

A Comparative Study of the Acceptance and Tolerance of Orange Juice and "Commercial Instant Breakfast Drink" by 114 Infants

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IT is generally accepted that a supplementary source of vitamin C should be added to the diets of bottle-fed infants;^{1,2} 25 to 30 mg. per day is the recommended quantity for this purpose.² This supplementation usually is given in the form of orange juice, either freshly squeezed, canned, as reconstituted frozen concentrate, or as a multivitamin product.

In view of the desirability of supplying a continuous, adequate amount of vitamin C to infants, reports on the vitamin content of oranges were reviewed. A considerable variation in this content was noted. Holmes et al.³ found a range of from 27 to 67 mg. of ascorbic acid per 100 cc. of orange juice, and further reported that forty-four samples of juice gave twenty-six different values. Other workers have reported from 32 to 64 mg.⁴ and from 45 to 51 mg.⁵ of ascorbic acid per 100 cc. of orange juice. California oranges were found to have a significantly higher mean ascorbic acid content than Florida oranges.⁶ The vitamin content of Florida oranges varied with the season of picking, variety, root-stock differences, and geographical location;⁷ oranges on the outside of trees, where there was more sunlight, had more ascorbic acid than oranges within the trees;⁸ the weight of the orange and the quantity of peel or juice did not reflect the vitamin content.⁹

Allergic reactions to orange juice pose another problem. Allergy to citrus fruits is reported to be quite common, especially in chil-

dren, and is often seen as atopic dermatitis (eczema). Although this is generally outgrown, it can impede infant feeding. Great care should always be used in extracting the juice of the orange, both commercially and in the home; the rind oils are irritants, and may cause allergic reactions. Chemical changes and bacterial growth in orange juice may also cause untoward reactions.¹⁰

The use of synthetic vitamin C as a replacement for orange juice in infant feeding has already been advocated.^{11,12} The advantages this would offer include a fixed and known vitamin quantity, elimination of potential allergens and spoilage factors, and for the mother, reduced preparation chores, such as cutting and squeezing oranges when fresh oranges are used. Canned and frozen juice involve little effort and are satisfactory alternatives. There is no indication that the synthetic vitamin is less utilized or less effective than the naturally occurring form.¹³⁻¹⁵

It was decided to evaluate a powdered preparation, "Commercial Instant Breakfast Drink" (CIBD)‡ which contains a fixed vitamin potency, requires no refrigeration, and can be reconstituted CIBD with commercially available orange juice§ and a control solution||

‡ General Foods product, Tang[®] containing sugar, citric acid, gum arabic, carboxymethylcellulose, sodium citrate, calcium phosphate, vitamin C, hydrogenated vegetable oil, natural and artificial flavors (includes butylated hydroxyanisole, a preservative), vitamin A, artificial color.

§ Blue Boy Dairy, Rochester, New York

|| Data on control: 12.8 per cent dextrose solids, and coloring in a mixture of U. S. Certified Yellow Colors No. 5 and 6.

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which contained approximately 13 per cent dextrose and certified color, U.S.P., on the basis of the readiness of acceptance by infants and the provocation of any intolerance signs such as gastrointestinal upset, allergy, or other irritations.

SELECTION OF PATIENTS

The babies were selected from the ward service of Strong Memorial Hospital. All babies born between March 1 and May 1, 1959, were treated in the order of the mother's admission to the hospital. By May 1, 160 babies had been born and the only ones excluded from the study were those born prematurely, one born with an intestinal anomaly, and one with severe brain damage. Other babies were later dropped from the study because of the mother's failure to return for follow-up studies and because of unreported changes of residence.

METHOD OF STUDY

During the mother's confinement, the floor nurse, who was chosen particularly for this task, informed her about the study. She described how free "orange juice" would be delivered twice weekly to the home for three months. A three month supply of a multivitamin supplement* would also be provided. The mother was told how to administer the "orange juice," was given an instruction sheet, and was told to note the baby's reactions. Her history was taken, including the normalcy of pregnancy and birth and family allergies. When there was family allergy no attempt was made to shield the baby from potential irritants.

After the confinement, public health nurses who periodically visited the homes, reported to us the mother's cooperation with the study.

The services of a local Rochester dairy that delivers both milk and orange juice were enlisted. These mixtures were prepared at the dairy and packaged in 1 pint containers. They were: (1) CIBD, (2) chilled orange juice, and (3) a control solution prepared to resemble orange juice. Each of the three solutions carried an identifying code number, and babies were assigned their number in serial rotation. The physicians and nurses did not know what the codes represented. The babies received the same number solution each delivery. A second trial period was then begun by changing the number of the solution.

* Zymabasic Drops (A, D, C, B₆ aqueous solution) supplied through the courtesy of Mr. Gerald Hoke of The Upjohn Company, Kalamazoo, Michigan.

TABLE I
Responses to Ingestion of Juice

Data	Solu- tion 1 (CIBD)	Solution 2 (Com- mercial Orange Juice)	Solution 3 (Con- trol)	Total
Number of babies	38	39	37	114
Reactions (no. of babies)				
Rash.....	10	15	14	39
Vomiting.....	1	3	3	7
Diarrhea.....	0	0	0	0
Total reactions	11	18	17	46
No reactions..	27	21	20	68
% reactions...	29	46	46	40.4 (for entire group)
Reports on the acceptability of the solution to the infants were as follows:				
"Didn't like"...	4	3	8	15

The following instructions were issued: "Start by mixing water half and half with the orange juice supplied to you by the dairy. The first day use 1 teaspoonful of orange juice and 1 teaspoonful of water. The second day use 2 teaspoonfuls of orange juice and 2 teaspoonfuls of water. Increase the mixture daily until you are giving 6 teaspoonfuls of each (1 ounce). Then decrease the amount of water gradually until you are using 2 ounces of straight orange juice." (Note: the term "orange juice" could mean any of the three solutions.)

The mothers were required to report the amount of "orange juice" taken by their baby and whether there was vomiting, diarrhea, colic, colds or sniffles, or skin disturbances. It is noteworthy that the test was conducted during the late spring and summer months when baby skin irritations are most common.

When the baby was one month old (and on "orange juice" for two weeks) he was brought back to the clinic for an examination. This was repeated at the ages of eight, twelve and sixteen weeks. Specific inquiries were made at each visit regarding the baby's response to the "orange juice."

All babies were bottle-fed on evaporated milk and sucrose formulas except for six who were breast-fed. The majority of babies did not begin to receive single grain cereal and other solid foods until they were at least fourteen weeks of age.

RESULTS

A total of 114 babies were studied starting from the age of two weeks for a period of at

TABLE II
Family History of Allergy

Data	Solution 1 (15)		Solution 2 (21)		Solution 3 (25)	
	No History	Past History	No History	Past History	No History	Past History
Rash.....	6	4	12	3	11	3
Vomiting....	0	1	1	2	0	3
Didn't like...	3*	1	2*	1	8*	0
No reactions..	19	4	15	3	15	7
Total infants	28	10	30	9	34	13

NOTE: Figures in parentheses represent total number of reactions.

* Rash developed and baby did not like juice.

least three months. Thirty-eight babies received "CIBD"; thirty-nine received a commercial, fresh orange juice; thirty-seven received the control solution which resembled orange juice. The adverse reactions which developed during the time the juice was administered are recorded in Table I. The term

TABLE III
Treatment of Rash

Data	Treatment and Result	Solution 1	Solution 2	Solution 3	Total
Stopped juice	Improved.....	1	8	3	12
	No change.....	4	1	2	7
	Refused.....	0	0	1	1
Total..		5	9	6	20
Continued juice	Improved.....	4	2	7	13
	No change.....	4	5	3	12
Total..		13	16	16	45

"reaction" is used for any symptoms which occurred although it does not necessarily indicate they were due to the juice.

The rashes reported were nonspecific macular to maculopapular rashes with erythematous bases. In no case was any rash reported to itch. Response situations were studied and evaluated carefully to eliminate the possibility of any etiologic factor other than the solution

TABLE IV
Time of Onset of Rash

Rash Onset	Solution 1	Solution 2	Solution 3	Total
Mild				
Before juice.....	2	1	1	4 mild before juice
Within 1 week.....	5	3	7	15 mild 1 week
Later.....	2	4	1	7 mild longer
? onset.....	0	4	2	6 mild ?
Total.....	9	12	11	32
Moderate				
Before juice.....	1	0	1	2 medium before juice
Within 1 week.....	1	1	0	2 moderate 1 week
Later.....	1	2	2	5 moderate longer
? onset.....	0	1	0	1 moderate ?
Total.....	3	4	3	10
Severe				
Before juice.....	0	0	0	0 severe before juice
Within 1 week.....	0	0	1	1 severe 1 week
Later (eczema).....	1	0	1 (eczema)	2 severe longer
? onset.....	0	0	0	0
Total.....	1	0	2	3
Grand total.....	31	16	16	45

TABLE V
Body Distribution of Rash

Rash Distribution	Solu- tion 1	Solu- tion 2	Solu- tion 3	Total
Face only.....	4	5	7	16
Diaper only.....	0	1	3	4
Generalized.....	5	7	3	15
Seborrhea or eczema.....	4	3	3	10
Total.....	13	16	16	45

being tested. No form of therapy was given for the rashes at any time. The response to the three solutions is given in Table II.

Solution 1 (CIBD) gave the lowest percentage of side reactions: 29 per cent compared to 46 per cent for commercial orange juice (solution 2) and 46 per cent for the control solution (solution 3).

Babies with a history of family allergy accounted for a considerable proportion of the reactions. They were: 40 per cent (six of fifteen reactions) for solution 1; 29 per cent (6 of twenty-one reactions) for solution 2; and 24 per cent (6 of twenty-five reactions) for solution 3. Of thirty-two babies with a history of family allergy, eighteen (56 per cent) showed an undesirable reaction in the course of this study.

When the feeding of solutions was discontinued the following appearance of a rash in twenty babies, eight of nine who had been receiving commercial orange juice improved only one of five receiving CIBD improved, and three of six on the control solution improved (Table III). As an extra check on results, babies were switched from one solution to another by changing the meaning of the code during the last weeks of the juice distribution. An effort was made to supply fifty additional infants with a different solution, but they could not be followed up adequately due to conditions beyond our control. Some rashes developed in infants, without apparent cause, before any of the solutions could be administered. These data are listed in Tables IV and V.

Application of standard statistical methods¹⁶ to the data in Table II indicates that the probability of an untoward reaction is independent of the solution used. For rashes alone, $x^2 =$

1.58, $p > 0.3$, and for all reactions including the "didn't like" category, $x^2 = 3.07$, $p > 0.2$.

CONCLUSION

A comparative study was made of the responses of 114 infants to three solutions: orange juice, a synthetic preparation and a control solution which did not contain any natural orange juice ingredient. Acceptability and response as recorded indicated that rashes are common in small babies and, that at an early age, taste is a factor. These responses occurred in the group receiving the control solution, to at least the same extent as in those receiving the test solutions, thus raising the question as to the validity of the tag "allergic reaction" so frequently used in connection with a rash in children on orange juice. Statistical tests failed to indicate a significant difference in the incidence of untoward reactions to the three solutions employed.

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