

ผลการป้องกันฟันผุเปรียบเทียบระหว่างการให้ทันตสุขศึกษาโดยกำหนดเป็นช่วงเวลา
ติดตามต่อเนื่องกับการให้ตามรอบการรับวัคซีน: การศึกษาโคฮอร์ตย้อนหลัง
ในเด็กก่อนวัยเรียน จังหวัดน่าน ประเทศไทย
Comparative Caries Preventive Effects of a Serial Oral Health Counseling Program
Versus Routine Oral Hygiene Instruction Provided on Vaccination Visits: A
Retrospective Cohort Study in Preschool Children in Nan, Thailand

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Abstract

Background: Serial oral health counseling has been locally initiated and implemented in a sub-district health facility without dental professionals in Nan, Thailand; to extend coverage of the counseling service for caregivers of preschool children. Nonetheless, its caries preventive effect, compared to a pre-existing, nationally-implemented program of oral hygiene instruction on vaccination visits to facilities with affiliated dental personnel, has never been evaluated.

Objective: To compare caries preventive effects of serial oral health counseling (index cohort) and routine oral hygiene instruction on vaccination visits (referent cohort) given to caregivers of Thai children aged under 5 in Nan, northern Thailand.

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ผลการป้องกันฟันผุเปรียบเทียบระหว่างการให้ทันตสุขศึกษาโดยกำหนดเป็นช่วงเวลา
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ในเด็กก่อนวัยเรียน จังหวัดน่าน ประเทศไทย

Methods: In this retrospective cohort study, two cohorts receiving oral health education service with different patterns were observed. Serial oral health counseling, every 3 months was given to caregivers of 50 children at Health Promoting Hospital, without affiliated dental hygienists, was observed in the index cohort. The referent cohort received oral hygiene instruction and tooth brushing demonstration in a dental model provided on vaccination visits for caregivers of these other 30 children at a hospital with affiliated dental hygienists in another sub-district. The intervention effect was evaluated using multilevel Poisson regression, controlling for sex, age, and baseline caries prevalence, and taking dependency of caries occurrence in individual into account.

Results: Caries prevalence at baseline for the index group was 1.99%, while the reference group was caries-free ($p=0.090$). Caries prevalence at 1-year increased in both groups and a significant difference between groups was determined (9.13% and 5.66%, $p=0.026$). After adjustment for sex, age and baseline caries prevalence, a superior caries preventive effect in the index cohort was determined, though it was not statistically significant (adjusted caries prevalence ratio 0.72; 95%CI 0.25, 2.07; $p=0.546$). A difference in the intervention effect among children of the same cohort was also identified (Random effect: $p<0.001$).

Conclusion: Caries preventive effect of serial oral health counseling program was not inferior to that of oral hygiene instruction on vaccination visits. Serial oral health counseling would therefore be an alternative program in local health facilities without affiliated dental hygienists. Nonetheless, the caries preventive effect of the program might vary according to interpersonal differences.

Keywords: Dental caries, Serial oral health counseling, Cohort study, Oral epidemiology

บทคัดย่อ

ภูมิหลัง: การให้ทันตสุขศึกษาโดยกำหนดเป็นช่วงเวลาติดตามต่อเนื่องเป็นรูปแบบการจัดบริการที่เริ่มใช้โดยโรงพยาบาลน่านเพื่อขยายความครอบคลุมของบริการทันตสุขศึกษาให้ครอบคลุมพื้นที่รับผิดชอบที่ขาดแคลนทันตภิบาลผู้ให้บริการ อย่างไรก็ตามการจัดบริการนี้ยังขาดการประเมินผลการป้องกันฟันผุโดยเปรียบเทียบกับบริการทันตสุขศึกษาตามรอบการรับวัคซีนของเด็กในหน่วยบริการที่มีทันตภิบาลประจำ

วัตถุประสงค์: เพื่อเปรียบเทียบผลการป้องกันฟันผุในเด็กก่อนวัยเรียน (อายุต่ำกว่า 5 ปี) ที่ผู้ปกครองได้รับบริการทันตสุขศึกษาโดยกำหนดเป็นช่วงเวลาติดตามต่อเนื่อง (กลุ่ม Index cohort)

เปรียบเทียบกับกลุ่มที่ผู้ปกครองรับบริการทันตสุขภาพตามรอบการรับวัคซีนของเด็ก (กลุ่ม Referent cohort) ในจังหวัดน่าน

วิธีการศึกษา: การศึกษาที่ติดตามจากเหตุไปหาผลซึ่งเหตุการณ์เกิดขึ้นในอดีต (Retrospective cohort study) นี้เปรียบเทียบผลการป้องกันฟันผุของการจัดบริการทันตสุขภาพ 2 รูปแบบ โดยสังเกตในเด็กในกลุ่ม Index cohort จำนวน 50 คน ซึ่งผู้ปกครองได้รับบริการทันตสุขภาพด้วยวิธีการฝึกปฏิบัติการแปรงฟันจริงในเด็ก ตามกำหนดช่วงเวลาทุก 3 เดือน ณ โรงพยาบาลส่งเสริมสุขภาพที่ไม่มีทันตภิบาลประจำ เปรียบเทียบกับเด็กในกลุ่ม Referent cohort จำนวน 30 คน ซึ่งผู้ปกครองได้รับบริการทันตสุขภาพด้วยการสาธิตการแปรงฟันในแบบจำลองฟันตามการมารับวัคซีนของเด็ก ณ โรงพยาบาลส่งเสริมสุขภาพที่มีทันตภิบาลประจำประกอบด้วยบริการเยี่ยมบ้านทุก 6 เดือน วิเคราะห์ผลการป้องกันฟันผุของบริการโดยสถิติ Multilevel Poisson regression ที่ควบคุมตัวแปรกวนคือเพศ อายุ และความชุกฟันผุ ณ เริ่มต้นของเด็ก และพิจารณาความเสี่ยงการเกิดฟันผุรายบุคคลในการวิเคราะห์

ผลการศึกษา: ความชุกฟันผุ ณ เริ่มต้นในกลุ่ม Index คือ 1.99% แต่ในกลุ่ม Reference ปรารถจากฟันผุ ($p=0.090$) ความชุกฟันผุ ณ การติดตาม 1 ปีเพิ่มขึ้นในทั้ง 2 กลุ่มและต่างกัน (Index 9.13% and Reference 5.66%, $p=0.026$) เมื่อปรับอิทธิพลของตัวแปรกวนแล้ว ผลการป้องกันฟันผุในกลุ่ม Index นั้นมากกว่าในกลุ่ม Reference อย่างไม่มีนัยสำคัญทางสถิติ (ค่า Adjusted caries prevalence ratio 0.72; 95%CI 0.25, 2.07; $p=0.546$) ผลของบริการแม้ในกลุ่มเดียวกันก็ให้ผลแตกต่างกันในเด็กแต่ละคน (ค่า Random effect: $p<0.001$)

สรุปผล: ผลการป้องกันฟันผุของบริการทันตสุขภาพซึ่งกำหนดเป็นช่วงเวลาติดตามต่อเนื่องมากกว่าบริการที่จัดรูปแบบตามรอบการรับวัคซีน ดังนั้นจึงเป็นทางเลือกการจัดบริการในพื้นที่ซึ่งขาดแคลนทันตบุคลากรให้บริการ อย่างไรก็ตามผลการป้องกันฟันผุอาจแตกต่างกันตามแต่ละบุคคล

คำสำคัญ: โรคฟันผุ ทันตสุขภาพ การศึกษาโคฮอร์ต ระบาดวิทยาโรคช่องปาก

Introduction

Dental caries continues to be a significant public health problem among Thai preschool children, aged less than 7. According to the oral health status in 5- to 6-year-old children, revealed from the 2nd to the 7th National Oral Health Survey in Thailand, 1984 to 2012, percentages of caries-free children were only 25.6 in 1984 and then uncontrollably decreased to the lowest of 12.6 in 2000 before returning to 21.5 in 2012 (Bureau of Dental Health, 2013a). This secular trend of relatively low caries-free percentages implies that the proportions of 5- to 6-year-old children with dental caries have persisted as high as 75

percent or more. In the younger group of 3-year-old children, proportions of children with dental caries in deciduous teeth showed a fluctuating secular trend from 1989 to 2012, starting from the highest of 66.5 per cent in 1989 and fluctuating within the range of 61.4 to 65.7 per cent before a sharp reduction to the lowest of 56.7 per cent in 2012 (Bureau of Dental Health, 2013a). Regardless of the recent decrease of the caries trend, more than half of the 3-year-old children have recently experienced dental caries. Moreover, according to the survey in 2012, less than half of caregivers (44.2%) provided oral hygiene care for these children (Bureau of Dental Health, 2013b). Prolonged bottle feeding—a habit that potentially induces dental caries—was also found in 39.4 per cent. For both groups of 3- and 5-year-old children, sweetened milk—a major source of sugar exposure to oral environment—was commonly consumed by 48.9 and 49.9 per cent, respectively (Bureau of Dental Health, 2013b).

In an attempt to control the disease burden, The Dental Health Division, Department of Health, Ministry of Public Health initiated a program entitled “My First Toothbrush” in 1992 to incorporate preventive oral health activities for preschool children with other services provided by Well Baby Clinics in public hospitals nationwide (Taupradist, Ratchagool & Visalseth, 1998). The program has been implemented since then as a set of services that include gratis provision of a toothbrush once for each child and routine oral hygiene instruction given to caregiver on the child’s vaccination visits. The program’s effectiveness has also been proved by increased regular oral hygiene care of preschool children by caregivers (Taupradist, Ratchagool & Visalseth, 1998). Nonetheless, since these activities require ongoing contribution of dental hygienists affiliated in the facility, the program is impractical in settings without such personnel.

In the context of the central district of Nan, northern Thailand, there are currently only 7 of 16 Health Promoting Hospitals which possess affiliated dental hygienists. Provision of the mentioned oral health education program has been lacking in these facilities without dental personnel. Alternative strategy to improve the service coverage is thus needed. Serial oral health counseling is a local initiative of the Dental Department of Nan Hospital. Three major principles that underly the design of serial oral health counseling program include efficient workforce allocation, appropriate timing of serial counseling, and practical skill development for caring of child’s oral hygiene. The first principle of efficient workforce allocation was adopted in an attempt to overcome the

mentioned shortage of dental hygienists working fulltime in the local hospitals and to achieve coverage of the oral health service. Dental hygienists and dentists from the provincial hospital were thus allocated to periodically provide the service in the local facilities without affiliated dental hygienists. The second principle of appropriate timing of serial counseling was importantly considered to specify the optimal period of caries occurrence monitoring and to evaluate sustainability of caregivers' oral hygiene care given to their children. The recall period of every 3 months was specified for this program based on a guideline for management of dental caries in infants, children, and adolescents (American Academy of Pediatric Dentistry, 2013). This timing of periodic recall was suggested suitable even for the most unfavorable conditions of high caries risk and without parents' engagement with children's oral health care (American Academy of Pediatric Dentistry, 2013). Consequently, control of caries occurrence in high-risk cases, together with caries prevention among those of subsequent risk levels, would be expectedly achieved. The last principle of practical skill development for caring of child's oral hygiene was undertaken by instructing hands-on tooth brushing practice for caregivers in their own children's mouths. In addition, unlike the pre-existing instruction during vaccination visits, the counseling program specified a schedule for periodic visits by dental hygienists to local facilities and caregivers together with their children were appointed specifically for oral hygiene instruction and hands-on practice. To evaluate this recently implemented program, a systematic assessment of the dental caries preventive effect was required. The aim of this study was, therefore, to compare the effects of serial oral health counseling program and the pre-existing program of routine oral hygiene instruction on vaccination visits in prevention of dental caries among Thai preschool children in Nan, northern Thailand.

Methods

1. Design and participants

This study adopted a retrospective cohort design to compare the effectiveness of the serial oral health counseling program (index cohort) and routine oral hygiene instruction on vaccination visits (referent cohort). Both services were provided to caregivers to prevent dental caries occurrence in Thai preschool children.

Eligible participants were preschool children– aged between 12 months and not more than 5 years old –without underlying disease, whose caregivers were willing to participate in all routine activities until the outcome assessment visit after one year. This study collected data from all eligible participants.

2. Study sites

Two comparable sub-districts in the central district of Nan were selected for study. Selection of the study locations was based on the matching of the number of affiliated health personnel (registered nurses, public health technical officers, auxiliary employees) and the range of services provided by the Health Promoting Hospital in each sub-district, geographical distance from the provincial center, agriculture-based economy, and a predominantly flat region accessible by road transport. Thuem Tong Sub-district, the selected site for the index cohort, is 11 kilometers from the provincial center. The local hospital within this area provided Well Baby Clinic services without affiliated dental hygienists to give routine oral health education. In contrast, the local hospital in Bor Suak Sub-district– 12 kilometers from the provincial center where the referent cohort was observed–possessed an affiliated dental hygienist who provided routine oral hygiene instruction on vaccination visits.

3. Service administration

For each observation site, a local officer was responsible for making routine appointments for each service. A public health technical officer undertook the task of making the appointments with the index cohort, while the affiliated dental hygienist took this role with the referent cohort. Announcement of both services was made public through community wire broadcasting systems for 7 days before routine appointment and eligibility assessment at the local facilities.

The organized commencement visit for baseline data collection and subsequent activities were made in September 2013. The caregivers who attended this first visit were requested to accompany their children to attend activities in all subsequent sessions. The duration of observation was for 1 year and details of services in each cohort have been summarized in Figure 1. At the commencement and outcome assessment visits, oral examination in all children was undertaken in the Well Baby Clinic of each facility by the same unaffiliated dental hygienist from an outside provincial hospital. Since this study was

retrospectively conducted for evaluation of program effectiveness, the single assessor of baseline and follow-up outcomes undertook the assessment on routine service neither knowing that the data were later adopted for research nor having incentive or punishment regarding assessment results. Though the assessor was not blinded, differential attempts to distort assessment results of the two cohorts would not occur by the times of both assessments.

Oral examination and the caries detection method in this study complied with the ones suggested by World Health Organization for practical reasons (World Health Organization, 2013). All children were in the supine position with their head on the lap of the examiner. Flashlights were used during the visual inspection, together with the use of a dental explorer to detect dental caries. Intra-examiner calibration was carried out prior to both assessments at baseline and 1-year follow-up. The calibration was part of the annual intra- and inter-examiner calibration and dental service development training for representative dental personals from provincial and all district hospitals in Nan. The intra-examiner calibration was conducted by asking assessors to examine about 20 pre-selected children, with all conditions expected to be found in field service, twice and the level of agreement was evaluated to be well beyond 85 per cent.

The value of caries prevalence was calculated using the number of carious teeth in the whole group divided by the total number of all erupted teeth in all children examined in that group. Routine caregiver interviews for information regarding the child's oral health-related factors were undertaken, both at baseline and final assessment, through a routine self-administered questionnaire. In case of an illiterate caregiver, a face-to-face interview was conducted and the questionnaire was completed by the dental hygienist.

		Eligibility assessment (n=93)	
		Index cohort (n=60)	Referent cohort (n=33)
Registration			
Service & Follow-up		Commencement visit: <ul style="list-style-type: none"> ▪ Oral examination in child and record of baseline dental status[†] ▪ Caregiver interview[†] ▪ Inform of further periodic visit[†] ▪ Illustrative use of straw to scrape plaque deposit on child's tooth surface[†] ▪ Oral hygiene instruction* ▪ Hands-on tooth brushing practice for child by caregiver* 	Commencement visit: <ul style="list-style-type: none"> ▪ Oral examination in child and record of baseline dental status[†] ▪ Caregiver interview[†] ▪ Routine oral hygiene instruction using dental model on vaccination visits[‡] Home visit made every 6 months for oral hygiene instruction and hands-on tooth brushing practice [‡]
		Follow-up every 3 months (total 3 times) for re-counseling and monitoring of oral hygiene practice ^{†,*}	Follow-up on vaccination visits (number of visits varies due to different ages of children) [‡]
Assessment		Outcome assessment at 1 year (n=50) [†] , loss to follow-up n=10	Outcome assessment at 1 year (n=30) [†] , loss to follow-up n=3

[†] by unaffiliated (external) dental hygienist, [‡] by affiliated dental hygienist, * by dentist

Figure 1 Flowchart summarizing service activities and assessment in two observed cohorts

4. Oral health interventions and evaluation

In the index cohort, the use of a straw to scrape out plaque deposits from the child's tooth surfaces was undertaken by the dental hygienist. This service was to motivate the need for proper tooth brushing provided by the caregivers and to show the difficult-to-reach dental surfaces, especially the posterior portion in child's mouth. Oral hygiene instruction, hands-on tooth brushing in the child's mouth, and monitoring of tooth brushing practices in all subsequent follow-up visits were serviced on a case-by-case basis by the same dentist. For the index cohort, an appointment for a re-counseling session was made every 3 months after the first visit. Contents of re-counseling were based broadly on what had been instructed in the first visit. Hands-on tooth brushing in the child's mouth

was evaluated on a case-by-case basis and additional advice was given to improve the caregiver's skill for tooth brushing with their child. Caregivers also participated in group discussions about the difficulties of oral hygiene practice for their children at home and possible solutions for different issues were suggested by peers, the dentist, and the dental hygienist.

Unlike the index group, oral hygiene instruction in the artificial dental model was given routinely to caregivers during vaccination visits for their children in the referent cohort by the affiliated dental hygienist. The numbers of vaccination visits among participants in the reference cohort were 1 to 2 visits, due to differences in participants' ages and the corresponding schedules of vaccination (Figure 2). Apart from the routine oral hygiene instruction, the affiliated dental hygienist in the referent cohort also provided home visit and hands-on instruction of oral hygiene care in children for caregivers every 6 months.

Measurement of service adherence was obtained by telephone appointment reminders made by responsible personnel in each facility. Outcome assessment visits were made in August 2014 for each subject and all caregivers completely adhered to service in both groups. Outcome assessment methods adopted the protocol for oral examination and caregiver interview upon the commencement visits in both cohorts.

Protocol for vaccination	
Age:	Vaccine:
Newborn	Bacillus Calmette-Guérin (BCG) Hepatitis B – 1 st Administration (HB1)
2 months	Diphtheria, Tetanus, Pertussis – 1 st Administration (DPT1) Oral Polio Vaccine – 1 st Administration (OPV1) Hepatitis B – 2 nd Administration (HB2)
4 months	Diphtheria, Tetanus, Pertussis – 2 nd Administration (DPT2) Oral Polio Vaccine – 2 nd Administration (OPV2)
6 months	Diphtheria, Tetanus, Pertussis – 3 rd Administration (DPT3) Oral Polio Vaccine – 3 rd Administration (OPV3) Hepatitis B – 3 rd Administration (HB3)
9-12 months	Mump, Measles, Rubella – 1 st Administration (MMR1)
1-1.5 year	Diphtheria, Tetanus, Pertussis – 4 th Administration (DPT4) Oral Polio Vaccine – 4 th Administration (OPV4) Japanese encephalitis – 1 st & 2 nd Administrations, 1-2 weeks apart (JE1 & JE2)
2-2.5 years	Japanese encephalitis – 3 rd Administration (JE3)
4-6 years	Diphtheria, Tetanus, Pertussis – 5 th Administration (DPT5) Oral Polio Vaccine – 5 th Administration (OPV5) Bacillus Calmette-Guérin (BCG) – <i>only if never been administered</i>
12-16 years	Mump, Measles, Rubella – 2 nd Administration (MMR2)

Feasible vaccination visits in this study

Figure 2 Routine protocol of vaccination service and feasible range of vaccination visits for dental education service in the referent cohort

5. Statistical methods

This study intended to analyze only the children who had complete data at baseline and at 1-year follow-up. Descriptive statistics was used to summarize participants' characteristics. A baseline comparison of the participants' characteristics and oral health-related factors was conducted using the independent t-test and exact probability test. Tooth-level data were further used to determined caries prevalence—both at baseline and follow-up—and for estimation of the intervention effect. Caries prevalence was determined according to the formula:

$$\text{Caries prevalence (\%)} = (\text{Number of carious teeth} / \text{Total number of existing teeth}) \times 100$$

Since total number of existing teeth in children which were ‘at risk’ of dental caries in each group would dynamically change over the course of 1-year follow-up, e.g., newly-erupted teeth at different points in time of the follow-up period, denominators—or total number of existing teeth—used to calculate caries prevalence at baseline and follow-up according to the formula were therefore different. In this context of analysis, although static cohorts of children—fixed number of children—were followed from baseline to the 1-year follow-up, a dynamic cohort of teeth nested within each child was actually analyzed.

To determine the intervention effect, each tooth was considered as a unit of analysis, instead of each individual as earlier mentioned; the number of teeth was thus considered as the study size. The caries prevalence ratio was used as a measure of the intervention effect. The incidence rate of dental caries was not applicable in this context of analysis because ‘time at risk’ of caries contributed by each tooth within the dynamic cohort of teeth could not be determined. In other words, it was impractical to routinely conduct oral examination in each child frequently to precisely detect new occurrence of caries, or to identify cohort zero-time (starting point of observation) of each newly-erupted tooth which became at risk of caries. Adjusted prevalence ratio was estimated using multilevel Poisson regression, controlling for sex, age, and baseline dental caries prevalence, and taking dependency of caries occurrence in individual into account (Zou, 2004; Parodi & Bottarelli, 2006; Todem, 2012; Matranga, Castiglia & Solinas, 2013). Caries occurrence at follow-up was used as the dependent variable in the model. Since the caries occurrence was a binary outcome, the modified Poisson regression approach for binary data was therefore applied to estimate the adjusted prevalence ratio (Zou, 2004). Sex and age were adjusted in the model to ensure control of related, unknown, or non-measurable confounding variables. Baseline dental caries prevalence was also adjusted to ensure control of differences in caries prevalence between the two cohorts. Apart from the fixed-effect part, the mixed model also included a random-effect part. The individual was specified as a group variable in the random-effect portion, taking dependency of caries occurrence by each child into consideration.

6. Ethics

This study protocol was approved by the Nan Hospital Ethical Review Committee for Research in Human Subjects, approval code NN0032.2/129 issued on January 6, 2015.

Results

1. Subjects and retention

There were 60 and 33 subjects who initially attended the commencement visit in index and referent cohorts, respectively. Nonetheless, 10 (16.7%) and 3 (9.1%) subjects failed to attend follow-up sessions in the index and reference cohorts ($p=0.368$). In a few subjects in the index cohort, the same caregivers couldn't attend a follow-up visit before the outcome assessment, other caregivers accompanied these children in substitution and these representatives conformed with activities in that visit and these subjects were still taken in to the final analysis. The ultimate numbers of subjects who completely attended each service of 1-year duration were 50 and 30 for the index and reference cohorts, respectively.

2. Baseline data

Baseline characteristics and oral health-related factors in both cohorts were comparable (Table 1). More than half of subjects in each cohort were male. The average age of children in each group was around 2 years old. Mothers and others family members shared the caregiver role for children in both cohorts. All of the children in the index cohort received oral hygiene from their caregivers, while a child aged 15 months in the reference was allowed to take care of herself with no tooth brushing. Most of the oral hygiene care in both cohorts was undertaken through tooth brushing, except for some children whose care was through other means, e.g. mouth rinsing. Most children in both groups consumed powdered milk. Risk behaviors for dental caries, including sleeping during bottle-feeding and snacking between meals, were common in both cohorts.

Table 1 Children's characteristics and oral health-related factors at baseline

Characteristics	Index cohort	Referent cohort	p-value
	(n=50)	(n=30)	
	n (%)*	n (%)*	
Sex			
Male	30 (60.0)	17 (56.7)	0.817 [†]
Female	20 (40.0)	13 (43.3)	
Age (months)			
12 - 24	12 (24.0)	8 (26.7)	
25- 36	22 (44.0)	20 (66.6)	
37- 48	14 (28.0)	2 (6.7)	
49- 60	2 (4.0)	0	
Mean (SD)	32.1 (9.91)	29.2 (7.22)	0.167 [†]
Min-Max	13-53	15-45	
Caregiver			
Mostly mother	13 (26.0)	12 (40.0)	0.219 [†]
Mother and others	37 (74.0)	18 (60.0)	
Oral hygiene caretaker			
Child	0	1 (3.4)	0.547 [†]
Mother	39 (78.0)	22 (73.3)	
Others	11 (22.0)	7 (23.3)	
Care by tooth brushing			
No	6 (12.0)	2 (6.7)	0.703 [†]
Yes	44 (88.0)	28 (93.7)	
Milk intake			
Breast feeding	9 (18.0)	11 (36.7)	0.141 [†]
Powdered milk	38 (76.0)	16 (53.3)	
Unsweetened UHT milk	2 (4.0)	2 (6.7)	
Sweetened UHT milk	1 (2.0)	1 (3.3)	
Asleep while bottle-fed			
No	16 (32.0)	11 (36.7)	0.808 [†]
Yes	34 (68.0)	19 (63.3)	
Snack between meals			
No	8 (16.0)	7 (23.3)	0.555 [†]
Yes	42 (84.0)	23 (76.7)	

UHT = ultra-high temperature processing, *Column percentage, [†]Exact probability test, [‡]Independent *t*-test

3. Follow-up data

Oral hygiene caretakers in both cohorts were similar at baseline. Nonetheless, tooth brushing was practiced in all children after service provision in both cohorts. Change in milk consumption was the same in both groups. Less breast feeding and more unsweetened UHT milk consumption were observed. Proportions of sleeping while being bottle-fed were less reported. Snacking between meals was reported relatively the same as baseline in both cohorts (Table 2).

Table 2 Children's characteristics and related oral health factors at 1-year assessment

Characteristics	Index cohort	Referent cohort	p-value [†]
	(n=50)	(n=30)	
	n (%)*	n (%)*	
Oral hygiene caretaker			
Child	0	1 (3.3)	0.322
Mother	40 (80.0)	21 (70.0)	
Others	10 (20.0)	8 (26.7)	
Care by tooth brushing			
No	0	0	-
Yes	50 (100.0)	30 (100.0)	
Milk intake			
Breast feeding	1 (2.0)	1 (3.3)	0.385
Powdered milk	31 (62.0)	13 (43.4)	
Unsweetened UHT milk	17 (34.0)	15 (50.0)	
Sweetened UHT milk	1 (2.0)	1 (3.3)	
Asleep while bottle-fed			
No	27 (54.0)	17 (56.7)	1.000
Yes	23 (46.0)	13 (43.3)	
Snack between meals			
No	8 (16.0)	7 (23.3)	0.555
Yes	42 (84.0)	23 (76.7)	

*Column percentage, [†]Exact probability test

4. Clinical outcomes

At baseline, the number of teeth per child in both cohorts was comparable [Mean(SD): 6.0(4.60) in index and 5.9(3.55) in reference, $p=0.859$]. At 1-year follow-up, the number of teeth per child increased to 16.6(4.05) and 16.5(3.07), $p=0.870$. Non-significant difference in caries per child at baseline was identified [index 0.1(0.63), reference 0, $p=0.299$]. Caries per child at follow-up of the index cohort resembled that of the reference [index 1.5(2.31), reference 0.9(1.84), $p=0.239$]. Caries prevalence at baseline for the index group was 1.99% while children in the reference were caries-free, $p=0.090$. Caries prevalence at 1-year increased in both groups and significant difference was determined (9.13% and 5.66%, $p=0.026$).

After adjusting for sex, age and baseline caries prevalence by multilevel mixed-effects Poisson regression, a superior caries preventive effect in the index cohort was determined, though it was not statistically significant (caries prevalence ratio 0.72; 95%CI 0.25, 2.07; $p=0.546$). (Table 3). The likelihood ratio test revealed that the random effect model was significantly different from the fixed effect model ($p<0.001$) and thus heterogeneity of the intervention effect on individuals was determined.

Table 3 Comparative effect of serial oral health counseling program (index cohort) and routine instruction provided on vaccination visits (referent cohort)

Characteristic s	Index cohort		Referent cohort		Caries prevalence ratio	95% CI	p- value
	Baseline	1-year	Baseline	1- year			
Children	50	50	30	30	0.72*	0.25, 2.07	0.546
Teeth number	302	832	176	495			
Teeth/child (SD)	6.0 (4.60)	16.6 (4.05)	5.9 (3.55)	16.5 (3.07)			
Caries (teeth)	6	76	0	28			
Caries/child (SD)	0.1 (0.63)	1.5 (2.31)	0	0.9 (1.84)			
Prevalence**	1.99%	9.13%	0%	5.66%			

*Adjusted for sex, age, and baseline caries prevalence by multilevel Poisson regression

** % Caries prevalence: $100 \times [\text{caries (teeth)} / \text{teeth number}]$

Discussion

This study revealed that the effect of serial oral health counseling program every 3 months was not inferior to routine oral hygiene instruction given on vaccination visits in terms of caries occurrence prevention, regardless of differences in dental caries at baseline; the index cohort possessed pre-existing caries compared to the caries-free condition in the reference. Observed similarity of caries preventive effects could be on account of several factors. Irrespective of differences in case-by-case and group approaches in oral hygiene instruction, a study suggested an equivalent effect on personal practice competency and improvement of oral hygiene in adults (Ziebolz, Herz, Brunner, Hornecker & Mausberg, 2009). This evidence might remain true in this study and others when adults assumed the role of oral hygiene caretakers for children (Castilho, Mialhe, Barbosa & Puppini-Rontani, 2013; Hooley, Skouteris, Boganin, Satur & Kilpatrick, 2012; Mannaa, Carlén & Lingström, 2013; Grembowski, Spiekerman & Milgrom, 2008). Although oral hygiene practice instructors in two cohorts were different—dentist in the index and dental hygienist in the reference, the observed clinical effects on caries prevention were the same. This might be due to the fact that the required competency for oral health education service of dental hygienist working routinely in Well Baby Clinics of Health Promoting Hospital resembled that of dentists in general dental practices (Bureau of Dental Health, 2009). This suggested flexibility in selection of dental personnel providing this service in local facility, if applicable. Although some literature inters that providers of oral hygiene instruction might not play a direct role in formation of oral health habit (Paunio, Rautava, Helenius & Sillanpää, 1994), continuous support to improve awareness and maintenance of oral hygiene care for children should still be considered (Mattila, Rautava, Sillanpää & Paunio, 2000; Saied-Moallemi, Virtanen, Ghofranipour & Murtomaa, 2008; Blinkhorn, Wainwright-Stringer & Holloway, 2001). Oral health education services in the referent cohort possessed this element of continuous support just like the service similarly designed elsewhere (Oredugba, Agbaje, Ayedun & Onajole, 2014). The continuous support was also a shared key element in oral health education services in the index group and this could be another contributing factor for the non-inferior effect.

Issues to be emphasized for further ongoing support include the habits of sleeping while being bottle-fed and snacking between meals. According to Table 2, the majority of children in both cohorts continued the habit of having snack, between meals (84.0% in

index, 76.7% in reference). Considerable proportions of children were also determined as being asleep while being bottle-fed (46.0% in index, 43.3% in reference). Encouragement and counseling for modification of these risk behaviors should be additionally provided to caregivers of these children in further subsequent visits.

Loss to follow-up in both cohorts was not statistically significant. This evidence primarily supported that the loss to follow-up occurred without a specific differential direction. Reasons traced from some of the lost subjects were inconvenience to attend subsequent follow-up visits and moving away from the location. These losses occurred at random in both groups and further support the notion that non-differential loss to follow-up resulted in dilution of the service effects in both cohorts (Delgado-Rodriguez, 2004; Silva, 1999).

Although this study selected 2 locations of observation on the basis of matching of healthcare setting and socioeconomic context, co-intervention influencing dental caries occurrence in both cohorts was still believed to occur. Nonetheless, the comparability of service, geographical location, social environment, and residents' lifestyles would result in similarity of co-intervention in whatever form in these cohorts (Krishna, Maithreyi & Surapaneni, 2012).

Serial oral health counseling is a potential program for local areas without affiliated dental hygienists because the service requires only periodic visits of dental personnel to local hospitals for 1 day out of every 3 months. Although the dentist also contributed to the counseling in the index cohort of this study, provision of the counseling did not necessarily require highly specialized skills in dental treatment. Service provision could, therefore, be undertaken either by a dentist or hygienist. Service administration was simple and local residents co-operatively attend the activities. Costs of service production were economical compared to curative dental services (e.g., dental restoration, pulpal therapy). Without an additional workload, this service was a part of a routine community visit by dental personnel from secondary care hospitals. Therefore, sustainability of the program could be achieved when routinely executed.

Statistical analysis of effects on caries prevention in both cohorts was based on a total number of 80 children, 1,332 teeth at follow-up, and 109 events of caries. According to recommendations of 7 binary events required for 1 parameter in Poisson regression modeling (Zou, 2004; Vittinghoff & McCulloch, 2007), this study should have 35 caries

event for regression of 5 parameters (including intercept). Nonetheless, power back calculation by the standard statistical software showed that we had more than 99% statistical power. This indicated that the non-difference in caries prevalence in both cohorts truly reflected non-inferiority of the two service modes.

Conclusion

Serial oral health counseling program was not inferior to oral hygiene instruction on vaccination visits in caries preventive effects among preschool age children in Nan and would be a potential alternative for oral health education services in local areas without affiliated dental hygienists. Nonetheless, caries preventive effects of the program might vary according to interpersonal difference.

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