Ethical approval and informed consent health and social care essay

Introduction

Throughout the world, a demographic revolution is underway. The proportion of older people is growing faster than of any other age group. Approximately 600 million people are aged 60 years and over, and this number will double by 2025. By 2050, it will be 2 billion, 80% living in developing countries. This poses tremendous challenges to health and social policy planners, particularly because disease patterns will shift concurrently. Chronic diseases such as cardiovascular disease, hypertension, cancer and diabetes are prevalent in old age, are fast becoming the leading causes of disability and mortality. Nutrition is one of the important components of health, functional independence and quality of life in elderly population1. In this age group, malnutrition is common2 and the risk of malnutrition increases with the advancing age3–5. Age associated reductions in food intake combined with the presence of debilitated diseases, social isolation, economic limitations, altered health status and multiple hospital admissions complicate the nutritional balance in elders. With the increase in the elderly population and the greater number of teeth being retained into old age elderly people are more prone for many oral diseases. Studies have shown 47% of the elderly show evidence of root caries [34]. Dental caries is considered to be a significant risk factor for tooth loss (11-14) leading to reduction in chewing ability in elderly people. In addition, the process of age-related bone loss that occurs throughout the skeleton may also affect the alveolar bone that supports the teeth, resulting in increased risk of tooth loss and edentulism. Periodontal disease also increases with age and are shown to be exacerbated by nutritional deficiencies [35]. Saliva plays a central role in the

maintenance of oral homeostasis. The complex mixture of proteins, glycoproteins, mucins, and ions helps prevent many oral diseases. Saliva is important for oral clearance, buffers acids generated by oral bacteria and has antimicrobial action against many pathogenic microorganisms (M. Leander et. al). Any changes in saliva predispose individuals to be at risk for serious oral complications. Nutritional status acts as a modifying factor in the development of many oral diseases. Very few studies have assessed the relation between saliva, nutritional status and oral health. Rhodus et. al found an association between low salivary secretion and deficient intake of nutrients in both hospitalized and home-dwelling elderly people. Another study by Dormenval et. al showed that there was a relation between poor nutritional status and reduced salivary flow rate in hospitalized elderly. Samnieng et. al showed that the elderly group having hyposalivation had a lower Mini Nutritional Assessment score compared with the group having normal salivation. Study by Anna. Maija et. al however; found no such association between salivary flow rate and nutritional status of home dwelling elderly. Most of these studies assessed salivary flow rate without considering other salivary parameters (pH, buffering capacity, total protein and total calcium). Also these studies assessed the oral health status only in terms of masticatory function and majority of these were conducted on hospitalized elderly people. Hence, the present study was planned to assess the relationship of salivary factors (flow rate, pH, buffering capacity, total protein and total calcium), dental caries and nutritional status among institutionalized elderly people.

Materials & methods:

A cross-sectional descriptive study was conducted in three oldage homes in Nellore city in the month of August 2012. A total of nine oldage homes are in Nellore city, out of which three oldage homes accepted to participate for the study. All the institutionalized elderly aged 50 years and above were included for the study. Those participants who were bedridden and unable to communicate verbally were excluded.

Ethical Approval & Informed consent:

Ethical approval for the study was obtained from the institutional ethics committee, Narayana Dental College and Hospital, Nellore and from the Directors of the respected oldage homes. The principal investigator explained the study procedure in detail to the participants and they were also clearly informed that the participation was purely voluntary and consent was taken from all participants.

Study Procedure:

The study proceeded in three parts. The first was an interview using a specialized proforma for collecting information on the demographic data and nutritional assessment this was followed by clinical examination and finally the third part consisted of salivary collection and analysis. The specially designed proforma collected basic demographic details of subjects and assessed their nutritional status using Mini Nutritional Assessment, which was developed to be used on elderly populations [Guigoz Y, Vellas J, Garry P (1994)]2. The MNA is composed of 18 simple and rapidly measured items, can be performed in less than 15 minutes. The test involves (1)

anthropometric assessment (weight, height, arm and calf circumferences, and weight loss); (2) general assessment (six questions related to life style, medication, and mobility); (3) dietary assessment (eight questions related to number of meals, food and fluid intake, and autonomy of feeding); and (4) subjective assessment (nine self-perception of health and nutrition). The scoring for each part categorizes the elderly patients in the following manner: (1) well-nourished (normal); (2) at risk to malnutrition (borderline); (3) malnourished. Following the nutritional assessment, clinical examination was carried out for recording dental caries using dentition status index(WHO 1997 basic methods)4.

Saliva Collection:

Participants were advised to refrain from intake of any food or beverages (Water exempted) one hour before collecting saliva. The participants were then instructed to sit in a relaxed position and asked to chew the paraffin wax for 5 min, spit the saliva into a pre-weighed container. Finally, the collected samples were transported in a thermal insulation box maintaining a constant temperature of 40C and were sent to the laboratory within 30 minutes for further analysis. Salivary Analysis was performed by trained laboratory technician at the central laboratory of Narayana Medical College, Nellore. Estimation of Flow Rate of Saliva was calculated in g/ml which is equivalent to ml/min [Mahvash Navazesh, 2008]. The pH was measured by a manual pH meter (Systronics, India) and the buffering capacity was determined by the modified Ericsson method for smaller volumes [Ericsson Y]. The total protein and calcium levels of the samples were measured by an auto analyzer (Erba, Chem-7). The principle for estimation of total proteins

and calcium levels was based on the end point enzymatic method and were assessed by using salivary diagnostic kits.

Standardization of instruments:

The reliability of the laboratory equipment, was tested with every eighth sample being retested for Flow rate, pH, buffering capacity, Total protein and Calcium levels these values were found to be consistent. Statistical analysis: Data analysis was performed using the SPSS 16 version. Analysis of variance (ANOVA) was done to determine the difference between groups and the t-test was used to compare the data. Pearson's rank order correlation was done to determine the association between MNA and caries risk and physicochemical properties of saliva.

Results:

A total of 96 elderly people were present in the three oldage homes which participated in the study. Out of 96 elderly people 7 were bed-ridden and 8 people were unable to communicate verbally hence, excluded from the study. Analysis of the demographic data among the elderly subjects' revealed the mean age of 70. 12±7. 32yrs there was a higher representation of females (58. 02%) when compared to males (Table1). The subjects were categorised based on their Nutritional status according to the Mini Nutritional assessment (1994)2 criteria. About 43% of subjects were at risk of malnourishment and 14% were malnourished (Table 2). Analysis of salivary parameters in relation to nutritional status of subjects showed that salivary flow rate decreased in malnourished subjects (0. 50±0. 100) when compared to well-nourished subjects (0. 93±0. 260). Hyposalivation was observed in subjects (0. 5ml/min) who were malnourished. The buffering capacity also

showed a decrease in the subjects who were malnourished (1. 90±0. 260) when compared to well-nourished subjects (2. 00±0. 366) however; this was not statistically significant (Table 3). Comparison of mean DMFT scores in relation to the nutritional status revealed that the caries experience increased with poorer nutritional status which was statistically significant (Table 4). On analysing the caries experience, nutritional status and salivary parameters, a positive co-relation was observed between nutritional status and salivary flow rate (fig 1) where as a negative co-relation was observed between caries experience and improved nutritional status of subjects (fig 2). Table 1: Demographic characteristics of the study subjects: Characteristics of the study subjectsPercentage of subjectsAge group in years50-596. 17%60-6937. 03%70-7941. 97%80-8914. 81%GenderMale41. 97%Female58. 02%Table 2: Categorization of the subjects based on their nutritional status: MNA groupsnMalnourished14%At risk of malnourishment43%Well nourished43%Table 3: Salivary parameters of the subjects in relation to their nutritional status:

Salivary parameters

Groups

Mean±S. D

p-value*

Flow rate(ml/min)MalnourishedAt Risk of malnourishmentWell nourished0. 50±0. 1000. 82±0. 2090. 93±0. 260p <0. 001*pHMalnourishedAt Risk of malnourishmentWell nourished6. 68±0. 3546. 81±0. 2276. 78±0. 266Buffer Capacity (ml)MalnourishedAt Risk of malnourishmentWell nourished1. 90±0. 2862. 04±0. 3402. 00±0. 366Total ProteinMalnourishedAt Risk of

malnourishmentWell nourished2. 06±0. 5872. 41±0. 7162. 38±0. 809Total CalciumMalnourishedAt Risk of malnourishmentWell nourished7. 32±1. 3917. 18±1. 7066. 72±1. 809* Significant at the 0. 001 level (2-tailed); post-hoc test. Table 4: Dental caries experience of the subjects in relation to their nutritional status:

MNA groups

[DMF(T)]

p-value

Malnourished12. 45±5. 574P <0. 05*At Risk of malnourishment10. 51±8. 535Well nourished6. 34±5. 765

*Significant at the 0. 05 level (2-tailed); post-hoc.

Fig1: Correlation of Nutritional status with salivary flow: Fig 2: Correlation of Nutritional status with DMFT:

Discussion:

In recent years, very few studies have been published on malnutrition among elderly people. Thus the present study was planned to assess the relationship of salivary factors (flow rate, pH, buffering capacity, total protein and total calcium), dental caries and nutritional status among institutionalized elderly people. More than 50% of the institutionalized elderly were at risk of malnutrition. The mean MNA score in the present study was 23. 14±2. 790 which compared to the MNA scores (22. 7±5) in studies conducted among elderly by Saletti A et. al 1997 and 1999 in Sweden. On the contrary in a study conducted in American among 350 healthy elderly people, the mean MNA score was 27. 18±1. 8 (Scheirlinckx

et. al., 1997) which was bit high compared to our study. Indian reference values for MNA in healthy elderly people have not been determined. The validated version of MNA as an instrument for assessment of nutritional status in elderly was used in the present study. MNA questionnaire has been validated against the clinical assessment by experienced physicians (Guigoz et. al., 1996)2. Based on the nutritional assessment score the elderly subjects in the present study were classified into three MNA groups of them 14% were malnourished and 43% were at risk of malnourishment and 43% were well nourished. In our study we found that there is reduced salivary flow rate in malnourished group when compared to well-nourished group. In one study (Anna-Maija et. al. 2012) they found that there was no significant relationship between salivary flow rate and nutritional status, the reason may be salivary collection was not done following the circadian rhythm. In another study (P. Samnieg et. al 2012) they found hyposalivation in malnourished group when compared to well-nourished group. According to past literature nutrition has an important role on oral health which is essential for the formation of healthy teeth and maintainence of oral and circumoral tissues throughout life. Inadequate amount of nutrient intake can result in fragile and friable oral tissues which cause diminution of cell integrity and renewal, proper function of tissues and salivary gland function in elderly. Physiological process like aging can bring morphological appearance of salivary gland. There is evidence from animal experiments that malnutrition reduces flow rate of saliva and changes its composition (Johansson et. al 1985; Johansson and Ericson 1987). In our study, qualitative analysis of saliva (pH, Buffering capacity and total protein) though they were not statistically significant they were found to be reduced in malnourished

when compared to well-nourished. The reason might be, as per the literature decreased salivary flow rate leads to decreased pH and buffering capacity which has a direct relationship on the increased caries experience. So, in our study we found that nutritional status has an impact on salivary gland hypofunction which lead to decreased pH, buffering capacity and increased caries experience in malnourished group when compared to well-nourished group. The known fact about the other components of saliva like total protein and total calcium was low when compared to levels in plasma. As per the known literature, calcium levels in saliva should increase with the increase in salivary flow rate but in our study we found negative relation with the salivary flow which was not statistically significant with the nutritional status also. One study (Nobuoko Murayama et. al., 1999) showed that there was no relationship between the protein-energy malnutrition and the total protein of saliva. Our study has also found that there was no significant relationship between the salivary total protein and malnutrition. So, to conclude that in our study we found malnourished group had decreased salivary flow rate which lead to decreased pH and buffering capacity resulting in increased caries experience when compared to the well-nourished group. Further, research should be done to know the relationship of salivary changes, caries experience and risk of malnourishment.