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REGISTRATION NO: BG0117014

Dissertation

Submitted to

KAHER, Belagavi, Karnataka

In partial fulfilment

of the requirements for the degree of

M.D.

IN

GENERAL MEDICINE

DEPARTMENT OF GENERAL MEDICINE

J. N. MEDICAL COLLEGE

BELAGAVI- 590010. KARNATAKA

APRIL 2020

THESIS TOPIC

"STUDY OF FACTORS AFFECTING THE PATIENT GLOBAL VISUAL ANALOUGE SCALE IN PATIENTS OF RHEUMATOID ARTHRITIS: A CROSS SECTIONAL STUDY"

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KAHER, BELAGAVI, KARNATAKA

Declaration by the Candidate

I hereby declare that this dissertation entitled **"STUDY OF FACTORS AFFECTING THE PATIENT GLOBAL VISUAL ANALOUGE SCALE IN PATIENTS OF RHEUMATOID ARTHRITIS: A CROSS SECTIONAL STUDY"** is a bonafide and genuine research work carried out by me in the department of General Medicine, Jawaharlal Nehru Medical College, Nehru Nagar, Belagavi-590010.

Date:

Place: Belagavi

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Endorsement by the HOD/ Principal/ Head of the Institution

This is to certify that the dissertation entitled **"STUDY OF FACTORS AFFECTING THE PATIENT GLOBAL VISUAL ANALOUGE SCALE IN PATIENTS OF RHEUMATOID ARTHRITIS: A CROSS SECTIONAL STUDY"** is a bonafide research work done in Department of General Medicine, Jawaharlal Nehru Medical College, Nehru Nagar, Belagavi-590010.

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Sub: Acceptance Letter

Sir/Madam,

The softcopy of thesis entitled "Study of Affecting the Patient Global Visual Analogue Scale in Patients of Rheumatoid Arthritis" A one year cross sectional study has been submitted for Anti-Plagiarism check through Turnitin software. The scan has been carried out and the scanned output reveals a match percentage of 9% (Nine percentage) which is within the acceptable limits of 10% as per the guidelines given by UGC.

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Yours sincerely,

Coordinator
Department of Medicine,
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LIST OF ABBREVIATIONS

GLOSSARY	ABBREVIATIONS
ACR/EULAR	American College Of Rheumatology/ European League Against Rheumatoid Arthritis
Anti-CCP	Anti Cyclic Citrullinated Protein
DAS 28	Disease Activity Score 28
DMARD	Disease Modifying Anti Rheumatoid Drugs
HAM-A	Hamilton Anxiety Rating Scale
HAM-D	Hamilton Depression Rating Scale
MHAQ	Modified Health Assessment Questionnaire
PGA	Patient Global Assessment
PhGA	Physician Global Assessment
PRO	Patient Reported Outcomes
SDAI	Simple Disease Activity Index
SJC	Swollen Joint Count
TJC	Tender Joint Count
VAS	Visual Analogue Scale

ABSTRACT

:ABSTRACT:

BACKGROUND:

Rheumatoid arthritis is a chronic inflammatory arthritis marked by symmetrical peripheral polyarthritis. It results in damage to the joints involved and physical disability .

Patient reported outcomes(PRO) provide the patients perspective of their condition and their overall health status. The patient global assessment(PGA) is the commonly used PRO in RA

The patients are asked to rate their global assessment of disease activity on a visual analogue scale of 0 -100 by answering the question " Considering all of the ways your arthritis has affected you , how active do you feel your arthritis is ?"

Hence "The PGA not only assesses the disease from patient perspective , but also includes various factors affecting the patients in addition to RA"

Physician global assessment obtains the perspective of the treating physician or the rheumatologist. The provider, based on his/her expertise evaluates the disease in a numerical scale, and grades the changes or the assessed RA status at that point. It is important to know the factors causing discrepancy between patient and physicians global assessment of disease activity.

AIMS AND OBJECTIVES :

The aim of this study is to identify the underlying latent factors affecting the patient global assessment and to determine the factors responsible for a discordant score in patients and physicians assessment of disease activity.

METHODS :

This study was a hospital based cross sectional study conducted from January 2018 to December 2018. The patients attending the OPD of Rheumatology and/or Medicine , fulfilling the inclusion criteria were included in the study. Their demographic data was collected. History and physical examination was done. They were given 4 questionnaire one each for Fibromyalgia, Modified Health assessment questionnaire, Hamilton's anxiety Rating scale and Hamilton's depression scale. The patients were asked to rate their Global disease activity on a Global VAS scale of 0-100 . The Physicians Global assessment score was given for every patient. The patients were grouped into two groups, those with a Patient Global VAS score < 50 and those with Patient Global VAS score >/= 50. The various latent factors that determined the Patients global VAS score was assessed. The patients were also grouped into two to include those with patient-physician concordant score (i.e, a difference between physician and patient global assessment less than 25) and those with patient-physician discordant score (i.e, a difference between physician and patient global assessment more than or equal to 25) .The factors that were responsible for discordance between the patients Global VAS score And the Physicians Global VAS score were identified. The data was evaluated by calculation of Chi-square and significance was determined by P value.

RESULTS:

In this study a total of 130 patients were included. The mean age of our study population was 45.59 years . 79.23% were females with a Female to Male ratio of 3.81:1 . The mean duration of the disease was 5.9 years. 66.92% were seropositive RA. 54.62% patients gave Patient Global VAS score of >/= 50. 66.15% patients had a discordance between patient and physician global assessment scores. Factor analysis identified the following factors that affected the patient Global VAS score which included pain, history of frequent analgesic use ,h/o sleep

disturbance ,absence of DMARD use, presence of extra articular manifestations, involvement of knee joint hampering mobility, a tender joint count more than 5,a swollen joint count more than 5, presence of symptoms suggestive of depression and anxiety , absence of a gainful employment , a family history of arthritis , Modified health assessment score > 3 ,Presence of fibromyalgia.

It also yielded factors that were associated with a discordance between patients and physicians Global VAS Score, these included pain, advanced age of the patient, knee joint involvement, presence of symptoms of anxiety, a family h/o arthritis, absence of gainful employment, sleep disturbance, overall health (Based on the MHA Q score), fibromyalgia.

CONCLUSION:

The various latent factors which can affect the way the patient perceive there disease severity include : pain, frequent analgesic usage, disturbed sleep ,lack of DMARD use ,presence of extra articular manifestations , involvement of knee joints hampering mobility , a tender joint count more than 5 ,a swollen joint count more than 5, presence of symptoms of anxiety or depression , lack of gainful employment , a family history of arthritis, a higher score on Health assessment score(>3) and fibromyalgia.

Factors that were associated with a discordance between patients and physicians Global VAS Score ,included pain, advanced age of the patient ,knee joint involvement hampering mobility ,presence of symptoms of anxiety , a family h/o arthritis ,absence of gainful employment ,sleep disturbance ,overall health(Based on the MHA Q score) ,fibromyalgia .

KEYWORDS:

Rheumatoid Arthritis, Patient Global VAS Score, Physician Global VAS score.

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INTRODUCTION

INTRODUCTION

Rheumatoid arthritis is defined as “Chronic inflammatory disease that affects the joint and results in destruction of the articular cartilage and the bone leading to functional disability” . If left untreated, the disease progresses to joint destruction and permanent deformities and disabilities, therefore it is important to diagnose Rheumatoid Arthritis early and treat it aggressively

RA is a systemic disease, apart from joint involvement, it may also result in various extra articular manifestation like lung involvement, subcutaneous nodules, pericarditis, vasculitis, hematological abnormalities etc.

Even though major progress has been made in early diagnosis and treatment of RA, the incomplete understanding of the triggering factors and the factors that keep inflammation going on remain as a hurdle to the complete cure of the disease. All the therapies available till date can only control the disease activity, reduce symptoms and delay the progression of disease, but cannot cure it. Therefore, the patient needs treatment lifelong.

During the course of treatment, the patients are regularly followed up and assessed. The patient’s global assessment of disease activity (PtGA) and physician’s global assessment (PhGA) are routinely assessed at the follow up. Most of the times it is observed that there is discordance between PtGA and PhGA, typically PtGA score higher than PhGA. This discordance arises because patient and physician focus on different aspects and have different perception of disease improvement. Therefore it is important to identify the factors that affect the patient’s global assessment of disease activity.

It is also important to know the factors that lead to discordance between patients and physician's global assessment of disease activity. The better understanding of such determinants helps the physician when sharing treatment decision with their patients.

Need for the study:

During the follow up of RA patient, the disease activity assessment is an important part of the patient examination. It helps the physician decide the line of management. Apart from the factors like tender joints and swollen joints, many latent factors affect the way the patient perceives their disease activity. Many studies have evaluated the role of factors like pain, fatigue, fibromyalgia and psychological factors in Patients Global VAS scoring. It was found in these studies that pain was a major factor affecting the Patient Global VAS. Many studies have also been conducted to identify the factors that cause a discrepancy in Patients Global VAS scoring and the Physicians Global VAS scoring , but such a study is not conducted in a rural part of India. This study aims at identifying the factors affecting the patient Global VAS and also the factors underlying the patient-physician discordance in Global VAS scoring in patients of RA in Indian population.

AIMS AND OBJECTIVES

AIMS AND OBJECTIVES:

- To identify the factors affecting the patient's Global visual analogue scale in patients of Rheumatoid arthritis.
- To identify the factors responsible for discordance in patients and physician's Global VAS Score.

REVIEW OF LITERATURE

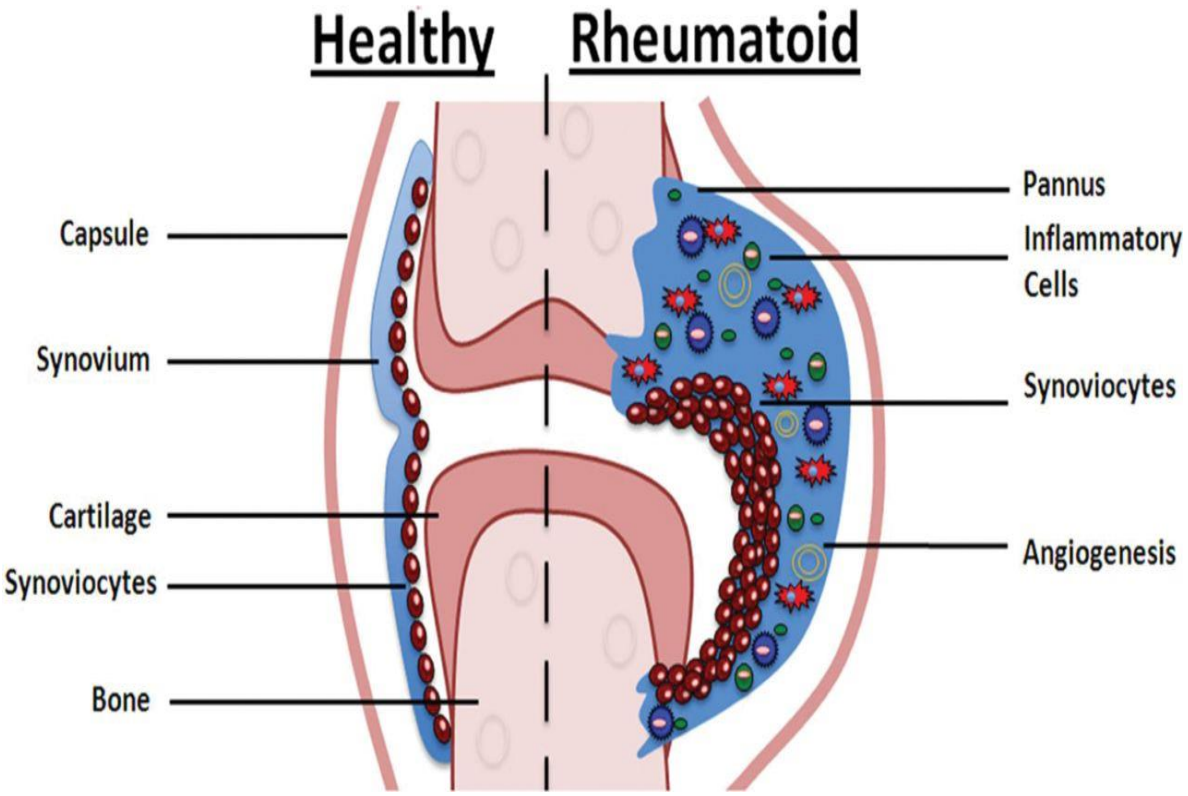
REVIEW OF LITERATURE

PATHOGENESIS OF RHEUMATOID ARTHRITIS (RA)

RA is a systemic chronic inflammatory disease with various extra-articular manifestations.[1, 2] Etiology and the pathogenesis of RA is multifactorial and mainly include genetic susceptibility and environmental triggers.[3, 4] The environmental factors include cigarette smoke, disturbances of intestinal, lung, and oral microbiota, industrial pollutants like silica crystals, and some specific bacterial and viral infectious agents .[5,6] Though the exact mechanisms are not clearly understood, development of RA in susceptible individuals leads to synovial hyperplasia and bone destruction. Alteration in innate and adaptive immune responses and subsequent production of autoantibodies targeting various molecules, including modified self-epitopes, are noted during the initial stages of the disease. Amplification of the chronic inflammatory state is noted in the advanced stages due to the action of innate (e.g. dendritic cells, macrophages and neutrophils) and adaptive immune cells (e.g. B and T lymphocytes). [7]

Within the synovium, macrophages and lymphocytes produce pro-inflammatory cytokines and chemokines (e.g., TNF-alpha, granulocyte-macrophage colony-stimulating factor, various ILs, interferon-gamma). The release of inflammatory mediators such as cytokines, chemokines, and metalloproteases results in systemic and joint manifestations of RA, including cartilage and bone destruction (Fig. 2.1). [8]

Fig. 2.1: Pathogenesis of RA



Reference: Hawtree S, Muthana M, Wilson AG. The role of histone deacetylases in rheumatoid arthritis fibroblast-like synoviocytes. 2013 May;41 (3): 783-788.

DIAGNOSING RA

The diagnosis of RA may depend on clinical signs, symptoms, and laboratory markers. Detailed history collection and physical examination are conducted in cases with observable symptoms such as pain on applying pressure, swelling, skin rashes or any other relevant features. The most common clinical investigations conducted are total count (TC), hemoglobin (Hb%), erythrocyte sedimentation rate (ESR), c-reactive protein (CRP), anti-cyclic citrullinated peptide (CCP) rheumatoid factor (RF) anti-streptolysin O titer (ASLO), urine routine examination, and X-ray of the affected joints(Wasserman 2011).[9] Elevated anti-CCP is a strong indicator of RA. Elevated ESR and CRP levels assist in measuring the levels of inflammation and positive anti-CCP, which is a strong indicator of RA. Positive RF is noted in

about 5% of the normal population, hence mere presence of RF cannot be considered as a criterion for the diagnosis.[10] Depending upon the associated clinical features, other specialized tests like anticytoplasmic antibodies (C-ANCA), antinuclear antibodies (ANA), and anti-dsDNA tests are also recommended.

MANAGING RA

The management of all types of arthritis are focused on the following three domains.

- Reducing the pain and other disease-related symptoms
- Attaining a disease-free state or reduced disease activity
- Reducing or eliminating the damages caused by the arthritis

With regard to RA, the management goals are intended to reduce the short-term (day-to-day basis) and long-term (deformity and disability) disease burden through various drug and non-drug modalities. Non-steroidal anti-Inflammatory drugs (NSAIDs) are generally prescribed to reduce the pain.[11] Physical measures like heat and cold, ultrasonic massages, short-wave diathermy, and infrared heat are also used. Disease-modifying drugs (DMARDs) such as methotrexate and biologics are used for treating moderate to severe RA. DMARD treatment helps in reducing the need for NSAIDs (painkillers), inflammation, and the incidence/severity of deformities and disabilities.[12] The primary focus of long-term management is reduction of disability and deformity. This can be achieved through physiotherapy, appropriate splinting, and occupational therapy; apart from the drug therapy .[13]

THE BURDEN OF RA:

Rheumatoid arthritis is the most common type of autoimmune arthritis. The disease occurs predominantly in middle-aged subjects (25 to 45yrs), with more prevalence in females than males (4:1). [14] The disease generally affects the multiple joints of both the sides of the body. The disease has variable progression pattern and may cause permanent damages to the joints. [15] The associated disease sequalae include inflammatory and destructive events such as pannus formation, synovial hyperplasia, joint malformation, and cartilage and bone erosions.[16] The disease primarily affects the mobility and physical function and mobility of the RA patients, which in turn results in substantial short-term and long-term morbidity.[17]

A 2010 study by cross et al. has reported that RA is the 42nd highest contributor to the global disability, and the disability-adjusted life years had increased from 3.3 million (M) (95% CI 2.6 M to 4.1 M) in 1990 to 4.8 M (95% CI 3.7 M to 6.1 M) in 2010.**[18]** Scott et al (2010) have reported that the disease is three times more frequent in females and it affects 0.5-1% of adults in developed countries.[17] As per the reports of World Health Organization-International League of Associations for Rheumatology and community oriented program for control of RA (WHO-ILAR COPCORD) survey in the year 2004, the corresponding prevalence noted in urban and rural population of India were 0.5% and 0.55% (Chopra A 2008).**[19]** The prevalence of RA in India is estimated to be around 0.5- 1% among adult population. Malaviya et al. have reported a prevalence of RA 0.75% in adults . [20]

OUTCOME MEASUREMENT IN RHEUMATOLOGY:

There is no single 'gold standard' strategy to evaluate disease severity, prognosis or treatment effectiveness in most rheumatic diseases. Hence multiple measures are used in the assessment of disease outcome.[21] Traditional patient assessment in the past comprised of objective clinical measures like erythrocyte sedimentation rate and x ray evidence of damage or physician-based clinical examination measures such as swollen and tender joint counts .[22], [23] However, in the past 25 years, clinicians have increasingly recognized the importance of evaluating the patient's perspective on the disease severity and the effectiveness of treatment. This has contributed to the development of various concepts and instruments to measure patient-reported outcomes. Research in the field of rheumatology has given wider attention for assessing domains such as physical function (or disability), pain, health status and disease activity. Various patient- reported outcomes measures that have been extensively investigated in patients with diverse rheumatic diseases include : " visual analog scale (VAS) for pain, 36-Item Short Form Health Survey, Arthritis Impact Measurement Scales, the Medical Outcomes Study, and the Health Assessment Questionnaire". Most of them have demonstrated excellent efficacy and reliability.[24,25],[26]

Diverse studies have reported that these outcome measures are similar in sensitivity to treatment effects as physician-reported measures or clinical measures.[27] [28] Over the years, patient-reported pain, physical function, and global assessment of disease status have been recognized as major endpoints in rheumatology.

In order to reduce the load of clinical examination in RA, significant inputs regarding the patient symptoms are essential. Several scales have been designed to gather various aspects of disease based on patient observations. The PROMs are measures that completely rely on patient

inputs.[29] They have been increasingly recognized for capturing information on overall health status. Moreover, their incorporation in the field of RA in routine clinical practice and research have been supported by various international bodies including "European Patients' Academy on Therapeutic Innovations (EUPATI), the Patient-Centered Outcomes Research Institute (PCORI), Food and Drug Administration (FDA) and the European Medicines Agency (EMA)". PGA was developed in the late 1970s and it was mainly used for the self-assessed pain measurement in RA .[30] The PGA scoring can be carried out using a numeric rating scale (NRS), a verbally administered NRS, or a visual analogue scale (VAS). [31]

RESPONSE SCALES

The most common types of response scales used in literature include verbal rating scale (VRS), numeric rating scale (NRS), visual analogue scale (VAS), faces scale and Likert (Likert-type) response scale (Fig. 2.2).[32]

Fig. 2.2: Types of response scales

Type of scale	Example
Likert scale	I feel that my leisure activities are affected after this illness. O Strongly agree O Agree O Undecided O Disagree O Strongly disagree
Visual Analog Scale (VAS)	To what extent do you feel that you have financial difficulties for the treatment of your disease? 0 ——— 10
Categorized/anchored VAS	What is the severity of your pain? 0 2 4 6 8 10
Pictorial scale	Circle the face that represents how do you feel about the treatment X? 
Rating scale	How many episodes have you had since last 7 days? ☐>10 ☐7-10 ☐5-7 ☐2-5 ☐<2
Checklist	Do you have lump in your breast? ☐ Yes ☐ No

Source: Deshpande PR, Rajan S, Sudeepthi BL, Abdul Nazir CP. Patient-reported outcomes: A new era in clinical research. Perspect Clin Res. 2011 Oct;2(4):137-44

VAS SCALE AND PATIENT/PHYSICIAN GLOBAL ASSESSMENTS

The visual analogue scale comprises of a vertical or horizontal line, generally 10 cm (100 mm), with verbal descriptors at both the ends. The respondent is asked to draw a line vertically to represent the severity of the effect in question. Measurements from the starting point (left end) of the scale to the patients' marks are recorded in centimeters and are interpreted as their pain.[33] The measurement from the beginning to the respondent's mark is recorded and the score is determined. It is used to track the progression of 'effect in question' and to compare between patients with similar conditions. Apart from pain, the scale is also been used to evaluate mood, appetite, asthma, dyspepsia, well-being and ambulation. [34] If descriptive phrases like 'mild', 'moderate', 'severe' or a numerical scale is added to the VAS, it could be termed as a graphic rating scale (GRS, Fig. 2.3).

Fig. 2.3: VAS scale for pain assessment

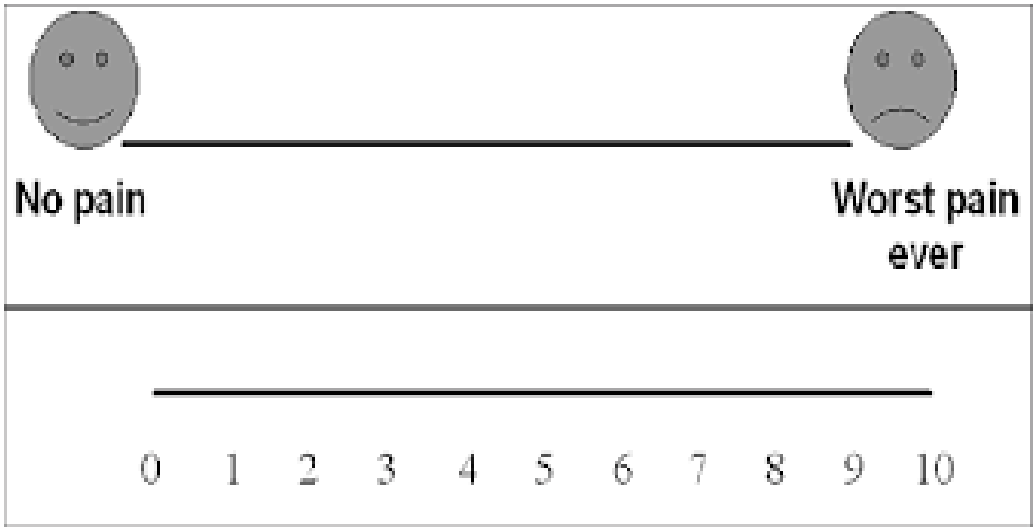
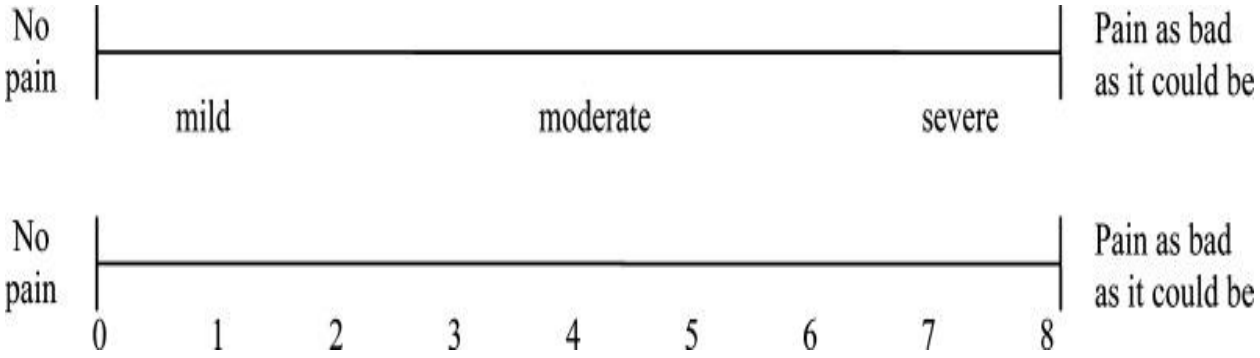


Fig. 2.4: Graphic rating scale for pain assessment



PATIENT GLOBAL ASSESSMENT

One of the primary measures to be considered in RA management is the perception of the affected patient about the disease, and overall health and wellbeing. The estimation of this perception is considered as patient global assessment (PGA). However, this measure is associated with lot of subjectivity. It has been reported to have an influence on the score. Apart from the severity level of the pain caused by RA, the factors that may influence the score include patient's depression and anxiety, fibromyalgia, advanced age, inability to participate in scoring (due to psychological or comprehending issues), and degenerative arthritis. The patient's education status has been shown to influence majority of the rating scales. This is one of the important components of the RA score . [35]

PGA is a crucial component of response criteria, validated disease activity scores, and the American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) definition of remission in RA. [1] Patients rate their global assessment using a response scale. This will be evaluated based on the answers given to the questions.

For example, “Considering all of the ways your disease affects you, how well are you doing in the past week?” Hence, the PGA assesses the disease based on the patient’s perspective and various factors affecting patients in addition to RA.[36]

PHYSICIAN GLOBAL ASSESSMENT

Physician global assessment obtains the perspective of the treating physician or the rheumatologist. The provider, based on his/her expertise evaluates the disease in a numerical scale, and grades the changes or the assessed RA status at that point. Similar to PGA, physician global assessment is based on a VAS of 100 mm in length with ‘0’ (‘no activity at all’, ‘no arthritis activity’) on the left end of the line and ‘100’ (‘worst activity imaginable’, ‘extremely active arthritis’) at the right end. The practitioner needs to draw a vertical line through the horizontal line to indicate the participant’s disease activity. The physician assessing the participant’s global disease will be having access to the joint assessments. The patient and the physician must complete the assessments independently. The line is subsequently measured from the left end of the line to the participant’s mark in mm (0 to 100) and the value is recorded (Anderson JK 2011).[37]

USE OF VAS SCALE FOR PAIN MEASUREMENT IN RA

Pain is the most prominent symptom noted in majority of the RA patients and it is the common reason for primary care visit.[38] Measurement of pain is an important part of assessment of RA. Increase in pain indicates elevated inflammation in early RA. Whereas in chronic RA, the cause for pain is multifactorial, comprising of both inflammatory and non-inflammatory components (central pain processing mechanisms). [39] Since none of the measures used in RA is specific, a single measure may not indicate the multi-dimensional aspects of the disease. For instance, pain assessment is highly subjective, and it may depend on the mental status and the

pain perception of the affected subjects.[40] In order to facilitate both the quantitative and qualitative measurements status of pain at a given point of time, various patient self-report questionnaires have been developed over the last 2 decades. There are several studies validating these questionnaires and their effectiveness in studying the underlying mechanisms that cause and control pain .[41] In RA patients, the progression of pain follows same pattern as that of other parameters of disease activity. [42]

Several studies have validated the sensitivity of GRS and VAS scales to treatment effects. Moreover, these scales have been found to correlate positively with other self-reported pain intensity measure.[43] One of the major advantages of VAS scale is that real difference in magnitude of pain can be noted upon considering pain intensity measured at two different points.[44] Sokka et al. have conducted a review of long-term RA follow-up studies that have evaluated changes in pain levels over 5 years using VAS scales. The study has noted that overall improvement in subjects with early disease in pain over 5 years was more significant. Whereas, it was less prominent in patients with longer disease duration. Such studies validate the use of VAS scale in RA management.

IMPLICATIONS OF PGA IN RA

PGA is generally administered to RA patients to quantitate the overall status of the disease/ patient, and / or disease activity at a given point of time. The advantages of the assessment include no cost, feasibility, and self-administration. The key strengths and weakness of using PGA in RA is discussed in table 2.1.

Table 2.1: Strengths and weakness of using PGA in RA

Strength	Weakness
Discordance between PGA and physician assessment, brings in additional information.	Discordance between PGA and physician assessment, may alter on decision making.
Good sensitivity to change in clinical trials.	Patient education level may influence it.
Reliability to test retest is good.	Difficulties of interpretation because it can be attributed to non RA diseases also like other comorbidities and psychological factors.
It is easy to score. It is also easy to incorporate in other scoring systems . Easy to conduct and interpret.	Interpretation may become difficult when there is uncertainty in attributing the score to permanent damage versus disease activity
May comprise of all patient-related aspects of the disease.	Very broad concept causing difficulties in interpretation.
Practical and feasible to capture when compared to joint counts, acute phase reactants or radiographic damage.	Responses may vary depending on the co existing health conditions and also wording of the question.

Reference: Nikiphorou E, Radner H, Chatzidionysiou K, Desthieux C, Zabalan C, van Eijk-Hustings Y, et al. Patient global assessment in measuring disease activity in rheumatoid arthritis: a review of the literature. Arthritis Res Ther. 2016 28;18(1):251.

PGA is one of the most widely used PROs in the field of RA and the literature findings indicate that it is the second most frequently captured PRO followed by physical function. [55] Moreover, it has become an integral part of major outcome measures and disease activity scores in RA namely "The 28-joint count Disease Activity Score (DAS28), the Simplified Disease Activity Index (SDAI), ACR/EULAR remission criteria, the Clinical Disease Activity Index (CDAI), and the Routine Assessment of Patient Index Data (RAPID3)".[56]

When compared to the objective measures of RA, PGA assists in a holistic assessment of the disease. Despite several advantages, PGA is associated with various limitations and challenges. Several ways of assessment and variations in wordings and phrasing used, and the time period of assessment cause differences in interpretation. Discordance with objective measures and other assessment tools should be addressed, while considering decision-making and treating to target for remission).[56]

DISCREPANCY BETWEEN THE PATIENT AND PHYSICIAN GLOBAL ASSESSMENTS

PGA assists in capturing diverse aspects of RA, hence it is well recognized as a global measure. The discrepancy between the two assessment measures is speculated to adversely impact the therapeutic decisions. A 2013 Ontario-based study has concluded the on the existence of discordance between the 2 assessment systems in a significant proportion of RA patients, regardless of the duration of the disease .[57] The study was conducted in 439 early RA patients and 737 established RA patients. The corresponding mean patient and physician global assessments were noted. They were 50.0 and 53.0, and 48.0 and 43.0 respectively. In both the groups elevated pain score, SJC and TJC increased the discrepancy between the assessments.[57]

A retrospective analysis of the RADIUS (RA Disease-Modifying Anti-Rheumatic Drug Intervention and Utilization Study) has also underscored the need of considering patients' assessments of their disease activity (HAQ, pain VAS, and PtGA) and joint counts by the clinician while measuring the disease outcome.[58]

A cross-sectional study by Castrejon et al. has identified pain as the only statistically significant explanatory variable for discordance noted in both osteoarthritis (OR 1.34, 95% CI 1.12-1.78) and RA (OR 1.47 95% CI 1.04-2.07) patients. Moreover, the discordance with their rheumatologists was found to be more for OA patients than RA because of increased patient global assessment.[59] A Korean study involving 4368 patients with RA has noted, fatigue pain, , high disease activity and sleep disturbance and gastrointestinal disease as the factors associated with the discordance between the two assessment in RA. Positive discordance was noted in 52.3% of the subjects (n = 2425), among them 33.7% (n = 1563) demonstrated marked discordance (≥25 mm) (Cho S-K 2017). [60]

Literature studies indicate that there is a need for further research involving larger population to clearly establish the factors influencing the discrepancy between the global assessment of patient and physician. A 2019 study by Akhavan et al. has concluded pain ($p< 0.0001$) and swollen joint count ($p< 0.0001$) significantly influence the discrepancy between the 2 assessment tools at the baseline, and the persistence of this association even after one year after achieving better disease control. [61] Moreover, the discordant subjects demonstrated significantly higher health assessment questionnaire disability index, fatigue and pain scores, PGA, physician global assessment, tender joints, composite measures of disease activity and comorbidities. The researchers highlighted the need for considering the aforementioned associations while managing RA.[61]

FACTORS INFLUENCING PGA

Several studies corroborate pain as the strongest factor influencing PGA.[36] A 2017 study by Challa et al. has identified pain as the second most influencing latent factor followed by fibromyalgia. Other factors that had been should to have an influence were degenerative arthritis, advanced age and psychological stress. The study has highlighted the need of considering all the factors that affects PGA to improve the decision making and outcomes of RA. The researchers also highlighted the need of evidence-based approaches targeting such specific domains to enhance the functional status and quality of life of the affected subjects.[36] A post hoc analysis of overall Japanese phase 3 clinical trials has also reported pain as the most crucial determinant of patient global assessment, whereas it was mainly explained by pain/joint counts for physician global assessment. [62]

Another study by Me et al., touted as the first study to investigate the association between health distress and PGA, has reported pain as the strongest determinant of PGA in RA. The researchers have noted that the determinants of PGA differed significantly with severity of fatigue, morning stiffness, health distress, and the DAS28. The association between pain and PGA was found to be twice when compared to any other measure in the overall group. Morning stiffness was identified as the second strongest predictor, which contributed directly to the association and indirectly through an association with pain severity. Disease activity is considered as a major factor influencing PGA. Pain along with joint damage impairs the quality of life of RA patients and also influences the PGA scores. Moreover, these outcomes indirectly influence RA disease activity. However, there are conflicting reports on the effect of co-morbidities.

The study by Karpouzas et al., conducted on 536 Hispanics with established RA, has identified pain, fatigue, depression, general health perceptions and tender joint count as the factors determining PGA. However, for physician assessments, the predictive factors were swollen joint count, tender joint count, fatigue, erythrocyte sedimentation rate and depression.[63] A large-scale population study conducted among 7,028 patients has demonstrated discordance in 36% of the patients from their physicians. [64] Furthermore, pain has been identified as the single most important determinant of PGA, and fatigue as the second determinant. [65]

Apart from the RA-related factors, there are studies reporting the effect of factors other than RA related factors on PGA namely education status, demographic features and geography.[56] A 2004 study by Nicolau et al. has reported lower level of education of the patients as the only important factor that determined the perception of RA disease activity, which has been assessed using pain score, HAQ, and TJC. [66]

A 2016 review by Nikiphorou et al. has reported that PGA may be influenced by non-objective measures of RA such as psychological distress and comorbidities, which in turn may cause a discordance between objective RA measures and PGA .[67] In stark contrast, a cross-sectional study involving 213 US Hispanics with RA has reported that there is no association between comorbidities including fibromyalgia and depression syndrome, and PGA. In addition, the researchers noted a significant association between positive discordance and patients' self-report of pain/disability, and the use of biologics.[68] A 2019 study by Sugitani et al. has demonstrated that the treatment intensification has contributed to significant improvement in both the assessment tools.[69] A cross-sectional, observational study involving 322 RA patients

reported significant correlation between severe RA and cognitive factors and depression (Cordingley L 2014).[70]

Review of literature shows that factors influencing the patient and physician global assessments in daily clinical practice have not been clearly elucidated The present study holds greater clinical significance, as there are no studies from India evaluating the factors affecting the PGA and those determining the discrepancy between patient and physician global assessment tools.

METHODOLOGY

METHODOLOGY

STUDY SITE: This study was conducted in the General Medicine Department, Dr. Prabhakar Kore Hospital, KLE University, Belgaum.

STUDY POPULATION: All the patients with a diagnosis of Rheumatoid Arthritis according to the "ACR/EULAR Classification criteria 2010", attending the OPD of Rheumatology/ General Medicine at KLES Dr. Prabhakar Kore Hospital and MRC, Belgaum were considered as the study population

STUDY DESIGN: The current study was a Cross-sectional study.

SAMPLE SIZE:

The formula for minimum sample size based on prevalence was

$$n = \frac{z_\alpha{}^2 P(1-P)}{d^2}$$

where P is the percentage of prevalence and d is the percentage likely difference in the prevalence. z_α is linked with the level of significance.

For 5% level of the significance $z_\alpha = 1.96$.

With P=80% and d=10% the sample size was 96. A total of 130 subjects were included in the study for final analysis.

SAMPLING METHOD: All the eligible patients were included in the study by convenient sampling till the sample size was reached.

STUDY DURATION: The data for the present study was collected between January 2018 and December 2018, for a period of one year

INCLUSION CRITERIA:

1. Patients aged above 18 years with a clinical diagnosis of Rheumatoid arthritis fulfilling the criteria of ACR/EULAR 2010 classification criteria for RA attending the OPD of Rheumatology/ General Medicine in KLES Dr. Prabhakar Kore Hospital and MRC Belgaum.

EXCLUSION CRITERIA:

1. Patients with disease duration less than 3 months
2. Patients unable to score their global Visual analogue scale or answer the questionnaire due to cognitive impairment
3. Patients with other connective tissue disorders

ETHICAL CONSIDERATIONS: The present study was approved by the Institutional Committee of Human Ethics. Informed written consent was obtained from all the subjects included in the study. All the subjects participating in the study were informed about the risks and benefits of the study. We maintained the study participants confidentiality.

DATA COLLECTION TOOLS: All the data that was collected was documented in a study proforma.

METHODOLOGY :

All the patients that fulfilled the inclusion and exclusion criteria were taken as study subjects after they were explained about the risk and benefit and obtaining informed consent. A probable case of Rheumatoid Arthritis was diagnosed according to the ACR/EULAR Classification criteria 2010. The diagnosis was confirmed with either one of the laboratory tests: Serum Rheumatoid Factor or Serum Anti-CCP. The subjects' demographic data was collected. Following history features were asked : The disease duration , history of analgesic use , history of DMARD use, presence or absence of sleep disturbance , extra-articular manifestations ,

history of habits like smoking and alcoholism , history of passive smoking , knee joint involvement , presence or absence of gainful employment and family history of arthritis . Patients were examined for Tender Joint count, swollen joint count, presence or absence of deformities and extra-articular manifestations. The patients were given four questionnaires: The FiRST questionnaire for Fibromyalgia, The Modified Health Assessment questionnaire, Hamilton's Rating scale for Anxiety and The Hamilton's Depression rating scale.

The Patients were then asked to score their Global Assessment on a Visual Analogue Scale ranging from 0 – 100, by answering this question:

"Considering all of the ways your arthritis has affected you, how active do you feel your arthritis is?"

The patients were also asked to score their pain on a Pain VAS Scale of 0 to 100.

The Physician then gave the Global VAS score based on the examination.

FOLLOW UP: No follow-up was done as the present study was a cross sectional study.

INVESTIGATIONS:

Serum Rheumatoid Factor OR Serum Anti- CCP.

STATISTICAL METHODS:

The data obtained was coded, entered into Microsoft excel spreadsheet. The data was analysed with SPSS version 20. The continuous data was expressed as mean ± standard deviation. The association between the demographic and clinical data with the outcome was tested using chi-square test. A probability(p) value of ≤ 0.05 was considered as significant statistically.

OBSERVATIONS AND RESULTS

RESULTS

A total of 130 patients were included in our study.

DESCRIPTIVE ANALYSIS

Table 5.1 . Distribution Of Patients Based On The Age

AGE GROUPS	NO OF PATIENTS	PERCENTAGE OF PATIENTS
18 – 29	15	11.54
30 – 39	29	22.31
40 – 49	33	25.38
50 – 59	32	24.62
>/= 60	21	16.15
Total	130	100

In our study the mean age was 45.59±13.23 years. Highest number of patients were in the age group of 40 to 49(25.38%) , followed by the age group of 50 to 59 (25.38%) .Least number of patients belonged to age group of 20 to 29 (11.54) . The oldest patient was of the age 78 years, the youngest being 18 year.

Table 5.2 : Distribution Of The Patients Based On Gender

GENDER	NO OF PATIENTS	% OF PATIENTS
MALE	27	20.77
FEMALE	103	79.23
TOTAL	130	100

In our study females outnumbered male patients significantly with female to male ratio 3.81:1

Table 5.3 : Distribution Of Patients Based On The Education

Education	No Of Patients	% Of Patients
NONE	22	16.92
PRIMARY	31	23.85
SECONDARY	38	29.23
PUC	18	13.85
DEGREE	21	16.15
TOTAL	**130**	**100.00**

In our study, maximum number of the patients were educated till secondary school 38 patirents (29.23%) followed by primary schooling 31 patients(23.85%)

Table 5.4 : Distribution Of Patients Based On The Disease Duration :

Duration of the disease	No of patients	% of patients
<1yr	13	10.00
1-5yrs	65	50.00
≥6yrs	52	40.00
Total	**130**	**100.00**

In our study maximum number of patients fell into disease duration group of 1 to 5 years i.e 65 patients(50%) .Only 13 patients i.e 10% belonged to disease duration group <1year . The mean disease duration was 5.91 , standard deviation being 5.70

Table 5.5 : Distribution Of Patients Based On The Serology Status :

Serology	No of patients	% of patients
Negative	43	33.08
Positive	87	66.92
Total	**130**	**100.00**

Out of 130 patients in our study , Seropositive RA was diagnosed in87(67%) patients (either RF or Anti CCP positive) i.e 66.92% were seropositive RA

Table 5.6 : Distribution Of Patients Based On The Patient Global VAS Score :

Patients global VAS	No of patients	% of patients
<50	59	45.38
≥50	71	54.62
Total	**130**	**100.00**

Patients were grouped into two groups based on their Global VAS Score , those who gave a score of <50 and those with a score of 50 or more . 71 patients i.e 54.62% gave a Global VAS score >/= 50 and 59 patients i.e 45.38% gave a Global VAS < 50. The least Global VAS score in our study population was 0 and the highest score was 100 . The mean Patient global VAS score was 51.46.

Table 5.7 : Distribution of patients Based On The Physician Global VAS Score :

Physician global VAS	No of patients	% of patients
<50	86	66.15
≥50	44	33.85
Total	130	100.00

In our study population , 86 patients(66%) were given a Global VAS score of less than 50 by their treating physician. The highest Physician Global VAS score was 90 and the least score was 0. The mean Physician Global VAS score was 36.08.

Table no 5.8 : Distribution Of patients Based on the Pain VAS Scoring :

Patient Pain VAS	No of Patients	% of Patients
<50	59	45.3
≥ 50	71	54.6
Total	130	100

In our study, patients were grouped into two based on their pain VAS scoring, those who gave a score <50 and those who gave a score of >/= 50 . it was found that out of 130 patients, 59(45.3%) gave a score less than 50 and 71(54.6%) gave a pain VAS score >/= 50.

Table 5.9 : Distribution Of Patients Based On The Discordance In Scoring Between Physician And Patient Global Assessment :

Patient physician Discordance	No of patients	% of patients
Concordant	86	66.15
Discordant	44	33.85
Total	**130**	**100.00**

A Global VAS score difference between the patient score and the physician score less than 25 was taken as a concordant score. A score difference of more than 25 was considered a discordant score. In our study population 86 patients i.e 66% had a concordant global VAS score.

ASSOCIATION BETWEEN VARIOUS FACTORS AND THE PATIENT GLOBAL VAS SCORE

Table 5.10 : Association Between Age Of The Patient And The Patient Global VAS Score :

Age Group	VAS<50	%	VAS≥50	%	Total	%	Chi-Square	P-Value
20-29yrs	7	46.67	8	53.33	15	11.54	7.1000	0.1310
30-39yrs	19	65.52	10	34.48	29	22.31		
40-49yrs	12	36.36	21	63.64	33	25.38		
50-59yrs	14	43.75	18	56.25	32	24.62		
≥60yrs	7	33.33	14	66.67	21	16.15		
Total	59	45.38	71	54.62	130	100.0		

Upon analysis with Chi-square test, No significant association found between the patients age and the patient global VAS score (p value : 0.1310)

Table 5.11 : Association Between The Gender Of The Patient And The Patient Global VAS Score

Gender	VAS <50	%	VAS≥50	%	Total	%	Chi-Square	P-Value
Male	16	59.26	11	40.74	27	20.77	2.6470	0.1040
Female	43	41.75	60	58.25	103	79.23		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

Out of 27 male patients , 16 gave a VAS score less than 50 and 11 gave a VAS score of >/= 50 Among the 103 female patients, 43 gave a VAS score less than 50 and 60 gave a score more than or equal to 50. No significant association was found between the gender of the patient and the patient Global VAS score (p Value: 0.1040)

Table 5.12:Association Between The Education Of The Patient And The Patient Global VAS Score :

Education	Vas <50	%	Vas >/= 50	%	Total	% Total	Chi-Square	P Value
Illiterates	6	27.27	16	72.73	22	16.92	7.5590	0.1090
Primary	16	51.61	15	48.39	31	23.85		
Secondary	21	55.26	17	44.74	38	29.23		
PUC	5	27.78	13	72.22	18	13.85		
Degree	11	52.38	10	47.62	21	16.15		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.00**		

No significant association was found between the education status of the patient and the patient global VAS score (p value < 0.1090)

Table 5.13 : Association Between The Disease Duration And Patient Global VAS Score

Disease Duration	VAS <50	%	VAS >=50	%	Total	%	Chi-Square	P-Value
<1yr	2	15.38	11	84.62	13	10.00	5.3070	0.0700
1-5yrs	31	47.69	34	52.31	65	50.00		
>=6yrs	26	50.00	26	50.00	52	40.00		
TOTAL	59	45.38	71	54.61	130	100		

Patients were grouped into 3 based on the disease duration. Highest number of patients were in the disease duration group 1 to 5 years i.e 65 patients(50%). The disease duration did not have a significant effect on the Patient Global VAS score (p-Value < 0.07)

Table 5.14 :Association Between History Of Analgesic Use And Patient Global Vas Score :

Analgesic Use	VAS <50	%	VAS >=50	%	Total	%	Chi-Square	P-Value
No	36	72.00	14	28.00	50	38.46	23.2200	0.0001*
Yes	23	28.75	57	71.25	80	61.54		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

Among 71 patients with a VAS >/= 50 , 57 patients(71.2%) who gave a Global VAS score of >/50 had a history of analgesic use for pain relief , compared to 1428% with no history of analgesic use. This was significant statistically with a p value of 0.0001

Table 5.15 : Association Between History Of DMARD Use And Patient Global VAS Score :

DMARD use	VAS <50	%	VAS >= 50	%	Total	%	Chi-Square	P-Value
No	0	0.00	25	100.00	25	19.23	22.6240	0.0001
Yes	59	56.19	46	43.81	105	80.77		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

Among 130 study population , only 25 patients had no history of DMARD use . All the patients who were not started on regular DMARD treatment , gave a global VAS score of >/= 50. This was statistically significant with a P- Value of 0.0001.

Table 5.16 : Association Between Sleep Disturbance And Patient Global Vas Score :

Sleep disturbance	VAS Score <50	%	VAS Score >/= 50	%	Total	%	Chi-Square	P Value
No	40	72.73	15	27.27	55	42.31	28.754	0.0001*
Yes	19	25.33	56	74.67	75	57.69		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

In our study population of 130 patients , 75 patients had sleep disturbance. Among the 75 patients with history of sleep disturbance , 56 patients(74.67%) gave a Global VAS score >/= 50. This was found to be significant statistically with a p-Value of 0.0001

Table 5.17 : Association Between Extra-Articular Manifestation And Patient Global VAS Score :

EAM	VAS<50	%	VAS>/= 50	%	Total	%	Chi-Square	P Value
No	53	51.46	50	48.54	103	79.23	7.3760	0.0070*
Yes	6	22.22	21	77.78	27	20.77		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

Among the patients included in study , 27(20.77%) had extraarticular manifestations. Among these , 21(77.78%) patients gave a Global VAS Score of >/=50. This finding was significant statistically with a p-Value of 0.0070

Table 5.18 : Association between Family History Of Arthritis And Patient Global Vas Score :

Factor	VAS<50	%	VAS>/= 50	%	Total	%	Chi-Square	P Value
Family History Of Arthritis								
No	45	41.28	64	58.72	109	83.85	4.5770	0.0320*
Yes	14	66.67	7	33.33	21	16.15		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

In our study only 21(16.15%) patients had a positive family history of arthritis. Among them 14(66.67%) patients gave a Global VAS score <50 , i.e Patients with a positive family history gave a lesser Global VAS score, which was significant statistically with a P Value of 0.0320 .

Table 5.19 : Association Between Habits And Patient Global VAS Score :

Factors	VAS <50	%	VAS >/=50	%	Total	%	Chi-Square	P-Value
Smoking								
No	50	43.10	66	56.90	116	89.23	2.2610	0.1330
Yes	9	64.29	5	35.71	14	10.77		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		
Alcoholism								
No	55	44.35	69	55.65	124	95.38	1.1490	0.2840
Yes	4	66.67	2	33.33	6	4.62		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		
Passive Smoking								
No	52	45.61	62	54.39	114	87.69	0.0200	0.8880
Yes	7	43.75	9	56.25	16	12.31		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

In our study population , 14(10.7%) patients had history of smoking. 6(4.62%) patients had history of alcohol intake and 16(12.31%)patients had history of passive smoking. There was no significant difference in scoring of Global VAS by smokers and non smokers (p value =0.133) . There was no significant difference in scoring of Global VAS among patients with or without history of alcohol intake and passive smoking (p=0.2840 and p = 0.8880 respectively)

Table 5.20 : Association Between Deformities And Patient Global VAS Score :

Deformity	VAS<50	%	VAS >/=50	%	Total	%	Chi-Square	P Value
No	49	46.67	56	53.33	105	80.77	0.3620	0.5470
Yes	10	40.00	15	60.00	25	19.23		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

In our study population, out of 130 patients, 25(19.2%) patients had deformities of the joints. There was no significant difference found in scoring of global VAS among patients with and without joint deformities (p value = 0.5470)

Table 5.21: Association Between Knee Joint Involvement And Patient Global VAS Score :

C/F	VAS <50	%	VAS >/=50	%	Total	%	Chi-Square	P Value
Knee Involvement								
No	45	69.23	20	30.77	65	50.00	29.823	0.0001
Yes	14	21.54	51	78.46	65	50.00		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

Among 130 study population, 65(50%) had knee joint involvement 65(50%) did not. Among those with knee joint involvement , 51 (78.46%) gave a Global VAS score >/= 50 and only 14 (21.5%) gave a score < 50. This association was statistically significant with a p value of 0.0001.

Table 5.22 : Association Between Patient Pain VAS and Patient Global VAS Score :

Pain VAS	Global VAS <50	%	Global VAS >/= 50	%	Total	%	Chi-square	P value
< 50	48	81.3	11	18.6	59	45.3	56.3931	0.00001
≥ 50	11	15.4	60	84.5	71	54.6		
Total	59	45.3	71	54.6	130	100		

In our study, out of 130 patients, 59 patients gave a pain VAS score less than 50, in them 48 patients i.e 81.3% gave a Global VAS < 50. Among the 71 patients with a Pain VAS score >/= 50 , only 11 patients, i.e 15.4% gave a Global VAS <50 . This indicates a strong association between Pain VAS and Patient Global VAS with a P value of 0.00001

Table 5.23: Association Between Tender Joint Count And Patient Global VAS

C/F	VAS <50	%	VAS >/=50	%	Total	%	Chi-Square	P Value
Tender Joint Count								
0—5	42	71.19	17	28.81	59	45.38	37.178	0.0001
6—10	12	46.15	14	53.85	26	20.00		
>10	5	11.11	40	88.89	45	34.62		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

Among 130 study population , Maximum number of patients i.e, 59(45.38%) had a tender joint count of 0-5. Among these patients only 17(28%) gave a Global VAS score of >/= 50.

Second highest number of patients i.e, 46(34.6%) patients had a tender joint count of > 10. Among them only 5(11%) gave a VAS score of < 50 . This finding was significant with a p value of 0.0001

Table 5.24 : Association Between Swollen Joint Count And Patient Global VAS

C/F	VAS <50	%	VAS >/=50	%	Total	%	Chi-Square	P Value
0—5	56	60.22	37	39.78	93	71.54	29.924	0.0001
6—10	0	0.00	18	100.00	18	13.85		
>10	3	15.79	16	84.21	19	14.62		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

In our study , 93(71%) patients had a swollen joint count of 0-5 . Among them 56(60.2%) gave a Global VAS score <50 . 18 patients had a swollen joint count of 6-10 , among these no patient gave a Global VAS <50 .Among the 19 patients with swollen joint count >10 , only 3 gave a VAS score < 50. This was significant statistically. (p value = 0.0001)

Table 5.25 : Association Between Fibromyalgia And Patient Global VAS Score :

FiRST Score	VAS < 50	%	VAS >/=50	%	TOTAL	%	Chi-square	P value
≥ 5	7	18.9	30	81.0	37	28.4	14.6152	0.0001
<5	52	55.9	41	44.0	93	71.5		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

A score of more than equal to 5 is indicative of presence of fibromyalgia. Among the study population , 37(81%) patients had Fibromyalgia. Among these patients 7(18.9%) gave a Global VAS score < 50 and 30 gave a score >/= 50. This was statistically significant (p Value 0.0001)

Table 5.26 : Association Between Modified Health Assessment Score And Patient Global VAS Score :

MAH Score	VAS <50	%	VAS >/=50	%	Total	%	Chi-Square	P Value
< /=3	45	84.91	8	15.09	53	40.77	56.385	0.0001
>3	14	18.18	63	81.82	77	59.23		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

Out of 130 patients, 77(59.23%) patients gave a MAH score >3 i.e, significant functional disability. Among these patients, 63(81.8%) gave a Global VAS score of >/= 50. This indicates a significant correlation (p value 0.0001)

Table 5.27 : Association between Depression And Patient Global VAS Score :

HAM D SCORE	VAS <50	%	VAS>/= 50	%	Total	%	Chi-Square	P Value
Negative (<7)	53	75.71	17	24.29	70	53.85	56.2860	0.0001
Positive (>/=7)	6	10.00	54	90.00	60	46.15		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

In our study population , 60(46.15%) patients had features suggestive of depression. Among these patients 54(90%) gave a Global VAS score of >/= 50 . 70(53%) patients did not have features suggestive of depression , among them only 17(24%) gave a Global VAS Score >/= 50. This was statistically significant (P value = 0.0001).

Table 5.28 : Association Between Anxiety and Global VAS Score :

HAM A SCORE	VAS<50	%	VAS>/=50	%	Total	%	Chi-Square	P Value
Negative (<7)	58	65.17	31	34.83	89	68.46	44.5610	0.0001
Positive(>/=7)	1	2.44	40	97.56	41	31.54		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

Among the study patients, anxiety features were present in 41(31.54%) patients. Among these, only 1(2.4%) patient gave a Global VAS Score < 50, the remaining 40(97.56%) gave a VAS score >/= 50 . This was a significant association with a P Value of 0.0001.

Table 5.29 : Association Between Employment And Patient Global VAS Score :

Gainfully Employed	VAS <50	%	VAS >/=50	%	Total	%	Chi-Square	P Value
No	7	11.86	52	88.14	59	45.38	48.9700	0.0001
Yes	52	73.24	19	26.76	71	54.62		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.0**		

In our study subjects, out of 71 patients who gave a Global VAS Score of >/= 50, only 19 were gainfully employed and Out of 59 patients that gave a VAS score < 50, 52(88%) were gainfully employed. This indicates a significant association between employment and Global VAS with a P value of 0.0001.

Table 5.30: Association Between Serology Status And Patient Global VAS Score :

Serology	Vas <50	%	Vas>=50	%	Total	%	Chi-Square	P Value
Negative	19	44.19	24	55.81	43	33.08	0.0370	0.8470
Positive	40	45.98	47	54.02	87	66.92		
Total	**59**	**45.38**	**71**	**54.62**	**130**	**100.00**		

Among the 71(54.62%) patients that gave a VAS score >/=50 , 47(54%) were seropositive. Among the 59(45.3%) patients that gave a VAS score < 50, 40(45%) were seropositive. This result was not significant statistically (p value = 0.8470)

IDENTIFICATION OF THE FACTORS CAUSING DISCORDANCE IN PATIENT AND PHYSICIAN GLOBAL VAS SCORE :

Table 5.31 : Association Between The Age Of The Patient And the Patient-Physician Discordance

Age Groups	Concordant	%	Discordant	%	Total	%	Chi-Square	P Value
20-29	10	66.6	5	33.3	15	11.5	9.8993	0.0421
30-39	24	82.7	5	17.2	29	22.3		
40-49	18	54.5	15	45.5	33	25.3		
50-59	24	75	8	25	32	24.6		
>/= **60**	10	47.6	11	52.3	21	16.1		
Total	**86**	**66.15**	**44**	**33.8**	**130**	**100**		

Among the 44(33.8 %) patients that gave a discordant score , maximum number of patients i.e, 15(45.5%) were in the age group of 40 to 49 years and the least number of patients i.e, 5(17.2 %) were in the age group of 30 to 39 years. Among the 86 patients that gave concordant score, maximum number of patients i.e, 24 belonged to the age group of 30 -39 years and 50 to 59 years. The result was statistically significant with a p value : 0.0421.

Table 5.32 : Association Between Gender And Patient Physician Discordance

Gender	Concordant	%	Discordant	%	Total	%	Chi-Square	P Value
Male	19	70.3	8	29.6	27	20.7	0.2706	0.6029
Female	67	65.0	36	34.9	103	79.2		
Total	**86**	**66.1**	**44**	**33.8**	**130**	**100**		

Out of 103 female patients, 36(34.9%) gave a discordant score and 67(65%) gave a concordant score. Among the 27 Male patients , 8 (29.6%) gave a discordant score and 19(70%) gave a concordant score. This was not statistically significant.

Table 5.33 : Association Between The Education Of The Patient And Physician Patient Discordance

Education	Concordant	%	Discordant	%	Total	%	Chi-Square	P Value
None	12	54.5	10	45.5	22	16.9	3.4589	0.4841
Primary	19	61.2	12	38.7	31	23.8		
Secondary	27	71.05	11	28.9	38	29.2		
Pre-University	12	66.6	6	33.3	18	13.8		
Degree	15	78.9	4	21.04	19	14.6		
Total	**86**	**66.1**	**44**	**33.8**	**130**	**100**		

Highest percentage of concordance was found in the group of patients who were educated till degree. Out of 19(14.6%) patients that were educated till degree, 15(78.9%) gave a concordant score. But this association was not significant statistically p value = 0.4841

Table 5.34 : Association Between the Duration Of The Disease And Patient-Physician Discordance :

Duration	Concordant	%	Discordant	%	Total	%	Chi-Square	P Value
< 1 Year	7	53.8	6	46.1	13	10	0.9791	0.6128
1 – 5 Yr	44	67.6	21	32.3	65	50		
</= 6 Yr	35	67.3	17	32.6	52	40		
Total	**86**	**66.1**	**44**	**33.8**	**130**	**100**		

Among 44(33.8%) patients who gave a discordant score , highest number of patients i.e, 21 , belongs to disease duration group 1-5 years. Among the 86(66%)patients that gave a concordant score , the highest number of patients i.e, 44 patients belonged to 1-5 year group. This result was statistically insignificant (p value=0.6128)

Table 5.35: Association Between Analgesic Use And Patient-Physician Discordance In Global Vas Score :

Analgesic use	Concordant	%	Discordant	%	Total	%	Chi-square	P-value
No	39	73	14	26.4	53	40.7	2.2053	0.1379
Yes	47	61	30	38.9	77	59.2		
Total	**86**	**66.1**	**44**	**33.8**	**130**	100		

Among 130 subjects , 77(59.2%) had history of analgesic use for pain relief, among them 30(38.9%) gave a discordant score . Among the 53(40.7%) patients without history of analgesic use, 14(26%) gave a discordant score. This was not statistically significant(p value = 0.1379)

Table 5.36 : Association Between DMARD Use And Patient Physician Discordance :

DMARD Use	Concordant	%	Discordant	%	Total	%	Chi-Square	P-Value
No	13	50	13	50	26	20	3.7877	0.51632
Yes	73	70.1	31	29.8	104	80		
Total	**86**	**66.1**	**44**	**33.8**	**130**	**100**		

Among 130 study population, 104(70.1%) patients were on DMARDs. Among them 73(70%) gave a concordant VAS score and 31(29.8%) patients gave a discordant score. Among the 26 (20%) patients that were not on DMARDs , 50% gave a concordant score and remaining 50% gave a discordant score . this was statistically insignificant.(p value=0.516)

Table 5.37: Association Between Sleep Disturbance And Patient-Physician Discordance In Global VAS Score :

Sleep disturbed	Concordant	%	Discordant	%	Total	%	Chi-square	P-value
No	43	78.1	12	21.8	55	42.3	6.1598	0.01306
Yes	43	57.3	32	42.6	75	57.6		
Total	**86**	**66.1**	**44**	**33.8**	**130**	**100**		

In this study, 75(57.6%) patients had disturbed sleep. Among them 32(42%) patients gave a discordant score and 43(57%) patients gave a concordant score. 55(42%) patients did not have disturbed sleep. Among them 43(78%) gave a concordant score and 12(21%) gave a discordant score. This finding was significant statistically, p value = 0.01306.

Table 5.38 : Association Between Extra Articular Manifestations And Patient Physician Discordance :

Extra Articular Features	Concordant	%	Discordant	%	Total	%	Chi-square	P-value
No	72	70	31	30	103	79	3.1131	0.0771
Yes	14	52	13	48	27	21		
Total	**86**	**66.1**	**44**	**33.8**	**130**	**100**		

Among 130 patients, 103(79%) patients did not have extra articular features. Among them 72(70%) patients gave a concordant score and 31(30%) had discordant score. This finding was statistically significant with p value = 0.0771.

Table 5.39 : Association Between Family History Of Arthritis And Patient Physician Discordance :

Family history of arthritis	Concordant	%	Discordant	%	Total	%	Chi-square	P-value
No	67	61	42	39	109	84	6.6173	0.010
Yes	19	90	2	10	21	16		
Total	**86**	**66**	**44**	**34**	**130**	**10**		

In our study, only 21(16%) patients had a positive family history of arthritis. Among them 19(90%) patients had a concordant global VAS score and 2(10%) had a discordant global VAS score. Patients with a family history of arthritis gave a more concordant score. This finding was significant statistically with p value= 0.010

Table 5.40 : Association Between Habits And Patient-Physician Discordance In Global Vas Score :

Factors	Concordant	%	Discordant	%	Total	%	Chi-square	P-value
Smoking								
No	76	66	40	34	116	89	0.195	0.65
Yes	10	71	4	29	14	11		
Total	**86**	**66**	**44**	**34**	**130**	**10**		
Alcoholism								
No	80	65	44	35	124	95	0.8954	0.3440
Yes	5	83	1	17	6	5		
Total	**86**	**66**	**44**	**34**	**130**	**10**		
Passive smoking								
No	75	66	39	34	114	88	0.0549	0.8147
Yes	11	69	5	31	16	12		
Total	**86**	**66**	**44**	**34**	**130**	**10**		

Among the study population, 14(11%) patients had history of smoking. 6(5%) patients had history of alcoholism and 16(12%) patients had history of passive smoking. No statistically significant association was found between the history of smoking, alcohol intake, passive smoking and the patient and physician global VAS score discordance. the p values were 0.65 , 0.344, 0.8147 respectively.

Table 5.41 : Association Between Deformities And Physician Patient Discordance In Global VAS Scoring :

Deformities	Concordant	%	Discordant	%	total	%	Chi-square	P value
No	72	69	33	31	105	80	1.4252	0.2325
Yes	14	56	11	44	25	20		
Total	**86**	**66.1**	**44**	**33.8**	**130**	**100**		

Among 130 study patients, 25(20%) patients had joint deformities. Among them 14(56%) patients had a concordant score and 11(44%) had a discordant score. Among the 105(80%) patients who did not have joint deformities, 72(69%) had a concordant score and 33(31%) had a discordant score. This was not statistically significant. (p value= 0.2325)

Table 5.42 : Association Between Knee Joint Involvement And Patient Physician Discordance

Knee Affected	Concordant	%	Discordant	%	Total	%	Chi-Square	P Value
No	52	80	13	20	65	50	11.1311	0.0008
Yes	34	52	31	48	65	50		
Total	**86**	**661**	**44**	**33.8**	**130**	**100**		

In the study population of 130, 65(50%) patients had knee joint involvement. Among the patients that had concordant VAS scoring , 34 patients had knee joint involvement and 52 patients did not have knee joint involvement. Among the patients without knee involvement, only 13(20%) patients had discordant score , 52(80%) had a concordant score. This finding was strongly significant statistically (p value= 0.0008)

Table 5.43 : Association Between Joint Count And Patient Physician Discordance

Joint Count	Concordant	%	Discordant	%	Total	%	Chi-Square	P Value
Tender Joint Count								
0—5	40	68	19	32	59	45	0.4917	0.7820
6—10	18	69	8	31	26	20		
>10	28	62	17	38	45	35		
Total	**86**	**66.1**	**44**	**33.8**	**130**	**100**		
Swollen Joint Count								
0—5	61	66	32	34	93	71	2.305	0.3158
6—10	10	56	8	44	18	14		
>10	15	79	4	21	19	15		
Total	**86**	**66.1**	**44**	**33.8**	**130**	**100**		

Among the study population, 45(35%) patients had TJC >10. Among them 28(62%) had a concordant score and 17(38%) had discordance. This finding was not statistically significant.

>10 swollen joint count was found in 19(15%) patients. Among them 15(79%) gave a concordant score and 4(21%) patients gave discordant score . However this finding was not statistically significant.(p value = 0.3158)

Table 5.44: Association Between Patient Pain VAS and Patient-physician Discordance in Global VAS scoring:

Pain VAS	Concordant	%	Discordant	%	Total	%	Chi-Square	P Value
< 50	49	83%	10	16.9	59	45.3	13.775	0.00002
≥50	37	52.1	34	47.8	71	54.6		
Total	**86**	**66.1**	**44**	**33.8**	**130**	**100**		

In our study population of 130 , 86 patients had a concordant score . Among them, 49(83%) patients gave a pain VAS score less than 50. 44 patients gave a discordant score, among them only 10(16.9%) gave a Pain VAS less than 50 . This indicates a strong correlation between Pain VAS score and Patient- Physician discordance with a p value 0.00002

Table 5.45 : Association Between Fibromyalgia And Patient Physician Discordance :

Fibromyalgia	Concordant	%	Discordant	%	Total	%	Chi-Square	P Value
Positive	11	29	26	71	37	28	30.6461	0.00001
Negative	75	81	18	19	93	72		
Total	**86**	**66.1**	**44**	**33.8**	**130**	**100**		

Among 130 patients with RA , 37(28%) patients had fibromyalgia. Among them, 11(29%) had a concordant global vas score and 26(71%) patients had a discordant score. This finding was statistically significant with a p value 0.00001. Among the 93(72%) patients without fibromyalgia, only 18(19%) had a discordant score.

Table 5.46 : Association Between Modified Health Assessment Score And Physician-Patient Discordance:

MAHQ Score	Concordant	%	Discordant	%	Total	%	Chi-Square	P Value
</= 3	45	85	8	15	53	41	14.0524	0.00017
>3	41	53	36	47	77	59		
Total	86	66.1	44	33.8	130	100		

A score of </= 3 on Modified health assessment questionnaire indicates no disability. In our study,53(41%) patients gave a score </= 3 on MAHQ. Among them 45(85%) had a concordant Global VAS score. Among the patients that had a discordant Global VAS score , ie.,44 , 36 patients gave a MAHQ > 3 and only 8 patients gave a MAHQ</= 3. This was statistically significant with a p value 0.00017

Table 5.47: Association Between Psychological Factors And Patient-Physician Discordance In Global Vas Score :

Factors	Concordant	%	Discordant	%	Total	%	Chi-Square	P Value
Ham D								
<7	42	60	28	40	70	53.85	2.56	0.10924
>/=7	44	73.33	16	26.66	60	46.15		
Total	86	66.1	44	33.8	130	100		
Ham A								
<7	68	76.40	21	23.59	89	68.46	13.243	0.0002
>/= 7	18	43.90	23	56.09	41	31.53		
Total	86	66.1	44	33.8	130	100		

A score >/= 7 on HAM-D and HAM-A indicates presence of features suggestive of depression and anxiety respectively.

Out of 130 patients, 60(46.15%) patients had features of depression, 44(73%) of them gave a concordant score and 16(26.6%) of them gave a discordant score. But this was not statistically significant (p value – 0.1092)

Among the 89(23.5%) patients who did not have features suggestive of anxiety, 68(76.4%) gave a concordant score and among 41(31%) patients with features of anxiety,23(56%) had a discordant score which was statistically significant with a p value of 0.0002

This indicates that patients with features of anxiety had a discordant score

Table 5.48 : Association Between Employment And Patient-Physician Discordance In Global VAS Score :

Gainfully employed	Concordant	%	Discordant	%	Total	%	Chi-square	P value
No	33	55.93	26	44.06	59	45.38	5.041	0.02475
Yes	53	74.64	18	25.35	71	54.61		
Total	86	66.1	44	33.8	130	100		

Out of 130 patients , 71 (54.61%) patients were gainfully employed. Among them 53(74.64%) patients gave a score of Global VAS that was concordant with that of physician. This was statistically significant with a P value of 0.0247 (<0.05). This shows the patients that were gainfully employed gave a more concordant score

Table 5.49 : Association Between Serology Status And Patient-Physician Discordance In Global VAS Score :

Serology	Concordant	%	Discordant	%	Total	%	Chi-square	P Value
Negative	28	65.1	15	34.88	43	33.07	0.0309	0.8604
Positive	58	66.6	29	33.33	87	66.92		
Total	**86**	66.1	**44**	**33.84**	**130**	**100**		

Among 130 patients, 87 were seropositive RA and 43 were seronegative RA .In the study population, 44(33.8%) patients gave a discordant score. Among them29 patients were seropositive and 15 were seronegative. No significant co-relation found between the serological status of the patient and the discordance between the patient and physician global VAS score (p value= 0.8604)

DISCUSSION

DISCUSSION

Rheumatoid arthritis is an autoimmune disease with global prevalence of 0.24%. It is twice more common in females (0.35%) than in males (0.13%) .[18] The burden of RA on a patient is related to both the extent of damage or inflammation and on the psychological and social factors a person is exposed to. Hence, the patient-related outcomes like HAQ and PGA are used as assessment tools for conducting a holistic and in depth assessment of the disease .[31] However, the patient's assessment of the disease may be different from that of the physician's and this can have adverse effects on the therapeutic decisions and management.[63] Determining the discrepancies between patient and physician opinion is critical for proper treatment of the disease. Additionally, it is important to understand the reason and factors leading to disagreement between the two to clearly understand the impact of the disease on the patient's quality of life.[76]

The present study was aimed at identifying the various factors affecting the patients global VAS in RA patients and it also studied the factors responsible for discordance in patients and physician's global VAS.

IMPACT OF DEMOGRAPHIC PROFILE ON PGA

The current study involved 130 RA patients with a mean age of 45.59 ± 13.23yrs. The majority of RA patients belonged to the age group of 40-49yrs. In concurrence with the previous findings, the male to female ratio (1:3.81) noted in the present study indicated increased female predominance of subjects with RA in comparison to men. Although both the genders show similar biological and immunological features, the quality of life of women is poorer than the

men (Aurrecoechea 2015).[77] This may be due to the menopausal status of woman as the majority of the population belongs to 40-49yrs age group, but in our study there was no significant association found between age of the patient and the Global VAS score. Additionally, Mollard et al. concluded that menopausal status is associated with functional decline in women with RA (Mollard 2018).[78] Majority of the patients in the current study had only secondary schooling as their educational background. Jiang et al. concluded that RA patients with higher education levels showed lesser pain and functional disability, probably because of a better understanding of the condition (Jiang 2015).[79] Similarly, a systematic review performed by Lopez-Castillo noted that educational level significantly influences the risk and clinical course of RA (Lopez-Castillo 2014).[80] Moreover, patient education also substantially improves adherence to treatment, thereby contributing to increased number of subjects achieving remission rate (Taibanguay 2019).[81] But in our Study no Significant association found between educational status of the patient and the Global VAS score. Majority of the patients in the present study had a disease duration of 1-5yrs with mean disease duration of 5.91 ± 5.70yrs and it was found in our study that disease duration had no significant effect on the patient Global VAS score. Around 66% of the study population was serologically positive and there was no significant association between serological status and the Patient Global VAS score.

PATIENT-PHYSICIAN GLOBAL VAS DISCORDANCE

The physical and psychosocial functions are crucial elements in determining the overall well-being of RA patients. Additionally, the status of the patient can be well understood by patient self-report and physician examination rather than biological indicators for the disease (Clarke 1992).[82] According to the new ACR/EULAR criteria, PGA plays a vital role in achieving RA

remission. The perception of disease activity varies between patients and physician and hence understanding the discordance between patient and physicians can facilitate the effective management of the disease (Furu 2014).[83] Moreover, it is equally important to understand the complexities underlying the discordance between patient and physician global assessments (Berkanovic 1995).[76]

In the current study, the patient global VAS score >/=50 was noted for 54.62% of the patients. However, according to the physician global VAS, only 33.85% of the patients had a score >50. Hence the percentage of discordance of physician score with that of the patients was 33.85%. The rationale behind this high discordance can be understood only by studying the underlying factors and by having discussions with patients and physicians to understand their ideas and motives behind their evaluations based on their experience (Vantuyl 2012).[84] Moreover, frequent visits to the rheumatologists are necessary for a clear understanding of the patient's condition, which also contributes to the reduction of the discrepancy with regards to disease perception of patient and physician. Besides that, the time differences when the patients are rated should be considered (Berkanovic 1995).[76]

The discrepancies can either attributed by the differences in the measures used by the patients and the rheumatologists to rate physical functioning of the patient or in assessments of the patient's physical functioning related to changes in pain, depression, and physical functioning (Berkanovic 1995).[76] The factors that are important to the patient may not be crucial for a physician to assess the disease activity, which emphasizes the need to comprehend the patient's psychological status as well as personal life factors (Nikiphourou 2016).[31] Ward et al. stated

that patients use a personal relative standard of comparison, while clinicians use a social standard of comparison to measure the RA rating (Ward 2016).[85]

This discordance highlights the need for clear communication between the patients and the physician. Moreover, it is paramount for the physicians to verify their perceptions with that of patients, and the patients should be educated about the importance of verifying the same and understanding them correctly (Berkanovic 1995).[76] The study by Gibofsky et al. corroborated this finding. The researchers have observed an improvement in the management of RA in a proportion of cases who had a better patient-physician communication (Gibofsky 2018).[86]

PATIENT GLOBAL VAS AND ASSOCIATED FACTORS

Patient reported outcomes is an essential and useful tool in managing RA irrespective of the age, gender and educational background (Amaya-Amaya 2012).[87] It is a crucial component in measuring disease activity among RA patients. The current study determined the factors influencing the patient global VAS which help is improving the treatment for RA and decreasing the patient-physician discordance of a global assessment. Use of analgesics, lack of DMARDs, sleep disturbances, extra-articular manifestations, knee involvement, Pain Vas >/=50, tender joint count >5, swollen joint count>5, family history of arthritis, MHAQ>3, HAM D>/=7(presence of features of depression), HAM-A>/=7(presence of features of anxiety) fibromyalgia and lack of gainful employment showed a higher score of global assessment, indicating a significant relationship of the aforementioned factors with patient global VAS.

ANALGESICS AND DMARD USAGE:

Analgesics and DMARDs are usually prescribed based on the subjective disease activity of the patient (al 2008).[88] The study performed by Gupta et al. has concluded that the frequency of analgesic intake in RA has a significant relationship with patient-reported functional capacity and well-being (Gupta 2014).[89] This is in line with the present study findings. On the other hand, contrary to the current findings, Lauper et al. noted that the usage of DMARDs was found to rely more on physician global assessment (Lauper 2019).[90] It is noted in this study that lack of DMARD usage was significantly associated with higher Global VAS score

SLEEP DISTURBANCE:

Sleep disorders and poor sleep quality are common among RA patients which are linked to pain, mood, fatigability, stress, and disease activity (Westhovens 2014).[91] However, Mustafa et al., showed that there was no association between sleep disorders and the quality of life in RA patients (Mustafa 2019).[92] Grabovac et al., showed an association between pain and non-optimal sleep (Grabovac 2018).[93] But, no study on the association between sleep disturbance and patient global assessment has been performed till date. In our study , a significant association was found between the presence of disturbed sleep and the Patient Global VAS score where patients with disturbed sleep gave a significantly higher Global VAS scoring.

EXTRA-ARTICULAR MANIFESTATIONS:

The extra-articular manifestations are more common in males than in females, although RA predominantly affects women (Cojocaru 2010)94. Yet, there are no studies evaluating the relationship between the PGA and extra-articular manifestations. In our study it was noted that patients with extra-articular manifestations gave a higher score on the Global VAS Scale.Thus it is important to consider this finding also while treating RA patients.

JOINT COUNT :

Joint counts such as tender joint count and swollen joint count are essential elements of disease activity measurements. An increase in the joint damage is linked to an increase in disability over time (Bombardier 2012).[95] According to Barton et al., the swelling and inflammation data are said to depend on the scoring of the physician, but the description of pain and tenderness is accurately evaluated by the patient, (Barton 2009).[96] This is in concurrence with the study by Kaneko et al (Kaneko 2018).[97] However, Smedstad et al. has concluded that the relative effects of disability and tender joints were not statistically significant, but pain and depression had significant impact on PGA (Smedstad 1997).[98] in our study a significant association was found between joint count and Patient Global VAS. Patients with TJC and SJC > 5 gave a significantly higher score on the Global VAS scale.

PSYCHOLOGICAL FACTORS :

Anxiety and depression both are said to have an impact on the patient's perception of the disease status (Duarte 2015; Yukioka 2013).[99,100] Our study was also in line with this finding, with patients who had features of depression and anxiety giving a higher score on the VAS scale.

EMPLOYEMENT:

Working disability is one of the major problems of RA. More than treatment cost, unemployment and working disability create an economic burden on the patient and society (allaire2001).[101] The present study also has shown an association between lack of gainful employment and patient global assessment.

KNEE JOINT INVOLVEMENT :

The current study also showed a significant association between the knee joint involvement and a higher score on global assessment . This is particularly important in an Indian population because of frequent use of squatting position or cross legged position as compared to a western population . Thus patients with knee joint involvement may perceive a higher global disease activity. Thus it is important that the treating physician take this into account while RA management. But supportive literature was not found to validate the results. Similarly, supportive literature on the association between family history of arthritis on PGA was not found to validate the results.

PAIN VAS:

The present study identified pain as one of the strongest factors affecting the patient Global VAS score. This was in line with the results obtained by Egsmose EL et al (2015) that concluded that patient global assessment was strongly associated with pain and fatigue. A study conducted by Divya N.V.Challa et al in 2017[35,36] on 70 patients also concluded that pain was a strong factor predicting patients Global VAS.

FIBROMYALGIA :

Many studies have identified fibromyalgia as a strong underlying factor driving the patient Global VAS score. Our study also identified fibromyalgia as a strong predictor of the patient Global VAS score. This was in line with the study conducted by Divya N.V. Challa et al (2017)[35,36] who identified fibromyalgia, advanced age, inability to participate, anxiety, depression, pain, degenerative arthritis as latent factors underlying patient global assessment

RELATIONSHIP BETWEEN DISCORDANCE STATUS AND FACTORS

The difference between the perception of the disease activity of patients and physicians has been well established and understanding the reason/ factors responsible for the discrepancy between patient and physician global assessment is crucial for the management of RA (Studenic 2012).[102] The present study has identified advanced age, use of analgesics, lack of DMARDs, sleep disturbances, family history of arthritis, knee involvement, fibromyalgia, pain, MHAQ score > 3, HAM-A score >/= 7(anxiety features) and lack of gainful employment as the factors associated with the discordance in this study.

AGE :

Khan et al. stated that the odds of higher patient scoring increased with higher age, which may be the reason for discordance in older patients (Khan 2012).[103] This is inline with the present study, which showed an association of age with the discordance between patient and physician global VAS. Patients with advanced age had a discordant global VAS score in our study.

GENDER:

The frequency of discordance between patient and physician assessment, noted in the study by Egholm et al., was higher in women than in men. But the gender of physician was independent of discordance (Egholm 2015).[104] In the current study, gender showed no correlation with discordance.

SLEEP DISTURBANCE : In our study Sleep disturbance was found to be associated with discordance and this in concurrence to the findings by Cho et al. (Cho 2016).[105]

KNEE JOINT INVOLVEMENT :Tanaka et al. pinpointed that the wrist, knee and elbow joints made the greatest contributions to physician global assessment, followed by the other joints (Tanaka 2005).[106] On the other hand, Tago et al. showed lower discordance because of high

joint involvement (Tago 2018).[107] However, the study by Kaneko et al. showed that with an increase in the duration of monitoring of the disease, the PGA becomes more sensitive to the joint involvement and destruction than physician global assessment, thereby causing discrepancy in the assessment by the patients (Kaneko 2014).[108] Akhavan et al. also concluded that active joints are one of the main clinical factors affecting the discrepancy in patients with RA (Akhavan 2013).[109] Similar to these findings, the present study, has also noted the association of discordance with knee involvement. In our study patients without knee joint involvement gave a global VAS score that was concordant with the physician score.

TJC AND SJC :A systematic review and meta-analysis by Barton et al. showed that there was a moderate correlation in the tender joint count measurement, but the swollen joint counts demonstrated lower levels of correlation between self-report and physician report (Barton 2009).[96] However, Khan et al. as well as Kaneko et al showed that swollen joint count was mostly influenced by physician global assessment (Khan 2012, Kaneko 2018).[103, 97] Moreover, Furu et al. stated that the discordance between patient and physician decreased with increase in the swollen joint count (Furu 2014).[83] Studenic et al. emphasized that one of the main determinants for the discrepancy was joint swelling along with pain (Studenic 2012).[110] In contrast, the present study showed no relationship between joint swelling and tender joints with discordance.

PSYCHOLOGICAL FACTORS :

Depression is common among the RA patients and higher depressive symptoms are associated with patient-physician discordance (Barton 2010).[111] In contrary, the current study showed no association of HAM D with the discordance. However, HAM-A score showed an association

with discordance, which is in line with the study conducted by Duarte et al., which stated that higher anxiety showed higher discrepancy (Duarte 2015).[99]

EMPLOYMENT: The current study concludes that Patients of RA who were gainfully employed had concordance in the global assessment scoring. Karpouzas et al. showed that worst work productivity consequently leads to a higher patient scoring, which would directly lead to a discrepancy in the scoring between patients and physician (Karpouzas 2017).[112] Literature review shows that there are no studies elucidating the relationship between use of analgesics and DMARDs MHAQ, family history of arthritis and the discordance between patient and physician global assessment.

FIBROMYALGIA : The present study concluded that presence of fibromyalgia was strongly associated with a discordant global VAS score. This is inline with a study conducted by Khan et al. 2010 who reported that among patients of RA , among the positive discordance group , 4.6% had fibromyalgia , while among the concordant group , 2.5% had investigator reported fibromyalgia. This was statistically significant. In our study the prevalence of fibromyalgia in the discordant group was significantly higher than the overall fibromyalgia prevalence in RA

PAIN VAS :

The present study concluded that patients with higher pain VAS score gave a Global VAS score that was discordant with that of physician score. This was in line with a study conducted by George A Karpouzas et al (2017)[63] on 653 patients which concluded that pain was the most significant predictor of discordance followed by physical impairment , fatigue, depression and TJC.

STRENGTHS AND LIMITATIONS OF THE STUDY

The present study holds significant relevance, as it provides an overview of various factors affecting the Patients Global assessment score and various factors responsible for discordance in patient and physician global VAS, in an Indian setting. As per the literature evidence, this is the first study from India reporting the relationship between patient-physician discordance and the various associated factors, especially from a rural setting. The limitations of the present study were : The education status of the patients was not evaluated gender- and age-wise, though education plays an important role in discordance. Additionally, positive and negative discordance was not considered in this study. Further studies evaluating the relationship of patient-physician discordance with education status of the patient, mood, and disease activity are highly warranted to customize the treatment approach based on the disease outcomes noted in each patient.

CONCLUSION

CONCLUSION

The factors which can affect the way the patient perceive their disease severity include: pain, frequent analgesic usage, disturbed sleep, lack of DMARD use, presence of extra articular manifestations, involvement of knee joints hampering mobility, a tender joint count more than 5, a swollen joint count more than 5, presence of symptoms of anxiety or depression, lack of gainful employment, a family history of arthritis, a higher score on health assessment score (>3) and fibromyalgia.

Among these most significant association was found with pain, fibromyalgia, score of more than 3 on the Modified health assessment questionnaire, sleep disturbance, lack of DMARD use, lack of gainful employment.

The factors that were associated with patients and physicians discordant Global VAS Score included pain, advanced age of the patient, knee joint involvement, presence of symptoms of anxiety, a family h/o arthritis, absence of gainful employment, disturbed sleep, higher Disability score (based on the MHA Q score) and fibromyalgia.

SUMMARY

SUMMARY

This was a cross sectional hospital-based study conducted to study the factors affecting the Patient Global VAS score in patients of Rheumatoid Arthritis and to identify factors responsible for the discordance in patient and physician global assessment of disease activity.

A total of 130 patients were included in the study. The mean age of our study population was 45.59 years ±13.23. 79.23% were females with a Female to Male ratio of 3.81:1. The mean duration of the disease was 5.9 years ± 5.70. 66.92% were seropositive RA. 54.62% patients gave Patient Global VAS score of >/= 50. 66.15% patients had a discordant patient and physician global assessment scores.

Factor analysis identified factors that showed a statistically significant association with the patient Global VAS score which included pain, history of frequent analgesic use ,h/o sleep disturbance ,absence of DMARD use, presence of extra articular manifestations, involvement of knee joint hampering mobility , a tender joint count more than 5,a swollen joint count more than 5, presence of symptoms suggestive of depression and anxiety , absence of a gainful employment , a family history of arthritis , modified health assessment score > 3 ,presence of Fibromyalgia.

But no significant association was found with the age of the patient (p=0.1301) ,the patients gender (p<0.1040) , the patients education status(p<0.1090) , the duration of the disease (p < 0.0700), habits like smoking(p<0.1330) , alcoholism(p<0.2840) , the deformities (P<0.5470) and the serological status (p<0.8470)

The study also yielded factors that were associated with a discordant patient- physicians Global VAS Score, these included pain, advanced age of the patient, knee joint involvement hampering mobility, presence of symptoms of anxiety, a family h/o arthritis, absence of gainful employment, sleep disturbance, overall health (Based on the MHA Q score), fibromyalgia.

However there was no significant association found between patient-physician discordance and the following factors: The patients gender($p<0.6029$), the patients education($p<0.4841$) , duration of the disease($p<0.6128$), the use of analgesic($p<0.1519$), the use of DMARD($p<0.5163$), the extra-articular manifestations($p<0.077$), smoking($p<0.65$), passive smoking($p<0.8147$),alcohol intake ($p<0.34403$), deformities($p<0.2325$),tender Joint count($P<0.7820$),swollen joint count($p<0.3158$) , presence of features of depression($p<0.1092$) and serology status ($p<0.8604$)

The present study holds significant relevance, as it provides an overview of various factors affecting the Patients Global assessment score and various factors responsible for discordance in patient and physician global VAS, in an Indian setting. As per the literature evidence, this is the first study from India reporting the relationship between patient-physician discordance and the various associated factors, especially from a rural setting. Main limitations of the present study were not considering positive and negative discordance.

IMPLICATIONS OF THE STUDY:

In Indian settings, squatting is an important part of daily life, thus patients of RA with knee joint involvement give a higher global assessment score and also higher disability score.It is also one of the major factors causing a discordance in patient physician global VAS scoring. So it is important to treat it aggressively even if only a single joint is involved.

Similarly, psychological factors like anxiety and depression were found to significantly affect the patient global VAS score and also cause a discrepancy between patient and physician global assessment. Thus, these features should be identified at the earliest and referral to psychiatrist should be considered.

Pain and fibromyalgia were found to be major determinants of global VAS as well as Patient –physician discordance. Thus, aggressive pain control and educating patients about fibromyalgia should be a part of RA treatment in order to improve the quality of life of these patients

SUGGESTIONS FOR FURTHER RESEARCH:

Further studies evaluating the factors influencing patient global VAS apart from active disease such as depression, fibromyalgia, impaired patient mobility are highly warranted to improve the quality of life and customize the treatment plan in patients of Rheumatoid arthritis.

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ANNEXURE

PROFORMA

STUDY OF FACTORS AFFECTING THE PATIENT GLOBAL VISUAL ANALOUGE SCALE IN PATIENTS OF RHEUMATOID ARTHRITIS: A CROSS SECTIONAL STUDY

Date:

O.P. No: IP No:

Name: Age:

Sex: Occupation:

Address: Income:

Phone No: Education: none[0]

Primary[1]

Secondary[2]

Preuniversity[

Degree[4]

CLINICAL PROFILE:

Chief Complaint:

<u>Disease duration:</u> < 1yr :[1] **2 to 10 yrs :[3]**

1 to 2 yrs: [2] **>10 yrs : [4]**

Use of DMARDS + / - [1]/[0]

Use of analgesics +/- [1]/[0]

Sleep disturbance +/- [1]/[0]

Extra articular manifestation +/- [1]/[0]

Personal History: smoking +/- [1/0]

Alcoholism +/- [1/0]

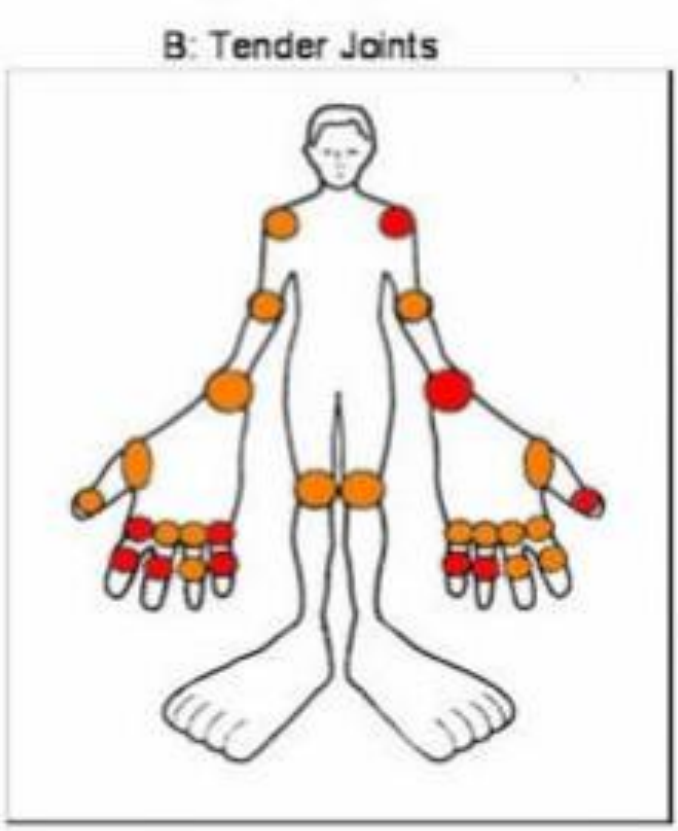
Passive smoking/ exposure to smoke +/- [1/0]

Family History: of arthritis +/- [1/0]

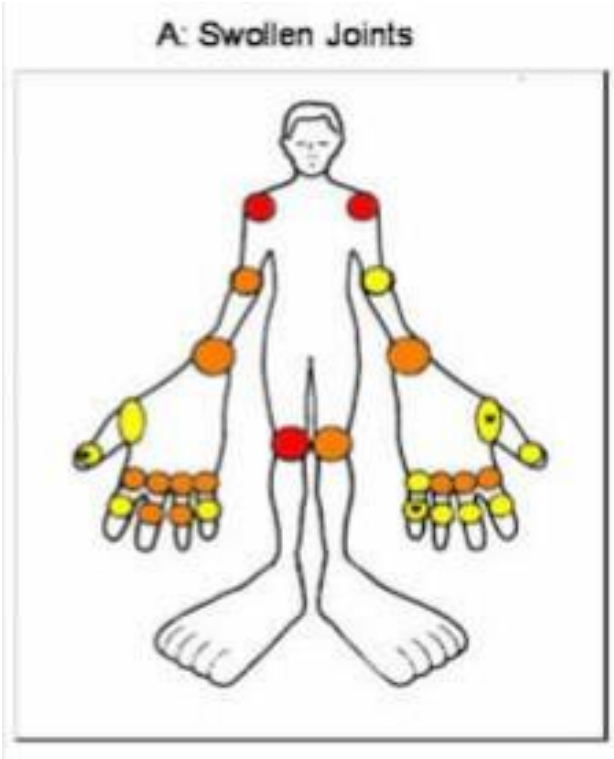
Physical Examination:

EXAMINATION OF JOINTS:

Tender joint count



Swollen joint count



PATIENT GLOBAL ASSESSMENT

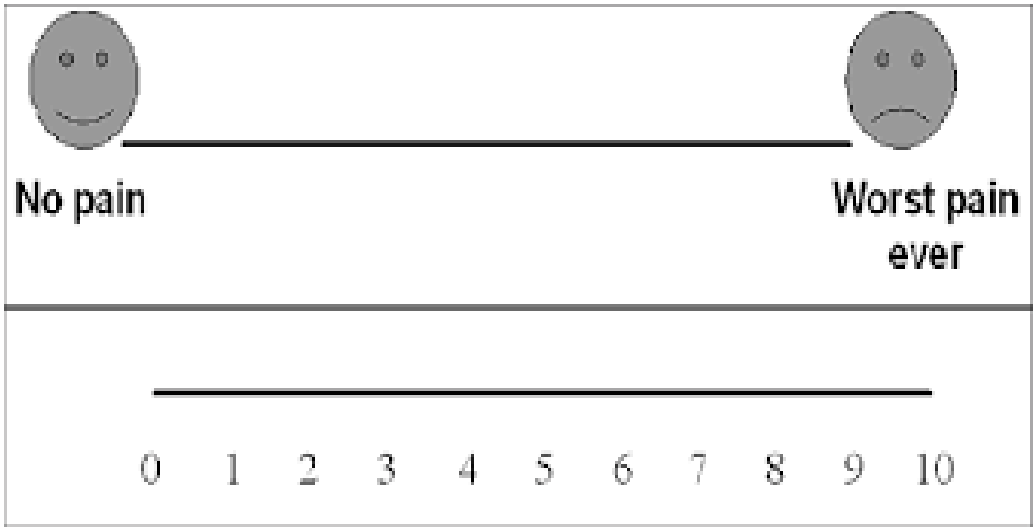
" *COSIDERING ALL OF THE WAYS YOUR DISEASE AFFECTS YOU , HOW WELL ARE YOU DOING IN THE LAST WEEK?"*

Note how severe you feel your disease state is with a mark (\) on the line below.

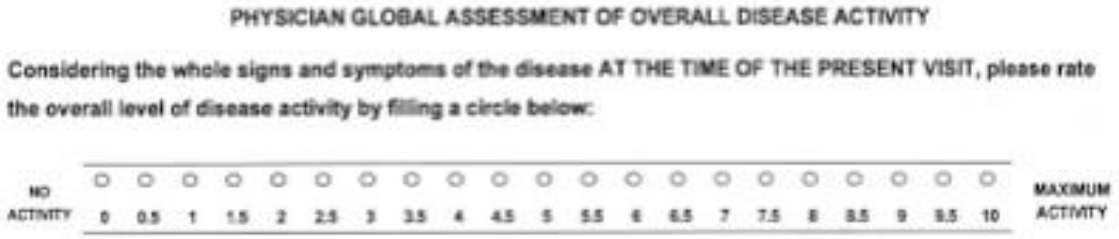
0 (mm) — 100 (mm)

Not At All Severe — Extremely Severe

PATIENT PAIN VAS :



PHYSCISIAN GLOBAL ASSESSMENT



Name:

DOB:

MRN:

Date Completed (dd/mm/yy) ☐☐ / ☐☐ / ☐☐

Modified Health Assessment Questionnaire (MHAQ)

Dear Patient, please read the questions below and put a cross (X) in the box that best describes your usual abilities OVER THE COURSE OF THE LAST WEEK.

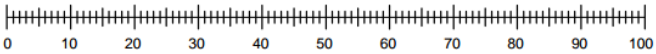
	Without **ANY** difficulty	With **SOME** difficulty	With **MUCH** difficulty	**UNABLE** to do
1. Dress yourself,including tying shoelaces and doing buttons ?	☐ 0	☐ 1	☐ 2	☐ 3
2. Get in and out of bed ?	☐ 0	☐ 1	☐ 2	☐ 3
3. Lift a full cup or glass to your mouth?	☐ 0	☐ 1	☐ 2	☐ 3
4. Walk outdoors on flat ground?	☐ 0	☐ 1	☐ 2	☐ 3
5. Wash and dry your entire body?	☐ 0	☐ 1	☐ 2	☐ 3
6. Bend down to pick up clothing from the floor?	☐ 0	☐ 1	☐ 2	☐ 3
7. Turn taps on and off?	☐ 0	☐ 1	☐ 2	☐ 3
8. Get in and out of a bus, car, train, or airplane?	☐ 0	☐ 1	☐ 2	☐ 3

For Rheumatologists use only

Add the totals for each of the four columns and use this value to look up and circle the MHAQ score in the grid below.

0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
0.000	0.125	0.250	0.375	0.500	0.625	0.750	0.875	1.000	1.125	1.250	1.375	1.500	1.625	1.750	1.875	2.000	2.125	2.250	2.375	2.500	2.625	2.750	2.875	3.000

Dear Patient, please draw a vertical line on the scale below that best represents **how active your arthritis has been in the last week.**

Not active at all  **Very active**

For Rheumatologists use only **Score** ☐

HAMILTON DEPRESSION RATING SCALE (HAM-D)

(To be administered by a health care professional)

Patient Name _____ **Today's Date** _____

The HAM-D is designed to rate the severity of depression in patients. Although it contains 21 areas, calculate the patient's score on the first 17 answers.

☐ **1. DEPRESSED MOOD**
(Gloomy attitude, pessimism about the future, feeling of sadness, tendency to weep)
0 = Absent
1 = Sadness, etc.
2 = Occasional weeping
3 = Frequent weeping
4 = Extreme symptoms

☐ **2. FEELINGS OF GUILT**
0 = Absent
1 = Self-reproach, feels he/she has let people down
2 = Ideas of guilt
3 = Present illness is a punishment; delusions of guilt
4 = Hallucinations of guilt

☐ **3. SUICIDE**
0 = Absent
1 = Feels life is not worth living
2 = Wishes he/she were dead
3 = Suicidal ideas or gestures
4 = Attempts at suicide

☐ **4. INSOMNIA - Initial**
(Difficulty in falling asleep)
0 = Absent
1 = Occasional
2 = Frequent

☐ **5. INSOMNIA - Middle**
(Complains of being restless and disturbed during the night. Waking during the night.)
0 = Absent
1 = Occasional
2 = Frequent

☐ **6. INSOMNIA - Delayed**
(Waking in early hours of the morning and unable to fall asleep again)
0 = Absent
1 = Occasional
2 = Frequent

☐ **7. WORK AND INTERESTS**
0 = No difficulty
1 = Feelings of incapacity, listlessness, indecision and vacillation
2 = Loss of interest in hobbies, decreased social activities
3 = Productivity decreased
4 = Unable to work. Stopped working because of present illness only. (Absence from work after treatment or recovery may rate a lower score).

☐ **8. RETARDATION**
(Slowness of thought, speech, and activity; apathy; stupor.)
0 = Absent
1 = Slight retardation at interview
2 = Obvious retardation at interview
3 = Interview difficult
4 = Complete stupor

☐ **9. AGITATION**
(Restlessness associated with anxiety.)
0 = Absent
1 = Occasional
2 = Frequent

☐ **10. ANXIETY - PSYCHIC**
0 = No difficulty
1 = Tension and irritability
2 = Worrying about minor matters
3 = Apprehensive attitude
4 = Fears

HAMILTON DEPRESSION RATING SCALE (HAM-D)

(To be administered by a health care professional)

☐ **11. ANXIETY - SOMATIC**
Gastrointestinal, indigestion
Cardiovascular, palpitation, Headaches
Respiratory, Genito-urinary, etc.
0 = Absent
1 = Mild
2 = Moderate
3 = Severe
4 = Incapacitating

☐ **12. SOMATIC SYMPTOMS - GASTROINTESTINAL**
(Loss of appetite , heavy feeling in abdomen; constipation)
0 = Absent
1 = Mild
2 = Severe

☐ **13. SOMATIC SYMPTOMS - GENERAL**
(Heaviness in limbs, back or head; diffuse backache; loss of energy and fatiguability)
0 = Absent
1 = Mild
2 = Severe

☐ **14. GENITAL SYMPTOMS**
(Loss of libido, menstrual disturbances)
0 = Absent
1 = Mild
2 = Severe

☐ **15. HYPOCHONDRIASIS**
0 = Not present
1 = Self-absorption (bodily)
2 = Preoccupation with health
3 = Querulous attitude
4 = Hypochondriacal delusions

☐ **16. WEIGHT LOSS**
0 = No weight loss
1 = Slight
2 = Obvious or severe

☐ **17. INSIGHT**
(Insight must be interpreted in terms of patient's understanding and background.)
0 = No loss
1 = Partial or doubtfull loss
2 = Loss of insight

TOTAL ITEMS 1 TO 17: _____
0 - 7 = Normal
8 - 13 = Mild Depression
14-18 = Moderate Depression
19 - 22 = Severe Depression
≥ 23 = Very Severe Depression

☐ **18. DIURNAL VARIATION**
(Symptoms worse in morning or evening. Note which it is.)
0 = No variation
1 = Mild variation; AM ( ) PM ( )
2 = Severe variation; AM ( ) PM ( )

☐ **19. DEPERSONALIZATION AND DEREALIZATION**
(feelings of unreality, nihilistic ideas)
0 = Absent
1 = Mild
2 = Moderate
3 = Severe
4 = Incapacitating

☐ **20. PARANOID SYMPTOMS**
(Not with a depressive quality)
0 = None
1 = Suspicious
2 = Ideas of reference
3 = Delusions of reference and persecution
4 = Hallucinations, persecutory

☐ **21. OBSESSIONAL SYMPTOMS**
(Obsessive thoughts and compulsions against which the patient struggles)
0 = Absent
1 = Mild
2 = Severe

Hamilton Anxiety Rating Scale (HAM-A)

Below is a list of phrases that describe certain feeling that people have. Rate the patients by finding the answer which best describes the extent to which he/she has these conditions. Select one of the five responses for each of the fourteen questions.

0 = Not present, 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Very severe.

1 Anxious mood [0] [1] [2] [3] [4]

Worries, anticipation of the worst, fearful anticipation, irritability.

2 Tension [0] [1] [2] [3] [4]

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax.

3 Fears [0] [1] [2] [3] [4]

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds.

4 Insomnia [0] [1] [2] [3] [4]

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors.

5 Intellectual [0] [1] [2] [3] [4]

Difficulty in concentration, poor memory.

6 Depressed mood [0] [1] [2] [3] [4]

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing.

7 Somatic (muscular) [0] [1] [2] [3] [4]

Pains and aches, twitching, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone.

8 Somatic (sensory) [0] [1] [2] [3] [4]

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation.

9 Cardiovascular symptoms [0] [1] [2] [3] [4]

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat.

10 Respiratory symptoms [0] [1] [2] [3] [4]

Pressure or constriction in chest, choking feelings, sighing, dyspnea.

11 Gastrointestinal symptoms [0] [1] [2] [3] [4]

Difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation.

12 Genitourinary symptoms [0] [1] [2] [3] [4]

Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence.

13 Autonomic symptoms [0] [1] [2] [3] [4]

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair.

14 Behavior at interview [0] [1] [2] [3] [4]

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc.

<7 : No Anxiety

7 -17 : mild anxiety

18 to 24 :mild to moderate anxiety

25 to 30 : moderate to severe:

>30 : severe

INFORMED CONSENT

STUDY OF FACTORS AFFECTING THE PATIENT GLOBAL VISUAL ANALOUGE SCALE IN PATIENTS OF RHEUMATOID ARTHRITIS

INTRODUCTION AND PURPOSE:

The present study is conducted among patients with rheumatoid arthritis attending the out-patient department of Rheumatology and Medicine in KLE's Dr.Prabhakar Kore Charitable Hospital and Medical Research Centre, Belgaum and will be investigated for factors affecting the patients global visual analogue scale on an out patient basis. You are requested to participate in the study and your participation is completely voluntary.

PROCEDURE:

If you agree to participate in this study, the relevant data will be collected as per the proforma and the final diagnosis will be confirmed.

After getting included in the study, you will be evaluated for Rheumatoid arthritis, joint examination will be done , few questionnaires will be asked to evaluate how the disease has affected your daily life, few blood investigations like CBC,ESR, CRP, Rheumatoid factor, Anti CCP will be done.

The various factors that affect the global assessment will be studied

BENEFITS: Patient will not be eligible for any kind of monetary benefits or free services by virtue of your participation in the study.

RISKS: Methods applied to do the study are safe.

COST OF PARTICIPATION:

The cost of the Investigation will be borne by the Study Subject. The other indirect expenses will be borne by the Investigator.

PRIVACY AND CONFIDENTIALITY:

The results of the study may be published in journals for scientific purposes. However, your identity will not be revealed. All information collected will be coded so that no one other than the investigator will know your identity.

WITHDRAWAL FROM THE STUDY:

You can withdraw from the study at any time if you wish to do so.

AUTHORIZATION TO PUBLISH THE RESULTS:

The researcher may use the information gathered from this study for presentation in scientific meetings. However, your identity will not be revealed.

QUERIES AND CONTACT:

If you have any queries regarding the study . If you have any questions about rights as a research participant you can contact Dr Roopa M Bellad, Professor, department of Pediatrics and Chairman, Jawaharlal Nehru Medical College Institutional Ethics Committee on human subjects' research.

CONSENT FORM

I voluntarily agree to take part in this study by signing below. I may withdraw at any time. I am not giving up any of my legal rights by signing this form. My signature below indicates that I have read this consent form, or it has been read to me and has been explained to me in my vernacular language and all my questions have been answered. I will be given a copy of this consent form.

Signature / Left Thumb print of the Participant or legally authorized representative

Participant's name ……...

Signature / Left thumb impression: ……...

of the participant

Name of the legally authorized: ……...
representative / guardian

Signature / Left thumb impression: ……...

Witness' name: ……...

Signature / Left thumb impression: ……...

Investigator's name and signature: ……...

Date:

Place:

ETHICAL CLEARANCE

K.L.E.UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
(Accredited 'A' Grade by NAAC)

Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 38 **Date: 22/11/2017**

To,

PG student in Medicine,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"STUDY OF FACTORS AFFECTING THE PATIENT GLOBAL VISUAL ANALOGUE SCALE IN PATIENTS OF RHEUMATOID ARTHRITIS – A ONE YEAR HOSPITAL BASED CROSS SECTIONAL STUDY IN KLE'S DR. PRABHAKAR KORE HOSPITAL, BELAGAVI"**, is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

1

SNO	NAME	OP NO	AGE	SEX	EDUCATION	DURATION OF THE DISEASE	ANALGESIC USE	DMARDS USE	SLEEP DISTURBANCE	EAM	SMOKING	ALCOHOLISM	PASSIVE SMOKING	F/H/O ARTHRITIS	DEFORMITIES	KNEE INVOLVEMENT	TJC	SJC	Patient Pain VAS	patient global vas	PHYSCISIAN GLOBAL VAS	FiRST (FIBROMYALGIA)	MHAQ	HAM D	HAM A	GAINFUL EMPLOYEMENT	SEROLOGY
1	VAHIDA	5153487	36	F	primary	15 years	NO	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	0	0	10	0	10	NEGATIVE	1	3	2	YES	positive
2	BABU ULAVI	1128449	54	M	secondary	3 years	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	2	4	50	50	25	POSITIVE	3	6	3	YES	negative
3	GAYATRI	4609778	56	F	None	4 months	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	0	0	25	30	20	NEGATIVE	2	4	1	YES	positive
4	LAXMAN	4713263	56	m	secondary	12years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	1	0	25	10	10	NEGATIVE	2	1	0	YES	negative
5	SHIVALEELA	4500744	45	F	none	15 yr	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	5	0	25	25	0	NEGATIVE	3	4	1	YES	positive
6	JAYASHREE	4462107	53	F	secondary	3 yr	YES	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	4	0	10	10	10	NEGATIVE	1	0	0	YES	positive
7	SHANTA	5075564	68	F	none	9yr	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	4	0	30	50	25	NEGATIVE	3	3	2	YES	positive
8	CHANDUBAI	4328646	78	F	none	15YR	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	PRESENT	5	3	50	60	30	NEGATIVE	6	8	3	NO	negative
9	SARASWATHI	4681224	26	F	primary	3yr	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	ABSENT	0	0	30	25	20	NEGATIVE	0	2	1	YES	negative
10	ANASUYA	4721418	30	F	primary	12yr	YES	YES	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	PRESENT	PRESENT	2	2	60	75	30	POSITIVE	5	9	4	YES	positive
11	NEELAMMA	4678263	65	F	none	2yr	YES	YES	PRESENT	PRESENT	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	PRESENT	3	1	50	50	30	NEGATIVE	11	20	7	NO	positive
12	VAISHALIU	4780171	36	F	secondary	11yr	YES	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	0	0	25	20	5	NEGATIVE	3	0	0	YES	positive
13	NIRMALA	5210706	38	F	degree	1.5 yr	YES	NO	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	13	5	70	75	50	POSITIVE	16	7	11	NO	negative
14	MAHADEVI	5209481	56	F	none	15 yr	YES	NO	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	5	2	30	70	40	NEGATIVE	13	8	9	NO	positive
15	LAXMI	5207825	40	F	primary	5 months	YES	NO	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	PRESENT	3	1	50	75	30	POSITIVE	8	8	7	NO	positive
16	JAYASHRI	1144747	42	F	preuniversity	1 yr	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	7	5	60	80	60	NEGATIVE	10	5	5	NO	positive
17	LEELA CHOUGALE	5243401	60	F	primary	10 yr	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	PRESENT	3	2	60	80	40	POSITIVE	12	11	9	NO	positive
18	LATA KURANE	5185143	56	F	preuniversity	1 yr	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	7	2	30	50	25	NEGATIVE	2	2	2	YES	positive
19	RAVJI CHOPDEKAR	4740939	67	M	primary	8 months	YES	NO	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	8	4	100	100	60	POSITIVE	15	8	5	NO	negative
20	BASAVARAJ ULLEGADDI	4727577	36	M	secondary	1 year	YES	YES	ABSENT	ABSENT	PRESENT	ABSENT	PRESENT	ABSENT	ABSENT	PRESENT	12	5	30	30	40	NEGATIVE	8	3	4	NO	positive
21	MEHBOOB INAMDAR	5013823	42	M	secondary	6 months	NO	NO	PRESENT	ABSENT	PRESENT	ABSENT	PRESENT	ABSENT	ABSENT	PRESENT	24	1	80	100	50	POSITIVE	16	12	6	NO	positive
22	JUBEDA PEUDARI	3893808	40	F	none	4 yr	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	18	6	100	95	70	POSITIVE	12	13	8	NO	negative
23	SUMANGALA RANGOLI	5163090	62	F	primary	8 yr	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	27	18	75	90	80	POSITIVE	20	19	19	NO	negative
24	VIMAL MANGULE	4946172	53	F	primary	2yr	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	11	6	80	90	60	POSITIVE	16	10	15	YES	positive
25	DEEPA WALVEKAR	3880619	22	F	degree	3yr	YES	NO	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	12	6	50	75	60	NEGATIVE	10	17	15	NO	positive
26	RAJESHWARI MULIMANI	4790587	29	F	preuniversity	7yr	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	16	10	75	80	60	POSITIVE	17	25	15	NO	negative
27	KAPIL MADHALE	4899051	26	M	degree	6yr	NO	YES	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	ABSENT	PRESENT	15	3	30	30	30	NEGATIVE	9	4	3	YES	positive
28	BAYABAI HATKAR	4984503	45	F	primary	4yr	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	7	2	30	50	25	NEGATIVE	7	14	10	YES	positive
29	JAYASHRI NARVEKAR	4753214	47	F	secondary	8yr	YES	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	3	0	30	30	15	NEGATIVE	2	6	6	YES	positive
30	RATNA ATADMANI	4815721	39	F	degree	6 months	YES	NO	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	8	12	45	60	70	NEGATIVE	10	4	7	NO	positive
31	SUNANDA KARENNAVAR	1863910	45	F	secondary	7 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	0	0	50	50	10	NEGATIVE	2	2	1	YES	positive
32	MAHADEVI KAJAGAR	3959824	49	F	none	20 years	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	PRESENT	PRESENT	4	3	90	100	30	POSITIVE	17	21	16	NO	positive
33	LALITA HOSKOTI	4737493	47	F	secondary	1yr	YES	NO	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	9	2	90	100	40	POSITIVE	14	13	10	NO	positive
34	MANASA KULKARNI	4678289	19	F	preuniversity	2	YES	YES	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	11	8	60	75	50	NEGATIVE	13	13	9	YES	positive
35	SUMITRA UJJINKOPPA	1128449	54	M	primary	8 year	NO	YES	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	2	1	10	20	10	NEGATIVE	2	0	0	YES	negative
36	YALLUKKA GOUNDADKAR	5099973	56	F	primary	1.5 year	YES	YES	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	4	0	40	75	50	POSITIVE	5	10	6	NO	positive
37	SHOBHA ARJUN	4642819	37	F	primary	1 year	YES	NO	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	11	20	50	75	80	NEGATIVE	7	8	6	NO	negative
38	SUSHILA TIGADI	4306591	55	F	secondary	1 year	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	PRESENT	24	24	60	75	75	NEGATIVE	13	21	18	NO	negative
39	AYUBKHAN PATHAN	3943109	52	M	secondary	8 year	NO	YES	PRESENT	ABSENT	PRESENT	ABSENT	PRESENT	PRESENT	ABSENT	ABSENT	10	7	50	50	50	NEGATIVE	11	13	7	NO	positive
40	KALLAPPA DHAWALE	3667521	48	M	primary	4 year	YES	YES	PRESENT	ABSENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	5	1	25	20	50	NEGATIVE	6	4	2	YES	negative
41	HUSENBI MAKANDAR	4867484	50	F	none	8 year	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	7	3	50	50	30	NEGATIVE	5	5	5	YES	positive
42	SUDHA PATIL	5237537	40	F	secondary	10 months	NO	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	28	28	80	90	90	NEGATIVE	13	14	9	NO	positive
43	GANAGAVVA YADAL	5070916	45	F	none	2 year	YES	NO	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	28	4	75	75	60	POSITIVE	13	10	5	NO	positive
44	SHANTABAI PATIL	4543776	52	F	primary	6 year	YES	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	2	2	25	25	25	NEGATIVE	2	4	3	YES	negative
45	SATTEWWA PATIL	4058383	60	F	secondary	14 year	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	PRESENT	1	1	75	75	45	POSITIVE	5	5	9	NO	positive
46	BALAVVA	4688781	60	F	none	2 years	YES	YES	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	27	22	50	75	75	NEGATIVE	15	13	9	NO	positive
47	SHARAVVA MADAR	3826249	40	F	none	3 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	PRESENT	ABSENT	6	2	50	50	30	NEGATIVE	1	9	4	YES	positive
48	PARVATI KALBURGI	4694336	56	F	preuniversity	1.5 years	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	22	10	70	80	70	NEGATIVE	10	10	7	NO	positive
49	MADHURI	5042806	39	F	degree	10 years	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	16	11	25	25	40	NEGATIVE	6	8	4	YES	positive
50	SHOBHA SANGANVAKAR	4294714	30	F	primary	3 years	YES	YES	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	6	0	10	25	20	NEGATIVE	4	7	4	NO	negative

51	MAHADEV	4792358	62	M	secondary	14 years	YES	YES	PRESENT	ABSENT	PRESENT	PRESENT	ABSENT	ABSENT	PRESENT	PRESENT	3	0	10	25	10	NEGATIVE	13	5	2	NO	negative
52	UJWALA PATIL	4048327	51	F	preuniversity	10 years	YES	YES	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	3	0	10	10	10	NEGATIVE	1	6	1	YES	positive
53	SAMEER BHUKEBHAG	4686370	23	M	postgraduate	6 months	YES	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	19	17	25	30	70	NEGATIVE	5	5	1	NO	positive
54	MADEVI JAGADAL	4685616	45	F	none	3 years	YES	YES	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	21	8	90	100	50	POSITIVE	11	23	15	NO	positive
55	VAISHALI NAVAGEKAR	5051430	31	F	degree	2 years	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	6	0	50	25	20	NEGATIVE	2	3	2	YES	positive
56	VIJAYASHREE PATIL	4605287	52	F	degree	8 years	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	25	3	40	50	40	NEGATIVE	11	11	6	NO	positive
57	YUSUF KHADARKHAN PAT	3138620	55	M	primary	15 years	YES	YES	ABSENT	ABSENT	PRESENT	ABSENT	PRESENT	PRESENT	PRESENT	ABSENT	1	1	10	5	10	NEGATIVE	1	3	2	YES	positive
58	MALLAPPA KHANAGOUDA	3826847	32	M	none	8 years	YES	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	1	1	10	10	10	NEGATIVE	5	3	2	YES	positive
59	RENUKA	4212348	32	F	secondary	15 years	YES	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	PRESENT	ABSENT	0	2	25	25	20	NEGATIVE	0	3	0	YES	positive
60	VANDANA	4750511	62	F	primary	20 years	YES	YES	ABSENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	PRESENT	18	9	50	75	60	NEGATIVE	10	6	4	NO	negative
61	ANASUYA	4744766	60	F	none	30 years	NO	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	1	2	50	20	20	NEGATIVE	9	7	2	YES	positive
62	MALLAPPA KHANAGOUDA	4658078	74	M	none	2 year	YES	NO	PRESENT	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	ABSENT	PRESENT	25	11	100	90	80	NEGATIVE	19	12	5	NO	negative
63	NAGARATHNA	5250012	28	F	secondary	2 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	2	0	60	25	10	POSITIVE	1	2	1	YES	positive
64	CHAMPAKKA	4825769	50	F	secondary	8 years	YES	NO	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	PRESENT	16	12	50	50	60	NEGATIVE	7	8	4	NO	positive
65	NUTHAN	4773686	25	F	degree	1.5 year	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	ABSENT	0	0	10	0	0	NEGATIVE	0	14	11	YES	positive
66	PRATIBHA	4828512	18	F	secondary	4 years	YES	YES	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	PRESENT	PRESENT	PRESENT	20	7	50	75	50	NEGATIVE	18	21	8	NO	positive
67	SUREKHA	4828528	37	F	secondary	4 year	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	5	4	25	10	25	NEGATIVE	2	6	5	NO	positive
68	CHANNAMALLAPPA	4654725	40	M	degree	10 years	YES	NO	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	ABSENT	PRESENT	PRESENT	12	5	75	100	50	POSITIVE	5	5	2	NO	positive
69	KAMALAVVA	4713753	50	F	none	1 year	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	2	0	50	75	10	POSITIVE	12	16	7	NO	negative
70	MALLAVVA	5073941	50	F	none	1 year	YES	NO	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	PRESENT	PRESENT	28	24	50	75	85	NEGATIVE	16	13	6	NO	negative
71	NEELAVVA	3424008	55	F	none	5 year	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	PRESENT	18	1	75	100	80	NEGATIVE	11	20	14	NO	positive
72	SHOBHA	4599893	50	F	secondary	1 year	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	PRESENT	PRESENT	ABSENT	PRESENT	5	0	50	25	40	POSITIVE	3	5	4	YES	negative
73	SANGAMESH	4397935	36	M	degree	1 year	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	PRESENT	PRESENT	ABSENT	PRESENT	8	0	50	25	30	NEGATIVE	4	2	4	YES	positive
74	ARUN KELVEKAR	4967529	68	M	degree	5 year	NO	YES	PRESENT	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	8	1	90	100	25	POSITIVE	20	12	13	NO	negative
75	SHANKAR	2182372	61	M	degree	1 year	YES	NO	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	11	0	60	50	15	NEGATIVE	2	4	7	YES	positive
76	PREMA	4583373	30	F	primary	8 months	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	16	0	50	50	30	NEGATIVE	8	17	8	NO	positive
77	SANGAVVA	4031182	36	F	primary	4 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	0	0	50	25	10	NEGATIVE	1	0	0	YES	negative
78	SIDDARAY	4762597	42	M	preuniversity	1 year	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	7	2	25	40	30	POSITIVE	2	2	2	YES	positive
79	ARPITA	4294714	30	F	degree	6 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	3	0	50	10	10	NEGATIVE	1	1	2	YES	positive
80	VEDA SAUNSHI	2691376	48	F	preuniversity	2 years	YES	NO	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	27	20	60	100	75	POSITIVE	16	11	8	NO	positive
81	RESHMA BIDKAR	5113394	48	F	degree	8 months	YES	NO	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	16	12	75	90	80	NEGATIVE	12	10	9	NO	negative
82	TANGEVVA ANGADI	3193016	44	F	secondary	10 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	3	0	60	10	10	NEGATIVE	1	2	2	YES	positive
83	BASAVARAJ PATIL	4513393	18	M	preuniversity	8 months	YES	NO	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	19	17	50	75	70	NEGATIVE	6	5	3	NO	positive
84	ANITA JADHAV	2726215	45	F	none	3 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	6	2	40	40	30	POSITIVE	1	9	4	YES	positive
85	ANDAVVA TEGGI	3207805	42	F	none	1 year	YES	NO	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	2	0	50	75	10	POSITIVE	12	16	6	NO	negative
86	SHWETA BUDRUK	4331434	23	F	degree	3 years	YES	NO	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	10	6	60	80	65	NEGATIVE	6	4	4	YES	negative
87	MAHADEVI	4384503	45	F	primary	3 years	NO	YES	ABSENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	6	0	25	25	20	NEGATIVE	2	3	3	YES	positive
88	KASHAWWA	2558428	38	F	primary	4 years	YES	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	5	4	10	10	25	NEGATIVE	2	4	5	YES	positive
89	BHARATHI	4931149	49	F	secondary	11 years	NO	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	5	0	10	10	10	NEGATIVE	1	10	3	YES	negative
90	GEETA KALAL	5048650	36	F	degree	15 years	NO	`YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	6	0	40	40	20	NEGATIVE	2	2	1	YES	negative
91	MAHALEKHA	5075262	48	F	primary	8 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	PRESENT	ABSENT	2	0	40	25	10	POSITIVE	1	3	3	NO	negative
92	ANJUM AHMED	3583243	48	F	secondary	2 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	2	0	25	25	10	NEGATIVE	1	3	1	YES	positive
93	JKHAJABI MANTUR	4854056	52	F	none	11 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	0	0	25	25	10	POSITIVE	1	0	0	YES	positive
94	VANDANA TARKAR	5049547	35	F	preuniversity	5 years	YES	YES	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	12	1	50	75	25	POSITIVE	12	6	5	YES	negative
95	DEEPA PAWAR	5108112	27	F	preuniversity	5 years	NO	YES	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	8	1	75	100	25	POSITIVE	20	13	4	YES	positive
96	IRAPPA MALLED	5026139	32	M	preuniversity	10 years	NO	YES	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	5	0	30	30	15	NEGATIVE	1	4	0	NO	negative
97	NARAYAN PENDUM	5032118	34	m	degree	8 months	YES	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	13	6	40	50	40	NEGATIVE	8	5	3	YES	negative
98	SURESH MADALAGI	1198372	73	M	degree	2 years	NO	YES	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	3	1	40	25	10	NEGATIVE	2	2	3	YES	negative
99	SHANTAVVA DUMANNAV	4276331	60	F	primary	14 years	YES	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	PRESENT	11	11	25	25	50	NEGATIVE	8	3	2	YES	negative
100	SHIVANAND	2214661	34	M	secondary	9 years	NO	YES	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	1	1	25	25	10	NEGATIVE	0	1	1	YES	negative
101	ANADA	4991645	60	F	secondary	4 years	YES	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	8	2	25	35	30	NEGATIVE	6	3	4	YES	negative
102	SUVARNA	5049692	58	F	primary	4 YEARS	NO	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	6	2	25	40	25	NEGATIVE	3	5	5	YES	negative
103	SAROJA PATIL	4524170	65	F	secondary	4 years	YES	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	ABSENT	8	2	25	35	30	NEGATIVE	6	3	4	YES	positive
104	RATNA BETASUR	5007398	38	F	preuniversity	2 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	2	0	10	25	10	NEGATIVE	2	3	2	YES	positive
105	SURESH BHADRANNAVAR	2146675	28	M	preuniversity	2 years	NO	YES	ABSENT	ABSENT	PRESENT	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	2	0	25	25	10	NEGATIVE	2	3	2	YES	negative
106	NAGAVVA NARGUND	3852328	35	F	secondary	8 years	YES	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	5	1	60	50	25	POSITIVE	3	6	4	YES	negative
107	VALUTAI GIJAVANE	5302778	43	F	secondary	20 years	NO	YES	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	10	3	75	90	30	POSITIVE	15	16	10	NO	positive
108	MEENAKSHI KARALINGAN	5295333	55	F	primary	2 years	YES	NO	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	16	6	75	100	75	POSITIVE	15	14	7	NO	positive
109	SUNANDA MADAPUR	5287927	56	F	secondary	1 year	YES	NO	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	PRESENT	20	18	30	75	75	NEGATIVE	16	16	10	NO	positive
110	VIJAYALAXMI HEGGANNA	5297986	41	F	secondary	12 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	4	2	50	30	20	NEGATIVE	4	5	5	YES	positive

111	SHOBHA KONO	4928654	44	F	preuniversity	14 years	YES	YES	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	PRESENT	18	10	50	75	75	NEGATIVE	13	15	9	NO	negative
112	SUPRIYA KUMBAR	5196560	30	F	degree	4 years	NO	YES	ABSENT	PRESENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	PRESENT	1	1	50	10	10	NEGATIVE	0	1	1	YES	positive
113	VIJAYALAXMI NAIK	4726842	50	F	postgraduate	1 year	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	0	0	10	5	5	NEGATIVE	0	0	0	YES	positive
114	TEJASHWINI HURALI	5152626	27	F	secondary	2 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	2	2	25	25	25	NEGATIVE	0	0	0	YES	positive
115	SHARADA KADALLI	2972650	76	F	secondary	25 years	NO	YES	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	10	3	75	90	30	POSITIVE	15	16	10	NO	positive
116	MEENAKSHI YALLI	3787160	31	F	primary	4 years	NO	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	6	2	50	40	25	NEGATIVE	3	5	5	YES	positive
117	SAVITRI RAMACHANDRA	5403356	55	F	primary	2 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	2	0	25	25	10	NEGATIVE	2	3	2	YES	positive
118	RANJANA PATIL	4077376	55	F	primary	10 years	YES	YES	ABSENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	14	10	50	70	65	NEGATIVE	8	10	5	NO	positive
119	LALITA SOLKAN PATIL	3919057	70	F	secondary	5 years	NO	YES	ABSENT	PRESENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	PRESENT	1	1	25	10	10	NEGATIVE	3	1	1	YES	positive
120	CHANGUNA	5190593	42	F	secondary	6 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	2	1	25	20	20	NEGATIVE	0	0	0	YES	positive
121	CHAMBAVVA CHIKERI	5317429	54	F	primary	6 months	YES	NO	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	16	6	50	100	75	NEGATIVE	15	14	7	NO	positive
122	VAISHNAVI BHOKADE	5285938	44	F	preuniversity	10 years	YES	YES	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	PRESENT	ABSENT	PRESENT	18	10	75	75	75	POSITIVE	13	15	9	NO	positive
123	RAJASHREE SHIRAGANVI	5185840	35	F	secondary	6 years	YES	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	5	1	25	50	25	NEGATIVE	3	6	4	YES	negative
124	YALLAWWA MELMATHI	5267777	55	F	primary	3 years	NO	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	0	0	25	25	10	NEGATIVE	1	3	2	YES	positive
125	JAYASHREE MOHAREER	2389891	47	F	secondary	10 years	NO	YES	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	PRESENT	PRESENT	5	3	50	60	30	POSITIVE	6	8	3	YES	negative
126	BHIMAPPA LANGOTI	5199489	34	M	preuniversity	1 year	YES	NO	PRESENT	ABSENT	PRESENT	PRESENT	ABSENT	PRESENT	ABSENT	ABSENT	20	18	75	80	75	NEGATIVE	16	16	10	NO	positive
127	CHANDRASHEKHAR HOSA	5287448	56	M	secondary	5years	NO	YES	ABSENT	ABSENT	PRESENT	PRESENT	ABSENT	ABSENT	PRESENT	ABSENT	6	4	25	40	25	POSITIVE	3	3	3	YES	positive
128	RESHMA HATTIWALE	3587339	29	F	preuniversity	8 months	YES	NO	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	18	12	50	90	60	NEGATIVE	13	16	10	YES	positive
129	NILUFER NAWAB	5407647	43	F	secondary	10 years	NO	YES	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	18	14	25	80	70	NEGATIVE	14	16	10	NO	positive
130	AKKAMAHADEVI SAVADI	3786890	70	F	primary	16 years	YES	YES	PRESENT	PRESENT	ABSENT	ABSENT	ABSENT	ABSENT	PRESENT	PRESENT	13	6	75	80	50	NEGATIVE	14	18	6	NO	negative