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KING ABDULLAH INTERNATIONAL MEDICAL RESEARCH CENTER
KING SAUD BIN ABDULAZIZ UNIVERSITY FOR HEALTH SCIENCES
National Guard Health Affairs



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Date of Receipt

Protocol Number

RSS18/041/J

1. **Title of Proposal:**

Assessment of pediatric first permanent molar status and treatment time needed under general anesthesia at KAMC-Jeddah

2. **Type of Project:** (Please check all applicable options)

Chart Review Diagnostic PhD Project Qualitative Research
Human Laboratory Msc Project Quantitative Research
Therapeutic Basic Science Other cross sectional

3. **Starting Date:**

15 July 2018

4. **Duration:**

5 weeks

5. **Total Fund Requested (SR):**


Not applicable

6. **Principal Investigator (PI):**Name: Raniah Baakdah Tel. No.(W): 21145 Mobile No.: **0568781100**Affiliation & Address: **KAMC - Jeddah, dental**Title/Position: **_ consultant pediatric dentist**E-mail: : **baakdar@hotmail.com** **ba-akdahra@ngha.med.sa**7. **Name of co- Investigators:** (instructions: there is no limit to the number of co-investigators and their expertise should cover the different research areas.)


Co-Investigators	Title/Position	Department	Signature
Ranin bashikh	intern	student	
Alanuod turky	intern	student	
Asrar sindi	intern	student	
Ebtesam aldegail	Dental student	student	
Dr.Anas Shabra	consultant	Dental department	
Dr.Wael Helwan	consultant	Dental department	
Dr.Jihan Turkustani	consultant	Dental department	
Dr.Nadia Muneeb	consultant	Dental department	
Dr.Reem Almashat	Assesstant consultant	Dental department	

8. Principal Investigator's Assurance:

The undersigned agrees to accept responsibility for the scientific and technical conduct of the proposed research and submission of progress reports if this application is approved.

Rania Baakdal  24/7/18
Name of Principal Investigator Signature Date

DEPARTMENT APPROVAL:

Bander alharbi  24/7/18
Name of Chairman Signature Date

9. Background: (Instructions: Literature review of previous studies on the subject; and justification of the study by stating the problem and its importance)

Introduction

Permanent first molar (FPM) teeth usually erupt when a child is six years of age. They are considered to be the most important permanent teeth because of their numerous roles in the development and maintenance of the occlusion. Saudi oral health reports indicated that caries experience among children was high, and most of the carious teeth were untreated[1]. FPM has been quoted as being the most caries-prone tooth in the permanent dentition, probably as a result of its early exposure to the oral environment and longer eruption time, and dentists must be careful in this period[2]. They should also be able to perform an accurate assessment of caries lesions activity in these teeth, which will be crucial to establish correct management and preventive approach In Saudi study, it was found that 75.5% of first permanent molars are affected with caries or pulpal pathology[3].

Proper care must be taken to maintain FPM throughout the life time. This could be done by utilizing an early preventive measures such as fluoride application or by pit and fissure sealants that may help tooth to be resistance to caries.

However, dental management among children is mostly delayed due to dental care neglect, difficult children management, high number of children with caries and a low number of pediatric dentists. Treatment of decayed FPM among children may range from sealing or restoring the tooth to maintain its pulpal vitality to de-

vitalization and endodontic treatment, possibly followed by the provision of a crown, and to early extraction. It was found that a 70% of first permanent molar extraction was due to badly decayed teeth [4].

In a survey about the used behaviour techniques by dentist in SA to treat pediatric patients, sixty percent (60%) of pediatric dentists in reported using GA to treat their patients[5] .General anesthesia (GA) is considered a good management method to control a child behavior and provide a quality dental care. According to a study done in Saudi Arabia the prevalence of a child younger than 5 years being under GA is 77% and 49% between the age of 5 to 8 [6].

Although high quality of dental treatment is required under GA, anesthetic duration should be considered to avoid additional risk to the patients. Increase in total dental anesthetic time was significantly related to an increase in post-operative complications[7]. Some hospitals recommended 30 minutes as a suitable limit for day stay GA [8.9]. Recently, clinical experience indicated that a maximum length of 2 hours for the whole procedure should not be exceeded when treatment was carried out on a day care facility. In Saudi multicentre study, the mean paediatric dental treatment duration under GA was 97.9 ± 49.9 min and ranged from 5 min to 224 min[3].

To the best of our knowledge there is a lack of studies in Saudi arabia regarding frequency of decayed FPMs under GA and type of treatment used for high caries risk children , Therefore , this study aims to determine the frequency of FPMs treatment and type that was performed for children under GA at KAMC-JED. Additionally,to measure the time needed to treat the cases with FPMs under GA .

10. Objectives of the Study:

10.1 Aim of the Study: (Instructions: state the goal you need to achieve)

- 1-Determine frequency of first permanent molars treated for pediatric patient under GA
- 2- determine type of (FPMs) treated for pediatric patient under (GA)

10.3 Secondary Objectives: (Instructions: these are subsidiary objectives that could be studied during the course of the project but are not the main objectives of the study, they are optional and vary according to the type of the study)

- 1-Determine surgery time for Dental rehabilitation procedure with first permanent molars .
- 2- Relate FPMs treatment type with patient demographic, surgery time, resident factors.

11. Materials and Methods: (Instructions: Describe the research methods that could best achieve the study objectives, recommend to attached flow charts)

11.1 Study Area/Setting: (Instructions: describe the area or setting where the study will be conducted. This description should cover the details relevant to the study topic)

The study will be conducted at King Abdulaziz Medical City in Jeddah through pediatric dental rehabilitation under GA procedure chart review from 2008 to 2018.

11.2 Study Subjects: (Instructions: Inclusion and exclusion criteria of the study subjects)

Inclusion : cases of pediatric dental rehabilitation cases under general anesthesia from 2008 – 2017 for children aged 5 years and above

Exclusion : cases with non erupted first permanent molars.

11.3 Study Design: (Instructions: mention the type of study design eg cross-sectional, case- control, intervention study, etc..)

This is a cross sectional study. It will include all cases of pediatric dental rehabilitation cases under general anesthesia from 2008 – 2017 for children aged 5 years and above, except cases with non-erupted first permanent molars.

11.4 Sample Size: (Instructions: mention the input criteria for sample size estimation.)

The list will involve all pediatric dental rehabilitation patients under GA, from 2008 to 2017, which will include 1007 cases and approximately 400 patient will be included in the study.

11.5

Sampling Technique: (Instructions: mention the sampling technique, (e.g. randomization) that will be used in order to obtain a representative sample for your target population.)

This study will include all pediatric patient under general anasthisia, so sampling technique is not required.

11.6 Data Collection methods, instruments used, measurements (Instructions: Describe the instruments used for data collection (questionnaire, observation recording from, etc.), and studied variables included in these instruments, as well as the methods used to test for the validity and reliability of the instrument. Techniques used should be briefly described and referenced. Study definitions [e.g., case definition] should be mentioned.

This cross sectional study will review the surgery chart for pediatric dental rehabilitation procedure under GA at King Abdulaziz Medical City (KAMC)- Jeddah from 2008 – 2017.

The data collection will be divided into sections :

- 1- patient demographic data (age, gender, date of birth, medical status) .
- 2- procedure information (date of OR , the treating physician /resident ,FPMs treatment surface and type , other teeth total treatment , complications report) .
- 3- surgical timing (start and end).

11.7 Data Management and Analysis Plan: (Instruction: Describe the analysis plan, tests used for data analysis and statistical package(s) used)

The data collected will be imported into SPSS version 24.

Descriptive statistics will be reported as averages and percentage where appropriate.

Analytical statistics will be performed using T test or chi square test to find the relationships between multiple variables.

Bibliographic References: (Instructions: mention recent articles relevant to the study subject and enumerated according to their order of appearance in the text)

1. Al-kateeb TL, Al-Marsafi Al, Omullane DM (1991). Caries prevalence and treatment need among children in an Arabian community. Community Dent Oral Epidemiol 19:277-280
2. Al-amoudi N, Salako NO and Massoud I (1996). Caries experience of children aged 6-9 years in Jeddah, Saudi Arabia. Int J Pediatr Dent 6:101-105
3. Bakdah R, Farsi N, Boker A, Al Mushayt A. The use of general anesthesia in pediatric dental care of children at multi-dental centers in Saudi Arabia. J Clin Pediatr Dent 2008 winter 33(2):147-53
4. Al-Samadani, K.H. and M.S. Ahmad, *Prevalence of First Permanent Molar Caries in and Its Relationship to the Dental Knowledge of 9–12-Year Olds from Jeddah, Kingdom of Saudi Arabia*. ISRN dentistry, 2012. **2012**.
5. Franklin, D., *Extraction of first permanent molars*. British Dental Journal, 2007. **203**(7): p. 408.
6. Jamjoom, M., et al., *Dental treatment under general anaesthesia at a hospital in Jeddah, Saudi Arabia*. International journal of paediatric dentistry, 2001. **11**(2): p. 110-116.
7. Atan S, Ashely P, Gilthorpe M.S, Scheer B, and Mason C, Roberts G (2004). Morbidity following dental treatment of children under intubation general anesthesia in a day-stay unit. Int J Pediatr Dent 14: 9–16.
8. Ogg TW, McDonald IA, Jennings RA, and Morrison CG (1983). Day-case dental anesthesia: evaluation of three methods of anesthesia. Br Dent J 155:14-17.
9. Holt RD, Chidiac RH. and Rule DC (1991). Dental treatment for children under general anesthesia in day care facilities at a London dental hospital. Br Dent J 170: 262-266.

12. **Ethical Considerations:** Informed Consent (Instructions: If needed, please attach Informed Consent and/or extra documents. Translated forms are provided when needed.)

IRB approval will be requested prior to the conduct of the study. All patient information will be confidential with no patient identifiers. Each subject will be assigned a study code number inserted. Given the retrospective nature of the study, no harm will be introduced to the patients. All data will be collected and will be locked in an electronic format. Privacy and confidentiality will be completely protected. No identifiers or personal information will be collected or stored. All data will be kept within NGHA premises both hard and soft copies.

14. **Workplan:** (Instructions: Please use this form as a template for the timeline of your project)

Task	Weeks				
	1	2	3	4	5
Progress report					

<p>15. Other Funding Agency</p> <p>Does this study need fund? Yes [] No [0]</p> <p>Is your study funded by another funding agency? Yes [] No [x]</p> <p>(If yes, specify the agency and available funds)</p>	<p>16.</p>	<p>17.</p>
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16. Budget (Please use the attached documents for the price list of equipments used in the project if applicable)

Budget Breakdown	Unit Cost (SR)	Total (SR)	Remarks
Personnel *			
<i>Total</i>			
Supplies and Equipment			
<i>Total</i>			
Patients Cost			
<i>Total</i>			
Others (please, specify and justify briefly)			

<i>Total</i>			
GRAND TOTAL			

- Funds allocated to all personnel should not exceed 30% of the total budget, otherwise justification letter should be included
- Unit cost of each task should be accurately given to allow proper budget evaluation.

17. Appendices: (Instructions: Data collection instruments, elaboration on methods and procedures to be used, etc.) (Please attach the related documents)

Excel Data collection sheet form