

# A CASE CONTROL STUDY TO ASSESS THE RISK FACTORS OF DEVELOPMENT OF FOOT ULCERS AMONG THE CLIENTS WITH DIABETES MELLITUS RESIDING IN SELECTED RURAL AREAS OF SEDARAPET, PUDUCHERRY.

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## ABSTRACT

This study was under taken to assess the risk factors in terms of poor diabetic foot care and that are the most important contributing factor for the development of foot ulcers and then to educate the clients to be aware of risk factors that can even lead them to loss of limb. Quantitative approach with case control design was used in this study. A total of 240 participants 80 in each group were selected using purposive sampling technique. Clients with Diabetic Foot ulcer were recruited as cases and clients with out were recruited as controls. One group of cases and controls were selected at Medical and Surgical wards of Pondicherry Institute of Medical Sciences Pondicherry and one group of controls were selected from the rural areas of Sedarapet and Kalapet Primary Health Centers Pondicherry. The samples were interviewed for

risk assessment and foot self-care practices using modified Inlow's 60 seconds scale. Monofilament testing was done to check the sensitivity of the non-ulcerated foot. The data was analyzed to find out the association of risk factors using Odd's Ratio. Participants with dry and fungus heavy callus build up have 8.7 times risk of foot ulcers than Participants with intact and healthy skin. Participants unkept the nails had 4.6 times risk than Participants well kept the nails. In the right leg Range of motion Group I (hallus limitus compared with full range of motion) Participants compared with hallus limitus had 2.3 times risk than Participants with full range and Group II ( hallus rigidus compared with full range of motion) Participants compared with hallus rigidus has 3.5 times risk than Participants with full range. In capillary refill Right Leg Group I (4-3 seconds compared with 5 seconds) Participants compared with 4-3 secs had 10.6 times risk than Participants with 0-5secs and Group II (2-1 seconds compared with 5 seconds) Participants with 2-1 secs has 23.4 times risk than Participants with 0-5secs. Participants with cold dampness of foot when compared with normal foot had the risk of 6.8 times risk of developing foot ulcer in the left leg. The study shows that improper maintenance of nails, foot and skin, slow capillary refill, cold dampness on foot and slow range of motion were the risk factors which significantly associated for development of foot ulcer among the clients with Diabetes Mellitus.

**Key words: Case Control, Foot Ulcer, Diabetes Mellitus**

## **BACKGROUND OF THE STUDY**

Foot problem in diabetes has no simple solutions. The hub of the management of the diabetic patients is the primary care physicians or the community care provider. At the primary level it is necessary to provide care for the patients. Higher incidences of diabetic foot ulcers are found among the patients with poor knowledge and faulty practices regarding diabetic foot care. There has been reduction of foot problems and promotion of healing of the foot ulcers after health education of foot care practices.

## **NEED FOR THE STUDY**

The investigator during the home visits also has observed that in spite of taking regular medications and followed diet control clients developed foot ulcers due improper management of foot care. So it becomes necessary to assess the risk factors of developing foot ulcer well ahead of time to prevent the complications.

## **STATEMENT OF THE PROBLEM**

A Case Control Study To Assess The Risk Factors of Development Of Foot Ulcers Among The Clients With Diabetes Mellitus.

**OBJECTIVE**

- To identify the risk factors of developing foot ulcers among clients with diabetic mellitus.

**METHODOLOGY**

- **RESEARCH APPROACH** - Quantitative approach
- **RESEARCH DESIGN** - Case control research design
- **STUDY SETTING** - Cases and controls-PIMS medical and surgical wards, controls- Sedarapet and Kalapet villages
- **TARGET POPULATION**

**Cases:** Clients with Diabetes Mellitus with foot ulcers.

**Controls:** Clients with Diabetes Mellitus without foot ulcers.

**SAMPLING CRITERIA****Inclusion criteria:**

**Cases:** Diabetic clients with foot ulcer.

**Controls:** Diabetic clients without foot ulcer.

**Exclusion criteria:**

**Cases:** Diabetic Client who have underwent foot amputation

**Controls :** Diabetic Client with diabetic foot ulcers

**SAMPLE**

The sample of the study is Clients with diabetes mellitus residing in the rural areas of Sedarapet Primary Health Centre and clients attending Medical and surgical outpatient department Pondicherry Institute of Medical Sciences (PIMS)

**SAMPLING TECHNIQUE :** purposive sampling technique

**INSTRUMENT AND TOOLS**

The tool has three parts.

**Part I:**

Details on Socio Demographic data such as Age, Education, Marital status, Occupation, income which was collected using semi structured Interview questionnaire.

**Part II:****COMPREHENSIVE FOOT EXAMINATION AND RISK ASSESSMENT TOOL**

The tool was prepared using Comprehensive Foot Examination and Risk Assessment. The

basic details were taken from Comprehensive Foot Examination report by the American diabetic association. The tool consists of following sections:

**i) Health Profile:**

History was collected regarding foot problems Pain, Numbness, Loss Of Sensation, Blood Sugar Level, And Everyday Inspection Of Their Foot.

**ii) Foot Care Practices:**

Questions on the practice of foot care was asked among the clients to assess the practice level among the clients like maintaining their foot, cleaning their foot, nail cut, regular use of footwear, maintaining their footwear regularly.

**iii) Diagnostic Test And Physical Signs**

This tool was prepared, the basic details were taken from In Low's 60 second diabetic foot screen – a Screening tool of the Canadian association of wound care assessment tool and was modified by the investigator to suite the study. In this tool clients foot will be assessed for Risk factors and monofilament test will be done to assess the sensation of the foot

**DATA COLLECTION PLAN**

Data collection was done over a period of 6 weeks. Data collection was done using Semi Structure Questionnaire Interview method. The tool consists of demographic data, risk assessment tool, foot care practices, checklist and monofilament testing. Risk assessment was done by collecting the details about duration of illness, regular use of medications, regular treatment, proper diabetic diet, any awareness about foot ulcer. Foot self care practices was assessed by asking their practices like regular use of footwear, use of footwear inside the home, use of moisturizing cream or oil, cleaning and drying their toe spaces, checking their footwear before using it. Monofilament testing was assessed at 10 sites to check the sensation of the foot. Clients with foot ulcer as cases were selected from Pondicherry Institute of Medical Sciences, one of the control clients with only diabetes was selected from Pondicherry Institute of Medical Sciences, and other one control from community area (Kalapet, Sedarapet). The samples were collected from the following dates:

WEEKS	CASES IN SURGICAL WARDS	CONTROLS IN MEDICAL WARDS	CONTROLS IN COMMUNITY
1 <sup>st</sup> week	26 cases	15 controls	11 controls
2 <sup>nd</sup> week	19 cases	29 controls	41 controls
3 <sup>rd</sup> week	17 cases	20 controls	25 controls
4 <sup>th</sup> week	15 cases	16 controls	17 controls

**ANALYSIS AND INTERPRETATION OF THE FINDINGS**

**SECTION A:** Socio demographic variables of the clients with Diabetes Mellitus.

**SECTION B:** Risk factors for developing foot ulcers among the clients with Diabetes Mellitus.

**SECTION C:** Association of Risk Factors among the clients with Diabetes Mellitus.

**Table: Multivariate Logistic regression analysis for Foot ulcer among the Hospital cases and controls**

**n=160**

RISK FACTORS	OR	95% Class Interval for OR		p value
		LOWER	UPPER	
Nails Right Leg	4.663	2.228	9.759	1
Nails Left Leg	4.714	2.285	9.727	1
Skin Right Leg	8.755	4.188	18.301	1
Skin Left Leg	7.621	3.698	15.706	1
Group I Capillary Refill Right Leg	10.635	4.35	26.002	1
Group II Capillary Refill Right Leg	23.429	2.272	241.594	1
Group I Capillary Refill Left Leg	9.067	3	21.284	1

**Regarding skin Right leg**

- Participants with dry and fungus heavy callus build up when compared with intact and healthy skin had 8.7 times risk of developing foot ulcer.

**Left leg**

- Participants with dry and fungus heavy callus build up when compared with intact and healthy skin had 4.6 times risk of developing foot ulcer.

**Regarding capillary refill Right Leg:****Group I [ 4-3 seconds compared to 5 seconds]**

- Participants with 4-3 seconds compared to 5 seconds of capillary refill had 10 times risk of developing foot ulcer.

**Group II [ 2-1 seconds compared to 5 seconds]**

- Participants with 2-1 seconds compared to 5 seconds of capillary refill had 3.5 times risk of developing foot ulcer.

**Left Leg:**

**Group I [ 4-3 seconds compared to 5 seconds]**

- Participants with 4-3 seconds compared to 5 seconds of capillary refill had 9.1 times risk of developing foot ulcer.

**Table : Multivariate Logistic regression analysis for Foot ulcer among the Hospital cases and controls**

n=160

RISK FACTORS	OR	95% C.I.for EXP(B)		P value
		LOWER	UPPER	
<b>Group I Range of Motion Right Leg</b>	2.348	1.127	4.892	1
<b>Group II Range of Motion Right Leg</b>	3.5	0.884	13.856	1
<b>Group I Range of Motion Left Leg</b>	2.292	1.112	4.724	1
<b>Group II Range of Motion Left Leg</b>	2.625	0.717	9.614	1

TABLE : Shows regarding range of motion

**RIGHT LEG:**

**Group II [ Hallus limitus compared to Full range]**

- Participants with Hallus Limitus had 2.6 times risk than participants with full range of movement.

**Group II [ Hallus rigidus compared to Full range]**

- Participants with Hallus Rigidus had 3.5 times risk than participants with full range of movement.

**LEFT LEG:**

**Group I [ Hallus limitus compared to Full range]**

- Participants with Hallus Limitus compared with full range had 2.2times risk of developing foot ulcer.

**Group II [ Hallus Rigidus compared to Full range]**

- Participants with Hallus Rigidus compared with full range had 2.6times risk of developing foot ulcer.

**Table : Multivariate Logistic regression analysis for Foot ulcer among the Hospital cases and Community controls**

RISK FACTORS	OR	95% C.I.for EXP(B)		P value
		Lower	Upper	
Nails Right Leg	8.59	4.071	18.126	1
Nails Left Leg	8.291	3.975	17.292	1
Cold Dampness Right Leg	4.98	1.361	18.226	1
Cold Dampness Left Leg	6.882	1.488	31.843	1
Group I Capillary Refill Right Leg	10.635	4.35	26.002	1
Group II Capillary Refill Right Leg	23.429	2.272	241.59	1
Group I Capillary Refill Left Leg	8.409	3.578	19.766	1
Group II Capillary Refill Left Leg	14.625	1.343	159.23	1

Table : shows that regarding nails.

**Right Leg:**

- Participants unkept the nails when compared with well-kept the nails had 8.5 times risk of developing foot ulcer.

**Left Leg :**

- Participants unkept the nails when compared with well-kept the nails had 8.2 times risk of developing foot ulcer.

**Regarding temperature. Right Leg :**

- Participants with cold dampness of foot when compared with normal foot had the risk of 4.9 times risk of developing foot ulcer.

**Left Leg :**

- Participants with cold dampness of foot when compared with normal foot had the risk of 6.8 times risk of developing foot ulcer.

**Regarding capillary refill.****Group I: [ Right leg 4-3 seconds compared to 5 seconds]**

- Participants with 4-3 seconds of capillary refill when compared with 5 seconds had 10.6 times the risk of developing foot ulcer.

**Group II: [ Right leg 2-1seconds compared to 5 seconds]**

- Participants with 2-1 seconds of capillary refill when compared with 5 seconds had 23.4 times the risk of developing foot ulcer.

**Group I: [ Left leg 4-3 seconds compared to 5 seconds]**

- Participants with 4-3 seconds of capillary refill when compared with 5 seconds had 8.4 times the risk of developing foot ulcer.

**MAJOR FINDINGS OF THE STUDY**

- Most of the participants 108(45.0%) were in the age group of less than 55years
- 132 (55.0%) participants were in the age group of more than 55years.
- Distribution of participants based on Gender shows that 135(56.3%) participants were Male and 1059(43.8%) participants were Female.
- Distribution of participants based on Educational status shows that 94(39.2%)were Undergraduate,63(26.3%) had Primary Education,8(3.3%) had Secondary education,53(22.1%) had Higher Secondary Education.
- Distribution of participants based on Occupation shows that 115(47.9%) were skilled employee,38(15.8%) were Unskilled employee,87(36.3%) were Unemployed.
- Distribution of participants based on Income shows that 152(63.3%) earns less than 5000 and 88(36.7%) earns more than 5000.
- Distribution of participants based on Living area shows that 160(66.7%) lives in Rural area and 82(34.2%) lives in Urban area.
- 32(40.0%) hospital cases 29(36.3%) hospital controls and 15(18.8%) community control participants did not monitor their blood glucose level.
- 62(77.5%) hospital cases 11(13.8%) hospital controls 22 (27.5%) community controls participants had pain in their foot.
- 75(93.8%) hospital cases 58(85.0%) hospital controls 76 (95.0%) community controls participants were not aware of foot ulcer.

**THE PRACTICE LEVEL OF THE PARTICIPANTS HOSPITAL CASES**

69(86.3%) clients were inspecting their feet, 72(90%) were examining their toe spaces regularly, 54(67.5%) did not use oil or moisturizer for their foot, 70(87.5%) participants don't



use footwear indoors, 45(56.3%) participants were not inspecting their footwear before wearing, 65(81.3%) trim their toe nails regularly, 74(92.5%) participants were not changing if their footwear is ill fit or damaged.

### HOSPITAL CONTROLS

75(93.8%) clients were inspecting their feet, 76(95%) were examining their toe spaces regularly, 64(80.0%) participants did not use oil or moisturizer for their foot, 73(91.3%) participants don't use footwear indoors, 56(70.0%) participants were not using inspecting their footwear before wearing, 69(86.3%) trim their toe nails regularly, 74(92.5%) participants were not changing if their footwear is ill fit or damaged.

### COMMUNITY CONTROLS

74(92.5%) clients were inspecting their feet, 74(92.5%) were examining their toe spaces regularly, 56(70.0%) participants did not use oil or moisturizer for their foot, 69(86.3%) participants don't use footwear indoors, 49(61.3%) participants were not using inspecting their footwear before wearing, 67(83.8%) trim their toe nails regularly, 69(86.3%) participants were not changing if their footwear is ill fit or damaged.

### IN ODDS RATIO

The odd's ratio value found for the risk factors among the hospital cases and controls were Improper nail care of right leg (OR=4.6), left leg (OR= 4.7), Improper skin care right leg (OR=8.7), left leg (OR=4.6), Slow range of motion in right leg Hallus limitus among Group I (OR=2.6), Hallus rigidus among Group II (OR=3.5) and Slow range of motion in left leg Hallus limitus among Group I (OR=2.2), Hallus rigidus among Group I I (OR=2.6) and Capillary Refill 3-4seconds in right leg (OR=10), 1-2 seconds (OR= 3.5) among Group I and in left leg 3-4 seconds among group I (OR=9.1).

Among the Community Controls the risk factors found with Odd's ratio were improper nail care of right leg (OR=8.5), left leg (OR=8.2), Cold Dampness of right leg (OR=4.9), left leg (OR=6.8), Capillary Refill 3-4 seconds in right leg (OR=10.6) among Group I, 1-2 seconds (OR=23.4) among Group II and Capillary refill 3-4 seconds in left leg among Group I (OR=8.4).

### CONCLUSION

The study shows that improper maintenance of nails, foot and skin, slow capillary refill, cold temperature on foot and slow range of motion were the risk factors identified for development of foot ulcer. The odd's ratio value found for the risk factors among the hospital cases and controls were Improper nail care of right leg (OR=4.6), left leg (OR= 4.7), Improper skin care right leg (OR=8.7), left leg (OR=4.6), Slow range of motion in right leg Hallus limitus among Group I (OR=2.6), Hallus rigidus among Group II (OR=3.5) and Slow range of motion in left leg Hallus limitus among Group I (OR=2.2), Hallus rigidus among Group I I (OR=2.6) and Capillary Refill 3-4seconds in right leg

(OR=10), 1-2 seconds (OR= 3.5) among Group I and in left leg 3-4 seconds among group I (OR=9.1). Among the Community Controls the risk factors found with Odd's ratio were improper nail care of right leg (OR=8.5),left leg (OR=8.2), Cold Dampness of right leg (OR=4.9), left leg (OR=6.8), Capillary Refill 3-4 seconds in right leg (OR=10.6) among Group I, 1-2 seconds (OR=23.4) among Group II and Capillary refill 3-4 seconds in left leg among Group I (OR=8.4).

## RECOMMENDATIONS

- The findings of the present study serves as the basis for the professionals and the students to conduct further studies like comparative study between the urban and the rural area.
- The risk assessment can be taught to all the nursing profession which will to identify the risk factors of Diabetes mellitus at the earliest.

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