Acute Ethanol Toxicity from Ingesting Mouthwash in Children Younger Than Age 6, 1989-2003

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Abstract

Purpose: The purpose of this study was to analyze American Association of Poison Control Centers (AAPCC) reports of suspected overingestion of mouthwash by children under age 6 and examine the effect of a 1995 Consumer Product Safety Commission (CPSC) rule requiring child-resistant packaging for mouthwashes containing at least 3 g (0.11 oz) of ethanol per package.

Methods: The volume of ethanol ingested per kg of body weight was computed for children at the 5th, 50th, and 95th percentiles. The potentially toxic and potentially lethal volumes of 100% ethanol at each weight were also determined. The authors used segmented regression to test the difference in slopes between 1989 to 1996 (preintervention) and 1996 to 2003 (postintervention).

Results: Incidence of overingestion rose from a low of 12.7 per 100,000 (1991) to 20.7 (1996). The increase ended with the adoption of the CPSC rule, declining to 16.8 per 100,000 in 2001 and rising to 17.9 in 2003.

Conclusions: This study's analysis suggests that the CPSC rule requiring child-resistant packaging on containers of mouthwash containing 3 g or more of ethanol has been successful in reducing AAPCC's reports of mouthwash overingestion. Health care providers should take a more active role by informing parents of the dangers associated with accidental ingestion of ethanol-containing mouthwash. Manufacturers should print warnings about the potential hazard of high ethanol concentrations on labels more prominent and they should stop producing mouthwashes with such high concentrations of ethanol. Moreover, they should also consider discontinuing packaging mouthwash in large containers. (Pediatr Dent 2006; 28:405-409)

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The public considers mouthwash to be safe since it is sold over-the-counter as a cosmetic. Most mouthwashes, however, contain significant amounts of ethanol and can be toxic, or even fatal, to a young child.[1,2] Ethanol is added to mouthwash to make nonpolar components (eg, essential oils) water-soluble and to kill oral bacteria associated with bad breath and plaque formation. Moreover, it also helps provide the clear, refreshing feeling people expect from a mouthwash. Although fatalities from ethanol-containing mouthwash are rare, ingestion by children occurs frequently, sometimes leading to nonlethal but toxic reactions.[3,4]

Mouthwashes have great potential to be ingested by children because they are made to look enticing, taste good, and are present in most homes. Moreover, children are able to ingest large amounts for their body weight and achieve high blood-ethanol levels very quickly.[5]

Mouthwashes are allowed to contain high levels of ethanol because they are classified as cosmetics by the US Food, Drug, and Cosmetics Act,[6] which is enforced by the Food and Drug Administration (FDA). Listerine (original formula) contains 26.9% ethanol by volume, the highest ethanol concentration of mouthwashes on the market today. Not only do some mouthwashes contain a high concentration of ethanol, as of the summer of 2005, but the containers available for retail purchase are often as large as 71 oz (2,100 mL)—more than enough ethanol to kill a child. Table 1 shows the ethanol content of mouthwashes commonly sold in the United States.[7]

The prevalence of acute ethanol toxicity related to ingestion of ethanol-containing mouthwashes has been estimated from calls to poison control centers collected as part of the Toxic Exposure Surveillance System (TESS). Using TESS data, Shulman and Wells[8] found that, from 1989 to 1994,

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Table 1. Ethanol Content of Mouthwashes Commonly Sold in the United States*

Mouthwash	Ethanol content (volume %)
Listerine (original)	26.9
Listerine (cool mint; natural citrus)	21.6
Scope (original)	15.0
Scope (cool peppermint)	14.5
Scope (citrus splash)	12.0
Act 2	11.0
Plax	8.7

*Source: Product labels.

the incidence of reports to the poison control centers was increasing.

Mouthwash contains denaturants (generally minimally toxic bittering agents[4]) to discourage consumption. Because mouthwashes are classified as cosmetics by the FDA, however, neither the ethanol concentrations nor the denaturant potency are regulated.

Ethanol is lipid-soluble and easily absorbed in the small intestine, where 80% of the absorption takes place.[9] As much as 80% to 90% of ingested ethanol can usually be absorbed in 30 to 60 minutes.[9] Since ethanol is poorly absorbed from the stomach, anything that delays gastric emptying will also delay its absorption. For example, absorption can be delayed by 2 to 6 hours by the presence of food.[9] Ethanol is detoxified primarily by oxygenation in the liver.

Symptoms of ethanol toxicity vary with blood concentration, which is a function of the: (1) quantity ingested; (2) ingestion rate; (3) body weight; and (4) individual's physiologic tolerance to ethanol. In adults, slight intoxication appears as: (1) mild euphoria; (2) decreased inhibitions; and (3) lack of coordination. Blood levels rise with increased ingestion, and the symptoms become more severe. At approximately 300 mg/100mL, symptoms include: (1) the inability to stand; (2) vomiting; and (3) impaired consciousness. A blood ethanol level increase may result in: (1) depressed reflexes; (2) unconsciousness; and (3) coma. At 500 mg/100mL, respiratory paralysis generally occurs, leading to death.[8] The lethal dose of ethanol for adults is 5 to 8 g/kg.[10]

Children exhibit many of the same symptoms as adults, but irritability is often the first noticeable sign of acute ethanol toxicity.[11] Severe symptoms in children include: (1) coma; (2) hypotension; (3) bradycardia; and (4) respiratory failure often resulting in death.[10] The lethal dose of ethanol for children is 3 g/kg,[9,10] and doses as small as 0.6 g/kg have been seen to induce toxic reactions in a small child.[3] In children, hypoglycemia is much more likely to result from ethanol ingestion than in adults. This ethanol-induced hypoglycemia can lead to brain damage and death if not treated correctly.[12]

The Consumer Product Safety Commission (CPSC) is an independent federal regulatory agency whose goal is to reduce the risk of injuries and deaths associated with consumer products.[13] The CPSC issued a rule under the Poison Prevention Packaging Act of 1970[13] that all mouthwashes with 3 g (0.11 oz) or more of ethanol per package must have child-resistant packaging.[13] This rule went into effect on July 24, 1995, and applied to all products packaged on or after that date.[13]

The purpose of this paper was to analyze reports of suspected overingestion of mouthwash by children under age 6 from 1989 to 2003,[1] comparing the period from 1989 to 1995 (preintervention) with the period from 1996 to 2003 (postintervention) to determine the effectiveness of the Consumer Product Safety Commission rule on child-resistant packaging.

Methods

The data for this analysis comprise publicly available summaries of TESS from 1989 to 2003.[1] To estimate the physiologic effect of swallowed mouthwash, the authors computed the volume of ethanol ingested per kg of body weight for children at the 5th, 50th, and 95th percentiles of a growth and development table.[14] To simplify the analysis, the authors averaged male and female weights for each age/percentile group from 6 months to 5 years in 6-month intervals.

Estimating ethanol doses

To determine the potentially lethal volume (PLV), the authors calculated the volume of 100% ethanol that would have to be ingested to yield a dose of 3 g/kg for children, a generally accepted lethal level.[9] The potentially toxic amount of ethanol is the amount that is likely to produce mild symptomatology. To calculate the potentially toxic volume (PTV), the authors determined the peak blood ethanol level using the formula: C_p=dose/V_d×body weight. The dose in mg was determined by the following formula: dose=ethanol ingested (mL)×ethanol concentration (%)×0.789 (density of ethanol). The volume of distribution (V_d), is 0.7 L/kg for children.[9]

The authors adjusted the frequencies of reports for the proportion of the population not served by a poison control center in a given year.[1] For example, in 1995, 82% of the population was served by a local poison control center so the number of reported exposures (3,598) was divided by 0.821 to estimate the adjusted number of reports (4,382). The authors estimated the annual incidence rate by dividing the adjusted number of reports by the proportion of children younger than age 6 from each year from the US census.[15] The authors explicitly assumed that the incidence rates of acute toxic reactions to ethanol are the same in the proportion of the population covered by poison control centers and the remaining proportion not covered in any given year. Furthermore, the authors assumed that the proportion of households that have ethanol-containing mouthwash has not changed from 1989 to 2003.

To test the hypothesis that the CPSC rule was responsible for a reduction in the adjusted incidence of TESS reports, the authors:

1. plotted the projected incidence of reports from 1989 to 2003 involving children younger than age 6 that were attributable to ethanol-containing mouthwashes; and
2. performed a piecewise (segmented) regression (SigmaPlot 9.0, SYSTAT Inc, Richmond, Calif) with the splines 1989 to 1995 (preintervention) and 1996 to 2003 (postintervention) and the knot at 1996.

Results

Table 2 shows potentially lethal and toxic amounts of 100% ethanol at the 5th, 50th, and 95th percentiles of a growth and development table. For example, a 4-year-old in the 50th percentile of a growth and development chart (16.2 kg) would need to ingest 5.95 mL (0.20 oz) of pure ethanol to achieve a potentially toxic volume and 64.35 mL (2.18 oz) of 100% ethanol to achieve a potentially lethal volume.

Table 3 shows the total number of AAPCC reports related to ethanol-containing mouthwashes in column A. In column B, the number of reports of children younger than age 6 is shown. The US population[15] is listed in column C, and the percentage of the US population served by the AAPC[1] is shown in column D. Column E adjusts the total number of reports younger than age 6 (column B) for the proportion of the population covered by the AAPCC in each given year. The total population of children younger than age 6[15] is shown in column F. In column G, the estimated incidence of poison exposures in a population of children younger than age 6 per 100,000 children is indicated.

Figure 1 shows the incidence rates for the 15 years of the authors' analysis and the regression lines for the 2 periods. A second-degree polynomial model provided an excellent fit for the data (R^2=0.95), and the slopes of the splines were significantly different (P<.0001).

Discussion

Children younger than age 6 comprised 49% of the 37,043 reported exposures to ethanol-containing mouthwash from 1989 to 1995.[1] After the CPSC rule, the percentage dropped to only 28% of the reported 112,440 from 1996 to 2003.[1]

The incidence of reported overingestion per 100,000 children younger than age 6 is on the decline since child-resistant packaging was required on ethanol-containing mouthwash. That is still too high, however, and the problem cannot be ignored. While there are many variables affecting the toxic dose, the ethanol content in many of the commonly used over-the-counter mouthwashes is at a dangerously high level.

The decline in the proportion of reports for children under age 6 from 1995 to 2001 could be due to changes in reporting trends—that is, fewer parents reporting the incidents or fewer exposures. Fewer parents or caregivers could be reporting fewer incidents of overingestion because they are more discriminating about when the child's health is at risk. They may also be less inclined to call unless they perceive a serious problem, or the proportion of caregivers aware of the existence of poison control centers has decreased – due to decreased awareness of the poison control network. Moreover, caregivers could be doing a better job keeping mouthwash away from young children, or child-resistant packaging has reduced the number of children who ingest mouthwash.

This large drop in the percentage of reports suggests that the CPSC rule was effective. There are, of course, other possibilities that might account for the change in trends. Three possibilities are that parents are either less:

1. aware of the fact that there are poison control centers;
2. aware of the symptoms of ethanol toxicity; or
3. inclined to call about marginal cases.

None of these alternatives are persuasive, so the authors attribute the downtrend to the CPSC rule.

It is difficult to explain the second inflection point in 2002 based on only 2 years of data. The authors could not identify any changes in the regulatory environment, nor are the authors aware of increases in the ethanol content of mouthwashes since 2002. Retail sales of mouthwashes, however, increased 12% from 1998 to 2002.[7] It is possible that this may be responsible by placing more children at risk. On the other hand, the authors are unable to explain why the incidence of reported overingestion has not declined to the levels seen in 1991 and 1992. Perhaps it will,

Table 2. Lethal and Toxic Amounts of 100% Ethanol at the 5th, 50th, and 95th Percentiles of a Growth and Development Table*

	Fifth %			50th %			95th %		
Age	Weight	Ethanol (mL)		Weight	Ethanol (mL)		Weight	Ethanol (mL)	
(ys)	(kg)	PTV†	PLV‡	(kg)	PTV†	PLV‡	(kg)	PTV†	PLV‡
0.5	6.2	2.27	24.66	7.6	2.83	30.33	9.1	3.40	36.00
1.0	8.3	3.12	32.88	9.9	3.69	39.12	11.9	4.25	47.06
1.5	9.6	3.40	37.99	11.4	4.25	45.07	13.6	5.10	53.86
2.0	10.5	3.97	41.67	12.4	4.54	49.04	14.9	5.39	59.25
2.5	11.1	3.97	43.94	13.3	4.82	52.73	16.1	5.95	63.79
3.0	11.8	4.25	46.78	14.1	5.10	55.85	17.3	6.24	68.60
3.5	12.4	4.54	49.04	15.1	5.39	59.82	18.9	6.80	74.84
4.0	13.3	4.82	52.73	16.2	5.95	64.35	20.1	7.65	79.66
4.5	14.3	5.10	56.70	17.2	6.24	68.32	21.9	7.94	86.75
5.0	14.9	5.39	59.25	18.3	6.80	72.57	23.5	8.50	93.27

*Based on averaged body weights for males and females (reference 14).
†Potentially toxic volume.
‡Potentially lethal volume.

Table 3. Reports to American Association of Poison Controls Centers (AAPCC) Related to Ethanol-containing Mouthrinses: Children, Younger Than Age 6, 1989-2003*

	A	B	C	D	E	F	G
Year	Total no. of reports	Total no. of reports <6	US population (in millions)†	Population served by AAPCC (%)*	Adjusted no. of reports <6 (B÷D)	Population <6 (in millions)†	Estimated incidence per 100,000 children <6 ([E÷F]×100,000)
1989	3,916	2,494	248.2	73	3,416	22.3	15.3
1990	4,015	2,317	249.6	77	3,017	22.5	13.4
1991	3,917	2,082	250.9	80	2,589	22.6	12.7
1992	4,214	2,245	252.2	78	2,878	22.7	12.7
1993	4,351	2,277	257.9	70	3,253	23.2	14.0
1994	6,948	2,937	260.3	83	3,539	23.4	15.1
1995	9,682	3,598	266.3	82	4,382	22.8	19.2
1996	12,509	4,157	269.4	86	4,823	23.3	20.7
1997	12,703	4,108	272.6	92	4,475	23.2	19.3
1998	12,564	3,935	275.9	93	4,218	22.9	18.4
1999	12,934	3,769	279.0	94	4,031	22.8	17.7
2000	14,394	3,822	281.4	96	3,973	23.1	17.3
2001	15,057	3,866	285.1	99	3,917	23.3	16.8
2002	16,204	4,058	291.8	100	4,062	23.4	17.4
2003	16,075	4,228	294.7	100	4,228	23.6	17.9

*American Association of Poison Control Centers.[1]
†Source: US Census.[15]

given time—or we may be seeing the result of less parental supervision.

There are several reasons to suspect that many mild to moderate cases of ethanol toxicity go unreported. Early symptoms of ethanol toxicity in children do not necessarily present themselves in a similar manner to adult symptoms and can therefore go unnoticed. When a child is simply irritable and lethargic, parents do not usually suspect ethanol toxicity. However, these are often the initial signs in children. Without a parent's suspicion of mouthwash ingestion, some health care providers may not include ethanol toxicity in their differential diagnosis. Finally, some parents are simply unaware that a local poison control center exists. Those who do may not always report a suspected overingestion if their child is only presenting with mild to moderate symptoms.

While the generally accepted lethal dose of ethanol for children is 3 g/kg, life-threatening reactions do occur at lower dosages. Ethanol-induced hypoglycemia is especially prevalent in children and can lead to death at levels below 3 g/kg, especially in malnourished children.[11]

Although the authors assumed 100% absorption of ingested ethanol in a minimal amount of time, there are many factors that may influence absorption. The presence of food, for example, would delay absorption. Therefore, the potentially toxic dose would be higher.

This study's principal limitation is that the authors' data are not documented toxicities, but rather reports of calls to poison control centers regarding suspected overingestion of ethanol-containing mouthwashes. The decision to call a poison control center is dependent on a caregiver's: (1) awareness of the poison control center network; (2) awareness that a child ingested mouthwash; and (3) threshold of concern over the ingestion. Consequently, the authors cannot determine the true incidence of ethanol toxicity. Moreover, to the extent that the proportion of households with children younger than age 6 who use ethanol-containing mouthwash has changed materially from 1989 to 2003, the validity of this study's results will be lessened.

While the CPSC rule has reduced the incidence of reported overingestion, it has not eliminated it. Therefore, the authors recommend the following actions to help decrease the likelihood of acute ethanol toxicity in children:

1. Dentists, physicians, and other health care providers should take a more active role by informing parents of the dangers associated with accidental ingestion of ethanol-containing mouthwash and encourage them to keep their mouthwash out of the reach of children.
2. Manufacturers should make warnings about the potential hazard of high ethanol concentrations on labels more prominent. The warning labels should have detailed emergency instructions in case of accidental ingestion.
3. Manufacturers should stop producing mouthwashes with such high concentrations of ethanol and they should also stop producing such large containers for their mouthwashes.

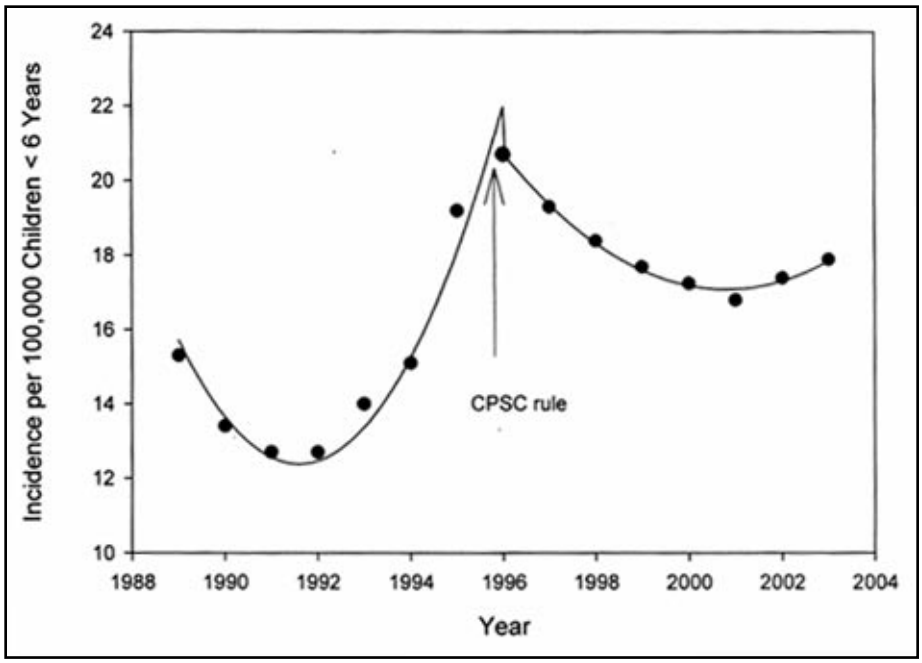

Figure 1. Segmented regression of incidence of reported overingestion of ethanol-containing mouthwashes, 1989-2003.

Conclusions

This study's results suggests that the Consumer Product Safety Commission rule requiring child-resistant packaging on containers of mouthwash containing 3 g or more of ethanol has been successful in reducing AAPC reports of mouthwash overingestion. Future studies should focus on the apparent increase in reports since 2002.

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