INTRODUCTION

Diabetes mellitus is one of the major chronic non-communicable diseases which have attained the status of a major epidemic in newly industrialized and developing nations. India is the second-largest contributor to the world’s diabetic load after China with a prevalence of 8.9%.1

Diabetes is a chronic disease that occurs when the pancreas does not produce enough insulin or the insulin produced is not effectively used causing hyperglycaemia.2 Uncontrolled blood glucose level for a longer set of time can cause irreversible harm to the circulatory system, eyes, kidneys and nerves leading to cardiovascular diseases, vision loss, nephritis and lower limb loss.3

The complications due to diabetes affect the foot in >30% of diabetic patients over 40 years of age.2 According to the guidelines of International Working Group (IWGDF), a diabetic foot ulcer (DFU) is a full-thickness infective non-healing ulcer over foot involving deeper tissue along with associated neuropathy, vasculopathy and bony changes located below the ankle in a diabetic patient.3 DFU patients are 15 times more at risk of undergoing a lower-extremity amputation and account for 85% of non-traumatic lower-limb amputations.4 Indian diabetic patients of rural area are more prone to DFU, the prevalence being 5.3-13.6% due to lack of knowledge of foot-care and proper footwear and habit of barefoot walking.4

Diabetes and its complication, especially DFU affects the quality of life in the physical health and daily activities, leisure, social and psycho-emotional as there is reduced mobility, difficulty in performing daily activities in the home and work leading to reduced productivity.10
AIMS AND OBJECTIVE

1. To study the impact of foot ulcer on health-related quality of life (HRQL) and employment-related factors among healed as well as unhealed diabetic foot ulcer patients
2. To validate the diabetic foot ulcer scale short form (DFS – SF) in the rural population of central India.

MATERIALS AND METHODS

The present study is a multi-centric, cross-sectional study carried out in diabetic patients attending three diabetic centres of medical college and tertiary care settings during the period from 1st June to 30th September 2019. A total of 118 diabetic foot ulcer patients were included in the study with written consent.

Inclusion criteria:

1. Patients aged between 18 years and 60 years with diabetic foot ulcer diagnosed for a minimum of one year with written consent.

Exclusion criteria:

1. Patients with severe physical or cognitive impairments
2. Patient not willing to give consent was excluded from the study.

The validation of the Hindi version of the Diabetic Foot Ulcer Scale-Short Form [DFS- SF] questionnaire was done as an initial step to use the scale in the tertiary care setting. We interviewed participants with two different scales (diabetic foot ulcer scale short form (DFS - SF), which was developed by MAPI Trust, the standardized general quality of life questionnaire to measure the quality of life for validation.

After obtaining written consent, all the 118 patients included in the study were interviewed using the Hindi version of Diabetic Foot Ulcer Scale-Short Form [DFS SF] questionnaire to assess the quality of life.

The thorough case history was taken related to understand the knowledge of the patients about their disease condition, change in their daily wedges status and bad effect on their working capacity and the working pattern was taken into consideration. Major problems were faced by the patients, after the occurrence of foot ulcer, expenditure pattern, health-seeking behaviour, and changes which occurred in their family life. A key informant interview with the moderator was carried out to understand the various management tactics used for the care of foot ulcer. Deductive themes were generated after the questionnaire, using the guidelines as per given for formative research.

At first, all the elucidating insights were determined for all the factors gathered. The composite variable ‘financial status’ was made from the information gathered on the announced month to month family unit use and the family unit resources possessed by the examination members. We gathered the complete example into two (recovered and unhealed) in light of the status of the wound and afterwards looked at the significant attributes of the gatherings. The normal of the subscale scores were begat as ‘Absolute personal satisfaction’ to get a general image of the elements related to HRQL among foot ulcer patients.

Our essential goal was to analyze the HRQL in the two gatherings of patients, for example, mended and unhealed. We utilized examination of covariance (ANCOVA) utilizing the ‘lm’ work in R. ANCOVA expect that the relapse slants of consistent result variable was different but parallel in the two groups after adjusting for other covariates.

RESULTS

Table I shows Interior consistency was evaluated as a proportion of unwavering quality to quantify routine working capacity in every one of the five spaces of DFS SF and Cronbach’s coefficient alpha assessed.

| Domain         | Number of Items in the scale | Average Item Correlation | Cronbach’s Alpha (α) |
|----------------|-------------------------------|--------------------------|----------------------|
| Leisure        | 5                             | 0.50                     | 0.84                 |
| Physical health| 5                             | 0.23                     | 0.60                 |
| Daily Activities| 5                            | 0.43                     | 0.79                 |
| Emotions       | 10                            | 0.21                     | 0.72                 |
| Treatment      | 4                             | 0.30                     | 0.63                 |

Table II shows the correlation matrix with SF 36 Vs DFS-SF. [*#” mention a strong correlation between the above-mentioned scales].
Table II: Correlation matrix with SF 36 Vs DFS-SF (n=49)

| DFS SF Scale       | SF 36 V2 Scale          |
|--------------------|-------------------------|
|                    | Physical Functioning    | Role Limitations due to physical health | Role Limitation due to emotional problems | Energy / Fatigue | Emotional Wellbeing |
| Leisure            | 0.38                    | 0.44                                 | 0.24                                  | 0.28            | 0.22                | 0.37                |
| Physical Health    | 0.59*                   | 0.62*                                | 0.29                                  | 0.35            | 0.54*               | 0.58*               | 0.60*               | 0.58*               |
| Daily Activities   | 0.52*                   | 0.45                                 | 0.37                                  | 0.36            | 0.63*               | 0.43                | 0.39                | 0.39                |
| Emotions           | 0.48                    | 0.47                                 | 0.35                                  | 0.40            | 0.56*               | 0.57*               | 0.43                | 0.65*               |
| Treatment          | 0.55*                   | 0.39                                 | 0.44                                  | 0.30            | 0.57*               | 0.30                | 0.30                | 0.64*               |

Table II shows the correlation matrix with SF 36 Vs DFS-SF. [*#* denotes the domains which showed a strong correlation between the above-mentioned scales.

Table III shows that 87 (73.7%) patients were observed in the unhealed group and 31 (26.3 %) were in the healed group. 58 (49.2%) had a one-time history of ulcer.

Table III: Disease characteristics of the study sample (n=118)

| Variables                  | Categories            | Frequency (%) |
|----------------------------|-----------------------|---------------|
| Status of wound            | Healed                | 31 (26.3)     |
|                            | Unhealed              | 87 (73.7)     |
| Medication discontinued at any point in time | Yes | 39 (33.1) |
|                            | No                     | 79 (66.9)     |
| History of foot ulcer      | One time              | 58 (49.2)     |
|                            | Two times             | 42 (35.6)     |
|                            | Three times           | 7 (5.9)       |
|                            | More than three times | 11 (9.3)      |

Table IV: Socio-demographic and clinical characteristics in the two groups

| Indicators | Healed ulcer (n=31) | Unhealed ulcer (n=87) |
|------------|---------------------|-----------------------|
| Mean age in years (SD) | 57.52 (8.4) | 57.71 (7.5) |
| Sex (%)    |                     |                       |

Table IV shows that socio-demographic and clinical characteristics in the two groups.

Table V shows significant results of two factors ANOVA for Subscale 1 – Leisure score.
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Table V: Results of two factor ANOVA for Subscale 1 – Leisure score, n (118)

| Variables          | Mean±SD     | Mean±SD     | Adj p values for indicator variable | Adj p values for wound status |
|--------------------|-------------|-------------|-------------------------------------|------------------------------|
| Wound status       |             |             |                                     |                              |
| Healed             | 73.07±20.88(31) | 45.23±22.03(87) |                                     |                              |
| Unhealed           | 46.30±24.83(27) | 44.75±20.86(60) | 0.57                               |                              |
| Sex                |             |             |                                     |                              |
| Female             | 65.42±19.48(12) | 64.53±24.83(27) | 0.42                               | 0.00*                        |
| Male               | 77.90±20.77(19) | 49.44±22.28(29) |                                     |                              |
| Age                |             |             |                                     |                              |
| ≤60 yrs            | 74.38±25.29(16) | 43.28±21.84(58) |                                     |                              |
| >60 yrs            | 71.67±15.66(15) | 49.14±22.28(29) |                                     |                              |
| SES groups         |             |             |                                     |                              |
| Low                | 75.36±21.26(14) | 40.54±25.83(28) | 0.48                               | 0.00*                        |
| Medium             | 70.42±21.79(12) | 49.00±23.23(25) |                                     |                              |
| High               | 73.00±21.39(5)  | 46.32±17.20(34) |                                     |                              |
| Education groups   |             |             |                                     |                              |
| Upper Primary      | 73.18±21.36(11) | 42.08±25.09(12) | 0.75                               | 0.00*                        |
| High School        | 71.11±21.46(18) | 45.09±22.96(55) |                                     |                              |
| Higher Secondary   | 95.00±NA(1) | 50.63±19.43(8)  |                                     |                              |
| Higher education   | 85.00±NA(1) | 45.42±22.10(12) |                                     |                              |

Table VI: Results of two factors ANOVA for Subscale 2 – Physical health score

| Variables          | Mean±SD     | Mean±SD     | Adj p Values | Adj p values for wound status |
|--------------------|-------------|-------------|--------------|------------------------------|
| Wound status       |             |             |              |                              |
| Healed             | 73.23±18.28(31) | 63.68±19.64(87) | 0.06         | 0.02*                        |
| Unhealed           | 57.22±19.03(27) | 66.58±19.37(60) |              |                              |
| Sex                |             |             |              |                              |
| Female             | 72.5±14.22(12) | 57.22±19.03(27) |              |                              |
| Male               | 73.68±20.81(19) | 66.58±19.37(60) |              |                              |
| Age                |             |             |              |                              |
| ≤60 yrs            | 78.44±15.57(16) | 64.31±19.75(58) | 0.23         | 0.02*                        |
| >60 yrs            | 67.67±19.81(15) | 62.41±19.71(29) |              |                              |
| SES groups         |             |             |              |                              |
| Low                | 70.00±22.27(14) | 60.54±19.97(28) | 0.17         | 0.02*                        |
| Medium             | 75.00±15.23(12) | 64.00±22.31(25) |              |                              |
| High               | 78.00±13.51(5)  | 66.03±17.40(34) |              |                              |
| Education groups   |             |             |              |                              |
| Upper Primary      | 60.46±21.03(11) | 54.17±19.64(12) | 0.01*        | 0.02*                        |
| High School        | 79.17±12.28(18) | 64.27±20.33(55) |              |                              |
| Higher Secondary   | 85.00±NA(1) | 69.38±18.21(8)  |              |                              |
| Higher education   | 95.00±NA(1) | 66.67±16.00(12) |              |                              |

Table VI shows significant results of two factors ANOVA for Subscale 2 – Physical health score
Table VII: Results of two factors ANOVA for Subscale 3 – Daily activities score

| Variables            | Mean±SD Wound status | Mean±SD | Adj p values | Adj p values for wound status |
|----------------------|----------------------|---------|--------------|-------------------------------|
| Wound status         | Healed               | Unhealed|              |                               |
| Sex                  |                      |         | 0.13         | 0.00*                         |
| Female               | 68.75±9.08(12)       | 55.93±21.62(27) |               |                               |
| Male                 | 80.26±16.20(19)      | 59.08±18.81(60) |               |                               |
| Age                  |                      |         | 0.62         | 0.00*                         |
| ≤60 yrs              | 75.31±12.31(16)      | 57.41±17.58(58) |               |                               |
| >60 yrs              | 76.33±17.57(15)      | 59.48±23.54(29) |               |                               |
| SES_groups           |                      |         | 0.00         | 0.00*                         |
| Low                  | 71.07±14.96(14)      | 51.25±8.49(28) |               |                               |
| Medium               | 77.92±15.15(12)      | 58.80±20.27(25) |               |                               |
| High                 | 84.00±10.84(5)       | 63.24±18.99(34) |               |                               |
| Education_groups     |                      |         | 0.13         | 0.00*                         |
| Upper Primary        | 70.00±17.89(11)      | 52.92±16.30(12) |               |                               |
| High School          | 77.78±12.27(18)      | 57.18±20.45(55) |               |                               |
| Higher Secondary     | 90.00±NA(1)          | 67.50±19.64(8)  |               |                               |
| Higher education     | 90.00±NA(1)          | 61.25±18.60(12) |               |                               |

Table VII shows significant results of two factors ANOVA for Subscale 3 – Daily activities score

Table VIII: Results of two factors ANOVA for Subscale 4 – Emotions score, n (118)

| Variables            | Mean±SD Healed | Mean±SD Unhealed | Adj p values | Adj p values for wound status |
|----------------------|---------------|-----------------|--------------|-------------------------------|
| Wound status         | Healed        | Unhealed        |              |                               |
|                     | 74.44±17.82(31)| 64.40±20.24(87)|              |                               |
| Sex                  |               |                 | 0.00*        | 0.01*                         |
| Female               | 66.88±16.38(12)| 55.65±19.78(27)|              |                               |
| Male                 | 79.21±17.40(19)| 68.33±19.34(60)|              |                               |
| Age                  |               |                 | 0.16         | 0.02*                         |
| ≤60 yrs              | 76.25±16.38(16)| 61.42±20.40(58)|              |                               |
| >60 yrs              | 72.5±19.62(15) | 70.35±18.87(29) |              |                               |
| Living status        |               |                 | 0.01*        | 0.01*                         |
| Living alone         | 75.00±NA(1)   | 51.50±18.49(10) |              |                               |
| With children        | NA            | 61.79±24.82(7)  |              |                               |
| With spouse          | 83.13±12.25(12)| 72.04±14.89(27)|              |                               |
| With whole family    | 68.61±19.33(18)| 63.02±21.45(43)|              |                               |
| Employment           |               |                 | 0.02*        | 0.01*                         |
|                     | 77.29±19.38(12)| 73.30±19.56(28)|              |                               |
|                     | 74.69±11.91(8) | 63.75±18.14(22)|              |                               |
|                     | 81.25±8.84(2)  | 60.71±15.99(7)  |              |                               |
|                     | 91.25±5.30(2)  | 60.56±20.53(9)  |              |                               |
|                     | 62.50±20.57(7) | 56.07±21.43(21)|              |                               |
Table VIII: (Continued)

| Variables          | Mean±SD              | Mean±SD              | Adj p values | Adj p values for wound status |
|--------------------|----------------------|----------------------|--------------|------------------------------|
| SES_groups         |                      |                      |              |                              |
| Low                | 75.18±18.44(14)      | 62.32±17.95(28)      | 0.85         | 0.02*                        |
| Medium             | 75.63±14.58(12)      | 66.30±22.98(25)      |              |                              |
| High               | 69.50±25.58(5)       | 64.71±20.34(34)      |              |                              |
| Education_groups   |                      |                      |              |                              |
| Upper Primary      | 78.18±18.41(11)      | 71.04±22.42(12)      | 0.46         | 0.02*                        |
| High School        | 71.53±18.23(18)      | 62.77±20.50(55)      |              |                              |
| Higher Secondary   | 87.50±NA(1)          | 65.94±23.22(8)       |              |                              |
| Higher education   | 72.50±NA(1)          | 64.17±15.24(12)      |              |                              |

Table VIII shows significant results of two factors ANOVA for Subscale 4 – Emotions score

Table IX: Results of two factors ANOVA for Subscale 5 – Treatment score, n (118)

| Variables           | Mean± SD                              | Mean± SD                              | Adj P values | Adj P values for wound status |
|---------------------|---------------------------------------|---------------------------------------|--------------|------------------------------|
| Wound status        | Healed                                | Unhealed                              |              |                              |
|                     | 79.03±12.35(31)                       | 64.66±15.45(87)                       | 0.08         | 0.00*                        |
| Sex                 |                                       |                                       |              |                              |
| Female              | 79.17±11.72(12)                       | 59.72±16.11(27)                       |              |                              |
| Male                | 78.95±13.05(19)                       | 66.88±14.75(60)                       |              |                              |
| Age                 |                                       |                                       | 0.45         | 0.00*                        |
| ≤60 yrs             | 81.64±12.39(16)                       | 62.93±14.99(58)                       |              |                              |
| >60 yrs             | 76.25±12.09(15)                       | 68.10±16.05(29)                       |              |                              |
| SES_groups          |                                       |                                       | 0.08         | 0.00*                        |
| Low                 | 78.13±14.66(14)                       | 61.38±15.78(28)                       |              |                              |
| Medium              | 79.69±9.66(12)                        | 63.50±15.59(25)                       |              |                              |
| High                | 80.00±13.55(5)                        | 68.20±14.79(34)                       |              |                              |
| Education_groups    |                                       |                                       | 0.01*        | 0.00*                        |
| Upper Primary       | 74.43±11.68(11)                      | 59.38±18.56(12)                      |              |                              |
| High School         | 80.56±12.11(18)                      | 63.86±15.76(55)                      |              |                              |
| Higher Secondary    | 100.00±NA(1)                         | 78.91±7.42(8)                         |              |                              |
| Higher education    | 81.25±NA(1)                         | 64.06±9.28(12)                        |              |                              |

Table IX shows significant results of two factors ANOVA for Subscale 5 – Treatment score
DISCUSSION

Populace based examinations over the world show that the rate of Type 2 diabetes mellitus is expanding among youthful grown-ups. This will prompt an expansion in the predominance of small scale and fullscale neuro-vascular complications associated with diabetes.

According to the international diabetic federation,5 globally, the number of diabetics in 2017 was 427 million and for 2019 was 463 million and the projected value for 2030 is 578 million (10.2%) and 700 million (10.9%) in 2045. The pervasiveness of Type 2 diabetes is expanding everywhere throughout the world and about 80% of individuals with diabetes live in lower economy countries.19 Around 2.2 million deaths in 2019 worldwide were attributed to diabetes.

DFU is one of the most feared complications of diabetes mellitus and constitutes a major public health problem due to their negative impact on the quality of life resulting in the overall poor prognosis of the disease. It leads to a long period of hospitalization, morbidity and mortality, thus incur substantial expenditure.6

The mean ± SD old enough in years for rustic diabetic population considered was 57.66 ± 7.71. This is like announced from different studies.7 Based on the injury status, the patients were gathered into recuperated and unhealed. Two gatherings didn’t contrast from one another concerning other segment qualities. Among the 118 patients examined, just 39 (33.1 %) were females. Among patients with a foot ulcer, there is a prevalence of males. This is found in India yet besides in created nations, where nearly everybody with foot ulcer might be accepting foot care.7

This affirms our notion that the male prevalence in our example isn’t because of any predisposition. Along these lines, this can’t be clarified because of predisposition preferring the male in accepting foot care. The male dominance could be ascribed to higher tobacco use and ensuing vascular issues alongside more presentation to open-air occupations. This uncovers youthful male diabetic working populace is at high danger of getting diabetic foot ulcer at an early age. This is consistent with studies by other studies.9 the majority of the study population were manual labourers including agricultural workers, carpenters, and drivers. Their knowledge regarding foot care practices and footwear were very minimal. A significant number of patients revealed that they were not taught to take the medicine routinely to keep up great glycemic control. The DFS SF has five subscales to quantify various areas of personal satisfaction, for example, relaxation, physical wellbeing, everyday exercises, feelings and treatment. Wound status as a fundamental indicator of good QOL.

The mean scores for every one of the subscales were essentially unique in the two injury status gathering (mend- and unhealed foot ulcer). The same finding has been found in different populaces. Because of the speculation tried, it was presumed that HRQL was reliably higher in the recuperated gathering, significantly after it was balanced for different indicators, for example, sex, ulcer duration.10 Various studies have shown that a diabetic foot ulcer patient has a significant impact on people’s psychological and emotional QOL particularly in their daily routines, family life and employment opportunities.6 Negligence or under treatment due to the financial crisis is a major roadblock in the treatment and eventually may lead to amputation, which further accentuates the depressive state due to disability. Dominant part detailed that they needed to take early retirement, had a loss of openings for work and needed to change their example work because of the event foot ulcer. This is like the announced examination by Others.11 As we expected the effect of diabetic foot ulcer among the youthful working populace was higher than that in the more established working populace. This shows the significance of early mending among youthful diabetics, which will straightforwardly add to increment in national salary. This is predictable with other studies.12 Timely intercessions and wellbeing instruction for diabetic foot ulcer centring youthful diabetics will assist with diminishing the general effect of diabetes on the economy, as the predominance of diabetic populace increments alongside youthful working populace.

Out of the 118 patients met 44 (37.3%) were accounted for that they needed to rely upon some trouble fund component to deal with the disastrous wellbeing spending. Patients with longer length of ulcer end up in calamitous degree of wellbeing spend. Comparative discoveries have been found from India.13 Longer-term of ulcer builds the money related weight on the family. This again underscores the early mediation and prevention.14

CONCLUSION

A diabetic foot ulcer is an ignored infection by the patient as well as by the general public and the wellbeing framework. Early recognition and great glycemic control will lessen the frequency of foot ulcer. The DFS SF is a decent scale to gauge the inert variable, HRQL. It has great build legitimacy against SF 36 v2. This scale can be utilized among the country diabetic foot ulcer populace for evaluating the HRQL. The HRQL is identified with the mending of the diabetic foot ulcer. The examination uncovers that injury status is a significant indicator of good HRQL among diabetic foot ulcer patients. The diabetic foot ulcer must be effectively treated so that to forestall crumbling of personal satisfaction.
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