

Economic Evaluation of a School-based Combined Program with a Targeted Pit and Fissure Sealant and Fluoride Mouth Rinse in Japan

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Abstract:

Background: In Niigata prefecture, Japan, a system has been developed based on a school-based fluoride mouth rinse program as follows; students with caries susceptible teeth are screened in a school dental examination, and encouraged to receive sealant placement in local dental clinics. However, the cost-effectiveness of sealant application in the public health has been questioned. The aim of this study was to estimate of the cost-effectiveness and cost-benefit ratio for a school-based combined program with fluoride mouth rinse and targeted fissure sealant in children residing in non-fluoridated areas in Japan.

Participants: The analysis was based on comparing an intervention group with two cohorts in the 8-year-old (n=66) and 11-year-old (n=58) participating in the combined program for four and seven years, respectively, with a control group of the same grades (n=43 and n=54 respectively).

Methods: The study measured mean differences in number of decayed and filled teeth (DFT) between the study groups and a combined program cost per child during study periods. The cost-effectiveness ratio was expressed as an individual annual program cost per DFT averted. In the cost-benefit ratio the mean difference in treatment cost between groups (program benefit) was compared to program cost.

Results: The mean reduced DFT differences between groups were 1.44 in 8-year-old and 3.17 in 11-year-old children. The cost-effectiveness ratio was ¥ 493 in the 8-year-old and ¥ 202 in the 11-year-old, respectively. The cost-benefit ratio was 1.84 in 8-year-old children and 2.42 in 11-year-old.

Conclusion: This combined program indicated acceptable cost-effectiveness and cost –benefit ratio.

Key Words: Cost-effectiveness, Cost-benefit ratio, Fluoride mouth rinse, Targeted fissure sealant.

INTRODUCTION

In Niigata prefecture, Japan, a system that followed a school-based fluoride mouth rinse program (FMR) has been built as follows; students with caries susceptible teeth without cavity formation are screened in school dental health examination twice a year periodically, and encouraged to consult a local dental clinic and receive sealant placement if necessary. Despite the large number of clinical trials [1,2] demonstrating the effectiveness of fissure sealants in preventing occlusal caries, however, it is unknown whether public programmes are cost-effective. Mitchell *et al.* [3] indicated that factors including durability and tooth selection, which influence the economic viability of sealants, must be considered and controlled if sealants are to be used cost-effectively. The durability of sealant applied on the tooth

surfaces has been advancing with quality improvement of the materials. Targeted sealant placement intended only for fissures at high-risk of dental caries development is presently suggested. Targeted sealant (TS) placement, a “high-risk strategy”, is based on the notion that resources should not be used for teeth at low risk that may not need them. However, the lack of supportive data on the effectiveness of risk-based strategies has to be acknowledged.

An assessment of the effectiveness of a risk-based strategy (TS) is necessary for the practice of a preventive program. Therefore, we evaluated the economic effect of the TS combined with FMR as the fundamental program. In Japan, few areas have water fluoridation, and school-based FMR carried out in nursery, primary and junior high school are more common. The combined program was based on the concept [4, 5] that in addition to strengthening the whole tooth surface with FMR [6], the sites of pits and fissures are protected by sealants. In introducing the combined program, Yoshihara and Sakuma [7] estimated the cost-effectiveness of sealant application using four strategies related to tooth selection and realized that a sealant program should be

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Table 1. School-based Caries Preventive Program in the Municipality where Intervention Group had Resided

	Age (y)	School Grade ^a	Regular Dental Examination	Fluoride Mouth Rinse	Targeted Fissure Sealant
Nursery school	4		once a year (in April)	daily method (0.05% NaF solution)	(-)
	5				(-)
Primary school	6	1st	↑ twice a year (in April and October) ↓	↑ weekly method (0.2% NaF solution) ↓	↑ application for sticky pits and fissures ↓
	7	2nd			
	8	3rd ^b			
	9	4th			
	10	5th			
	11	6th ^c			

a: Academic year : April – March

b: The grade of evaluation in younger group.

c: The grade of evaluation in elder group.

The data of the dental examination on April in 1999 was used in this analysis.

planned according to the caries prevalence level in population groups. The report also showed that if there are relatively few students with carious molars, the sealant should be applied only to high-risk teeth.

The caries prevalence rate declined markedly from 72.8% to 27.6% [8] in a primary school located in the area practicing school-based FMR starting from preschool age. Under these circumstances, 91.2% [9] of caries in all students was found on the occlusal surfaces. Therefore, in the same community FMR program that started at the age of four was combined with a TS program that started at the age of six. In this study we evaluated this effectiveness of the combined program from the economical point of view.

The aim of this study was to estimate the cost-effectiveness ratio and cost-benefit ratio of a school-based program combining FMR and TS and versus a control group of primary school children.

PARTICIPANTS AND METHODS

The study population were eight and eleven-year-old (3rd and 6th grade) children in 1999 who attended two primary schools in different municipalities. Only one school in one municipality conducted a school-based TS and FMR program (intervention group), and the other did not (control group). The parents of children in the intervention group gave informed consent to participation in the school-based program at the entrance of both nursery and primary schools. Both areas were non-fluoridated, tourist resort areas with a similar social and economic environment.

The subjects of the intervention group were allocated either to FMR continuously for four years in the 8-year-olds or for seven years in 11-year-olds. Eight children in the 8-year-old and nine children in 11-year-old group had limited participation in the FMR program, because of transferring from another school, and they were excluded. Sixty-six children in the 8-year-old and 58 children in the 11-year-old in the intervention group and 43 and 54 children, in the corresponding

control groups were analyzed. The children in both groups were questioned about their dental health behavior, using a questionnaire filled out by their parents. The 4 items in the questionnaire were: frequency per day of sweet beverages, snacks and tooth-brushing and habit of using fluoride toothpaste. The answers were compared between intervention and control groups in each age group. The statistical significance was analyzed using Fisher's exact test.

Table 1 shows school-based caries preventive program in the intervention group. The FMR component comprised a supervised, daily, 60-second mouth rinse with 0.05% neutral sodium fluoride (NaF) solution in nursery school for two years and 0.2% NaF solution weekly in primary school for two and five years, respectively. The nursery school director and school nurse in primary school were responsible for mixing and distributing the rinsing solution and the class teacher directly supervised the rinsing activity in each classroom. In the TS program, sealant application was performed by a school dentist based at the primary school (aided by an assistant). Sealant was placed on the surfaces of permanent molars which were classified as sticky when there was moderate resistance to the removal of explorers from occlusal surfaces and when there were no visible signs of caries at biannual examinations. It has been mentioned that the use of a sharp explorer is contraindicated; however, we considered that even if a sharp explorer made defects in sticky surfaces, sealant application would be able to repair the defects and protect against caries progression. Also, at each examination, the sealed teeth were examined for retention and thereafter sealant was replaced if necessary. The sealant procedure, using a light cured resin sealant (Teethmate F: Kuraray Co., Japan), followed the instructions of the manufacturer. Decayed teeth had been treated at the school dental clinic or in private clinics as per their parent's request.

In the control group, dental treatment, including sealant placement, had been performed as usual at two private clinics in that area.

In the intervention group, dental examinations were performed annually in nursery, and biannually in primary

Table 2. Cost Per Child of the Fluoride Mouth Rinse Program According to the Age of the Intervention Group

	School	Cost per Child of FMR Program During Participating Periods (yen)	
		8-year-old (n=66) ^a	11-year-old (n=58) ^b
Shared containers	nursery	81	93
	primary	43	121
Paper cups	nursery	1,800	1,800
	primary	360	900
NaF reagent	nursery	24	24
	primary	28	70
Total cost (yen) per child		2,336	3,008

a: participating in the program for 2years in each of nursery and primary school.

b: participating in the program for 2years in nursery and 5 years in primary school.

Table 3. Standard Expenditure of Caries Treatment According to Restorative Methods Based on Caries Progression

Tooth Group	Caries Progression	Need for Root Canal Therapy (RCT)	Restorative Methods	Expenditure on Caries Treatment
				Yen ^a
Anterior tooth	limited to buccal or lingual surface	not necessary	Composite resin (CR) restoration	2,880
	extended to proximal surface	not necessary	CR restoration	3,530
	progressing over pulp cavity	necessary	RCT + Facing crown with CR	29,380
Premolar	limited to occlusal or buccal or lingual surface	not necessary	CR restoration	2,880
	extended to proximal surface	not necessary	Metal inlay	6,840
	progressing over pulp cavity	necessary	RCT + Facing crown with CR	18,340
Molar	limited to occlusal or buccal or lingual surface	not necessary	CR restoration	2,880
	extended to proximal surface	not necessary	Metal inlay	7,210
	progressing over pulp cavity	necessary	RCT + Facing crown with CR	21,470

^abased on the list of treatment fees in Japanese dental insurance system in 2002

The expenditure does not include the fee charged for a patient's first or repeated visits.

schools from 1992 in the older and 1995 in the younger group till 1999. In the control group the examination was done once at the time of evaluation in 1999. Subjects were seated on a chair facing the examiners. Three calibrated examiners conducted dental examinations using an explorer (explorer point system #9 YDM Co. Japan) and a mouth mirror under artificial light. They diagnosed according to the criteria [10] of the World Health Organization (WHO). The oral health status of each subject was recorded as decayed and filled surfaces (DFS). The kappa coefficient for inter- and intra-examiner reproducibility of tooth scores ranged between 0.88 and 0.93, 0.95 and 0.97, respectively, indicating excellent agreement. No radiographs were taken. The primary outcome measure used in the economic evaluation was intervention effectiveness based on the difference in total DFT between groups.

Cost analysis was restricted to resource expenditures associated with operating the combined program. In determining the resources used for the FMR program, estimates were

based on the assumption that the shared containers were purchased once by each age group in the nursery and primary school respectively. The cost per child of the FMR program is summarized in Table 2. Also, the cost of a sealant placement (including replacement) had been determined as 1190 yen according to the list of treatment fees assessed in the Japanese dental insurance system in 2002.

The treatment costs associated with decayed and filled components of the DFS score at the last examination in 1999 were also calculated based on the above list. The decayed components were assumed to be restored. Table 3 shows the expenditure involved in using standard restorative methods, which was calculated by referring to the list.

Economic evaluation. The economic evaluations used were cost-effectiveness and cost-benefit analyses. The cost-effectiveness ratio – expressed as an individual annual program cost per DFT averted – was defined as:

$$C / (E2 - E1) = C / \Delta E$$

Table 4. Comparison of Mean Number of Teeth with Decayed, Filled, Sticky Fissure and Sealant Placement between Intervention and Control Groups in 1999

Age(y)		Intervention Group		Control Group		Difference (%) Between Groups	Significance of Difference
8	No. of children	66		43			
	No. of children with DF teeth (%)	2	(3.0)	23	(53.5)		*** ^a
	Mean DFT (±SD)	0.05	(0.27)	1.49	(1.74)	96.9	***
	Mean number of teeth with sticky fissure (±SD)	0.09	(0.34)	0.28	(0.55)	67.4	*
	Mean number of teeth with sealant placement (±SD)	0.26	(0.71)	0.42	(1.03)	38.4	
11	No. of children	58		54			
	No. of children with DF teeth (%)	11	(19.0)	46	(85.2)		*** ^a
	Mean DFT (±SD)	0.31	(0.78)	3.48	(2.81)	91.1	***
	Mean number of teeth with sticky fissure (±SD)	0.09	(0.34)	0.26	(0.83)	66.8	
	Mean number of teeth with sealant placement (±SD)	1	(1.01)	0.24	(0.73)	-314.9	***

Significance :***; p<0.001,**; p<0.01,*; p<0.05
a: χ^2 test, The others were analyzed using Welch's test.

where

C: total cost associated with the combined program in the intervention group/child /year

E1: mean DFT in the intervention group

E2: mean DFT in the control group.

The cost-benefit ratio – the ratio of the difference in dental treatment costs between groups and program costs of the intervention group – was defined as:

$$(TC2 - TC1) / PC = \Delta TC / PC$$

where

TC1: total cost associated with dental treatment in the intervention group/child

TC2: total cost associated with dental treatment in the control group/child

PC: total cost associated with the combined program in the intervention group/child.

All data were analyzed using STATA (version 9.0; Stata Corp.; Collage Station, Tx, USA).

RESULTS

There were no significant differences in all items between the two groups in 11-year-olds based on the questionnaire about their dental health behavior. In the 8-year-olds, the control group had significantly better behavior in frequency of tooth brushing and drinking sweet beverages than the intervention group. The rate of children brushing their teeth twice a day was 41.3% in intervention group and 76.2% in control group (p=0.001) and the percentage of children drinking few sweet beverages was 26.3% and 52.5% (p=0.025) respectively.

Table 4 summarizes the caries conditions of both groups by school grade. The mean DFT and caries prevalence rate was significantly higher in the control group than the intervention group for both school grades. The mean number of teeth with sticky fissures was also significantly higher in the control group for 8-year-old children. The mean number of teeth with sealant placement was significantly higher in the intervention group for 11-year-old children. Table 5 presents a comparison of the number of teeth receiving/requiring treatment in both groups. The number of decayed and filled teeth was also classified based on whether the proximal surface receiving/requiring treatment. There was no tooth that received/required root-canal therapy in both groups. The number of filled teeth was remarkably higher in the control group.

Table 6 summarizes the cost-effectiveness ratio by school grade. The annual cost per child was estimated to be 493 yen per DFT avoided in the 8-year-old and 202 yen in the 11-year-old. The cost-benefit ratio shown in Table 7 was estimated to be 1.84 in the 8-year-old and 2.42 in the 11-year-old. Both ratios were higher in the elder group.

DISCUSSION

The intervention group consisted of only one public primary school in the municipality, which has implemented a school dental health program as a municipal policy. The number of children was smaller than 80 in each school grade. Although the number of children is rather small for an epidemiological study, we could not find another school where such a dental program was practiced.

The subjects analyzed were eight-year-old and eleven-year-old children. These ages were selected for the following reasons. In the majority of 8-year-old children, the four first molars would have erupted. Those teeth would be kept under

Table 5. Comparison of the Number of Teeth According to Tooth Surface Condition by Tooth Type and Age between Intervention and Control Groups

Age(y)	Condition of Tooth Surface		Intervention Group			Control Group		
			Anterior Teeth	Posterior Teeth		Anterior Teeth	Posterior Teeth	
				Premolar	Molar		Premolar	Molar
8	sealant placement (including replacement)				21(5)			18
	sticky fissure				7			12
	decayed	limited to occlusal surface						2
		extended to proximal surface						
	filled	limited to occlusal surface			3		1	57
		extended to proximal surface			0	2		2
11	sealant placement (including replacement)				67(9)		3	11
	sticky fissure				5	1	2	6
	decayed	limited to occlusal surface						5
		extended to proximal surface				3		1
	filled	limited to occlusal surface			12	1	12	130
		extended to proximal surface		1	3	15	4	13

Sticky fissure was assumed to receive sealant placement in the intervention group. Therefore the cost was included in program cost of targeted sealant (expressed in boldfaced figure).

Table 6. Cost- Effectiveness Analysis in the Intervention Group Compared to the Control Group

		Children 8 Years Old ^a		Children 11 Years Old ^b	
		Intervention	Control	Intervention	Control
Mean DFT		0.05	1.49	0.31	3.48
DFT avoided / child		1.44		3.17	
Program cost (yen) / child	FMR	2,336	(-)	3,008	(-)
	TS	505	(-)	1,477	(-)
	Total	2,841	(-)	4,485	(-)
Cost effectiveness / child / year (yen)		493		202	

^a: period of participation in the FMR program : 4 years , in TS program : 2 years

^b: period of participation in the FMR program : 7 years , in TS program : 5 years

observation to decide whether or not to apply sealants. In 11-year-old the first molars would probably have matured and acquired caries resistance. The dental health status in the first molars was known in the 11-year-olds. Therefore most of those teeth would not need to have new sealant placements.

It was suggested that three categories of program costs must be taken into account [11]: first, dental health resources, which consist of the costs of organizing and operating the program; second, patient- and family-related costs, which include the value of all resources the patient and the

Table 7. Cost-Benefit Ratio in the Intervention Group Compared to the Control Group

	Children 8 years old		Children 11 years old	
	Intervention	Control	Intervention	Control
Program cost (yen) / child	2,841	(-)	4,485	(-)
Treatment cost (yen) / child	131	5,348	1,087	11,953
Difference of treatment cost (yen) / child	5,217		10,866	
Cost - Benefit ratio	1 : 1.84		1 : 2.42	

patient's family contribute to the process; the third category reflects costs borne by sectors other than the health care sector and target group. This study focused on measuring direct costs, the cost of containers and materials used in the FMR program and sealant placement fee in the TS program. The above-mentioned secondary costs were not included in the analysis because both groups lived in similar economic and health environments. The third cost type is irrelevant to this study.

Morgan *et al.* [12] estimated the cost of operating the FMR program, including the salaries of community health workers, who supervise the FMR, and the cost of the teacher's time; however, we did not assess either of these costs. Every primary school is staffed by one school nurse in Japan who arranges various kinds of preventive programs and supervises such activities in cooperation with school teachers under the direction of the school dentist. A school dentist, who is usually a privately practicing dentist, is commissioned by the Board of Education in local government. The direction of the health program is one of his tasks. Therefore, the cost related to manpower in FMR program did not need to be assessed.

The treatment fee given for a sealant application, 1190 yen, was used to calculate the TS program cost. The treatment fee in the social insurance system was based on the extent of carious lesions (e.g. whether the lesion included a proximal surface), the dental materials used in treatment, technical elements of treatment, presumptive treatment time, etc. So, the treatment fee embraces work force. Accordingly, the fee of sealant placement is the same, whether a dentist or dental hygienist performed the procedure. The fee of sealant application was also the same regardless of the kind of sealant material.

The cost of sealant replacement was included in the TS program cost. Sealant durability would therefore influence the economic viability of sealants. The rate of resealing was 31% (5/16) in 8-year-old and 16% (9/58) in 11-year-old. As our previous study [13] indicated that the majority of sealants failed within three years, sealants that survived over 3 years are not likely to need replacement. The influence of resealing on the program cost thereafter would not increase so much, even if the study period was prolonged.

In the assessment of dental treatment costs, our study assumed that the decayed component of the DFT would be restored. Also, our study assumed that the filled component would be restored using a standard method (Table 3); therefore, it is possible that the treatment costs could be lower than actual costs. Regarding calibration in caries diagnosis, all dentists in Niigata prefecture have diagnosed dental caries

according to the handbook of school dental health issued jointly by the Niigata prefectural government and dental association. The criteria of WHO used in this study was also quoted in the handbook. However, the selection of treatment methods has been left at the discretion of the dentists. In the private clinics, dentists who are earnest about sealant application recommend this procedure to their patients. They would place sealant on all occlusal surfaces soon after tooth eruption. In the control group, the mean number of sealed teeth was lower in 11-year-olds than 8-year-olds. It was considered that some sealants could not be identified because of severe wear. Therefore, it is probable that the treatment cost in the control group was estimated to be lower than the actual cost. Also, the same sealant material was used in those private clinics.

Morgan *et al.* [12] reported that the assumption of the dental examination rate between groups was closely related to the results. All students received annual examinations in spring under the school health law in Japan and some schools have an extra examination in the autumn. Both groups in this study also received examinations performed by each school dentist and supportive dentists twice a year and they were recommended dental treatment if necessary. Therefore, the examination rate did not influence our results.

The longer the program continues the more economic and beneficial the program is expected to become [14]. We evaluated 8-year-old and 11-year-old children. The FMR program was performed for 4 years in the younger and 7 years in the older group. The TS program was performed for 2 years and 5 years after entering the primary school. The cost-effective ratio was higher in 11-year-old than 8-year-old as expected. Equally, the cost-benefit ratio was higher in the older than the younger group. A residual beneficial effect [15] after FMR programs finished was reported. Further, the longer-term potential savings due to reductions in secondary caries and/or maintaining restored tooth surfaces should be considered. The economical effects will be expected to increase with continuation of the program.

Ahovuo-Saloranta A. *et al.* [1] investigated the question of whether the benefit of sealant treatment varies according to the baseline risk of the children. The caries risk of permanent teeth at baseline, that is, at 4 years-old when starting FMR in the intervention group can be considered equal between groups in our study, because all children were supposed to have no carious permanent teeth at that age. In fact, in the case of the intervention group the number of carious teeth in all 6-year-old students at the age of entrance into primary school was 1 in 1997 in the younger group and 0 in 1994 in the older group. Moreover, in 11-year-olds their dental health behavior was not significantly different between groups. In the 8-year-old control group, they had better oral

cleaning frequency and nutrition behavior than the intervention group.

Griffin *et al.* [16] analyzed the cost-effectiveness of 3 sealant delivery strategies: “seal-all”, seal children assessed to be at risk by screening (“risk-based”) and “seal none”. They reported that “risk-based” strategy dominated “seal-all” and “seal none” under their baseline assumptions. Quiñonez *et al.* [17] reported that under their theoretical model “risk-based” strategy improved clinical outcomes and saved money over “seal none”. The “seal all” further improved outcomes but at an additional cost compared to “risk-based”. We adopted a “risk-based” strategy, a TS method. The mean of the number of sealed teeth in the 11-year-old children was 1.00 in the intervention group. If sealants had been applied to all first molars, the program cost of sealant placement would have been more than three times higher. Moreover, in intervention group the total number of the first molars decayed, filled and with sticky surfaces in 11-year-old was 20 teeth (0.34 teeth per child) (Table 5), indicating that more than two of the first molars per child would remain sound without sealant. Risk-based sealant application is therefore a reasonable strategy.

Moreover, a study [18] showed that the possibility of limiting the use of sealants to the most “susceptible” teeth or individuals is appealing. Another study [7], in which the cost-effectiveness of four strategies for sealant application was calculated, indicated that the strategy of sealing only sticky surfaces was the most cost-effective in the group with low caries prevalence. It was also reported that sealing sticky fissure or non-cavitated caries in permanent teeth is effective to reduce caries progression [19-21].

Moreover, a report [22] that analyzed economic effects before and after (five years) the combined program similar to our study indicated that the cost-benefit ratio was 2.3 in both 8-year-old and 11-year-old students. The ratio for 11-year-old students was almost identical to our study. However, the sealant placement fee was different from our study. While we calculated the fee based on Japanese dental insurance system, in that study 2,500 yen was paid as trust money for each sealant. Accordingly the TS program cost was higher in that study than our study. On the other hand FMR program cost, which was not described in detail, was lower than in our study. Anyway that combined program also showed adequate economic benefits.

In conclusion, our results suggest that introduction of a program combining a school-based FMR and TS in non-fluoridated areas of Japan represents an efficient use of community resources.

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