

Research on Chewing Gum: Questions of Ethics

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Abstract

Guidelines for clinical research and ethics committees are significant contributions to decision made in science and law. But since research methods need to follow the changes and the development of science, guidelines for clinical research have to be continuously revised. Many innovations are perceived for their intended beneficiaries as benefits. Unfortunately, this is not always true. Therefore two issues should be mandatory in discussions of research ethics committees: 1) What constitutes a harmful intervention? 2) What procedures should be established for obtaining data and evaluating their relevance? These questions are too broad and there are no ethical solutions that can leap off a paper. But an example can be worked on. Dental caries is a public health challenge in any country and chewing gum may have an effect with respect to plaque reduction, at least in a short period of time. But sugar chewing gum cannot be used as a positive control in biomedical researches. However, trials referred herein allocated participants for a sugar chewing gum group. Therefore, the aim of this critical review is to emphasize that such a procedure is an example of a conscious disregard for the consideration which is due to trial participants. Were these desirable researches themselves or they had other purposes?

Keywords

Research Methods, Ethics in Research, Chewing Gum, Chlorhexidine

1. Introduction

It is already known that dental caries is a biofilm-dependent oral disease and fermentable carbohydrates are the key environmental factor for its initiation and development (Paes-Leme, Koo, Bellato, Bedi, & Cury, 2006). It has been suggested that sugar-free chewing gum used immediately after meals reduces caries. In fact, chewing gum may serve as an oral hygiene device when brushing may not be possible (Kakodkar & Mulay, 2010). The observed caries reduction may be ascribed to saliva stimulation throughout the chewing process, the lack of sucrose

and the inability of bacteria to metabolize polyols into acids (Mickenausch, Leal, Yengopal, Bezerra, & Cruvinel, 2007). Besides the observed caries reduction, it was suggested that chewing gum may improve aspects of cognitive function and mood (Smith, 2010). As a result, chewing gum manufacturers have made health promotion claims, suggesting, e.g., reparative action or substitution for mechanical hygiene (Imfeld, 1999).

2. Experimentation without Restriction

Can chewing gum prevent dental caries? Studies were conducted in Brazil in the eighties with a sucrose gum containing chlorhexidine digluconate, which had the commercial name of Den-den. There is no data on preclinical research or even on clinical trials, only a previous note by the author (Neder, 1981).

After the chewing gum was already being marketed, some articles were published in Brazilian journals. One of these articles (Lacaz-Netto, Macedo, & Rossetini, 1986) describes a clinical trial carried out to compare the benefits of Den-den with a gum sweetened with sorbitol and manitol and a sugar-packed gum (a positive control) with a negative control group. Six dental female students, twenty years of age on average were recruited and the trial went on for twelve days. The ethical implication of using a sugar-packed gum as a positive control was not even mentioned. Besides that, the small sample size undermines the reached conclusion that “any type of chewing gum is capable of reducing a high plaque index”.

A second study (Pinheiro, Vono, Pavarini, Bijella, Bastos, Moraes, & Silva, 1985) conducted in Brazil recruited fifty students, males and females, in a Dentistry School for two trials. The first trial sought to compare the effects of conventional chewing gum and Den-den on inhibition of dental plaque formation and the second sought to compare the effects of the same chewing gums on dental plaque dissolution. No difference between groups was observed in both trials.

Only after experimenting with human beings was an experiment finally conducted with rats. Thirty rats 20 to 21 days old were divided into three groups: the first group received Den-den added to the standard rat food; the second received conventional gum added to the standard rat food and the third group was the control. Researchers concluded that Den-den had neither anticariogenic effect nor reduced biofilm formation.

Afterwards, a chemical analysis revealed more than 70% of sucrose and a minimum amount of digluconate of chlorhexidine (approximately 0.02 mg/unit) in Den-den formulation. There is an intuitive explanation for this: Den-den chewing gum was produced in a candy factory and, in order to mask the unpleasant taste of digluconate of chlorhexidine, sugar was added.

The fact is that the Department of Health Surveillance (Jornal do Brasil, 1984), now the National Health Surveillance Agency, which is subordinated to the Brazilian Institute of Health, prohibited the manufacture of Den-den chewing gum because of the misleading propaganda: “Den-den chewing gum fights dental caries and protects your teeth”. According to the manufacturer, around fifty mil-

lion units of Den-den were sold per month in Brazil. Is it reasonable to consider that many children were harmed?

Researchers from Michigan University carried out a double-blind cohort study with 1277 fourth graders in Belize, Central America, from 1989 to 1993, in order to compare, side by side, various chewing gum formulations (Mäkinen, Bennett, Hujoel, Isokangas, Isotupa, Pape, & Mäkinen, 1995).

Children were examined by four calibrated dentists at baseline and after 16, 28 and 40 months on the program. Findings showed that sorbitol gum reduces caries rates, but xylitol gums are more effective. According to the authors, the most effective for caries prevention was the gum sweetened with xylitol chewed five times daily. Researchers also observed that sucrose gum usage leads to an increase in the caries rate. Is it possible they did not know that they would inevitably come to this conclusion? Anyway, the study carried out in Belize by researchers from Michigan University is an example of a double standard in an investigation: a sucrose chewing gum probably would not be tested in Michigan, USA, due the ethical implications.

In 1994 the Brazilian Association of Dentistry magazine (Editorial, O sorriso do chiclete, 1994) reported the Belize study, adding extemporaneous comments about Den-den. It starts by saying that “sorbitol, xylitol or chlorhexidine...(are) ingredients which researchers test in order to measure the efficiency of chewing gum (with these ingredients) to reduce dental caries and plaque”. And this editorial also reveals that Den-den was introduced to the Rocinha slum in Rio de Janeiro, Brazil, which at that time had 40 thousand inhabitants. It goes on to say: “results were significant because the poor families there were not in the habit of using a tooth brush. With the gum being chewed twice a day, dental plaque, especially among children, was reduced by 60%”. But no evidence was shown regarding how these findings were collected or evaluated. In fact, data never have been available (Vieira, 2015). “Humans are remarkably good at self-deception. But growing concern about reproducibility is driving many researchers to seek ways to fight their own worst instincts” (Nuzzo, 2015).

3. The Impact of Values

It has been suggested that xylitol inhibits the growth of *Streptococcus pneumonia* (Uhari, Kontiokari, Koskela, & Niemela, 1996). This brings to mind the clinical trial that was made in Finland, where 306 children were randomized into two groups: a positive control who received sucrose gum and an intervention group who received xylitol gum (8.4 g/day). The primary endpoint was an episode of acute otitis media. Children were monitored for two months. Researchers concluded that xylitol gum can have a preventive effect on acute otitis media.

However, the editorial (Winter, 1996) of the same journal (British Medical Journal) in which this article was published discussed reasons why a UK ethics committee would not allow the trial made in Finland to be carried out. Sucrose gum is a risk for the dental health of children susceptible to caries and the studies were not monitored by a pediatric dentist. Although the experiment did not

go on for very long, there was time enough for the habit of chewing gum to develop. The harmful intervention should not have been made. Notwithstanding, researchers ignored the risk.

Trials with sucrose gum in Belize and in Finland were carried out when the procedures and international guidelines for human experimentation were already well accepted. Researchers were guided for what kind of feeling? Search for truth?

4. Final Considerations

It is well known that both chlorhexidine and fluoride play valuable preventive roles in dental disease, although chlorhexidine has an unpleasant taste, alters taste sensation and produces brown staining on the teeth, which is very difficult to remove (Eley, 1999), (Smith, Moran, Dangler, Leight, & Addy, 1996). Fortunately, systematic reviews carried out all over the world concluded that more studies are necessary to confirm the possible effect of sugar free chewing gum on dental decay reduction (Touger-Decker & van Loveren, 2003). In Brazil, competence and ethical concerns in medical research have greatly improved (Hossne, Bontempo, & Vieira, 2010).

But it should be noted that researches on sugar-packed gum show that questions raised by human experimentation have no easy answers (Vieira, 2014). These examples emphasize the “need for greater awareness and restless analysis of the conflicting purposes of human experimentation: protecting man, advancing and improving well-being of society and future generations” (Katz, 1972). Science is a way of building knowledge about the universe, advancing and improving well-being of society and future generations, but methods and ethics are a must in research. In fact, science is inherently dependent on ethics but subject to corruption (Gardenier, 2011). And only “the process of critically examining past history will hopefully prompt a greater effort to curb potential abuse” (Bekier, 2010).

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