



VIPEHOLM DENTAL STUDIES – A REVIEW AND ANALYSIS

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INTRODUCTION

Humans, throughout time, has fallen victim to the afflictions of dental caries (DC), or more commonly known as tooth decay. With a history of over a million years,^[1] dental caries have been observed since the Paleolithic and Mesolithic ages.^[1] The word 'caries' originates from a Latin word which means 'rotten'.^[2] While this rotten appearance of teeth was unknown, numerous myths regarding the cause of caries arose over the years. The most common belief was that dental caries were caused by "tooth worms". This idea was rejected by the Pierre Fauchard who is today known as the "Father of Modern Dentistry".^[3] Overtime, information was discovered about this disease, including the treatment, prevention, and complications of dental caries.

Despite the advancements in oral disease science, dental caries still continues to be a worldwide health concern. The World Health Organization (WHO) defines dental caries as "a localized post eruptive pathological process of external origin involving softening of the hard tooth tissue and proceeding to the formation of a cavity". Here the external origin means the involvement of the bacteria, *Streptococcus mutans*, in the dissolution of hard dental tissues.^[4]

Statistics have shown that at least 36% of the individuals, worldwide, have dental caries in their permanent teeth.^[5] It is estimated that 59% of adolescents between the ages of 12 and 19 have dental caries, whether treated or untreated.^[5] The financial losses due to dental caries annually are projected to be around 27.7 billion US dollars.^[5] Regardless of the various successful dental treatment programs, the prevalence rate for dental caries still remains high. This high prevalence can be attributed to the fast changing diet and lifestyle, the general relaxed*(dismissive) attitude towards oral health, the expensive treatment costs, the lack of free government dental services in many countries, and also the cultural tabooing of treatment for caries in certain regions of the world. Today, dental caries are still regarded as the most chronic disease in children,^[4] affecting their deciduous teeth.^[5]

Several successful research studies have been conducted in the field of dentistry in order to understand caries, which is often considered as the primary etiological cause for oral health issues.^[6] Severe complications such

as periodontal and periapical abscess, cellulites, bacterial meningitis^[5] associated with caries were discovered. Studies have also elaborated upon the negative emotional aspects of the disease, linking due to loss of aesthetics and facial structure deformation due to loss of muscle tone.

Vipeholm Dental Study

One of the first large scale research studies in the history of dentistry was conducted in the 20th century at the Vipeholm Hospital in Sweden.^[7] Around this time, dental caries had become a highly prevalent issue in Sweden, with nearly 83% of the children being affected.^[7] Furthermore, there were no available large scale dental treatment programs to counter the disease during this period.

While enough scientific evidence was available to support that bacteria caused dental caries, the underlying basis for the chronic disease was still unknown. Therefore, the Swedish government commissioned the *Folktandvaren* (a public dental service) and it's to establish an interdisciplinary team of clinicians at the Vipeholm Hospital for the mentally disabled outside the city of Lund.^[7]

The study was conducted from 1945-1953 with a total number of 436 subjects. Individuals were split into various control and treatment groups with an aim to determine the relationship between diet, frequency of sugar intake and dental caries.^[8]

The experiments were conducted by splitting the subject population between two types of groups, the first being the carbohydrate study 1 (1947-1949) and carbohydrate study 2 (1949-1951). Once the participants were selected and the recording methods were designed, a vitamin study was conducted from 1946-1947, during which vitamin supplements A, C, and D were given to the subjects. The vitamin study was conducted to observe whether there was any decrease of carious activity in the presence of vitamins.^[8] It was soon established that none of the supplements had any effects on the carious activity and the study then proceeded to the carbohydrate phase. At this phase, sugar was administered either in a solution during meals or in sticky form (bread and toffee) in between meals.^[7,8] During the latter part of the study, participants in the toffee groups were further divided into an 8-toffee-group and a 24-toffee-group. Considering the respective groups, subjects were fed 8 and 24 pieces of toffee a day, in between meals.^[7] The diet in the carbohydrate study 1 contained 1800 kcal while that of carbohydrate study 2 contained 3000 kcal of sugar supplements.^[7] The toffee consumed were manufactured by the local factories and were similar to the one's consumed by Swedish children at the time.^[7,8]

RESULTS

The study positively established that sticky sweets consumed between meals, rather than during meals significantly increased the incidence rate of dental caries. It showed the major involvement of carbohydrates in the development of carious tooth surfaces. Subjects who consumed 24 pieces toffee a day developed 4.02 new carious tooth surfaces per person per year, relative to the subjects in the control group, who developed only 0.30 carious surfaces per person per year. By the end of the study, a total of 2125 new dental caries had been induced among the study population.^[9]

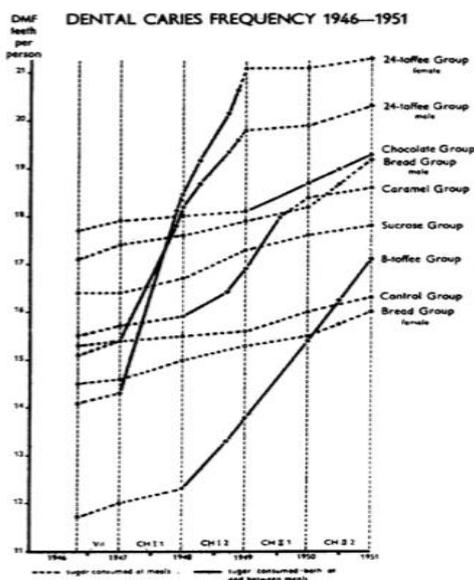


Figure 1. The diagram shows that the caries incidence was very low in subjects on the basic diet and when sucrose was given at meals (dotted lines). One exception is the male bread group, which showed a distinct increase in caries activity during the second year. Sugar given in sticky form between meals increased caries activity significantly (solid lines).

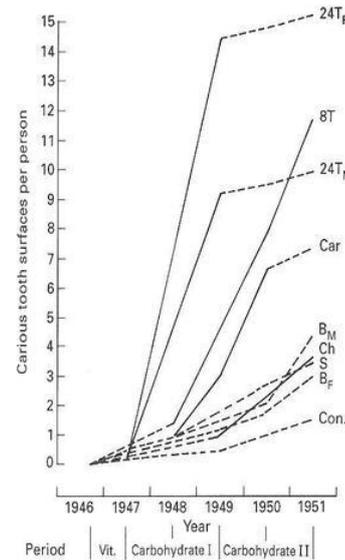


Fig. 6.10 The cumulative number of tooth surfaces attacked by primary caries only (including pre-cavitation lesions) in the control group and eight test groups, between 1946 and 1951. Solid line indicates that the subjects ate sugar both at and between meals; interrupted line indicates that subjects received sugar only at meals. Groups are as for Fig. 6.9. Data from Gustafsson et al. (1954), Table 12.

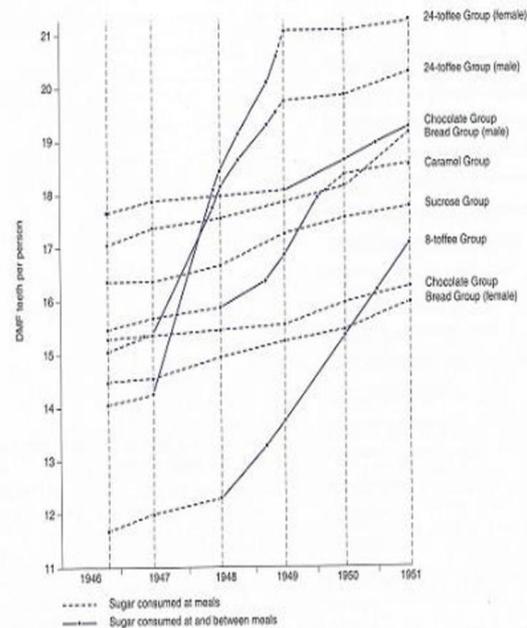


Figure 19.3 Information from the Vipeholm study: DMFT per person relative to the type and time of eating various sugars and sugar-containing products (Gustafsson et al., 1954).

Ethical considerations

Following the publication of the results, the study was negatively received for the way it was conducted. Some of the obvious concerns were that the study was conducted at an institution for the mentally challenged, a subject population that was clearly vulnerable.^[9,10] The hospital was chosen because provided a largely sedentary population easily observed over an extensive time frame, which was necessary for conducting a prospective study.

The subjects were not informed about their participation

in the study and were never asked for an informed consent.^[8] The fact that the subject population included a group of mentally challenged individuals unfits to make their own decisions should be condemned. The investigators overlooked the moral obligations of protecting such vulnerable individuals.

Researchers had argued that the study was successful as it yielded positive results in establishing the aim of the study. However, the suffering of unsuspecting subjects cannot be ignored in the wake of successful research results.

Apart from the choice of subjects and the violation of autonomy, the research had several additional flaws such as the following:

1. The study was conducted for a very long period of time, even though the investigators had begun to establish positive results within three years of the study. Almost half the subjects' teeth were completely rotten by this time frame and they mostly involved the molars, with at least three or more surfaces and increased Decayed, Missing, or filled teeth (DMFT) index.
2. The study did not enlist inclusion and exclusion criteria for the study. Most of the participants were divided on the basis of gender. Several other important criteria such as age, debilitating diseases, mental health of the subjects were not considered for participation.
3. The investigators did not conduct any diagnostic tests to exclude subjects that were suffering from any underlying diseases, which could have been aggravated in the presence of excessive sugar consumption. For example, diabetes mellitus is an endocrine disorder often observed in many mentally challenged individuals. Diabetes is known to be aggravated in the presence of the excessive sugar levels and severe cases often lead to toxicity and necrosis. Attempts to exclude such subjects from the study were not made.
4. The investigators ignored two important significant observations: First, despite the sugar consumption various subjects did not develop new carious lesions. Secondly, other subjects developed carious lesions even though they were not consuming the sugar substitutes. This observation shows that caries are bimodal in their expressions, which was already an established fact at the time the study was being conducted. This observation also showed that carbohydrate consumption is only one of the factors in inducing caries. Nevertheless, it ignored several other reasons such as the depth of fissures on the tooth surfaces, crowding and alignment of the teeth; all cause retention of food on the tooth surfaces and initiates the initial breakdown of the tooth tissue components in the presence of an increased salivary pH and overall oral cavity hygiene.
5. The study was conducted at a time when the role of fluoride in the prevention of dental caries was

already established. Various countries were already beginning to introduce topical fluoride treatments to prevent caries. Various participants were given 1mg of fluoride tablets during the vitamin study period. However, the systemic effects of such ingestion were never observed and topical application of fluoride on demineralized tooth tissue surfaces was not attempted.

6. Investigators did not provide treatment for dental caries that were induced specifically due to the forceful feeding of sugar substitutes, either during or after the study was conducted, despite knowing the possible complications associated with dental caries.
7. There were also no attempts made at introducing or teaching the subject population about brushing techniques, which could have helped maintain the bacterial accumulation in the oral cavity.

Analysis

The Vipeholm dental study was one of the first large scale studies conducted in the field of dentistry. It was also one of the first studies to be mostly publicly funded.^[7] Despite all the successful results it established, it not only paved way for further understanding and treating DC but also put researchers and government organizations into a dilemma.

The study was conducted at a time when there were few regulations enforced on the methodology of research. Regardless, the lack of regulations pertaining to the issue is not an excuse to overlook the moral and the ethical concerns of a research study. There is a substantial amount of literature which supports condemning the enrolment of vulnerable subjects in scientific research.^[11] The investigators should have first considered whether mentally challenged participants were the right study population for observing the relationship between sugar and dental caries.^[8] Often the salivary composition of such individuals is slightly different compared to that of mentally fit subjects. The inability to control facial musculature often leads to excessive pooling of the saliva in the mouth and causes an increased pH activity in the oral cavity, which is interlinked with the incidence of dental caries. The investigators should have also acquired an informed consent either from the subjects or their guardians prior to the study.

The investigators should have initially designed a protocol which gave clear information about the study with clarity in the inclusion and exclusion criteria. These criteria are absolutely necessary to develop successful research protocols and help in producing results that are effective, sound, and free from bias. It has often been argued that the Vipeholm study was mostly free from observer bias, which helped them achieve successful results, but that should also be attributed to the availability of the subjects within the confines of a controlled atmosphere. The mental status of the individuals should have been evaluated prior to the study, and the condition of the subject should have been

an important exclusion criterion for the study. The investigators should have conducted necessary diagnostic tests to eliminate and exclude subjects suffering from underlying debilitating diseases, endocrine disorders and lactose intolerance, which are relatively high among the selected subject population. This could have helped avoid further severe complications that might have arisen due to the degradation of the dental tissues. The investigators should have considered facts about dental caries that were already established, such as its bimodal expression. This could have helped the investigators define the study sample by selecting subjects which were only in the age groups of bimodality, thereby eliminating the agony inflicted upon several other subjects. Enrolled subjects who had a very high incidence of caries should have been eliminated from the study in order to avoid inflicting more suffering. Several reviews could have been conducted throughout the study to evaluate the progress, and the study should have concluded when there was enough evidence to support the primary aim of the study. This way the length of the study period could have been reduced and more research could have been conducted of the treatment aspect as well. Several researchers have argued that providing treatment was not the initial aim of the study, but it must be taken into consideration that the study was being conducted at a time when not much was known about the treatment for dental caries. Complications such as abscess that would arise due to caries would have been difficult to treat without any established line of treatment. The investigators should have considered using topical fluoride among the study population to reduce or control the incidence rate, once the results were established. Unfortunately, the study subjects were left in agony once the study was completed. With no treatment interventions and lessons on maintenance of oral hygiene, many suffered from regular complications associated with dental caries. This could have been countered with programs for oral hygiene care.

CONCLUSION

Research has been the key to understanding the prognosis of various diseases. The search for knowledge and answering the question “why” has led to establishing successful lines of treatments. The same is applicable to research in the field of dentistry. Modern dentistry has come a long way, starting from Etruscan dentistry, to the development of aesthetic composites, and eventually to the most recent development of caries vaccine. The Vipeholm study, being one of the first large scale studies, especially in dentistry. The study created a foundation not only for further research prospects, but also for the establishment of several dental health care programs and for the involvement of the governing bodies at a socio political level. Nevertheless, all progress was made at the physical, mental and emotional expense of 436 subjects who conscripted to participate in the study without their knowledge. Such a study would never be considered in today's world due to the development of regulations for conducting research with human subjects. Stricter federal

laws governing research, necessary informed consent, and humane researchers have made it safer and more rewarding. It is unfortunate that the study was being conducted at a time which lacked many rules that governing today's research. That the Nuremberg code, which is one of the most accepted codes of ethics and encircles around the principles of autonomy, beneficence and justice was published in the year 1947.^[9] There were no available institutional review boards to intervene and provide an overview on the ongoing research.^[10, 11] In the end, we must remember that research must be a balance of science and humanity. That the law of humanity is above everything, as the end result may not always justify the means.^[8]

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