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Use of a Homeopathic Preparation for “Infantile Colic” and an Apparent Life-Threatening Event



WHAT'S KNOWN ON THIS SUBJECT: An ALTE caused by ingestion of drugs or toxins has been reported rarely. Some homeopathic remedies are widely used for the treatment of colic; none of them has been associated with ALTE.



WHAT THIS STUDY ADDS: This retrospective case-control study describes an association between a homeopathic remedy Gali-col Baby and ALTE. This possible adverse effect calls for the study of efficacy and safety of homeopathic remedies.

abstract

OBJECTIVE: An apparent life-threatening event (ALTE) caused by ingestion of drugs or toxins has been reported rarely among infants. None of these agents was homeopathic medication. We report 11 infants who presented with an ALTE after ingestion of Gali-col Baby, a homeopathic agent indicated for “infantile colic.”

METHODS: A retrospective case-control study was conducted. Charts of all infants who were younger than 1 year and were admitted with an ALTE from January 2005 through August 2008 to the pediatric division at the Barzilai Medical Center were reviewed. Age-matched infants who were admitted on the same dates for a reason other than ALTE served as a control group. Information on medications administered before admission was recorded.

RESULTS: During the study period, 36 635 children visited the pediatric emergency department of the Barzilai Medical Center. There were 11 057 admissions to the pediatric division during this period, 115 of which were because of an ALTE. Eleven of these infants received Gali-col Baby before the event as opposed to none in the control group ($P < .005$). Three infants received a significant overdose, compared with the manufacturer's recommended dosage. After a thorough investigation, no other presumptive causes for ALTE were found among the 11 infants.

CONCLUSIONS: Gali-col Baby is associated with an ALTE in some infants. There are no published controlled trials on the efficacy or safety of its use; therefore, better control and supervision of Gali-col Baby and probably other homeopathic medications are needed to prevent possible serious adverse effects. *Pediatrics* 2010;125:e318–e323

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KEY WORDS

apnea, cyanotic spell, apparent life threatening event, homeopathic, Gali-col Baby

ABBREVIATION

ALTE—apparent life-threatening event

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An apparent life-threatening event (ALTE) was described by the National Institutes of Health consensus group in 1986 as “an episode that is frightening to the observer and that is characterized by some combination of apnea (central or occasionally obstructive), color change (usually cyanotic or pallid but occasionally erythematous or plethoric), a marked change in muscle tone (usually marked limpness), choking or gagging.”¹ ALTEs caused by ingestion of drugs or toxins have been reported by very few authors.^{2–7} A systematic review that summarized 8 relatively large series of ALTEs estimated the rate of parental administration of chemical agents as 1.5% (11 cases) of all infants who received a diagnosis of having an ALTE.⁶ The largest collection of infants with presumed chemical agent–induced ALTEs included 23 patients.⁷ Agents that were given by parents included both prescribed and over-the-counter medications such as ephedrine, barbiturate, phenytoin, nicotine, dihydroergotamine, oxybenzone, and cocaine. Reasons for drug administration included the need to sedate a fussy infant, misunderstanding of the potential risk to the infant, or intention to poison the child.⁴ One report specifically addressed the use of colic medication Dramamine/Donnatal and ALTEs, suggesting its anticholinergic and central nervous system depression effect as the cause for ALTE.³

The use of homeopathic remedies is constantly growing without strict regulation of their manufacture and consumption and without evidence of efficacy and safety.⁸ It is commonly believed by the public and by some medical practitioners that, because of the very low concentrations of active ingredients, they are free of toxic effects. Some homeopathic remedies are widely used to calm fussy infants during the first months of life.⁹ None of these medications has been reported,

to the best of our knowledge, as a cause of an ALTE.

During a pediatric conference on adverse drug reactions in June 2008, the association between ALTEs and the use of homeopathic remedies was discussed. One of the authors (Dr Aviner) was aware of 4 infants who, during 2005–2006, were admitted for an ALTE shortly after ingestion of a certain homeopathic remedy that is used to calm restless infants: Gali-col Baby (Unda SA, Brussels, Belgium). These infants were seen at 4- to 6-month intervals without any special clustering. This observation stimulated this study. We report our experience with 11 patients, including the index series, who experienced this phenomenon.

METHODS

The retrospective case-control study was conducted in the Pediatric Division of the Barzilai Medical Center, a medium-sized secondary hospital that serves a population of 500 000 people in southern Israel. The pediatric division has 36 beds and a 3-bed PICU. The population consists of mainly urban and some village inhabitants, with diverse ethnic backgrounds, characteristic of the Israeli population. Three of the researchers (Drs Aviner and Schlesinger and Nurse Dalkian) supervised the medical treatment of the patients.

A computerized search was conducted for admissions with 1 of the following diagnoses: ALTE, apnea, choking, cyanotic spell or episode, and sudden infant death syndrome. As a control group, we used age-matched patients who were admitted for reasons other than an ALTE on the days the study patients were admitted. We did a 2-to-1 matching by listing all patients who were admitted on the same day when a given patient with an ALTE was admitted and including the 2 patients closest in age to the patient with an

ALTE. Patients who were older than 1 year were excluded. When there were no admissions of patients who were younger than 1 year on the same day, we repeated the same procedure on the consecutive day. All charts, including the standardized template for histories used in our division, were examined for a notation stating the ingestion of any medication within 24 hours before admission. Demographic profile of the study and control groups and clinical data for all infants with an ALTE and Gali-col Baby ingestion were summarized. The study was approved by the institutional ethical committee.

Numerical data are expressed as means \pm SDs and medians (range), whereas categorical data are expressed as percentages. To examine differences between the 2 groups (with and without ALTE), we used (1) *t* test and nonparametric Mann-Whitney test for the numerical data and (2) χ^2 test and Fisher's exact test for the categorical data. All analyses were done by using SPSS 14.0.1 statistical software (SPSS Inc, Chicago, IL).

RESULTS

Patient Presentation

From January 2005 through August 2008, 36 635 children visited the pediatric emergency department at the Barzilai Medical Center. There were 11 057 admissions to the pediatric division during this period, 116 of which were because of 1 of the previously mentioned diagnoses. One patient with trisomy 18 was excluded.

Patients were aged 2 to 260 days (median: 31 days) on admission; 97 (84%) were younger than 3 months, and 81 (70%) were younger than 2 months. A group of 226 infants who were aged 0 to 12 months old and admitted on the same days as the study group infants for diagnoses other than the study group ones served as a control group. Age and gender distributions are elab-

TABLE 1 Demographic Profile of Study and Control Groups

Parameter	Total (N = 341)	Study Group (n = 115)	Control (n = 226)	P
Male, n (%)	166 (48.6)	65 (56.5)	101 (44.6)	.035
Gali-col baby (yes), n (%)	11 (3.2)	11 (9.5)	0 (0.0)	<.005
Age, d				
Mean ± SD	68.21 ± 51.31	55.25 ± 51.01	74.81 ± 50.30	
Median (minimum, maximum)	52.0 (1.0, 260.0)	39.0 (2.0, 260.0)	59.5 (1.0, 182.0)	.001
Hospital time, d				
Mean ± SD	3.12 ± 2.61	2.57 ± 2.53	3.39 ± 2.61	
Median (minimum, maximum)	3.0 (0.0, 20.0)	2.0 (0.0, 12.0)	3.0 (1.0, 20.0)	.006

orated in Table 1. The groups differ significantly from each other by gender, age, and days in the hospital. These differences are attributed to the limitation of the best matching method that we have used in this retrospective study.

For 54 (47%) patients, a presumptive cause for the ALTE was found. Thirty-six infants had gastroesophageal reflux, 11 had symptoms of bronchiolitis, 3 experienced breath-holding spells, 2 had suspected convulsions, and 2 infants

were found to have a group B streptococcal sepsis and urinary tract infection, respectively. For 20 (17.3%) infants, the use of some kind of medication was recorded within 24 hours before the ALTE. Eleven (9.5%) infants received Gali-col Baby, whereas none of the control group infants was given the same remedy ($P < .005$; Table 1). Other medications included Ventolin and Budicort by inhalation and Betnesol (2 patients), Terbutin by inha-

lation and Betnesol (2 patients), and inhalation of saline (1 patient). One infant who choked soon after a formula meal had been treated with Simethicone a few days before the event and with Lactulose 1 day before the ALTE. The ALTE in this child was attributed to choking and was thought to be unrelated to the drugs because of the long intervals between consumption and the ALTE.

All infants with Gali-col Baby ingestion were born after >37 weeks of gestation and were 14 to 49 days old on presentation (Table 2). All were described by parents as “excessive criers.” All were healthy before the ALTE with no upper respiratory symptoms. Only 1 infant (infant 11 in Table 2) had a history of frequent vomiting; he also had regurgitation at the time of the ALTE. None of the 11 infants had been fed soon before the ALTE.

TABLE 2 Summary of the Reported Cases of Apnea After Gali-Col Baby Ingestion

Case	Age, d	Gestation Length, wk	Birth Weight, g	Gender	Symptoms on Presentation	Gali-Col Baby Ingested	Time From Ingestion to Apnea, min	Workup	Hospitalization, d
1	31	38	3000	M	Apnea, red face	3 drops every 5 h	360	48-h monitoring, ABG, glucose electrolytes, Barium swallowing, EEG, ECG, chest radiograph	2
2	51	40	3175	F	Rolling eyes, flaccidity	5 drops every several hours	A few minutes after last of several doses, twice	24-h monitoring, ABG, glucose electrolytes, ECG, EEG, echocardiogram	2
3	30	38	3310	F	Apnea, stiff body	5 drops 3 times on the same day	10–20 after third dose	24-h monitoring, ABG, glucose electrolytes, EEG, ECG, brain ultrasound, lactate, ammonia	1
4	32	38	2715	F	Apnea, red face	Few drops every hour	10	24-h monitoring, ABG, glucose electrolytes, LP, blood culture, ECG, brain sonogram	1
5	37	37	2470	F	Choking, pallor, rolling eyes, stiff body	5 drops every 15 min, 3–4 times	5	24-h monitoring, ABG, glucose electrolytes, ECG, chest radiograph	1
6	14	38	2975	F	Choking, red face	5 drops every 30 min	5	24-h monitoring, ABG, glucose electrolytes, blood culture, ECG, gastrografin radiograph	2
7	42	39	3085	M	Pallor, rolling eyes, flaccidity	5 drops every few hours	Soon after, 5 episodes	24-h monitoring, ABG, glucose electrolytes, EEG, ECG	1
8	52	38	3220	M	Apnea, cyanosis, stiff body	5 drops as a single dose	0	48-h monitoring, ABG, glucose electrolytes, EEG, ECG, brain ultrasound	3
9	21	38	3285	F	Apnea, cyanosis, flaccidity, vomiting	NA	0	24-h monitoring, ABG, glucose electrolytes	1
10	27	39	3710	M	Cyanotic episode, color change, flaccidity	NA	0	24-h monitoring, ABG, glucose electrolytes	1
11	49	38	2180	F	Apnea, rolling eyes, regurgitation	NA	Same day	48-h monitoring, ABG, glucose electrolytes, ECG, chest radiograph	2

ABG indicates arterial blood gas; EEG, electroencephalogram; ECG, electrocardiogram; LP, lumbar puncture; NA, not available.

Clinical Features

The ALTE was noticed shortly after Gali-col Baby ingestion in most patients (Table 2). The manufacturer's recommended dose of Gali-col Baby is "up to 5 drops which might be repeated once in 15 minutes or according to the physician or pharmacist instructions." The amount of Gali-col Baby administered was available for 8 patients. For 3 patients, it was much greater than the manufacturer's recommended dose, 4 other infants received the drug several times a day, and 1 patient received a single recommended dose. Three of the parents who gave the drug several times a day said that they had also noticed limpness on previous doses but they thought it was a desirable effect of the medication. For the 3 infants for whom the amount of medication administered was not recorded, 2 infants experienced the ALTE shortly after Gali-col Baby administration and 1 on the same day (Table 2).

Nine of the 11 infants showed at least 2 symptoms of an ALTE (Table 2). None of them required resuscitation, and all were discharged within 13 days. Diagnostic workup varied from arterial blood gasses, blood glucose, and electrolytes to more elaborate ones including lumbar puncture, lactate, ammonia, electrocardiogram, electroencephalogram, brain sonography, gastrografin imaging, and echocardiogram (Table 2). Workup did not reveal a presumptive cause of the ALTE in any of these infants.

DISCUSSION

During the study period, 9.5% of the infants who were admitted with ALTE to our department had received Gali-col Baby on the day of the event, whereas none of the control group infants was given the same remedy ($P < .005$; Table 1). These findings indicate a possible causative relationship between Gali-col Baby administration and ALTE.

The rate of Gali-col Baby ingestion before an ALTE—9.5% in this study—is much greater than any single substance found to cause an ALTE in other studies. A recent systematic review of the literature found 8 studies that summarized cases of ALTE, with overall 1.5% of events caused by drugs and toxins.⁶ Three studies cited in that review reported ALTEs induced by drugs or toxins; Davies and Gupta² reported that opiates caused 3% of ALTE, Laisne et al⁵ found that toxins caused 4% of ALTEs, and Veereman-Wauters et al¹⁰ found 5% of ALTE to be related to breast milk opiates. In another recent work, 23 (8.4%) of 274 infants with an ALTE had clinically significant positive toxicology screening results for 1 of several medications.¹¹ The relatively higher rate of ALTE after Gali-col Baby ingestion and the absence of demonstrating any other cause for ALTE through the workup done on our patients on the basis of clinical judgment in each case strongly suggest that the ALTE was related to the consumption of the remedy.

In addition, we compared the rate of Gali-col Baby use among patients with an ALTE in our study with the rate of purchasing Gali-col Baby in pharmacies of 1 of the largest health maintenance organizations in the region served by the hospital (computerized database of Macabbi Health Services, Tel-Aviv, Israel). Gali-col Baby was introduced to the Israeli market during 1996–1997. During the study period, ~2000 infants were born to the population served by the health maintenance organization and 46 packages of Gali-col Baby were purchased. There was no increase in the number of packages of Gali-col Baby purchased during the study period. The maximal rate of purchase is thus 2.3% (only 1 family purchased 2 packages), approximately one quarter the rate of Gali-col Baby consumption among

patients who experienced an ALTE. It should be noted that in our study, we found 11 (9.5%) cases of Gali-col "users" of 115 cases in the study group, which is significantly higher than the 2.3% maximal rate of purchase ($P < .001$). Furthermore, Gali-col Baby was the only homeopathic remedy used for treatment of colic that was associated with an ALTE in our study, although it accounts for only 10.3% of the 4 remedies for treatment of colic sold during the study period (Simethicone 63.7%, Babyzin 23.7%, and Grip mixture 2.3%; same database).

Gali-col Baby ingredients include colocythis, chamomilla, Magnesia phosphorica, bryonia, nux-vomica, *Cuprum metallicum*, and *Veratrum album*. Non-active ingredients include xylitol, sorbitol 70%, glycerinum, methylis paroxybenzoas, propylis paroxybenzoas, musa aroma, flavum ex quinoileino, and aqua.

A literature search revealed toxic effects for 3 of the active ingredients of Gali-col Baby.^{12–19} *Citrus colocythis* was reported to cause acute colitis in 3 patients,¹⁷ interference with the liver's ability to synthesize protein, and kidney dysfunction and hemoconcentration.¹² Together with another plant, it caused the death of goats 1 day to 2 weeks after administration.¹² *Veratrum album* is a poisonous plant that can easily be mistaken for another plant. Four different groups reported its toxic effects: electrocardiographic changes including sinus bradycardia, left bundle branch block, arteriovenous dissociation and rhythm disorders, nausea, and vomiting.^{15,16,18,19} *Strychnos nux-vomica* may cause strychnine poisoning in the form of muscle spasms or convulsions.¹⁴

The contents of 2 Gali-col Baby bottles were analyzed by the Central Laboratory for Forensic Medicine of the Israel Police Force by gas chromatography-mass spectrometry. The quantitative

analysis revealed ethanol, propanol, and pentanol in addition to glycerol and sugars. These alcohols were not mentioned in the ingredient list of the remedy and might contribute to the toxic effect.

That none of the reported toxic effects was observed in our study might be related to the lag period between the ALTE and the first medical examination. All children had already recovered from the acute episode when first seen by the medical staff.

An ALTE occurred in 7 patients 5 to 20 minutes and up to 6 hours after Galicol Baby ingestion. In 4 patients, however, an ALTE took place immediately after the ingestion (Table 2). The interval between the ingestion of other drugs and toxins to an ALTE was not reported in other case reports of ALTEs.^{2,4,5,9,10,20} Most infants received high doses, up to 5 drops every 15 to 30 minutes several times (Table 2), significantly larger than the manufacturer's recommended dose. Two infants consumed 5 drops as a single dose or every few hours, and for 2 infants the amount ingested was not available. The interval in our patients and the violation of dosage instructions suggest that the cumulative nature of repeated doses produced a toxic effect. It is also possible that the short interval between consumption and adverse effect in these patients could be attributed to an idiosyncratic effect or choking. One of the limitations of this report is that it is retrospective and therefore data are not complete for all patients.

Although all 11 infants who had an ALTE that was suspected to be induced by Galicol Baby ingestion were dis-

charged without any known sequelae, their medical care involved admission to an ICU and an expensive unnecessary workup, loss of parental working days, and an unnecessary terrifying event for the people who witnessed it. Furthermore, a "benign" course in our patients does not guarantee a similar course in other events and circumstances.

Infants who are excessive criers are at greater risk for being shaken by their parents. Moreover, abuse of the dose of a medication by parents might raise suspicion of intentional poisoning. This form of abuse was recognized by Dine and McGovern,⁹ who summarized 48 cases of intentional poisoning of children by their abusive parents, and Hickson et al,⁴ who presented 9 cases of an ALTE caused by administration of chemical agents. Indeed, 1 report specifically addressed the use of colic medication that contained a Dramamine/Donnatal mixture as a possible cause of ALTEs;³ however, none of the parents in our report had any intention to harm their child. The 3 parents who admitted abusing the recommended dose did it out of frustration, facing their inconsolable fussy infants. Both have stated that they were not aware that a homeopathic remedy might have a toxic effect.

Theoretically, homeopathic medications are considered nontoxic because of the low concentrations of active material. According to the "homeopathic rules," such remedies contain very small concentrations of the active materials and as such have a very large "therapeutic" to toxic ratio. This makes one think that it is safe to use greater

than recommended doses and still be within the safety range; however, significant overdosing might have adverse effects as a result of the accumulation of some ingredients, including "nonactive" solvents. Alternatively, the amount of ≥ 1 active ingredient might not concur with the homeopathic rules; they might exist in pharmacologic concentration, reaching toxic levels with repeated doses.²¹ Furthermore, the finding in the remedy of 3 alcohols that were not declared on the ingredient list exposes the infants to adverse effects of alcohols, which are not appreciated by the caregivers. These may result from the lack of strict licensing requirements and the lack of supervision over these medications compared with "conventional" ones. Applying the same Good Clinical Practice rules and supervision on developing homeopathic remedies may reduce exposure to possible toxic effects.

The warnings to consult a physician and not to overdose, written on packages, are not effective and are not followed by the parents. Unfortunately, this is also true for conventional over-the-counter drugs such as cough and cold medications, despite unexpected deaths with these preparations.²² Indeed, Pitetti et al⁷ reported that approximately half of the positive toxicology screen results for infants with an ALTE (13 [4.7%] of 274) were for a medication found in an over-the-counter cold preparation. It is time for the efficacy and safety of homeopathic preparations to be studied before administration to infants to prevent unnecessary adverse effects.

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