“A HOSPITAL-BASED VALIDATION OF VITILIGO IMPACT SCALE-22 IN A TERTIARY CARE HOSPITAL IN NORTH KARNATAKA”

Submitted by

Dr. ANUSHA. S.

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Under the guidance of

DR. APARNA PALIT M.D.

PROFESSOR

DEPARTMENT OF DERMATOLOGY, VENEREOLOGY AND LEPROSY

B. L. D. E. UNIVERSITY’s

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RESEARCH CENTRE, VIJAYAPUR.

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Date: **Dr. ANUSHA. S.**

Place: Vijayapur

B. L. D. E. UNIVERSITY's

SHRI B. M. PATIL MEDICAL COLLEGE HOSPITAL &

RESEARCH CENTRE, VIJAYAPUR.

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Date:

Place: Vijayapur

DR. APARNA PALIT$_{\text{M.D.}}$
Professor,
Department of Dermatology,
Venereology and Leprosy
B. L. D. E. U's Shri. B. M. Patil
Medical College Hospital &
Research Centre, Vijayapur.

B. L. D. E. UNIVERSITY's

SHRI B. M. PATIL MEDICAL COLLEGE HOSPITAL &

RESEARCH CENTRE, VIJAYAPUR.

ENDORSEMENT BY THE HOD AND PRINCIPAL

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Dr. Arun. C. Inamadar M.D.,D.V.D.
Professor & Head
Department Of Dermatology,
Venereology & Leprosy
B. L. D. E. U's Shri. B. M. Patil
Medical College Hospital &
Research Centre, Vijayapur.

Date:
Place: Vijayapur

Dr. S. P. Guggarigoudar M.D.
Principal,
B. L. D. E. U's Shri. B. M. Patil
Medical College Hospital
& Research Centre,
Vijayapur.

Date:
Place: Vijayapur

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Date: **Dr. ANUSHA. S.**

Place: Vijayapur

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Date: **Dr. ANUSHA.S.**

Place: Vijayapur

LIST OF ABBREVIATIONS

QOL	-	Quality of life
VIS-22	-	Vitiligo impact scale – 22
WTP	-	Willingness to pay
WHO	-	World health organization
VAS	-	Visual analogue scale
GHQ-12	-	General health questionnaire – 12
SF-36	-	Short form – 36
DLQI	-	Dermatology life quality index
DQoLS	-	Dermatology quality of life scales
VLQI	-	Vitiligo life quality index
VIS	-	Vitiligo impact scale
S	-	Symptoms domain
E	-	Emotion domain
F	-	Social functioning domain
PCS	-	Physical component score
MCS	-	Mental component score

ABSTRACT

Background

Vitiligo is known to have a major psychosocial impact among the sufferers. The psychological impact does not correlate with the extent of the disease. There are various scales (general health indices, dermatology specific indices and vitiligo specific indices) to measure the QOL in patients with vitiligo. Vitiligo impact scale - 22 is a recently developed vitiligo specific scale validated among of a group of North Indian patients. Since the effect of vitiligo on QOL in patients may vary depending upon the region, locality, population, social status, level of education and existing beliefs and taboos, it is important to validate VIS-22 in various population.

Objective

To validate the vitiligo impact scale – 22 in South Indian patients

Method

It was a hospital based, longitudinal study. One hundred and fifty three patients suffering from vitiligo and 155 controls suffering from other short term skin diseases attending the dermatology out-patient department of a tertiary care hospital were included in this study. Detailed history with respect to the onset and duration of symptoms, any treatment received, recurrence, and pre-existing medical conditions were recorded. Clinical examination of the patient was done to note the type of vitiligo and subsequent repigmentation or worsening of condition over the 12 week study period. All patients were given visual analogue scale, dermatology life quality index, skindex-16 and vitiligo impact scale - 22 to respond at first visit, and subsequently at 2 and 12 weeks.

Results

A total of 153 vitiligo patients and 155 controls were enrolled in the study. Among the 153 vitiligo patients who were enrolled in the study, 124 completed the study at the end of 12 weeks.

The criterion validity showed strongest correlation with Skindex-16 (r=0.832). The convergent validity evidenced strongest correlation with bothDLQI (r=0.752) and Skindex-16 (r=0.832). Convergent validity showed a strong correlation with emotional and functioning domain of Skindex-16 at baseline (r=0.713 and 0.702 respectively) and at 12 weeks (r=0.770 and 0.789 respectively). An excellent reliability was seen between the scores between baseline and 2 weeks (r=0.954). The VIS-22 scores were found to be responsive at week 12 and a similar trend was noted in VAS, DLQI and Skindex-16.

Conclusion

VIS-22 is a valid, highly reliable and responsive scale to measure the impairment of QOL among vitiligo patients. The scale has better measurement properties compared to DLQI and Skindex-16 with questions which are specific to vitiligo patients.

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INTRODUCTION

Vitiligo is an acquired skin disorder characterized by sharply demarcated, depigmented macules and patches. It occurs due to progressive loss of melanocytes.[1] The disease affects nearly 1 – 4% of the population.[2] The incidence among Indian population is estimated to be 3 – 4%.[3]

Vitiligo is known to have a major psychosocial impact among some South East Asian cultures.[4] The patients experience psychological distress and social stigmatization.[5] It is particularly stigmatizing in Indian population due to their darker skin colour which gives a strong contrast.[6]

A marked reduction of quality of life (QOL) has been observed among patients suffering from vitiligo.[4] Patients with vitiligo suffer from major depression.[7] The general appearance of the skin in vitiligo can affect an individual's self image.[8] The psychological impact does not correlate with the extent of the disease. Rather, it is particularly distressing when the lesions are located on the exposed parts of the body, such as, face and extremities.[4,9,10] Many patients feel that they are victims of rude remarks, are being ridiculed and discriminated. These feelings are more among the young and active group of patients. Women probably have a greater impairment of QOL as compared to men.[7]

It is evident from various studies that vitiligo causes emotional, social and occupational impact upon affected patients.[2] Peer pressure among children and adolescents has been observed.[6] Difficulties in getting married, marital disharmony even ending up in divorce are the particularly unwanted situations the affected young adults have to cope up with.[2,8]

Many studies have been conducted to estimate the quality of life in vitiligo patients. The results showed that psychologic upsets are frequent among these patients. These include

anxiety, depression, suppressed interpersonal and social behaviour, poor body image, embarrassment, sleep disturbances, and suicidal tendencies.[7]

These observations indicate that the psychological impact of vitiligo need to be evaluated to help the patients have a better quality of life.

Measurement of QOL helps a clinician to assess the effect of a disease upon various aspects of a patient's life; such as social, psychological, physical and occupational, in a standardized and quantitative way. Moreover it helps in recognition of psychological and functional limitations in a given patient; decision of treatment and hence, improving the physician patient relationship.[2]

There are various scales to measure the QOL in patients with vitiligo, such as, general health measures and skin disease specific questionnaires.[9] Some vitiligo specific scales are also available for this purpose. These scales have an added advantage of having disease-relevant questions and thus having a higher acceptability among patients and dermatologists. These allow to detect the varying degree of distress among patients.[4]

Vitiligo impact scale-22 (VIS-22) is a recently developed vitiligo specific scale by Gupta *et al*.[4] It has been found to be effective to assess the QOL in patients with vitiligo and was validated among a group of North Indian patients .[4]

Since the effect of vitiligo on QOL in patients may vary depending upon the region, locality, population, social status, level of education and existing beliefs and taboos, it is important to validate VIS-22 in various population.

The present study was conducted to validate VIS-22 among South Indian population suffering from vitiligo attending a tertiary health care centre in North Karnataka.

OBJECTIVE OF THE STUDY

1. To validate the vitiligo impact scale – 22 in South Indian patients

REVIEW OF LITERATURE

Vitiligo is an acquired skin disorder characterized by sharply demarcated, depigmented macules and patches that result from progressive loss of melanocytes.[1] Histopathologically, it is characterized by degeneration and disappearance of melanocytes in the involved skin.[3]

The term vitiligo has originated from the Latin word “vitium” meaning blemish. The term was first coined by Roman physician Celsus, in the second century AD. Vitiligo was referred to as “Sweta Kustha” meaning “white leprosy” in the ancient Indian epic, “Atharvaveda”.[3]

EPIDEMIOLOGY

The world-wide prevalence of vitiligo is about 1-4%.[2] In India, about 3-4% population are estimated to suffer from vitiligo. Incidence of up to 8% has been reported in studies from India.[3] Although vitiligo affects all races, a higher incidence has been noted among people with Fitzpatrick skin types III and IV.[3]

Most cases have an onset around second to third decade of life, whereas segmental vitiligo begins usually before ten years of age.[1,3] The incidence is equal among both the genders. A higher female preponderance has been reported due to their cosmetic concerns.[11]

ETIOPATHOGENESIS

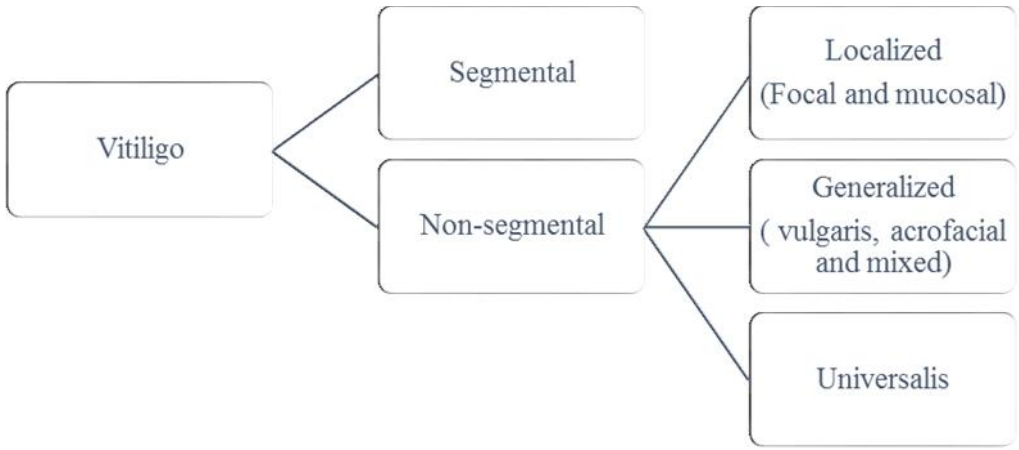
The inheritance of vitiligo is polygenic. Various mechanisms of action prevail, which work together to cause progressive loss of melanocytes in vitiligo (‘convergence’ or ‘integrated’ theory). The various mechanism/hypotheses that prevail regarding etiopathogenesis of vitiligo have been listed below.[1]

1. The autoimmune/autoinflammatory theory
2. Self-destruction theory of Lerner
3. Neurogenic theory
4. Defective keratinocyte metabolism with low catalase level in the epidermis.
5. Defective tetrahydrobiopterin and catecholamine biosynthesis.
6. Loss of melanocytes through inhibition of their adhesion to fibronectin by extracellular matrix molecules.

CLASSIFICATION

Vitiligo can be broadly classified based upon the extent of depigmentation as segmental and non-segmental forms.[1,11] The various clinical types and subtypes of vitiligo have been presented in figure 1.

Figure 1: Classification of vitiligo[1,3,11]



1. **Segmental vitiligo**: characterized by depigmented macules and patches in unilateral dermatomal distribution. The lesions do not cross the mid line.
2. **Focal vitiligo**: characterized by one or few depigmented macules in one anatomical area, but not distributed in a segmental pattern.
3. **Mucosal vitiligo**: characterized by appearance of lesions in the mucous membrane alone.
4. **Vitiligo vulgaris**: characterized by multiple scattered macules and patches in more or less symmetrical pattern. It is the most common presentation of vitiligo.
5. **Acrofacial vitiligo**: the lesions are present over distal fingers and toes, and facial orifices in a circumferential pattern.
6. **Mixed vitiligo**: the lesions are a combination of acrofacial and vitiligo vulgaris, or segmental and acrofacial vitiligo.
7. **Vitiligo universalis**: characterized by complete or near complete depigmentation of the whole body. It is the most severe form of vitiligo.

The various special clinical phenotypes of vitiligo are as follows:[11]

- Trichrome, quadrichrome and pentachrome vitiligo
- Confetti vitiligo or vitiligo ponctué

CLINICAL FEATURES

The characteristic lesion of vitiligo is a well-defined, depigmented macule or patch with/without associated depigmentation of hair (leukotrichia/poliosis) over the lesions.[3] The lesions vary in number and enlarge progressively with a convex outline at the border.[1] The commonly involved body sites are extensor surfaces, skin overlying the digits, periorificial area and less commonly the flexural areas. The most common site of involvement among

Indians is the pretibial area followed by distal fingers and toes.[3] Koebner's phenomenon is a commonly observed feature of vitiligo.[1,3,11]

The lesions of vitiligo are asymptomatic, except occasional pruritus or burning that may precede or accompany the onset of lesions in some patients.[3,12] However at any age, it causes great cosmetic concern and has great psychological impact on affected patients.

TREATMENT

The various treatment modalities available for patients with vitiligo are medical, surgical, phototherapy and camouflage. [1,3]

Though there is extensive advancement in the therapy of vitiligo, it is often treatment-resistant and recurrences are common. This further adds to the woes of the patients and treatment failure or recurrences are additive to the impaired QOL.

IMPACT OF VITILIGO ON A PATIENT'S LIFE

Vitiligo affects the lives of sufferers in various ways;

1. Emotional and psychological distress
2. Impact in occupation
3. Vitiligo influencing a child's psychosocial development

Emotional and psychological distress

Skin plays a major role in an individual's physical and mental well-being, and a sense of self confidence.[7,8] Thus any abnormal appearance of the skin is known to have a profound effect on patients' social interactions and result in psychological distress.[5,8]

Vitiligo has great social significance in India due to the depigmentation being more obvious on darker skin. This unusual look of the sufferers is associated with enormous social

stigma and affects the interpersonal relationships.[6,12,13] Patients with vitiligo feel distressed, have restricted social interaction at school and work places, and may even face ridicule within the family.[5.8] Young individuals may find it difficult to get their match and marital disharmony is frequent among couples if one of the partners has vitiligo.[5,14] It has been noted that stigma is more among the less educated strata of the society.[15]

The degree of impairment of QOL in vitiligo patients does not depend on the extent of involvement. The degree of upset is more when the exposed body parts, such as head, neck and extremities are involved.[7,12] They have a feeling of embarrassment and this is reflected on their choice of clothings which cover the lesions.[2,7,16] The patients feel that they are often being subjected to rude remarks, looked down upon and often feel discriminated.[7,17] Women have a greater impairment of QOL as compared to men.[2]

Patients with vitiligo suffer from various psychological disorders; these include, depression, irritability, anger, anxiety, suppressed interpersonal and social behaviour, poor body image, low self-esteem and suicidal ideations.[17,18] These problems are more common among the younger age group.[2,8]

Salzer and Schallreuter have conducted a hospital based study on 117 patients of vitiligo (F=89, M=28). Nearly 75% of the patients in this study considered their disfigurement intolerable to the extent of moderate to severe. Five out of 12 personality dimensions were deranged as compared to normal controls. It was also noted that 26.5% of the patients with such impairment of QOL belonged to well-educated strata of the society.[16]

In a study by Sampogna *et al*, including 181 vitiligo patients, 60% reported worry of worsening of disease, 37% anger, 34% embarrassment, 31% depression and 28% shame. Social life was affected in 28% of the patients suffering from vitiligo.[2] Sixty eight percent of the study subjects were women and they reported a higher impairment in QOL as compared

to men. The impairment of QOL was comparatively less among patients who had another family member suffering from vitiligo.[2]

Garg *et al* (2014) conducted a study in North India with detailed literature review on impact of QOL among patients with vitiligo. The study subjects reported their feelings as; being stared at, avoidance due to disgust and feared for chance of spread to contact. Patients experienced multiple psychological problems and these were reported more frequent among younger population.[2]

Porter *et al* surveyed 158 vitiligo patients to study the impact of vitiligo in sexual relationships. One third of the patients reported to have a negative impact on their sexual life and attributed it to the embarrassment faced by them in beginning a new relationship.[7,13,14] A similar study by Parsad *et al* among 180 North Indian patients with vitiligo reported negative effect on sexual relationships. This negative impact was more upon the men suffering from vitiligo and resulted in embarrassment.[19]

Willingness to pay (WTP) is an index that reflects the burden of disease on its patients. Radke *et al* conducted a study (2009) to estimate WTP among 1023 vitiligo patients (71.5% women). The mean dermatology life quality index among the patients with vitiligo in this study was 7.0 (F=7.5, M=5.5). The study results revealed that 32.9% of the vitiligo patients were ready to pay more than €5000 to achieve complete disease remission. Highest WTP was noted among middle-aged patients and especially among women.[20]

The chronic, unpredictable and recalcitrant course of the disease and lack of cure in many cases is demoralizing and disempowering for these patients.[21-23] These reflect the negative impact of vitiligo on the quality of life of affected patients.[24] Hence, it is important to recognize and help the patients to deal with the psychosocial distress associated with the disease.

Impact in occupation

Patients with vitiligo have a restricted job opportunities in some fields due to their unusual look.[25] Some patients also incur financial losses as they have to take leave from their jobs due to their treatment appointments like phototherapy.[2] Career options like defence services, media and airlines industries are restricted for these patients.[6]

Vitiligo influencing a child's psychosocial development

Children have a rapid psychological and social development, and emotional vulnerability. Childhood vitiligo is known to impede a child's health related QOL. Negative experiences during childhood has an impact on childhood development and adult life.[17,26] Children with vitiligo often avoid or restrict themselves from sports like swimming where chance of exposure of their skin lesions is high.[17]

Homan *et al* have conducted a study among 283 young adults who had developed vitiligo before the age of 15. This study reported that negative experiences in childhood due to vitiligo caused significant impact in their social development. However, the psychosexual development of such children was comparable to that of healthy controls. Furthermore, a negative childhood experience was significantly associated with higher QOL impairment in early childhood.[27]

COPING-UP STRATEGIES ADOPTED BY PATIENTS

Patients suffering from vitiligo are known to adapt behavioural and cognitive strategies to cope up with their condition. The patients have to deal with their own emotional as well as others behaviour towards their disease. Some avoid situations like social gathering, sports or sexual relationships where their skin may be visible.[28] Similarly, many use concealment, either by wearing clothes that cover their lesions or by using cosmetics to

camouflage their patches.[29] Many social support groups have come into existence where they help patients to overcome their distress and reduce the impact of the disease on their QOL.[30]

EVALUATION OF QUALITY OF LIFE

World health organization (WHO) defines quality of life as "an individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns".[17]

The measurement of quality of life can be done by dividing into three main domains:[17]

1. Physical functioning (symptoms and functional difficulties)
2. Psychological state (emotional and cognitive functions)
3. Social interaction (work, daily activities and public relations)

Studies have shown that extent of vitiligo does not directly correlate with the patient's satisfaction after treatment and also does not correlate with clinical improvement of the disease clinically.[4] This emphasizes that QOL in vitiligo needs to be evaluated separately from the extent of vitiligo.[4] Moreover, measurement of QOL helps in recognition of psychological and functional limitations in a given patient; decision of treatment and hence, improving the physician patient relationship.[2]

Assessment of QOL in patients with vitiligo is of immense importance as it determines the following:

1. Impact of vitiligo on patient's life at presentation.
2. Impact of the disease on patient's life following institution of treatment, i.e. therapeutic response.
3. Effectiveness of a given treatment modality for vitiligo.

Various methods of assessing quality of life in patients with vitiligo have been discussed in the following section.

There are several scales available to measure the quality of life in patients with vitiligo. Some dermatology related measures and few vitiligo specific measures are available for this purpose. The various indices for measurement of QOL have been presented in Table 1.

General health indices

***Visual analogue scale (VAS)*:** VAS is commonly used to measure panic, depression, fatigue and pain. Although, it was originally developed to assess the intensity of pain, subsequently it was used for evaluation of quality of life. It is a ten centimetre long scale oriented either horizontally or vertically, the beginning of which refers to no impact (0 points) and the end to the highest impact on QOL (10 points). The patients indicate the impact of their disease by indicating the point that corresponds to the impact vitiligo has on their QOL.[33]

The disadvantage of VAS is that it is not suitable for people with cognitive problems that impair the understanding of the scale or marking the line with pen, this is also true for elderly people and young children.[33]

***General health questionnaire – 12 (GHQ-12)*:** GHQ-12 is a screening index used to assess the psychiatric morbidity. It consists of 12 items and a score of ≥5 indicates psychiatric morbidity.[34]

Mattoo *et al*, conducted a study to detect the psychiatric morbidity of vitiligo using general health measures, one of which was GHQ-12. It was observed that the psychiatric morbidity noted among the vitiligo patients was 25%. This value was slightly less than the psychiatric morbidity reported in dermatologic diseases other than vitiligo which ranged from 30 – 45%.[34] The values showed that there was no difference between the psychiatric

morbidity of vitiligo and other dermatologic diseases. Thus, GHQ-12 cannot be considered exclusively to measure the impact on QOL in vitiligo patients.

Table 1: Indices for measurement of QOL[4,6,31,32]

1.	General health indices	• Visual analogue scale (VAS) • Short form – 36 (SF-36) • Euroqol – 5 • Sickness impact profile • General health questionnaire – 12 (GHQ-12) • WHO quality of life Berf • Rosenberg self-esteem scale
2.	Dermatology specific indices	• Skindex - 29 • Skindex - 16 • Dermatology life quality index (DLQI) • Dermatology quality of life scales(DQoLS) • Dermatology-specific quality of life instrument
3.	Vitiligo specific indices	• Vitiligo life quality index (VLQI) • VitiQoL • Vitiligo impact scale (VIS) • Vitiligo impact scale – 22 (VIS - 22)

***Short form – 36 (SF-36)*:** SF-36 is a 36 item questionnaire consisting of 8 domains: physical functioning, social functioning, role physical, role emotional, bodily pain, mental health vitality and, general health perceptions. The questions referred to the problems faced in the last four weeks. A score ranging from 0 to 100 was calculated for each domain. A higher score indicates a better quality of life.[5]

In a study by Homan *et al*, 245 adults with vitiligo completed the questionnaire. Among them 81.3% reported difficulty in functioning and to carry out their usual activities due to emotional disturbances. Seventy two percent of the patients were observed to have mental health problems.

The limitation of the general health measure is that similar results are observed among most of the diseases. These include components of bodily pain and limitations of physical activities which are not of great importance for dermatologic diseases, especially vitiligo which is more of cosmetic concern among the patients. Hence, these cannot be exclusively used to measure the impact of quality of life among vitiligo patients.

Dermatology specific measures

***Skindex – 29*:** It is a dermatology specific questionnaire consisting of 29 items which are subdivided into three subscales concerning symptoms, emotions and functioning. Each item has five response possibilities ranging from 'never' (score: 6) to 'all the time' (score: 6).[35] The percent score of each subscale is calculated with higher score indicating a higher impairment in QOL.[35]

In a study by Sampogna *et al* including 181 patients suffering from vitiligo, the mean Skindex – 29 score for the subscale emotion was 37.2%, functioning 22.3% and symptoms 12.2%. It was noted that most patients suffered from emotional disturbances followed by impaired social functioning. Sixty percent of the patients were worried about their disease

getting worse, followed by anger (37%), embarrassment (34%), depression (31%) and, shame (28%).[35]

***Skindex – 16*:** Skindex – 16 is a self-administrated questionnaire consisting of 16 items which again consists of subclasses concerning symptoms, emotional state and social functioning. It is a modification of earlier mentioned scale, Skindex – 29.[36] The scores for each question range from 0 – 6 with '0' being 'never bothered' and '6' being 'always bothered'. The percent score for each domain is calculated and is categorized as poor QOL (>75%), moderate QOL (50 – 75%) and good QOL (<50%).

Abolfotouh *et al* conducted a cross-sectional study among 283 patients with various dermatologic diseases, of which 19.4% had vitiligo. Worry was the commonest difficulty faced by the patients with vitiligo (57.2%), followed by fear of progression or occurrence of new lesion (45%), and embarrassment (33%). The highest mean score in all patients was in social functioning domain (87.3%), followed by symptom (72.4%) and emotional state (57.6%). However, the emotional state and social functioning were more affected in vitiligo sufferers as compared to other dermatologic diseases.

***Dermatology life quality index (DLQI)*:** DLQI is the first dermatology-specific QOL instrument developed in 1994 by Finlay *et al*.[37] It is a simple 10-question validated questionnaire that has been used in 36 different skin conditions.[31] The ten items included in the questionnaire are symptoms, feelings, daily routine, clothing, social activities, sports and exercise, work/study, personal relationships, sexual relationships, and treatment.[38] The score for each question range from 'not at all' (score: 0) to 'very much' (score: 3). The total scores range from 0 – 30. Higher the score, greater is the impairment of QOL.

Kent *et al* validated DLQI among 614 patients who were the members of a vitiligo support group (Vitiligo society) via a postal survey. The DLQI scores showed statistically

significant correlation with their symptoms of distress and perceived stigma. A statistically significant but weak relationship was established between DLQI scores and extent of lesions.[39]

A similar postal survey was conducted by Ongenae *et al*, where a total of 119 vitiligo patients were interviewed using DLQI. The mean DLQI was 4.95. The patients scored significantly lower for questions related to symptoms and treatment. Highest scores were found for questions regarding feelings, daily routine, clothing and social activities. The DLQI score and the score on sexual relationship showed significant association, with women having a higher score (mean: 6.45) as compared to men (mean: 3.13).[38]

Kiprono *et al* conducted a cross sectional study among 88 patients of vitiligo to assess their QOL using DLQI. The study showed moderate impact on QOL of the patients with a mean (±SD) DLQI score of 7.2 (±4.8). Seventy three percent of the patients perceived that vitiligo had moderate to severe impact on their QOL. However, 49.2% of these patients had only mild disease clinically. This difference was statistically significant and implied that the QOL was not dependent upon the extent of vitiligo.[40]

The dermatology specific measures included questions related to physical symptoms of the patients which were of least significance in vitiligo. Concerns related to vitiligo were not specifically addressed by these questionnaires. This led to development of vitiligo specific measures.

Vitiligo specific measures

***Vitiligo life quality index (VLQI)*:** VLQI is the first vitiligo specific quality of life instrument developed by Senol *et al*. The scale consists of 25 items with score ranging from “never” (score = 0) to “all the time” (score = 4). The total score ranges between 25 and 100 and a

higher score indicates a higher impairment on QOL of the patients. The scale particularly focusses on the emotional and social impact of vitiligo on the sufferers.

The study by Senol *et al* was conducted to validate VLQI among 183 vitiligo sufferers. The mean (±SD) VLQI score was 44.0 (±12.1). The score was validated by correlating the mean score with DLQI. The study indicated that patients with body surface area (BSA) involvement of >5% had a statistically higher VLQI score as compared to the patients with BSA <5%. Nearly 82% of the patients preferred VLQI to express themselves and reflect the psychosocial problems faced by them. However, no statistically significant relationship was established between the treatment history and the VLQI scores.

The limitation of this study was that the study subjects were of skin types II to IV. The patients with skin types V and VI were not included, who usually have the highest impact of vitiligo on QOL.

***VitiQol*:** Lilly *et al* developed a 15-item instrument "VitiQol", a vitiligo specific scale and tested it upon 90 patients. The score for each question was calculated on a seven point Likert scale (0-6). The final score ranged from 0 to 90; higher scores indicated poorer QOL. The study dealt in specific about participation, limitation, social stigma and behaviour of patients with vitiligo. A correlation of 0.051 was found between self-reported severity and VitiQol scores. It also showed higher effect on QOL in individuals with exposed patches compared to unexposed patches.[41]

The test-retest reproducibility was not evaluated in this study and the study was done at a single point of time regardless of the time of diagnosis and treatment duration with no follow up on the patient.

Hedayat *et al* conducted a similar study to evaluate QOL among 173 vitiligo patients using VitiQoL. The mean VitiQoL score was 30.5 and was significantly correlated with

VASI. Women had a higher impairment of QOL as compared to men with vitiligo. QOL was better among the well-educated strata of the study population. Extensive disease and psychiatric illnesses like anxiety and depression were associated with a poor quality of life, although the scores were not statistically significant. Higher impact on QOL was seen among patients with BSA involvement of more than 15-20%. Disease duration less than 5 years and more than 15-20 years was associated with a lesser impairment in QOL.

***Vitiligo impact scale (VIS)*:** Krishna *et al* developed a vitiligo specific QOL scale "VIS" and studied it on 180 patients.[9] It was a 27 item scale where 19 items were common to all patients, 5 items for married, one item each for unmarried, working or studying. The items were grouped under the domains: self-confidence, depression, anxiety, social interactions, attitude, marriage related problems, occupational and peer pressure related problems, and family worries. Each question had score ranging from 0 to 4, the higher score representing a higher impairment of QOL.[9]

Fifty seven males and forty three females were included in the study and impairment of QOL in women was statistically significantly higher as compared to men. However, no statistical significance was observed in other parameters like marital and employment status, age, duration of vitiligo and visibility of lesions. The results correlated moderately with DLQI and Skindex-16.

The limitation of this scale was that, it included 5 items specific for married people. This lead to a higher score among married patients with vitiligo as compared to unmarried patients.

***Vitiligo impact scale – 22 (VIS-22)*:** Recently a new scale "Vitiligo Impact Scale-22 (VIS-22)" was developed by Gupta *et al*.[4] It is a specially designed questionnaire with specificity to assess the extent of impairment of QOL in patients with vitiligo.

It is a modification of vitiligo impact scale where the number of items for married patients were reduced from five to one, equalizing the scale for both married and unmarried group. It is a valid, reliable and responsive health related QOL instrument. It consists of a set of 22 questions which are given to the patients to respond. Since there is no standard protocol to assess the psychological impact of vitiligo, patient's own opinion has been given a higher value, so that the patient-perceived severity can be assessed.[4] 'VIS-22' was developed in All India Institute of Medical Sciences in New Delhi (2014) and was validated among a sector of North Indian patients attending that institution. The VIS-22 has been presented in Table 2.

From review of the literature it is evident that vitiligo causes a great impact on QOL of affected patients. Studies assessing QOL of patients with vitiligo using "vitiligo-specific-scales" are few. VIS-22 has been studied among North Indian patients suffering from vitiligo. Indian population is highly variable in various parts of the country with regard to language, socioeconomic status, culture, faith and taboos. Hence, it is important to revalidate the scale in various geographic areas in India. This is necessary to assess reliability of the scale in different population groups where its effectiveness may differ.

Hence this hospital based study was planned to re-validate 'VIS-22' among a group of South Indian patients suffering from Vitiligo.

Table 2: Vitiligo Impact Scale – 22 (VIS-22)

Scoring: 0-Not at all 1-A little 2-A lot 3-Very much

		0	1	2	3
1	Do you think this disease in incurable				
2	Do you change your doctor				
3	Do suggestions and advice from others about the disease bother you				
4	Do other people feel that this disease spreads by touch				
5	Do you have problems in wearing your choice of clothes				
6	Do you feel helpless				
7	Do you face difficulties in adhering to the treatment				
8	Do your parents keep asking you to seek treatment				
9	Do you feel life is not worth living with this disease				
10	Do you feel depressed				
11	Do you keep thinking about this disease				
12	Have you stopped/reduced going to parties/get-togethers				
13	Do your friends/relatives avoid you				
14	Do you think about bringing your life to an end				
15	Do you observe any kind of dietary restriction				
16	Does the amount of money you have spent on the treatment bother you				
17	Do you believe that this is the worst disease anyone can have				
18	Do you get embarrassed when meeting people				
19	How worried will you be if you develop new lesions				

If you are married, please answer the following question

20	Do your in-laws worry about your white patches				

If you are unmarried, please answer the following question

20	Are you facing problems in getting married				

If you are working, please answer the following questions

21	Do your colleagues treat you differently because of the disease				

If you are studying, please answer the following questions

22	Do your classmates treat you differently because of the disease				

METHODOLOGY

SOURCE OF DATA

A “hospital-based validation of vitiligo impact scale-22 in a tertiary care hospital in North Karnataka” was conducted in the department of Dermatology, Venereology and Leprosy of B.L.D.E.U’s Shri B. M. Patil Medical College Hospital and Research Centre, Vijayapur, Karnataka. Cases and controls were recruited from the out patient section of the department (OPD). The study was conducted between November 2015 to May 2017.

METHOD OF DATA COLLECTION

Patients suffering from vitiligo irrespective of gender, above 15 years of age were enrolled for the study. A total of 153 cases were enrolled. Total 155 patients suffering from short term skin diseases, unlikely to result in psychological morbidity (e.g., mild dermatitis, bacterial infections etc.) attending the OPD were taken as controls. Before enrolment of both patients and controls, their educational status was enquired. This was because participation in the study required minimum educational level so that the study subjects could read, understand and respond to the questionnaires. Informed written consent was taken from all the study subjects.

Inclusion criteria:

1) Patients > 15years, suffering from any clinical type of vitiligo.
2) Patients with educational status of at least secondary level.

Exclusion criteria:

1) Patients suffering from mental and cognitive impairments.

2) Patients with other major skin disorders along with vitiligo like psoriasis, severe acne vulgaris, alopecia, melasma, which are likely to result in psychological morbidities.
3) Patients with associated hypothyroidism which may cause a depressed mood.

METHOD

Detailed history with respect to the onset and duration of lesions, disease progression, any treatment received, repigmentation, family history were recorded from the patients in scheduled proforma.

Initial clinical examination of the patient was done and the skin lesions were recorded on a body chart present in proforma (1^{st} visit record). Each patient was assessed twice: one at the first visit and next after 12 weeks.

Before starting the assessment each patient was explained about the scales in a simpler manner in local language. In every visit each patient was assessed using the following tools:

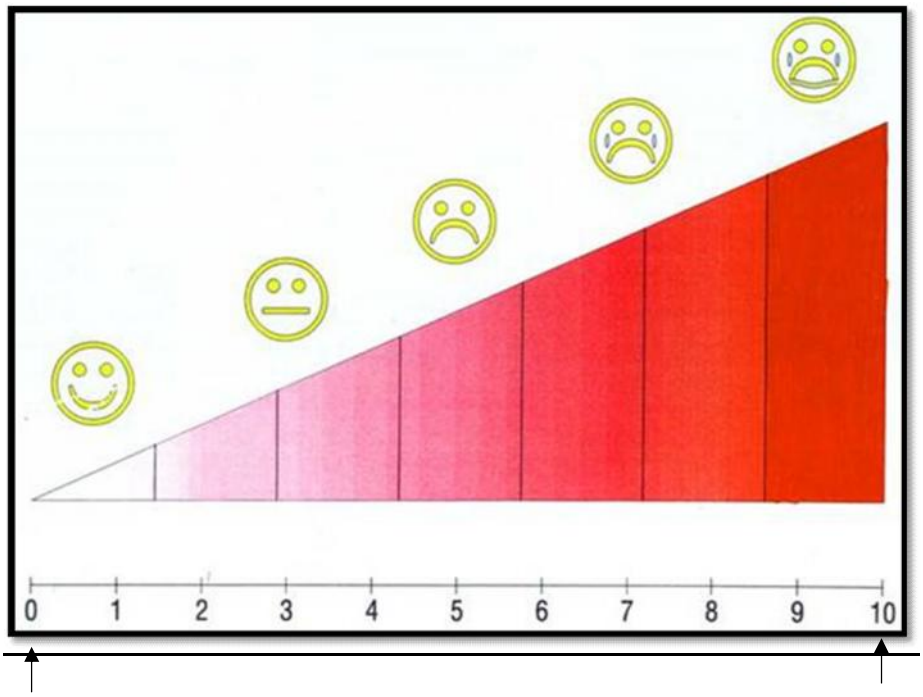
1) Visual analogue scale (VAS ; assessment of patient perceived severity of disease)
2) DLQI
3) Skindex-16
4) VIS-22

For DLQI, Skindex-16 and VIS-22, test-retest reliability was determined by assessing the patient twice; once at the time of presentation and again 2 weeks later. These data were utilized to compare the test-retest reliability of these three instruments.

Scales and scoring

1) ***VAS***: It is a 10 cm (100mm) long line oriented horizontally on which patients indicate the psychological impact of vitiligo by marking the line at a point that corresponds to their agony, being informed that the beginning of the scale refers to no impact on QOL (0 points) and the end to the highest impact on QOL they can imagine (10 points). The length from left end to the vertical mark made by the patient is measured in millimetres. The visual analogue scale has been presented in Figure 2.

Figure 2: Visual Analogue Scale



No impact on QOL Highest impact on QOL

2) ***DLQI*****:** It is a 10-question validated questionnaire. The questionnaire is completed by the investigator based on the answers by the patients. The questionnaire has been presented in Table 3:

Table 3: Dermatology Life Quality Index

Sl No.	Questions	0	1	2	3
1.	Over the last week, how itchy, sore, painful or stinging has your skin been?				
2.	Over the last week, how embarrassed or self-conscious have you been because of your skin?				
3.	Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?				
4.	Over the last week, how much has your skin influenced the clothes you wear?				
5.	Over the last week, how much of your skin affected any social or leisure activities?				
6.	Over the last week, how much has your skin made it difficult for you to do any sport?				
7.	Over the last week, has your skin prevented you from working or studying? If 'No', over the last week how much has your skin been a problem at work or studying?				
8.	Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?				
9.	Over the last week, how much has your skin caused any sexual difficulties?				
10.	Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up your time?				

The scoring of each question has been represented in Table 4:

Table 4: Scoring in DLQI

Sl No.	Response	Score
1.	Very much	3
2.	A lot	2
3.	A little	1
4.	Not at all	0
5.	Not relevant	0
6.	Question 7, 'prevented work or studying'	3

The scores range from 0 – 30. Higher the score, greater is the impairment of QOL. The scores were interpreted as follows:

a) 0 – 1 : no effect at all on patient's life

b) 2 – 5 : small effect on patient's life

c) 6 – 10 : moderate effect on patient's life

d) 11 – 20 : very large effect on patient's life

e) 21 – 30 : extremely large effect on patient's life

3) ***Skindex-16***: It is a 16-item scale (Table 5). The questionnaire is completed by the investigator based on the answer by the patients. The scores for each question range from 0 – 6 with '0' being 'never bothered' and '6' being 'always bothered'. The questionnaire has three domains as follows:

a) Questions 1- 4 : focuses on symptoms

b) Questions 5 – 11 : focuses on emotion

c) Questions 12 – 16 : focuses on functioning of the patient

Table 5 : Skindex - 16

Sl No.		0	1	2	3	4	5	6
1	Your skin condition **itching**							
2	Your skin condition **burning or stinging**							
3	Your skin condition **hurting**							
4	Your skin condition **being irritated**							
5	The **persistence / reoccurrence** of your skin condition							
6	**Worry** about your skin condition (eg: that it will spread, get worse, scar, be unpredictable, etc)							
7	The **appearance** of your skin condition							
8	**Frustration** about your skin condition							
9	**Embarrassment** about your skin condition							
10	**Being annoyed** about your skin condition							
11	**Feeling depressed** about your skin condition							
12	The effects of your skin condition on your **interactions with others** (eg: interactions with family, friends, close relationships, etc)							
13	The effect of your skin condition on your **desire to be with people**							
14	Your skin condition making it hard to **show affection**							
15	The effects of your skin condition on your **daily activities**							
16	Your skin condition is making it hard to **work or do what you enjoy**							

The scores for each domain is summated over the patients and percent score is calculated. The QOL range for each and overall domain were categorized as follows:

i. <50% : good QOL

ii. 50 – 70% : moderate QOL

iii. >75% : poor QOL

4) ***VIS-22*** : It is a 22-item questionnaire (Table 2) which was given to the patients to respond. It was translated to the regional language (Kannada) for better understanding of the patients (Annexure ii).

The scoring is done as follows:

a) 0 : not at all
b) 1 : a little
c) 2 : a lot
d) 3 : very much

The scores are banded with the following range with DLQI as an anchor instrument

i. 0 – 10 : no effect at all
ii. 11 – 20: small effect
iii. 21 – 30: moderate effect
iv. 31 – 48: large effect
v. 49 – 66: extremely large effect

Follow up:

Each patient was followed up for therapeutic purpose as and when necessary. Repeat assessment of the patients with all four QOL scoring systems was done after 12 weeks.

INVESTIGATIONS

This study did not require to assess the patients with laboratory parameters. However, for the sake of patient management, following investigations was done as and when necessary:

- Complete hemogram
- Peripheral blood smear
- Random blood sugar
- Routine urine analysis
- Liver function tests
- Blood urea and serum creatinine
- Thyroid function tests

After initial assessment all patients were administered appropriate treatment; like topical, systemic and phototherapy.

STATISTICAL ANALYSIS:

Clinico-epidemiological data collected from the patients were calculated with mean ± standard deviation (SD) and are represented diagrammatically. The criterion and construct validities were evaluated using Spearman's correlation coefficient. Paired t – test was used to assess known – groups validity. Student's t – test was used for disease specificity of VIS-22. Spearman's rank coefficient, paired t- test, and ANOVA were used to estimate first, second and third measures of responsiveness, respectively.

ETHICAL CLEARANCE:

Institutional ethical clearance was undertaken for the study

The clinical photographs of a patients with various types of vitiligo have been presented in figure 3 to 6.

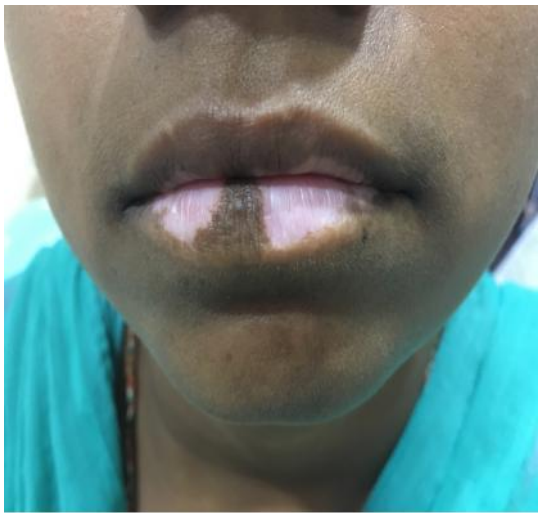


Figure 3: Focal vitiligo on lips

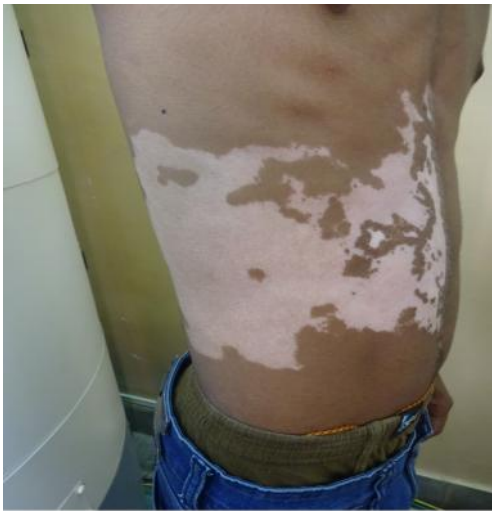


Figure 4 : Segmental vitiligo

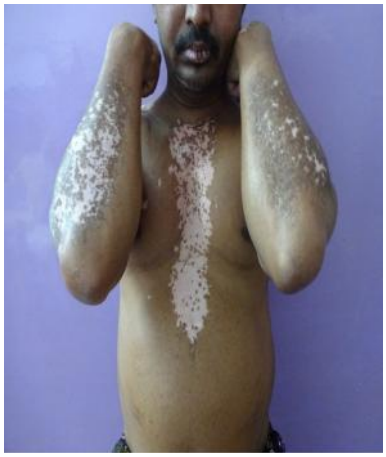


Figure 5: Vitiligo vulgaris: trunk and extensor aspect of forearms

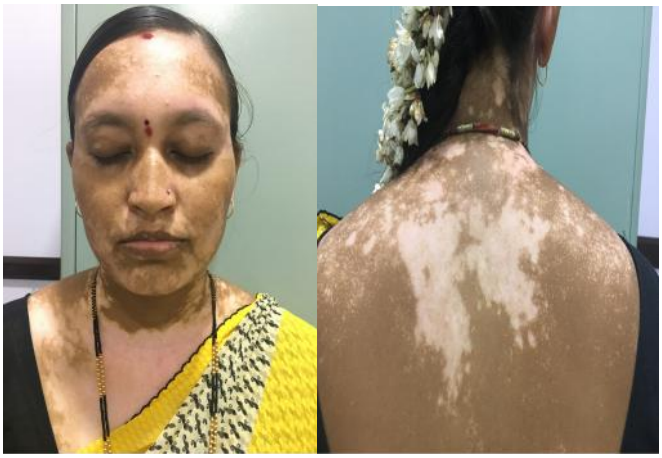


Figure 6: Vitiligo vulgaris: face and trunk distribution

RESULTS

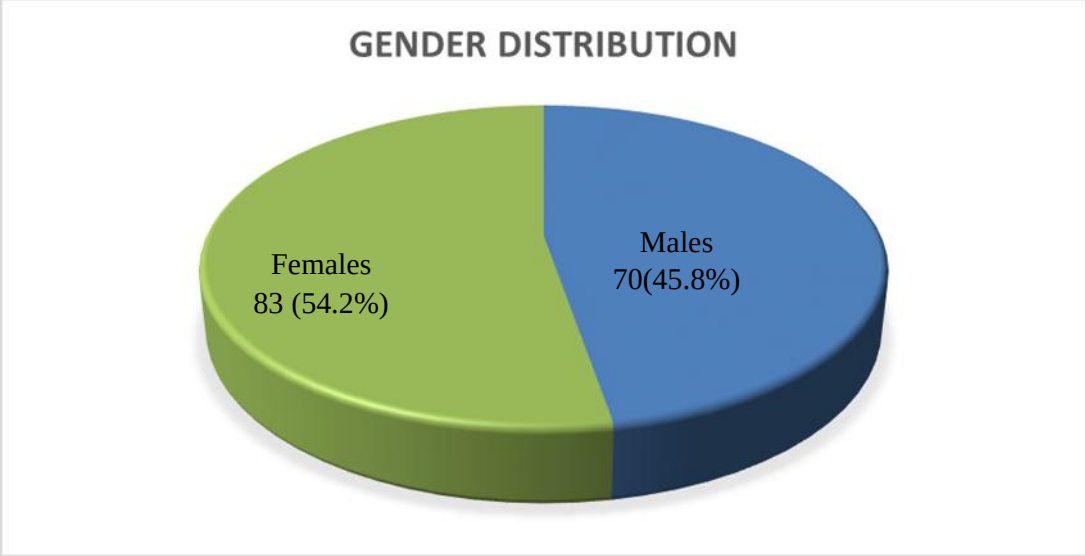
A hospital based prospective study was conducted from November 2015 to May 2017. Total 153 cases of vitiligo and 155 controls were included in the study.

Among 153 cases who were enrolled in the study, 124 (81.04%) completed the study at the end of 12 weeks. Twenty nine (18.95%) patients were lost to follow-up.

Gender distribution

Among 153 cases, 70 were males (45.8), and 83 were females (54.2%). There was no statistically significant difference in the gender distribution of vitiligo. Figure 7 presents the gender distribution of the patients with vitiligo included in the study.

Figure 7: Gender distribution of patients with vitiligo



Among 155 controls, 98 were males (63.2%), and 57 were females (36.8%). Table 6 presents the gender distribution of cases and controls.

Table 6: Gender distribution of cases and controls

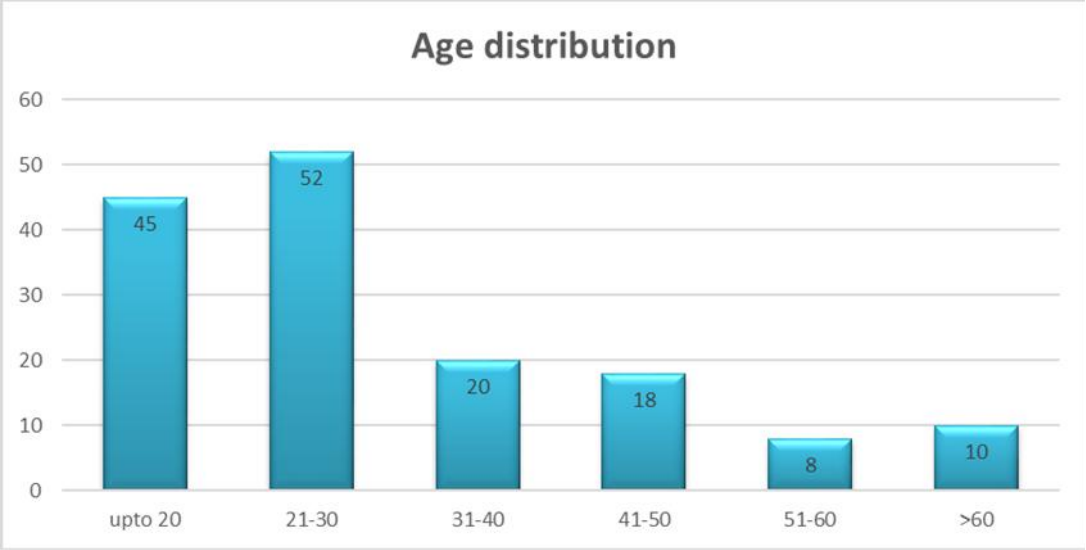
Sex	Cases	Control	p value
	n(%)	n(%)	
Male	70(45.8)	98(63.2)	0.002*
Female	83(54.2)	57(36.8)	
Total	153(100)	155(100)	

Note: * significant at ($p<0.05$)

Age distribution

The age of the cases enrolled in the study ranged from 15 to 72 years. The mean (± SD) age of the study population was 31.24 (±15.0) years. Maximum number (n=52; 34%) of patients belonged to the age group of 21-30 years. Figure 8 presents the age distribution of the patients with vitiligo included in the study.

Figure 8: Age distribution of patients with vitiligo



The mean (±SD) age of the controls was 29 (±12.9) years. There was no statistically significant difference between the mean age of cases and controls ($p = 0.268$).

Other parameters

Marital and education status

Among 153 cases of vitiligo, 86 were married (56.2%) and 67 were unmarried (43.8%).

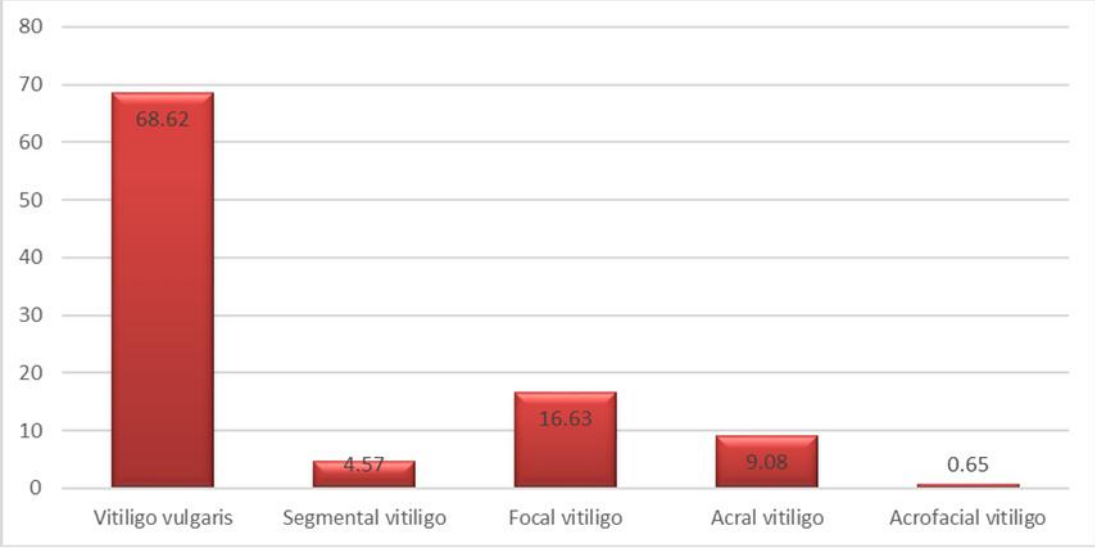
Out of 153 patients with vitiligo, 103 (67.4%) had an education up to 12th standard or lower and 50 (32.6%) had an education above 12th standard.

Clinical features

Cases

Most prevalent clinical type was vitiligo vulgaris in 105 (68.62%) patients, followed by focal vitiligo in 25 (16.63%), acral vitiligo in 15 (9.08%), segmental vitiligo in 7 (4.57%) and acrofacial vitiligo in 1 (0.65%) patient. Figure 9 presents the percentage distribution of clinical types of vitiligo.

Figure 9: Percentage distribution of clinical types of vitiligo



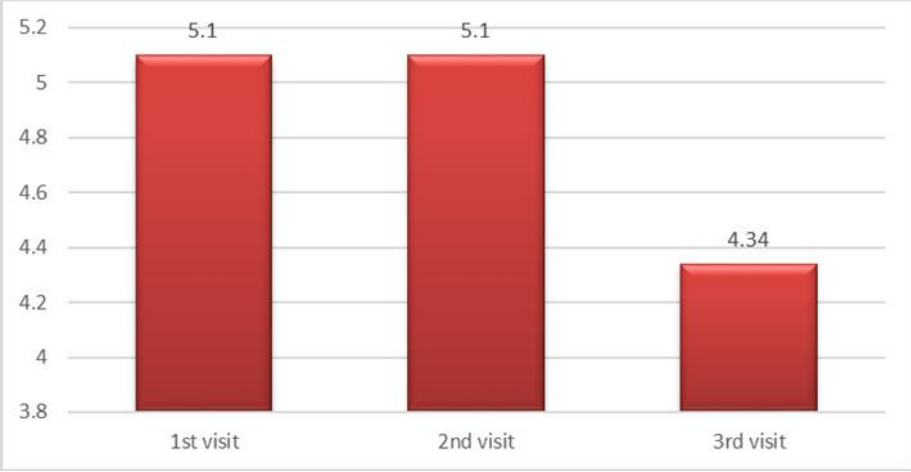
Controls

The controls were patients who suffered from various dermatological diseases like superficial dermatophyte infections, Pityriasis rosea, scabies, seborrheic dermatitis, polymorphic light eruptions, acute urticarial, milia, aphthous ulcers, fissured feet, eczema and keratolysis exfoliativa.

Visual analogue scale

The total VAS score of vitiligo patients ranged from 0 – 10. The mean (± SD) of VAS score among vitiligo patients were 5.1 (±2.5) on first (week 0), 5.1 (±2.6) on second (week2) and 4.34 (± 2.8) on third visit (week 12). Figure 10 presents the mean VAS scores among the vitiligo patients during the study period.

Figure 10: Mean VAS scores among vitiligo patients



The mean (± SD) of VAS score among controls were 5.0 (±2.4) on first, 5.1 (±2.7) on second and 4.34 (±1.4) on third visit. Table 7 presents the comparison of mean VAS scores of cases and controls on first visit and subsequent follow ups.

Table 7: Comparison of mean VAS scores of cases and controls

Visits	Cases	Controls	p value
	Mean (±SD)	Mean (±SD)	
1st visit	5.1 (±2.5)	5.0 (±2.4)	0.572
2nd visit	5.1 (±2.6)	3.5 (±2.7)	<0.001*
3rd visit	4.3 (±2.8)	1.0 (±1.4)	<0.001*

Note: *significant at p<0.001

Dermatology life quality index

The total DLQI scores for vitiligo patients ranged from 0 – 19. The mean (±SD) of DLQI score among vitiligo patients were 5.6 (±4.6) on first, 5.6 (±5.0) on second and 5.3 (±5.3) on third visit. Figure 11 presents the DLQI score of vitiligo patients of first visit and subsequent follow ups.

Figure 11: Mean DLQI score of vitiligo patients

The mean (± SD) of DLQI score among controls were 6.1 (±3.6) on first, 4.1 (±3.7) on second and 1.0 (±1.4) on third visit. Table 8 presents the comparison of mean DLQI scores of cases and controls.

Table 8: Comparison of mean DLQI scores of cases and controls

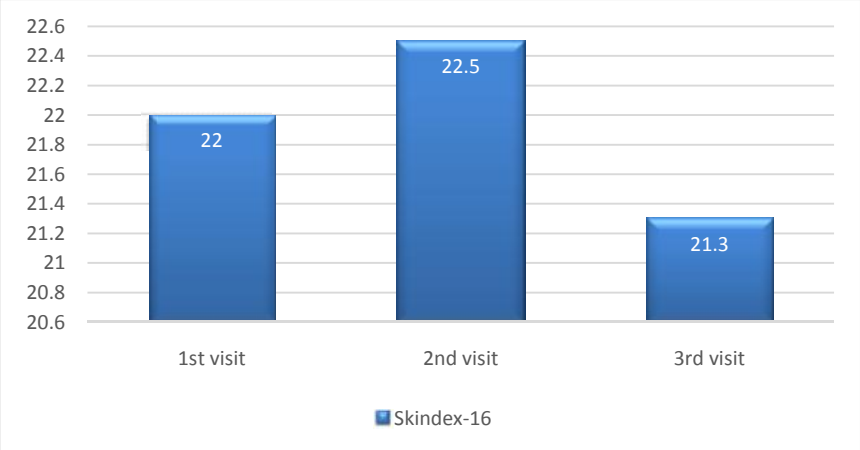
Visits	Cases		Controls		p value
	Mean	SD	Mean	SD	
1st visit	5.6	4.6	6.1	3.6	0.337
2nd visit	5.6	5.0	4.1	3.7	0.005*
3rdvisit	5.3	5.3	1.0	1.4	<0.001*

Note: *significant at p<0.005

Skindex-16(%)

The mean (± SD) of Skindex-16 (%) score among vitiligo patients were 22.0 (±14.0) on first, 22.5 (±15.0) on second and 21.3 (±16.8) on third visit. Figure 12 presents the mean Skindex-16 (%) score of vitiligo patients of first visit and subsequent follow ups.

Figure 12: Mean Skindex-16 (%) scores of vitiligo patients



The mean (±SD) Skindex-16 scores among controls were 20.1(±11.5) on first, 14.9(±13.2) on second and 3.1(±4.1) on third visit. Table 9 presents the comparison of mean Skindex-16 (%) scores of cases and controls.

Table 9: Comparison of mean Skindex-16 (%) scores of cases and controls

Visits	Cases	Controls	p value
	Mean (±SD)	Mean (±SD)	
1st visit	22.0 (±14.0)	20.1 (±11.5)	0.203
2nd visit	22.5 (±15.0)	14.9 (±13.2)	<0.001*
3rd visit	21.3 (±16.8)	3.1 (±4.1)	<0.001*

Note: *significant at p<0.001

The mean (±SD) of individual domain of Skindex-16 i.e symptoms (S), emotional state (E) and social functioning (F) during 1st, 2nd and 3rd visit for both cases and controls have been presented in Table 10.

Table 10: Mean Skindex-16 (%) individual domain scores of cases and controls

Visits		Cases	Controls	p value
		Mean (±SD)	Mean (±SD)	
1st visit	S	6.0 (±9.4)	30.2 (±18.3)	<0.001*
	E	38.2 (±21.2)	22.0 (±14.1)	<0.001*
	F	11.4 (±15.5)	9.0 (±12.8)	0.139
2nd visit	S	7.2 (±13.2)	24.1 (±20.6)	<0.001*
	E	39.7 (±20.6)	16.2 (±15.9)	<0.001*
	F	11.5 (±17.4)	6.0 (±10.0)	0.002*
3rd visit	S	5.4 (±13.1)	7.7 (±9.8)	0.106
	E	37.5 (±23.5)	2.4 (±3.8)	<0.001*
	F	11.1 (±18.5)	0.4 (±2.1)	<0.001*

Note: * significant at p<0.05

The emotional status was most affected domain among vitiligo patients (38.2%) followed by social functioning (11.3%) where as symptoms domain was most affected among controls (20.66%). Figure 13 presents the comparison of mean Skindex-16 (%) value of individual domains of cases and controls.

Vitiligo impact scale – 22

The total VIS-22 score of vitiligo patients ranged from 1 – 46. The mean (± SD) of VIS-22 score among vitiligo patients were 19.1 (±10.8) on first, 18.5 (±9.1) on second and 18.8 (±11.9) on third visit. Figure 19 presents the mean VIS-22 score of vitiligo patients on first visit and subsequent follow ups.

The mean (± SD) of VIS-22 score among controls were 6.8 (±7.0), 4.7 (±5.8) and 0.9 (±1.2) on first, second and third visits respectively. Table 11 presents the comparison of mean VIS-22 scores of cases and controls.

Figure 13: Comparison between mean Skindex-16 (%) value of individual domains of cases and controls

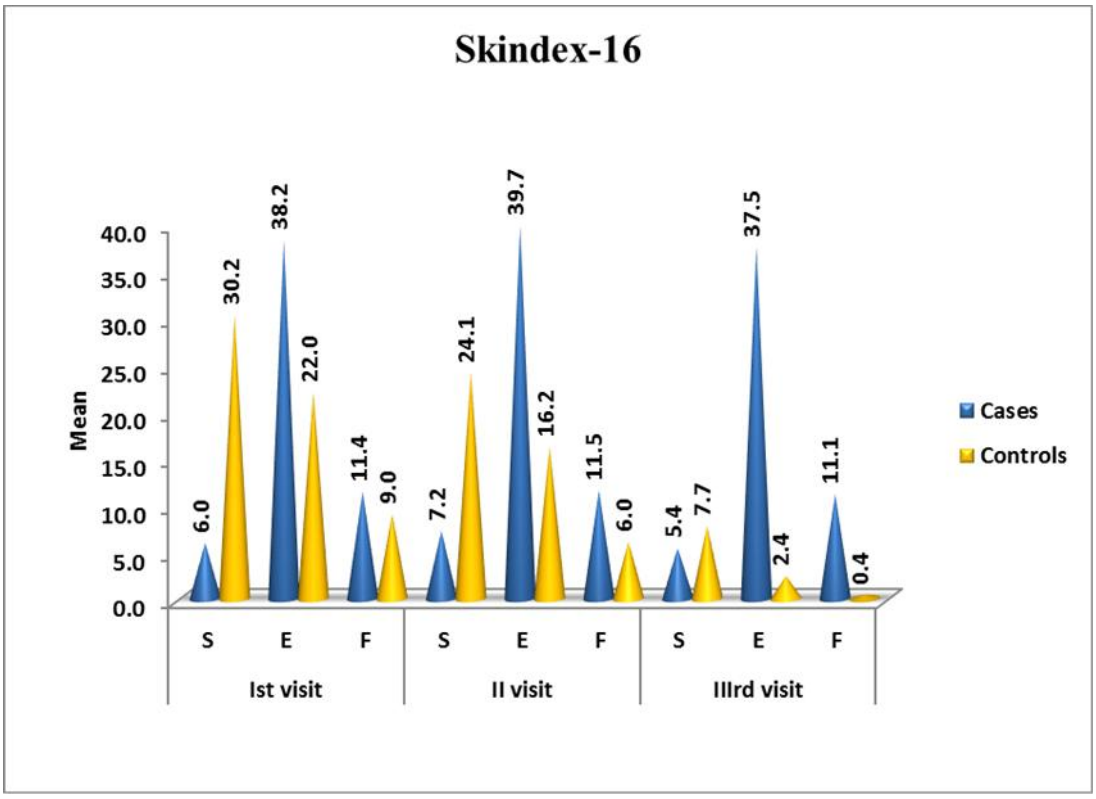


Figure 14: Mean VIS-22 scores of vitiligo patients

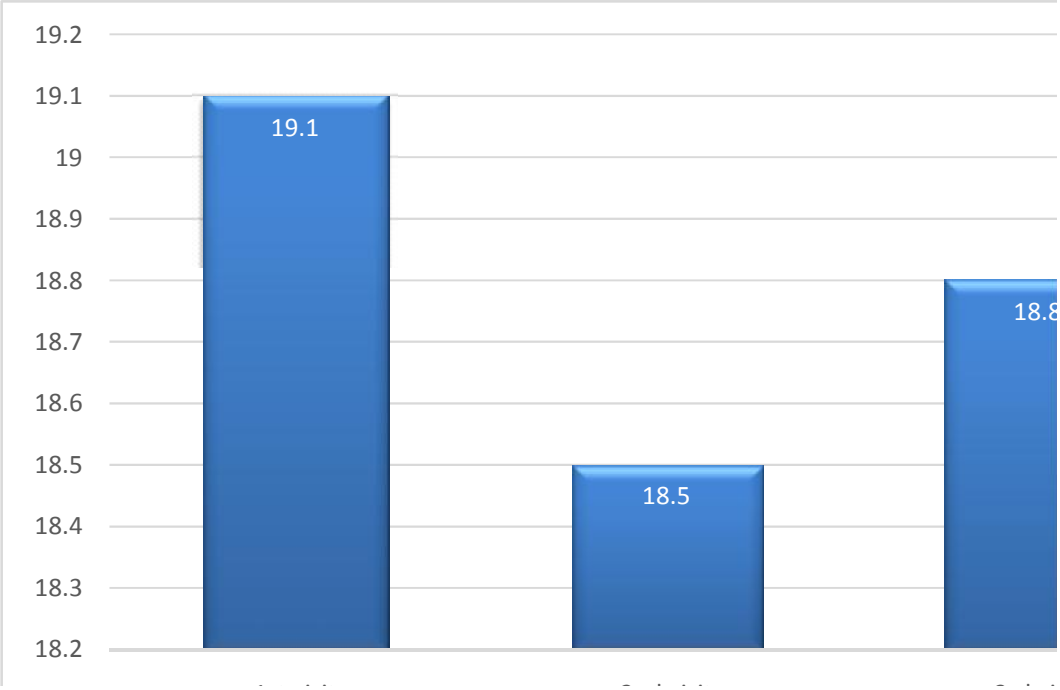


Table 11: Comparison of mean VIS-22 scores of cases and controls

Visits	Cases	Controls	p value
	Mean (±SD)	Mean (±SD)	
Ist visit	19.1 (±10.8)	6.8 (±7.0)	<0.001*
II visit	18.5 (±9.1)	4.7 (±5.8)	<0.001*
IIIrd visit	18.8 (±11.9)	0.9 (±1.2)	<0.001*

Note: *significant at p<0.001

Treatment received by patients with vitiligo

The patients with vitiligo had received following treatment

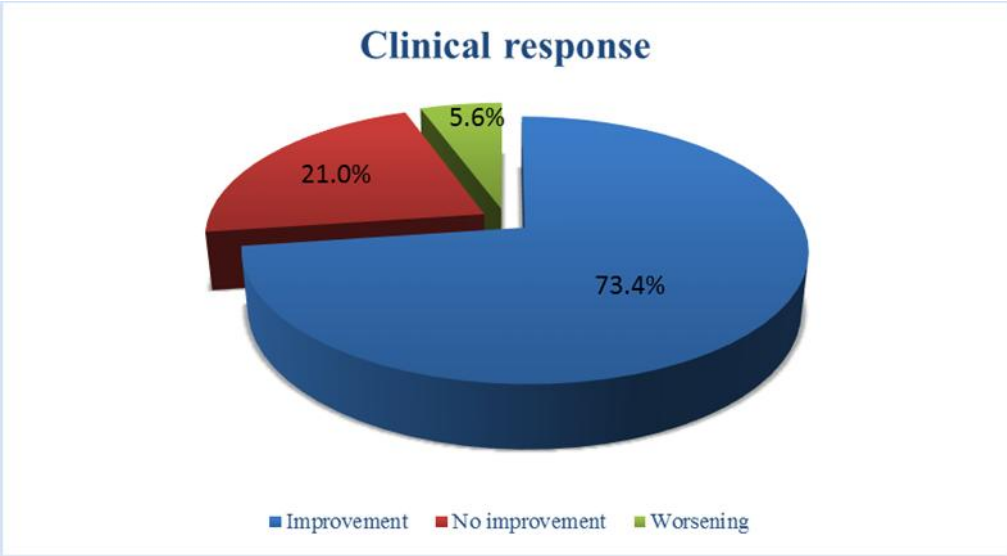
1. 72 received narrow band UVB therapy (NB-UVB)

2. 23 received a combination of oral mini pulse with betamethasone, topical calcineurin inhibitor (tacrolimus) and phototherapy (either NB-UVB or Excimer lamp therapy)
3. 42 received Excimer lamp therapy with topical tacrolimus
4. 9 received only topical tacrolimus
5. 5 received PUVAsol
6. 2 underwent suction blister roof grafting and mini punch grafting each followed by Excimer lamp therapy

Clinical response of patients with vitiligo

Among 153 patients with vitiligo, 91 (73.4%) showed improvement of their skin lesions, where as 27 (21.0%) showed no clinical response i.e no clinically significant change. Seven (5.6%) patients had worsening of their skin lesions characterized by minimal or no repigmentation and appearance of new depigmented lesions. Figure 15 presents the clinical response of the patients with vitiligo during the 12 week study period.

Figure 15: Clinical response of patients with vitiligo



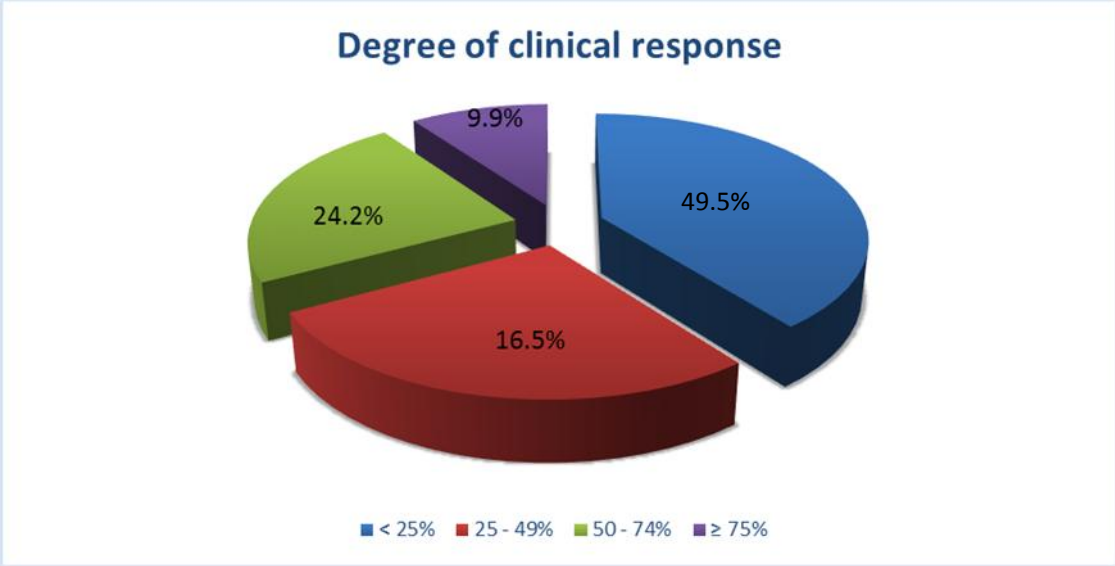
Correlation with degree of clinical response

The clinical improvement of the vitiligo patients were graded as

a. Mild improvement - <25%
b. Moderate improvement - 25 - 49%
c. Good improvement - 50 - 74%
d. Excellent improvement - ≥ 75%

Among the 91 patients who showed clinical improvement in their disease, 45 (49.5%) patients showed mild improvement, 15 (16.5%) showed moderate improvement, 22 (24.2%) showed good improvement and 9 (9.9%) showed excellent improvement. Figure 16 represents the degree of clinical response among vitiligo patients with clinical improvement.

Figure 16: Degree of response among vitiligo patients with clinical improvement



Correlation of change in scores with change in disease status

A statistically significant correlation was found ($p < 0.001$) between scores of each individual scale at baseline and third visit in relation to changes in disease status (either worsening of disease status or clinically good/excellent response). However, there was no

significant correlation between these two parameters when there was mild to moderate response to therapy. The correlation between the individual scores and change in disease status of vitiligo patients have been presented in Table 12 and Figure 17 and 18.

Figure 17: Correlation of change in baseline individual scores and disease status

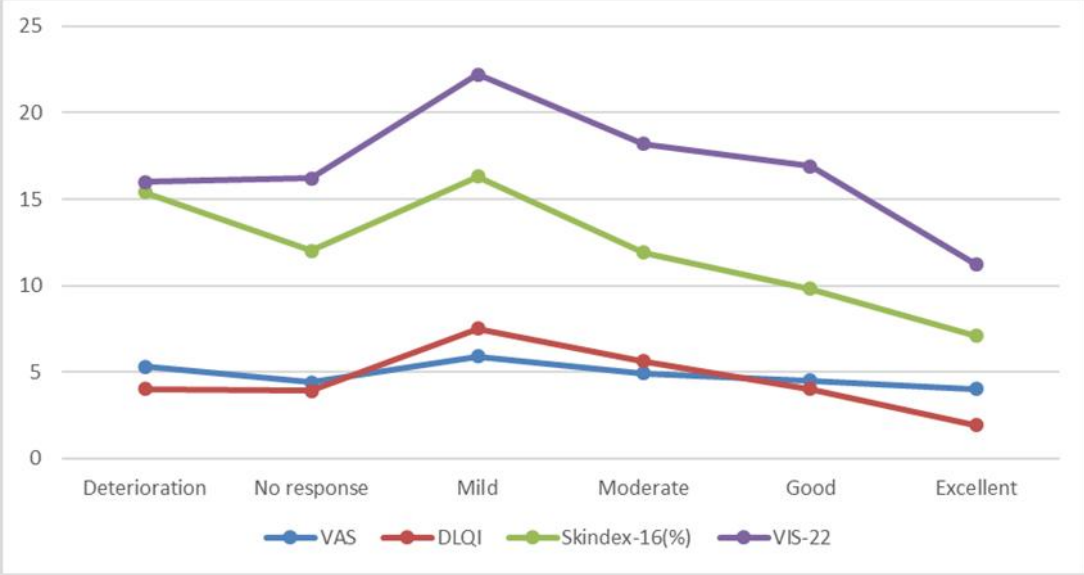


Figure 18: Correlation of change in 3rd visit individual scores and disease status

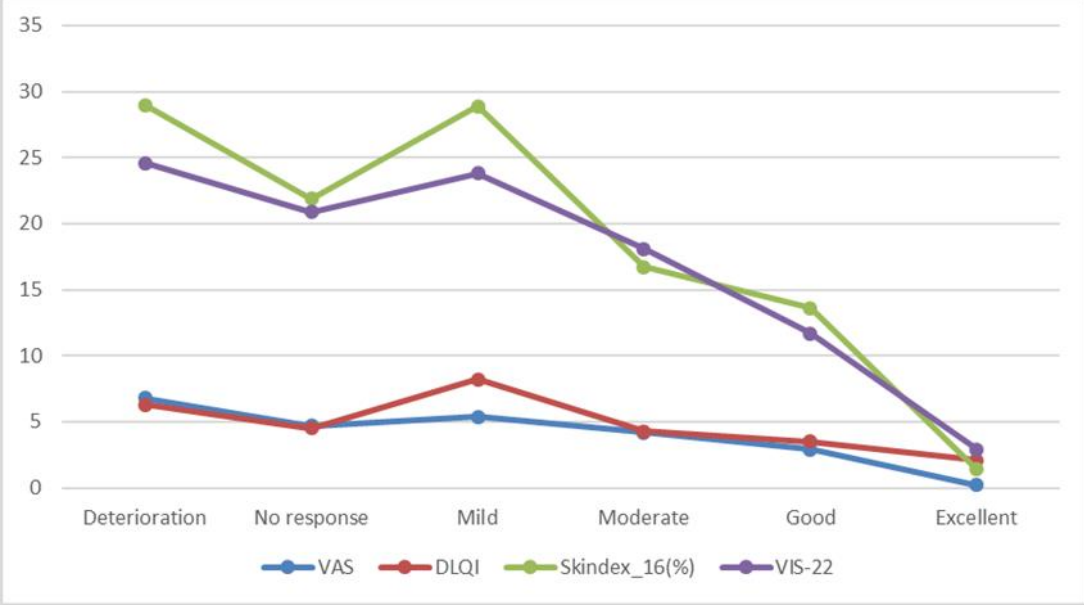


Table 12: Correlation of change in individual scores and disease status

	Response	Visit	Mean (±SD)	Mean change	p value
VAS	Deterioration	Baseline	5.3 (±3.1)	1.5	0.001*
		3rd visit	6.8 (±3.6)		
	No response	Baseline	4.4 (±2.5)	0.3	0.147
		3rd visit	4.7 (±2.5)		
	Mild	Baseline	5.9 (±2.4)	-0.5	0.008*
		3rd visit	5.4 (±2.5)		
	Moderate	Baseline	4.9 (±2.4)	-0.8	0.016*
		3rd visit	4.2 (±2.1)		
	Good	Baseline	4.5 (±2.8)	-1.7	<0.001*
		3rd visit	2.9 (±1.7)		
	Excellent	Baseline	4.0 (±2.1)	-3.8	0.001*
		3rd visit	0.2 (±0.4)		
DLQI	Deterioration	Baseline	4.0 (±3.2)	2.3	0.019*
		3rd visit	6.3 (±4.3)		
	No response	Baseline	3.9 (±3.5)	0.6	0.016*
		3rd visit	4.5 (±3.8)		
	Mild	Baseline	7.5 (±5.3)	0.7	0.043*
		3rd visit	8.2 (±6.3)		
	Moderate	Baseline	5.6 (±4.3)	-1.3	0.002*
		3rd visit	4.3 (±4.0)		
	Good	Baseline	4.0 (±3.5)	-1.4	<0.001*
		3rd visit	2.6 (±2.5)		
	Excellent	Baseline	1.9 (±2.1)	-1.8	0.017*
		3rd visit	0.1 (±0.3)		
Skindex-16(%)	Deterioration	Baseline	20.4 (±15.4)	8.6	0.006*
		3rd visit	29.0 (±19.9)		
	No response	Baseline	17.3 (±12.0)	4.6	<0.001*
		3rd visit	21.9 (±14.2)		
	Mild	Baseline	27.1 (±16.3)	1.9	0.169
		3rd visit	28.9 (±19.1)		
	Moderate	Baseline	17.4 (±11.9)	-0.7	0.52
		3rd visit	16.7 (±11.9)		
	Good	Baseline	19.3 (±9.8)	-5.6	0.003*
		3rd visit	13.6 (±5.8)		
	Excellent	Baseline	12.7 (±7.1)	-11.3	0.002*
		3rd visit	1.4 (±2.4)		
VIS-22	Deterioration	Baseline	16.0 (±7.8)	8.6	0.008*
		3rd visit	24.6 (±11.3)		
	No response	Baseline	16.2 (±7.0)	4.7	<0.001*
		3rd visit	20.9 (±7.6)		
	Mild	Baseline	22.2 (±13.3)	1.6	0.074
		3rd visit	23.8 (±14.1)		
	Moderate	Baseline	18.2 (±8.3)	-0.1	0.899
		3rd visit	18.1 (±9.4)		
	Good	Baseline	16.9 (±7.0)	-5.2	<0.001*
		3rd visit	11.7 (±4.1)		
	Excellent	Baseline	11.2 (±6.0)	-8.3	0.004*
		3rd visit	2.9 (±2.3)		

Note: *significant at p<0.005

Criterion validity

The mean (±SD) scores at the first visit for the VAS, DLQI, Skindex-16 and VIS-22 were 5.1 (±2.5), 5.6 (±4.6), 22.07 (±14.0) and 19.1 (±10.8) respectively. The VAS [correlation co efficient (r) = 0.676, p value <0.001] showed moderate correlation with VIS-22. The DLQI showed strong correlation (r = 0.752, p value <0.001), and Skindex-16 showed strongest correlation (r = 0.832, p value<0.001) with VIS-22. Similar strength of correlation were found between the scales at week 12.

Convergent validity

The VIS-22 showed strong correlation with DLQI and Skindex-16 (p < 0.001). The total scores of VIS-22 showed poor correlation with the symptom domain of Skindex-16 (r = 0.462), while showed strong correlation with emotion and social functioning domains (r = 0.713 and 0.702 respectively) at baseline. At week 12, moderate correlation was found with symptom domain (r = 0.613) and strong correlation with emotion and social functioning domain (r = 0.770 and 0.789 respectively). The correlation between the VAS, DLQI, Skindex-16 and VIS-22 at baseline and at week 12 has been presented in Table 13 and 14 respectively.

Table 13: The correlation between the VAS, DLQI, Skindex-16 and VIS-22 at baseline

Group	Scales	VAS	DLQI	Skindex-16 (%)	VIS-22	Skindex-16 (%)		
						S	E	F
Cases	VAS	1	.604**	.719**	.676**	.324**	.747**	.456**
	DLQI	.604**	1	.771**	.752**	.683**	.572**	.725**
	Skindex-16 (%)	.719**	.771**	1	.832**	.626**	.890**	.780**
	VIS-22	.676**	.752**	.832**	1	.462**	.713**	.702**
Controls	VAS	1	.450**	.486**	.266**	.547**	.421**	.160*
	DLQI	.450**	1	.847**	.560**	.574**	.707**	.690**
	Skindex-16 (%)	.486**	.847**	1	.732**	.659**	.861**	.792**
	VIS-22	.266**	.560**	.732**	1	.209**	.768**	.691**

Note:** Correlation is significant at the 1% level (2-tailed), * Correlation is significant at the 5% level (2-tailed)

Table 14: The correlation between the VAS, DLQI, Skindex-16 and VIS-22 at week 12

Group	Scales	VAS	DLQI	Skindex-16 (%)	VIS-22	Skindex-16 (%)		
						S	E	F
Cases	VAS	1	.710**	.807**	.783**	.403**	.820**	.601**
	DLQI	.710**	1	.883**	.806**	.834**	.660**	.890**
	Skindex-16 (%)	.807**	.883**	1	.876**	.726**	.889**	.880**
	VIS-22	.783**	.806**	.876**	1	.613**	.770**	.789**
Controls	VAS	1	.608**	.778**	0.141	.834**	.551**	.353**
	DLQI	.608**	1	.787**	.321**	.659**	.715**	.646**
	Skindex-16 (%)	.778**	.787**	1	0.172	.942**	.885**	.487**
	VIS-22	0.141	.321**	0.172	1	0.117	.219*	0.071

Note:** Correlation is significant at the 1% level (2-tailed), * Correlation is significant at the 5% level (2-tailed)

Test re-test reliability

The scores of VAS, DLQI, Skindex-16(%), and VIS-22 at baseline and second visit showed a strong correlation ($r=0.954$ and $p < 0.001$). Thus indicating that all the four scales are reliable at 2 week interval. The correlation of test re-test reliability of the scores are presented in Table 15.

Table 15: Correlation of test re-test reliability

Scales	Baseline Mean (±SD)	Week 2 Mean (±SD)	Paired correlation (baseline and week2)	p value
VAS	5.0 (±2.5)	5.1 (±2.6)	0.955	<0.001*
DLQI	5.5 (±4.7)	5.6 (±5.0)	0.974	<0.001*
Skindex-16	21.3 (±13.8)	22.5 (±15.0)	0.93	<0.001*
VIS-22	18.3 (±10.1)	18.5 (±9.1)	0.957	<0.001*

Note: *significant at p<0.001

DISCUSSION

Vitiligo is known to cause a great psychosocial impact on its patients and it is particularly more distressing among South East Asian population. Indians are particularly susceptible to this vitiligo-related morbidity due to their darker skin tone which gives a strong contrast.[4,6] It is associated with an enormous social stigma, psychological distress and affects the interpersonal relationships.[5] The physical appearance of a sufferer of vitiligo can affect self image grossly.[8]

It has been observed that there is a marked reduction in the QOL of the patients suffering from vitiligo.[4] However, the degree of impairment of QOL in vitiligo patients does not depend on the extent of involvement.[7,12] Impairment of QOL in patients suffering from vitiligo has been extensively studied. There are various scales available for this purpose, such as, general health measures and skin disease specific questionnaires.[9] Some vitiligo specific scales are also available for this purpose like VLQI, VitiQol, VIS.[4]

VIS-22 is a recently developed vitiligo specific scale that has been found to be effective to assess the QOL in patients with vitiligo and was validated among a group of North Indian patients.[4] The effect of vitiligo on QOL in patients may vary depending upon the region, locality, population, social status, level of education and existing beliefs and taboos. In this study, we have evaluated the validity, test-retest reliability and responsiveness of VIS-22 among South Indian population suffering from vitiligo attending a tertiary health care centre in North Karnataka.

In the present study the males to female ratio was 1:1.1. There was no statistical significance in the gender distribution of vitiligo. The mean (±SD) age of study population was 31.24 (±15.0) years. In the study by Gupta *et al*, the male to female ratio was 1.5:1 and the mean (±SD) age of vitiligo patients were 29.80 (±10.67).[4]

It was observed that the emotional status of Skindex-16 scale was the most affected domain among vitiligo patients (38.2%) followed by social functioning (11.3%) and symptoms (6.0%) whereas symptoms domain was most affected among controls (20.66%).

The mean (±SD) DLQI scores among vitiligo patients was 5.6 (±4.6) showing a moderate effect on QOL of vitiligo patients and is comparable to the results from earlier studies. The present study the mean (±SD) scores of DLQI, Skindex-16 and VIS-22 are 5.6 (±4.6), 22.0 (±14.0) and 19.1 (±10.8) respectively. In the study by Gupta *et al* [4], the mean (±SD) scores of DLQI, Skindex-16 and VIS-22 were 8.25(±6.93), 31.98 (±23.11) and 26.50 (±14.47).

The criterion validity showed a strong correlation of VIS-22 with Skindex-16 ($r = 0.832$, $p < 0.001$), followed by DLQI ($r = 0.752$, $p < 0.001$) and a moderate correlation was found with VAS ($r = 0.676$, p value <0.001) at baseline. Similar results were noticed at 12th week. The results were comparable to Gupta *et al* where VIS-22 showed a strong correlation with Skindex-16 ($r = 0.761$, $p < 0.001$) and VAS ($r = 0.7076$, $p < 0.001$) and a moderate correlation with DLQI ($r = 0.5889$, $p < 0.001$).

The convergent validity in the present study is evident by a strong correlation of VIS-22 with DLQI and Skindex-16 ($p < 0.001$). The total scores of VIS-22 showed poor correlation with the symptom domain of Skindex-16 ($r = 0.462$), while showed strong correlation with emotion and social functioning domains ($r = 0.713$ and 0.702 respectively) at baseline. At week 12, moderate correlation was found with symptom domain ($r = 0.613$) and strong correlation with emotion and social functioning domain ($r = 0.770$ and 0.789 respectively).

Similar results were found in the study by Gupta *at al* where the convergent validity was evident by strong correlation of VIS-22 with DLQI and Skindex-16 ($p < 0.001$). The

total scores of VIS-22 showed poor correlation with symptom domain of Skindex-16 (r= 0.36), while showed a moderate to strong correlation with emotion and social functioning domains (r = 0.63 and 0.74 respectively). Similar results were noted between baseline and at 12^{th} week.

In the present study a statistically significant difference ($p < 0.001$) was found in mean (±SD) VIS-22 scores of cases 19.1 (±10.8) and controls 6.8 (±7.0). Similar results were noted by Gupta *et al* where the VIS-22 scores were significantly high compared to controls. The test – retest reliability of VAS (r = 0.955), DLQI (r = 0.974) , Skindex-16 (r = 0.93), and VIS-22 (r = 0.957) at baseline and second visit showed a strong correlation ($p < 0.001$) which was comparable to the study results of Gupta *et al* with a high reliability of 0.9053 for VIS-22 followed by DLQI (r = 0.8242) and Skindex-16 (r = 0.7166).

In this study VIS-22 showed a significantly higher scores in clinical non responders (mean change = 4.7, $p < 0.001$) similar to Gupta *et al* which also showed a significant high scores (mean change = 10.412, p = 0.01). In this study Skindex-16 also showed a significant higher scores (mean change = 4.6, $p < 0001$) in clinical non responders whereas DLQI showed a minor difference (mean change =0.6, p = 0.016) and it was not statistically significant. However in the study by Gupta *et al* DLQI showed a significant difference (mean change = 3.391, p=0.01) whereas the difference of Skindex-16 was not statistically significant (mean change = 5.476, p=0.27) in clinical non responders.

From the above discussion it is evident that VIS-22 is a valid, reliable and a responsive instrument for measurement of QOL in patients with vitiligo. It was established from the study results of Gupta *et al* among a group of North Indian patients with vitiligo. This finding has been validated in this study results among a group of South Indian patients indicating efficacy of VIS-22 in determining QOL among those patients from varied

background. However, this require further validation in other parts of India and other countries among different population of vitiligo patients to label it as universally effective QOL determinant in patients with vitiligo.

CONCLUSION

Vitiligo is known to cause a marked reduction of the quality of life among its sufferers. It causes emotional, social and occupational impact upon affected patients. Psychological upsets are frequent among these patients.

Measurement of QOL helps a clinician to assess the effect of a disease upon various aspects of a patient's life; such as social, psychological, physical and occupational, in a standardized and quantitative way. Moreover it helps in recognition of psychological and functional limitations in a given patient; decision of treatment and hence, improving the physician patient relationship.

Vitiligo specific scales are available for this purpose with an added advantage of having disease specific questions. Vitiligo impact scale – 22 is a recently developed vitiligo specific QOL measurement scale which has been found to be effective to assess the QOL in patients with vitiligo.

A strong correlation was established between VIS-22, Skindex-16 ($r = 0.832$), DLQI ($r = 0.72$) and VAS ($r = 0.676$). The scores of VIS-22 was significantly higher in patients with vitiligo compared to controls. Significant high validity, reliability and responsiveness ($p < 0.001$) of VIS-22 was evidenced in the study. Similar trends were noted with DLQI and Skindex-16 in its measurement properties, while being specific to the needs of patients with vitiligo.

The results of this study establish that " Vitiligo Impact Scale -22 " is a valid, reliable and responsive quality of life measurement instrument. However studies in other cultures and countries are required to accept the scale as an international standard vitiligo specific scale. Although the sample size in the present study was adequate to assess and validate the scale a larger sample size will be helpful in assessing the interpretability of the scores.

SUMMARY

A hospital based prospective study to validate vitiligo impact scale-22 at a tertiary care hospital in North Karnataka was conducted between November 2015 to May 2017. All patients aged more than 15 years and an educational qualification of at least secondary level were taken into the study. Patients suffering from vitiligo were taken as cases and those suffering from other short term skin diseases were taken as controls. The patients were asked to respond to VAS, DLQI, Skindex-16 and VIS-22 scales on first visit, week 2 and week12.

Following are the salient observations of the study:

- The mean (± SD) of VAS score among vitiligo patients were 5.1 (±2.5) on first (week 0), 5.1 (±2.6) on second (week2) and 4.34 (± 2.8) on third visit (week 12).
- The mean (±SD) of DLQI score among vitiligo patients were 5.6 (±4.6) on first, 5.6 (±5.0) on second and 5.3 (±5.3) on third visit.
- The mean (± SD) of Skindex-16 (%) score among vitiligo patients were 22.0 (±14.0) on first, 22.5 (±15.0) on second and 21.3 (±16.8) on third visit.
- The emotional status was most affected Skindex-16(%) domain among vitiligo patients (38.2%) followed by social functioning (11.3%). Least affected was the symptoms domain (6%) among the vitiligo patients.
- The mean (± SD) of VIS-22 score among vitiligo patients were 19.1 (±10.8) on first, 18.5 (±9.1) on second and 18.8 (±11.9) on third visit.
- Among 153 patients with vitiligo, 91 (73.4%) showed improvement of their skin lesions, where as 27 (21.0%) showed no clinical response i.e no clinically significant change. Seven (5.6%) patients had worsening of their skin lesions.

- Among the 91 patients who showed clinical improvement in their disease, 45 (49.5%) patients showed mild improvement, 15 (16.5%) showed moderate improvement, 22 (24.2%) showed good improvement and 9 (9.9%) showed excellent improvement.
- All the scales showed very good test re-test reliability.
- A statistically significant correlation was found ($p< 0.001$) between scores of each individual scale at baseline and third visit in relation to changes in disease status (either worsening of disease status or clinically good/excellent therapeutic response).
- The VAS ($r = 0.676$, p value <0.001) showed moderate correlation with VIS-22 at first visit. Similarly, the DLQI showed strong correlation ($r = 0.752$, p value <0.001), and Skindex-16 showed strongest correlation ($r = 0.832$, p value<0.001) with VIS-22. A similar strength of correlation were found between the scales at week 12.
- The total scores of VIS-22 showed poor correlation with the symptom domain of Skindex-16 ($r = 0.462$), while showed strong correlation with emotion and social functioning domains ($r = 0.713$ and 0.702 respectively) at baseline.
- At week 12, moderate correlation was found with symptom domain ($r = 0.613$) and strong correlation with emotion and social functioning domain ($r = 0.770$ and 0.789 respectively).

BIBLIOGRAPHY

1) Geel NV, Speeckaert R. Acquired pigmentary disorders. In: Griffiths CEM, Barker J, Bleiker T, Chalmers R, Creamer D, editors. Rook's textbook of dermatology, 9th edn. Oxford: Willey Blackwell: 2016.p-88.34-88.40.
2) Garg S, Sarkar R. Impact of vitiligo in afflicted patients. Pigment Int 2014;1: 81-89.
3) Prasad D, Kumaran SM. Depigmentary and hypopigmentary disorders. In: Sacchidanand S, Oberai C, Inamadar AC, editors. IADVL Textbook of dermatology, 4th edn. Mumbai: Bhalani Publishing Home; 2015. p -1308 – 1322.
4) Gupta V, Sreenivas V, Mehta M, Khaitan BK, Ramam M. Measurement properties of the Vitiligo Impact Scale-22 (VIS-22), a vitiligo-specific quality-of-life instrument. Br J Dermatol 2014; 171: 1084–1090.
5) Homan MWL, Spuls PI, de Korte J, Bos JD, Sprangers MA, van der Veen JP. The burden of vitiligo: patient characteristics associated with quality of life. J Am Acad Dermatol 2009; 61: 411-420.
6) Pahwa P, Mehta M, Khaitan BK, Sharma VK, Ramam M. The psychosocial impact of vitiligo in Indian patients. Indian J Dermatol Venereol Leprol 2013; 79: 679-85.
7) Ongenae K, Beelaert L, Geel NV, Naeyaert. Psychological effects of vitiligo. J Eur Acad Dermatol Venereol 2006; 20-1-8.
8) Parsad D, Dogra S, Kanwar AJ. Quality of life in patients with vitiligo. Health Qual Life Outcomes 2003; 1: 58.
9) Krishna GS, Ramam M, Mehta M, Sreenivas V, Sharma VK, Khandpur S. Vitiligo impact scale: An instrument to assess the psychosocial burden of vitiligo. Indian J Dermatol Venereol Leprol 2013; 79: 205-210.

10) Sangma LN, Nath J, Bhagabati D. Quality of life and psychological morbidity in vitiligo patients: A study in a teaching hospital from north-east India. Indian J Dermatol 2015; 60: 142-146.

11) Birlea SA, Spritz RA, Norris DA. Vitiligo. In: Goldsmith LA, Katz SI, Gilchrest BA, Paller AS, Leffell DJ, Wolff K, editors. Fitzpatrick's dermatology in general medicine, 8th edn. New York: Mc Graw Hill; 2012. p – 792 - 803.

12) Osman AM, Elkordufani Y, Abdullah MA. The psychological impact of vitiligo in adult Sudanese patients. Afr J Psychiatry 2009; 12: 284-286.

13) Mashayekhi V, Javidi Z, Kaifar B, Manteghi AA, Saasatian V, Esmaeili AH, *et al*. Quality of life in patients with vitiligo: A descriptive study on 83 patients attending PUVA therapy unit in Imam Reza hospital, Mashad. Indian J Dermatol Venereol Leprol 2010; 76: 592-593.

14) Choi S, Kim DY, Whang SH, Lee JH, Hann SK, Shin YJ. Quality of life and psychological adaptation on Korean adolescents with vitiligo. J Eur Acad Dermatol Venereol 2010; 24: 524-529.

15) Premkumar R, Kar B, Rajan P, Richard J. Major precipitating factors for stigma among stigmatized vitiligo and psoriasis patients in brown – black skin shades. Indian J Dermatol Venereol Leprol 2013; 79: 703-705.

16) Kent G, Abadie MA. Psychologic effects of vitiligo: A critical incident analysis. J Am Acad Dermatol 1996; 35: 895-898.

17) Mitrevska NT, Eleftheriadout V, Guarneri F. Quality of life in vitiligo patients. Dermatol Ther 2012; 25: S28-S31.

18) Mattoo SK, Handa S, Kaur I, Gupta N, Malhotra R. Psychiatric morbidity in vitiligo and psoriasis: a comparative study from India. J Dermatol 2001; 28: 424-432.

19) Parsad D, Pandhi R, Dogra S, Kanwar AJ, Kumar B. Dermatology quality of life index score in vitiligo and its impact on treatment outcome. Br J Dermatol 2003; 148: 373-374.

20) Radtke MA, Schafer I, Gajur A, Lagenbruch A, Augustin M. Willingness to pay and quality of life in patients with vitiligo 2009; 161: 134-139.

21) Talsania N, Lamb B, Bewley A. Vitiligo is more than skin deep: a survey of the members of the vitiligo society. Clin Exp Dermatol 2009; 35: 736-739.

22) Ramam M, Krishna G. Measuring severity of vitiligo. Indian J Dermatol Venereol Leprol 2012; 78: 5-7.

23) Firooz A, Bouzari N, Fallah N, Ghazisaidi B, Firoozabadi MR, Dowlati Y. What patients with vitiligo believe about their condition. Int J Dermatol 2004; 43: 811-814.

24) Wang KY, Wang KH, Zhang ZP. Health-related quality of life and marital quality of vitiligo patients in China. J Eur Acad Dermatol Venereol 2011; 25: 429-435.

25) Pichaimuthu R, Ramaswamy P, Kar B, Joseph R. A measurement of the stigma among vitiligo and psoriasis patients in India. Indian J Dermatol Venereol Leprol 2011; 77: 300-306.

26) Balaban OD, Atagun MI, Ozguven HD, Ozsan HH. Psychiatric morbidity in patients with vitiligo. Duden Adam J Psychiatr Neurosci 2011; 24: 306-313.

27) Homan LMW, Korte JD, Grootenhuis MA, Bos JD, Sprangers MAG. Impact of childhood vitiligo on adult life. Br J Dermatol 2008; 159: 915-920.

28) Thompson AR, Kent G, Smith JA. Living with vitiligo: dealing with difference. Br J Health Psychol 2002; 7: 213-225.

29) Dolatshahi M, Ghazi P, Fiezy V, Hemami MR. Life quality assessment among patients with vitiligo: comparison of married and single patients in Iran. Indian J Dermatol Venereol Leprol 2008; 74: 700.

30) Schmid-Ott G, Kunsebeck HW, Jecht E, Shimshoni R, Lazaroff I, Schallmayer S *et al*. Stigmatization experience, coping and sense of coherence in vitiligo patients. J Eur Acad Dermatol Venereol 2007; 21: 456-461.

31) Finaly AY. Quality of life indices. Indian J Dermatol Venereol Leprol 2004; 70: 143-148.

32) Senol A, Yucelten AD, Ay P. Development of a quality of life scale for vitiligo. Dermatol 2013; 226: 185-190.

33) Reich A, Heisig M, Phan NQ, Taneda K, Takamori K, Takeuchi S, *et al*. Visual analogue scale: evaluation instrument for the measurement of pruritus. Acta Derm Venereol 2012; 92: 497-501.

34) Mattoo SK, Handa S, Kaur I, Gupta N, Malhotra R. Psychiatric morbidity in vitiligo: prevalence and correlates in India. J Eur Acad Dermatol Venereol 2002; 16: 573 – 578.

35) Sampogna F, Raskovic D, Guerra L, Pedicelli C, Tabolli S, Leoni L, *et al*. Identification of categories at risk for high quality of life impairment in patients with vitiligo. Br J Dermatol 2008; 159: 351-359.

36) Abolfotouh MA, Al-Khowailed MS, Suliman WE, Al-Turaif DA, Al-Bluwi E, Al-Kahtani HS. Quality of life in patients with skin diseases in central Saudi Arabia. Int J Gen Med 2012; 5: 633-642.

37) Amer AAA, Gao XH. Quality of life in patients with vitiligo: an analysis of the dermatology life quality index outcome over the past two decades. Int J Dermatol 2016; 55: 608-614.

38) Ongenae K, Geel NV, De Schepper S, Naeyaert JM. Effect of vitiligo on self-reported health-related quality of life. Br J Dermatol 2005; 152: 1165-1172.

39) Kent G, Al-Abadie M. Factors affecting responses on dermatology life quality index items among vitiligo sufferers. Clin Exp Dermatol 1996; 21:330-333.

40) Kiprono S, Chaula B, Makwaya C, Naafs B, Masenga J. Qulity of life of patients with vitiligo attending the regional dermatology training center in North Tanzania. Int J Dermatol 2013; 52: 191-194.

41) Lilly E, Lu PD, Borovicka JH, Victorson D, Kwasny MJ, West DP. Development and validation of a vitiligo-specific quality-of-life instrument (VitiQoL). J Am Acad Dermatol 2013; 69: e11-18.

42) Hedayat K, Karbaksh M, Ghaisi M, Goodarzi A, Fakour Y, Akbari Zahara, *et al*. Quality of life in patients with vitiligo: a cross-sectional study based on vitiligo quality of life index (VitiQoL). Health Qual Life Outcomes 2016; 14:86.

ANNEXURES

B.L.D.E.UNIVERSITY'S
SHRI.B.M.PATIL MEDICAL COLLEGE, BIJAPUR – 586103

NO|60|2016
24|8|16

INSTITUTIONAL ETHICAL COMMITTEE

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this college met on 30-6-2016 *at* 11: am *scrutinize the Synopsis of Postgraduate Students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has accorded Ethical Clearance.*

Title A Hospital-based validation of Vitiligo impact scale-22 in a tertiary care hospital North Karnataka.

Name of P.G. Student : Dr. Anusha. S.

Name of Guide/Co-investigator': Dr. Aparna Palit.
Professor, Dept. of Dermitology.

DR.TEJASWINI VALLABHA
CHAIRMAN

Following documents were placed before E.C. for Scrutinization
1)Copy of Synopsis/Research Project
2)Copy of informed consent form.
3)Any other relevant documents.

Institutional Ethical Committee
BLDEU's Shri B.M. Patil
Medical College,BIJAPUR-586103.

PROFORMA

SCHEME OF CASE TAKING

B.L.D.E.U'S SHRI B. M. PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE, BIJAPUR.

Department of Dermatology, Venereology and Leprosy.

Name: SL NO:

Age: Date:

Sex: IP NO/ OP NO:

Address:

Occupation:

Education Status:

Marital Status:

1. Chief complaints:
2. Age of onset:
3. Site of onset:
4. Progressive/Non progressive:
5. H/O kobnerization:
6. Spontaneous/Drug induced;
7. H/O Handling chemicals:
8. Family history:
9. Treatment history:

10. Repigmentation: Spontaneous/ Following treatment

11. Type of Repigmentation:

- Perifollicular :
- Marginal :
- Diffuse :

12. H/O Itching:

13. H/O Other autoimmune diseases: Personal/Family

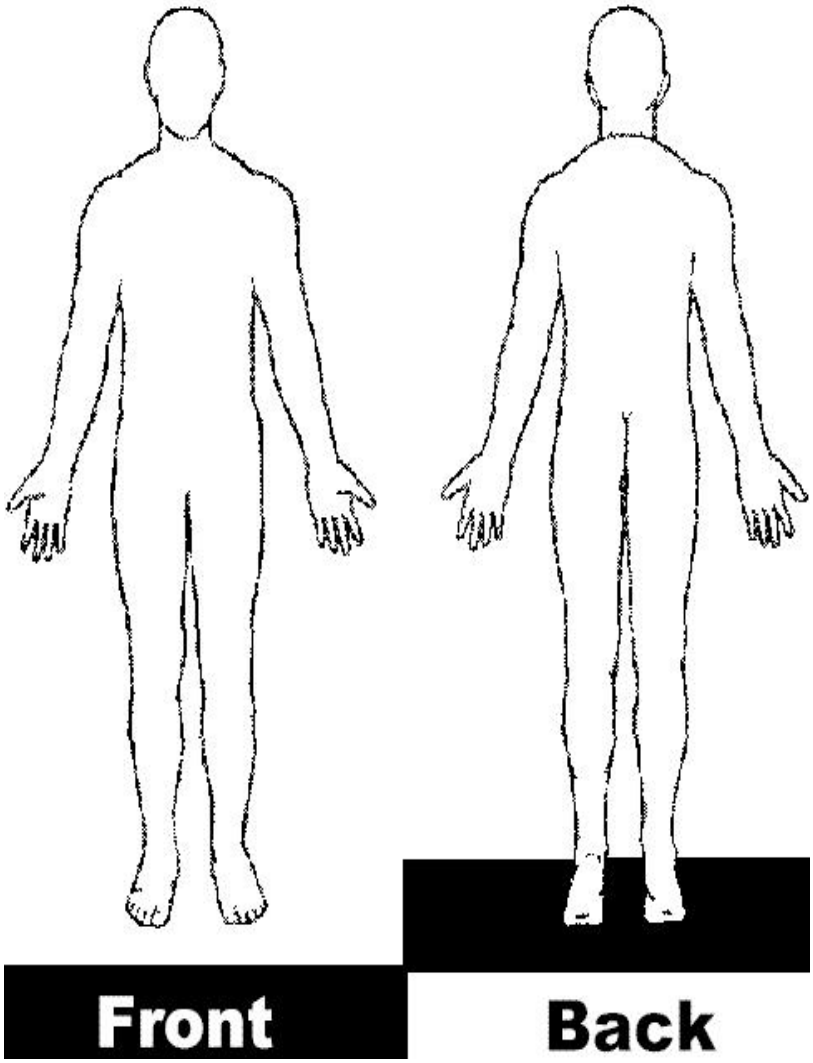
- Diabetes mellitus:
- Pernicious anemia:
- Thyroid disorders:

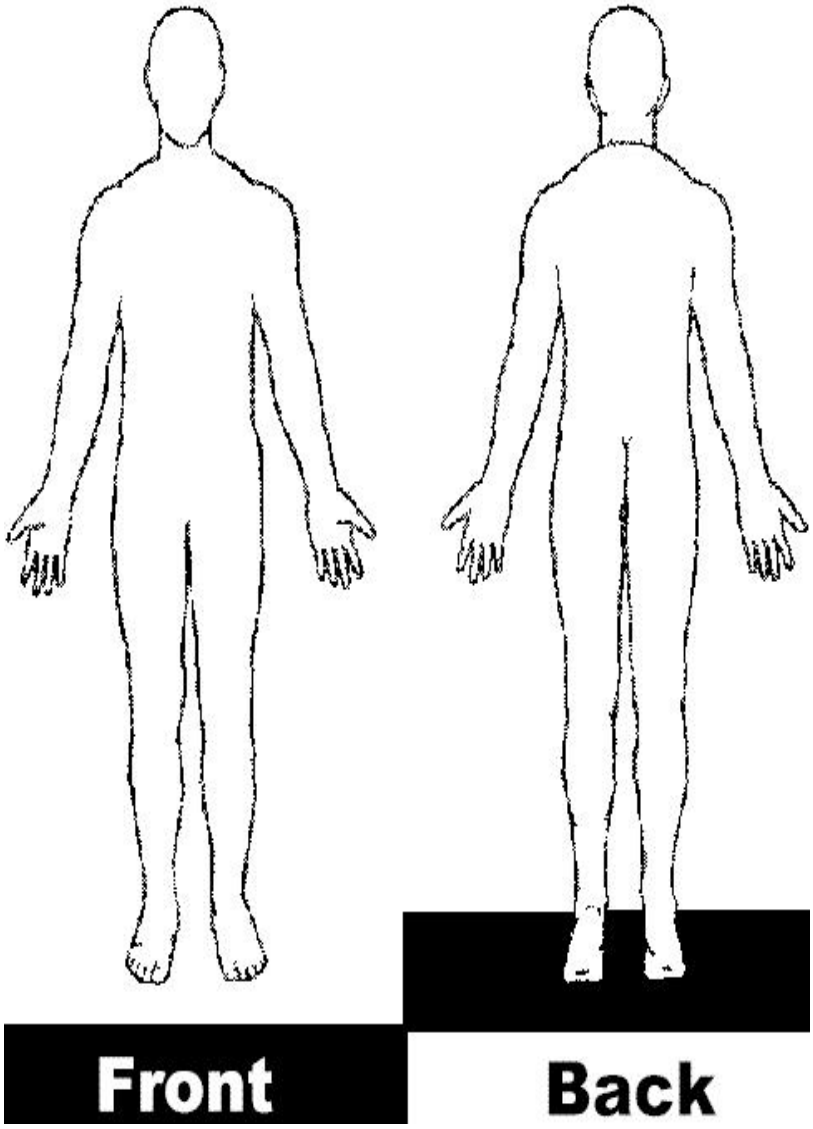
14. H/O Atopy:

General Physical Examination:

Weight:	BP:	Pulse rate:
Pallor:	Cyanosis:	Icterus:
Clubbing:	Lymphadenopathy:	Edema:

Cutaneous Examination:

	First visit
Body surface area	
Site	
No of lesions	2-5/ 5-10/ >10
Type of lesion	
Koebner's phenomenon(+/-)	
Evidence of repigmentation	
Type of repigmentation	

	Follow up at 12th week
Body surface area	
Site	
No of lesions	2-5/ 5-10/ >10
Type of lesion	
Koebner's phenomenon(+/-)	
Evidence of repigmentation	
Type of repigmentation	

Systemic Examination

Cardiovascular system :

Respiratory system :

Central nervous system :

Abdominal examination :

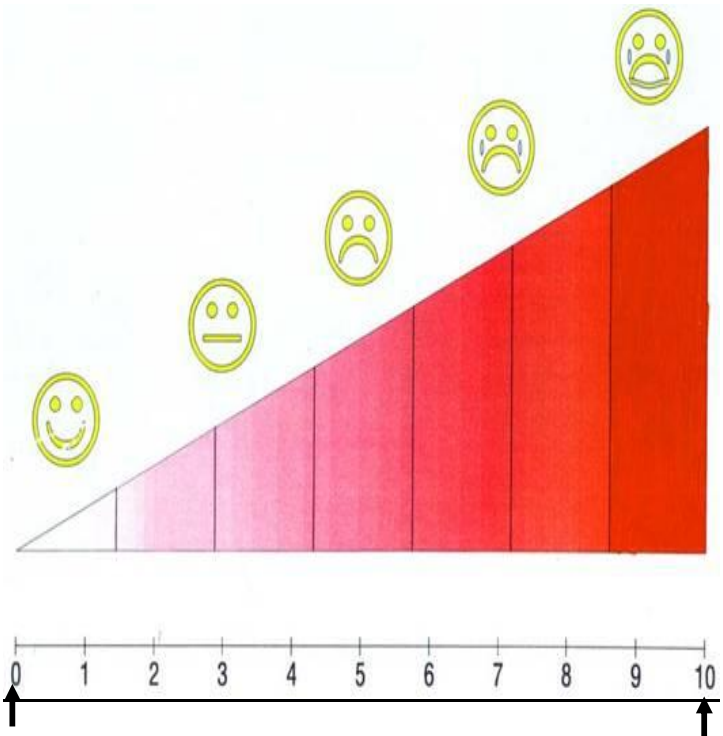
Diagnosis:

B.L.D.E.U'S SHRI B. M. PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE, BIJAPUR.

Department of Dermatology, Venereology and Leprosy.

QOL Assessment Scales In Vitiligo

Visual Analogue Scale



Dermatology Life Quality Index

Sl No.	Questions	0	1	2	3
1.	Over the last week, how itchy, sore, painful or stinging has your skin been?				
2.	Over the last week, how embarrassed or self-conscious have you been because of your skin?				
3.	Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden?				
4.	Over the last week, how much has your skin influenced the clothes you wear?				
5.	Over the last week, how much of your skin affected any social or leisure activities?				
6.	Over the last week, how much has your skin made it difficult for you to do any sport?				
7.	Over the last week, has your skin prevented you from working or studying? If 'No', over the last week how much has your skin been a problem at work or studying?				
8.	Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives?				
9.	Over the last week, how much has your skin caused any sexual difficulties?				
10.	Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up your time?				

Skindex-16

Name: Sex: Education:

Age: Occupation: Score:

These questions concern skin condition which has bothered you the most during the past week.

During the past week, how often have you been bothered by:

Sl No.		0 (Never Bothered)	1	2	3	4	5	6 (Always Bothered)
1	Your skin condition **itching**							
2	Your skin condition **burning or stinging**							
3	Your skin condition **hurting**							
4	Your skin condition **being irritated**							
5	The **persistence / reoccurence** of your skin condition							
6	**Worry** about your skin condition (eg: that it will spread, get worse, scar, be unpredictable, etc)							
7	The **appearance** of your skin condition							
8	**Frustration** about your skin condition							
9	**Embarrassment** about your skin condition							
10	**Being annoyed** about your skin condition							
11	**Feeling depressed** about your skin condition							
12	The effects of your skin condition on your **interactions with others** (eg: interactions with family, friends, close relationships, etc)							
13	The effect of your skin condition on your **desire to be with people**							
14	Your skin condition making it hard to **show affection**							
15	The effects of your skin condition on your **daily activities**							
16	Your skin condition is making it hard to **work or do what you enjoy**							

Please check you have answered **EVERY** question. Thank you.

Vitiligo Impact Scale-22 (VIS-22)

Name- Sex- Education-

Age- Occupation- Score-

Scoring: 0-Not at all 1-A little 2-A lot 3-Very much

		0	1	2	3
1	Do you think this disease in incurable				
2	Do you change your doctor				
3	Do suggestions and advice from others about the disease bother you				
4	Do other people feel that this disease spreads by touch				
5	Do you have problems in wearing your choice of clothes				
6	Do you feel helpless				
7	Do you face difficulties in adhering to the treatment				
8	Do your parents keep asking you to seek treatment				
9	Do you feel life is not worth living with this disease				
10	Do you feel depressed				
11	Do you keep thinking about this disease				
12	Have you stopped/reduced going to parties/get-togethers				
13	Do your friends/relatives avoid you				
14	Do you think about bringing your life to an end				
15	Do you observe any kind of dietary restriction				
16	Does the amount of money you have spent on the treatment bother you				
17	Do you believe that this is the worst disease anyone can have				
18	Do you get embarrassed when meeting people				
19	How worried will you be if you develop new lesions				

If you are married, please answer the following question

20	Do your in-laws worry about your white patches				

If you are unmarried, please answer the following question

20	Are you facing problems in getting married				

If you are working, please answer the following questions

21	Do your colleagues treat you differently because of the disease				

If you are studying, please answer the following questions

22	Do your classmates treat you differently because of the disease				

ಈ ಕೆಳಗಿನ ಪ್ರಶ್ನೆಗಳು ಬಿಳುಪಿನ ರೋಗವು ನಿಮ್ಮ ಜೀವನದ ಮೇಲೆ ಮಾಡುತ್ತಿರುವ ಪರಿಣಾಮಗಳನ್ನು ಅಳೆಯುತ್ತದೆ. ದಯವಿಟ್ಟು ಪ್ರತಿಯೊಂದು ಪ್ರಶ್ನೆಯನ್ನು ಜಾಗರೂಕತೆಯಿಂದ ಓದಿ ನಿಮ್ಮ ತಿಳುವಳಿಕೆಗೆ ತಕ್ಕಂತೆ ಉತ್ತರಿಸಿ

ಹೆಸರು: ಲಿಂಗ: ವಿದ್ಯಾಭ್ಯಾಸ:

ವಯಸ್ಸು: ಉದ್ಯೋಗ: ಅಂಕ:

ಅಂಕಗಳು: ೦ – ಏನೂ ಇಲ್ಲ, ೧ – ಸ್ವಲ್ಪ, ೨ – ಜಾಸ್ತಿ, ೩ – ಬಹಳ ಜಾಸ್ತಿ

	೦	೧	೨	೩
೧. ನಿಮಗೆ ಈ ರೋಗವು ಗುಣವಾಗುವುದಿಲ್ಲ ಎಂದು ಅನಿಸುತ್ತದೆಯೇ?				
೨. ನೀವು ನಿಮ್ಮ ವೈದ್ಯರನ್ನು ಬದಲಾಯಿಸುತ್ತೀರಾ?				
೩. ಈ ರೋಗದ ಬಗ್ಗೆ ಬೇರೆಯವರ ಅನಿಸಿಕೆ, ಸಲಹೆ ಸೂಚನೆ ಮತ್ತು ಕಿವಿಮಾತು ನಿಮ್ಮ ಮೇಲೆ ಏನಾದರೂ ಪರಿಣಾಮ ಬೀರುತ್ತದೆಯೇ?				
೪. ಈ ರೋಗವು ಸ್ಪರ್ಶದಿಂದ ಹರಡುತ್ತದೆಯೆಂದು ಬೇರೆ ಜನರಿಗೆ ಅನಿಸುತ್ತದೆಯೇ?				
೫. ನಿಮಗೆ ಇಷ್ಟವಾದ ಬಟ್ಟೆಬರೆಗಳನ್ನು ತೊಡುವುದರಲ್ಲಿ ತೊಂದರೆಯಾಗುತ್ತಿದೆಯೇ?				
೬. ನೀವು ಅಸಹಾಯಕರೆಂದು ನಿಮಗೆ ಅನಿಸುತ್ತದೆಯೇ?				
೭. ನಿಮಗೆ ಚಿಕಿತ್ಸೆಯನ್ನು ಪಾಲಿಸಲು ಕಷ್ಟವಾಗುತ್ತದೆಯೇ?				
೮. ನಿಮ್ಮ ಪೋಷಕರು ಚಿಕಿತ್ಸೆ ಮಾಡಿಸಿಕೊಳ್ಳಲು ನಿಮಗೆ ಹೇಳುತ್ತಿರುತ್ತಾರೆಯೇ?				
೯. ಈ ರೋಗದ ಜೊತೆ ಜೀವನ ನಡೆಸುವುದು ಸಾರ್ಥಕವಲ್ಲ ಎಂದು ಅನಿಸುತ್ತದೆಯೇ?				
೧೦. ನಿಮಗೆ ಖಿನ್ನತೆ ಉಂಟಾಗುತ್ತಿದೆಯೇ?				
೧೧. ನೀವು ರೋಗದ ಬಗ್ಗೆ ಯೋಚನೆ ಮಾಡುತ್ತಾ ಇರುತ್ತೀರಾ?				
೧೨. ನೀವು ಸಭೆ ಸಮಾರಂಭಗಳಿಗೆ ಹೋಗುವುದನ್ನು ಕಡಿಮೆ ಮಾಡಿದ್ದೀರಾ/ನಿಲ್ಲಿಸಿದ್ದೀರಾ?				
೧೩. ನಿಮ್ಮ ಸ್ನೇಹಿತರು/ಸಂಬಂಧಿಕರು ನಿಮ್ಮಿಂದ ದೂರ ಇರಲು ಪ್ರಯತ್ನಿಸುತ್ತಿದ್ದಾರೆಯೇ?				
೧೪. ನೀವು ನಿಮ್ಮ ಜೀವನವನ್ನು ಕೊನೆಗಾಣಿಸಲು ಯೋಚಿಸುತ್ತೀರಾ?				
೧೫. ನೀವು ಆಹಾರಸೇವನೆಯಲ್ಲಿ ಪಥ್ಯವನ್ನು ಪಾಲಿಸುತ್ತೀರಾ?				
೧೬. ಈ ರೋಗದ ಚಿಕಿತ್ಸೆಯ ಸಲುವಾಗಿ ಖರ್ಚು ಮಾಡಿರುವ ಹಣದ ಮೊತ್ತದ ಬಗ್ಗೆ ನಿಮಗೆ ಚಿಂತೆಯುಂಟಾಗುತ್ತದೆಯೇ?				
೧೭. ನೀವು ಈ ರೋಗವು ಯಾರಿಗಾದರೂ ಬರಬಹುದಾದ ಹೀನವಾದ ರೋಗವೆಂದು ನಂಬುತ್ತೀರಾ?				
೧೮. ನಿಮಗೆ ಯಾರನ್ನಾದರೂ ಭೇಟಿಯಾಗುವುದರಲ್ಲಿ ಮುಜುಗರ				

	೦	೧	೨	೩
ಎನಿಸುತ್ತದೆಯೇ?				
೧೯. ನೀವು ರೋಗದ ಹೊಸ ಲಕ್ಷಣಗಳು ಕಾಣಿಸಿಕೊಂಡಲ್ಲಿ ಚಿಂತೆಗೊಳಗಾಗುತ್ತೀರಾ?				
ನೀವು ಮದುವೆಯಾಗಿದ್ದಲ್ಲಿ ದಯವಿಟ್ಟು ಕೆಳಗಿನ ಪ್ರಶ್ನೆಯನ್ನು ಉತ್ತರಿಸಿ				
೨೦. ನಿಮ್ಮ ಅತ್ತೆ ಮಾವಂದಿರು, ಗಂಡ/ಹೆಂಡತಿಯ ಮನೆಯವರು ನಿಮ್ಮ ರೋಗದ ಬಗ್ಗೆ ಚಿಂತಿತರಾಗಿರುತ್ತಾರೆಯೇ?				
ನೀವು ಮದುವೆಯಾಗದೇ ಇದ್ದಲ್ಲಿ ದಯವಿಟ್ಟು ಕೆಳಗಿನ ಪ್ರಶ್ನೆಯನ್ನು ಉತ್ತರಿಸಿ				
೨೦. ನಿಮಗೆ ಮದುವೆಯಾಗುವುದರಲ್ಲಿ ಅಡಚಣೆಯುಂಟಾಗುತ್ತಿದೆಯೇ?				
ನೀವು ನೌಕರಿ ಮಾಡುತ್ತಿದ್ದಲ್ಲಿ ದಯವಿಟ್ಟು ಕೆಳಗಿನ ಪ್ರಶ್ನೆಯನ್ನು ಉತ್ತರಿಸಿ				
೨೧. ನಿಮ್ಮ ಸಹೋದ್ಯೋಗಿಗಳು ಈ ರೋಗದಿಂದ ನಿಮ್ಮನ್ನು ಬೇರೆಯೇ ರೀತಿಯಲ್ಲಿ ಕಾಣುತ್ತಾರೆಯೇ?				
ನೀವು ವಿದ್ಯಾರ್ಥಿಯಾಗಿದ್ದರೆ ದಯವಿಟ್ಟು ಈ ಕೆಳಗಿನ ಪ್ರಶ್ನೆಯನ್ನು ಉತ್ತರಿಸಿ				
೨೨. ನಿಮ್ಮ ಸಹಪಾಠಿಗಳು ರೋಗದಿಂದಾಗಿ ನಿಮ್ಮನ್ನು ಬೇರೆಯೇ ರೀತಿಯಲ್ಲಿ ಕಾಣುತ್ತಾರೆಯೇ?				

INFORMED WRITTEN CONSENT FORM

B.L.D.E.U's SHRI B M PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE, VIJAYAPUR-586103

RESEARCH INFORMED CONSENT FORM

TITLE OF THE PROJECT : - A HOSPITAL BASED VALIDATION OF VITILIGO IMPACT SCALE -22 IN A TERTIARY CARE HOSPITAL IN NORTH KARNATAKA

PG GUIDE : - DR APARNA PALIT

PG STUDENT : - DR. ANUSHA S

PURPOSE OF RESEARCH:-

I have been informed that this project will be studied to measure the psychological impact of vitiligo.

BENEFITS:-

I understand that my participation in this study will help the investigator to study the various scales for assessment of QOL in vitiligo which helps in better assessment of patients' perception of their disease as well as effectiveness of therapy.

PROCEDURE:-

I understand that relevant history will be taken and I will undergo detailed clinical examination after which necessary investigations will be done whenever required.

RISK AND DISCOMFORTS:-

I understand there is no risk involved during the procedures performed.

CONFIDENTIALITY:-

I understand that medical information produced by this study will become a part of my hospital records and will be subjected to the confidentiality and privacy regulation of the said hospital. Information of a sensitive personal nature will not be a part of the medical records, but will be stored in the investigator's research file.

If the data are used for publication in the medical literature or for teaching purposes no names will be used and other identifiers such as photographs and audio or videotapes will be used only with my special written permission. I understand I may see the photographs, videotapes and hear the audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:-

I understand that I may ask more questions about the study at any time concerned. Dr.Anusha S is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which may influence my continued participation.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:-

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in this study at any time without prejudice. I also understand that Dr. Anusha S may terminate my participation in this study at any time after she has explained the reasons for doing so and has helped arrange for my continued care by my own physician, if this is appropriate.

INJURY STATEMENT:-

I understand that in the unlikely event of injury to me resulting directly from my participation in this study and if such injury were reported promptly, then medical treatment

will be available to me, but no further compensation will be provided. I understand that by my agreement for my participation in this study, I am not waiving any of my legal rights.

I have explained to (patient's / relevant guardian's name) the purpose of the research, the procedures required, and the possible risks and benefits to the best of my ability in patient's own language.

_____ _____

Investigator / P. G. Guide Date

I confirm that …….…….(Name of the PG guide / chief researcher) has explained to me the research, the study procedures that I undergo and the possible risks and discomforts as well as benefits that I may experience. I have read and I understand this consent form. Therefore, I agree to give my consent for my participation as a subject in this research project.

_____ _____

Participant / guardian Date

_____ _____

Witness to signature Date

KEY TO MASTER CHART

V1	-	First visit
V2	-	visit at week 2
V3	-	Visit at week 12
BSA	-	Body surface area
Sex distribution		
M	-	Male
F	-	Female
Marital status		
M	-	Married
UM	-	Unmarried
S	-	Symptom domain
E	-	Emotion domain
F	-	Social functioning domain