Research Protocol for-A Study of Association between Vataprakopak Hetu and Asthikshaya with Special Reference to Bone Mineral Density: A Case Control Study

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Abstract

Asthikshaya is a condition in which there is diminution of asthi dhatu takes place. Similar symptoms occur in osteoporosis. It is a major health problem of ageing population. Fracture is the most common complication of osteoporosis which increases the risk of morbidity as well as mortality. The causative factors of asthikshaya are not mentioned separately in ayurvedic text. According to ayurvedic principal of ashrayashrayee bhava, the factors causing vitiation of vata are responsible for the kshaya of asthi dhatu. But this association is not studied yet. So the objective of this study is to find association between factors causing vitiation of vata and asthikshaya. Two groups having 100 patients each will be enrolled for the study. Group-1 is cases having BMD t-score less than or equal to-1 and group 2 is controls having BMD t-score -1 and above. Every individual subjective will be assessed on subjective and objective parameters. 10 vatarakopak hetu will be analysed in these patients. Their existence, quantity, duration and frequency will be asked for. Observations obtained on the basis of examination of patients through the study will be entered in CRF and data collected will be presented in the form of table and graphs. Continuous variables will be compared between case and control by performing independent t-test. Categorical variables are compared by Chi-2 test. Association of risk factors and disease (cases) will be assessed by calculating odds ratio, 95% confidence interval. $p<0.05$ will be taken as statistical significance. We expect that this study proves this association then it will be very helpful in awaring the population regarding avoidance of these causes, prevention of disease and its further complications.

Keywords: Vataprakopak hetu; Asthikshaya; Osteoporosis; Ashrayashrayee Bhava; Bone mineral density

Introduction

Ayurveda is one of the most ancient medical sciences of the world. It states that panchamahabhutas are present in the body in the form of Doshas, Dhatus and Malas comprising various organs and organ systems.

The state of equilibrium of Dosha, Dhatus, Malas is health and its disturbance is termed as illness. [1] Thus along with doshas dhatu and their related strotas plays an important role in maintenance of the health. The main function of dhatus is Dharana and Poshana of theSharira. Amongst the SaptaDhatu,Asthi is the fifth Dhatu.

It is predominant of Prithvimahabhuta and acts as a hard support for all other soft tissues to grip on. [2] Eighteen typeof Kshaya had been described by AcharyaCharaka, three DoshaKshaya, seven DhatuKshaya, seven Mala Kshaya and one OjaKshaya. Asthikshaya is a type of DhatuKshaya.

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[3] Asthikshayais a condition in which there is Kshaya(diminution of Asthi Dhatu(bone tissue. There is qualitative and quantitative decrease of Prithvimahabhuta at the level of Asthi. The ability to hold up the body is decreased leading to weakness in the bones due toloss of its Sthira, Sandra, Sthula and Sanghata properties. The etiological factors of Asthikshaya are not mentioned separately in the text. Asthi Dhatuis the main site of Vata Dosha. According to the principal of Ashrayashrayee Bhava, Prakupita Vata leads to Kshaya of Asthi Dhatuas Vata and Asthiare inversely proportional to each other. [4] So the factors responsible for vitiation of Vata cause Asthikshaya. Asthivahasrotodushti in the firm of Kshaya occurs in Asthikshaya. In Srotodushtihetu of Asthivahasrotas 'Vatalanam cha Sevanat' is mentioned. [5] Consumption of Vataprakopakahara-vihara is one of chief cause of Asthivahasrotodushti. Vataprakopakahara-vihara are the Hetu which are having properties similar to Vata and excessive exposure to these acts causeVataDusti in the form of Prakopa and lead to diseases of Vata. These factors are excessive exercise, intake of dry vegetables, irregular dietary habits which includes excessive fasting, dieting and limited foods, excess of food also, excess of worry, grief, fear, hunger, waking at nights, letting out excess of blood, Dosha, DhatuMala and time factor (Adanakala and Vridhavastha. For better understanding these factors leading to Vataprakopa can be classified asAharaj (Dietary, Viharaj(Lifestyle, Manasika (Mental and anya. [6,7] There are two main reasonsby which vitiation of Vata takes place - Dhatukshaya and Margavarodha. [8] Due to consumption of RukshadiAahara, all the DhatusRasa, Rakta, Mamsa etc. subsequentlyundergoKshaya causing Dhatukshaya. This Dhatukshaya results into the vitiation of Vata. Another type of Samprapti occurs due to SantarpanotthaHetusevana such as Adhyashana, diwaswapwhich cause Margavrodha. Here Kapha is found as AnubandhiDoshatogether withVata. The symptoms of Asthikshaya are similar to Osteoporosis, in which there is a decrease in bone mass leading to increased bone fragility and susceptibility to fractures. It is a major health problem of ageing population.

In Osteoporosis, most of times there is a long dormant period before clinical symptoms develop. Most prevalent complications seen are fractures of vertebral bodies, ribs, proximal femur, humerus, distal radius with minimal trauma. [9] Nearly 75% of hip, spine and distal forearm fractures among 65 years old or over. Worldwide, 1 in 3 women over age 50 will experience osteoporotic fractures, as will 1 in 5 men aged over 50. By 2050, the global osteoporosis sufferers will reach 6 million including both males and females, 3/4 of who will reside in developing countries. [10] Bone Mineral Density is useful for the diagnosis of Osteoporosis. It measures the amount of minerals (such as calcium) per square centimeter of bones. Bone Mineral Density (BMD) test is an important predictor of having a fracture in the future. [11] Ayurveda highlights more on prevention of disease rather than its treatment. Nidanparivarjanam is one of the important aspects in treating disease; hence etiopathogenesis study of disease is important in all aspects. [12] Many studies carried out on Asthikshaya, but this type of study to find association between Asthikshaya and its causes is not yet carried out. Here, an effort is made to find out associationof VataprakopakHetu as etiological factors in Asthikshaya with special reference to bone mineral density.

Materials

Infectious diseases occurred commonly in prior era, which are now irradiated by invention of modern medicines. In today's era, metabolic diseases are occurring commonly which are not completely curable. Osteoporosisis a major global health problem. Like many other diseases such as cardiovascular diseases, arthritis it has no early symptoms and is diagnosed after a fracture occurred due to a simple trauma. Osteoporotic fracture can turn out to be life threatening; 1 in 5 persons die during the first year after a hip fracture, whereas nearly one third need nursing home placement after hospital discharge, and fewer than one third recover their pre fracture level of physical function.

[13,14] Advanced age , sex hormone deficiency , a diet having low calcium, magnesium and vitamin-D, smoking, alcoholism, prolonged corticosteroid therapy, low Body Mass Index (BMI)are some of the causes of Osteoporosis. [15] Perhaps it has been seeing that people taking nutritious, rich calcium diet are also suffering from the disease. So there is a need to find out the causes of this disease according to Ayurveda. The present study will be helpful to rule out the factors responsible for Asthikshaya and also to aware the population about the causative factors for prevention of disease.

Research question

A. Is there any association between Vataprakopak Hetu as and Asthikshayawith special reference to bone mineral density?

Hypothesis

Null Hypothesis (H0): There is no association between Vataprakopak Hetu and Asthikshaya with range of bone mineral density.

Alternative Hypothesis (H1): There is association between Vataprakopak Hetu and Asthikshaya with range of bone mineral density.

Objectives

To find association between Vataprakopak Hetu and Asthikshaya

To study Vataprakopak Hetu in patients of Asthikshaya.

To aware the population about the prevention of disease and further complications of Asthikshaya.

Methods

Study design

The study is case control study in which cases will be subjects having BMD T-score less than or equal to -1 and controls will be subjects having BMD T-score -1 and above.

Age and sex match control will be taken.

Bone mineral density (WHO criteria for osteoporosis) [16]

T-score

Normal = -1 and Above

Osteopenia = Between -1 to -2.5

Osteoporosis = less than or equal to -2.5

Severe osteoporosis = less than -2.5 with fracture

Setting (location of study)

The study will be conducted at DMM Ayurved Mahavidyalaya, Yavatmal and DMAMCH and RC, Nagpur.

Participants: Total of 200 patients will be enrolled for the study (100 cases and 100 controls).

Case: Subjects having BMD T-score less than or equal to-1(Patients having Osteopenia and severe osteoporosis will be considered as cases)

Control: Subjects having BMD T-score-1 and above

Age and Sex match control in 1:1 ratio will be taken i.e. one control per case will be studied.

Duration of Study: 3 Years

Inclusion Criteria and Exclusion Criteria

Inclusion criteria

Patient between the age group 40 years-60 years irrespective of age and sex.

Willing to give written well inform consent.

Exclusion criteria

Patients suffering from traumatic fractures and pathological osteoporosis.

Patients who are consuming any drug which is known to affect bone metabolism i.e. vitamin d, calcitonin, corticosteroid for 3 month, heparin, warfarin, cyclosporine, sodium fluoride, Bisphosphonates, estrogen, anticancer, antiepileptic drugs.

Patients having H/o IDDM, hyperparathyroidism, thyrotoxicosis, malabsorption syndrome, paget's disease, endocrinal disorder, congenital anomalies, bedridden patients and patients having other serious systemic disease.

Sample size and sample size calculation

Sample size is determined on the basis of proportion of osteoporosis are on following assumptions.

Assumption

Expected incidence of osteoporosis =24%

Absolute precision(%) =10

Desired confidence level(1-α) % =95

Required sample size =70 in each group

During study, a sample size of 100 in each group will be taken.

Software used for sample size calculation is n Master Version 2.0

$$n = \frac{Z^2_{1-\alpha/2} * p * (1-p)}{d^2}$$

Where

p =Incidence of osteoporosis

d =Absolute precision

α =5%

Z1- α/2 =1.96 [17]

Grouping of sample

Group 1: Subjects who have BMD t-score <-1

Group 2: Subjects who have BMD t-score -1 and above

Diagnostic criteria

Bone mineral density

Sign and symptoms of Asthikshaya[18-23]

Asthishool(pain)

Sandhishool

BalaKshaya/Dourbalya

MamsaKshaya

Keshpatana

Sparshasahyata(tenderness)

AtimandaChesta

SandhiShaithilya

Dantashoola/Dantapatana (Dental deformity/fall)

Nakhbheda/Nakhapatana/Nakharukshata(Nail deformity)

Lomapatana

Shmashrupatana

Rukshata

Asthibadaha-Mamasaabhilasha

Atimanda-chesta

Angabhanga

Medakshaya

Kamp

Vaman

Shosha

Kathorata

Shoph

Criteria of Assessment

Patient fulfilling the diagnostic criteria will be selected for the study. Every individual subjective will be assessed on following parameters

Subjective parameters

Ten Vatarakopak Hetu will be analyzed to find the association. It includes Aharaj, Viharaj and ManasikHetu. The existence of these Hetu will be asked to both the groups. If any of them is found in patient then its quantity, duration and frequency will be asked.

Objective parameters

CBC-Hb%,TLC,DLC,ESR

Serum calcium

Urine-routine microscopic

Bone mineral density

Methods of Data Collection

The data will be collected both qualitatively and quantitatively. Qualitative data will be acquired with the help CRF and questionnaire. Quantitative data will be collected in the form of biochemical parameters and values of the bone mineral density.

CRF-Proforma for collecting demographic variables.

Questionnaires

Investigations

CBC-Hb%, TLC, DLC, ESR,

Serum calcium,

Urine-Routine and Microscopic

BMD by Bone Densitometer

Data management and analysis procedure

Data collected will be entered into microsoft excel spread sheet. Categorised data will be expressed in frequency and percentages. Continuous variables will be presented as mean ± SD.

Plan for statistical analysis

Continuous variables will be compared between case and control by performing Independent t-test. Categorical variables are compared by Chi-2 test. Association of risk factors and disease (cases) will be assessed by calculating Odds Ratio, 95% confidence interval. $p<0.05$ will be taken as statistical significance.

statistical software STATA version 14.0 will be used for statistical analysis.

Observations and Results

Observations obtained on the basis of examination of patients through the study will be entered in CRF and data collected will be presented in the form of table and graphs.

Discussion

Asthikshaya is one of the major metabolic bone disorders. Ayurveda emphasizes more on prevention of disease rather than its treatment. Nidanparivarjanam is one of the important factors in treating disease; hence etiopathogenesis study of disease is significant in all aspects. The causes of Asthikshayaare not mentioned separately in Ayurvedic texts. As per Ayurvedic principle of Ashrayashrayee Bhava, the factors causing vitiation of Vata will cause decrease in Asthi Dhatu. Samanya Nidana (general etiological factors) leading to the Kshaya of 18 types includes mostly the Vataprakopak Nidana. Many studies carried out on Asthikshaya, but this type of study to find association between Asthikshaya and its causes is not yet carried out. A number of related studies have been reported. [24-27] Related studies have evidences available in GBD studies. The observation from the study will be subjected to the statistical analysis if this study will prove this association then it will be very helpful to aware the population regarding avoidance of causes, prevention of disease and thereby further complications of Asthikshaya.

Conclusion

On the basis of statistical analysis conclusion will be drown. If the study proves successful further studies may be done on other diseases whose causes are not explained in text.

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