

Study Protocol

A Cross-sectional study to Assess *Pandu Vyadhi*(Anemia) with special Reference to RBC indices and Morphology: A Study Protocol

Abstract:

Background: Ayurveda is a science of life & its holistic approach towards Dietary habits, seasonal regimes, daily regimes, lifestyle practices helps to maintain health of an individual. Inadequate dietary intake or lack of balanced diet leads to malnutrition & has major role in manifestation of various diseases *Pandu vyadhi* is one among them. Considering the sign & symptoms the disease is correlated with Anemia. It is a major global public health problem & most prevalent nutritional deficiency disorder affecting one third of the world's population. The disease is more prevalent in low-income countries. It affects the patient both physically & mentally. Among the different form of therapies used for treatment of anemia in modern medicine shows adverse effects ranging from mild to severe. So there is need to seek out the safe & effective Ayurvedic treatment for anaemia. Clinical symptoms & laboratory investigations both are necessary for accurate diagnosis of disease. But due to lack of proper investigative methods a case of anemia becomes difficult to diagnose for its different types as per Aurveda.

Aim - To study & assess *Pandu vyadhi* with Special Reference to RBC indices and Morphology on peripheral smear.

Methods- This is descriptive cross sectional study which focuses on assessing *Pandu vyadhi* with Special Reference to RBC indices and Morphology on peripheral smear.

Conclusion: The present study generates reliable data of *Pandu vyadhi* in relation to various laboratory parameters which helps to plan specific treatment as mentioned in Ayurvedic classics for different types of *Pandu vyadhi*. The use of large sample size will also improve the precision of the study and increase the generalizability of the result.

Keywords –Anemia, Ayurveda, *Pandu vyadhi*, Nutritional disorder, RBC indices, RBC morphology.

Introduction:

Maintenance of health of a healthy individual and cure of ailment of a diseased person through its holistic approach is the prime aim of Ayurveda. ¹ The manifestation of disease can be prevented by following protocol given by our Acharyas in the form of lifestyle practices, Dietary habits, following daily & seasonal regimes etc. Malnutrition caused because of either lack of balanced diet or due to inadequate dietary intake has major role in manifestation of various diseases *Pandu vyadhi* is one among them. ^{2, 3} *Pandu vyadhi* described in all classical texts of Ayurveda. It is *pitta* (one among Ayurveda's three *doshas*) predominant disease associated with *rasa* (primary product of digested food) & *rakta dhatu* (blood tissue). *Pandu* means pallor or paleness. Considering paleness or pallor as the prominent feature we can correlate *Pandu vyadhi* with Anemia. It is considered as one of the *varnoplakshitroga* (diagnosed by change in colour) and mainly diagnosed by *Pandur varna* (paleness) of body. ^{4,5}

Anemia is a major global public health problem and the most prevalent nutritional deficiency disorder in the world. One-third of the world's population is affected due to anaemia. It is the condition in which number of circulating red blood cells (RBC) or Hemoglobin (Hb) concentration in the blood is below the lower limit of normal range and insufficient to meet body's physiologic needs.⁶ WHO (World Health Organization) defines the anemia as hemoglobin (Hb) levels below 12.0 g/dl in females & 13.0 g/dl in males respectively. As compared to high-income countries anemia is more prevalent in low-income countries. Anemia shows significant impact on mortality and also leads to both reduced work capacity & economic developments. It is the major cause for hospitalization & mortality in older adults. It causes delay in growth, increases risk of infections during childhood & leads to poor cognitive & motor development & ultimately hampers the work productivity in later life. In children & adolescents the most common etiological factors observed for anemia includes nutritional deficiencies, chronic disease & underlying pathophysiology etc.^{7,8,9} The patients of anemia shows vague symptoms from fatigue to impaired or reduced cognitive performance. The symptoms of anemia may include weakness, lethargy, shortness of breath, giddiness, syncope & reduced exercise tolerance.^{9, 10}

According to WHO anemia is very common in general population and around 1.62 billion people are suffering from anemia across the world which nearly equals to 24.8%. It affects all groups of population. For developing & developed countries it acts as a significant burden for social & economic development.¹¹ The study conducted by Surekha Kishore & et. al. showed that the prevalence of anemia in their study population was 53.2%.¹² Concentration of haemoglobin is the most common indicator and parameter used for the diagnosis of anaemia. Along with the Hb concentration, complete blood count (CBC) also can be used for diagnosing anaemia where red cell counts, PCV, MCV, MCH & MCHC are calculated and compared with the values adjusted for age & sex. Peripheral blood smear study is also done to detect abnormal RBC.¹³

In modern medicine Anaemia is treated with various forms of therapies. Some of them may have adverse effects ranging from mild to severe.¹⁴ So there is need to seek out the safe & effective Ayurvedic treatment for anaemia. Clinical symptoms & laboratory investigations both are necessary for accurate diagnosis of disease. But due to lack of proper investigative methods a case of *Pandu vyadhi* become difficult to diagnose for its different types. So we cannot provide proper Ayurvedic treatment as per its different types mentioned in the Ayurveda classics. Keeping a view, the study on *Pandu vyadhi* in relation to various laboratory parameters is very essential for proper diagnosis so that we can apply the specific treatment as mentioned in Ayurvedic classics for different types of *Pandu vyadhi*. So, this study is planned to assess different types of *Pandu roga (vyadhi)* with some common haematological parameters.

Rational of the Study-

Pandu is the most common clinical entity observed by the physician in his day-to-day clinical practice. Majority of the people are facing this problem all over the world. It can cause range of symptoms including fatigue, debility, dizziness, drowsiness, lethargy & feeling of exhaustion & so on. It affects the patient both physically & mentally. If not treated properly it may manifest other diseases. Proper diagnosis must be required for effective & safe treatment of the disease. The present study will help to understand the etiological factors of *Pandu roga* in the community. Also, the study will help to find out the prevalence of various

types of *Panduroga*. Again, we will be able to plan for the better preventive and curative strategies for different types of *Pandu roga* in the study community.

Aim - To study & assess *Pandu vyadhi* with Special Reference to RBC indices and Morphology on peripheral smear.

Objectives -

Primary Objectives:

1. To study the distribution of various types of *Pandu vyadhi* according to their sign & symptoms.
2. To observe the relation of various types of *Pandu vyadhi* with RBC indices & Morphology on peripheral smear.

Secondary Objectives:

1. To study the etiological factors for various types of *Pandu vyadhi*.

Methods:

Study Design—This is a Descriptive Cross-Sectional Study. The study will be started after approval from Institutional ethical committee of DMM Ayurved Mahavidyalaya &Rugnalaya, Yavatmal which is one of the renowned Colleges under Maharashtra University of Health Sciences, Nashik, India. First the screening of the patients will be done at OPD level & written consent will be obtained from each study participant. The subjects of study will be recruited on the basis of sign & symptoms of *panduvyadhi*. The assessment of study participants will be done with the help of a semi-structured questionnaire & to assess the objective parameter assessment criteria for RBC indices & Morphology on peripheral smear will be used.

Study Population- The study population consist of the any patient from age group 18 to 60 years attending the OPD & IPD at our institute and showing sign & symptoms of *PanduRoga* as per Ayurveda Classics will be included under the study.

Inclusion Criteria— The following are the inclusion criteria for the present study,

1. All patient having general symptoms of *Pandu Roga* as per Ayurvedic classics will be included under the study.
2. All patient having specific symptoms mentioned as per classics for different types of *Pandu Roga* will be included under study.
3. All the patients of age group between 18 years to 60 years.
4. Patients will be selected irrespective of gender, religion, occupation & socio-economic status will be selected for study.
5. Patients willing to participate in trial with written consent.

Exclusion Criteria— Following are the exclusion criteria of the present study,

1. Anemia due to malignancy, tuberculosis, acute blood loss will be excluded.

2. The patients having seropositive for HIV, HBsAg, HCV etc. will be excluded.
3. Pregnant women & lactating mother will be excluded.
4. Patients with Chronic Kidney Disease.
5. Patients with blood trait disorders like Thalassemia, Sickle cell anemia
6. Patients with Chronic liver diseases, alcoholic liver diseases, liver cirrhosis etc. will be excluded.

Variables:

1. Socio-demographic variable - Name, age, sex, education, religion, occupation, habitat, economic status of the participants.
2. Other - Hb, RBC & various RBC indices like PCV, MCH, MCV, MCHC etc.

Data sources/ measurement:

Constructing tools for data collection: Data collection tools will be prepared;

- Patient Information Sheet and Consent forms.
- Preformed questionnaires was devised to collect information from the subjects, pertaining to the following areas,
 - a. Demographic & socio-economic profile.
 - b. *Hetu* (Etiological factors) of *panduvyadhi*
 - c. *Samanya lakshanas* (General symptoms) of *Panduvyadhi*
 - d. *Lakshans* (Sign & Symptoms) of different types of *Panduvyadhi*
 - e. CBC and Peripheral blood smear.

Instruments used for data collection:

- a. Interview schedule
- b. Torch
- c. Stethoscope
- d. Weighing machine
- e. Sphygmomanometer
- f. EDTA tube for blood sample collection
- g. Disposable syringe 2ml, Tourniquet, Cotton & Spirit
- h. Glass slide & Leishman's stain, distilled water.
- i. Centrifuge machine
- j. MICROS 60 Cell counter.
- k. Microscope

Bias: To minimize the bias Simple Random sampling method was used for selection of each participant in the present study.

Sample Size & Sampling Method -

Sample Size:

The study conducted by Surekha Kishore & et.al¹² showed that the prevalence of anemia in their study population was 53.2%. So, considering this my sample size will be as follows,

$$N = 4PQ / L^2$$

$$= 4 \times 53.2 \times 46.8 / 72$$

$$= 9959.04/49$$

$$= 203.24$$

$$\approx 210$$

Where, P = Prevalence of Anemia = 53.2%, Q = 100 – P = 46.8%, L = Allowable error = 7%

Sampling Method: -

The sample population will be collected by simple random sampling method.

Statistical Methods:

The data will be compiled in Microsoft excel and analyzed with the help of SPSS 24 version software. Qualitative data will be represented in form of frequency and percentage. Association between qualitative variables will be assessed by Chi-Square test. Quantitative data will be represented using mean \pm SD and Median. Relationship between Quantitative data will be assessed using Pearson's Correlation. Results will be graphically represented where deemed necessary.

Mechanisms to Assure the Quality of the Study:

Simple random sampling method will be used to avoid selection bias. Blood samples will be collected with duly aseptic measures and will be processed the same day of collection. For safe storage of collected data cloud storage, cloud backup, USB flash drive will be used.

Key Result:

At the end of study appropriate results will be drawn from the collected data. The differences in various types *Panduvyadhi* are found on the basis of RBC indices and morphology on peripheral smear.

Discussion:

Literature review: The literature related to this topic is mainly cited in this study. Excess use of alkaline, sour, saline, hot, incompatible dietetics & unwholesome food substances, Excessive intake of black gram, sesame oil, sleeping during day time, physical exercises during indigestion, erratic administration of bio-purification therapies, affliction by mental factors like anxiety, fear, anger, grief. Excess consumption of wine, eating mud etc. all these factors are responsible for manifestation of *pandu vyadhi*.¹⁵ According to the study conducted by Singh A et al. *Dincharya* (Daily regime), *Rutucharya* (Seasonal regime) & *Ahar vidhi* (dietary guidelines) given in Ayurveda are very effective in reducing sign & symptoms of *pandu vyadhi*.¹⁶ Rai S et al. (2015) conducted a comparative study to find correlation between various subtypes of *panduvyadhi* & different types of anemia. According to this study

features of *pittajpandu* (a subtype of *panduvyadhi*) were observed in patients of haemolytic anemia. While features of other subtypes of *pandu* like *Vataj&Kaphaj* were observed in all deficiency anemias especially the iron deficiency group & in megaloblastic anemia patients respectively.¹⁷

Strengths and limitations:

This is the first 'Cross-sectional study' to assess the different types of *panduvyadhi* on the basis of RBC indices and morphology on peripheral smear in the study community. The study definitely helps the physician for planning better preventive and curative strategies for different types of *Pandu roga* in the study community.

Ethical Consideration:

Approval for this protocol has been gained by the Institutional Ethics Committee (Ref. No. IEC/2023/Circular No.2/Dated 09/02/2023) of D.M.M Ayurved Mahavidyalaya & Rugnalaya, Yavatmal 445001, Maharashtra, India. An Informed Consent Form (ICF) will be filled by all the subjects after explaining the purpose of the study.

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