

A report on a trial of the low additive, low salicylate diet in the treatment of behaviour and learning problems in children

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Abstract Five hundred and sixteen children attending a metropolitan child psychiatry service trialed a low additive low salicylate (LALS) diet as part of management of behavioural and learning problems. The mean age was 7.8 years; 85% were males. A positive response was obtained in 79.5% of children, with a normal range of behaviour achieved in 54.5%, of the 25% in whom diet was necessary but not sufficient, half also required stimulant medication. Non-responders were 9.3%, those not available to follow up were 8.7% and those not implementing the treatment 2.5%. As well almost 50% limited or excluded other foods, particularly chocolate, milk and wheat. Amongst presenting problems change occurred in behaviour, social, learning, activity, sleep and allergic problems. There was no gender effect, but an age effect was evident with the proportion of responders in the under nine group being significantly higher. If there was a family history of allergy, and where there was intolerance to any food, the likelihood of a positive outcome was higher, but outcome was not affected by a belief that food affected the child. Additives and salicylates are better thought of as aggravating the underlying predisposition in susceptible children, rather than as causative agents. (*Aust J Nutr Diet* 1991;48:89-94).

Keywords: diet, additives, salicylates, hyperactivity, food allergy, child behaviour.

Introduction

The role of food as a factor in behavioural and learning disorders had been under discussion for 15 years following Feingold's hypothesis that artificial colours and flavours cause hyperactivity (1). At first the public hoped it was an easy answer to an often complex problem, and was very enthusiastic. When double blind controlled studies in the 1970s (2-5) largely refuted the initial extravagant claims, many professionals dismissed the hypothesis altogether and public interest waned. Early research in Australia included studies by Cook and Woodhill (6), Levy (7) and clinical research by Salzman (8) and Breakey (9).

Since then double blind trials have shown the presence of food intolerance to many additives, salicylates, amines, monosodium glutamate (MSG), and yeast in a variety of conditions (10,11). These have included overactivity and behaviour problems in children (12,13). As well, analyses of the amounts of salicylates in Australian food have been published (14), making research in this area more scientific.

The foods excluded in research into hyperactivity have changed too. Egger et al. (15) used an oligoantigenic diet, and reported that 81% of 76 children improved, and 27% achieved a normal range of behaviour. Rowe (16) excluded azo dye additives, artificial colourings, preservatives and perfumes. Of 55 children, 72.7% demonstrated improved behaviour and 47.3% remained improved following diet liberalisation. Eight of those who improved were included in a double-blind study and two were significant reactors. In the light of this it is now timely to reflect on whether a strict, moderate or 'liberal' elimination diet should be used in children with behaviour, activity or learning problems.

This clinical study reports on a trial of the low additive low salicylate (LALS) diet in the management of behaviour and activity problems in 516 children, identifies the clinical issues in the implementation of the diet, and clarifies the needs and direction for future research. The LALS diet excludes artificial colours and flavours, most strong aromatic smells, salicylates, many preservatives, MSG, and chocolate. It limits intake of added natural colours, flavours, amines and yeast spreads.

Method

The use of clinical controls was considered initially. However, random allocation to a no-treatment control group was considered unethical, and use of the treatment in those outside was impractical. Later, the use of capsules for a double blind design was also considered when these became available. They are useful for showing whether or not patients react to a specific dose of a particular additive or substance.

In a study of 136 hyperactive children (17) 132 were shown to react to at least one substance in a double-blind challenge of salicylates, amines, brewers' yeast and additives, and in only five instances was this a placebo. It was also shown that there was a 95% correlation between positive challenge results in 342 food intolerant patients and follow-up reports of foods identified as causing reactions (17), showing patient reports to be useful.

The next step addressed in this study was to determine if the dose of problem items usually taken in food in children presenting with behavioural problems, is sufficient to produce reactions. During the trial, attempts were made to diminish the likelihood of a placebo response in the presentation of the treatment. Patients were told that it was not known which children would respond, nor which presenting symptoms would change if they did, or the amount of change, nor which of the groups of excluded substances would be tolerated by them individually during food challenge reintroduction. They were encouraged to develop a 'detective' approach. As well, follow-up occurred at least six months after the diet trial.

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Subjects

The 516 families taking part in the study were seen by a dietitian (JB) within the Division of Youth, Welfare and Guidance of the Queensland Department of Health. The clinics comprise an outpatient child psychiatry service providing comprehensive assessment and treatment for young children and adolescents with emotional problems. The model of service provision is an eclectic approach including family involvement, utilising a multidisciplinary team. The 12 clinics attended are spread throughout the Brisbane metropolitan area. The dietitian attended each clinic for one day each 12 weeks.

The sample was derived from three sources. The majority, 447 (86.6%), were families attending the clinic as patients, 39 (7.6%) were members or contacts of the self-help Queensland Hyperactivity and Allergy Association, and the remainder, 28 (5.4%), were referred from general practitioners. The sample comprised: **Group 1** (197) who attended from mid-1984 to mid-1986; **Group 2** (206) attended from mid-1986 to mid-1988; and **Group 3** (113) from mid-1988 to mid-1989.

Clinic patients were referred for diet therapy after reporting that they believed food affected their child, if there was a family history of some type of allergy, or if other interventions were partly satisfactory or unsuccessful. Where more than one child in a family was referred then the presenting child or the oldest became the sample subject. The sample was 2.5% of the clinic population.

There were 438 (84.9%) boys and 78 (15.1%) girls. Distribution in the three groups was similar. This distribution reflects the pattern of total clinic attendances. The subjects ranged from two to 16 years. The mean age was 7.8 years (sd 3.3), and was similar in all three groups.

The patient's date of birth, allergy history, presenting problems, referral source, diet implementation date, other food limitations, medication use, and progress were recorded. Considerable effort was invested to maximise those followed up.

The diet

The diet used was the Low Additive Low Salicylate (LALS) diet. It was based on the Feingold diet of 1976 (1), updated by clinical findings since then, and incorporated data on salicylate levels from A.R. Swain (1982, pers. comm.). Considerable effort was made to ensure that diet therapy and written information were detailed and consistent.

Because reaction to problem items is dose-related, the diet included 'use occasionally' foods to test. These were included so families had sufficient drinks and desserts to provide a diet which could be adhered to for a long period. A comprehensive commercial food list was compiled and revised yearly.

Families were given:

- a summary of items excluded;
- a diet list of 'allowed', 'use occasionally', and 'disallowed' foods;
- a commercial food list;
- a menu guide; and
- a diet manual (optional, especially to Group 1).

(Copies of the diet information can be obtained, by request from JB).

Treatment implementation

The testing phase

On the first visit the family was encouraged to use the test diet. A Free of Additives Free of Salicylate (FAFS) diet was used where the child was under five years, if the family was very motivated, or if the problem was severe. Others used a strict Low Additive Low Salicylate (LALS) diet which allowed more vegetables. No additional fruit or 'use occasionally' foods could be used during the trial. If other foods, e.g. milk or wheat, were limited or excluded, their preferred intake was maintained during the trial. In a small number, a liberal Controlled Additive Controlled Salicylate (CACCS) diet was used at first.

In the diet therapy session the diet was explained and applied to the family's eating pattern so that alternatives to favoured food, were found. Suggestions were given with regard to planning meals, shopping, cooking methods, outings, parties, incorporating any other diets used in the family, as well as on voluntary exclusions by fussy eaters. Unless the family was certain the child reacted adversely to foods there was no assumption the diet would be useful. Other clinic support and therapies continued as usual. Using the diet did not alter the child having responsibility for his or her actions.

The challenge phase

At the end of the test phase families were asked to record outcome and where there was any doubt about response they were asked to deliberately challenge with favoured disallowed foods until a definite adverse reaction occurred or for one week. Often challenges occurred in the normal course of living where a child at an outing would obtain a disallowed food and the result noted. A challenge in the usual home situation would then be carried out.

If there was no change during the trial the family was encouraged to return to a normal diet and increase emphasis on other management techniques and treatments.

Many families had reported reactions to foods but few had clarified and recorded responses to be sure of the food implicated, the amount involved, or the specific outcome. So each was encouraged to record progress in a Diet Detective Book.

The treatment phase

Once the diet trial showed the need for the diet, therapy changed to long term management and the LALS diet was used. An important part of treatment was food reintroduction. Each food reintroduced was regarded as a challenge test item. Parents were given guidelines on 'use occasionally' foods to test. These were listed in order of reported tolerance incorporating salicylate and other problem content dosage, and formed the progress report.

As well, diet therapy dealt with such issues as the level of strictness necessary, disliked foods, managing the food for the whole family, motivation and contriving adherence while the child interacted with school, friends and well-meaning relatives. Since many had developmental delays in other areas it is probably not surprising that many had immature eating patterns; mothers were reassured and a food introduction program implemented.

Gradually, finer points and diet flexibility were included as well as how to ensure adequate nutrition. Vitamin,

mineral or other food treatments which may have been considered by parents were discussed. Where milk, grains or other foods were limited, exclusion and challenge reintroduction were conducted to ensure justification for exclusion or to gradually reintroduce to tolerance level.

Diet therapy also included managing the child coping with a special diet. This varied with the types of behaviour present as part of the presenting problem, e.g. sneakiness and stubbornness, and particularly with the age of the child. The concept of being a 'Diet Detective' and testing one food at a time 'to see how well he handled himself' was used to encourage responsibility in the child. Treatment was adjusted to incorporate differing stages of development as the child matured. Parents often thought, incorrectly, that primary school children who understood their diet would not continue to need supervision. Some children moved to the CACS diet as problems were managed or in late teenage. The dietitian usually saw mothers but mothers were encouraged to bring their children and often did, especially when motivation was low. Often, returning mothers attended as a group.

Outcome definitions

A *good diet responder* was a child whose mother reported a positive relationship between the use of the diet and the decrease in presenting symptoms, with deterioration after diet breaks, or following reintroduction of foods with some additives. This is important as initial improvement can be a placebo effect but it does not explain the deterioration particularly where it is a desired food or when no reaction is convenient. There were grades of response ranging from mothers who were sure but family and friends were not supportive in belief or implementation of the diet, to those where the change was dramatic and noticed by all friends, relatives and teachers. In a 'good responder' the diet was sufficient treatment; a normal range of behaviour was achieved.

For Groups 2 and 3 a category of *responder* was separated out. These were defined as those children who got much worse if the diet was broken but in whom the diet was not sufficient treatment. It includes those who also used medication to help with behaviour and learning problems. (For Group 1 this category was constructed retrospectively.) As a clarification, 'responders' included those whose parents answered 'no' to the question, 'would you give, or let someone else give your child a glass of red cordial?'

A *non-responder* was a child in whom the diet was not a useful treatment. This included those who reported no change after the diet trial and also the small number of children whose parents reported reactions to foods but in whom the diet could not be managed and was therefore not a useful treatment.

A child whose family at follow-up reported that they had not implemented the treatment was included in the 'not implemented' group.

Results

Descriptive statistics are presented for treatment response in variables of clinical interest. Since they were categorical in nature, Chi-square tests were used. Presenting problems included behaviour in 319 (75.8%), learning in 255 (49.4%), activity in 216 (41.9%), allergies in 224 (43.4%), social problems in 176 (34.1%), and sleep problems in 77 (14.9%). There were 44 (8.5%) on stimulant medication and 22 (4.3%) on antidepressants, 24 (4.7%) on asthma medication

and 13 (2.5%) on other medications. Table 1 shows diet treatment outcome.

Table 1. Diet treatment outcome after a low additive and low salicylate diet therapy trial.

Outcome definition	n	%
Good responder	281	54.5
Responder	129	25.0
Total responders	410	79.5
Non-responders	48	9.3
Not implemented	13	2.5
Not available for follow-up	45	8.7

Parents in 410 families reported that the LALS diet was useful in the management of the presenting symptoms to the extent that they persisted with this difficult treatment for more than six months. Compliance was surprisingly high considering the effort involved in monitoring all meals, including food eaten at school and socially.

There was no gender differential observed among 'responders' but an age effect was evident. The proportion of 'responders' under nine years of age was significantly higher than in the older age group (Table 2).

A family history of allergy was reported in 351 (68%); none was reported in 50 (9.7%) of the total. In Group 3, where total data were computed, if there was a history of allergy the likelihood of a positive outcome was greater (Table 2, $p < 0.05$). The likelihood of a positive outcome was stronger again in those who were intolerant to some food (milk, grains, chocolate or common food allergens) (Table 2, $p < 0.001$). However, absence of a history of allergy in 59 families in the total group did not preclude a positive outcome. The outcome in those families who believed food affected their children—172 (83%) of Groups 2 and 3—was no different from the group as a whole.

Some foods were not tolerated as well as expected with respect to the salicylate analysis (14) in those who proved to be salicylate sensitive, especially in younger children. Some foods were reported so often they justified alteration to become test foods. They included 'golden delicious' and 'red delicious' apples, pear peels (i.e. pear juice, nectar and dried [no preservative] pears), and lemon (fruit and natural lemon flavoured drinks [no colour]). On the other hand avocado, and dilute pure mango and golden passionfruit drinks were better tolerated than expected. The availability of cheap tropical fruit made trials of individual fruits easier. Other substances or factors producing reactions in some included artificial flavours, vanilla (both natural and artificial), many strong smells, infections both viral and bacterial, (i.e. factors separate from the coloured and flavoured medications used in treatment), overtiredness and additional stress in the family.

As well, there were many who found they needed to exclude foods outside the exclusions of the LALS diet. The foods included were milk, grains or chocolate and other common food allergens (Table 3).

Another interesting finding was that children who were reported as reacting to chocolate also presented with a greater likelihood of activity and social problems (Odds ratio = 1.55, $p < 0.02$). The Odds ratio for the likelihood of sleep problems in this group was also high (Odds ratio = 1.55, $p = 0.09$). Many of those who had adverse reactions to foods in

Table 2. Diet treatment outcome with age, food intolerance and allergy history^(a).

	<i>Good responder</i> n(%)	<i>Responder</i> n(%)	<i>Non-responder^(b)</i> n(%)	<i>Total</i> n(%)
Age (years)				
2-8	187(39.7)	63(13.4)	37(7.9)	287(60.9)
9-16	94(20.0)	66(14.0)	24(5.1)	184(39.1)
Total	281(59.7)	129(27.4)	61(13)	471(100)
Chi-Square = 11.65, df = 2, p<0.005				
Intolerance to some food				
Yes		213	11	224
No		197	50	247
Total		410	61	471
Chi-square = 23.1, df = 1, p<0.001				
Family history of allergy				
Yes		74	9	83
No		17	8	25
Total		91	17	108
Group 3 only. Chi-square = 4.99, df = 1, p<0.05				

(a) Those not available for follow-up are not included.

(b) This also includes those in the 'not implemented' group.

Table 3. Numbers of families who excluded or limited foods other than LALS^(a) diet exclusions.

<i>Reason for exclusion/limitation</i>	<i>n</i>	<i>%</i>
Intolerant to some food	249	48.3
Limited	156	30.2
Excluded	119	23.1
Milk intolerance	124	23.9
Limited	78	15.0
Excluded	46	8.9
Grains intolerance	41	7.9
Limited	21	4.0
Excluded	20	3.9
Chocolate intolerance	158	30.6
Limited	88	17.0
Excluded	70	13.6
Common food allergens intolerance	58	11.2
Limited	28	5.4
Excluded	30	5.8

(a) Low Additive Low Salicylate diet.

infancy presented with allergic symptoms so it is less surprising that the presence of allergies was significantly higher in those who had problems with milk (Odds ratio = 2.00, p<0.001).

Improvement occurred in all presenting problems with individual variations in the degree of improvement across presenting problems. A Chi-square test of homogeneity between presenting problems and outcome revealed that the proportion with learning problems were over-represented in the 'non-responder' group (Chi-square = 5.37, df = 10, p<0.05).

Discussion

In this clinical study of 516 children, 79.5% found the LALS diet useful in the management of behavioural and learning problems with 54.5% achieving normal functioning. The results were consistent in the three groups over the five years. This rules out the impact of media or confounding due to local 'history' effects.

Feingold (1) hypothesised that artificial colours, flavours and salicylates caused hyperactivity. The improvement observed in this study was one of degree where the additives and salicylates aggravated an underlying predisposition in susceptible children. The effect is not all-or-none, with some children, but not all, achieving normal functioning. The results here are similar to those of Egger et al. (15) who reports 81% of his group as responding to diet with 27% achieving normalisation.

In following-up those using the diet it is important not to simply ask, 'are you still using the diet?' since it was found that some parents answered 'no' when the restrictions had become voluntary or when several low-additive foods had been tolerated. When asked, 'do you still need to exclude additives and some fruit?', the clarification between those not prepared to use excluded foods because of reactions, and 'non-responders', can be made. Rowe (16) stated that within her so-called placebo group where improvement continued 'off the diet' it was 'difficult to assess whether there may have been an unconscious reduction of such foods relative to pre-intervention quantities'.

Where some early research on the Feingold diet reported a positive effect (3,5) it was in younger children. This may be because the younger children have earlier, clearer reactions and those beginning school have had problems investigated. In more older children, problem foods may be eaten for a few days before deterioration occurs. As well, established behaviours in older children complicate the effect of a single intervention.

Other research into food intolerance has reported changes in the main presenting symptom as well as other symptoms (10). So even where a child has not had a significant improvement in learning, the treatment may still be very useful if other problems improve. Learning problems are complicated by parameters independent of concentration problems. Sleep problems, often reported as decreasing, have been unnoticed in early research but are also emphasised by Rowe (16).

Since this is a clinical study other treatments were considered for the children. There is a role for both diet and medication in some, (particularly where learning problems

persisted), as well as behavioural and psychotherapeutic help.

It is becoming popular to begin dietary management with many food as well as additives exclusions. However this makes dietary management much more difficult and does not appear to be necessary. Since only 24% had problems with dairy foods and only 8% with grains, these foods should not be excluded by everyone trialing diet initially. It was only necessary to completely exclude milk or grains in less than half of these. This is an area where the role of the dietitian is very important in conducting a careful family diet history and organising gradual food reintroduction.

Since the 31% who reported problems with chocolate is a conservative estimate (Swain (18) reported 52% of hyperactive children reacting to double-blind challenges with amines), and since chocolate is an easy exclusion, it is best excluded initially. It becomes a bonus if it is tolerated. With hindsight, it is probable that the results of early research were confounded by the usage of chocolate bars and cookies as the vehicle for test doses of colours (3-5), especially considering the particular correlation between the presentation of activity and reported intolerance to chocolate.

There were no reported adverse effects of the diet. Where there was a risk of nutrients being insufficient (vitamin C, and calcium where milk was excluded) alternative food sources were encouraged or an appropriate supplement suggested. The greater concern in thin, active children is ensuring sufficient overall energy intake. It is important to ensure no unnecessary exclusions, often by helping parents who have become afraid to reintroduce groups of food. Occasionally a parent needs special interventions to ensure a child is not starved.

The reported intolerance to some low-salicylate foods raises some questions. It is known that as fruit ripens salicylate levels drop, e.g. in 'delicious' apples, and amine levels rise, e.g. in bananas (A. Swain, pers. comm.). The content may vary with season (a variation in bouquet is expected in grapes) or variety. Hence the bland 'golden queen' peach is better tolerated than the tasty varieties. It is also necessary to be open to the possibility that other natural substances in fruit could be a problem to some individuals.

Some other issues were demonstrated as important in clinical management: 1. the frequent occurrence of a withdrawal (worsening of symptoms) when the diet is initiated; 2. a build-up effect, often taking four to five days for problems to recur after a food reintroduction; 3. a reaction delayed for up to 24 hours (also reported by Swain (17)); 4. the size of serves, their frequency of use and the inclusion of other foods containing similar items, all affecting the dose of additives and salicylates; and, 5. the need to ensure exclusion of artificial flavours, and to minimise contact with strong smells. Overall it can be seen that the dietitian has an important role and that diet therapy, like any other therapy, is not just a matter of handing a patient a written outline.

There is a need for further research. The diet itself needs further refinement. The role of artificial flavours and smells may be important but cannot be tested using double-blind methodology. At present it is suggested that dietary exclusions should exclude, allow or limit all those compounds and foods outlined in the diet, individualising it by incorporating family diet history factors. New foods should be reintroduced one at a time as challenge items. A dietitian familiar with the diet and its management in children with behaviour problems

is essential. All presenting symptoms need to be considered and monitored, partial responses should be expected, individual variation presumed, and the role of other interventions, particularly medication, should also be incorporated. The age of the child and the presence of an atopic family history can be important in selecting the sample. Finally, the need to consider withdrawal, delayed and build-up effects, as well as dose are important in ensuring sufficient time (seven days) between double-blind or food challenges. Research in this area is not neat or easy as the families are often coping with very difficult children.

These factors should also be noted by clinicians who sometimes give support to families excluding obvious additives where they are reported a problem by parents. If dietary intervention is considered potentially useful it should be done properly for the child's sake. The maximum effect of the diet can be clarified, or if it is useless it can be discontinued. Diet histories showed that many families try 'alternative health' diets or decide on food exclusions without telling their doctor. Dietary intervention is difficult, but where there is improvement, parents report it is better than managing a difficult child. The diet is occasionally useful in teenagers with behavioural problems, but it is important to ensure that the teenager, not just the parents, is motivated to use the treatment as there are many issues to be managed.

In conclusion it can be said that the Low Additive and Low Salicylate (LALS) diet has a place with other management, in the treatment of children with behaviour and learning problems. Comprehensive diet therapy is necessary. The reintroduction of other individual foods to tolerance level helps ensure maximum nutrition and long-term management. The concept of the child being a 'Diet Detective' helps the child have an inquiring attitude in using diet therapy to help manage him-or herself.

Dietary factors should be considered as aggravating the underlying predispositions in susceptible children rather than as causing hyperactivity, with a positive outcome being one of degree. Individuals vary in the areas and degree of change. The National Health and Medical Research Council Nutrition Policy Statement of 1978 (18), considering the relationship of diet and hyperkinesis, states that 'such a relationship has not been established'. It is suggested that this statement be reviewed to incorporate this and other research since then.

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