be considered to be in a pro-inflammatory state. We will now list what we consider to be the main therapeutic hypotheses that may have been reinforced by the introduction of a high nutritional quality diet such as the TMD.

Firstly, we would stress an improved anti-inflammatory response, perhaps due to a balancing of the inflammatory system. By ingesting more plant-based foods, the omega-3/omega-6 ratio remains balanced. Predominantly eating food with a low glycaemic index/load, helps to control insulin levels; this hormone may interfere in the formation of anti-inflammatory eicosanoids, by blocking the Δ -desaturase enzyme [38-39]. Similarly, the TMD is rich in vitamins, minerals and antioxidants, many of which are indispensable co-factors in the enzymatic chemical reactions involved in the body's defence processes [40].

Secondly, there is a drop in the "antigenic load", due to eating food that is recognised and assimilated by the human species. The TMD is an ancient diet, dating back to way before documented history, and which has stood the test of time. Many of the foodstuffs eaten as part of the Western diet contain materials not recognised or assimilated by the human body. Many of these products are not absorbed by the intestine, thus encouraging non-specific microflora that is alien to human intestinal microbiota. The excess "antigenic load" inherent in the Western diet of today-which has multiplied available foodstuffs by the thousand - may misadjust our immune system, making it weaker and notably hyperplastic, to the extent that it obstructs the respiratory tract. The benefits of breastfeeding in the prevention of AOM have been proven, due to the presence in breast milk of antibodies, antibacterial enzymes, glycosylated proteins, anti-viral fats and leukocytes [41], but also due to decoy receptors for bacterial pathogens, such as oligosaccharides [42]. Components that favour the development of standard saprophytic flora, which prevents the development of oto-pathogens [43]. These components are currently being added to formula milk, to improve its immune boosting quality [44,45]. Probiotics are also added, with satisfactory results in the reduction of URIs and AOM [14]. After ceasing breastfeeding, the occurrence of AOM increases, particularly upon the introduction of cow's milk [43].

Thirdly, we should highlight the "transient hypogammaglobulinemia" of infancy. The IgA antibody is highly specialised in the defence system of the mucosae, and is believed to be responsible for blocking both the respiratory and alimentary antigens on the surface of these membranes. At the age of 12 months, IgA levels are just 20% of those in adults [46] and it therefore does not seem appropriate to increase the "antigenic load" of an infant's diet, which under the historical feeding pattern, was limited to breast milk until beyond the age of 18 months, and the introduction of just a few solid foods.

We should also mention the "intestinal microbiota", which represents almost 5% of our body weight, and would appear to play a key role in the development of our natural defences. The mechanisms by which the intestinal flora regulates our immune responses are unclear, but it seems sensible to encourage the development of an intestinal microbiota typical of the human species, given that evolution and genetic

coding must have established a specific symbiosis between nutrition, intestinal microbiota and immunity that should not be altered [47-49].

One of the necessary characteristics of any research study is for it to be easily reproduced, using small groups and at a low cost. The work presented herein is easy to reproduce at any primary attention paediatrician's office. It is essential to work with a nutritionist to run the programme "Learning to eat the Mediterranean Way". Although the absence of a control group and the lack of systematic analysis in our study prevents us from fully affirming that the dietary intervention was the direct cause of the improvements observed, such a favourable spontaneous clinical improvement could not be expected. Further supporting our hypothesis is the almost complete remission of recurrent AOM at our doctor's office since the implementation of the TMD in all patients from birth.

The change in the "medical model" entailed by these research studies should not go unnoticed. It is no longer a question of providing a remedy for an illness using external drugs that are alien to the human defence system. The proposed treatment is based on equipping the body with everything it needs to heal itself. This could be applied to other childhood pathologies, as described in previous publications [36-38]. We are still far from a detailed understanding of the complex web of the pathogenic mechanisms of inflammation, the microbiota and its connection to the immune system, but we can take clinical resolution as "evidence", following the lead of "common sense", which is none other than a return to basic eating habits: The Traditional Mediterranean Diet. This diet may make an important contribution to the healing and prevention of recurrent AOM. Going back to our roots, to the words of Hippocrates, the "father of medicine": "Let food be thy medicine and medicine be thy food".

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