

Article

Recurrent Acute Otitis Media Could Be Related to the Pro-Inflammatory State That Causes an Incorrect 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, which we found to be excessively high in animal-based and industrially-processed foods, we observed a significant reduction in recurrent colds and their bacterial complications. We promote an original way of treating these diseases, since until now the conventional treatment is based on pharmacological and surgical treatment. From our point of view, the mucosa that covers the entire ENT area is in a pro-inflammatory and hyper-reactive state, as a consequence of the alterations produced by an inadequate diet. For us there is no difference in the nutritional treatment of the different mucous membranes that cover the ENT area. 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 pre-postest comparison study with 48 girls and 42 boys aged 1–5 years, each of whom had been and included on the 1-year 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 occasions/patient/year, to 0.66 ($p < 0.001$), and the used of symptomatic treatments dropped from 7.63 to 2.75 ($p < 0.001$). The level of family satisfaction was very high. Conclusions: the adoption of the Traditional Mediterranean Diet has been demonstrated to significantly reduce occurrence of acute otitis media and may contribute to the treatment of patients diagnosed with recurrent acute otitis media.

Keywords: acute otitis media; recurrent acute otitis media; mediterranean diet; traditional diet; dietary intervention; nutritional therapy



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1. Introduction

Acute Otitis Media (AOM) is the most commonly-occurring bacterial complication in childhood, generally presenting alongside upper respiratory infections (URIs). It occurs most frequently in children under 2 years of age, and is one of the most common causes of consultation with primary care paediatricians (25–40%). 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. It is the leading reason for the prescription of antibiotics for children. The pathogens most commonly involved in AOM are *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis* [1,2]. Viruses are a contributing factor in AOM, but no direct role as the cause of inflammation of the middle ear has been proven. 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 [3].

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 [4,5]. 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 [6], the administration of probiotics [7], and vaccination against pneumococcus, with insignificant results [8,9]. Prophylactic antibiotics have also been proposed during the colder months of the year, in 3–6-month cycles; no satisfactory results have been obtained [10]. Finally, adenoidectomy and the insertion of grommets has also been recommended, with contradicting results [11].

There is little available literature linking diet to the development of RAOM. Breast-feeding has been highlighted as a highly effective protection factor during early infancy. Unfortunately, the protective effect disappears before the end of breastfeeding [12], at the time when weaning starts. Studies performed by our group on the role of the Mediterranean Diet in recurrent inflammatory processes during childhood, have revealed a significant reduction in URI and its most common bacterial complications, after modifying certain feeding errors in the patients' diet. In line with our main line of argument in which we link recurrent inflammatory episodes with cessation of the Mediterranean diet, we considered completing this study on the effects of the Traditional Mediterranean Diet (TMD) [13–18] in patients diagnosed with RAOM.

2. Material and Methods

2.1. Study Design: Inclusion and Exclusion Criteria

The design was for a prospective pre-posttest comparison study, with each patient examined for one year. The study consecutively included patients aged 1 to 5, diagnosed with RAOM, attending a primary attention paediatrics office between May 2010 and January 2019, with the informed consent of parents or legal guardians. Those patients who had congenital pathology of the ENT area and those who had undergone surgical treatment were excluded from the study. The study focused on dietary re-education based on the TMD [19], using the nutritional education programme “Learning to Eat the Mediterranean Way”; We had already expanded our data on the program [13–18] via previous studies of the effect of the TMD on recurrent colds and childhood asthma. In the last years of the study, 17 children were requested inflammatory markers from the laboratory: PCRhs, IL-1, IL-6, TNF-alpha, C3 and C4, to assess the pro-inflammatory state. The study was approved by the Ethics and Research Committees at Ciudad Real University Hospital. (Internal code: C-95, Act March 2017).

2.2. Study Variables

Parameters for Clinical Evolution and Treatment

The diagnosis of AOM was made following the criteria of the Clinical Practice Guideline of the American Association of Pediatrics (CPG-AAP) [20], which defines AOM when 3 criteria are met: 1. Acute presentation; 2. Presence of exudate in the middle ear cavity demonstrated by tympanic bulging, pathological pneumatoscopy or otorrhea 3. Inflammatory signs and symptoms such as otalgia or evident reddening of the eardrum. The CPG-AAP [21] itself later added some considerations, such as the rapid appearance of signs and symptoms of inflammation in the middle ear. Following the CPG-AAP criteria, we have diagnosed as Recurrent AOM (RAOM) those patients who present 3 or more separate and well-documented episodes of AOM in the previous 6 months or 4 or more episodes in the previous 12 months with at least 1 episode in the last 6 months. Sometimes it is difficult to establish the diagnosis of AOM with certainty, as it because it does not meet all the established criteria of the CPG-AAP, so we define it as “probable AOM” according to the criteria of the Spanish Association of Pediatrics [22], and we maintain the patient under initial observation (Initial observation of the CPG-AAP), with symptomatic treatment until seeing the evolution of the clinical picture. “Probable” cases of AOM were not taken into

account [23]. All patients were diagnosed with AOM by the paediatrician, who assessed the presence of trans-tympanic fluid with a portable tympanometer (MicroTymp'3[®], Welch Allyn, NY, USA); and otoscopy and audiometry were performed on collaborating children, with a portable audiometer (Audioscope[®] Welch Allyn, NY, USA); A paediatric assessment was made when there was a new episode of AOM, with a follow-up after 10 days. Periodic check-ups were also carried out by the paediatrician to assess the evolution of the RAOM at 4 and 12 months, coinciding with the control of the dietary pattern. 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. 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 [24].

The following secondary variables were considered: number of upper respiratory infections (URI), 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, 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.

2.3. Clinical and Therapeutic Assessment Performed on Parents or Guardians

In order to assess the impact that nutritional therapy has on the perception of the patients' families, 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.

Table 1. 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	4th Month	12th 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

2.4. Pondered Height Growth Parameters

By limiting certain foods forming part of Western culture, we have assessed the height growth in the patients included in the study. This was carried out 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.

2.5. TMD Adherence Parameters

The traditional Mediterranean diet is characterized by a high content of fresh, raw, perishable and seasonal foods, rich in vegetable fibre, minerals, vitamins, enzymes and antioxidants; Abundant fruits, vegetables, legumes, and whole grains, one of whose characteristics is its low-moderate glycaemic index; Sufficient polyunsaturated fats from crude oils, nuts, seeds and fish; Low protein and saturated fat content of animal origin and, a low use of precooked and industrial foods. This means, in daily practice, the limitation of products such as white bread, industrial pastries, cow's milk, red and processed meats, sugary industrial beverages and precooked fast food [25,26]. The TMD is based on the Decalogue that the Foundation of the Mediterranean diet [27] proposes to us through its website (Table 2).

Table 2. Mediterranean diet: 10 basic recommendations.

1. Use olive oil as your main source of added fat.
2. Eat plenty of fruits and vegetables; fruits, vegetables, legumes and nuts.
3. Bread and other grain products (pasta, rice, and whole grains) should be a part of your everyday diet.
4. Foods that have undergone minimal processing, that are fresh and locally produced are best.
5. Consume dairy products on a daily basis, mainly yogurt and cheese.
6. Red meat should be consumed in moderation and if possible as a part of stews and other recipes.
7. Consume fish abundantly and eggs in moderation.
8. Fresh fruit should be your everyday dessert and, sweets, cakes and dairy desserts should be consumed only on occasion.
9. Water is the beverage par excellence in the Mediterranean Diet.
10. Be physically active every day, since it is just as important as eating well.

To assess the new dietary habits of patients and their families, we used the KidMed 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 [13–18]. The Traditional Mediterranean Diet has been proclaimed Intangible Heritage by UNESCO [28]. In Table 3, we expose the differences between TMD and the diet promoted by “Western civilization”.

Table 3. Differences between the Traditional Mediterranean Diet and the “Western civilization” Diet.

Traditional Mediterranean Diet	Western Civilization Diet
Breastfeeding	Adapted milk
Varied, seasonal fruit	Jars of baby food and canned fruits
Vegetables (including leafy vegetables)	Jars of baby food, canned vegetables and leafy vegetables
Pulses and non-processed nuts	Processed legumes and nuts
Minimally processed and fermented (in the traditional way) whole grains	Refined, processed cereals with industrial fermenting agents
Fermented milk (mainly from goats and sheep)	Processed dairy (mainly from cows)
Occasional lean meat (in small quantities)	High consumption of red and processed meats
Minimally processed, perishable, fresh and local foods	Non-perishable processed and ultra-processed foods
Homemade food	Pre-cooked food
Limits on products with added chemicals	Presence of chemical agents (suspected of negative interactions)

2.6. Sample Size and Statistical Analysis

In order to calculate the sample size, a significance level of 0.05 and a power 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 non-normally distributed variables, after checking using the Shapiro-Wilk test. The significance level was set at $\alpha = 0.05$.

3. 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 male, with an average age of 2.9 years (Table 4).

Table 4. 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)	0.95 ± 0.11	0.93 ± 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

All the patients included in the study were assessed after 4 months and 12 months by the nutritionist and the paediatrician. The results obtained were similar in both sexes, and so they are treated jointly hereafter. The number of episodes of AOM decreased 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-mild). URIs decreased from 6.56 ± 1.45 to 2.64 ± 1.45 ($p < 0.001$). The need to go to the emergency room also decreased from 2.1 ± 0.89 occasions per year, to 0.35 ± 0.21 ($p < 0.001$). Table 5 shows the data from the previous year and at the end of the study year.

Table 5. Evolution during the previous year and during the year of treatment.

	At the Start of Treatment	Year of Treatment	<i>p</i>
Number of AOM	3.84 ± 0.73	0.48 ± 0.65	0.001
Intensity of AOM episodes	1.60 ± 0.40	0.09 ± 0.12	0.001
Number of URIs (upper respiratory infections)	6.56 ± 1.45	2.64 ± 1.45	0.001
Other complications	1.53 ± 1.22	0.56 ± 0.63	0.001
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

The level of family satisfaction was high, as shown on the questionnaire, in terms of the improvement observed (Table 1) which was completed by all the participating tutors. The anthropometric variables before the study, at 4 months and after the process, are shown in Table 6.

Table 6. Anthropometric assessment at the start, after 4 months and after one year.

	At the Start of Treatment	At 4 Months of Treatment	After One Year of Treatment	<i>p</i>
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	0.01

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 (Table 7).

Table 7. 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 40 g cheese/day	82	82	100
Sweets and snacks every day	26	5	4

The TMD test also showed a satisfactory evolution, from low quality levels to optimum levels (Table 8 and Figure 1). Of the 17 children who were asked for inflammatory markers, all had elevated TNF-alpha and some also raised other markers such as IL-1, IL-6 and PCR-hs. These values were negativized in 16 patients at the end of the nutritional treatment, while the symptoms disappeared.

Table 8. TMD Test (%).

	At the Start of the Study	After 4 Months of Study	After One Year of Study
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

Table 8. Cont.

	At the Start of the Study	After 4 Months of Study	After One Year of Study
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.	25.1	72.1	84.8
Moderate to low intake of dairy products: 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, without processed foods.	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

Table 8. Cont.

	At the Start of the Study	After 4 Months of Study	After One Year of Study
Limits intake of additives, avoiding “junk” food (<1/week)	35.6	66.7	70.0
Regular physical exercise (running, playing, walking, climbing, etc.) or sport.	71.1	75.6	81.1
Mealtimes together, avoiding the television or other technology.	68.9	81.1	84.4

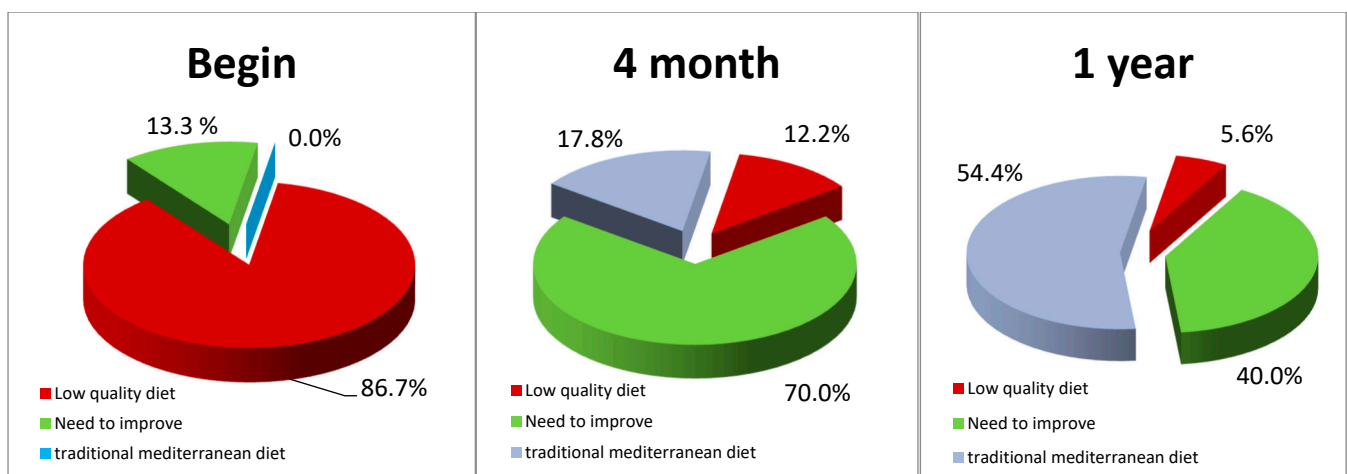


Figure 1. Evolution of quality of diet, measured using TMD Test.

4. Discussion

We are studying the effects of the Mediterranean Diet on inflammatory diseases that affect the ENT area. We promote an original way of treating these diseases, since until now the conventional treatment is based on pharmacological and surgical treatment. From our point of view, the mucosa that covers the entire ENT area is in a pro-inflammatory and hyper-reactive state, as a consequence of the alterations produced by an inadequate diet. For us there is no difference in the nutritional treatment of the different mucous membranes that cover the ENT area. We have published several studies, in which we apply nutritional therapy in recurrent inflammatory diseases of the ENT area, such as recurrent acute rhinosinusitis, recurrent colds, otitis media with effusion, persistent nasal obstruction, recurrent wheezing (childhood asthma) and now this study on RAOM [13–18]. We believe that it has a place in this special issue, since it is a good example of nutritional therapy in mucositis, which affects the ENT area. The results have been very satisfactory. It is the same treatment that we apply to recurrent rhinosinusitis, and we believe that the pathogenic mechanisms involved are the same. In the editorial that presides over this special issue: “Promotion and restoration of health with the amazing Mediterranean Diet vs an increase in childhood pathology due to the disastrous Diet of ‘Western civilization’”, we explain more extensively the need to improve the food diet, if we want to solve the great inflammatory problems that affect the mucous membranes (-itis). In short, we are trying to show a global view of the alterations that affect the ENT mucosa. and we believe that this article can be a good example to understand the effects of the Mediterranean Diet on different inflammatory and recurrent diseases, as the title of this special issue indicates. According to our results, the Mediterranean diet is capable of preventing and contributing to the resolution of most inflammatory diseases of the ENT area.

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. At the end of the intervention year, none of the patients treated met the criteria for classification as recurrent AOM. 60% of the patients did not have any AOM again, and 28% only one, when the usual thing with the conventional treatment is that new episodes had been repeated and had ended up in the ENT specialist consultation, many of them being intervened with tubal implants and/or adenoidectomy. The number of AOM episodes decreased by 87.5%, from an average of almost 4, to less than 0.5% episodes per year.

Although the effectiveness of the immune system increases with age and recurrent episodes spontaneously disappear, neither could such a convincing and satisfactory evolution be prevented, preventing patients from having surgery. Even the youngest children stopped having AOM within a few weeks of starting nutritional therapy. We observed a notable decrease in the degree of intensity of AOM, such that in addition to a reduction in total AOM cases, patients who followed nutritional guidelines experienced fewer symptoms. It is important to note that during the time that the incorporation of patients to the study lasted, we extended the application of TMD to the entire paediatric population (siblings, relatives, patients with other recurrent pathologies, and infants under two years of age). This led to a progressive decrease in patients diagnosed with AOM, so the achievement of the sample size was delayed [29].

As we have verified in previous studies [14], URIs, which are among the main factors predisposing patients for inflammation in the middle ear, decreased notably [30]. In our study, we observed a 60% reduction in URIs compared to the previous year. Likewise, intense pain as a result of AOM is one of the most frequent causes of paediatric emergencies, and we observed a significant reduction of 83.5% in such emergencies compared to the previous year. As a consequence of the decrease in URIs and AOM, the use of symptomatic treatment decreased by 63.2%. Likewise, antibiotic treatment was reduced by 86.4%, which indicates the greater benignity of infectious processes. The degree of satisfaction that the parents showed in the clinical evolution test was high, with scores that indicate a good therapeutic and clinical evolution. In the first four months, improvements were already observed with respect to the situation of the previous year, so that loyalty increased and monitoring was easier. There was a good tolerance to the proposed diet, with easy adaptation and without great culinary difficulties. 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. The group of patients who underwent blood tests showed a striking elevation of TNF- α as well as, to a lesser extent, other inflammatory markers, which could suggest that a pro-inflammatory diet could alter the inflammatory mechanisms [31,32]. 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. We find this absence surprising, as if it were taken for granted that the quality of food is not important in the balance and maintenance of the inflammatory and immune system. Our proposal is very simple: let's give the body the food and lifestyle it needs to defend itself and avoid those factors that harm it. We want to highlight that the majority of published studies on the treatment of RAOM are based on the application of external actions to the organism, such as the use of drugs or surgical intervention. Primary prevention and strengthening of the immune system have not been taken into account, dietary factors have not been considered, when probably the deconfiguration of the inflammatory system and the immune system are at the base of the RAOM [33,34]. Research has suggested the protective effect of breastfeeding for at least 6 months, although other risk factors accumulate after that age [35]. Among them, the early introduction of adapted milk has been noted [10,36] as well as the abuse of antibiotics [37]. A pan-European study [38] 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. It has also been shown that patients with AOM show altered regulation of key immune mediators during health and pathogenesis, and are susceptible to being treated by an immunomodulatory intervention [39]. Predominantly eating food with a low glycaemic index/load—typical of TMD—helps to control insulin levels; this hormone may interfere in the formation of anti-inflammatory eicosanoids, by blocking the $\text{la } \Delta$ -desaturase enzyme [40]. 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 immune processes. Children with RAOM have been shown to have poor responses of pro-inflammatory cytokines and antiviral chemokines [41]. HMGB1 (High-mobility group box protein 1) that acts as a mediator between innate and acquired immunity, is overexpressed and can play a role in the progression and recurrence of RAOM acting as an inflammatory marker and cytokine [42].

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 [43]. Children with RAOM show immaturity in antigen presenting cells with a suboptimal response of T cells and B memory [44]. The absence of Toll-2 receptors (TLR2) can lead to prolonged inflammation of the middle ear. TLR2 is essential for the timely resolution of inflammation since it has been proven to promote macrophage recruitment and bacterial clearance in the mouse [45]. The pro-inflammatory actions of PAF (platelet-activating factor) can be favourably modulated with TMD and regulate its metabolism [46]. The benefits of breastfeeding in the prevention of AOM have been proven, due the presence in breast milk of antibodies, antibacterial enzymes, glycosylated proteins, anti-viral fats and leukocytes [10], but also due to decoy receptors for bacterial pathogens, such as oligosaccharids [47]. Components that favour the development of standard saprophytic flora, which prevents the development of otopathogens [48]. These components are currently being added to formula milk, to improve its immune boosting quality [49]. Probiotics are also added, with satisfactory results in the reduction of URI and AOM [6]. After ceasing breastfeeding, the occurrence of AOM, increases with artificial feeding [50]. It is important to remember the "transient hypogammaglobulinemia" of infancy. At the age of 12 months, IgA levels are just 20% of those in adults [51], 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 complementary foods. Finally, we must take into account the "intestinal and nasopharyngeal microbiota" [52]. The mechanisms by which the intestinal flora regulates our immune responses are unclear, but it seems sensible to encourage the development of a 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 [53,54].

Among the limitations of the study, we note the impossibility of establishing a control group with standard dietary guidelines, since we had considered them pro-inflammatory and unsuitable for children. We also had difficulty obtaining our sample, since we extended the TMD to the entire paediatric space, which resulted in a reduction in the incidence of AOM. We consider the presence of nutritionists essential to be able to make satisfactory changes in the diet and to be able to reproduce these studies. We believe that the absence of these professionals is the cause of the poor nutrition that our society suffers.

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 [29,54]. 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.

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