Research Protocol

DOI: 10.7860/JCDR/2023/58804.17664

Dentistry Section

Evaluation and Correlation of Vitamin D Levels and Jaw Bone Mineral Density in Premenopausal and Postmenopausal Female Patients Undergoing Implant Therapy: Protocol for a Cross-sectional Study

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ABSTRACT

Introduction: Vitamin D deficiency is one of the most common nutritional deficiencies worldwide. The amount and quality of bone at the implant installation site have an impact on the implant's prognosis however, the effects of menopause on jaw bone remain unknown. Few studies have looked at the prevalence of vitamin D deficiency in India's general population, but none have looked at the link between vitamin D deficiency (osteoporosis) and postmenopausal women's jaw Bone Mineral Density (BMD). This is the first study of its sort in India to look at postmenopausal women's vitamin D levels and jaw BMD.

Need of the study: The present study would enhance the relationship between vitamin D levels and BMD in premenopausal and postmenopausal females and will help to conclude the effect of menopause on bone quality and quantity which should be considered in dental treatment.

Aim: To evaluate and correlate vitamin D levels and jaw BMD in pre and postmenopausal females undergoing implant therapy.

Materials and Methods: This cross-sectional study will include 50 partially or completely premenopausal (n=25) and postmenopausal females (n=25) having edentulous anterior and posterior maxillary and mandibular jaws. Females will be tested to evaluate their vitamin D levels and jaw BMD with Cone Beam Computed Tomography (CBCT) and results will be recorded in Hounsfield Units (HU) using Planmeca romexis viewer software. Chi-square test and Students t-test will be used.

Keywords: Bone density, Cholecalciferol, Oestrogen levels, Osteoporosis

INTRODUCTION

Vitamin D insufficiency affects around one billion people around the world [1]. Vitamin D deficiency can be caused by a lack of sunlight or a dietary deficiency. It is also limited to elderly people who have chronic illness [1]. Lower dietary calcium and vitamin D levels have resulted in inadequacy in postmenopausal women, potentially increasing bone loss. Vitamin D levels in serum range from 30-55 ng/mL on average. A level <20 ng/mL has been judged insufficient, while a range of 20-30 ng/mL has been regarded as inappropriate [1].

Intake of proper vitamin D and calcium nutrition is usually regarded as the cornerstone of osteoporosis prevention and treatment. Supplementing with vitamin D and calcium has a proven advantage in elder postmenopausal women, with or without the intake of calcium and vitamin D supplementation, has been found to enhance BMD (as demonstrated in spine density and decreased bone loss at the hip bone), as well as decrease bone turnover and non vertebral fractures [2]. Subclinical vitamin D deficiency has been associated with bone density loss in postmenopausal women [2].

Postmenopausal women have lower oestrogen levels, leading to a significant bone mass reduction, known as postmenopausal osteoporosis [3]. There are roughly 30% of postmenopausal women in the United States and Europe having osteoporosis, with 40% of these women experiencing atleast one fragility fracture over their remaining lives [3].

Osteoporosis has been linked to an increased rate of tooth loss and loss of the tooth-supporting alveolar bone, in addition to a greater incidence rate of hip, spine, and wrist fractures [3].

The quantity of inorganic minerals in our bones is normally measured using BMD. Mineralised bone is vital for maintaining bone strength and is required in the event of fractures or the prevention of disorders such as osteopenia and osteoporosis. The BMD levels are affected by a variety of factors, including gender, age, inheritance, bone-loss disorders, alcohol consumption, sedentary lifestyle, BMI, and low vitamin D levels. BMD is affected by other diseases like diabetes and hypertension [4]. After reaching peak bone mass between the ages of 18 years and 20 years, the skeletal maturation process is complete, and thereafter, BMD levels begin to fall. Because osteoporosis and low bone mass are less common in men than in premenopausal and postmenopausal women [4].

Teeth loss can cause jaw bone neuromuscular instability, lower masticatory efficiency, vertical dimension loss, and poor aesthetics [5]. Now-a-days, the rehabilitation of oral tissue and function with a dental implant is proven to be effective and predictable [5]. The prognosis of an implant is influenced by its BMD (both quantitative and qualitative) at the implant placement site [6]. Bone amount, which can be assessed more precisely by many X-rays Computed Tomography (CT) systems, is an important determinant for implant placement feasibility and the potential for bone grafting [7].

As a result, CBCT, which is more objective and reliable, may be the ideal radiographic tool for morphological and qualitative characterisation of residual bone, and it has been utilised in the majority of investigations. The software programme in CT machines determines the HU, which vary from -1000 (air) to 3000 (enamel) [7].

The correlation of vitamin D level and menopausal condition on jaw bone about its BMD for dental implant therapy has not been well-documented therefore this study will be conducted with the following objectives:

- To evaluate the vitamin D levels amongst premenopausal and postmenopausal females.

- To evaluate the jaw BMD amongst premenopausal and postmenopausal females using CBCT.
- To estimate the correlation among the following variables- age of the premenopausal and postmenopausal group, vitamin D levels, BMD.

REVIEW OF LITERATURE

Vitamin D and BMD are critical for sustaining the structure and function of bones [1]. When a woman reaches menopause, her body's vitamin D levels begin to dwindle. Similarly, the menopausal status of the women was found to be substantially linked with BMD. In comparison to postmenopausal women, women in their reproductive years had significantly higher BMD [1]. This emphasises oestrogen's function in bone maintenance, calcium management, and its direct relationship with vitamin D levels [1]. Labronici PJ et al., compared vitamin D levels to BMD in postmenopausal women with and without fractures. After correcting for age, the results revealed a strong association between vitamin D levels and BMD [1].

A study by Munakata N et al., looked at the impact of menopause on BMD and mandible width, and concluded that menopause has an effect on bone quality and quantity in the partially edentulous molar region of the mandible, which should be considered in dental treatment for postmenopausal women [6]. Suganthan N et al., conducted their study on that BMD of hip bones were assessed by Dual-energy X-ray Absorptiometry (DEXA) and blood samples were taken to evaluate vitamin D levels and they concluded that because their study revealed a higher vitamin D deficiency prevalence among postmenopausal women with suspected osteoporosis [8]. So to prevent fracture, treatment of vitamin D deficiency with supplementation is essential. Khan AW et al., in their research focused on the influence of menopause on vitamin D levels and BMD, as well as the relationship between the two [9]. They also discovered that women in their reproductive years had much higher BMD than those after menopause. For women with vitamin D deficiency and low BMD, calcium and vitamin D supplementation, as well as frequent sun exposure and dietary adjustments, are indicated.

A review was done by Man PW et al., and Mezquita P et al., on the relationship between BMD and blood vitamin D levels in the Chinese population. Low BMD is linked to the prognosis of hip fractures in Chinese individuals, as low vitamin D levels are linked to low BMD [10,11]. In 2001, postmenopausal women were the subjects of a similar study. Vitamin D insufficiency was found to accelerate bone loss and was a major factor in increasing the risk of fractures, which increased the likelihood of osteoporosis in otherwise healthy postmenopausal women. Another study by Harinarayan CV et al., was conducted concerning vitamin D and BMD in premenopausal and postmenopausal women [12]. Women of reproductive age and postmenopausal women with low BMD levels were shown to have low vitamin D levels. Patients with vitamin D deficiency and low BMD were given vitamin D and calcium supplements to prevent diseases like osteoporosis, osteoarthritis, and ostopaenia later in life.

Postmenopausal females with compromised bone conditions should be routinely examined for vitamin D levels. This will help the clinician to get an accurate knowledge and understanding of the patient's condition. Accordingly, implementing various therapies to increase BMD can be advocated in patients undergoing dental implant therapy.

Vitamin D testing should be done regularly in postmenopausal females who are undergoing dental implant therapy and have a compromised bone condition, so that concrete decision can be made about whether or not to start Vitamin D supplementation/ therapy as a routine to increase BMD. And its implications affect the treatment's overall planning and prognosis.

MATERIALS AND METHODS

It is a cross-sectional study, which will be conducted in the Department of Prosthodontics, Crown and Bridge, Sharad Pawar Dental College, Sawangi (Meghe), DMIMS DU, Wardha and duration of the study will be two years. Ethical approval for this study has been obtained by the Institutional Review Board {Ref no:DMIMS(DU)/ IEC/2022/777}.

Inclusion criteria:

- All premenopausal and postmenopausal females either edentulous or partially edentulous and willing to participate in the study.
- No history of oophorectomy or hysterectomy
- Patients indicated for an implant-supported restoration.
- The patient should not have any medical conditions (besides osteoporosis) that would make implant treatment more complicated.
- They should have no local disease or condition that could interfere with implant treatment, such as periodontal disease, endodontic problems, caries, occlusal problems, tooth fracture, or tooth wear, as well as bony lesions.

Exclusion criteria:

- Hyperparathyroidism, renal dystrophy, oophorectomy, and skeletal bone disorders significantly affect bone metabolism.
- As well as the usage of bone-related medications such as corticosteroids, oestrogens preparations, bisphosphonates, and vitamin D supplements.
- Uncontrolled diabetes, uncontrolled hypothyroidism, the habit of smoking, alcoholics
- Pregnancy
- Psychological instability
- Cancer radiation and chemotherapy
- History of radiation therapy to the jaws
- Habit of bruxism
- Bad oral hygiene which continues despite motivating treatment.

Sample size calculation: Cochran formula for sample size estimation:

$$n=\frac{Z^2_{\alpha/2}P(1-P)}{E^2}$$

Where,

$Z_{\alpha/2}$ is the level of significance at 5% i.e., 95% Confidence interval=1.96

p=0.02 Khan AW et al., [9]

E=Error of Margin=6%=0.06

$$n=\frac{1.96^2\times0.02\times(1-0.02)}{0.06^2}=20.91$$

=25 patients are needed in each group and so total sample size of 50 will be considered.

This study will be conducted on 50 female patients including 25 premenopausal females and 25 postmenopausal females with partially or completely edentulous anterior and posterior regions of both maxillary and mandibular jaw. Females will be tested to evaluate their vitamin D levels. Electrochemiluminescence is being used to determine vitamin D levels in the blood. BMD measurement of the jaw will be measured with CBCT and recorded in HU using Planmeca viewer software.

STATISTICAL ANALYSIS

Chi-square test, Students t-test will be used. The level of significance at 5% i.e., 95% Confidence interval=1.96 will be considered in the study. Software used will be Statistical Package for Social Sciences (SPSS) version 27.0, GraphPad Prism and 7.0V.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Jul 08, 2022
- Manual Googling: Oct 18, 2022
- iThenticate Software: Nov 04, 2022 (22%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Jul 07, 2022**
Date of Peer Review: **Aug 05, 2022**
Date of Acceptance: **Nov 06, 2022**
Date of Publishing: **Mar 01, 2023**