

## Reviewed evidence about the safety of the daily use of alcohol-based mouthrinses

**Celso Augusto Lemos-Júnior<sup>(a)</sup>  
Germano Eduardo Miguel  
Villoria<sup>(b)</sup>**

<sup>(a)</sup>PhD, Department of Stomatology, School of Dentistry, University of São Paulo, São Paulo, Brazil.

<sup>(b)</sup>Coordinator and Professor, Specialization Course in Periodontics, Gama Filho University, Rio de Janeiro, Brazil.

**Abstract:** Current scientific knowledge provides clear evidence that alcohol-based mouthwashes can be beneficial in a daily oral health routine, including dental hygiene and plaque control. Several issues are worth discussing, in spite of the wealth of supporting evidence. Despite some undesirable effects to some people, like burning sensation, and some contraindications, like the use by infants, alcohol addicts and patients with mucosal injuries, there is no reason to avoid the use of alcohol-containing mouthwashes as long as they are used following proper guidance by dental professionals and the manufacturers' instructions. The alleged correlation between oral cancer and alcohol-based mouthrinses presents so little, weak, inconsistent and even contradictory evidence in the literature that any kind of risk warning to patients would be uncalled for. Antimicrobial mouthrinses are safe and effective in reducing plaque and gingivitis, and should be part of a comprehensive oral health care regimen that includes brushing, flossing and rinsing to prevent or minimize periodontal disease.

**Descriptors:** Alcohol, ethyl; Mouthwashes / Adverse effects.

**Corresponding author:**

Celso Augusto Lemos Júnior  
Universidade de São Paulo  
Faculdade de Odontologia  
Departamento de Estomatologia  
Av. Professor Lineu Prestes, 2227  
Cidade Universitária  
São Paulo - SP - Brazil  
CEP: 05508-000  
E-mail: [calemosj@usp.br](mailto:calemosj@usp.br)

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## Introduction

In the past decades, mouthrinses have served a variety of purposes, among which is the therapeutic prescription to treat halitosis and minor mouth infections, besides other oral care problems.<sup>1</sup>

The extensive use of various types of rinsing solutions has led to studies aiming at investigating side effects of the widespread use of such products.<sup>1</sup>

The alcohol content of mouthrinses, besides having antiseptic properties, serves the purpose of breaking down or dissolving active principles, in addition to that of preserving the formula components,<sup>2,3</sup> although such content does not directly contribute to effective biofilm and gingivitis control.<sup>4,5</sup> Nevertheless, it is common knowledge that, like other substances, alcohol may have certain side effects. As of the 1970s, a number of studies have been published suggesting a possible connection between the daily use of alcohol-based mouthrinses and the development of oropharyngeal cancer, and that has led researchers to question the safety of using alcohol as a component of mouthrinses.<sup>2</sup>

This paper aims to review the literature about the side effects of the use of alcohol-based mouthrinses.<sup>1</sup>

## Literature Review

This review has the purpose of discussing the major potentially harmful effects that may question the safe use of alcohol-based mouthrinses.

### Xerostomia

Xerostomia is a subjective perception of dryness of the mouth resulting from one or more factors that affect the quantity and quality of the salivary flow. It may lead to soft tissue discomfort, difficulty in chewing and swallowing, caries, insomnia, fungal infection and halitosis. All these conditions may cause a negative impact on a patient's life quality.<sup>6</sup>

A comparative study investigating the effects of mouth rinsing with an alcohol-based solution

against mouth rinsing with an alcohol-free solution does not point to significant differences between both types of solutions after a week's use as regards salivary flow and dry mouth symptoms in healthy adult subjects.<sup>7</sup>

### Burning or sore sensation

Some patients have reported a burning or sore sensation in the oral tissues after using an alcohol-based mouthrinse.<sup>4</sup>

Alcohol may cause a painful sensation that is directly subordinated to its concentration level and to length of rinsing. Alcohol-based mouthrinses are not recommended for patients with existing soft tissue injury.<sup>2,8,9</sup>

The longer the rinsing the more painful it feels. This sensation declines and eventually ceases when the product is no longer used. While ethanol is the key pain-inducing factor, other agents may also augment the symptom.<sup>9</sup> Recent research reveals that the burning and painful sensation in the soft tissues is also felt when alcohol-free solutions are used.<sup>10</sup>

Lower alcohol level and the addition of a mild flavoring agent have yielded good results in reducing the burning or sore sensation.<sup>7</sup>

Diluting the product for initial use and then gradually increasing its concentration has shown to have higher acceptance by patients.<sup>11</sup>

### Mouthrinse ingestion by children

Ethanol ingestion is an uncommon yet well-documented cause of hypoglycemia in children. Hypoglycemia induced by alcohol ingestion, followed by convulsions, was originally recorded in 1961. Later work that investigated the ingestion of mouthrinses show that these alcohol-based oral care products can be potentially lethal.<sup>12,13</sup> According to the American Association of Poison Control Centers, 6% of the 251,012 cases of human poisoning in 1983 were caused by alcohol and glycol ingestion. Of these, 86.2% of the subjects were children below six years of age.<sup>14</sup> In 1994, the Centers received 2,937 calls reporting ingestion of alcohol-based mouthrinses. These figures stand for 168 recorded exposure cases for every 100,000 children below six years of age. For a child weighing only 26 pounds, 5 to 10 ounces of a mouth-

rinse containing 26.9% of ethanol stands for about 2 ounces of alcohol, which can be potentially lethal.<sup>15</sup>

The literature relates that ethanol can affect normal glycogenolysis and glyconeogenesis, causing hypoglycemia conditions brought about by children ingesting the solution.<sup>12,16</sup> However, it should be noted that, contrary to what happens with adults, poor nutritional conditions or long fasting before alcohol ingestion are not necessarily determining factors of hypoglycemia in children.<sup>12</sup>

Poisoning is one of the most frequent causes of infant death. It should be highlighted that little ingestion of ethanol, whether in the form of beverages or other alcohol-based liquids, can potentially induce death by hypoglycemia.<sup>12,17,18</sup>

Alcohol-based mouthrinses whose packaging does not warn against its use by infants can be easily purchased in the market.<sup>1</sup> The American Dental Association (ADA) and the Food and Drug Administration (FDA) have recently required that industries that produce mouthrinses at a higher than 5% ethanol concentration bear in their packaging a safety seal device and labels that clearly inform caution procedures regarding the intake of such solutions by children.<sup>1,15</sup>

### **Use by alcohol addicts**

The sale of alcoholic beverages on Sundays is forbidden in several American states. Some reports discuss the case of alcohol addicts who are craving for alcohol and so resort to alcohol-based after-shave lotions, fuels or mouthrinses as a substitute for alcoholic beverages.<sup>18,19</sup> The dependence on such products has been recorded and is primarily related to easy access to such products rather than to social or financial factors.<sup>19</sup>

When taken in large quantities, mouthrinses can contribute to severe metabolic acidosis, multiple organ failure, and even death.<sup>20</sup>

The use of alcohol-based mouthrinses is not recommended for those who are recovering from alcohol addiction, as it can drive them back to craving for alcohol and addiction.<sup>21</sup>

### **Mouthwashes and oral cancer**

Tobacco smoking and alcohol consumption are the primary cause of oral and pharyngeal cancer,

while sun irradiation is the primary cause of lip cancer, but there are also other minor risk factors as nutrition, occupation and metabolic gene polymorphisms. Nowadays more researchers are considering clinical studies that would investigate the link between human papillomavirus (HPV) and some oral cancers.<sup>22</sup> However, oral cancer can occur in the absence of tobacco and alcohol.<sup>23,24</sup>

In 2008, more than 14,000 new cases of oral cancer are estimated to occur in Brazil. It is the fifth most common type of cancer in men and the seventh in woman.<sup>25</sup> Approximately 75% of the patients are diagnosed in advanced stages resulting in a 50% rate of mortality in five years. Most of the patients are smokers and heavy drinkers.<sup>25</sup>

A great consumption of alcohol moderately increases the risks of cancer of the mouth, pharynx, esophagus and liver.<sup>26</sup> However, alcohol (ethanol) is not carcinogenic in animals.<sup>7</sup> It is recognized that the risk of oral cancer associated with alcoholic beverages is related to certain carcinogens found in the beverage (e.g. urethane) rather than the alcohol itself.<sup>21</sup> The ethanol in mouthwashes does not contain the trace amounts of carcinogens found in alcoholic beverages and ethanol has never been demonstrated to be carcinogenic either in laboratory animals or in humans.<sup>21</sup>

It is well established that alcohol-containing beverages strongly enhance the effect of smoking in producing cancer, although the exact mechanism is unknown. Researchers have suggested that the ethanol in beverages acts by altering the surface of cells or mucosal tissues of the oral cavity, and that this alteration may increase the exposure to or facilitate the action of the carcinogens in tobacco or even in the beverages themselves. Another explanation is that the alcohol could act by a systemic mechanism.<sup>23,27</sup> The relationship between alcohol and oral cancer may be even more complex, involving liver damage and increase in DNA transcription errors during cell regeneration, and additional factors such as the severe dietary deficiencies very common among alcohol abusers.<sup>23</sup>

Several epidemiological and experimental studies have been published in the last three decades about alcohol-based mouthrinses and oral cancer<sup>23,24,28-35</sup>

(Table 1) besides other review papers and Official Statements.<sup>26,36-41</sup>

The first publication that suggested a link between oral cancer and alcohol-containing mouth-

washes was a case/control study performed with 200 patients with oral cancer and 50 general surgical patients as a control group.<sup>35</sup> It identified 11 people who did not smoke or consume alcohol bever-

**Table 1** - Mouthwash and Oral Cancer - an overview of epidemiological studies (updated and adapted from Blanc, Baruzzi<sup>38</sup>, 2007).

Publication and Year	Study	Characteristics and Critical Analysis	Mouthwash alcohol content	Conclusions
Weaver <i>et al.</i> <sup>35</sup> (1979)	<ul style="list-style-type: none"> <li>• Case/control</li> <li>• 200/50 (11/10)</li> </ul>	<ul style="list-style-type: none"> <li>• Small sample</li> <li>• Lack of comparability between cases and control</li> </ul>	Considered	Significant excess risk only in non-smokers and non-drinkers.
Blot <i>et al.</i> <sup>42</sup> (1983)	<ul style="list-style-type: none"> <li>• Case/control</li> <li>• Women</li> <li>• Telephone interview</li> <li>• 206/352</li> </ul>	No consistent dose-response relationship	Unknown	<ul style="list-style-type: none"> <li>• No association among women</li> <li>• Slightly increased risk in non-smokers</li> </ul>
Wynder <i>et al.</i> <sup>43</sup> (1983)	<ul style="list-style-type: none"> <li>• Hospital-based investigation</li> <li>• Case*/control</li> <li>• 571/568</li> <li>• (157/157 women)</li> </ul>	<ul style="list-style-type: none"> <li>• Lack of comparability between cases and controls</li> <li>• No dose-response relationship in non-smoking and non-drinking women</li> <li>• Possibility of confounding by tobacco and alcohol use</li> </ul>	Not reported	<ul style="list-style-type: none"> <li>• No association among men</li> <li>• Doubtful moderate association in women</li> </ul>
Mashberg <i>et al.</i> <sup>44</sup> (1985)	<ul style="list-style-type: none"> <li>• Veterans Hospital-based</li> <li>• Case*/control</li> <li>• 95/913 males at risk</li> </ul>	Tobacco and alcohol consumption was considered	Considered	Inverse association between mouthwash use and oral cancer, regardless of the amount of alcohol consumption
Young <i>et al.</i> <sup>45</sup> (1986)	<ul style="list-style-type: none"> <li>• Multi-hospital based</li> <li>• Case*/control</li> <li>• 317/306</li> </ul>	Neither tobacco nor alcohol consumption were controlled	Not reported	No association
Kabat <i>et al.</i> <sup>34</sup> (1989)	<ul style="list-style-type: none"> <li>• Multi-hospital based</li> <li>• Case*/control</li> <li>• 125/107</li> </ul>	Frequencies, duration of use, and dilution or rinsing practices were considered	Not reported	No association
Winn <i>et al.</i> <sup>37</sup> (1991)	<ul style="list-style-type: none"> <li>• General population</li> <li>• Case*/control</li> <li>• 866/1249</li> </ul>	<ul style="list-style-type: none"> <li>• Adjusted for tobacco and alcohol consumption</li> <li>• Increased risk related to duration and frequency of mouthrinse use</li> </ul>	Considered	Increased risk, 40% in males and 60% in females
Winn <i>et al.</i> <sup>24</sup> (2001)	<ul style="list-style-type: none"> <li>• General population</li> <li>• Case/control</li> <li>• 342/521</li> </ul>	<ul style="list-style-type: none"> <li>• Unable to evaluate the accuracy of the reporting of tobacco, alcohol or mouthrinse use</li> <li>• No evidence of a dose-response effect for any of several measures of mouthrinse use</li> </ul>	Considered	No association
Guha <i>et al.</i> <sup>27</sup> (2007)	<ul style="list-style-type: none"> <li>• Multi-center based</li> <li>• Case*/control</li> <li>• Europe (E) and Latin America (LA)</li> <li>• 924/928 (E)</li> <li>• 2,286/1,824 (LA)</li> </ul>	Mouthwash use was strongly correlated with the presence of oral lesions due to the symptoms	Not reported	A significant risk factor for all sub-sites
Marques <i>et al.</i> <sup>26</sup> (2008)	<ul style="list-style-type: none"> <li>• Multi-hospital based</li> <li>• Case*/control</li> <li>• 309/468</li> </ul>	No information about when mouthwash use began	Not reported	Daily mouthwash use showed a stronger association to pharynx than to mouth

\*Includes lips and/or pharynx, and/or larynx, and/or salivary glands.

ages, although 10 out of the 11 used mouthwashes, including nine who used a product with 27% of alcohol. Although no overall relative risk was provided, the authors reported that the case/control study results were not statistically significant.<sup>35</sup>

Researchers re-contacted subjects in an earlier case/control study of oral cancer among women in southern United States.<sup>42</sup> The original investigation had focused on the use of tobacco and beverages, but not on mouthwash use. It identified 255 case subjects (237 of whom were interviewed) and 502 control subjects (410 were interviewed). For all forms of oral and pharyngeal cancer, a relative risk of 2.0 to 4.0 among women who dipped snuff, 3.0 among women who smoked, and about 5.0 among women who consumed alcohol was reported. Re-searching the same subjects about the use of alcohol-containing mouthwash through a telephone interview with 206 case subjects and 352 control subjects, a relative risk of only 1.2 for mouthwash use was obtained. The author found no association between mouthwash use and oral cancer among tobacco users.<sup>42</sup>

In a hospital-based investigation of 571 patients with oral cancer and 571 control subjects, the results were negative for mouthwash use and oral cancer among men, but the crude data indicated a moderate association between daily mouthwash use and oral cancer, with a relative risk of 2.8, although the results showed no relationship between oral cancer and duration of mouthwash.<sup>43</sup> No information was available about the alcohol content of the products used or whether the mouthwash was used to conceal tobacco or alcohol odors in the breath.<sup>43</sup>

In a study conducted among 95 men with oral cancer and 913 men serving as control subjects from the New Jersey Veterans Hospital, the authors found a weak, inverse association between mouthwash use and oral cancer.<sup>44</sup> The relative risk for users was 0.8 in the overall data and 0.9 after controlling for smoking or beverage consumption. Among mouthwash users, an inverse association was found between oral cancer and the alcohol content of the mouthwash used. A relative risk of 0.6 was observed for the users of the product with the highest alcohol content. It is important to remember that the public

of the Veteran's Hospital are typically heavy smokers and alcohol consumers.<sup>44</sup>

In a multi-hospital case/control study of 317 oral cancer patients and 306 control subjects who had cancer of the head and neck "not thought to be related to tobacco use" or cancer of the larynx, the relative risk with mouthwash use was 1.0 among men and 0.5 among women. The results were similar for cancer of the mouth and oropharyngeal and hypopharyngeal cancer. Again, no information about the alcohol content was available for the products used neither was there any information about the time at which product use began, whether before or after the first signals of the disease.<sup>45</sup> The study results were distinctly negative, but issues may be raised about the study's design. For example, combining the first control group, which had a presumably typical smoking pattern, with the second control group (cancer of the larynx), which probably had a high level of smoking, may be questioned. Interpretation of the results may also be questioned, as the negative findings for mouthwash use were validated despite the fact that neither smoking nor drinking were controlled.<sup>45</sup>

In another multi-hospital-based investigation of 125 case subjects and 107 control subjects, the authors found no association between mouthwash use and oral cancer. Although no information was available regarding the alcohol content of the products used, this study provided an important finding for interpreting all mouthwash studies.<sup>34</sup> Moderately strong associations (2.6 to 3.2) were found among woman who used mouthwashes to disguise breath odors of tobacco or alcohol. However, the relative risk was only 0.7 or 0.8 among women who used mouthwashes to conceal food odors or for other reasons.<sup>34</sup>

In a case/control study of oral epithelial dysplasia among 127 subjects from two large pathology laboratories,<sup>46</sup> the authors examined eight variables describing mouthwash use and the alcohol content of the products used. The general findings were negative, as were those for all eight variables. They found that the relative risk varied inversely with the percentage of alcohol in the mouthwash used, even after the authors controlled for smoking and beverage

ages. The conclusion was that there is no relationship between mouthwash use and oral epithelial dysplasia.<sup>46</sup>

In a large case/control study with 342 case subjects and 521 control subjects from Puerto Rico with oral cancer, the authors affirmed that they were unable to evaluate the accuracy of the reporting of tobacco, alcohol and mouthwash use. They found no association between mouthwash use and oral cancer.<sup>24</sup> The crude and adjusted relative risk were both 1.0 and there was no evidence of a dose-response effect for any of the several measures of mouthwash use. The findings were positive for mouthwash use (relative risk of 2.8) among nonsmokers who abstained from alcohol. The authors considered these subjects to be the most likely to demonstrate any actual effect of mouthwash use on oral cancer. This consideration is speculative at best, especially in view of the strong interaction between alcohol abuse and smoking in the etiology of oral cancer. The extreme imprecision of the relative risk of 2.8 (95% confidence interval, 0.8-9.9) may indicate that chance is a highly credible explanation for the findings.<sup>25</sup>

The largest study performed until the moment with 924 cases and 928 controls in Central Europe, and 2,286 cases and 1,824 controls in Latin America<sup>27</sup> about oral health and the risk of squamous cell carcinoma concluded that periodontal disease and daily mouthwash use may be independent causes of cancer of the head, neck and esophagus.<sup>27</sup> The authors did not relate when the subjects began using mouthwashes, whether with the first symptoms of the disease, or even which kinds of alcohol-containing mouthwash were used. They suggest that, in order to be reliable, future studies should stratify by alcohol content, brand, reason to use, and how long the mouthwash was retained in the mouth.<sup>27</sup>

A review of the evidence conducted by the Food and Drug Administration (FDA) and American Dental Association (ADA) found the following four deficiencies:<sup>11</sup> 1) lack of a dose-response analysis based on frequency and/or duration of mouthwash use and inconsistent findings between studies, 2) lack of a scientific or biological basis to explain inconsistent findings between males and females, 3) absence of correction for alcoholic beverage ingestion and to-

bacco use, and 4) inclusion of cases of pharyngeal cancer as oral cancer, an improper classification. As mouthwashes are only used in the oral cavity, the findings are inconsistent, often contradictory and do not fulfill basic pharmacological requirements.<sup>11</sup>

In a recently published case/control study performed in seven reference hospitals with 309 patients with squamous cell carcinoma of the mouth and pharynx and 468 controls matched by sex and age,<sup>26</sup> the authors found that daily mouthwash showed a stronger association to pharynx (odds ratio 4.7, 95% CI 1.8-12.5) than to mouth cancer (odds ratio 3.2, 95% CI 1.6-6.3). For those patients who answered that they had regular gum bleeding, the authors found a stronger association too (odds ratio 3.1, 95% CI 1.2-7.9). They concluded that gum bleeding, no dental care and daily mouthwash use were factors associated with oral cancer regardless of tobacco and alcohol consumption. The authors comment about the potential bias involved in their own study. As in others studies, the fact that the subjects may use mouthwashes to reduce the aftertaste left by smoking or drinking may be an important potential bias in the multiple logistic regression analysis adjusted for smoking and alcohol consumption.<sup>26</sup> In Brazil, where the study was conducted, a self-medication culture is widespread among the population, so the first symptoms of the disease could have led patients to search for a self resolution. Thus, mouthwash use could have been a consequence and not a cause of the disease, particularly considering that data on mouthwash brand, frequency of use and time at which the use began were not recorded.

## Final remarks

The rationale for the daily use of antimicrobial mouthrinses is well known and can be divided in two main arguments: 1) the inadequacy of the mechanical plaque control performed by most people for the control and prevention of periodontal diseases, and 2) as a method of delivering antimicrobial agents to mucosal sites throughout the mouth that may harbor pathogenic bacteria capable of recolonizing supragingival and subgingival tooth surfaces, thereby providing a complementary mechanism of



plaque control.<sup>32</sup> Antimicrobial mouthrinses are safe and effective in reducing plaque and gingivitis, and should be part of a comprehensive oral health care regimen that includes brushing, flossing and rinsing to prevent or minimize periodontal disease.<sup>6</sup> Most mouthwashes with antiplaque properties (essential oil and some chlorhexidine mouthwashes) contain denatured alcohol as a delivery vehicle. Nevertheless, a review by the Food and Drug Administration and the American Dental Association found that the

evidence about oral cancer and alcohol-containing mouthwashes is inconsistent and contradictory.<sup>21</sup>

The literature reviewed here indicates that despite some undesirable effects to some people, like burning sensation, and some contraindications, like the use by infants, alcohol addicts and patients with mucosal injuries, there is no reason to avoid the use of alcohol-containing mouthwashes as long as they are used following proper guidance by dental professionals and the manufacturers' instructions.

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