A COST-EFFECTIVENESS ANALYSIS OF GLASS IONOMER CEMENT AS FISSURE SEALANT IN SCHOOL-BASED FISSURE SEALANT PROGRAMME IN THE DISTRICT OF PONTIAN, JOHOR

by

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LIST OF ABBREVIATIONS

1. GIC	Glass Ionomer Cement
2. RBS	Resin-Based Sealant
2. TA	Amalgam Restoration
3. TC	Composite Restoration
4. SD	Standard Deviation
5. IQR	InterQuartile Range
6. FPM	First Permanent Molar
7. SPM	Second Permanent Molar
8. dft	decay filled teeth
9. DMFT	Decay Missing Filled Teeth
10. OR	Odds Ratio
11. LR	Likelihood ratio
12. CI	Confidence Interval
13. ADA	American Dental Association

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ABSTRAK

TAJUK: ANALISIS KEBERKESANAN KOS DALAM PENGGUNAAN SIMEN IONOMER KACA SEBAGAI PENGAPAN FISUR DALAM PROGRAM PENGAPAN FISUR DI SEKOLAH-SEKOLAH DI DAERAH PONTIAN, JOHOR

Pengenalan : Penjagaan Kesihatan Oral Masyarakat memberi fokus kepada langkah-langkah pencegahan seperti pemfluoridaan, promosi kesihatan oral, saringan kanser oral dan program pengapan fisur di sekolah. Sehingga kini, tiada lagi penilaian lokal yang dibuat terutamanya berkaitan dengan keberkesanan kos yang melibatkan pengapan fisur.

Objektif: Menentukan status permukaan oklusal gigi kekal molar pertama kiri bawah dalam kumpulan pengapan fisur dan tanpa pengapan fisur selepas tempoh 5 tahun, menentukan kos ekstra pengapan fisur untuk kumpulan pengapan fisur, kos komplikasi dan kos setiap permukaan karies tercegah bagi kedua-dua kumpulan, dan akhir sekali membandingkan status gigi kekal molar pertama kiri bawah di antara kumpulan berpengapan fisur dan tanpa pengapan fisur.

Metodologi : Kajian kumpulan retrospektif ini dijalankan di Pontian bermula dari bulan Jun 2004 hingga bulan Oktober 2005. Ia terbahagi kepada dua fasa, fasa 1 berkaitan analisa kos dan deskriptif yang melibatkan 618 orang dari kumpulan

berisiko karies tinggi dan fasa 2 berkaitan komponen soalselidik yang melibatkan 322 murid-murid sekolah berisiko tinggi karies.

Fasa 1 menumpukan kepada rekod rawatan gigi (LP8) dan data kewangan dari pejabat pentadbiran data dikumpul dari 1998 hingga 2003. Untuk fasa 2, subjek yang dipilih secara teknik persampelan rawak telah diberi borang soal selidik mengenai status sosio-demografi. Analisa kos dibuat berdasarkan program yang dikhaskan bagi langkah pencegahan pengapan fisur.

Keputusan : Kadar retensi simen ionomer kaca sebagai pengapan fisur dalam kajian ini adalah 19.4%, dan kehilangan keseluruhan pengapan fisur pula adalah 80.6%. Status permukaan oklusal gigi kekal molar pertama kiri bawah yang sihat bagi kumpulan pengapan fisur adalah 88.4%, manakala bagi kumpulan tanpa pengapan fisur, nilainya adalah 76.7%.

Terdapat 11.6% daripada gigi berpengapan fisur dan 23.3% daripada gigi tanpa pengapan menjadi karies selepas susulan selama 5 tahun. Kos ekstra pengapan fisur untuk kumpulan pengapan fisur adalah RM1,294.73, kos komplikasi bagi kumpulan pengapan fisur adalah RM 988.83, kos komplikasi bagi kumpulan tanpa pengapan fisur adalah RM 1,927.10. Kos bagi setiap kes karies permukaan tercegah bagi kumpulan pengapan fisur adalah RM 8.37 (95%CI 8.03,8.72) manakala kos bagi setiap kes karies permukaan tercegah untuk kumpulan tanpa pengapan fisur adalah RM 8.35 (95%CI 7.98,8.72).

Status permukaan oklusal gigi kekal molar pertama kiri bawah berkait rapat dengan kumpulan pengapan fisur dan kumpulan tanpa pengapan fisur dengan *odds ratio* 1.91 (95% CI 1.05,3.49). Untuk tujuan ini, faktor-faktor seperti umur, jantina, etnik, tahap pendidikan ketua keluarga, pendapatan bulanan keluarga, lokasi, pengalaman karies desidus (dft), dan pekerjaan adalah dikawal pada kedua-dua analisa univariabel (OR kasar = 1.78; 95% CI 1.02,3.07) dan analisa multivariabel (OR=1.91; 95% CI 1.05,3.49)

Kesimpulan: Kadar retensi simen ionomer kaca dalam kajian ini adalah rendah. Status permukaan oklusal gigi kekal molar pertama bawah pada mereka yang menerima pengapan fisur mempunyai pencegahan karies yang lebih baik. Manakala, kumpulan tanpa pengapan fisur lebih cenderung untuk mengalami karies. Memandangkan kepada lebih banyak nikmat kesihatan dan kelebihan yang akan dirasai oleh mereka yang menerima pengapan fisur, kesimpulannya program fisur sealan ini adalah berkesan dari segi kos walaupun jumlah keseluruhan kosnya tinggi sedikit daripada kos bagi kumpulan tanpa fisur.

ABSTRACT

TITLE: A COST-EFFECTIVENESS ANALYSIS OF GLASS IONOMER CEMENT AS FISSURE SEALANT IN SCHOOL-BASED FISSURE SEALANT PROGRAMME IN THE DISTRICT OF PONTIAN, JOHOR

Introduction: Community oral Health Care mainly focused on preventive measures such fluoridation, oral health promotion, oral cancer screening and school-based fissure sealant programme. To date, there has been no local evaluation of fissure sealant effectiveness especially in term of its cost.

Objectives: To determine the status of occlusal surface of lower left FPM in sealed group and unsealed group after 5-year follow up, to determine the extra cost for sealed group, cost of complication and cost per averted occlusal caries for both groups and to compare the status of lower left permanent molar between sealed and unsealed groups.

Methodology : This was a retrospective cohort study conducted in Pontian from June 2004 to October 2005. There were two phases in the study i.e. phase 1 for descriptive and cost analysis which involved 618 high caries risk group and phase 2 for questionnaire component which involved 322 high caries risk school children.

Phase 1 only focused on dental treatment record (LP8) and financial data from administrative office and the data was collected from 1998 to 2003. For phase 2, subjects who were selected by a random sampling technique were given questionnaire for socio demographic status. Costing analysis was done based on the specified programme for the fissure-sealant preventive measure only.

Results: The total retention rate of glass ionomer cement as fissure sealant in this study was 19.4% and the total loss was 80.6%. The status of sound occlusal lower left FPM in the sealed group was 88.4% and in the unsealed group was 76.8%. There was 11.6% of sealed teeth and 23.3% of unsealed teeth which developed caries after a 5-year follow up. For cost analysis, the extra cost for the sealed group was RM 1,294.73, cost complication for the sealed group was RM 988.83, cost complication for the unsealed group was RM 1,927.10 and lastly cost per averted occlusal caries in the sealed group was RM 8.37 (95%CI 8.03,8.72) and cost per averted occlusal caries in the unsealed was RM 8.35 (7.98,8.72).

Significant association was found between the status of occlusal lower left FPM and sealed/unsealed group while other associated factors being controlled at both univariable (crude OR=1.78; 95%CI 1.02,3.07) and multivariable analyses (OR=1.91; 95% CI 1.05,3.49).

Conclusion: The retention rate of GIC in this study was low. Occlusal status of lower left first permanent molar in those with fissure sealant have better caries prevention. The unsealed group has higher chances to develop caries. Considering the health gain (reduced caries) and the benefit enjoyed by those receiving fissure sealant, it is concluded that this fissure sealant programme is cost-effective even though the total calculated cost is slightly higher than that in unsealed group.

OPERATIONAL DEFINITIONS

1. "Glass ionomer cement" (GIC) refers to polyalkenoate cement contain flouride ions.

2. "Fissure sealant" refers to a material that had been applied to the fissures and pit on the surface of permanent molar tooth. It is atraumatic (painless) procedure to prevent tooth decay.

3. "High caries risk group" refers to a group of school children whose permanent molars with deep/complex pit and fissures (DMFT=0) and / or had number of decayed and filled deciduous teeth more than 3(dft > 3) (Oral Health Division, 2003)

4. "Status of the occlusal surface" refers to the condition of occlusal surface of lower left FPM either sound or caries.

5. "Caries" refers to either the tooth was filled with filling materials or being extracted. The unfilled caries is not considered in this study because in the calculation of complication, we only consider the tooth with treatment either restoration or extraction.

6. "Sealed group" refers to a group of high-caries-risk school children whose lower left FPM received GIC as sealant in 1998.

7. "Unsealed group" refers to a group of high-caries-risk school children whose lower left FPM had not received GIC as fissure sealant but sound in 1998.

8. "Extra cost for sealed group" refers to the total cost to organize a fissure sealant programme including the extra cost of man-hour, extra cost for office space rental, the cost of specific consumables and the cost of complication.

9. "Extra-cost of man-hour" refers to the salary of dental nurse attributed to sealant.

10. "Extra-cost for office space rental" refers to rent of the school space attributed to sealant. The rent was assumed for electricity, water and equipment used.

11. "Cost of specific consumables" refers to the cost of specific material attributed to sealant only.

12. "Cost of complication" refers to the total cost of treatment needed if caries occured.

13. "Cost savings of averted caries" refers to the cost needed to prevent one episode of occlusal caries of lower left FPM.

14. "Efficacy of fissure sealant" refers to the benefit of the preventive measure of the service – for example, the benefit of fissure sealant is to prevent tooth becoming decay (Burt, 1977)

15. "Effectiveness of fissure sealant" refers to the effect of the activity and the end results for population achieved in relation to the stated objectives, for example, the effectiveness of fissure sealant would be reduced if occlusal caries developed early in the target group if compared with the non-sealed group (Burt, 1977)

16. "Efficiency" refers to the effects or end results achieved in relation to the effort expended in terms of money, resources and time. It is usually related to economic evaluation including cost-effectiveness analysis (Burt, 1977).

17. "Split mouth design for fissure sealant" refers to the fissure sealant was done on the permanent molar and the contra lateral tooth act as control.

CHAPTER 1

INTRODUCTION

1.1 Primary Health Care

Primary health care has been defined by the World Health Organization (WHO) in 1978 as "essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community can afford to maintain at every stage of their development in the spirit of self-reliance and self -determination". It forms an integral part of the country's health system, of which it is the central function and main focus, and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and community with the national health system, bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process (WHO/UNICEF, 1978).

Primary Health care is an approach that addresses illness prevention and health promotion more broadly (Oral Health Division, 2005). In this system, services will be provided in the community. As an example, for the school children, the team will visit the school and provide the care as well as the health promotion. In Malaysia, Ministry of Health (MOH) acts as the primary provider, planner and organizer of medical, health and oral health care services for the nation. It provides care at three levels – primary, secondary and tertiary.

Primary care mainly focuses on preventive measures while secondary and tertiary levels focus on palliative and rehabilitative measures (Oral Health Division, 2005).

1.2 Primary Oral Health Care

Oral health care in Malaysia is provided by both public and private sectors. In the public sector, oral health care programme is divided into three components, namely primary, specialist and community oral health care (Oral Health Division, 2005).

Primary oral health care is targeted at various priority groups such as preschool children, school children, antenatal mothers, the elderly and children with special needs. Specialist oral health care mainly comprises oral surgery, paediatric dentistry, oral pathology and oral medicine, orthodontics, periodontology and restorative dentistry. Compared to specialist oral health care which is corrective in nature, community oral health care emphasizes mainly on preventive measures such as fluoridation, oral health promotion, oral cancer screening and school-based fissure sealant programme.

1.2.1 Dental school-based programme

With more than 40% of the population below the age of twenty, oral health care for school children continues to be a priority (Oral Health Division, 2002). School dental service for school children is a comprehensive curative and preventive programmes delivered via school dental clinics, mobile dental clinics and mobile dental teams.

Extensive coverage of school children has been made possible through outreach approach using mobile dental teams. The mobile dental team comprises an effective mix of operating personnel namely dental officers, dental nurses, dental surgery assistants and health attendants (Oral Health Division, 2005).

Once a year, every school child is screened and treated by the dental personnel in the school using portable unit and referral to the nearest dental clinic is made if needed. The aim of the programme is to render school children orally fit before they leave school, and the positive result is evident with the increase of caries-free percentage for the 12-years-old for the last 3 decades, from 21.2% (1970/71) to 28.7% (1988) to 44.87% (1997) to 57.3% (2003) (Oral Health Division, 2003). The latest percentage at 57.3% however, is still below the National Oral Health Goals 2010, which is 60%.

In 1997, a survey was done in Malaysia for school children and it revealed that more than 70% of caries were found to occur on occlusal surface on molars which was least protected by fluorides and constituted 44% and 39% of tooth decay in the 12-years-old and 6-years-old respectively, as compared to 12-17% for mesial and distal surface (Oral Health Division, 1997).

Realizing this, Oral Health Division, Ministry of Health, Malaysia had introduced a community preventive programme incorporated in the Malaysian incremental dental care programme for school children. This is also known as school-based fissure sealant programme.

It is a comprehensive and systematic programme which is designed specifically for school children who are highly susceptible to tooth decay. The progress achieved by the students with regard to their teeth conditions is reviewed systemically in the school by the mobile dental teams.

1.3 Background of the study

Fissure sealant is defined as a material that is placed in the pits and fissures of occlusal surfaces of the teeth mainly premolars and molars. The purpose is to provide physical barrier to the impaction of substrate for cariogenic bacteria in those crevices, and hence to prevent caries from developing (Burt and Eklund, 1999). Introduced in the late 1960s, its use is very simple, by merely applying thin layer of sealants directly on the fissures without using any invasive procedures (Buonocore, 1971). There are two types of fissure sealant i.e. Resin-Based Sealants (RBS) and Glass Ionomer Cement (GIC).

The first generation of RBS, which is no longer available, cured through ultraviolet (uv) light. The second generation cures automatically through chemical reactions, while the third generation cures from visible light. The fourth generation has flouride incorporated into the resins (Mejare *et. al.*, 2003). In the middle of the 1970s, conventional GIC was introduced as an alternative to the RBS. This material is recommended for restoration of anterior and posterior primary teeth. However, the cement is relatively brittle (Frankenberger, 1997).

In more recent years, high-viscosity GICs were developed, characterized by simple handling properties (hand-mixing apparatus and consistency suitable for placement with a finger) and with anticariogenic properties (Mount, 1995). Sealant application is a simple procedure that requires attention to all details of technique, especially moisture control for resin-based fissure sealant (Burt, 1984). However, for sealant application with GIC, the procedure is much simpler; neither prophylaxis nor etching is needed.

The effectiveness of pit and sealants has been demonstrated in many studies. A meta-analysis review of 24 studies regarding fissure sealant by Llodra *et al.* (1993) revealed that the overall effectiveness of fissure sealant in preventing decay was 71.4% (95% CI 69.7%; 72.9%). However, this depends on the longevity of sealant i.e. clinical retention which is related to its eficacy (Ripa, 1993). Studies showed that the GIC had lower retention rates if compared with the resin-based materials (Poulsen *et al.,* 2001; Songpaisan *et al.*, 1995; Mejare *et al.,* 2003). It has been suggested that the GIC, through its flouride release, can prevent the development of caries even after the visible loss of sealant material (Mount, 1995; Seppa *et al.*, 1991).

It was clearly stated that sealants are more effective when placed in children with risk factors for occlusal caries. These are the children who had caries experience in one or more of their first and second permanent molars, children with dft ≥ 3 in the mixed dentition stage age 7, 8 and 9 and also the children with special needs e.g. the handicapped, the medically compromised and the socially disadvantaged (Dennison, 2000).

There is another important factor which needs to be evaluated i.e. the efficiency of fissure sealant. This factor usually related the outcome of the programme to the efforts expanded in terms of money, resources and time. (Burt, 1977). In this study, the efficiency of GIC as fissure sealant will be measured by using cost-effectiveness analysis.

1.4 Problem statement

Methods of preventing dental caries can be divided into two general categories: (a) those which require personal application by a dentist or auxiliary, such as topical flouride and flouride application, and (b) those which do not require personal application, such as water flouridation and flouride rinsing.

The existing evidence shows that the second category is more efficient or more cost-effective in public programmes than the first group. There is a study which compared 4 different types of preventive strategy i.e. community water flouridation, school water flouridation, school mouth rinse and school-based fissure sealant programme. The finding of the study revealed that the most cost effective prevention strategy is community water flouridation which costs US$ 0.87 per child, while the most expensive is the fissure sealant school-based programme which costs about US$ 11.31 per child (Niessen, 1984). However, a local study looking into the cost-effectiveness of preventive programmes had not been done.

1.5 Justification for the study

In Malaysia, there are two types of materials used for sealant i.e. RBS and GIC. The choice of material is based on the administrator of each district. In Pontian, dental nurses use GIC as fissure sealant in school-based fissure sealant programme.

In general, many literatures (Poulsen *et al.*, 2001; Frencken *et al.*, 1998; Arrow *et al.*, 1995) support the effectiveness of GIC as fissure sealant. It is also well documented that the use of GIC will reduce the time as compared to RBS (Smales *et al.*, 1997; Arrow and Riordan, 1995; Forss *et al.*, 1994). As fissure sealant requires professional application, its efficiency in a public programme deserves some consideration, even when it is shown to be effective. The evaluation of efficiency is more commonly known as economic evaluation. There are four methods of economic evaluation i.e. cost-minimization, cost-effectiveness, cost-utility and cost-benefit analysis (Cunningham, 2001). According to Burt (1984), the cost-effectiveness analysis is to determine whether the intervention is worthwhile or not.

Since the school fissure sealant programme was launched in 1998, there has been no evaluation of its cost-effectiveness. The sealant material has a direct impact of the total cost of the programme, which includes total man-hour, use of office space and also it may alter the outcome of the overall preventive dental programme.

Thus, a study of cost-effectiveness of fissure sealant would justify whether this programme is cost effective or otherwise by using the GIC as fissure sealant.

1.6 Rationale

1.6.1 GIC as Fissure Sealant Material

There are two types of fissure sealant i.e. RBS and GIC. RBS have been tested on many occasions and have shown to be an effective method of caries prevention for children in young adults (Weintraub, 2001; Fairhust *et al.*, 1982). In Pontian, however, the school-based fissure sealant programme is mostly delivered by mobile dental teams. This makes RBS unsuitable material of choice as the conditions require proper moist control, hence demanding extra time and equipment.

The advantages of GIC, compared to resin-based sealant, are, its fluoride release, moisture tolerant nature and relatively short application time (Mount, 1995). Its chemical adhesion to the hard substances has been cited as the most important advantage of the GIC (Smales *et. al.*, 1997). It is also stated that GIC, when applied as a pit and fissure sealant, has been shown to be a promising method for caries prevention (Lavonius *et. al.*, 2002)

Other studies have reported the retention rate and caries prevention of GIC as fissure sealant. Even though the retention rate of GIC sealant is poor if compared to RBS, there is no difference in caries incidence for both materials (Poulsen *et al.*, 2001; Arrow and Riordan, 1995; Forss *et al.*, 1994).

1.6.2 Importance of cost-effectiveness evaluation

Cost-effectiveness analyses are used to determine the least expensive way of achieving the same objective. In cost-effectiveness analysis (CEA), effectiveness may be measured in physical terms or in targeted results, and need not be a monetary value (Horowitz, 1981). For example, if the objective for dental health gain is to increase the percentage of caries-free-mouth from 57% to 60%, this analysis will compare the cost of various preventive programmes and determine the least expensive way of reaching this target.

The aim of the cost-effectiveness analysis (CEA) study performed is to compare costs and consequences of caries preventive programme in a population (Werner *et. al.*, 2000). The Consensus Development Conference on Sealants concluded that recent studies have shown that a properly placed sealant will last for a period approximating that of a typical amalgam restoration and the cost is usually less (National Institutes of Health, 1984).

One study by Quinonez *et. al* (2005) provides evidence that sealing children's permanent molars can improve outcomes and save money by delaying or avoiding invasive treatment and the destructive cycle of caries. In this study, the cost for treatment unsealed tooth was US 68.10, for risk-based sealed tooth was US 53.80 and for seal-all tooth was US 54.60.

Another researcher in Australia found in his study that the cost-effectiveness ratio was AUS $ 11.80 per averted caries. He also concluded that sealant preventive programme became more cost effective with each successive year.

However, the cost-effectiveness ratio for the unsealed group in this study was not mentioned (Crowley *et al.*, 1996). Furthermore, it is difficult to conduct a cost-benefit analysis for dental preventive programme because it requires monetary value for both cost and benefit of preventing caries (Burt, 1984). Thus, this study will also compare and determine the cost-effectiveness of fissure sealant school-based programme in prevention of caries on occlusal surface of lower left FPM.

1.6.3 Importance of the study

The importance of this preventive programme evaluation is mainly for effective allocation of resources, which consist of personnel, time, facilities, equipment and knowledge. It is meant to optimize improvements to be made in oral health within limited resources. A programme which looks attractive from a patient's view point may look unattractive from the government's budget (Cunningham, 2001).

Dental caries is perceived both by professionals and public to have decreased, and this has contributed to the fact that administrators and politicians becoming less enthusiastic about caries prevention programme (Schwarz, 1998). However, the prevalence of dental caries still appear to be high in some age group. Oral Health Division (2003) reported that the percentage of caries-free mouth among 16-year-old is 26.5% with DMFT = 3.3. It is still below our National Health Goals for 2010 whose aim is to achieve 40% of children aged 16 to have caries-free mouth.

Furthermore, Oral Health Division (2000) reported that there was 2.8% of adults aged between 35 to 44 years old who were edentulous. Thus, this evaluation is important to study the possibility of utilizing GIC (FUJI IX) as material of choice for school-based fissure sealant programme considering its effectiveness.

1.7 Introduction into the study area

Pontian is one of the eight administrative districts in the state of Johor. It is situated about 60 kilometers from Johor Bahru (Appendix A). There are five government dental clinics in Pontian area.

One is the Main dental clinic which is located in Pontian Town itself. The other four clinics are in Air Baloi (14 kilometers from Pontian), Benut (28 kilometers from Pontian), Serkat (28 kilometers from Pontian) and Pekan Nanas (20.5 kilometers from Pontian). All of the clinics are equipped with their own mobile dental teams, comprising of one dental nurse, one health attendant and a driver. As for the main dental clinic, the mobile team consists of four dental nurses, four health attendants and a driver.

Every year, the teams visit 82 primary schools and 13 secondary schools under school dental service programme which comprise of 19,995 primary school children and 14,781 secondary school children (Dental Department, 2001). As mentioned previously, the school dental services are dental check-up, curative and preventive programme which including fissure sealant programme.

1.8 Conceptual framework

Dental school-based preventive programmes aim to render school children orally fit before leaving school. In this preventive programme many activities are arranged and implemented. In 1998 a Fissure sealant programme was introduced as one of the school-based preventive programme.

The cost and effectiveness of fissure sealant programme are influenced by several factors. These include types and variability of operators, working environment, patients factors, materials used and its procedures. The above factors are unquantifiable and will be controlled in this study.

When a cost-effectiveness analysis is to be done there are additional factors that govern the success of the study. Some of these factors are quantifiable and some are not. The quantifiable factors are measurable cost (capital cost, salaries, building rent, consumables and complication), sealant durability (percentage of sealant retention). The intangible cost includes the pain, suffering, satisfaction and the combined effect with fluoride.

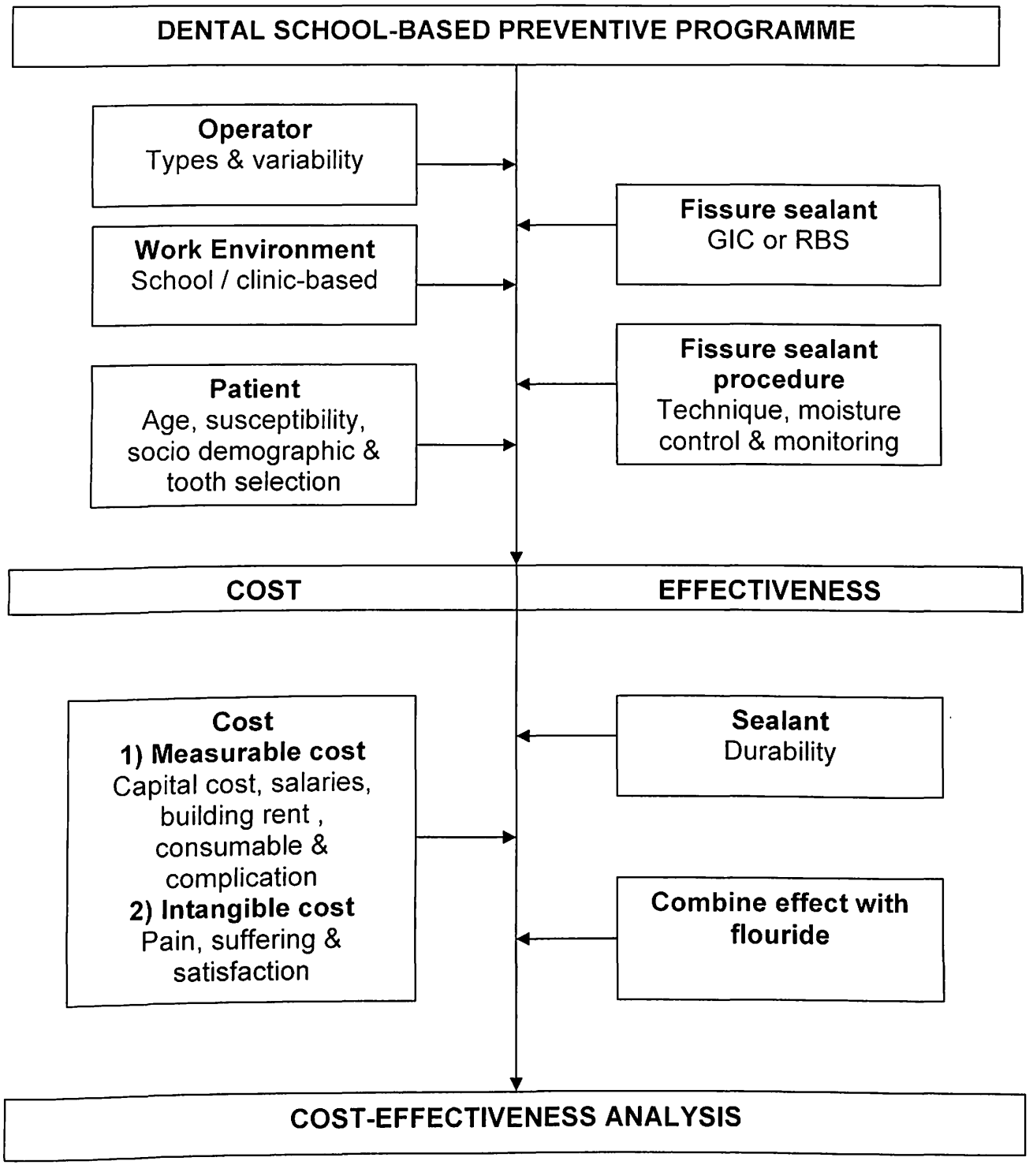

Figure 1: Conceptual frame work of the study

CHAPTER 2

OBJECTIVES, RESEARCH HYPOTHESES AND QUESTIONS

2.1 General Objective

To study cost-effectiveness of GIC as fissure sealant in school-based fissure sealant programme for high caries risk group.

2.2 Specific Objectives

1) To determine the retention of sealant after 5 years follow up
2) To determine the caries status of occlusal surface of lower left first permanent molar in sealed group and unsealed group after 5 years follow up
3) To determine the cost-effectiveness of fissure sealant for high caries group
4) To compare the caries status of occlusal lower left first permanent molar between sealed and unsealed groups

2.3 RESEARCH HYPOTHESES

1) The GIC as fissure sealant is cost-effective in school-based preventive programme for high caries risk group.
2) There is relationship between the application of fissure sealant and the caries status of occlusal lower left FPM.

2.4 RESEARCH QUESTIONS

1) What is the retention rate of sealant after 5 years follow up?

2) What is the caries status of occlusal surface of lower left FPM for sealed and unsealed group after 5 years follow up?

3) How much is the extra cost for the sealed group, the cost for complication and the cost per averted caries for both groups?

CHAPTER 3

LITERATURE REVIEW

3.1 Historical development of fissure sealant as preventive measure

In 1923, a researcher called Hyatt suggested a technique called "prophylactic odontomy" which referred to minimal operative preparation of sound fissures and restored it with amalgam. The idea, however, was not fully accepted as it contradicted with Black's cavity restoration with "extension for prevention". But later, it led to a widespread use of the "preventive restoration" (Burt and Eklund, 1999).

In many years, researchers tried to find various chemicals to be painted onto the tooth surface to prevent caries, but none proved successful. Only in 1955, a researcher, Buonocore, developed acid-etch technique which enabled the adherence of the material successfully to enamel in the oral environment (Burt and Eklund, 1999). In the late 1960s, the "bis-GMA" formulation was developed and proved successful in a trial (Buonocore, 1971). This formulation had become the basis of the sealant products. The first sealant, Nuva Seal, was accepted as fissure sealant by American Dental Association in 1972 (American Dental Association, 1976).

The first generation of resin-based sealant, original bis-GMA was polymerized under light cure. The second generation is chemically polymerized while the third generation is cured by visible light.

The second and third-generation sealants are coloured to make them more visible at clinical examination (Burt and Eklund, 1999). Currently, among the most widely used resin-based sealant are Nuva-Seal, Delton, Kerr, Concise and Alpha-Seal (Llodra *et al.,* 1993; Weintraub, 2001).

A second group of materials used as fissure sealants are the glass polyalkenoate cements that were introduced in 1970s (Mclean and Wilson, 1974). The first generation was ASPA (Williams *et. al.*, 1976), followed by the high viscosity GICs, e.g. FUJI IX and FUJI III (GC), which were developed in 1990s. There are other GIC cements developed in 1980s such as Ketac-Fill (ESPE) and FUJI II LC (GC) which were recommended for restoration purposes (Frankenberger, 1997).

3.2 Effectiveness of fissure sealant

Effectiveness is defined as the effect of the activity and the end results, outcome or benefits for the population achieved in relation to the stated objective (Burt, 1977). Sealant is the most effective and long-lasting preventive agents that the health provider can give to their patients. With the protection of the smooth surfaces by some flouride and the protection of pits and fissures by the routine use of sealants, we can prevent caries from

developing. In a study by Fairhust *et al.* (1984), a comparison was made between sealed tooth using resin-based sealants and the unsealed tooth and the finding revealed that after one year, the effectiveness of the sealant ranged from 76% to 87%.

It has also been shown that, out of 20,110 fissure sealant teeth done in 1999 among school children in Kelantan, only 6 % of them developed caries when reviewed in 2000 (Kelantan Annual Report, 2000). A systematic review for caries preventive effect of fissure sealing of occlusal tooth surface done by a Swedish researcher revealed the relative risk reduction of 33 % for resin-based sealant teeth, relative to untreated control, whereas, for GIC, the relative risk reduction was 22 % (Mejare *et. al.*, 2003).

A six-year clinical evaluation of fissure sealants study also showed that all occlusal caries developed only in the control group (without fissure sealant). There was only one case of sealant lost in the fissure sealant group and it was without occlusal caries. The caries in this case group were due to mesial caries (Shapira, 1986).

A study done in Syria which used GIC as fissure sealant on 101 teeth revealed that the odds ratio of unsealed tooth to become caries was 2.6 (95%CI 1.2;5.7) if compared to sealed tooth (Taifour *et. al.*, 2003). In Finland, 13% of the permanent molars sealed at age 6 developed occlusal caries and 15 % developed approximal caries during the 13 year period. Among the teeth sealed once/twice (n=120), the caries rate was 8 % and this might have been

due to technical problems when initially sealing the molars (Lavonius *et. al.*, 2002).

3.3 Factors that contribute to the effectiveness of fissure sealant

The effectiveness of fissure sealant programme depends on many factors such as the patient age, patient and tooth selection, influence of dft index, operator variability, maintenance phase and isolation of tooth (Folke *et al.*, 2004; Poulsen *et al.*, 2001; Holst *et al.*, 1998; Bravo *et al.*, 1996; Straffon *et al.*, 1985; Rock and Bradnock, 1981).

3.3.1 Patient's age

The goal of a sealant programme is to seal occlusal surface of permanent teeth as soon as their eruption and before initiation of caries (Bohannan *et al.*, 1984). Fissure sealant is best applied within two years of molar eruption and it is recommended in primary teeth (NIH, 1984). Incidence of occlusal caries in permanent molar is the highest at the age of 7 to 9 years while the approximal surface at the age of 12 to 13 (Vehkalahti and Solavara, 1991).

Sealing the fissure of the molar tooth at the age of 7 to 9 will reduce the incidence of occlusal caries in later year. Vehkalati and Solvara (1991) had shown that 60% of the occlusal surface of the permanent teeth that was sealed at the age of seven are still sound at age fifteen. On the contrary, 53% of sound unsealed teeth developed occlusal caries at age fifteen.

However, Folke *et al.* (2004) had shown that age at which fissure sealant is placed was not significant in preventing occlusal caries.

3.3.2 Patient and tooth selection

Fissure sealant application is a sensitive technique. Selection of tooth and susceptible children are of paramount importance in determining the outcome of the fissure sealant (Simonsen, 1987; Eklund, 1986; Ripa, 1985).

Realizing the importance of these factors, the Ministry of Health, Malaysia has outlined the criteria for children and teeth selection (Oral Health Division, 2003).

The criteria are as follows:

a) Selection of patient
    1) Children who have had caries experience in one or more of their first or second permanent molars.
    2) Children who have had caries experience in their first permanent molars shall be considered for fissure sealing of their second permanent molars
    3) Children of Standard 1, 2 and 3 with dft ≥ 3 in the mixed dentition stage
    4) Children with special needs e.g. the handicapped, the medically compromised and the socially disadvantaged.

b) Selection of tooth

1) Caries-free first and second permanent molars exhibiting deep and/or complex fissure patterns.

2) First and second permanent molars exhibiting incipient enamel lesions i.e. chalky white lesions. However, first and second permanent molars exhibiting caries with entry into dentine can be considered for preventive resin restorations.

3) The tooth must have all visible fissures, deep/complex fissures, no existing restoration and no signs of approximal caries.

The above criteria are supported by Denisson (2000) and guidelines by National Institute of Health (NIH), USA (1984). They recommended fissure sealant to be placed in the high caries risk children i.e. children with extensive caries (dft≥3) in their primary teeth. However, it was found out that the higher the dft, the higher was the risk of sealant failure (Bravo *et al.*, 1996).

3.3.3 Operator variability

It is by now accepted that adequately trained auxiliaries and hygienists are able to attain retention rate at par with that by qualified dentists. Their involvement in fissure sealing programme has been advocated as a mean of reducing cost because of the differences in salary between the two groups (Houpt, 1983).

But, more important than that, is the attitude and motivation of the operator and the ability to obtain adequate moisture control during the sealant placement. A study done in Johor showed that resin-based sealants applied by dental nurses have higher retention rate than that by government dental officers (examination on the sealed teeth after 12 months and 30 months of sealant application) (Muzini *et al.*, 2003). Meanwhile, a finding by Folke *et al.* (2003) revealed that dentists and registered dental assistants showed, respectively 3 times and 2 times the risk of sealant failure with highly significant p value of less than 0.001 in survival analysis, compared to the registered dental hygienists. However, in Zimbabwe, the highest survival of sealant was done by the dentists which is at 94.2% and the lower percentage was achieved by the junior dental therapist (64.5%).

This indicates that the success rate of sealant application somehow relies on sufficient experience gained by the operators, regardless of their ranks (Frencken *et al.*, 1998). Horowitz (1980) also agreed that in countries which permit the expanded functions of auxiliary personnel, the use of pit and sealant should be in various pilot study programmes to determine its feasibility and efficiency.

3.3.4 Maintenance phase

Monitoring and maintenance phase also play important role in determining the success of sealant (Fairhust *et al.*, 1984). The maintenance phase done periodically will increase the success rate of fissure sealant (Chestnut *et al.*, 1996; Romcke *et al.*, 1990).

It also has been recommended by American Dental Association (ADA) (1976) that the occlusal surface of sealed tooth be checked at certain periods and reapplication be considered in case of sealant loss. In dental public programmes , it is recommended that retention be checked twice a year or at least once a year (Horowitz, 1980).

3.3.5 The isolation of the tooth

The main objective for the isolation of the tooth is to ensure that its occlusal surface is dry during sealant application. Moisture control is critical to the success of sealant placement because according to Simonsen (1987), saliva needs only to contact with etch enamel for less than a minute for contamination to take place. However, this will depend on children behaviour, i.e., whether they will cooperate, which will make the isolation easier. There are two methods usually used for isolation of the tooth, i.e. cotton roll and rubber dam. A study conducted by Straffon (1985) showed that after 3 years of sealant application, there is no significant difference between the retention of the sealed teeth isolated using cotton rolls and that of the sealed teeth isolated using rubber dam. Thus, isolation is not so critical if GIC is used as fissure sealant material (Mount, 1995).

3.4 Advantages of GIC as fissure sealant

There are advantages of using GIC as fissure sealant material. Review of literature revealed the following advantages.

3.4.1 Ease of application

Sealant application using resin-based material is simple but meticulous as it requires attention to all details of technique, especially moisture control. Even slight moisture control in application and curing will result in failure (Arrow and Riordan, 1995). In contrast, the application of GIC is much easier. This is because of their ease of manipulation and its resistance to moisture (Mount, 1998; Weerheijm, 1996). For GIC application for sealant, it needs neither prophylaxis nor etching phase. After food and plaque have been removed with an explorer, the tooth surface is washed using wet cotton wools pellets. The conditioner is applied later into the pits and fissures according to the manufacturer instructions. After rewashing the surface with wet cotton wool pellets, the pits and fissure will be dried using dry cotton wool pallets and sealant application is done by using index finger (press-finger technique). Then, the visible excess of mixture will be removed by a carver or a large excavator and a layer of petroleum jelly or varnish will be applied onto the sealant. It is also advisable for the patient not to eat for at least one hour (Oral Health Division, 2003).

3.4.2 Effectiveness of GIC as fissure sealant

Although the retention rate for this cement was significantly poorer than the RBS (Table 1), a study done by Arrow and Riordan (1995) in Western Australia using the split-mouth design showed the effectiveness of GIC (Ketac-Fil) was 80.6 % if compared with the resin-based sealant and its relative risk was 0.19 which indicates its protective effect of preventing caries.