Development of a Risk Assessment Tool for Diabetic Foot Ulcer among Diabetic Patients

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Abstract: *Recently, there is no risk assessment tool for diabetic foot ulcer (DFU) in diabetes mellitus (DM) patients. It is necessary to develop risk assessment tool to early detect DFU in DM patients. This study is descriptive study which used tool development process included, 3 phases; 1) literature review to select journal reveled high statistic association using adjusted odd ratios (AOR), 2) group and categorized the risk factors associated with DFU, and 3) score the items. From literature review, there were 15 journals with AOR. Fifty factors were collected then grouped them to 15 items. Those items were: 1) age, 2) sex, 3) history or current smoker, 4) body mass index (BMI), 5) insulin use, 6) duration of DM, 7) poor diabetes control, 8) skin assessment, 9) foot deformity, 10) neuropathy sensory, 11) peripheral vascular disease, 12) history of amputation, 13) history of ulceration, 14) history of myocardial infarction, and 15) retinopathy. Then, there were 3 factors added by clinical judgment which included poor foot care, unhealthy diet, and physical inactivity. Finally, the researcher grouped, categorized and defined those items and scored each item by consultation with statistician. The total score of the risk assessment for DFU range from 3 – 23. The researcher then designed the tool format. In conclusion, the risk assessment tool for DFU in DM patients (version 1) was developed. Further, testing its psychometric properties is recommended.*
Keywords: *Development; diabetic foot ulcer; assessment tool*

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I. Introduction

Diabetes Mellitus (DM) is complex chronic disease that exhibits an increase in glucose due to insulin deficiency (Tapan, 2005; Wijaya & Putri, 2013). World Health Organization [WHO] (2013) predicts the increasing number of DM will be triple from 2000 to 2030 around the world. Data from Daniel et al. (2011) and the International Diabetes Federation [IDF] (2013) showed that 347 million people have DM and around 5.1 million people died and 548 USD billion in health spending has taken place.

The impacts among diabetic patients are high risk of micro-vascular and macro-vascular diseases (The Emerging Risk Factors Collaboration et al., 2010; Fioretto, Dodson, Ziegler, &Rosenson, 2010; Li et al., 2015). Diabetic foot ulcer (DFU) is a common problem in diabetic patients (Nehring et al., 2014). The statistic of prevalence of DFU among DM patients is approximately 5.3% - 10.5% (Reiber, 1998; Reiber, 2001; Madanchi et al., 2013) and the incidence of DFU is around 1-4% per year per among the population (Bartus&Morgolis, 2004; Khalil et al., 2014).

The effects of DFU can influence economic burden of patients, their families, health care providers and governments (Boulton et al., 2006; Ogbera et al., 2006). According to Frygberck et al. (2006) cited in Purwanti (2013),DFU is the main cause of morbidity, long hospitalization, and increased cost to patients. The ideal management to prevent and treat DFU is feet checking regularly, give knowledge to patients and healthcare providers, appropriate footwear, determining risk of DFU and early treatment of foot problems (International Working Group on the diabetic foot, 2000; Aalaa et al., 2012).

Literature review in risk factors related to DFU among diabetic patients of 15 studied examined using adjusted odd ratio (AOR) showed 15 factors. They are: 1) age 2) sex (male) 3) body mass index (BMI) example height, weight, and waist size 4) current and/or history of smoking 5) insulin use 6) macro-vascular complication such as history of stroke and history of acute myocardial infarction (AMI) 6) duration of DM 7) micro-vascular complication such as retinopathy 8) poor glycemic control such as HbA1c 9) fissures 10) callus 11) foot deformity such as hallux rigidus, hallux valgus, hammer toe, flat foot, charcot foot 12) neuropathy sensory 13) peripheral vascular disease 14) previous foot ulcer and 15) previous amputation.

An assessment tool is important to assess risk factors related to DFU. A study of systematic review supporting the instrument or a reliably assessment is needed for international clinical guidelines to assess risk of

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DFU among DM (Crawford et al., 2013). Based on Alavi et al. (2014) the early identification of high risk for DFU is crucial to decrease the number of morbidity and mortality and also nurses as part of an inter-professional approach which is often needed to support patients' needs.

Recently, there is no risk assessment tool for diabetic foot ulcer (DFU) in diabetes mellitus (DM) patients. Therefore, the ADA risk classification (Boulton et al., 2008). and risk stratification tool and diabetes foot screening from New Zealand Society [NZSSD] (Garret et al., 2014). (Boulton et al., 2008). The tools have strong risk factors to predict DFU, but not cover all the risk factors for DFU which is strong prediction of DFU supported by AOR. Supported byMeta- analysis and systematic review about predicting factors related DFU it would suggest that future study should comprehensively assess factors associated with DFU such as illness, signs and diagnostic test (Crawford et al., 2007). It is necessary to develop risk assessment tool to early detect DFU in DM patients.

II. Method

This tool development process included: 1) literature review that selected journals which showed high statistic association using adjusted odd ratios, 2) group risk factors based on the similar purpose of result, and 3) categorize and score the items

III. Results

1. Literature review

Literature review has gotten by searching the journal from google scholar, google and endnote. The researcher specify the journals, there are journal of diabetes and metabolic disorder, journal diabetes metabolism, diabetes care, and journal of diabetic foot complication that specified explore about diabetes and diabetes' complication. The keywords of sources are "risk factors, diabetic foot ulcer, diabetes mellitus". Inclusion criteria are the journal which has full text and the statistic using AOR. The stage of literature review resulted15 journals that have adjusted odd ratio (AOR). The researcher chose AOR because high statistic association which using two methods used to address confounding are stratification and multiple regression techniques (Szumilas, 2010). From 15 studies, the researcher had collected 50 risk factors which high associated with DFU. From 50 risk factors, some risk factors can be grouped into one item and some of risk factors were deleted because only supported by 1 study.This reason to delete only one study support has showed in Crowford, Inkster, Kleijnen, and Fahey (2007) that they delete the factors that only supported by one study.

2. Group and categorize the risk factors

The total risk factors after deleting and grouping were 15 risk factors. They were: 1)age, 2) sex, 3) history or current smoker, 4) body mass index, 5) insulin use, 6) duration of DM, 7) poor diabetes control, 8) skin assessment, 9) foot deformity, 10) neuropathy sensory, 11) peripheral vascular disease, 12) history of amputation, 13) history of ulceration, 14) history of myocardial infarction and 15) retinopathy. Then, there were 3 risk factors added by clinical judgment which included 1) foot care, 2) unhealthy dietary and 3) physical inactivity.

3. Categorize, define and score the items

The researcher categorized the items into 4 components where were demographic data, foot assessment, behavioral assessment, and complication disease. Finally, the component and items were scored by consultation with statistician. The total score of risk assessment tool for DFU ranges from 3 – 23 (tool version 1), the tool can be seen in table 1. Low score means low risk while high score means high risk.

2. Group and categorize the risk factors

3. Score the items

Table 1 Risk assessment tool for DFU (tool version I)

RISK ASSESSMENT TOOL FOR DFU	
Components of assessment	**Scoring**
A. Demographic Data	
Research code Age:_____ Years old Gender : Female / Male Duration of DM : _____ Years History of ulceration : No [ ] Yes [ ], Specify: History of amputation : No [ ] Yes [ ], Specify:	< 50 [1] ≥ 50 [2] F [1] M[2] < 10 Years [1] ≥10 Years [2] No [0] Yes [1] No [0] Yes [1]
B. Foot Assessment	

1. Neuropathy sensory	Normal [0] Abnormal [1]

2. Peripheral Vascular Disease
   a. Absent pulse of dorsalispedis; Yes [ ] No [ ]
   b. Absent pulse of posterior tibial; Yes [ ] No [ ]
3. Skin assessment, Inspection
   a. Callus Yes ( ) No ( )
   b. Fissures Yes ( ) No ( )
4. Foot deformity, Inspection:
   a. Hammer toe
      Yes ( ) No ( )
   b. Claw toe
      Yes ( ) No ( )
   c. Hallux valgus
      Yes ( ) No ( )
   d. Hallux rigidus
      Yes ( ) No ( )
   e. Pesplanus
      Yes ( ) No ( )
   f. Charcot
      Yes ( ) No ( )
   g. Limited joint mobility
      Yes ( ) No ( )
   h. Other: _____
	Normal [0]
	Abnormal [1]
	
	None [0]
	Only 1 [1]
	>1 [2]
	
	None [0]
	Only 1 [1]
	>1 [2]

C. Behavior assessment	

1.   Current and/or history of smoking
2.   Insulin use : No [ ] Yes [ ],
3.   Abnormal of BMI
   BMI = Weight (Kg) / (Height M * Height M)
4.   Poor diabetes control
   a.   Physical inactivity
   b.   Bad Dietary
5.   Foot care (using foot care instrument)
	No [0] Yes [1]
	No [0] Yes [1]
	Normal [0] Low [1] High [2]
	
	None [0]
	Only 1 [1]
	>1 [2]
	Good [0] Bad [1]

C. Complication Disease	

1. Retinopathy
   2. Stroke
   3. Acute Miocardial infarction
	None [0]
	Only 1 [1]
	>1 [2]

TOTAL SCORE (3 – 23)	

IV. Discussion

The risk assessment tool has to be simple and clear because the tool will be used to predict risk level of DM patients for DFU. Based on Alavi et al., (2014), the early identification of risk for DFU is crucial to decrease the number of morbidity and mortality. Nurse as part of an inter-professional team need to detect risk for DFU and prevent DFU in patients. If the tool is simple and clear, it will be easy to apply. Risk assessment tool for DFU among DM patients has to be objective and discriminative which helps to differentiate risk among DM patients.

The researcher grouped risk factors in to items, from 50 risk factors become 15 risk factors based on the characteristic of the risk factors' result. If the result of risk factors were same, the researcher made it into 1 item.The researcher grouped the risk factors bade on the purpose of the results of the risk factors in which grouping is an act or process of placing in groups or a set or arrangement of things in a group (Dictionary.com, 2016). For examples: Hammer toe, flat foot, charchot foot, hallux rigius, hallus valgus were grouped become foot deformities. Monofilament insensitifity, loss of protective sensation, peripheral neuropathy present were grouped become neuropathy sensory. ABI, peripheral vascular disease, absent pulse were grouped become peripheral vascular disease.Then, the researcher categorized the risk factors or items of instrument based on characteristic of the items which divided into 4 dimensions. There are 1) demographic data, 2) foot assessment, 3) behavioral assessment, and 4) DM complication diseases. Categorize means put into category which category is defined as group in a complete system (Oxford, 2008). Some items were deleted because only have 1 study which supported the item. Based on Crawford et al. (2007) showed that only accepted two or more reports which present estimated of effectiveness in their systematic review.

V. Conclusion

The risk assessment tool for DFU in DM patients (tool version I) was developed. The tool includes 15 items and the total range from 3 -23. Further, testing its psychometric properties is recommended.

References

[1]. Aalaa, M., O Tabatabaei, M., M Sanjari,.M Peimani, and MR Mohajeri, T. (2012). Nurses' role in diabetic foot prevention and care: a review. **Journal of Diabetes & Metabolic Disorders, 11**:24.

[2]. Alavi, A., R. Gary, S., Dieter, M., Laurie, G., Mariam, B., David, G.A., Kevin, W., Thomas, B., Elizabeth, A.A., and Robert, S.K. (2014). Diabetic foot ulcers.Part I. Pathophysiology and prevention.**Journal of American Academy Dermatology. Vol. 70**, Issue 1, Pages 1.e1-1e18. Doi: http://dx.doi.org/10.1016/j.jaad.2013.06.055 (Abstract).

[3]. Alex, R., Benjamin, R., Blessed, W., D. Nathaniel, S.D., Clarence, S., Jacob, J., Venkata, R.M., Jasmine, H.P., and K.S. Jacob.(2010). Risk factors for foot ulcers in patients with diabetes mellitus-A short report from Vellore, South India.**Indian Journal of Community Medicine; 35** (1): 183-185. Doi: 10.4103/0970-0218.62582.

[4]. Al-Kafrawy, N.A.E.F.,Ehab, A.B.E.M,. Alaa, E.A.E.D., Osama,M.E., & Omnia, M.A.Z. (2014). Study of risk factors of diabetic foot ulcers.**Menoufia Medical Journal, 27**:28-34.

[5]. Bortoletto, M.S.S., Selma, M.A., Tiemi, M., Matia, C.L.H., Alberto, D.G., and Ana, M.R.S. (2014).Risk factors for foot ulcers-Across sectional survey from a primary care setting in Brazil.**Primary Care Diabetes; 8**: 71-76.

[6]. Boulton, Cavanagh and Rayman. (2006). **The Foot in Diabetes**.United State: John Wiley and Sons.

[7]. Boulton, A.J.M., David, G.A., Stephen, F.A., Robert, G.F., Richard, H., M. Sue, K., et al. (2008). Comprehensive foot examination and risk assessment. **Diabetes Care,Vol. 31**, number 8.

[8]. Boyko, E.J., Jessie, H.A., Victoria, S., Ruby, C.F., Denise, R.D., and Douglas, G.S. (1999). A prospective study of risk factors for diabetic foot ulcer**. Diabetes Care, 22**: 1036-1042.

[9]. Crawford, M. Inkster, J. Kleijnen, and Fahey. (2007). Predicting Foot Ulcers in Patients with Diabetes: A Systematic Review and Meta-Analysis. **Q J Med; 100 :**65-8. Doi:10.1093/qjmed/hcl140.

[10]. Crawford, F., C. Mccowan., B.D. Dimitrov., J. Woodburn., G.H. Wylie., E.Booth., G.P.Leese., H.L.Bekker., J.Kleijnen., and T.Fahey. (2010). The risk of foot ulceration in people with diabetes screened in community setting: finding from a cohort study. **Q J Med, 104**: 403-410. Doi: 10.1093/qjmed/hcq227.

[11]. Crawford, F, et al,. (2013). Protocol for a systematic review and individual patient data meta-analysis of prognostic factors of foot ulceration in people with diabetes: the international research collaboration for the prediction of diabetic foot ulcerations (PODUS). **BMC Medical Research Methodology, 13**:22.

[12]. Daniel C, Benno, Roderick and Harald.(2011). Prevention of Type 1 Diabetes in Mice by Tolerogic Vaccination with a Strong Agonist Insulin Mimetope.**Journal of Experimental MedicineVol. 208** no. 7. 1501-1510. doi: 10.1084/jem.20110574.

[13]. Deribe, B., Kifle, W., and Gugsa, N. (2014).Prevalence and factors influencing diabetic foot ulcer among diabetic patients attending Arbaminch Hospital, South Ethiopia.**Journal Diabetes Metabolic, 2**:322. Doi: 10.4171/2155-6156.1000322.

[14]. Dubsky, M., Alexandra, J., Robert, B., Vladimira, F., Jelena, S., Nicolaas, C.S., and Benjamin, A.L. (2012). Risk factors for recurrence of diabetic foot ulcers: prospective follow-up analysis in the Eurodiale subgroup**. International Wound Journal,** 1742-4801. Doi:10.1111/j.1742-481X.2012.01022.x.

[15]. International Diabetes Federation.(2011). **IDF Diabetes Atlas**. Sixth Edition: International Diabetes Federation.

[16]. Khalil, Assaad, A.Zaki, A.AbdelRehim, M.H. Megalla, N. Gaber, H.Gamal, and K.H.Rohoma.(2014). Prevalence of Diabetic Foot Disorders and Related Risk Factors among Egyptian Subjects with Diabetes.**Journal of Primary Care Diabetes.**

[17]. Lavery, L.A., David, G.A., Steven, A.V., Terri, L.Q., John, G.F. (1998).Practical criteria for screening patient at high risk for diabetic foot ulceration.**Arch Intern Med; 158**: 157-162.

[18]. Leymarie, F., J.L.Richard., and D. Malgrange. (2005). Factors associated with diabetic patients at high risk for foot ulceration. **Diabetes Metab; 31**: 603-605

[19]. Li, L., Linong, J., Xiao, G., Qiuhe, J., Weijun, G., Xinyue, Z., Xing, L., Hongyu.,Benli, S., Jinhua, Y., &Xilin, Y. (2015). Prevalence of microvascular disease among tertiary care Chinese with early versus late onset of type 2 diabetes.**Journal of Diabetes and Its Complication, 29**; 32-37.

[20]. Madanchi, Nima, OzraTabatabaei-Malazy, Mohammad Pajouhi, RaminHeshmat, BagherLarijani and Mohammad-Reza Mohajeri-Tehrani. (2013). Who Are Diabetic Foot Patients? A Descriptive Study on 873 Patients.**Journal of Diabetes & Metabolic Disorder, 12**:36.

[21]. Molvear, A.K., Marit, G., Birgitte, E., Truls, O., Kristian, M., and Marjolein, M.I. (2014). Diabetes-related foot ulcers and associated factors: results from the Nord-Trondelag Health Survey (HUNT3) (2006-2008). **Journal of Diabetes and Its Complications, 28**:156-161.

[22]. Nehring, Piort, BeataMrozikiewicz-Rakowska, Monika Kryzewska, AgnieszkaSobczyk-Kopciol, RafatPhiski, GrazynaBroda and WaldemarKarnafel. (2014) .Diabetic Foot Risk Factors in Type 2 Diabetes Patients: A Cross-Sectional Case Control Study. **Journal of Diabetes & Metabolic Disorder, 13**:79.

[23]. Ogbera, Anthonia, Olufemi F, Augustine O. (2006). High Cost, Low Awareness and a Lack of Care – The Diabetic Foot in Nigeria. **Clinical Care Volume 5,**Issue 3.

[24]. Peter, E.J.G., David, G.A., and Lawrence, A.L. (2007).Risk factors for recurrent diabetic foot ulcers.**Diabetes Care, Vol. 3**, No.8. Doi: 10.2337/dc07-0445.

[25]. Purwanti, Okti Sri. (2013). Analisis factor resikoulkus kaki diabetic pada diabetes pasien di rumahsakit Dr. Moewardi (Analysis of risk factors of foot ulcers on diabetes mellitus patients in Dr. Moewardi Hospital). **Master Thesis**. University of Indonesia, Depok [in Indonesia].

[26]. Reiber, Edward, and Douglas.(2001). **Lower Extremity Foot Ulcer and Amputataion in Diabetes.Chapter 18**.Pages 409-428.

[27]. Samann, A., O.Tajiyeva.,N.Muller., T.Tschuner., H.Hoyert., G.Wolf., and U.A.Muller. (2008). Prevalence of diabetic foot syndrome at the primary care level in Germany: a cross sectional study. **Diabetic Medicine; 25**: 557-563. Doi: 10.1111/j.1464-5491.2008.02435.x.

[28]. Shahi, S.K., Ashok, K., Sushil, K., Surya, K.S., Sanjeev, K.G., and T.B. Singh.(2012). Prevelence of diabetic foot ulcer and associated risk factors in diabetic patients from North India. **The Journal of Diabetic Foot Complications, Vol.4**, Issue 3, No. 4: 83-91.

[29]. Tapan, Erik. (2005). **Penyakitdegeneratif (Degenerative diseases).**Elex Media Komputindo : Jakarta [in Indonesia].

[30]. Wijaya and Putri.(2013). **Keperawatan medical bedah (Medical surgery nursing).**NuhaMedika : Yogyakarta [in Indonesia].