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**RATE OF REJECTION OF HAEMATOLOGY SAMPLES IN PATHOLOGY DEPARTMENT IN PORT
MORESBY GENERAL HOSPITAL: A RETROSPECTIVE STUDY**

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ABSTRACT:

The objectives of this study were to determine the rate of rejection of blood samples sent to the haematology section in the Pathology laboratory and to identify the areas of sample collection and the reasons for rejection. This retrospective study was conducted at the Port Moresby General Hospital within the period April 2012 to March 2013. The data was retrieved from the sample registration records in the haematology section. The percent cumulative rate of sample rejection over the 12 months duration of the study was 1.44%. The areas with the highest rate of rejected samples were those from the accident and emergency ward (23.19%) followed by children's ward (22.39%). Some of the causes for rejection were clotting of blood samples (19.24%) followed by requisition forms without samples (18.32%) and unlabelled samples (15.65%). Thus, technical errors in the pre-analytical phase of the laboratory testing were among the common reasons for rejection. This include insufficient blood collection, not inverting the sample bottle straight after collecting the blood for effective mixing with the anti-coagulant to prevent clotting, incorrect labelling of samples and request forms, and sending samples unaccompanied by request forms. The pre-analytical phase is vital in ensuring sample integrity and correct patient identification.

Keywords: Haematology, Anticoagulant, Blood sample, Rejection

INTRODUCTION:

Port Moresby General Hospital (PMGH) is owned by the state and is located at 3 mile in the National Capital District (NCD). It is the main referral hospital in Papua New Guinea (PNG). The facilities include, Outpatient (general enquires, accidents and emergency department, adult outpatient clinics, children outpatient); Children's ward (Wards 2A-Cardiac, 2B-Resperitory track, 2C-Diarrhoea, 2D-Tuberculosis and Special Care Nursery); Gynaecology wards (Ward 9, Ward 10, Anti-natal clinic and Labour ward); Medical wards (4A, 4B, 4C, and 4D); Surgical wards (3A, 3B, 3C); Intermediate ward; Special wards (intensive care unit); Consultation clinic and Dental clinic. Specialities include Heart Foundation units, Pathology laboratory, X-Ray department and Pharmacy department.

Haematology laboratory is one of the Pathology laboratory sections of the PMGH. It receives specimen and samples every day from outpatient draw stations, inpatient wards, and drop offs from patients and doctor offices. It serves the public and private hospitals as well as clinics in NCD and the whole country.

The common haematology requests received include, full blood count and blood coagulation profile that require blood to be added into specific volume of anticoagulant to maintain the

un-clotted blood [1]. The haematology results generated from samples that are submitted are only reliable if the required amount of blood samples are collected in the appropriate containers labelled appropriately and transported immediately to the haematology laboratory [1]. It is sometimes difficult to reject a blood sample, especially from neonates; however, accurate results cannot be obtained from poorly collected blood samples. Therefore laboratories establish rejection criteria and policies that must be appropriately implemented to ensure high quality control and quality assurance [2 - 4]. The haematology standard operating procedure (SOP) manual provides guidelines for the collection and handling of blood samples, but with no clear documented reasons for rejection.

The objectives of this study were to determine the rate of rejection of blood samples sent to the haematology section in the Pathology laboratory and to identify the areas of sample collection and the reasons for rejection.

METHODOLOGY:

This was a retrospective study carried out to investigate the rate of haematology specimen rejection in Pathology department at the PMGH during the period April 2012 to March 2013. The data were retrieved from the laboratory records of samples for routine haematology

testing. The data was appropriately sorted and all required information including monthly rejections, rejection sites, and reasons for rejection were obtained and tabulated for analyses.

The study proposal was granted ethical clearance by the School of Medicine and Health Sciences Research and Ethics Committee. Additional ethical clearance and permission were obtained from the Medical Service Officer at the PMGH and the National Department of Health Papua New Guinea.

RESULTS:

A total of 75,353 blood samples were received for haematology analysis from April 2012 to March 2013. It was noted that 74,267 were analysed and of these 1086 samples were rejected giving the rejection rate of 1.44% (1086/75,353) as shown in Table 1. As shown in the Table the highest rejection rate (2.065) was in March 2013 and the lowest (.076%) was in April 2012.

Rejected Samples and sites of collection:

The highest number, 80.20% (871/1086) of rejected samples were from the various wards and clinics in PMGH. This was followed by 8.93% (97/1086) from other health centres and clinics (Gerehu, Laloki, 6-mile, Gordon, Tokarara, Taurama, and University of Papua New Guinea) within NCD. The rate of rejected

samples from other hospital and clinics is shown in Table 2.

In the PMGH, the rate of rejected haematology samples varies at the different wards and clinics. The highest rate of rejection site was from the accidents and emergency ward with 23.19% (202/871), followed by children's ward- (2A, 2B, 2C, 2D, 2E,) including children's outpatient with 22.39% (195/871). Rejections from all the other wards were less than 10% as shown in Table 3.

Reasons for specimen rejection:

Reasons for specimen rejection indicated that the clotted samples for full blood examination were the most common with 19.24% (209/1086). Other causes of rejection observed were requisition forms without samples, 18.3% (199/1086), 15.65% (170/1086) unlabelled samples, 13.90% (151/1086) without laboratory request forms, 12.89% (140/1086) with incorrect tube/incorrect cap and the other reasons are shown in Table 4.

The rate of rejection in the children wards was mainly specimen insufficient with 14.87% (29/195), followed by clotted specimen and wrong tube with 11.79% (23/195) each. While in the accident and emergency rate of rejection was due to no requisition form 17.82% (36/202), followed by forms without sample and unlabelled, 16.34% (33/202) respectively and clotted sample, 11.4% (23/202).

Table 1: Monthly distribution of total number of blood samples received, analysed, and rejected over the 12 months duration of the study.

Year	Month	Total Receive	Total Analysed	Total Rejects	Rejection Rate (%)
2012	April	6,026	5,980	46	0.76
2012	May	6,890	6,797	93	1.35
2012	June	6,196	6,090	106	1.71
2012	July	6,902	6,804	98	1.42
2012	August	6,981	6,885	96	1.38
2012	September	6,171	6,101	70	1.13
2012	October	7,232	7,165	67	0.93
2012	November	6,173	6,085	88	1.43
2012	December	4,155	4,073	82	1.97
2013	January	5,000	4,915	85	1.7
2013	February	6,362	6,257	105	1.65
2013	March	7,264	7,115	150	2.06
TOTAL		75,353	74,267	1,086	1.44

Table 2: Number (%) of rejected samples and sites of collection during the 12 months duration of the study

Hospitals and Clinics	Number (%) of rejected samples
Port Moresby General Hospital (all wards/outpatient and consultation offices)	871 (80.2%)
Other health centres and clinics within National Capital District	97 (8.9%)
Not specified	80 (7.4%)
Private Hospitals and private clinics	37 (3.4%)
Outside provinces	1 (0.1%)
Total	1086 (100%)

Table 3: Distribution (%) of rejected samples from the Wards and clinics in PMGH

Wards and clinic in PMGH	Number (%)
Accident and Emergency	202 (23.19%)
Children's Ward (2A, 2B, 2C, 2D, 2E, COPD)	195 (22.39%)
Medical Ward (4A, 4B, 4C, 4D)	81 (9.3%)
Surgical Ward (3A, 3B, 3C)	78 (8.96%)
Special Care Nursery	74 (8.50%)
Antenatal Clinic (10)	48 (5.51%)
Heduru clinic (Sexually transmitted disease)	48 (5.51%)
Gynaecology (Ward 9)	43 (4.94%)
Labour Ward	23 (2.64%)
Consultation Clinic	17 (1.95%)
Ward 8	14 (1.61%)
Intensive care unit	14 (1.61%)
Ward 7	11 (1.26%)
Psychiatry (Ward 6)	7 (0.80%)
Pathology	6 (0.69%)
Eye clinic	4 (0.46%)
Diabetes clinic	3 (0.34%)
Skin Clinic	2 (0.23%)
Dental Clinic	1 (0.11%)
TOTAL	871 (100%)

DISCUSSION:

Identifying the technical errors and rate of rejection is important in the quality of laboratory results. We conducted a retrospective study to identify the proportions of rejected specimens at the haematology laboratory. We detected an overall specimen rejection rate of 1.44%. The specimen rejection rates differ from developing [6 – 10] and developed countries [7 – 11]. In this retrospective study the rejection rate were

similar to that reported in India 1.99% [6] and in Turkey 0.56% [7]. The highest prevalence of rejected specimen 2.1% (150/7264) was in March 2013, the lowest prevalence, 0.76% (46/6026), was in April 2012. Table 4 shows the data obtained for all the other months.

The causes for rejection were due to clotting of specimens (19.24%) followed by requisition forms without samples (18.32%) and unlabelled samples (15.65%). The clotted samples, is

probably due to poor gentle mixing after blood collection and leaving the tubes horizontally instead of keeping them vertical [7].

Parentmark and Landberg [10], reported that mixing blood samples after collection is important but may produce haemolysis. In this study haemolysis number was very low (0.18%) in contrast to other studies elsewhere. Laboratory request forms without blood specimen are the second most common reason (18.32%) for sample rejection, which is due mainly to preanalytical errors. Goswami et al., [6] clearly identified that wrong patient identification should be targeted throughout the hospital that can lead to unsuitable specimens eventually rejected when received in the medical laboratory.

It was observed that unlabelled samples (15.56%), no laboratory request form (13.90%), wrong tube/wrong cap (12.89%), insufficient sample (9.30%), name/details not correspond (5.89%), wrong request form (0.28%) are mostly due to carelessness or to get the job done hurriedly [6]. It is not surprising to see insufficient blood collected from children and neonates who may be frightened during the phlebotomy procedures. Furthermore collection of blood from children and neonates is difficult and requires a specialist phlebotomist and not a ward staff. Hence ward staff should be

trained to collect blood samples for haematology and biochemistry [7].

The rejection rate was higher at the accident and emergency followed by children's ward but less in the clinic at the PMGH. The highest rate of rejected samples was in the accident and emergency ward (23.19%) followed by children's ward (22.39%). This proves that proper training, guidance and supervised collection can help to attain efficacy as well as minimize these preventable errors which are beneficial to patients and physicians [6, 8].

One of the limitations of our study was that we could only give the results of the wards but not the different sections of those wards at the PMGH.

CONCLUSION:

Blood sample rejection in haematology prevents sample analysis and leads to new sample request, which delay in patient's diagnosis and treatment [9]. The total rate of rejected blood samples in haematology section at the Pathology laboratory in PMGH during the period of this study was 1.44%. In PMGH the rejection rate was higher in accident and emergency ward (23.19%) and children's wards including the children's outpatient (22.39%). The main reasons for the specimen's rejection were the unwanted clotting (19.24%) and followed by requisition forms without sample (18.32%). For these reasons there is a

need to improve blood collection techniques, handling and transportation on haematology blood samples so that required tests are performed appropriately and accurate results generated [2]. Further studies should be done to enhance documentation, include policy on sample rejection in the SOP manual and periodic training for healthcare personnel working in the wards and clinics with high rates of rejection.

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ZINC NUTRITIONAL STATUS AND ANTHROPOMETRIC INDICES OF PRESCHOOL CHILDREN LIVING IN A RURAL COMMUNITY IN EDO STATE, NIGERIA

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ABSTRACT:

Zinc deficiency impairs growth and development but epidemiological data for zinc nutrition status among preschool children living in rural areas of Nigeria is lacking. The aim of the present study was to assess the zinc status and anthropometric indices of children aged between 6 and 60 months, living in a rural community in Edo State, Nigeria. In this community-based cross-sectional study, five out of the nine political wards (quarters) in the community were randomly selected; all the households with children aged between 6 and 60 months were included the study. A total of 252 children were selected to participate after obtaining informed consent from their parents. Steps were taken to avoid exogenous zinc contamination of the blood samples which were collected in the mornings. The serum zinc levels of the subjects were determined, using flame atomic absorption spectrophotometry. The weights, heights, head and mid-upper arm circumferences of each child were measured, using standard procedures. Z-scores of anthropometric indices of height-for-age, weight-for-age and weight-for-height were computed to assess the nutritional status of the children. The mean age of the study population was 32.7 ± 17.0 months. The prevalence rates of stunting, underweight and wasting among the children were 18.2%, 14.7% and 11.1%, respectively. The overall mean serum zinc concentration was $4.77 \pm 3.02 \mu\text{mol/L}$, with a range of $1.0\text{--}16.52 \mu\text{mol/L}$. Of the 252 children, 220 (87.3%) had mean serum zinc concentration below $7.65 \mu\text{mol/L}$, representing severe zinc deficiency. The highest mean serum zinc concentration was found among children aged 6 to 12 months and this was followed by a progressive decline in serum zinc concentration from the age of 13 months up to 48 months. Correlation between the serum zinc concentration of the children and their age and social class of the parents were as follows: age, $r = 0.09$, at $p = 0.15$; social class, $r = 0.08$; at $p = 0.21$. The children with wasting had the lowest mean serum zinc concentration compared with either the group with underweight or stunting. The zinc nutritional status of preschool-age children in this community clearly indicates a suboptimal zinc status at the time of this study. According to the IZiNCG criteria, this should be considered as a public health problem among preschool-age children in this community. To effectively address the issue, social mobilization, intensive education and awareness campaign, with all target groups and policy makers are urgently required. Public health measures aimed at improving their zinc nutritional status should also be considered.

Keywords: Zinc status, rural community, preschool children, stunting, underweight, wasting.

INTRODUCTION:

Zinc is an essential micronutrient which is ubiquitous in human biological systems and vital for protein synthesis, cellular growth, cellular differentiation, immune function and cognitive development [1]. The zinc content of foods which is the major source of zinc in an individual's body, varies widely. Some of the good sources of dietary zinc include red meats (especially organ meats) and sea foods (especially oysters and shellfish), poultry, pork, fish and dairy products [1]. Vegetables are good plant sources of zinc [1]. Zinc intake from breast milk varies during lactation as the breast milk content decreases from approximately 12mg/L in colostrums to 1.6, 1.1 and 0.5mg/L at 3, 6 and 12 months, respectively [2]. After the age of six months, older breast feeding infants depend on complementary food for a substantial part of their zinc requirements and this represents the period of special concern regarding zinc nutrition [3]. Complementary foods containing phytates are not only low in zinc content but some also, reduce bioavailability of zinc from breast milk [4]. Processing of certain foods may affect availability of zinc for absorption. For example, heat treatment can cause food zinc to form complexes that are resistant to hydrolysis, thereby making zinc unavailable for absorption [1]. In preschool children, suboptimal zinc nutrition constitutes a significant health risk with regard to growth and cognitive development [1,3]. Attained height is the result of interaction

between genetic endowment and both macro- and micronutrient consumption and bioavailability during the growth period. Linear growth occurs through a process of cell proliferation, the addition of new cells to growth plate of the bone and hypertrophy, resulting in expansion of growth plate [5]. Some micronutrients affect the insulin-like growth factor-I (IGF-I) system. For example, animal studies show that zinc deficiency in rats causes not only growth retardation but also a decrease in both IGF-I plasma concentration and growth hormone (GH) receptors, which return to normal after zinc repletion [6]. In addition, through its influence on the GH/IGF-I system, zinc deficiency has been observed to affect bone metabolism [7]. The role of zinc in growth also may be explained in part through its participation in DNA synthesis [8]. In many developing countries, including Nigeria, growth disorders among children are under-diagnosed because weights and particularly, heights are not routinely measured and recorded during visits to healthcare institutions for other ailments. Studies have shown conclusively that zinc supplementation improves linear growth in infants, preschoolers and older prepubertal children [9, 10], confirming the requirement of adequate zinc intake for normal growth. In some developing countries, zinc deficiency is common and represents a major public health problem [11-15]. The report of a study in Cameroon revealed a zinc deficiency prevalence of 82.6% in children [16]. The major

aetiologic factors of childhood zinc deficiency in developing countries include low intake of zinc-rich foods, poor bioavailability of zinc, and the presence of parasitic infections of the gastrointestinal tract [17-19]. In the paediatric age group, nutritional status is classified as underweight (Weight-for-Age; WAZ: less than minus 2SD, Z-score); Wasting (Weight-for-Height; WHZ: less than minus 2SD, Z-score); and Stunting (Height-for-Age, HAZ: less than minus 2SD, Z-score) [20]. Stunting (HAZ) results from chronic undernutrition which retards linear growth; whereas wasting (WHZ) results from inadequate nutrition over a shorter period and underweight (WAZ) encompasses both stunting and wasting [20]. Nigerian complementary foods consist mainly of starchy tubers (yam, cassava, cocoyam) and cereal-based gruels made from maize, millet, guinea corn [21, 22]. These food items may have inadequate zinc content [22]. The results of some Nigerian studies have revealed high prevalence of zinc deficiency, ranging from 41.5% to 63.3% [12, 15]. The purpose of the present study was to assess the zinc nutritional status and anthropometric indices of children aged between 6 and 60 months, living in a rural community in Edo State, Nigeria.

SUBJECTS AND METHODS:

This descriptive cross-sectional study was conducted over a period of 3 months, from January to March, 2013. Ethical approval for the study was obtained from the Ethics and

Research Committee of the University of Benin Teaching Hospital. The details of the study were explained to the chief of Udo community (the Uwague) with his subordinates (heads of the political wards) in attendance. Each of the heads of the political wards informed the heads of every household within his domain. Informed consent was also obtained from the parents of the children who participated in the study.

Study area location:

The study was conducted in Udo, a rural community in Ovia South West Local Government Area (LGA) of Edo State, Nigeria. The community is made up of 9 political wards (quarters), namely Ogbe, Efa, Ihogbe, Oliha, Ikpema, Igbesanwan, Ido, Ebo and Aragua. Each of these wards is headed by a chief. These chiefs in the wards are subordinate to the Uwague, the overall chief of Udo community. The major occupation of the inhabitants is subsistent farming. Some of the men and women are also engage in hunting and petty trading, respectively. In a nearby community (Okomu), there is Palm Oil Extracting Factory which process palm nuts into palm oil and where some of the men are employed as unskilled workers.

Sampling and recruitment of study population:

The study population consisted of children aged between 6 and 60 months who were residing with their parents at Udo community

during the study period and whose parents gave consent. The houses in the community were numbered and labelled. The members of each of the households were interviewed to determine the number and ages of persons in each household. Direct head counts carried out revealed that children aged between 6 and 60 months were 1,028 in the study area. The minimum sample size for the study population was obtained, using the minimum sample size determination table by Bartlett et al [23]. Based on this table, the minimum sample size obtained was 213. To accommodate losses of blood samples (e.g., haemolysis) and unforeseen laboratory problems a high attrition rate of 35% was built-in, resulting in a final sample size of 292. An interviewer-administered questionnaire was used in obtaining socio-demographic information. Fifty percent of the 9 wards (approximately 5) in Udo community were selected, using a table of random numbers. The political wards selected were Efa, Ogbe, Ihogbe, Ikpema and Aragua. Due to the uneven population size in these political wards, an appropriate random sampling technique was used in selecting the subjects from the selected political wards. The number of children between the ages of 6 to 60 months in each of these political wards was known and so, the number to be selected from each of the wards was allocated proportionately, using percentages as follows: Efa 28% (82 children), Ogbe 36% (103 children), Ihogbe 18% (53 children), Ikpema

5% (16 children) and Aragua 13% (38 children). The number of households in each ward was known. Some of the households did not have the category of children of interest in this study. In addition, some parents refused to give consent. Thus, the number of households available for study was reduced. The households with children aged 6 to 60 months and whose parents gave consent were included in the study. To ensure adequate spread, a maximum of two children from each household were recruited. The socio-economic status of the parents was determined [24]. This was analyzed via combining the highest educational attainment of the mother and father's occupation. In this social classification System, classes I and II represent the high social class, class III represents middle social class and class IV and V represent low social class. In this way, the subjects were categorized into high, middle and low socio-economic classes. The family size was categorized into small size (no sibling or one to two siblings); medium size (3 or 4 siblings); large size (5 or more siblings).

Anthropometric measurements:

We strictly followed the standard procedure recommended by the International Society for the Advancement of Kinanthropometry (ISAK) in the measurement of the height (length if the child was aged below 2 years), weight, mid-upper-arm circumference and head circumference of all the children [25]. To

eliminate inter-observer error, all the anthropometric measurements were performed by trained personnel. All the children were physically examined.

Blood sample collection and serum zinc analysis:

Before collection of blood sample, the socio-demographic data of the parents or guardian of each child were obtained, using an interviewer-administered questionnaire. Three to 4mls of venous blood was collected from each child. We followed the recommended steps necessary to avoid exogenous contamination of the blood sample by zinc [26]. To minimize effects of diurnal variation, the blood samples were collected in the mornings. To prevent transfer of zinc from the blood cells to the serum, the blood samples were stored in a cool box at 2 to 10°C until centrifuged to separate the serum from the blood cells. Following centrifugation, the serum was transferred to a screw-top vial for storage at -20°C, until analysis [27]. The serum zinc was analysed by flame atomic absorption spectrophotometer (FAAS); the equipment used was Alpha 4-model, S/No 4200 by Chemtech Analytical, United Kingdom.

Although various cut-off points for zinc deficiency have been used in different studies, in consonance with the report of previous studies [26, 28, 29], serum zinc concentration

below 7.65µmol/L (50.03µg/dl) defined severe clinical zinc deficiency in our study.

Data analysis:

The data were collated and entered into an Excel spread sheet. Accuracy of the data entered was double checked. Data were analysed, using Microsoft Excel and SPSS (Statistical Package for Social Sciences) version 20.0. Measures of central tendency and dispersion involving the mean and standard deviation were computed for all quantitative data. Confidence intervals, frequency distribution and percentages were calculated. Correlation and multiple linear regression analysis were employed to evaluate the degree of relationships between variables. Test for significant differences between means of variables was carried out, using the Single Factor Analysis of Variance (ANOVA). The level of statistical significance was set at $p < 0.05$.

RESULTS:

We analyzed the data of a total of 252 children aged between 6 and 60 months. Of this number, 134(53.2%) were males and 118(46.8%) females. The mean age was similar for both sexes and the combined mean age was 32.7 ± 17.0 months. The age distribution of the children indicates that 13 to 24 months age group accounts for the highest (26.2%) proportion.

Table 1: Anthropometric parameters, correlation between serum zinc concentrations and anthropometric indices

Parameters	Mean \pm SD	95% Confidence Interval	Correlation coefficient (r) with Zinc conc	p-value
Weight (kg)	12.0 \pm 3.0	11.6-12.4	- 0.08	0.2
Height(cm)	88.3 \pm 12.4	86.8-89.8	- 0.11	0.07
MUAC(cm)	15.3 \pm 1.3	15.1-15.5	- 0.09	0.15
BMI(kg/m ²)	15.4 \pm 2.1	15.1-15.7	0.08	0.23
OFC(cm)	47.4 \pm 2.4	47.4-47.7	0.07	0.34

MUAC = Mid-upper-arm circumference; OFC = Occipito-frontal circumference; BMI = Body mass index; Significant: p < 0.05

Table 2: Mean serum zinc concentrations by different variables

Variables	Subjects N = 252 (%)	Serum Zinc conc. Mean \pm SD μ mol/L	95% CI	F	p-value
Age (months)					
6-12	37(14.7)	5.43 \pm 3.52	4.30-6.56	0.248	0.29
13-24	66(26.2)	5.03 \pm 3.14	4.27-5.79		
25-36	57(22.6)	4.78 \pm 2.92	4.02-5.54		
37-48	40(15.9)	4.05 \pm 2.44	3.29-4.81		
49-60	52(20.6)	4.48 \pm 2.95	3.68-5.28		
Gender					
Male	134(53.2)	4.95 \pm 3.21	4.41-5.49	0.997	0.33
Female	118(46.8)	4.57 \pm 2.80	4.06-5.08		
Social class					
Low	207(82.1)	4.66 \pm 2.91	4.26-5.06	0.800	0.44
Middle	42(16.7)	5.30 \pm 3.48	4.25-6.35		
High	3(1.2)	5.05 \pm 3.97	0.56-9.53		
Family size					
Small	79(31.3)	5.27 \pm 3.45	4.51-6.03	1.55	0.21
Medium	112(44.4)	4.56 \pm 2.89	4.22-5.10		
Large	61(24.3)	4.53 \pm 2.64	3.87-5.19		
Weight-for-age					
Normal	214(84.9)	4.78 \pm 3.00	4.38-5.18	0.340	0.97
Underweight	37(14.7)	4.70 \pm 3.23	3.65-5.74		
Overweight	1(0.4)	4.14 \pm 3.02	0-10.06		
Height-for-age					
Normal	163(64.7)	4.81 \pm 3.01	4.35-5.27	0.196	0.82
Stunted	46(18.2)	4.85 \pm 3.26	3.91-5.79		
Tall	43(17.1)	4.50 \pm 2.84	3.65-5.35		
Weight-for-height					
Normal	217(86.1)	4.92 \pm 3.06	4.51-5.33	2.176	0.12
Wasted	28(11.1)	3.94 \pm 2.86	2.88-5.00		
Overweight	7(2.8)	3.30 \pm 1.20	2.41-4.19		

The distribution of social class of the 252 families was as follows: low 207(82%), middle 42(17%) and high 3(1.0%). The mean weight, height, mid-upper-arm circumference and head circumference of the children are shown in Table 1. Of the 252 children, the weight and height values were within normal limits in 214(84.9%) and 163(64.7%), respectively. Only one (0.4%) child was overweight. Forty three (17.1%) of the children were taller than expected for their age. Of the 252 children, the values of the mid-upper-arm circumference (MUAC) were normal in 249(97.2%), low in 2(0.8%) and elevated in one child.

Based on the head circumferences, eight (3.2%) out of all the subjects had small heads and 2(0.8%) had big heads. As depicted in Table 1, there was a negative correlation between serum zinc concentrations and weight, height or mid-upper arm circumference but these were however, not statistically significant. As shown in Table 2, the prevalence rates of stunting, underweight and wasting were 18.2%, 14.7% and 11.1%, respectively. The overall mean serum zinc concentration was $4.77 \pm 3.02 \mu\text{mol/L}$, with a range of 1.0-16.52 $\mu\text{mol/L}$. Of the 252 subjects, 220(87.3%) had a serum zinc concentration below 7.65 $\mu\text{mol/L}$, representing severe zinc deficiency. As depicted in Table 2, the highest mean serum zinc concentration was found among children aged 6 to 12 months, followed by a progressive decline in serum zinc

concentration from the age of 13 up to 48 months. As a group, the children with wasting had the lowest mean serum zinc concentration compared with either the group with underweight or stunting (Table 2). Correlation between the serum zinc concentration and age or social class of the subjects or family size (number of children) were as follows: age, $r = 0.09$, $p\text{-value} = 0.15$; social class, $r = 0.08$; $p\text{-value} = 0.21$, family size, $r = -0.07$; $p\text{-value} = 0.25$.

DISCUSSION:

We found a generally low mean serum zinc concentrations across all the age groups, gender and social classes with an overall high prevalence rate of zinc deficiency. Such a low mean serum zinc concentration has been reported from Saudi Arabia [29], Nepal [30] and Nigeria [31]. In the study from Saudi Arabia, the mean serum zinc concentration was 5.65 $\mu\text{mol/L}$, with a range of 0.5-13.9 $\mu\text{mol/L}$ among healthy children [29]. The mean serum zinc concentration reported in the study in Nepal was $6.8 \pm 3.5 \mu\text{mol/L}$ [30]. Similarly, Atinmo et al reported that among 10 apparently healthy Nigerian children used as control subjects, the serum zinc concentration ranged from 5.6 to 10.5 $\mu\text{mol/L}$ [31]. However, the prevalence of zinc deficiency was not reported in both studies [29, 31]. In contrast, the mean serum zinc concentration found in the present study is much lower than $12.50 \pm 2.30 \mu\text{mol/L}$

reported among preschool children in Iran [32]. This difference may be a reflection of the regional variation in zinc status, even among developing countries.

With regard to age, the highest mean serum zinc concentration was found among children aged 6 to 12 months but the differences were not statistically significant from the other age groups. This was followed by a trend toward a progressive decline from the age of 13 months up to 48 months. Two separate studies involving preschool children in India and Australia have reported a similar age-related trend in zinc status [13, 33]. The trend towards a progressive decline in mean serum zinc concentration from the age of 13 months up to the age of 48 months could be explained by the challenges of introduction of complementary foods with low zinc content and high phytate. This precarious state of nutrition may be further compounded by high rates of infections. Infections are known to be associated with lower serum zinc concentrations [13]. The high prevalence of intestinal parasitic infections in toddlers (aged 1-to-3-year olds) in some developing countries is a factor that can contribute to the lower serum zinc concentration in this group of children [14, 18, 19, 32]. In children, intestinal parasitic infections is a known cause of poor zinc status [14, 18, 19].

The mean serum zinc concentration varied with social class of the families of the subjects; the mean serum zinc concentration was lowest in

the low social class group. Children from families in the low socio-economic class may have reduced access to zinc-rich foods which are more expensive, mostly from animal sources, accounting for the lower serum zinc concentration we observed among them. In addition, higher prevalence and intensity of intestinal parasitic infections has been associated with low socio-economic conditions in children of peasant farmers in Calabar, Nigeria [35]. In that study, the authors attributed the high prevalence and intensity of intestinal parasitic infections to inadequate water supply and poor sanitary disposal of human wastes linked to poor socio-economic conditions [35]. The main occupation of the inhabitants in the rural community, in our present study is subsistence farming, heightening the possibility that this factor may be contributory.

In the present study, differences in the serum zinc concentrations and age as well as gender were not statistically significant, but a trend towards a higher serum zinc concentration in infants, boys, high social class and small family size was observed.

In the present study, we found a low serum zinc concentration in all categories of anthropometric indices. Where a difference existed, it was not statistically significant. This finding is in consonance with some [30, 36] but not other studies [37, 38]. The lack of

significant relationship between serum zinc concentration and the anthropometric indices might suggest that other factors capable of limiting growth such as chronic infection and simultaneous existence of two or more micronutrient deficiencies may play a role. Some studies have shown co-existence of deficiency of more than one micronutrient in preschool children [39].

Our data indicate that 18.2% of preschool children in this community were stunted. Although the prevalence rate (18.2%) of stunting was slightly less than the 20% cut-off indicating zinc deficiency of public health importance, it still remains a cause for concern, especially because of the known adverse effects of zinc deficiency on growth, cognitive development and the incidence as well as intensity of bacterial infections in preschool age children [10,13,26]. The prevalence rate of stunting in the present study is similar to 18.6% reported in a study conducted in Vhembe district, South Africa [40] but much lower than 41.26% reported among preschool children in a rural community in Cameroon [41].

The 18.2% prevalence rate of stunting we found is strikingly different from the 0.8% prevalence rate reported in another study in Nigeria [15]. The reason for this difference is not clear. However, it should be noted the National Center for Health Statistics (NCHS) reference standard [42] was used in our

present study compared to the World Health Organisation (WHO) reference standard used in the other study for anthropometric classification [15]. Reports show that prevalence of stunting may be higher when WHO 2006 reference standard is used compared with when NCHS reference standard is used [43]. The results of another Nigerian study that used WHO reference standard revealed a prevalence rate of stunting of 12.5% [39]. The prevalence of wasting found in our study was similar to the 11.9% and 14.8% reported in two separate studies among Nigerian preschool children [15, 39]. One limitation of the present study was our inability to assess the dietary zinc intake and its bioavailability in the diets of the children.

In conclusion, the zinc nutritional status of preschool children in this community is suboptimal; public health measures aimed at improving their zinc nutrition status should be considered. Public health measures such as nutrition education (e.g., dietary diversification, improvement in food processing techniques), targeted supplementation, and fortification of staple foods with zinc are suggested.

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TRANSFERRING THE ABORIGINAL AUSTRALIAN FAMILY WELLBEING EMPOWERMENT PROGRAM FROM A PAPUA NEW GUINEA UNIVERSITY CONTEXT TO BROADER COMMUNITY SETTINGS: A FEASIBILITY STUDY

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ABSTRACT:

This study aims to assess the feasibility of transferring the Aboriginal Family Wellbeing empowerment program (FWB) from a Papua New Guinea (PNG) tertiary setting to broader community contexts to address the problem of endemic interpersonal violence and to generate pilot data to inform future community wellbeing interventions in PNG. Levels of wellbeing among a convenience sample of 100 participants recruited from Bereina station, Kairuku- Hiri District and other parts of the National Capital District and Central Province were assessed using a cross-sectional survey with an anonymous self-administered questionnaire. Follow-up FWB pilot workshops conducted in Bereina station for participants in the wellbeing survey used standardised FWB workshop evaluation questionnaires to obtain community feedback on the relevance of the program. Up to one in four females and over half of males who completed the survey reported being a victim of actual or threatened violence in the last 12 months. In terms of wellbeing, participants were least satisfied with their standards of living and most satisfied with spirituality. Workshop participants could see that FWB has the potential to address community concerns, including interpersonal violence, as it provides a process for identifying basic community needs and introduces skills to address conflict. The challenges and opportunities involved in sustaining such programs at community levels are highlighted.

Keywords: Feasibility, Transferring, Family wellbeing, Interventions, Interpersonal violence, Community, Sustainability

INTRODUCTION:

Interpersonal violence imposes a significant burden of health harm on both men and women in Papua New Guinea (PNG), including increased HIV risk, hospital admission and

death [1,2]. Violence for men most often takes the form of criminal assault or tribal fights [2]. For women violence involves domestic and family violence and rape, and torture or even murder of women accused of sorcery [3]. The

United Nations Development Program (UNDP) [4] rates PNG 140 out of 146 countries in gender inequality; two-thirds of women in PNG have reported violence and domestic violence accounts for 90% of female trauma in women and girls [2,3, 5].

Interpersonal violence is aggravated by growing unemployment and associated alcohol and drug use among young adults. In PNG, youth unemployment is a major concern, especially for those who have completed primary, secondary or even tertiary education [6,7]. In urban settlements, towns and big villages across the country, there are growing numbers of youths who are unemployed and not engaged in economic or community activities. They are the so-called “drop outs” or “forgotten generation” and are often involved in excessive use of alcohol and drugs, including home brewing, which leads to disharmony within family and communities [6,7, 8]. These young people are also more susceptible or vulnerable to infectious diseases, including HIV, because of the risks associated with excessive alcohol and drug use [9].

Health practitioners, whose role is to provide help at the individual, family and community level, are also affected by interpersonal violence. The level of safety and security in the workplace has been shown to be a factor in health worker motivation [10].

Despite efforts including legislative change, public awareness campaigns and training the levels of interpersonal violence in PNG are

worsening [11,12]. The history of PNG as an independent nation is littered with well-intended, gender-informed policies, plans, programs and other initiatives [11]. The problem has been the lack of a systematic approach to endemic interpersonal violence. Such an approach requires needs assessment, the selection of appropriate, evidence-based interventions in relation to those needs, pilot testing of the interventions and the assessment of their outcomes to establish their feasibility and acceptability, followed by the design of compelling trials to determine what will work in practice [11].

Previous pilot studies established the acceptability and feasibility of the Aboriginal Australian Family Wellbeing (FWB) program in the context of training University of Papua New Guinea (UPNG) public health students in community development [13,14,15]. The students, as well as community and church leaders who later became aware of the program, recommended the potential usefulness of FWB to tackle the high levels of interpersonal violence in PNG communities [13,15].

The present paper responds to the student recommendation and subsequent invitations by church and community leaders by testing the appropriateness of FWB as an interpersonal violence intervention in a community setting. The aim is to generate relevant baseline data to inform future FWB and other community interventions in PNG.

Overview of the FWB program:

This overview of the history, rationale and previous practical application of the FWB program provides a context for the methods and outcomes of the present study.

FWB is an evidence-informed group intervention developed by Aboriginal Australians in 1993 [16] to enhance their individual and collective capacity to negotiate a changing and uncertain world and manage problems associated with being a minority population in their own country [17,18,19].

The program recognises that there are no easy strategies to manage complex problems such as racism and discrimination, transition from traditional to modern lifestyles, poverty, intergenerational trauma, interpersonal violence and substance abuse. FWB seeks to impart communication, self-reflection and analysis skills to empower people to create support networks, develop resiliency and resolve apparently insurmountable problems using creativity and innovation [13,17,19,20].

The FWB approach to empowerment has four main components. First, people meet in small interactive groups and introduced to the premise that as individuals they have the capacity to take control of their lives and make positive changes to improve their day-to-day situation, however dire that may be. Second, a safe space where these ideas can be

discussed and developed is established through the development of negotiated group agreements and peer-support relationships based on confidentiality, honesty, empathy and trust. Third, experiential exercises show participants how to think and communicate effectively emphasising human qualities such as creativity, perseverance, forgiveness, commitment and generosity. Fourth, participants are encouraged to recognise their own experience and knowledge, strengths and basic human needs. Alternative ways of dealing with emotional problems, difficult relationship patterns, violence and abuse, conflict and crisis are explored to suggest strategies for change. Participants are encouraged to share their fears and insights with others, to build support networks, practise problem and conflict resolution, identify change objectives and implement and monitor changes.

Underpinning the entire process is the teacher, as role model and guide, creating a supportive environment where students and teachers, as co-learners, to experience what Fullan and Scott [21] referred to as “deep learning” pedagogy. In consequence participants not only have greater influence and agency in their personal situation, but can become agents for change in their family, workplace and broader community [17,19,22,23].

METHODOLOGY:**Study Design:**

Based on previous FWB pilots in the context of UPNG public health training [13], the study adopted an exploratory mixed-methods design in which quantitative measures were administered to complement qualitative workshop evaluation data. Two main research questions guided the present study: 1) What is the level of wellbeing in the communities identified as potential sites for the FWB feasibility study? 2) How feasible is the Australian FWB as an interpersonal violence intervention in a PNG community setting? Wellbeing among study participants was assessed using three measures: a) perceived levels of safety and violence in participants' social environments; b) psychosocial empowerment; and c) subjective wellbeing. FWB feasibility in the community setting was assessed using standardized FWB qualitative workshop evaluation questions.

Participants and Setting:

The study was part of the UPNG problem-based learning approach to public health education. The FWB Empowerment and Change course was designed to train students to assess community needs with regards to FWB and to facilitate and evaluate the program in a community setting. Two groups were selected for the quantitative wellbeing survey through a process of convenience sampling. Firstly, each of 10 public health students

administered the wellbeing survey to 5 participants in their workplace, providing a group of 50 survey participants working in various health facilities in the National Capital District (NCD) and Central Province. Secondly, in response to invitations by community and church leaders interested in the FWB program, a research group made up of 14 public health students led by a lecturer in the Division of Public Health (DPH) in School of Medicine and Health Sciences (SMHS) UPNG administered the wellbeing survey to a total of 50 local participants at Bereina station, in the Kairuku-Hiri District of Central Province. The Bereina community survey was followed by FWB pilot workshops for community leaders and youth, facilitated by members of the DPH research group. A total of 50 people, 27 (54%) men and 22 (44%) women attended the FWB community workshop, while 1 (2%) was a missing data. Half the survey participants thus came from outside the community where the FWB pilot workshop was conducted.

Measures:

The quantitative component was a cross-sectional survey of the 100 participants. The sample size was calculated to allow for comparison of the prevalence of violence between females and males. After reviewing the literature by Ganster-Breidler [24] it was estimated that 65% of women and potentially 20% of men would have experienced physical violence. Using a sample size calculator for

80% power and alpha error of 0.05, the samples size of 44 participants was obtained to detect a statistically significant difference in the prevalence of violence between females and males with 95% confidence. However, the sample size was increased to 100 to cover for unexpected non-response rate and sample errors. Three quantitative measures of wellbeing were included in the survey. The first uses five questions taken from the Australian Bureau of Statistics (ABS) Personal Safety Survey (PSS), designed to measure perceived levels of violence in the participants' social environment. Three questions use a nominal scale (yes/no answers); two use an ordinal scale ranging from 1 (very unsafe) to 5 (very safe). For the purposes of this survey, violence was defined as any incident involving the occurrence, attempt or threat of either physical or sexual assault experienced by a person during the 12 months prior to the survey [13]. Psychosocial empowerment is measured by the Growth and Empowerment Measure (GEM14) developed specifically to evaluate psychosocial empowerment among FWB participants [25]. This tool consists of 14 items, and has three subscales: the 'Inner Peace' subscale (items 2, 3, 4, 10, 11, 12, 13, and 14); the 'Self-Capacity' subscale (items 5, 6, 7, and 9); and "other" (items 1 and 8) which address strength, happiness, and connectedness. All items on the GEM14 are rated on a 5-point scale between two extremes. For example, for item 1, which asks about knowledge, the lowest

point on the scale is "I feel like I don't know anything", while the highest is "I am knowledgeable about things important to me". The measure provided an overall score (maximum score =70), as well as scores for each of the three subscales [13]. The final measure, the Australian Unity Well-Being Index, is a scientific measure of "subjective wellbeing" [26] which asks people to rate their satisfaction from 0 (completely dissatisfied) to 10 (completely satisfied), across eight aspects of their personal life: health, personal relationships, safety, standard of living, achieving in life, community connectedness, spirituality or religion and future security. An overall score was calculated for this index (maximum score = 80) [13]. Qualitative data to assess the feasibility of FWB in a PNG community setting were obtained using a workshop evaluation questionnaire administered to participants immediately after the 1-day FWB workshop. As well as collecting demographic data (age and gender), the qualitative questionnaire asked participants to provide feedback on what they liked and/or disliked about the program; the extent to which their expectations were met; how they intended to use FWB skills in family, workplace, and broader community settings; and to suggest ways to improve the program [13]. The workshop evaluation feedback was supplemented by the head of the DPH research team's diary reflections regarding his efforts to support the Bereina community leaders to

implement priority issues arising from the pilot workshop.

The FWB intervention:

Prior to the FWB community workshop, the DPH research team undertook several planning visits to the Bereina community and trained 10 community and church leaders in the FWB program. As well as building potential local facilitator capacity, the aim was to give opinion leaders the opportunity to provide judgements regarding the cultural appropriateness of FWB prior to piloting the program with the broader community. The 10 community and church leaders, in collaboration with members of the DPH research team, then facilitated a 1-day FWB workshop targeting the youth of the Bereina community. Key FWB topics covered in the workshop include group agreement, human qualities, basic human needs, understanding relationships, life journey and conflict resolution; understanding emotions and crisis, loss and grief, beliefs and attitudes and understanding interpersonal violence. Following the workshop, the DPH research team members supported the community over 5 months towards translating issues arising from the workshop discussions and evaluation into action.

Ethical approvals:

The study was approved by the Human Research Ethics Committee at James Cook University (JCU), Australia and the UPNG

School of Medical and Health Sciences (SMHS) Research and Ethics Committee. Consent was also obtained from the community leaders. The purpose of the questionnaires was explained to the participants. They were also told that completion of the questionnaire represented their consent to participate in the study, that participation was voluntary and that participants were free to withdraw from the study at any time.

Data analysis:

The approach to the quantitative data analysis was largely descriptive. Answers to survey questions were cross tabulated according to the participants' gender, age-group (<24, 25-34 or 35-54 years) and socioeconomic status (employment and education). The statistical significance of differences in violence rates between females and males was assessed with 95% confidence intervals (CIs) and χ^2 test. Rates, rate differences and the 95% CIs were calculated with continuity correction according to the Wilson [27] procedure using the online calculator vassarstats.net. Differences between females' and males' scores on continuous variable scales were tested by conducting a series of independent sample t-tests. $P < 0.05$ was reported for significance of results.

Qualitative responses to the FWB workshop were analysed thematically. The analytic process was based on the six steps recommended by Braun & Clarke [28]: 1)

familiarize ourselves with the data; 2) search for codes; 3) create themes; 4) review themes; 5) name and define themes; and 6) write the report [16].

RESULTS:

Quantitative measures:

One hundred participants consented to the study but 98 completed questionnaires were returned; of these 54 were male and 44 female participants. Two questionnaires were not completed because the participants did not specify their gender, age or employment status. The gender distribution, age groups, employment status and educational level of the participants are presented in Table 1.

Of the 100 participants 46% reported being victims of physical violence or threats in the previous 12 months; 10% had been victims of actual or attempted break-in and 32% reported that another person had made them fearful. Of all episodes of abuse, the majority of the victims (73%) knew the person who harmed or threatened them or made them fearful and 60% knew the person who broke in or attempted to do so (Table 2). Physical violence or threats affected males more often than females ($\chi^2(1, N = 98) = 11.01, p < .001$), Table 2. 47.8% of the victims of physical violence or threats were aged 24 or younger.

Table 1: Victims' profile by the type of abuse

Variable	Total n=100†	A victim of physical or threatened violence *n=46				A victim of an actual or attempted break-in*n=10				Been made fearful by another person* n=32			
		Female		Male		Female		Male		Female		Male	
		n	%	n	%	n	%	n	%	n	%	n	%
Female/Male	44/54	12	27.3	34	63.0	4	9.1	6	11.1	14	31.8	18	33.3
Age group													
≤ 24	42	6	13.6	16	29.6	2	4.5	2	3.7	8	18.2	14	25.9
25 to 34	36	4	9.1	14	25.9	0	0.0	4	7.4	4	9.1	4	7.4
35 to 54	20	2	4.5	4	7.4	2	4.5	0	0	2	4.5	0	0.0
Employment													
Employed (FT & PT)	16	4	9.1	4	7.4	0	0.0	0	0.0	0	0.0	2	3.7
Unemployed	56	8	18.2	20	37.0	2	4.5	2	3.7	8	18.2	10	18.5
Student	8	0	0.0	4	7.4	2	4.5	2	3.7	2	4.5	4	7.4
Retired	6	0	0.0	0	0.0	0	0.0	0	0.0	4	9.1	0	0.0
Other	12	0	0.0	6	11.1	0	0.0	2	3.7	0	0.0	2	3.7
Education													
Grades 1-6	22	4	9.1	10	18.5	0	0.0	4	7.4	2	4.5	4	7.4
Grades 7-10	58	4	9.1	20	37.0	2	4.5	2	3.7	8	18.2	12	22.2
Grades 11-12	2	2	4.5	0	0.0	2	4.5	0	0.0	2	4.5	0	0.0
Vocational	8	0	0.0	2	3.7	0	0.0	0	0.0	0	0.0	2	3.7
University	4	2	4.5	0	0.0	2	4.5	0	0.0	2	4.5	0	0.0

† - Two participants did not specify their gender, age and employment status; six participants did not specify their education; *In the last 12 months; ** The highest proportions were marked in bold for female and male independently, except for gender; FT – full time; PT – part time

Table 2: Prevalence of abuse by gender

	Female (n = 44)		Male (n = 54)		Rate difference		p-value (χ^2 male vs female)
	N (%)	95% CI*	N (%)	95% CI*	%	95% CI**	
A victim of physical or threatened violence in the last 12 months	12 (27.3)	15.4 to 43.0	34 (63.0)	48.7 to 75.4	35.7	14.4 to 52.8	<0.001
A victim of an actual or attempted break-in in the last 12 months	4 (9.1)	2.9 to 22.6	6 (11.1)	4.6 to 23.3	2.1	-13.0 to 15.7	NS
Been made fearful by another person over the past 12 months	14 (31.8)	19.0 to 47.7	18 (33.3)	21.5 to 47.6	1.5	-18.3 to 20.6	NS

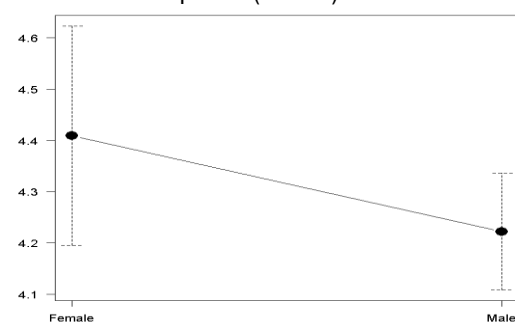
NS - Not statistically significant

*95% confidence interval of a proportion including continuity correction; **95% confidence interval for the difference between two independent proportions including continuity correction

Figure 1: Average Response Safety at Home

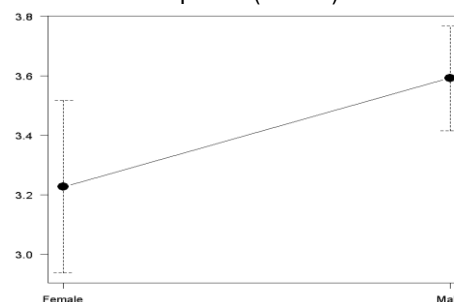
How safe do you feel at home when you are alone during the day? Response range: min 0 (very unsafe) to max 5 (very safe)

Mean \pm SD: response (overall): 4.32 \pm 1.13



How safe do you feel at home when you are alone during the night? Response range: min 0 (very unsafe) to max 5 (very safe)

Mean \pm SD: response (overall): 3.46 \pm 1.61



*Error bars represent standard errors (SE). When SE bars overlap, the difference between the two mean scores is not statistically significant ($p > 0.05$); Y-axis represents average score ranging from 0 (very unsafe) to 5 (very safe); SD: standard deviation

Both genders felt less secure at home when alone during the night compared to during the day (Figure 1). Females tend to feel safer during the day when alone, compared to males, who reported feeling more secure during the night. These differences were not statistically significant.

The mean scores obtained for survey participants' wellbeing are presented in Table 3. The questionnaire used and the format of the response options are presented in Annex 1. Even though the differences between scores for the female and male participants were not statistically significant, some findings are worth highlighting. The level of overall satisfaction

and wellbeing appeared to be marginally higher among females compared to males ($p > 0.05$). Both men and women scored the least satisfaction with their standards of living (Q2) and the most satisfaction with spirituality (Q8) ($p > 0.05$). Women were less satisfied with

personal relationships (Q6) and future security (Q9) when compared to men ($p > 0.05$). Men, on the other hand, were most unhappy about life as a whole, their achievements in life, safety, being a part of the community and health.

Table 3: Wellbeing survey results

	Q 1 Life	Q2 StandL	Q3 Hlth	Q4 Ach	Q5 Rel	Q6 Safe	Q7 Comm	Q8 SpR	Q9 Sec	Overall
Females, Mean(SD)	6.80 (2.52)	6.50 (2.95)	7.76 (2.54)	6.73 (2.37)	7.04 (3.64)	7.09 (2.87)	7.23 (2.69)	7.44 (2.90)	6.93 (3.03)	7.06 (2.72)
Males, Mean(SD)	6.67 (2.17)	6.18 (2.64)	7.00 (2.19)	6.85 (2.29)	7.15 (2.70)	6.95 (2.20)	6.98 (2.54)	7.53 (2.45)	6.96 (2.38)	6.92 (2.39)
p-value	0.778	0.573	0.140	0.796	0.851	0.774	0.638	0.875	0.951	0.416

*The result is not significant at $p > 0.05$

Table 4: GEM survey results

Questions	Female, Mean (SD)	Male, Mean (SD)	p- value
Q1. I feel like I don't know anything	4.27 (1.05)	4.09 (1.02)	0.401
Q2. I feel like I don't know how to do much of anything	4.09 (1.18)	4.02 (1.28)	0.774
Q3. I feel slack, like I can't be bothered to do things even when I want to	4.14 (1.15)	4.13 (1.10)	0.977
Q4. I feel unhappy with myself and my life	4.04 (1.38)	4.24 (1.10)	0.433
Q5. I am held back from what I could do, there are no opportunities for me	3.68 (1.57)	3.76 (1.33)	0.780
Q6. I feel that other people don't admire or value me	3.96 (1.26)	3.76 (1.17)	0.433
Q7. Have no voice. I can't express myself. Nobody listens to me	4.00 (1.19)	3.98 (1.16)	0.939
Q8. I feel isolated and alone, like I don't belong	4.16 (1.38)	4.49 (0.79)	0.131
Q9. I am not hopeful that anything will change for me	4.60 (0.86)	4.47 (0.79)	0.444
Q10. Mostly I feel shame or embarrassed	3.93 (1.47)	4.22 (1.18)	0.285
Q11. I do things for other people all the time. I am not looking after myself or my family well	4.51 (1.30)	4.24 (1.05)	0.654
Q12. I am always worrying and nervous. I can't relax or slow down	3.93 (1.13)	4.18 (1.00)	0.246
Q13. I live in fear of what's ahead	3.64 (1.49)	4.02 (1.15)	0.160
Q14. I feel a lot of anger about the way my life is	3.51 (1.46)	3.87 (1.16)	0.169
Q15. If I was threatened by another person, I have no-one close to me who would help and support me	4.00 (1.28)	4.15 (0.89)	0.506
Q16. If I was threatened by someone I knew, I would not know what to do	4.02 (1.37)	4.35 (0.93)	0.163
Overall	4.03 (1.28)	4.12 (1.07)	0.514

*The result is not significant at $p > 0.05$

The data in table 4 show the mean scores for the GEM survey. The questionnaire used and the format of the response options are presented in Annex 1. Difference between

genders was not statistically significant. The lowest mean scores among women were received for Feeling anger about the way my life is (Q14) and for men Holding back from

what I could do (Q5). The highest mean scores for women were Being unhelpful that anything will change for me (Q9) and for men Feeling isolated and alone (Q8).

Qualitative measures:

Four main themes emerged from the analysis of the data obtained from FWB pilot program participants. These themes are relevance of program content; acceptability of the delivery process; personal and community change; and sustainability. To ensure anonymity, quotes are not identified by the names of participants, but rather by numbers in brackets.

Relevance of Program content:

Community participants could see that the program content was relevant to the day-to-day issues they faced. Program topics such as basic human needs provided a framework for people to better understand the nature of their problems. For example, one person referred to the “importance of our basic needs in life” (4) while another said they learnt “many good things that will help me in my future life” (16). Community participants could see how program ideas were appropriate for healing and strengthening community relationships: comments such as “reunite families, youths- and the community”, and “It will help me to solve problems in the family and the community” (7) were frequently found in program feedback. The topic of conflict resolution was seen as particularly valuable as

it gave people ideas about how they could start to address family violence. For example, one person said: “Helping us to understand violence and help to resolve conflict... and bring up a better family” (12).

Acceptability of the Delivery Process:

Community participants clearly appreciated the process through which FWB was delivered. They liked having the opportunity to participate within a safe environment that encouraged openness. For example one person said “What I found was useful was doing group discussions and participating in the session” (19); while another said “Well actually the whole course was useful, but in particular was group discussion- openness in participants” (29). Several people commented on the quality of the program facilitators. One participant said “I think the training was just pleasant, and the facilities [facilitators] were just very active, and the way they present was just amazing” (17). However one person would have preferred external rather than local facilitators: “If ever there should be other courses why not other facilitator rather than our own people” (19). Despite this criticism this person was still very positive about their learning: “But otherwise, I really am happy with this course” (19). Other criticisms of the delivery related to lack of time and program resources. Some felt that the one day wasn’t long enough to cover all of the material: “We should learn more over two days” (24); “Every topic I find useful, but need more

time in presentations” (28). For one participant the program felt rushed: “Everything was alright but just that we need to really look into time management- we had to rush because time had caught up with us” (29). Another person suggested that “...more exercises be conducted so that we could understand better” (10). Community participants also recommended that more resources be provided and developed for the local context; for example they suggested: “... making some small booklets or hand sheets.” (28), “... manuals and handouts of our own” (21).

Personal and Community Change:

Participation in FWB led to change in a number of ways. Some said that the program gave them a sense of hope that life could be better in the future. For example, one person said “I thank you for coming to our forgotten generation to help in building in them the hope for a better FAMILY LIFE in their community” (12). Community participants spoke of how the program had an important impact on their life: “I enjoyed and learned a lot of notes for physical and spiritual education. It’s the great privilege for all of us as Bereina youths, have experienced how effective the programme” (19); “...it had a very big impact in my life, and also I have learnt a lot...” (19). One area of learning was self-care; for example one person said: “I learnt about how to look after myself and my family members” (20); Some people spoke of taking on leadership roles, including

building skills in FWB program facilitation: “I’m looking forward to improve my skills in facilitating the given sessions.” (14); “This is my first time to be a Facilitator. Thank God for your heart; to save the youths of Bereina district” (32).

Program Development and Sustainability:

The transfer and acceptance of FWB into this community was a first step; the next challenge is how to develop and sustain the program. Community participants clearly wanted more opportunities to participate in the program and to continue learning. They said, for example: “My suggestions is that we should have more of this course so that we could learn more and help our community to change to become a better people in our community” (5); “This is the first of its kind that we had in our District, to equip our youths in order to prevent them from involving themselves in doing wrong things. This training will help them in the Family Wellbeing.” (28). Several community participants were keen to expose other groups, such as married couples, to the program ideas: “More participants especially young married youth.” (27); “I suggested that if I am married; we should come as couples to attend this training course. Reason: So my partner will know and understand each other in this training.” (7). Some community participants had suggestions for organizing the program: “We need to set up proper time for next training: - advise all other participants to attend;” (11).

There were ideas for integrating FWB into existing community programs such as the spiritual development activities run by the church. For example, one community participant said: “I suggest that the course could be improved by teaching the youth more of spiritual lessons and drama activities” (1). Others gave thought to how those who had done the training might sustain their learning and distract themselves from problems such as drug abuse. Several people suggested starting small farming projects, for example: “We should have some projects like farming looking after animals and projects like making gardens so that we the youths come together so we can do away with drugs and us to become good to the community and also to help in our needs and wants of our family.” (5); “I should make good things after this course like projects farming making gardens, and help our community and work together” (6).

Leadership support was seen as critical to program sustainability. This could be achieved in a number of ways, such as encouraging village elders and chiefs to participate in the course or by training more people to be program facilitators. One participant said “If possible could you arrange for this course for village elders and chiefs. After this training for other community leaders would be very useful” (27); another suggested “Train the Facilitators...before training participants” (28).

The workshop feedback was largely confirmed by the leader of the DPH research team

reflections on his follow up activities designed to support the community implement priority issues arising from the workshops. He observed workshop participants using the basic human-needs topic to identify the many difficulties they face, including poverty and access to health care, education, housing, clean water and vegetables. They found the solution-focused emphasis of the FWB program useful for planning how to address some of these difficulties and they wanted more sessions to be run. The community went to significant lengths to enable the program to continue, highlighting the community’s perception of the relevance and importance of the program. The community lacked a training centre where the program could be delivered, so the young people were organised to build a shelter from local materials. FWB participants then contributed money and bought a brick-making machine to make bricks to build permanent homes and classrooms at the local school. Further, with the assistance of the DPH team leader, community leaders developed an activity plan to address some of the other local problems. This plan included small projects such as growing vegetables, cooking food for sale or sewing clothes and selling these at the local market.

DISCUSSION:

The study aims to assess the need for the Aboriginal Family Wellbeing empowerment program (FWB) and the feasibility of

transferring the program from a PNG university setting to broader community contexts to address the problem of endemic interpersonal violence and to generate pilot data to inform future community wellbeing interventions in PNG. The findings highlight the very real social challenges confronting PNG and the relevance and applicability of programs such as FWB at community levels. The fact that study participants experience their social environment as stressful and unsafe cannot be overstated. As many as one in four females and more than one in two males reported being a victim of physical or threatened violence in the last 12 months. Nearly half of the victims were aged 24 or younger, and knew their abusers. Both men and women were least satisfied with their standards of living and the most satisfied with spirituality. The extent to which spiritual beliefs and attitudes serve as internal resources for individuals and communities to cope with the day-to-day stresses of life requires further investigation. There is little doubt that the FWB program has much to offer the ubiquitous problem of interpersonal violence in PNG. Community members who participated in the workshops could all see the potential for FWB as a tool for addressing community concerns. Outcomes included providing a process for identifying basic community needs and offering skills for young people to better address needs such as food, shelter, education and interpersonal relationships that are based on respect. Engaging young people in meaningful

activity will in the long run improve community safety and wellbeing [27]. Despite the clear relevance of the program and the calls for FWB to be continued and expanded, the reflections of the DPH team leader on the enthusiasm generated by the FWB workshop and his attempts to support the community channel such enthusiasm into action highlight a particular dilemma often confronted in community programs. When offered external support and new opportunities, community members are often keen to begin on a process of improving conditions in their community and it is by working with communities that researchers learn most and can help to bring about lasting change. However, this requires time that university staff and students do not usually have and they cannot always be there to support local initiatives. In Bereina, this problem can be overwhelming for the external facilitators as they question their capacity to meet community needs and expectations. How should an external community development facilitator balance raising hopes and aspirations with what can realistically be achieved? This conundrum highlights the need to tread carefully and take a strategic approach to change. Arguably, the most important and realistic role universities can play is to remain focused on their core business, in this case, the training of public health students. These students, as the health workforce and opinion leaders of the future, are the ones most suitable to take their new knowledge back to

the community. Opportunities for ongoing university support and mentoring, refresher training courses and the utilization of local or online communities of practice could also be explored (although internet infrastructure is very variable in PNG). As it is a pilot study, the results of this research cannot be generalised to other settings. Studies have demonstrated however that small pilot studies can contribute and provide information to national planning [29, 30]. The PNG government is committed to addressing interpersonal violence, and in 2014 the PNG National Department of Health (NDoH) launched a policy platform which incorporates a rights-based and empowerment approach. This policy, the National Health Gender Policy (NHGP) states “Today, the policy environment in gender and health is ripe. The health sector provides opportunities for integrating a gender perspective both organizationally within the NDoH and in health sector policies and plans” [12]; While the policy environment may be ripe, the greatest challenge lies in implementing and evaluating such policies [11]. Integrating practical interventions such as FWB in routinely available community education, health and other development programs and services provide a potentially valuable way forward.

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Annex 1: SURVEY QUESTIONNAIRES:

Table I: Growth and Empowerment Measure (GEM survey questions)

#	Question
Q1	I feel like I don't know anything
Q2	I feel like I don't know how to do much of anything
Q3	I feel slack, like I can't be bothered to do things even when I want to
Q4	I feel unhappy with myself and my life
Q5	I am held back from what I could do, there are no opportunities for me
Q6	I feel that other people don't admire or value me
Q7	Have no voice. I can't express myself. Nobody listens to me
Q8	I feel isolated and alone, like I don't belong
Q9	I am not hopeful that anything will change for me
Q10	Mostly I feel shame or embarrassed
Q11	I do things for other people all the time. I am not looking after myself or my family well
Q12	I am always worrying and nervous. I can't relax or slow down
Q13	I live in fear of what's ahead
Q14	I feel a lot of anger about the way my life is
Q15	If I was threatened by another person, I have no-one close to me who would help and support me
Q16	If I was threatened by someone I knew, I would not know what to do

Table II: Australian Unity Wellbeing Index survey questions

#	Question
	Thinking about your own life and personal circumstances:
Q1	How satisfied are you with your life as a whole?
Q2	How satisfied are you with your standard of living?
Q3	How satisfied are you with your health?
Q4	How satisfied are you with what you are achieving in life?
Q5	How satisfied are you with your personal relationships?
Q6	How satisfied are you with how safe you feel?
Q7	How satisfied are you with feeling part of your community?
Q8	How satisfied are you with spirituality or religion?
Q9	How satisfied are you with your future security?

Table III: Personal Safety survey (PSS) questions

#	Question
Q1	Have you been a victim of physical or threatened violence in the last 12 months?
Q1a	IF YES to previous question, did you know the person who harmed or threatened you?
Q2	Have you been a victim of an actual or attempted break-in in the last 12 months?
Q2a	IF YES to previous question, did you know the person who broke-in or attempted to break-in?
Q3	Has another person made you fearful over the past 12 months?
Q3a	IF YES to previous question, did you know the person who made you fearful?
Q4	How safe do you feel at home when you are alone during the day?
Q5	How safe do you feel at home when you are alone during the night?

NEED OF COMBINING PROTON PUMP INHIBITORS WITH PROKINETICS: A PROSPECTIVE OBSERVATION STUDY CONDUCTED IN INDIA

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ABSTRACT:

Gastro esophageal reflux disease (GERD), a highly prevalent disorder has adverse impact on quality of life. An estimated 40% of GERD patients have incomplete response to therapy by standard proton pump inhibitors (PPI). For these PPI refractory patients, doubling the PPI dose or switching to another PPI are usually pursued by the treating physicians, even though that might not be optimal. Therefore, an appropriate second line treatment should focus on addition of gastro-prokinetic drugs that stimulates gastric motility. This prospective observational study was conducted in 118 patients suffering from symptoms suggestive of GERD. The study was carried out at four centers in Indian National Capital region. The major objectives were to assess the overlap between GERD and delayed gastric emptying and to predict the need for combination therapy of PPI with pro-kinetic drug using Frequency Scale for the Symptoms of GERD (FSSG) score. The mean total FSSG score was 16.37 ± 7.50 . From 118 patients, 98 (83.05%) met the criteria for GERD with FSSG total score more than eight. The mean reflux score was 7.43 ± 4.08 , while the mean dysmotility score was 8.94 ± 4.83 . GERD patients in this study had high mean FSSG score, whereas dysmotility symptoms proved to be more dominant than acid reflux. Based on the findings of this study, combination therapy of PPI with prokinetics is recommended in subsets of patients with high FSSG score.

Keywords: Gastric emptying, Dysmotility score, Gastroparesis, Reflux score

INTRODUCTION:

Gastroesophageal reflux disease (GERD) is a chronic condition which develops when the reflux of stomach contents cause troublesome symptoms and/or complications [1]. The prevalence of GERD in India ranges from 8-20% according to recently conducted studies based on different case definitions and study methodology [2]. The subtypes of GERD

include erosive esophagitis (EE), non-erosive reflux disease (NERD) and Barrett's esophagus. Approximately 70% of patients with GERD have NERD, EE accounts for approximately 25 % of GERD patients whereas Barrett's esophagus for ~5 % [3].

The gastrointestinal motility disorder called gastroparesis is characterized by delayed gastric emptying in the absence of a

mechanical obstruction. Symptoms of gastroparesis may vary from patient to patient, but generally include nausea, vomiting, early satiation, bloating, and upper abdominal discomfort, along with objective evidence of gastric retention. A study of the incidence of gastroparesis in 100 patients with gastroesophageal reflux showed 41% had delayed gastric emptying [4]. However, certain patient populations, such as diabetic patients, may be at an increased risk for both conditions [5-6]. Proton pump inhibitors (PPIs) are the most effective agents for increasing the intragastric pH and have become the mainstay pharmacotherapy for acid disorders. PPIs suppress gastric acid by inactivating gastric proton pumps responsible for acid secretion [7-8]. Up to 40% of GERD patients report either partial or complete lack of response of their symptoms to a standard PPI dose once daily [9]. Refractory GERD is diagnosed in patients who are unresponsive to PPI treatment that have been administered for 4 to 8 weeks, once daily. Patients with refractory GERD typically need more aggressive acid suppressive therapy or the use of other therapeutic modalities like transient lower esophageal sphincter relaxation reducers and, in the case of gastroparesis, co-administration of prokinetic agents to regulate gastric emptying [4]. It remains difficult to identify the particular subset of GERD patients who have gastroparesis, particularly if patients do not report classic symptoms of gastroparesis, including bloating,

nausea, vomiting, and early satiety, or these symptoms are misinterpreted as GERD-related. Therefore, it is important that gastroparesis be considered in all patients with GERD, allowing physicians to develop an optimal therapeutic strategy that addresses both disease states directly [4]. The most frequently used prokinetic drugs like Levosulpiride (Levobren®, Levopraid®) and Domperidone (Motilium®) augment gastric emptying, avert retention and reflux of acid or food, increase lower esophageal sphincter pressure and enhance esophageal peristalsis. Domperidone and Levosulpiride have both antiemetic and prokinetic properties since they antagonize dopamine receptors in the central nervous system as well as in the gastrointestinal tract where dopamine apply compelling inhibitory effects on motility [10-11].

The diagnosis of GERD has evolved over the years influenced by technologic and therapeutic progresses. Currently, a scoring system called the frequency scale for the symptoms of GERD (FSSG) has been developed in Japan to evaluate GERD symptoms [14]. This questionnaire specific to GERD contains 12 questions which include seven questions for reflux score and five questions to score the dysmotility. FSSG score has been validated against the endoscopic findings in Japan with the cut-off score at 8 (FSSG score 8 or above), showed sensitivity of 62%, specificity 59% and accuracy of 60% [12-14]. Miyamoto et al [15] found that high score

FSSG is one of the factors related to failure of PPI monotherapy, in addition to female, alcohol consumption and obesity. Thus, GERD with a high FSSG score requiring PPI combination therapy with pro-kinetic drug for a more satisfactory outcome [15]. The current study was undertaken to evaluate the symptom profile of GERD patients and the symptom overlap between GERD and delayed gastric emptying so as to determine FSSG score in order to predict the need for combination therapy of PPI with pro-kinetic drug or PPI monotherapy only.

SUBJECT AND METHODS:

This was a prospective, multicenter, observation study conducted in seven gastroenterology clinics across Delhi, Gurgaon and Noida in Indian National Capital region. The study was conducted in accordance with the Indian Council of Medical Research guidelines for Biomedical Research on Human subjects and the Declaration of Helsinki [16, 17]. Ethical clearance was not obtained as it was a questionnaire based observation study [16, 17]. Outpatients who visited these seven gastroenterology clinics during the period of April 2016 to July 2016 and willing to participate were enrolled in this study. On study entry, patients provided a medical history and underwent a physical examination.

Inclusion Criteria:

Ambulatory patients (male and females) aged between 18 to 65 years, and at least a 3-month

history of symptoms suggestive of GERD and/or delayed gastric emptying were eligible for inclusion in this study.

Exclusion Criteria:

The patients with history of cancer of the gastrointestinal tract or major illnesses (end-stage heart, liver, or lung disease, alcoholism, any other cancer or malignancy, or AIDS), pregnancy, hepato-biliary disease, patients who were receiving dialysis or who had undergone prior gastric surgery, those known or suspected to be using illicit drugs, and lactating mothers were excluded from the present study. Unresponsive patients were excluded if they refused to answer the study questionnaire.

FSSG Score Evaluation:

Seven questions in FSSG questionnaire in Table 1 (question number 1, 4, 6, 7, 9, 10 and 12) were related to acid reflux, and 5 questions (question number 2, 3, 5, 8 and 11) were related to dysmotility disorder. There were 5 answer choices for each question in the FSSG scale, never (for score = 0), occasionally (score = 1), sometimes (score = 2), often (score = 3), and always (score = 4).

Thus, the score for reflux/acid-related symptoms ranged between 0-28; the score for dysmotility symptoms ranged between 0-20. High FSSG score is one of the factors related to failure of PPI mono therapy, thus, GERD with a high FSSG score requires PPI combination therapy with pro-kinetic drug for a more satisfactory outcome [14].

Table 1: FSSG questionnaire [14]

#	Questionnaire	Indicative disorder
1	Do you get heartburn?	Reflux/acid-related symptoms
2	Does your stomach get bloated?	Dyspeptic/ dysmotility symptoms
3	Does your stomach ever feel heavy after meals?	Dyspeptic/dysmotility symptoms
4	Do you sometimes subconsciously rub your chest with your hand?	Reflux/acid-related symptoms
5	Do you ever feel sick after meals?	Dyspeptic/ dysmotility symptoms
6	Do you get heartburn after meals?	Reflux/ acid-related symptoms
7	Do you have an unusual (e.g. burning) sensation in your throat?	Reflux/acid-related symptoms
8	Do you feel full while eating meals?	Dyspeptic/ dysmotility symptoms
9	Do some things get stuck when you swallow?	Reflux/acid-related symptoms
10	Do you get bitter liquid (acid) coming up into your throat?	Reflux/acid-related symptoms
11	Do you burp a lot?	Dyspeptic/dysmotility symptoms
12	Do you get heartburn if you bend over?	Reflux/ acid-related symptoms

Statistical Analysis:

All the data was recorded in the entry form, and further organized using descriptive statistics, presented as mean \pm SD for numerical data, and proportion (%) for the categorical data. The

statistical analysis was carried out by using graph pad prism 7 using paired T test. Values of $p < 0.05$ were considered statistically significant.

Table 2: Demographics and scores

#	Parameters	Results obtained (N = 118)
1	Gender;	
	Male	68 (57.6%)
	Female)	50 (42.4%)
2	Age range	18 – 65 years
3	Chief complaint	Number (%) of patients
	Heartburn	99 (83.9 %)
	Regurgitation	85 (72.0 %)
	Heartburn+ Regurgitation	81 (68.6 %)
4	FSSG Score: Total (Mean \pm S.D.):	16.37 \pm 7.50
	Reflux Score	7.43 \pm 4.08
	Dysmotility/Dyspeptic score	8.94 \pm 4.83

RESULTS:

In all, 118 patients completed the FSSG score questionnaire of which 57.6% (68) were males and 42.4 % (50) females. The mean age of all

the patients was 36.8 \pm 3.4 year; their age range was 18 to 65 years.

FSSG score that was conducted on 118 patients, revealed the mean total score of

16.37 ± 7.50 with the lowest score of 5 (reported in two patients), and the highest total score of 37 (reported in one patient).

When used the cut off 8 (FSSG score 8 or above), then from the 118 patients with GERD suggestive symptoms, 98 (83.05%) patients met criteria for GERD with cut off 8. Patients having total FSSG score of more than or equals to 8 are more likely of having GERD where combination therapy of PPI and prokinetics may be required. The rest of the 20 (16.95%) patients do not qualify for GERD FSSG score.

Of the 118 patients studied, the symptoms of dysmotility (8.94 ± 4.83) was predominant than symptoms of acid reflux (7.43 ± 4.08).

Mean score of reflux (7.43 ± 4.08) represents 26.5% of the total reflux score (total score 28), while the mean dysmotility score was 8.94 ± 4.83 which is 44.7% of the total score of dysmotility (total score 20). Thus from 118 patients studied, the dysmotility symptoms were predominant than symptoms of reflux.

DISCUSSION:

The relationship between gastroparesis and GERD is multifactorial. The delay in gastric emptying associated with gastroparesis can lead to prolonged gastric retention of food that may have a propensity to reflux [4]. It is believed that in this group of patients delayed gastric emptying is associated with a progressive dilatation of the proximal stomach which, in turn, shortens the length of the lower

esophageal sphincter until it becomes incompetent – similar to the way distension of a balloon shortens its neck. With a shortened sphincter, and with greater amounts of solid and liquid materials in the stomach after meals because of its defective emptying, reflux occurs. Not surprisingly, these patients complain more often than those with normal gastric emptying of dyspepsia, postprandial distention, generalized bloating and abdominal pain, in addition to the usual symptoms of gastroesophageal reflux [5].

In patients with GERD refractory to standard therapy, a higher index of gastroparesis suspicion is therefore recommended. In a patient with GERD symptoms of heartburn, other gastrointestinal symptoms such as early satiety, nausea, and vomiting indicates that the patient may also have gastroparesis. The presence of delayed gastric emptying could be a reason for a suboptimal treatment response in these patients [4]. Furthermore, a meta-analysis by Ren LH et al [11] has reported that, combination therapy with PPI and prokinetics improve patient quality of life, by decreasing number of reflux episodes.

In this study, mean FSSG score was quite high (16.37 ± 7.50). Findings of this study are in accordance with the previous findings reported by Miyamoto et al [15]. According to these authors a high FSSG score becomes a factor associated with failure of PPI monotherapy [15]. They found that a group that failed with PPI monotherapy had a mean FSSG score of

17.4, and then that group was given a combination therapy of PPI with prokinetics. Miyamoto and colleagues proposed that pretreatment FSSG scores can be used to predict the need for the addition of a prokinetic agent to PPI therapy prior to treatment [15]. Japanese physicians usually add prokinetic agent to the standard dose of a PPIs instead of doubling the dose of the PPI for cases refractory to PPI monotherapy [18]. PPIs are unstable at a low pH dysmotility slows down gastric emptying, resulting in retention of PPIs. Based on these findings, combination of PPIs with prokinetic should improve the effect of PPIs [14-15]. Furthermore, Ndraha et al, [18] validated similar findings in their clinical experience and stated that combination of PPIs with prokinetics improves the effect of PPIs.

CONCLUSION:

GERD patients in this study have a high mean FSSG score, suggesting that dysmotility symptoms are more dominant than acid reflux. Based on these findings, combination therapy of PPI with prokinetics is recommended in subsets of patients with high FSSG score. Since the FSSG score was high which is suggestive of dysmotility predominance, likelihood of patients responding to combination of PPI with prokinetics is much higher compared to PPI alone. Furthermore, there is a need of future studies to evaluate the FSSG score improvement in patients receiving

combination therapy of PPIs with prokinetic compared to PPIs monotherapy alone.

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CHEILOSCOPY AS AN ADDITIONAL FORENSIC PARAMETER: A REVIEW

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ABSTRACT:

Criminal activities involving human life always puts lives at stake. Newer advances in other fields especially medicine and dentistry is essential in solving the mysteries of death. Different disciplines insert a part of the puzzle until it is complete. Fingerprints, DNA profiling, Forensic anthropology are commonly employed in personnel identification, mass disasters and others. Investigators may also rely on lip prints to identify possible suspects or to support evidence gained in specific investigations. A lip print at scene of crime can be the basis for inference as to the number of people involved, gender, habits, occupational traits, and others, based on the pathological changes present. This review deals with lip prints and their possible acquisition and usage.

Keywords: Lip print, Cheiloscopy, Forensic investigation, Lip tracing, Crime, Lips

INTRODUCTION:

Mathew Arnold stated that, "Truth sits upon the lips of dying men" [1]

The positive identification of living or deceased persons using the unique traits and characteristics of the teeth and jaws is a cornerstone of forensic science. Lip prints have been with us since the beginning of man, similar to the prints on a person's finger, palm and foot which are unique to that individual and are used for identification [1,2]. The external surface of lip

has abundant elevations, wrinkles and grooves on labial mucosa called sulci laborium noted originally by the anthropologist R. Fischer in 1902 [1,2,3]. The use of lip prints in personal identification was first recommended in France by Edmond Locard [2,4]. Until 1950, anthropology simply stated the existence of lip prints without affirming a pragmatic use, until Synder conducted an investigation on traffic disasters and proved that the characteristics of lips are individually distinctive [1,2,3,4]. In the

period 1968-1971 two Japanese scientists, Y. Tsuchihashi and T. Suzuki at Tokyo University established that lip prints are unique for each human being [4,5]. Since then widespread research on lip patterns are going on with an intention of using them for personal identification and evidential work in legal proceeding. The importance of cheiloscropy is linked to the fact that lip prints are genetic, developing at the 6th month of intrauterine life and are stable, constant even after death, and exclusive to each person except in monozygotic twins [6]. A lip print at the scene of a crime can be a center for ruling the disposition of the event, the number of the people involved, sexes, cosmetics used, habits, occupational traits, and the pathological changes of lips themselves [4].

Documentation of Lip Prints:

Other than the visible prints, there can be formation of latent or persistent lip prints due to the minor salivary and sebaceous glands on the lip and the moisturizing action of tongue. These can be obtained from clothing, cups, glasses, cigarettes, windows, doors [4,6,7]. Recording these prints is a delicate process and various methods have been tried to establish the exact patterns.

Transfer mediums: Lipstick, lip rouge, or other suitable transfer mediums can be applied to the lips and lip prints can be recorded on a strip of cellophane tape on the glued surface, which can then be transferred to a white paper and subsequently be visualized with the use of the magnifying lenses [1-7] [Figure 1]

Williams suggested that after lipstick is applied to the lip, multiple records or several “sets” of lip prints should be taken, with the mouth in a particular position, such as pursed in order to ensure that all parts of the lips are recorded [8,9]. The latent prints can be lifted using materials such as aluminum powder or magnetic powder [6]. Conventional powder methods for lip prints are unsuitable, as the brush tends to smear or leave streak marks on the print which may be interpreted as false characteristics.

The oil content in long lasting lipsticks can interfere with the conventional powders used [8,9]. When the effectiveness of several fingerprint powders and reagents on lipstick prints was analyzed by a study, red (Dragon’s Red), fingerprint black, and silver metallic powders were found to be the most effective [8].



Figure 1 : A – D Shows the procedure of recording of lip print using cellophane tape ¹⁴

Williams also suggested powdering method using magna brush and magnetic powder wherein lip prints are recorded on glossy porous surface or a smooth nonporous surface and then subjected to a heat source until they solidify [9].

Lysochrome is a generic term for compounds that have the ability to dye fatty acids and are better than chemical agents because they react with fats and physical reagents and provide sufficient time to work even when little reagent is used as shown by Alvarez et al [10]. Kumar et al conducted a study to analyze and compare the effectiveness of lysochrome dyes (Sudan III, Sudan black and Oil Red O) with fluorescent dyes in development of latent lip prints and found

flouroscent dyes to be better in documentation of the prints [6]. Finger printer, a special roll, usually used for finger print collection, can also be used on the lips to record their pattern. Alvarez et al conducted a study on latent lip prints and concluded that the developing method of lip prints is no different from that used in the case of fingerprints and so no special equipment was needed [8].

Photography:

Proper lighting is essential to accentuate contrast on a non porous surface. Errors are common as the central area and the angle of the lips are never in the same plane leading to blurred or

partial images of the lips. The dawn of digital photography has wiped out this error [2, 8]. In deceased persons, lip prints have to be obtained within 24 hours to prevent them from post mortem changes [11].

Classification:

Lip prints were classified by Santos in 1967 [2, 12] into 4 variants: Straight line, Curved line, Angled line and Sine-shaped line. These lines again may be arranged as vertical, interspersed,

brachial, reticular and undiffered. In 1970, Suzuki and Tsuchihashi gave a new classification which is highly followed by most [2,13]: Type I: Vertical, comprising of complete end-to end longitudinal fissures; Type I': Comprises of incomplete versus longitudinal fissures; Type II: Branching Y shaped pattern; Type III: Interspersed groove – criss cross pattern; Type IV: Reticular - chequered pattern fence like and Type V: Others/ Undifferentiated (Figure 2).

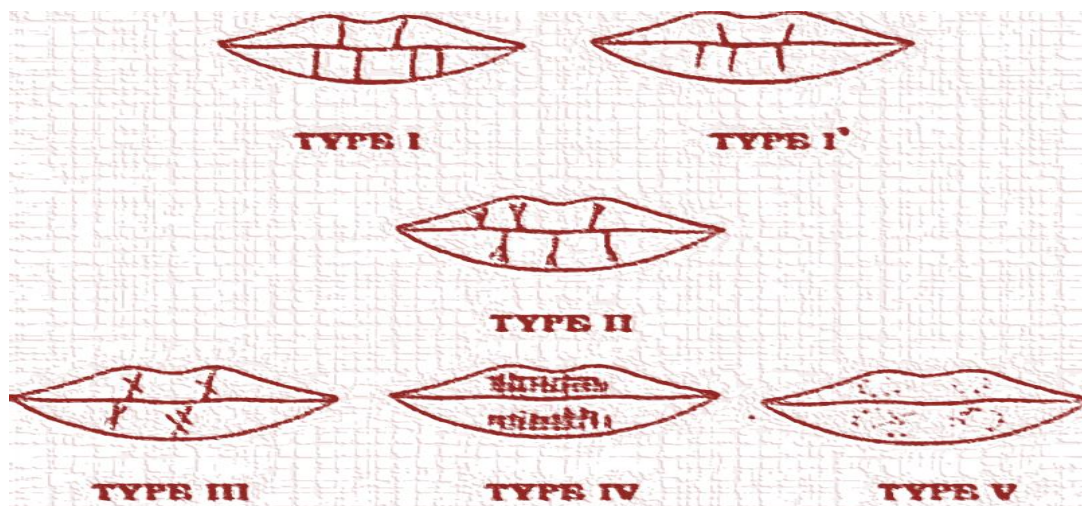


Figure 2 : Suzuki and Tsuchihashi s classification of Lip ^{7,15}

Various studies have been conducted with the objective of determining the most common lip patterns and their distribution in either sex. Sharma et al [13] Randhawa [14] and Vahanwala S [15] proved that type 1 and 1' are more common in females; but variation in the

distribution of patterns i.e Type II, type IV and type III were common in males as seen by the same authors respectively. Verma P et al [3] and Sivapathasundram et al [7] showed type II to be dominant in both male and female population. In a study by Narang et al [5] the accuracy of

cheiloscopy in sex determination was 86.40%. These disparities maybe due to difference in pressure exertion, direction and method used for recording lip prints as these are present in transition zone of lips which is highly mobile. Age changes like immaturity of lips in juveniles and reduced anatomic details and tonicity in the aged can also have a considerable effect on the lip pattern, thereby making the correct identification of sex in these groups contentious [6]. This discrepancy highlights the call for sole consistent procedure for print collection [13]. There were similarity in the lip prints of mothers and daughters found by Augustine et al [16] and Yats et al [17]. There have been various studies conducted based on the correlation of fingerprints and blood groups with that of the lip patterns, but variable results have been documented owing to the smaller number and disparity of population based studies [3,11,17]. Studies have also shown that saliva and DNA retrieved from the exfoliated cells found in the lip prints as the furrows and grooves on the lips seemed to facilitate routes for saliva to spread over the lips to maintain good hydration [13,14].

Lip prints in Biometrics:

Over the last three decades there has been tremendous research done on development of systems based on fingerprint, face, iris, voice and others [16] Michal Choras has re-affirmed the

belief in his recent studies that the lip can be used as a primary biometric modality for successful identification purposes [18]. Lukasz Smacki has also proposed a method of lip print digitization and usage in identification [18]. Lip print based system offers the advantage of being used in conjunction with face and voice based systems so as to enhance their performance. In addition to this development of lip based authentication system will also be beneficial in forensic applications [4, 18].

CONCLUSION:

Lip prints are considered unique to an individual and analogous to fingerprints. Lip print analysis is a process that provides both qualitative and quantitative results, thus its application in the forensic field should be widely accepted by both law enforcement and the legal professionals. The collection of the visible as well as latent lip prints with a suitable transferring and recording media is important for its consideration as positive forensic evidence and that identity can be established by a combination of methods which makes the identification process relatively flawless. In addition, newer advancements in techniques, equipment, methods and teaching will have to be developed. Similarly we believe that various studies have to be carried over a wider class of individuals in order to establish the individuality of the lip prints.

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DOSIMETRIC AUDIT OF DIAGNOSTIC AND THERAPEUTIC ANGIOGRAPHIC PROCEDURES AT AMINU KANO TEACHING HOSPITAL KANO NIGERIA

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ABSTRACT:

Angiography is the gold standard for the diagnosis and treatment of vascular and related diseases. However, the challenges and peculiarities of the procedure may result in increased fluoroscopy time and number of acquired images, which increased personnel and patients' radiation exposure. This study determines the dose area product readings following diagnostic and interventional angiographic procedures in an attempt to establish reference values for patient radiation dose optimization. This retrospective study reviewed the cases of 25 patients that were managed at the teaching hospital. Types of angiographic procedure, exposure parameters as well as radiation dose parameters were documented. Fluoroscopy time, number of frames acquired for each examination, fluoroscopy and frame radiation doses were equally recorded. Of the 25 patients, 6 were for 4-vessel cerebral Digital Subtraction Angiography (DSA), 3 for both lower limbs DSA, 4 for both lower limbs DSA and angioplasty, 3 for Inferior Vena Cava (IVC) filter placement, 2 for pulmonary arteriography, 2 for renal artery embolisation, and 5 for unilateral lower limb DSA and angioplasty. Renal artery embolization had the highest fluoroscopy and frame radiation doses (73764 cGy.cm² and 4090 mGy) compared to others. Measured Dose Area Product (DAP) doses were above the Diagnostic Reference levels (DRLs) available in the literature thereby necessitating the need for radiation dose optimization through, continuous dose management.

Keywords: Angiography; Interventional radiology; fluoroscopy, Radiation doses

INTRODUCTION:

Angiography is the gold standard technique for the diagnosis and treatment of vascular and related diseases [1]. The main application of angiography includes: stenotic vascular disease, aneurysms, emboli, occlusive disease,

and thrombosis. The challenges and peculiarities of the procedure may result in increased fluoroscopy time and number of the acquired images. This may potentially increase the radiation dose both to the patient and personnel involved during the procedure.

However, if the protocols are optimized, the diagnostic information required from the procedure may be obtained at minimum possible radiation dose to the patient [1].

Radiation absorbed dose is the total amount of ionizing radiation absorbed by a material or tissues. It is expressed in Gray (Gy) upon exposure. Exposure may be defined as the total electrical charge per unit mass that x rays and gamma ray photon generate in dry air at standard temperature and pressure [2].

During angiographic procedures, the radiologists performing the examination stay close to the radiation field, and therefore can be exposed to scattered radiation from the patient and leakage radiation from the X-ray housing tube. Depending on the magnitude of fluoroscopy time, such exposure can be sufficiently high to cause some deterministic effects. In general, the radiation dose per examination is low, but nevertheless, the accumulated radiation dose might become significant over several years [3]. The Food and Drug Administration (FDA) of the United States of America has reported cases where radio-induced skin injuries, such as peeling or skin necrosis, have been observed due to prolonged X-ray irradiation of patients during interventional radiology procedures [4]. Some recommendations, like establishing protocols for each procedure, and determining the radiation dose rates for fluoroscopy systems to reduce the potential of radiation-induced skin injuries of patients have been suggested [4]

More recently, according to the Royal College of Radiology, the number of interventional radiology examinations has increased by more than 50% from 2007 to 2009 in the United Kingdom [5]. However, there are no published data available for the local population in Nigeria. Therapeutic interventional procedures performed for vascular anomalies such as aneurisms, arterio-venous malformations and arterio-venous fistulas, patients are often exposed to substantial amounts of radiation associated with the use of fluoroscopic imaging [4]. Therefore, the Euratom 97/43 directive introduced the obligation to evaluate radiation doses involved in “high-dose procedures”, including those of interventional radiology [6].

Quantities that can be used as radiation absorbed dose parameters are: Entrance Skin Dose ESD in (mGy), and Dose Area Product (DAP) in (Gy.cm²), number of images associated with screening time or effective radiation dose. The most frequently used quantity for measuring radiation output during angiography is DAP (Gy.cm²) reading and it is used for setting DRLs [3].

In Nigeria at the moment, no study has been conducted to assess the radiation dose during angiographic examinations or DRLs established as a tool for radiation dose optimization. Therefore, performing radiation dose survey will be of practical importance in protecting both the patients and the personnel working in the angiography environment

against unintended radiation exposure. The aim of this study was to determine the DAP values of different angiographic procedures at the Aminu Kano Teaching Hospital (AKTH), which is one of the only three hospitals in the Nigeria with a functioning catheter laboratory at the time of the commencement of this study.

SUBJECTS AND METHODS:

The study population consisted of all patients referred for Angiographic procedures (diagnostic and/or therapeutic) at the study site. Only data of patients that had angiographic examinations (diagnostic and therapeutic) with complete dosimetry records of fluoroscopy time and radiation dose values were included. Those with incomplete record were excluded. Ethical clearance was sought and obtained from the research ethics board of the AKTH.

The study was retrospective, cross-sectional and quantitative in design carried out at the AKTH in the densely-populated city of Kano, located in north-western Nigeria. The angiographic procedures were performed using digital single-plane Innova-3100 General Electric angiography imaging system equipped with flat panel detector. Our medical physicist checked the equipment six monthly for scheduled quality control tests, however no record of such tests was kept. Tube warm up is daily performed by the radiographer before procedure commences as instructed by the medical physicist. All procedures were performed by the board-certified radiologists,

co-assisted by the radiographers. Information recorded on the data spreadsheet include: demographic data (age, weight and gender), clinical indications, type of angiography performed, radiation exposure parameters (kV and mAs), and DAP readings (fluoroscopy dose, cumulative radiation dose, fluoroscopy time, total radiation dose of acquired frames and number of frames) for each procedure.

The DAP meter used in our angiography machine has the following specification: model XTP8100G. The DAP meter information was obtained from the display console of the angiography machine. The acquired data was analysed using statistical package for social science (SPSS) version 20. The means, Standard deviation, ranges and percentages were calculated and recorded.

RESULTS:

The study involved 25 patients, consisting of 15 males (60%) and 10 females (40%). The age of the patients ranged from 15 – 81 years with mean and (\pm Standard Deviation) of 51.4 ± 21.1 years. Their mean weight was 61.1 ± 9.8 Kg. The range of angiography procedures performed during the review period included: 4-vessel cerebral DSA 24%, both lower limbs DSA 12%, both lower limbs DSA and angioplasty 16%, IVC filter placement for prevention of pulmonary thrombo-embolism (either through the jugular or femoral routes) 12%, pulmonary arteriography (with or without

thrombolysis of pulmonary thrombus) 8%, renal artery embolism in advanced renal cell

carcinoma 8%, and unilateral lower limb DSA and angioplasty 20%.

Table 1: Fluorodose parameters for diagnostic and therapeutic angiography procedures

Procedures	No. of Patients	kVp Mean \pm SD (Range)	mA Mean \pm SD (Range)	Time (min) Mean \pm SD (Range)	DAP in cGy.cm2 Mean \pm SD (Range)
4-Vessel cerebral DSA	6	84 \pm 0.0 (84 - 84)	4 \pm 3 (1 - 9)	41 \pm 30 (12-77)	27610 \pm 10098 (11141-41179)
Both lower limb DSA and angioplasty	4	83 \pm 2 (80 - 84)	1 \pm 1 (0.5-3)	37 \pm 24 (15-70)	23876 \pm 16864 (6648-39671)
IVC Filter Placement	3	83 \pm 2 (80-84)	16 \pm 9 (5-22)	4 \pm 3 (2-8)	7426 \pm 6859 (1991-15133)
Unilateral lower limb right or left DSA and angioplasty	5	80 \pm 5 (74-84)	1 \pm 0.6 (0.5-2)	30 \pm 27 (5-76)	27236.6 \pm 36250 (1952-89206)
Renal artery Embolization	2	85 \pm 1 (84-85)	5 \pm 2 (4-7)	50 \pm 51 (13-86)	73764 \pm 77182 (19188-128340)
Both lower limb DSA	3	80 \pm 7 (72-84)	3 \pm 4 (0.5-8)	29 \pm 20 (11-50)	19455 \pm 13838 (5728-33401)
Pulmonary arteriography	2	84 \pm 0.0 (84-84)	7 \pm 1 (6-7)	18 \pm 2 (17-20)	27443 \pm 3459 (24997-29889)

Table 2: Frame radiation dose parameters for diagnostic and therapeutic angiography procedures

Procedures	No. of patients	kVp Mean \pm SD (Range)	mA Mean \pm SD (Range)	Dose in mGy Mean \pm SD (Range)
4-Vessel cerebral DSA	6	73 \pm 6 (67-82)	158 \pm 18 (146-175)	1611 \pm 598 (605-2888)
Both lower limbs DSA and angioplasty	4	69 \pm 3 (67-72)	150 \pm 9 (146-163)	1891 \pm 1412 (559-3303)
IVC Filter Placement	3	83 \pm 8 (74-88)	161 \pm 12 (153-175)	530 \pm 466 (146-1048)
Single lower limb right or left DSA and angioplasty	5	71 \pm 8 (66-85)	149 \pm 6 (142-155)	2243 \pm 3132 (168-7769)
Renal artery Embolization	2	75 \pm 4 (72-78)	171 \pm 5 (167-174)	4090 \pm 4397 (981-7199)
Both lower limbs DSA	3	73 \pm 11 (67-86)	150 \pm 8 (146-159)	1093 \pm 626 (398-1613)
Pulmonary arteriography	2	74 \pm 1 (73-75)	176 \pm 1 (175-176)	1544 \pm 156 (1433-1654)

Table 3: Radiation dose values of the present study compared to the values established in the literature

Procedure	Reference	No. of Patients	Fluoro time (min) Mean (Range)	DAP in cGy.cm ² Mean (Range)	Dose in mGy Mean(Range)
4-Vessel cerebral DSA	This study	6	41.1 (11.6-76.5)	27610.2 (11141-41179)	1610.7 (605-2888)
	Ercole et al.[7]	100	9.89 (1-48)	1422.1 (330-5233)	
	Korir et al.[8]	51	32.2 (12.3-65.5)	1970 (50-9780)	517 (57-1259)
Both lower limb DSA and Angioplasty	This study	4	36.8 (15.1-69.8)	23875.7 (6648-39671)	1891 (559-3303)
	Marshall et al.[9]	500	30.4 (14.5-55)	2488 (219-2771)	
IVC Filter Placement	This study	3	4.0 (1.7-7.9)	7426 (1991-15133)	530 (146-1048)
	Korir et al.[8]	1	5	1890	41
Single lower limb right or left DSA and angioplasty	This study	5	30.4 (4.5-75.5)	27236.6 (1952-89206)	2243 (168-7769)
	Marshall et al.[9]	500	30.4 (14.5-55)	2488 (219-2771)	
Renal artery Embolization	This study	2	49.5 (13.3-85.6)	73764 (19188-128340)	4090 (981-7199)
	Korir et al.[8]	8	11 (4-29)	1577 (380-5695)	540 (103-1798)
Both lower limb DSA	This study	3	29.3 (10.9-50.3)	19455 (5728-33401)	1093 (398-1613)
	Korir et al.[8]	34	9 (3-48)	850 (110-3980)	283 (57-1259)
Pulmonary arteriography	This study	2	18.4 (16.9-19.9)	27443 (24997-29889)	1543 (1433-1654)
	Korir et al.[8]	4	15.5 (11-16.8)	3440 (666-6311)	322 (82-617)

Table 1 shows the descriptive analysis of the fluoroscopy exposure parameters, time and DAP readings. The procedure with the highest

fluoroscopy time and DAP reading was renal artery embolization, even though it was the least frequently performed procedure. IVC filter

placement was found to be the procedure with the lowest fluoroscopy time and DAP reading. The table also showed that the interventional procedures have longer fluoroscopy times compared to diagnostic.

Table 2 showed the descriptive analysis of the frame exposure parameters and frame dose in mGy. The renal artery embolization has the highest frame dose. Meanwhile, the IVC filter placement has the least frame dose.

Table 3 showed a comparison of the distribution of fluoroscopy time and DAP readings for the interventional procedures considered in this study with values obtained in the literature. A difference of more than 100% was observed between the radiation dose values obtained in this study and values reported in the literature.

DISCUSSION:

The findings of the present study showed intra-examination variation in terms of measured DAP radiation dose, which compares with the findings of Korir et al[8]. These variations are linked to the individual peculiarities of the cases, determined by the individual anatomy and pathology severity, the patient body size, clinical technique, available accessories, protocol, and operator experience [8]. These factors also explained the larger “mean” value of DAP dose recorded when compared to the short DAP and fluoroscopy time published in the literature as shown in table 3. One of the reasons may be because the angiography

center is newly established (became operational in the year 2011), and many accessories/consumables needed for speedy procedures are lacking to perform the examinations within a limited time frame. This should be of concern to the appropriate authorities in AKTH, because of the need to have rigorous training for the personnel and making the necessary resources available; so that procedures can be done within minimum time frame. The operator competency qualification level on the use of equipment, system dose reduction methods, and customized optimal imaging techniques were found to be essential in the optimization process [10]. Judicious choice of field of view size, and fluoroscopy pulse modes without adversely affecting the clinical quality of information obtained also play a role as a practical optimization method worthy of consideration [11].

Imaging technique and patient radiation doses: As expected, direct linkage between DAP readings and fluoroscopy time was noted in the present study Table 1 & 2. However, no association between the kV and radiation dose values observed. This perhaps could be explained as the kV build in the protocol is constant, and only the fluoroscopy time and mA changed. An integrated dosimetry system in fluoroscopy equipment provides a practical opportunity for radiological protection of patients, and also the possibility of advising

patients on potential radiation induced injuries and managing radiation dose during difficult as well as extensive procedures [7]. The machine used in the present study, has integrated DAP meter that estimates the radiation output during interventional procedures. The radiation doses measured in this study were above 2Gy, this indicates the possibility of early transient erythema in Peak Skin Dose (PSD) measurements. The skin injuries were possible in these examinations although variable individual radio sensitivity can influence the outcome. Patients exposed to radiation doses of these magnitudes should be advised on possible erythema effect. Patients with multiple interventional sessions should be checked subsequently for possible skin injuries on most exposed area of the body, and the irradiation exposure records should be analysed. The measured radiation exposure should therefore form an integral part of the patient's medical records within an institutional radiation safety program. The recording of the displayed dose data is critical towards developing age and size specific protocols, developing diagnostic reference levels, tracking radiation exposure of patients undergoing multiple sessions of fluoroscopically guided procedures or multiple imaging modalities [8]. DAP measurements can also be useful for dose estimation, and for patients found later to have been pregnant during the exposure period [8]. The time for interventional procedures was relatively long and varied even for the same type of

examination. The DAP and fluoroscopy time measured in this study were above the available reference levels in the literature Table 3. The renal artery embolization was performed with longer fluoroscopy time (49.5 mins) resulting in the observed high radiation dose measurements. Conversely, IVC filter placement and lower limb arteriogram examinations were performed with less fluoroscopy time (4.0 mins) leading to lower patient radiation dose. Patient dose management in interventional angiography is complicated by numerous beam projections, diverse patient anatomy, varying lesions, and disease presentations. To promote a radiation safety culture and optimization of interventional procedures, there is a need to provide specific training on radiation protection to the interventionists, establish an effective quality assurance program, and develop guidelines for validating and verifying the operator actions [12].

The findings of this study indicate that the published optimized patient radiation dose results from Healthcare Level I (HCL I) institutions (with at least one physician for every 1000 people) are important but should not lead to the false impression that the application of radiation protection principles, X-ray equipment, and procedures, follows a standardized scheme across the world [4]. Throughout the world, radiation protection of both patients and operators is a work in progress requiring regular analysis and

continuous improvement by the medical personnel, especially the imaging scientists who are more than the medical physicists in the developing countries. The difficulty of comparing radiation exposure results in the literature has been linked to a lack of standardization of data acquisition and uncontrolled variation in patient size, equipment differences, radiographic technique, and advances in technology [8].

There is an expanding use of high radiation dose modalities to perform complex medical procedures which results in high radiation exposures to patient. All the interventional procedures performed in this study, their measured DAP readings were within the levels of causing early transient erythema and skin epilation. This occurrence poses new challenges to the radiation protection community already faced with low availability of technically skilled personnel such as the radiographers, radiologists and medical physicists to handle the optimization of radiological protection of patients undergoing complex fluoroscopically guided procedures.

Based on the findings of this study professional guidelines and operational dose saving technology need to be developed and applied. The techniques for radiation dose reduction options include, the use of appropriate filtration, application of pulse fluoroscopy, appropriate compensation for various attenuation properties for patient body habitus, careful use of beam angles, reduction of the source to

image distance, avoiding repeated procedures on the same patient, regular clinical training of the operators and motivation of catheterization personnel [13].

CONCLUSION:

Interventional procedures performed in this study demonstrated a wide variation in DAP readings for the same examination type, and the mean DAP values exceeded the available DRLs in the literature. Optimization of these high radiation dose procedures could be enhanced through clinical training on acceptable equipment performance, standard operating procedures, and development of curriculum for continuous training of operators. These training skills should minimize the fluoroscopy time, dose rate, and the number of images acquired without compromising on the quality of the clinical images that are obtained.

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CASE REPORT:**DERMOID CYST IN THE FLOOR OF THE MOUTH- A CASE REPORT*****Jagadish H Chandra, ****^Priyanka K Shetty, **Veena KM and ***Nitin Gonsalves**

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ABSTRACT:

Dermoid cysts are rare developmental benign lesions that arise as a result of ectodermal differentiation of multipotent cells. Histologically the cysts are classified as dermoid, epidermoid and teratoid cysts depending on the presence of adnexal structures and derivatives of germ layers. When dermoid cysts appear in the floor of the mouth they can cause difficulty in deglutition and respiration. The differential diagnosis of dermoid cyst could be infection, ranula or tumor. Intraoral or extra oral approach for enucleation is the method of treatment. Dermoid cysts have a good prognosis with low malignancy and recurrence rate. A case report of a dermoid cyst in the floor of the mouth is presented in this paper along with clinical, histopathological evaluation and the treatment.

Keywords: Dermoid cyst, Floor of the mouth, appendages, enucleation.

INTRODUCTION:

Dermoid cysts are rare developmental or acquired lesions occurring most frequently on the face, scalp, neck and trunk representing <0.01% of all cysts of the oral cavity [1]. They occur in the region where the fusions of embryonic elements occur. Hence they are usually seen in the midline of the floor in the oral cavity. It is a cyst lined by epithelium containing all the skin appendages like hair follicle, sebaceous glands and sweat glands. Dermoid cysts may be found in any age group. Highest incidence of the cyst is between the 15

and 35 years age group [1]. Women are affected more than men. The most common location of dermoid cyst in the head and neck region is the lateral aspect of eyebrow followed by floor of the mouth [2]. Pathogenesis of the dermoid cyst is unknown with the most acceptable theory being the entrapment of the epithelium during the fusion of first and second branchial arches [3-6]. Clinically it presents as an asymptomatic slow growing mass and is usually diagnosed after reaching a considerable size. The treatment of choice is surgical excision [5].

In this case report, we describe a case of a large dermoid cyst occurring in the floor of the mouth in a male patient.

CASE REPORT:

An 18 year old male patient reported with the complaint of an intra oral swelling below the tongue since 4 years, which was initially small in size and gradually increased to present size. Patient had difficulty in speaking and swallowing. Swelling was asymptomatic. He was moderately built with no signs of physical illness and no relevant medical history reported. On examination, a diffuse swelling of 5 x 3.5 cm in the floor of the oral cavity which is smooth and non tender, doughy pitting type, non pulsatile, not fixed to the underlying structures was found (Fig 1a). There were no palpable lymphnodes. Based on the history and clinical features the following differential diagnosis were considered; i) Ranula, ii) Lipoma and iii) Vascular malformation. Ultra sonography was performed. The report was suggestive of mucous extravasation cyst. Hence surgical excision of the lesion was planned under General anesthesia. General Anesthesia was administered with all the necessary precautions. The patient was painted and draped under aseptic conditions. A trans mucosal sublingual incision was placed in the floor of the oral cavity extending from 34 to 44 (Federation Dentaire Internationale -FDI

tooth numbering system). Flap was elevated carefully by considering the anatomy of the region. The ducts of sub mandibular gland and rivinus were isolated. Care was taken not to traumatize the lingual nerve and sub lingual vessels. The lesion was well encapsulated. The resection was done in toto (Fig1b). Homeostasis was achieved by applying pressure and placing gauze packs. Copious irrigation of the area was done using normal saline. The margins of the incision were approximated and sutured using (4-0) vicryl to get a water tight closure.

The resected specimen was sent for histopathological examination. On gross examination, one single bit of formalin fixed tissue was received measuring around 7x4x2 cms, brownish white in colour, soft in consistency and was having a definite border (Fig 2a). The lumen showed a yellowish coloured, foul smelling, and gritty cheesy material (Fig 2b). Microscopic examination with Hematoxylin & Eosin [H&E] stained section revealed a cyst lined by orthokeratinised stratified squamous epithelium. Some areas showed a prominent granular cell layer. The cyst wall had a fibrous capsule that showed sebaceous and sweat glands (Fig 3a). Few hemorrhagic areas were seen and the capsule had keratin flakes (Fig 3b). Final histologic diagnosis was dermoid cyst of the epidermoid type.

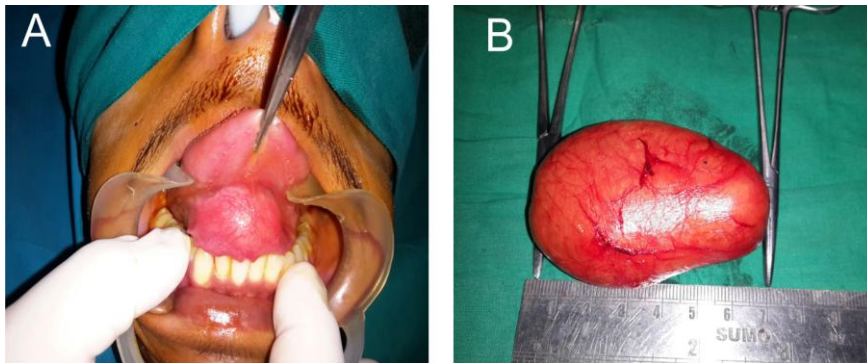


Fig 1: (A) Intra oral swelling in floor of mouth; (B) The resected lesion

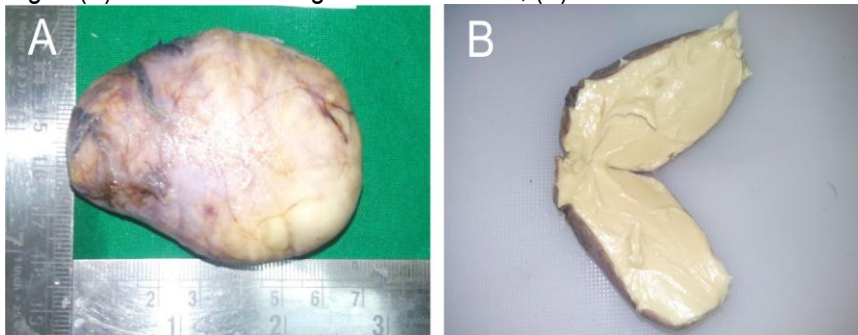


Fig 2: (A) Formalin fixed tissue; (B) Cross section showing gritty cheesy material

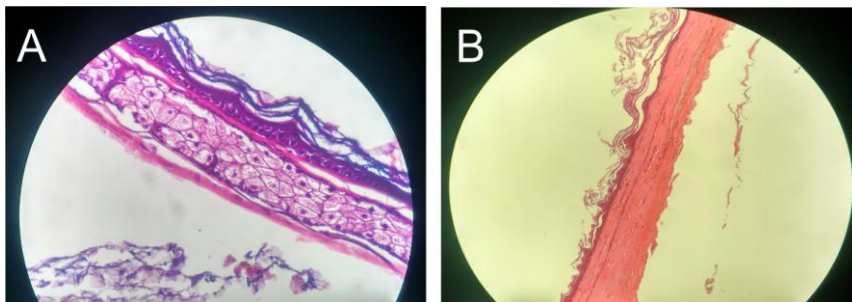


Fig 3: (A) Hand E section showing orthokeratinised stratified squamous epithelium with sebaceous glands (40x); (B) Keratin filled cystic cavity

DISCUSSION:

Several theories have been proposed to explain the development of dermoid cysts [3,7]. Dermoid cyst can occur anywhere in the body where fusions of embryonic elements occur. In the oral cavity, floor is the most common site in the midline. Because of their rarity, lateral dermoid cysts of the floor of the oral cavity are

rarely considered in the differential diagnosis of lateral submandibular masses. The term dermoid cyst in the floor of the oral cavity is used to describe three types of histologically related cysts in the respective area: dermoid, epidermoid, and teratoid cysts [8]. These histological variations are categorized according to Meyer's classification [9].

Anatomically, dermoid cysts are possibly divided into three different types- median genioglossal, median geniohyoid, and lateral cysts depending on the relationship between the cyst and the muscles of the floor of the oral cavity. Although floor of the oral cavity in the midline is most favored site, occasional occurrence involving the buccal mucosa, tongue, lips, uvula, temporomandibular joint, dermal graft, intradiploic, intracranial, and intraosseous location within the mandible and maxilla also have been cited in literature [10,11].

Dermoid cyst of the oral cavity varies ranging from few millimeters to 2 cm in diameter. Many a times there might be a sudden increase in the size of the lesion which may be due to the onset of puberty which results in the secretion of sebum from sebaceous glands. They are slow growing in nature and are of doughy consistency. They exhibit pitting after application of pressure measuring about 2.5 x 1cm in diameter. If the cyst is present above the genioglossus muscle, it lifts the tongue causing difficulty in speaking and swallowing. If it occurs below the genioglossus muscle then it produces sub mental swelling giving a double chin appearance. In the present case, the patient had a cyst which elevated the tongue leading to difficulty in speaking and swallowing which was suggestive of presence of cyst above the genioglossus muscle.

Fine needle aspiration cytology, ultrasound, Computerized Tomography (CT) and Magnetic Resonance (MR) imaging provide essential information on the cyst location that allows optimal preoperative planning. Ultrasonographic findings comprise solid and cystic structures within a heterogeneous mass [12]. On CT scans, the dermoids appear as moderately thin walled, unilocular masses filled with a homogeneous, hypoattenuating fluidic substance with numerous hypo attenuating fat nodules giving the pathognomonic “sack-of-marbles” appearance [13].

MR imaging of dermoid cysts gives variable signal intensity on T1-weighted images and is usually hyperintense on T2-weighted images and is of considerable importance in depicting the relationship of cystic mass and muscles of floor of the mouth. The preferably chosen treatment for cysts in the floor of the oral cavity is their total excision (enucleation) via intraoral or extra oral approach or a combination of both, determined on each occasion by the size and location of the cyst [2,14,15].

The patient was treated with intraoral approach. Proper care was taken not to rupture the cyst, as cystic contents may act as irritants to fibrovascular tissues, causing postoperative inflammation [16].

Post operative instructions were given. Capsule amoxicillin 500mg and Tab Brufen 400 mg was given. The patient was seen after ten days for

suture removal and followed up after 3 months with no signs of recurrence.

CONCLUSION:

In conclusion, dermoid cysts are rarely found in the floor of the oral cavity and it needs to be differentially diagnosed from other diseases and conditions of that area. Their clinical picture involving a detailed examination of the size and anatomical location usually aids in better diagnosis. The importance of prompt and effective surgical treatment helps to prevent recurrence of this cyst.

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CASE REPORT**TRAUMA INDUCED CALCIFICATION - AN ENIGMA**

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Running title: Calcified canal– A Case series

ABSTRACT:

Pulp chamber is considered as a very important and integral part of the tooth. Pulp chamber undergoes different types of morphological and pathological alterations. Calcified canals are one amongst other pathological alterations. Calcified root canals have been a challenge to the diagnostician and the dental physician before diagnosis and after diagnosis respectively. It is considered that the impact of an irritant to the tooth, like trauma, caries, infection and age changes can precipitate calcification. Calcification makes a dentist to negotiate with his treatment planning and at times it can be a surprise element.

Keywords: Pulpal calcification, Trauma, Ellis Classification, Pulpal necrosis

INTRODUCTION:

Calcification is considered to be the pulpal sequelae to trauma and aging phenomenon in an individual [1]. The exact mechanism of pulp canal calcification is unknown. Theoretically it may be because the sympathetic/parasympathetic blood flow to odontoblasts is altered, resulting in uncontrolled reparative dentin [1]. Another theory is that hemorrhage and blood clot formation in the pulp after injury is a nidus for calcification if pulp remains vital [2].

Microscopically, this calcific metamorphosis is characterized by multifocal, dystrophic calcifications usually, composed of ill-defined secondary dentin [3,4]. Pulpal calcification remains to be a challenging task for dentist in treating and achieving a desired outcome. Herein we report two case of trauma induced pulpal calcifications.

CASE REPORT 1:

A 22 year old medically fit male patient came to the department of oral medicine and radiology

with a chief complaint of broken teeth in upper front tooth region since 5 years associated with a fall from a two wheeler. Patient gave a history of root canal treatment 5 months ago, which he had to discontinue due to personal reasons. He gave no history of deleterious habits and was moderately built and nourished. No significant extraoral findings were noted. Intraoral examination revealed loss of crown structure involving enamel and dentine in relation to right and left maxillary right central incisor.

Discoloration of the crown was seen in left maxillary central incisor with an access opening seen on the lingual aspect. On palpation and percussion no tenderness was evident.

A provisional diagnosis of Ellis Class IV fracture in relation to left maxillary central incisors and Ellis Class II fracture in relation to right maxillary central incisors was given. Electric pulp testing was conducted with negative response. Intraoral periapical radiograph was advised which revealed wide pulp chamber and canal, with open apex in the left maxillary central incisor with root resorption at the apex. Maxillary right central incisor revealed calcification of the root canal (Figure

1). A final diagnosis of Ellis Class IV fracture with root resorption in relation to left maxillary central incisor and Trauma induced pulpal calcification was given in relation to Maxillary right central incisor. Patient was referred to the department of endodontics for endodontic therapy.

CASE REPORT 2:

A 24 year old female patient came to the department of oral medicine and radiology with a chief complaint of discolored teeth in upper front tooth region since 2 years, with no history of pain; patient gave a history of fall 4 years ago. Past medical and dental history was non contributory. Intraoral examination revealed yellowish discoloration of coronal aspect of right maxillary central incisors. No tenderness elicited on palpation and percussion.

A provisional diagnosis of Ellis Class IV fracture was given. Electric pulp testing gave a negative response. Intraoral periapical radiograph revealed calcification of coronal and radicular part of the pulp canal, suggestive of trauma induced calcification (Figure 2). Patient was referred to speciality of endodontics and prosthodontic evaluation.



Figure 1: Pulpal calcification seen in Maxillary right central incisor. widening of pulp chamber and canal along with root resorption of maxillary left central incisors

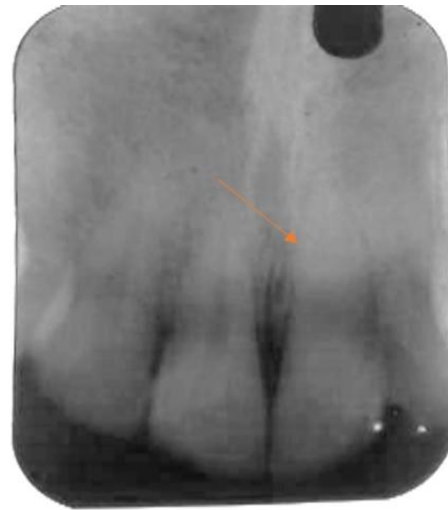


Figure 2: Pulpal calcification seen in Maxillary right central incisor

DISCUSSION:

Dental pulp calcification presents as masses of calcified tissue present on the level of the pulp chamber and roots of the teeth [5]. Dental pulp calcification occurs in all age groups with an increase in frequency in older age groups and in those teeth where there is an insult to pulp [6]. The formation of pulp stones has also been associated with long-standing irritants such as caries, deep fillings, and chronic inflammation. Despite a number of microscopic and histochemical studies, the exact cause of such pulp calcifications remains largely unknown [7].

The two chief morphologic forms of pulp calcifications are discrete pulp stones (pulp nodules, denticles) and diffuse calcifications. Pulp stones are classified as per their structure

into true denticles and false denticles. True denticles are made up of localized masses of calcified tissue that resemble dentin because of their tubular nature. Actually these tubules bear greater resemblance to secondary dentin than to primary dentin, since the tubules are few and irregular. They are considerably more common in pulp chamber than in root canal [8].

False denticles are composed of localized masses of calcified material and unlike true denticles do not exhibit tubules. Instead the nodules appear to be made up of concentric lamellae or layers deposited around a central nidus. The exact nature of this nidus is unknown, although Johnson and Bevelander believe it is composed of cells, as yet unidentified, around which is laid down a layer of reticular fibers that subsequently calcify [8].

Pulp calcifications have been noted in patients with systemic or genetic disease such as dentin dysplasia, dentinogenesis imperfecta and in certain diseases such as Vander Woude syndrome [9].

The presence of calcifications does not affect the threshold of electric pulp testing, as was obtained in both the reported cases. Completely calcified canals can be untreated, but should be kept on constant observation, and if discoloration of the coronal aspect of the teeth is noted, prosthetic rehabilitation becomes mandatory [10]. In case of partially calcified canals management includes, orifice recognition, biomechanical preparation and use of chelating agents like EDTA can be considered [11,12].

CONCLUSION:

Knowing the anatomy of the teeth and its developmental and pathological changes plays a major role in giving beneficial treatment to the patient. Evaluation of such pathologies and age changes are of utmost importance so that more and more research can be carried out in giving clarity about any such kind of phenomenon.

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