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Rani Ritu
Assistant Professor of Medical Surgical Nursing, RPIIT& MS, Bastara Karnal, Haryana, India

Kumari Vinay
Associate Professor of Medical Surgical Nursing, M.M College of Nursing, Maharishi Markandeshwar University, Mullana, Ambala, Haryana, India

N Sembian
Associate Professor of Medical Surgical Nursing, M.M College of Nursing, Maharishi Markandeshwar University, Mullana, Ambala, Haryana, India

Correspondence
Rani Ritu
Assistant Professor of Medical Surgical Nursing, RPIIT& MS, Bastara Karnal, Haryana, India

Development of foot ulcer risk assessment tool for diabetic patients in selected hospitals of Haryana

Rani Ritu, Kumari Vinay and N Sembian

Abstract
A useful instrument for the prediction of foot ulcer requires a highly sensitive with specificity, good predictive value and easy to use in the clinical practice. Objective of the study was to develop and validate foot ulcer risk assessment tool for diabetic patients. A methodological study was conducted on diabetic patients without foot ulcer and with foot ulcer attending O.P.D or admitted in selected hospital of Haryana (n=100). From related review of literature, experts' guidance and investigators' personal experience, a list of risk factors were identified. These identified risk factors were compared with standardized risk assessment scales i.e. Chinese version of the diabetes self-care scale (C-DSCS), the foot care subscale of the summary of diabetes self-care activity questionnaire (SDSCA) and Diabetes foot self-care behavior scale. The final draft of tool consists 22 items. Overall cronbach's alpha coefficient of present tool was 0.83 signifying that tool was having a good internal consistency. Test-retest reliability was 0.68 which indicates the stability of tool. Content and face validity was done by the opinion of experts. The content validity index calculated which was 0.80 signifying that tool was having a good content validity. For construct validity of the tool, known group technique was used. There was a statistically significant difference between the scores of diabetic patients without foot ulcer and with foot ulcers. It signifies that tool was having good construct validity. The range of rating score was 27 to 75, with the assumption that higher the scores, the greater the risk of foot ulcer development. At a cutoff point of ≥42, the best balance between the sensitivity and specificity was achieved, i.e. sensitivity was 86%, specificity 84%, Positive predictive value 84% and negative predictive value was 85%. The cut-off point of the tool was ≥42, patients who are having a score ≥42, are at risk for development of foot ulcer. The finding of the study revealed that foot ulcer risk assessment tool was good reliability and validity. It can be used in prediction of foot ulcer in diabetic patients.

Keywords: Diabetic patients, Foot ulcer, Risk assessment tool

Introduction
Globally Diabetes is one of the most common non communicable disease. It is the fifth leading cause of death in most high -income countries and there is substantial evidence that it is epidemic in many low and middle-income countries [1]. Over the past 30 years the status of diabetes has changed from being considered as a mild disorder of the elderly to one of the major causes of morbidity and mortality affecting the youth and middle aged people [2]. In 2010, an estimated 285 million people worldwide had diabetes mellitus. The number of people globally with diabetes mellitus is projected to rise to 439 million by 2030 [3]. Diabetes is fast gaining the status of a potential epidemic in India. In 2000, India (31.7 million) topped the world with the highest number of people with diabetes mellitus followed by China (20.8 million) with the United States (17.7 million) in second and third place respectively [4]. Diabetes has a several complications that can become life threatening. Diabetes is a disease that is strongly associated with both microvascular and macrovascular complications [5]. One major complication of diabetes is foot ulceration, which occurs in as many as 15–25% of type 1 and type 2 diabetic patients over their lifetimes. Studies show that between 2 and 6% of diabetic patients will develop a foot ulcer every year [6]. Many overlapping factors lead to foot ulceration. The complications contributing to the onset of ulceration include poor vision, limited joint mobility and the consequences of cardiovascular and cerebrovascular disease. However, the most common precipitant is accidental trauma, especially from the ill fitted footwear [7] Other Risk factors for diabetic foot ulcer including older age, long duration of diabetes, tobacco chewing, insulin administration and rural location of patients [8].

There is currently no instrument that measures all aspects of foot ulcer development like physical, self-care, modified personal factors and shows good reliability and validity in the world. The present Foot ulcer risk assessment tool measure all aspects of foot ulcer development like physical, self-care and modified personal factors.

Objective

- To develop and validate foot ulcer risk assessment tool for diabetic patients.

Delimitation

- The study was delimited to the diabetic patients without foot ulcer and with foot ulcer of selected hospital of Haryana**.**

Material and Methods

A methodological study was conducted. Purposive Sampling Technique was used to select the sample of 100 patients (50 diabetic patients without foot ulcer and 50 diabetic patients with foot ulcer) from MMIMS&R Hospital, Mullana, Ambala, Haryana, Community Health Center, Mathana, Kurukshetra, and Community Health Center, Ladwa, Kurukshetra. The data was collected from patients admitted or attending O.P.D in above areas. The criterion for selection of sample was as follows: For Diabetic patients without Foot Ulcer. Diabetic patients without having foot ulcer at the time of data collection, Diabetic patients more than 18 years of age., Able to understand Hindi or English and Patients willing to participate. For Diabetic patients with Foot Ulcer Diabetic patients having foot ulcer at the time of data collection, more than 18 years of age, Able to understand Hindi or English, Patients willing to participate and exclude the Patients who were not able to recall, respond and comprehend. Data were collected from November 2013 to January 2014. The data was collect using face-to-face interviews. Ethical approval to conduct study was obtained from institutional ethical committee of M.M. University, Mullana was obtained before contacting participants and collecting data. For try out of final draft of tool 100 Participants were interviewed to obtain data on demographics and foot ulcer risk assessment tool.

Phases of study

Phase I- Preliminary Preparation: Phase-I was completed in three steps.

a) Review of literature The review of literature for the present study was done for various risk factors that are causing foot ulcers in diabetic patients. Books, Journals and foot ulcer risk assessment tools were reviewed for current topic.

b) Generation of Item Pool: From literature review and through guidance from Nursing and Medical personnel. Risk factors for foot ulcer were selected from the content and the items were pooled together.

c) Preparation of Preliminary Draft: The blue print of foot ulcer risk assessment tool for diabetic patients was prepared with 46 items. Items were categorized under following domains. 1. Physical risk factors 2. Self care risk factors 3. Personal risk factors

Phase II- Validation of first draft and subsequent drafts of foot ulcer risk assessment tool

Modified Delphi technique was used to ensure content validity of the first draft and subsequent drafts i.e. 2nd and final draft of tool. Thirteen experts of panel were selected. The members of panel were Nursing and Medicine experts. The draft of tool was circulated among experts of panel for content validity of tool. They were requested to go through the items and give their suggestions regarding the tool. In terms that items are not relevant, somewhat relevant, quite relevant and highly relevant in order to measure the content validity of the tool. The suggestions given by panel of experts were compiled and recirculated back to same experts so that next draft of tool was prepared on the basis of agreement of experts for the suggestion given. The experts were requested to give their opinion for each modification or suggestions in terms of agree and disagree. If 50% experts agree on a suggestion, then suggestion were incorporated**.** Same steps were followed in each draft validation. The final draft of tool consists 22 items.

Phase III-Pilot Study

It was conducted to ensure the feasibility of the study. The data was collected from 10 diabetic patients without foot ulcer and 10 diabetic patients with foot ulcer from Medicine and Surgical ward of MMIMS&R Hospital. Sample was selected on the basis of inclusion and exclusion criteria of the study. Consent was taken from the patients after explaining nature and duration of study. Results of pilot study was shows that tool was feasible for final data collection, language of the tool understandable, clear and took 40 minute for scoring.

Phase IV- Try Out Of Foot Ulcer Risk Assessment Tool

The consensuses was taken from the entire panelist regarding final draft of foot ulcer risk assessment tool which was used for final tryout, when no modifications were suggested then final draft was tried out on 100 subjects. Sample was selected on the basis of inclusion and exclusion criteria of the study. Consent was taken from study subjects. Nature and purpose of study was explained to participants. Data for final study was collected from 50 diabetic patients without foot ulcer and 50 diabetic patients with foot ulcer in selected hospitals of Haryana by using structured interview technique.

Findings

Sample Characteristics: Diabetic patients without foot ulcer and with foot ulcer were homogenous and comparable in terms of sample characteristics.

Clinical characteristics: Diabetic patients without foot ulcer and with foot ulcer were homogenous and comparable in terms type of diabetes, frequency of checking blood sugar, frequency of checking blood pressure, frequency of checking blood cholesterol, smoking, tobacco chewing, co-morbidity and heterogeneous in terms of duration of diagnosis of diabetes and random blood sugar level.

Item analysis: Self care factors item number three having same responses of all the subjects and showing no variability so that item three was deleted from the tool.

Reliability of foot ulcer risk assessment tool

Internal consistency: The tool was administered to 100 patients, 50 diabetic patients without foot ulcer and 50 diabetic patients with foot ulcer. Data was analyzed by using SPSS (version 16.0). The internal consistency was calculated by cronbach‟s alpha. Total Cronbach‟s alpha for the developed tool was found to be 0.83 (Cronbach‟s alpha coefficient should be >0.7035)

Test- Retest reliability of foot ulcer risk assessment tool: During the final tryout of the foot ulcer risk assessment tool, the test retest group was formed from (n=15) diabetic patient without foot ulcer. The tool was coded with order number from 1 to 15. The patients were interviewed with the foot ulcer risk assessment tool. After the 5 day, same patients were interviewed with same code number. The total instrument test retest reliability was 0.68. (Normal value is. 70-1). This shows that the foot ulcer risk assessment tool has positive association.

Validity

Content validity: Content validity performa was circulated to the 13 experts of panel. Which was having 30 items and experts were asked to evaluate the items: not relevant, somewhat relevant, quite relevant, and highly relevant. Averaging approach was used. Content validity of foot ulcer risk assessment tool was checked by calculating the content validity index through the performa which was filled by the experts. Content validity index came out to be 0.80 (values of CVI higher than 0.78 are considered having good content validity

Face validity: By seeing the tool majority of experts suggested that all the risk factors for foot ulcer risk assessment tool were well organized and structured. Thus the face validity of the tool was considered good.

Construct validity

Known group validity: Independent "t" test was applied it shows that, there was a statistically significant difference between the scores of diabetic patients without foot ulcer and with foot ulcers. The diabetic patients with foot ulcer earned a higher score as compared to diabetic patients without foot ulcer. It signifies that tool was having good construct validity (Table 1).

Table 1: "t" test showing Comparison of diabetic patients without foot ulcer and with foot ulcer in terms foot ulcer risk assessment score. N=100, Selected Variable Group Mean MD_D t Value p Value

Foot ulcer risk assessment score	Diabetic patients	36.36	18.700	10.585	0.000
	Without foot ulcer (n=50) With foot ulcer (n=50)	55.06			

"t"(98)= 1.980, S- significant(<0.05)

Predictive Validity

The predictive validity at each score was calculated by sensitivity, specificity, predictive value positive (PVP) and predictive value negative (PVN) tests (Table 2).

Table 2 It reveals that sensitivity; specificity, positive predictive value and negative predictive value tests of the risk assessment tool for prediction of foot ulcer, and these were calculated at each score from ≥27 to ≥75. Sensitivity was ranging from 12 % to 100%, specificity was ranging from 6 % to 100%, Positive predictive value from 51% to 100 % and negative predictive value from 51% to 100 %. At a cutoff point of ≥42, the best balance between the sensitivity and specificity was achieved, i.e. sensitivity was 86%, specificity 84%, Positive predictive value 84% and negative predictive value was 85%. At 86% sensitivity there are 14% chances of false negative results and 84% specificity there are 16 % chances of false positive results. The cut-off point of the tool was ≥42, patients who are having a score ≥42, are at risk for development of foot ulcer.

Table 2: Sensitivity, Specificity, positive predictive value (PPV) and negative predictive value (NPV) tests. N=100

cut off points total score	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
≥27	100	6	51	100
≥28	98	6	51	75
≥29	98	6	51	75
≥30	98	10	52	83
≥31	98	12	52	85
≥32	96	14	52	77
≥33	96	20	54	83
≥34	92	30	56	78
≥35	92	34	58	80
≥36	90	40	60	80
≥37	90	46	62	82
≥38	90	60	69	85
≥39	90	62	70	86
≥40	88	70	74	85
≥41	86	76	78	84
≥42	86	84	84	85
≥43	84	88	87	84
≥44	84	92	91	85
≥45	84	92	91	85
≥46	80	94	93	82

≥47	80	96	95	82
≥48	80	96	95	82
≥49	80	100	100	83
≥50	80	100	100	83
≥51	76	100	100	80
≥52	76	100	100	80
≥53	72	100	100	78
≥54	70	100	100	76
≥55	70	100	100	76
≥56	70	100	100	76
≥57	70	100	100	76
≥58	70	100	100	76
≥59	44	100	100	64
≥60	38	100	100	61
≥61	38	100	100	61
≥62	26	100	100	57
≥63	26	100	100	57
≥64	26	100	100	57
≥65	26	100	100	57
≥66	26	100	100	57
≥67	12	100	100	53
≥68	12	100	100	53
≥69	12	100	100	53
≥70	60	100	100	51
≥71	60	100	100	51
≥72	60	100	100	51
≥73	60	100	100	51
≥74	60	100	100	51
≥75	60	100	100	51

Discussion

Globally Diabetes is one of the most common non communicable disease [5]. One major complication of diabetes is foot ulceration. Identification of patients at risk for foot ulcer development is perhaps the most important issue in foot ulcer prevention. The investigator developed a risk assessment tool for the prediction of foot ulcer in patients, which is composed of 22 items. The purpose of present study is to develop and validate foot ulcer risk assessment tool for diabetic patients. In the present study, majority of diabetic patients without foot ulcer and with foot ulcer were in the age group of 35-69 years i.e. 84% and 76% respectively. Majority of the diabetic patients without foot ulcer and with foot ulcer were male i.e. 56 % and 62% respectively. Majority of the diabetic patients without foot ulcer had monthly income of Rs. 10001-20000 (58%) whereas majority of diabetic patients with foot ulcer had monthly income of Rs. ≤ 10000 (52%). Majority of diabetic patients without foot ulcer and with foot ulcer were educated up to secondary level. I.e. 32% and 52% respectively. Majority of the diabetic patients without foot ulcer and with foot ulcer were having type II Diabetes Mellitus (80 % and 78%), were having 1-5 years of diabetes (66 % and 58%) and also were having random blood sugar level >200 mg/dl (66 % and 90 %). Majority of the diabetic patients without foot ulcer and with foot ulcer were checking blood sugar in every 2 months (92 % and 88%), were checking blood pressure in every 2 months (96% and 92%) and also were checking blood cholesterol > 6 months (100 % and 98%). Among diabetic patients without foot ulcer 44% were current regular smoker as compared to 50% diabetic patients with foot ulcer. Majority of the diabetic patients without foot ulcer (64%) never chewed tobacco as compared to 44% diabetic patients with foot ulcer. Majority of the diabetic patients without foot ulcer was not having any co-morbidity (58%) as compared to diabetic patient with foot ulcers were having some co-morbidity (56%).It shows that as blood sugar level having significant association with presence or absence of foot ulcer. As the blood sugar level increases more chances of development of foot ulcer.

Number of foot care behavior scales have been developed that Includes, Chin yen –fan and Huang Tzu-Ting, 2013 had developed Diabetes foot self-care behaviour scale [9]. That was composed of one factor structure with seven items. The item of Diabetes foot self-care behaviour scale were I (my caregiver) examine the bottoms of my feet, I (my caregiver) examine between the toes of my feet, I (my caregiver) wash between my toes, I (my caregiver) dry between my toes after washing, If my skin is dry, I (my caregiver) apply moisturizing lotion to my feet, Before I put on my shoes, I (my caregiver) check the inside of the shoes, I break in new shoes slowly. Diabetes foot self-care behaviour scale did not include items Numbness of feet, burning sensation of feet, pain in legs at rest /pain in legs at walking, decreased ability to feel hot and cold objects with feet, excessive exposure of sun to feet (10 am-2 pm), assume sitting position/standing position/crossleg position for >30 minute, examine feet for swelling, compare nails of both feet for color changes, soak feet in water for more than 2-3 minutes, use hot water bottle/heating pad for warm feet, wear cotton socks, walk/working barefoot, wear very tight lower clothes (panties, leggings, socks) and tobacco chewing/ tobacco sniffing and use tobacco paste related items which has been identified an important risk factors in diabetic patients without and with foot ulcer.

In terms of reliability, in the present study Cronbach's alpha coefficient was higher for the foot ulcer risk assessment tool (.83) than that for Diabetes foot self-care behavior scale (.73). The Cronbach's alpha coefficient of >.70 indicates acceptable internal consistency. This is consistent with our findings and supports good reliability of the tool.

Furthermore, test retest reliability of foot ulcer risk assessment tool with a 5 days interval was (0.68). Diabetes foot self-care behavior scale test retest reliability over a 2-week period was 0.92.Content validity of present tool was assured with calculating content validity index. Content validity index came out to be 0.80 (values of CVI higher than 0.78 are considered having good content validity), signifies that tool was having a good content validity. 7 items in the tool had items score to total score correlation less than 0.2 showing incompatibility with the overall tool. Hence those 7 items were deleted from the tool. The deleted item were apply cream between toes, cut the feet nails straight, cut feet nails too short, cut nails with blade, soak nails <2 minutes in lukewarm water before trimming, cigarette smoking and perform range of motion exercise for foot daily. Similarly in Diabetes foot self-care behavior scale content validity was assured with calculating content validity index. Averaging approach was used to calculate the content validity index through the performa which was filled by the experts. Content validity index scores ranged from 0.83 to 1. Because of low item discrimination index and low factor loading, several items were excluded. This is consistent with our findings and supports good content validity of the tool.

Independent" t" test was applied it shows that, there was a statistically significant difference between the scores of diabetic patients without foot ulcer and with foot ulcers. The diabetic patients with foot ulcer earned a higher score as compared to diabetic patients without foot ulcer. It signifies that tool was having good construct validitySimilarly in Diabetes foot self-care behaviour scale known groups technique was used to validating a measure. Mann whitney Z test was applied. There was a statistically significant difference between the Diabetes foot self-care behaviour scale scores of patients with and without a history of foot ulcers. Those with such a history earned a higher average diabetes foot self-care behaviour scale score than those without history of disease. This is consistent with our findings and supports good known-groups validity for the tool.

For calculating predictive validity, There was no difference from the cutoff point between 17-26 hence, at a cutoff point ≥27 to ≥75 Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) tests were calculated at each different score. Sensitivity was ranging from 12 % to 100%, specificity was ranging from 6 % to 100%, Positive predictive value from 51% to 100 % and negative predictive value from 51% to 100 %. At a cutoff point of ≥42, the best balance between the sensitivity and specificity was achieved, i.e. sensitivity was 86%, specificity 84%, Positive predictive value 84% and negative predictive value was 85%. At 86% sensitivity there are 14% chances of false negative results and 84% specificity there are 16 % chances of false positive results. The cut-off point of the tool was ≥42, patients who are having a score ≥42, are at risk for development of foot ulcer. The present foot ulcer risk assessment tool provides good reliability and validity. It includes all aspects of foot ulcer development physical, self-care, modifiable personal factors and having good sensitivity, specificity, positive predictive value and negative predictive value.

Conclusion

Foot ulcer risk assessment tool had good reliability and validity. Foot ulcer risk assessment tool can use for prediction of foot ulcer.

Recommendations

The study can be utilized in clinical areas to identify the diabetic patients at risk of developing foot ulcer. Comparative studies can be conducted to establish concurrent validity by using foot ulcer risk assessment tool and another standaerized tool. Standards or protocols on preventive measures for foot ulcer among high risk patients can be developed based on the identified risk factors. A prospective study can be conducted with diabetic patients to identify risk factors for development of foot ulcer. Foot ulcer risk assessment tool can be implemented on a large sample to develop reliable, valid foot ulcer risk assessment tool and calculate construct validity. A similar study can be conducted in different setting with large sample size. A study can be conducted to collect observation to identify risk factors. Feasibility of tool can be assessed at different settings for calculating sensitivity and specificity to establish appropriate cut off points. A study can be conducted to measure time taken to complete the study.

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