Validation of PUFA Index in Assessing Untreated Dental Caries Among Malaysian Adult Subpopulation

RESEARCH PROTOCOL

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Introduction

Dental caries is considered a major factor of tooth ache and tooth loss in population all over the world (Fejerskov & Kidd 2003). In the year 2000, 90% of the adult Malaysian population had been reported to be living with caries (Oral health Division, Ministry of Health, Malaysia 2011). Dental caries in its advanced stages may influence the health and quality of life, causing pain, disturbances in sleeping patterns, eating difficulties, and reduced body weight (Jorge et al. 2014). In severe cases, it might even lead to hospitalization (Figueriredo et al. 2011). In many developing nations, access to oral health service is extremely restricted and teeth are often left untreated or extracted because of pain or discomfort (Peterson 2003).

Traditionally, information on caries has been gathered by utilizing the DMFT index. The DMFT Index is expressed as the total number of teeth that are decayed (D), missing (M), or filled (F) in an individual. This established index provides information on the presence of caries, the restorative needs and any surgical intervention performed on a patient (Larmas 2010). The drawback of DMFT is that it fails to give information about the clinical outcomes of untreated dental caries. A deep caries cavity with pulpal involvement is still considered as decayed and pulpal involvement is not mentioned at all in the caries scoring system.

Hence, a new index was developed to record the full continuum of untreated dental caries. The PUFA index complements the DMFT index by recording the advancement of the caries lesion into surrounding tissues, including pulpal involvement (P), ulceration due to tooth fragments (U), fistula formation (F) and abscess (A) (Monse et al. 2010). Ideally, this index should reflex the underlying pulpal and periapical involvement of the carious lesion, thereby serving as a screening tool for further clinical and radiographic examinations to diagnose an pulpal and periapical diseases.

The PUFA index had been used in prevalence study among Philipino (Monse et al. 2010), Polish (Baginska et al. 2013) and Indian (Mehta & Sumatibhalia 2014) children. The reproducibility of the index was good, with intraexaminer kappa value of 0.85 and intraexaminer kappa values ranging from 0.80 to 0.97 (Monse et al. 2010). Despite that, currently the capability of the index in meeting the intended purpose of capturing the clinical sequelae of untreated dental caries was not assessed. This limits its use in triaging patients in a large practice, or in epidemiological survey (prevalence study) of a population. Therefore, it is paramount to ensure the index performs adequately as a screening tool when compare to conventional clinical procedures in disease detection. Furthermore, the PUFA index should also be tested in an adult population since the existing literature focused only on children.

Besides PUFA, variants of indices using the same concept were developed. In an attempt to simplify PUFA, Pulpal Involvement-Roots-Sepsis (PRS) Index was modified by redefining P as caries process reached pulp chamber, R as non-restorable caries. Also, Fistula and Abscess were combined as S (Baginska & Stokowska 2013). On the other hand, the Caries Spectrum and Treatment (CAST) Index was developed to combine both ICDAS II and PUFA (Frecken et al. 2011), but this resulted in a complex index with ten codes.

Other than indices, more accurate measurements such as radiographs were sometimes used as a screening tool for pulpal and periapical diseasess. In fact, radiological assessment is crucial because chronic apical periodontitis often develops without subjective symptoms (Huumonen & Ørstavik 2002). However, there is no standard criteria for the registration of apical periodontitis in surveys and epidemiological study, either for periapical radiographs or panoramic radiographs. This makes comparison between studies difficult. With the validated Periapical Index (PAI), calibrated observers could use it for such purpose (Huumonen & Ørstavik 2002). Nevertheless,

periapical and panoramic radiographs were reported with high specificity (0.98 and 1.00, respectively) but low sensitivity (0.55 and 0.28, respectively) when compared against CBCT (Estrela et al 2008). Hence, the use of these conventional imaging tends to detect only advanced lesions and therefore underestimate disease prevalence.

Apart from the issue of accuracy, the use of panoramic radiographs were controversial, especially in striking a balance between increased radiation exposures, cost to the health care system and diagnostic yield (Rushton et al. 2001). Panoramic radiographs, in combination with a limited number of intra-oral radiographs, yield good diagnostic information with low radiation dose (Molander et al 1993). Therefore, many dentists reported using it for screening oral diseases in new patients (Rushton et al 1999). Although many radiological findings could be observed on panoramic radiographs, Rushton et al. (2001) argued against its use because the findings are also revealed on bitewing radiographs, or are often not contributive towards treatment planning.

Problem Statement

The PUFA index complements the widely used DMFT index by recording the advancement of the caries lesion into surrounding tissues, which includes pulpal involvement (P), ulceration due to tooth fragments (U), fistula formation (F) and abscess (A). However, this new index has yet to be validated, hence limits its use in prevalence study. On the hand, despite the importance of radiological diagnosis, screening pulpal and periapical diseases using panoramic radiographs (orthopantomographs OPG) are plagued with issues of accuracy and radiation risk. Therefore, comparison of the two screening methods, using PUFA index or panoramic radiograph, will inform clinicians and researchers in selecting the appropriate tool for screening pulpal and periapical diseases.

Research Questions

a. How reliable is the PUFA in screening pulpal and periapical diseases?
b. How reliable is the PAI in screening pulpal and periapical diseases?
c. How accurate is the PUFA in screening pulpal and periapical diseases?
d. How accurate is the PAI in screening pulpal and periapical diseases?
e. Is there a difference in the accuracy of PUFA and PAI in screening pulpal and periapical diseases?

Hypotheses

a. The PUFA index is highly reliable in screening pulpal and periapical diseases.
b. The PAI is highly reliable in screening pulpal and periapical diseases.
c. The PUFA index is highly accurate in screening pulpal and periapical diseases.
d. The PAI is highly accurate in screening pulpal and periapical diseases.
e. There is a difference in the accuracy of PUFA and PAI in screening pulpal and periapical diseases.

Research Objective

General Objective:

To evaluate the reliability and accuracy of PUFA and PAI in screening for clinical outcomes of untreated caries, specifically pulpal and periapical diseases.

Specific Objectives:

a. To determine the intra- and inter-examiner reliability of PUFA in screening pulpal and periapical diseases.
b. To determine the intra- and inter-examiner reliability of PAI in screening pulpal and periapical diseases.
c. To determine the sensitivity, specificity and predictive values of PUFA in screening pulpal and periapical diseases.
d. To determine the sensitivity, specificity and predictive values of PAI in in screening pulpal and periapical diseases.
e. To compare the accuracy of PUFA and PAI in screening pulpal and periapical diseases.

Methods

Participants

The study will be carried out in Primary Care Clinic, Univeristi Kebangsaan Malaysia. Consecutive sampling will be used, all eligible patients are invited to participate. The inclusion criteria are as follow:

i. New patient, not receiving active dental treatment at the time of the study
ii. Adult patient (18 years old or above)
iii. Has at least 12 teeth in the oral cavity
iv. Presented with the clinical situation for which radiograph(s) were indicated (American Dental Association 2012)
v. No radiograph was taken within the last 6 months

At the time of this study, the UKM dental clinic routinely ordered OPG for patients with multiple dental problems, particularly if they need periodontal, prosthodontic, orthodontic treatment or oral surgery. Hence, only patients who required OPG according to the screening procedure of this institution is included. Pregnant or medically compromised patients (American Society of Anesthesiologists ASA3) will be excluded.

Sample size is estimated using the method described in Buderer (1996). Based on the systematic review, the prevalence of periapical radiolucency was about 5% (Pak et al 2012). As there was no prior data, the sensitivity of PUFA was assumed conservatively at 0.50 and specificity at 0.80. Therefore, a total of 1921 and 65 teeth are required, based on the assumed sensitivity and specificity, respectively. Since each patient must have at least 12 teeth, 161 patients will be sufficient for estimation of both sensitivity and specificity. Assuming 2% of the radiographs have

overlapped images, poor contrast or poor quality, the sample size was adjusted to a total of 165 patients.

The unit of interest for analysis is at tooth level. A tooth is considered present in the mouth when any part of it was visible. The teeth excluded for scoring are unerupted teeth, congenitally missing teeth or supernumerary teeth, teeth removed for reasons other than dental caries, and primary teeth retained in the permanent dentition.

Reference Standard

The reference standard is the clinical diagnosis. This will be carried out by an endodontic postgraduate student, using the diagnostic criteria of AAE. Comprehensive examination will be carried out for each tooth, followed by investigation using OPG, periapical radiograph, periodontal probing, heat test, cold test, electric pulp tester when indicated, to aid in arriving at the definitive diagnosis. To observe the As Low As Reasonably Achievable (ALARA) principle, additional periapical radiographs were taken only when radiographic assessment is impossible with the OPG because of overlapping, blurred images or obscured periapical region. Because OPG has lower sensitivity than periapical radiograph in detecting apical periodontitis, periapical radiograph is also taken when periapical lesion cannot be seen on OPG but a tooth is having large caries or showing signs and symptoms of pulpal and periapical diseases. At the end of this comprehensive examination, each tooth will have pulpal and apical diagnoses.

Index Test 1: PUFA

Two independent, trained dentists are employed to screen the participants using DMFT and PUFA indices, blinded to the clinical diagnosis and PAI scoring. The examination is done using only a mouth mirror. Each tooth was scored either Decayed, Missing or Filled.

If the tooth is present, PUFA scoring is done. A particular tooth can be scored as either one of Normal, Pulpal involvement, Ulceration, Fistula or Abscess. In case of doubt concerning the extent of odontogenic infection, the basic score (Pulpal involvement) is given. Lesions in the surrounding tissues that are not related to a tooth with visible pulpal involvement as a result of caries are not recorded.

Index Test 2: PAI

The OPG will be taken for all participants by qualified radiographers using Sirona Orthophos (Sirona Dental System GmbH, Bensheim, Germany). All radiographs will be evaluated by two trained dentists, blinded to the clinical diagnoses and the PUFA scoring. Each tooth is scored for the periapical status using the Periapical Index (PAI) proposed by Ørstavik et al (1986).

Ethical consideration

Ethics approvals will be obtained from the research ethics committee of the university. The research will be conducted in accordance with the Declaration of Helsinki. Informed consent will be obtained from all participants in written form. Emergency treatment will be carried out if the patient is in pain or showing sign of systemic spread of infection (e.g. swelling, fever). Following the study, all participants will be arranged for appropriate treatment.

Data analysis

The demographic data of the patients will be analyzed using descriptive statistics. Mean DMFT and PUFA scores will be calculated. The assessment of the teeth will be tabulated.

The pulpal diagnosis and apical diagnosis for each tooth will be dichotomized as Disease or No Disease. To determine the accuracy of the test, the outcome of PUFA is dichotomized as Positive (PUFA>0) or Negative (PUFA=0) for each tooth. Similarly, the PAI was dichotomized as Positive (PAI≥3) or Negative (PAI<3). Intra- and inter-examiner reliability will be determined using Cohen's kappa. Sensitivity, specificity, positive predictive value and negative predictive value will be calculated. To compare the two index tests, ROC contrast estimation will be computed.

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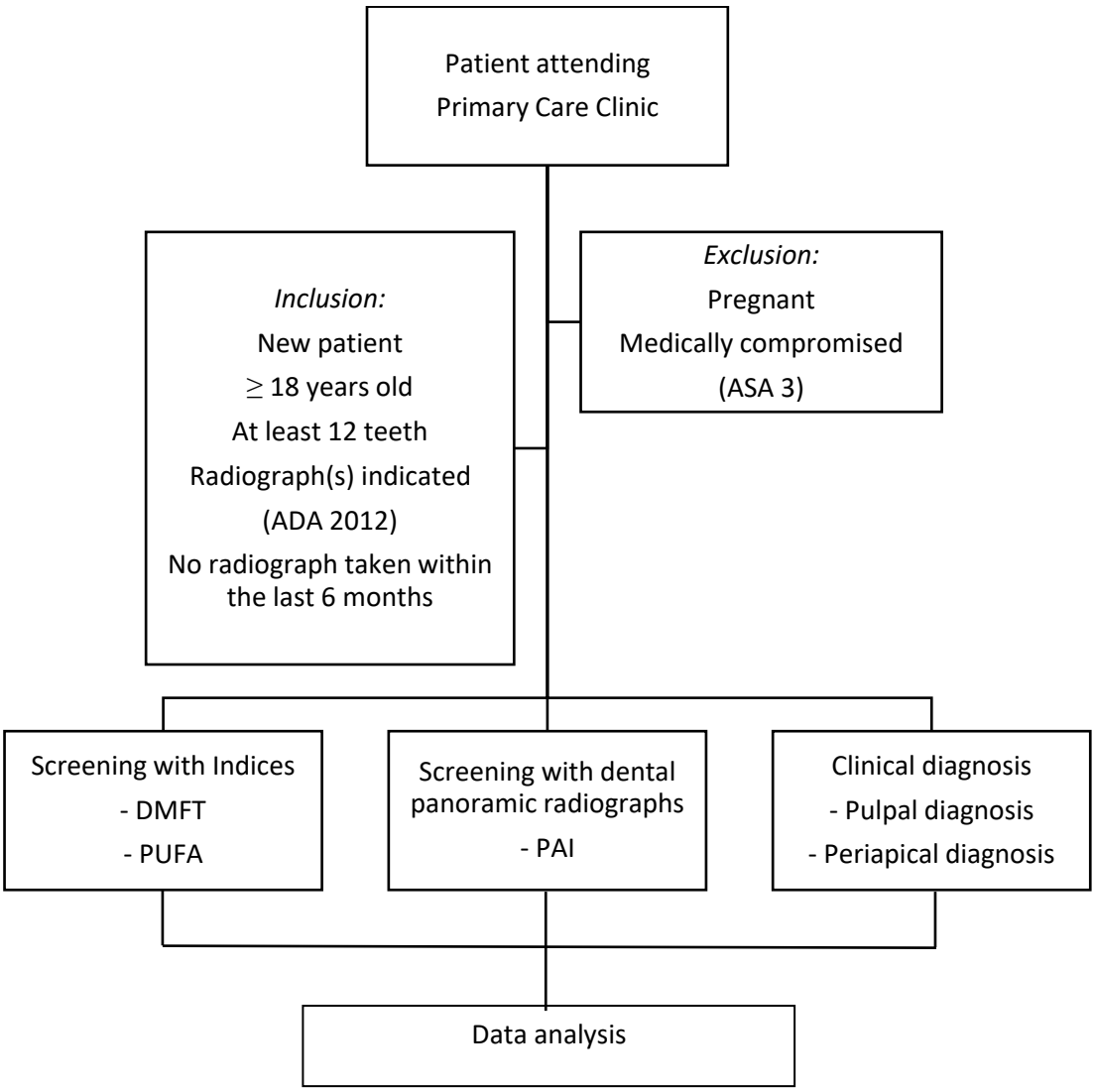
Appendix 1. Flow chart



Appendix 2. Dummy tables

A total of x patients were invited to participate.

X fulfill the inclusion criteria.

X declined to participate because ……

Table 1. Demographic distribution of the patients examined

	Count (%)	Mean (SD)
Total number of patient assessed		
Gender		
Male		
Female		
Age		
Age		
DMF		
Decayed		
Missing		
Filled		
DMFT		
DMFT > 0		
PUFA		
Pulpal involvement		
Ulceration		
Fistula		
Abscess		
PUFA		
PUFA > 0		

Table 2. Distribution of teeth assessed using DMFT, PUFA, PAI, Pulpal Diagnosis and Periapical Diagnosis

	Count	Percent
Total number of teeth assessed		
DMFT		
Decayed		
Missing		
Filled		
PUFA		
Pulpal involvement		
Ulceration		
Fistula		
Abscess		
PAI		
1		
2		
3		
4		
5		
Pulpal diagnosis		
Normal pulp		
Reversible pulpitis		
Symptomatic irreversible pulpitis		
Asymptomatic irreversible pulpitis		
Pulp necrosis		
Previously treated tooth		
Previously initiated therapy		
Apical diagnosis		
Normal apical tissue		
Symptomatic apical periodontitis		
Asymptomatic apical periodontitis		
Chronic apical abscess		
Acute apical abscess		
Condensing osteitis		

Table 3. Intra- and inter-examiner reliability (Cohen's kappa) of DMFT, PUFA and PAI

	DMFT	PUFA	PAI
Intra-examiner reliability 1			
Intra-examiner reliability 2			
Inter-examiner reliability			

Table 4. Accuracy of PUFA and PAI

	Gold Standard = Pulpal Diagnosis		Gold Standard = Periapical Diagnosis	
	PUFA	PAI	PUFA	PAI
TP				
FN				
TN				
FP				
Sensitivity				
Specificity				
PPV				
NPV				

Table 5. ROC contrast estimation

Gold Standard	Contrast	Estimate	SE	95% Wald Confidence Limits		Chi-square	*P*
				Lower	Upper		
Pulpal diagnosis	PUFA-PAI						
Periapical diagnosis	PUFA-PAI						