



Efficacy of Nursing Skin Care Protocol on Prevention of Skin Related Problems among Newly Diagnosed Diabetic Patients

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Authors' contributions:

This work was carried out in collaboration among all authors. Author PJD designed the study, wrote the protocol, and wrote the first draft of the manuscript. Authors MY and RA managed the literature searches and approved the final draft. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Background: Approximately 400 million people would be afflicted with diabetes by 2025, projected worldwide. In India, about 50.9 million people suffer from diabetes, and this figure will go up to 80 million by 2025. Diabetes leads to blindness, kidney failure, heart attacks, stroke and foot ulcer. Skin problems are increasing in diabetic patients. It is estimated that 30% of diabetes patients will experience a skin problem at some stage throughout the course of their disease. Many skin care guidelines are given for diabetic foot care, but nursing skin care protocol for diabetic patients is not available. Less attention is given to complete skin care in diabetes routine care. There is need to develop Nursing skin care protocols for prevention of skin problems in diabetes.

Objectives: To validate the developed nursing skin care protocol on prevention of skin related problems among newly diagnosed diabetic patients, to assess the skin problems in experimental group and control group, and to assess the efficacy of nursing skin care protocol in experimental group and routine skin care with coconut oil in control group.

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Methodology: Study design is randomized controlled trial. Study will be carried out in hospital setting with 140 participants. Random allocation and concealment with single blinding will be done. Intervention is Nursing skin care protocol consist of Daily skin inspection, Bathing, Drying, clothing, Application of lotion, Hydration, Injury prevention, Nail care and Hair care, Sugar control, Dermatological consultation and Physician consultation. Semi structure questionnaire, skin assessment tool [GI, Glammal score for xerosis, Visual Analogue Scale for pruritus, Questionnaire on erythema, hair and nail colour changes] and self-reported practice checklist will be used to collect data.

Expected Results: Investigator expects newly diagnosed diabetic patients will not develop any skin related problems after using Nursing skin care protocol.

Conclusion: Diabetic patients will be able to utilize developed nursing skin care protocol routinely to prevent skin related problems.

Keywords: Nursing skin care protocol; diabetic patients; skin related problems; routine skin care.

1. INTRODUCTION

Diabetes is a metabolic disease that raises blood sugar level. The hormone insulin moves sugar from the blood into the cells to be stored or used for energy. With diabetes, our body either doesn't produce enough insulin or can't effectively use the insulin it does make [1].

Diabetes is one of the most prevalent diseases in the world. By 2025 nearly 400 million people would be affected by it. In India, nearly 50.9 million people suffer from diabetes, and this number is likely to go up to 80 million by 2025, making India the 'Diabetes Capital' of the world. Delhi alone has an estimated 29.8 lakh people suffering from this disease [2].

1.1 Background and Need

The worldwide prevalence of diabetes among adults over 18 years of age has increased from 4.7% in 1980 to 8.5% in 2014. Diabetes prevalence is rapidly rising in middle- and low-income countries. In 2016 diabetes was the seventh leading cause of death, as per WHO. Regular physical activity, healthy diet, maintaining weight and avoiding tobacco use are the ways to prevent or delay the onset of type 2 diabetes [3].

Skin problems are one of the most common problems among diabetic patients. 30% of patients with diabetes mellitus will experience a skin problem at some stage throughout the course of their disease. Candida and impetigo are more common skin conditions in diabetic patients [4].

A study revealed that, Cutaneous infections were noted in 148 (37%) diabetics of which fungal infections were the most common seen in 106 (26.5%) patients, followed by xerosis in 121

(30.25%) and acrochordons in 71 (17.75%) patients. Cutaneous changes associated with neurovascular complications included diabetic foot in 3%, diabetic dermopathy in 2%, and pigmented purpuric dermatosis in 0.25% of the diabetics. Study revealed that a joint effort between dermatology and general medicine is necessary for the early recognition and treatment of the skin conditions and also to ensure adequate sugar control [5].

Diabetes is associated with a broad range of dermatologic conditions. Many of skin problems are present in diabetic patients. To improve health and quality of life in diabetes, patient's education and lifestyle changes are crucial [6].

Study found that out of 630 sample, 325 (51.5 %) knew diabetic foot as the most common complication followed by hypertension 223 (35.4 %), neuropathy 184 (29.2 %), hypoactive sexual arousal 160 (25.4 %), arousal disorder 135 (21.5 %), eye diseases 112 (17.7 %), heart disease 58 (9.2 %), and renal disease 34 (5.4 %). Analysis revealed that 378 (60.0 %) of T2D patients did not have knowledge on diabetes complications, 169 (26.9 %) had inadequate knowledge on diabetes complication while 82 (13.1 %) had adequate knowledge [7].

A study with 51 diabetic patients revealed a total of 36 dermatologic disease entities. The overall prevalence of one or more identifiable/apparent skin conditions was 85.4%. The most common skin conditions were infections (31.7%) (mostly mycoses), non-Candidal intertrigo (20.5%), eczemas (15.2%) (mostly neurodermatitis), psoriasis (11.2%), diabetic dermopathy (11.2%), and prurigo (9.9%). According to sex, there was no significant difference in the prevalence of skin disorders but confirmed that frequent

dermatologic evaluation of these diabetic patients is warranted [8].

Evidence promises that daily applications of a moisturizing formulation on the body, particularly on compromised lower extremities, often control both pruritus and xerosis [9].

Skin problems are increasing in diabetes. Diabetic patients are prone to develop skin problems. These problems are due to increased sugar level, as well as due to complications of diabetes like chronic kidney disease, neuropathy, decreased circulation and sometime the side effects of medicine also may lead to, xerosis, pruritus, erythema and other skin problems. Many studies are carried out on diabetic foot ulcers and its management. Above Review suggested that use of emollients, skin hygiene, skin examination and dermatological consultation is needed for proper skin care in diabetes skin conditions to prevent many of the skin disorders in diabetes. Many skin care guidelines are given for diabetic foot care, but nursing care protocols for diabetic patients are not available for prevention of skin related problems in diabetic patients. Less attention is given to complete skin care in diabetes routine care. Thus, the investigator felt that there is need to develop Nursing Skin Care Protocols for prevention of skin problems in diabetic patients.

Title: Efficacy of Nursing Skin Care Protocol on prevention of Skin related problems among newly diagnosed diabetic patients.

Research Question: Does the Nursing Skin Care Protocol be effective in prevention of skin related problems in newly diagnosed diabetic patients?

Explanation for choice of comparators: Routine skin care with coconut oil application on skin will be used as comparator with Nursing skin Care Protocol, which consist of skin inspection, cleaning of skin [Bathing], drying, clothing, application of lotion [glycerine mixed with liquid paraffin] hydration, prevention of injury, care of nail and hair, sugar control, dermatological consultation, physicians consultation.

1.2 Objectives

- 1) To validate the developed nursing skin care protocol on prevention of skin related problems among newly diagnosed diabetic patients.
- 2) To assess the skin problems in experimental group.

- 3) To assess the skin problems in control group.
- 4) To assess the efficacy of nursing skin care protocol prevention of skin problems in newly diagnosed diabetic patients in experimental group and routine care in control group.
- 5) To compare the effectiveness of Nursing Skin Care Protocol in experimental group and routine skin care in control group.
- 6) To associate the baseline level of skin related problems with selected demographic variables among newly diagnosed diabetic patients in experimental and control group.

1.3 Hypotheses

H0: There is no significant relationship between Nursing Skin Care Protocol and prevention of skin related problems among newly diagnosed diabetic patients.

H1: There is a significant relationship between Nursing Skin Care Protocol and prevention of skin related problems among newly diagnosed diabetic patients.

H2: There is a significant association between the skin related problems and selected demographic variables among newly diagnosed diabetic patients.

Trial Design: Annexure II is attached
Single blind, parallel group Randomized controlled Trial

2. METHODOLOGY

Study Setting: The study setting will be medicine outpatient and inpatient department of Acharya Vinoba Bhave Rural Hospital Sawangi Meghe Wardha.

2.1 Eligibility Criteria

2.1.1 Inclusion criteria

Newly diagnosed Diabetic patients who are,

1. Diagnosed within zero to one year
2. 18 years and above
3. Male and female
4. Able to read and understand English, Marathi, Hindi
5. Willing to participate

2.1.2 Exclusion criteria

Newly diagnosed Diabetes patients who are,

1. Critically ill

2. Undergoing any skin treatment.
3. Diagnosed with skin disorders
4. Having thyroid disorder

to the investigator before they make any changes.

2.2 Intervention for Experimental Group

Nursing Skin Care Protocol will be made by investigator, depending on the evidenced based guideline for skin care. It will include, skin inspection, cleaning of skin [Bathing], drying, clothing, application of lotion, hydration, prevention of injury, care of nail and hair, sugar control, dermatological consultation, physicians consultation. It will be provided for the each newly diagnosed diabetic patients under study in experimental group. Instructions for the skin care will be given according to protocol.

2.3 Control Group

Newly diagnosed diabetic patients of control group will receive routine skin care with instruction of only coconut oil application on skin as lotion. Participant will be instructed to informed

2.4 Procedures for Monitoring Adherence

Follow up will be done on phone and physical examination will be carried out by investigator in 3 observation. A checklist will be given to the participant for daily marking and it will be produced on follow up day to investigator for record. Participant are allowed to visit the physician and dermatologist if they develop any skin problems during the trial and they also will be instructed to inform to investigator.

2.5 Outcomes

Primary outcome: Development of Nursing Skin Care Protocol for newly diagnosed diabetic patients and prevention of skin related problems.

Secondary outcome: Early detection of skin related problems among newly diagnosed diabetic patients and prompt action.

Participant timeline: Annexure -II is attached.

Sample size:--Sample size formula with desired error of margin

$$n = \frac{Z_{\alpha/2}^2 \times P \times [1-P]}{e^2}$$

Where,

$Z_{\alpha/2}$ is the level of significance at 5% i.e. 95% confidence interval

=1.96

P = Proportion of inflammatory skin diseases =20.7%

=0.207

e= desired error of margin

= 10%=0.10

$$n = \frac{1.96^2 \times 0.207 \times [1-0.207]}{0.10^2} = 63.06$$

0.10²=63.06

Total sample size = 140, Experimental group 70+ control group 70

Recruitment: Subjects will be identified through existing patients of selected Hospital and through physician referrals. Investigator, will select the experimental and control group.

Allocation: Lottery method will be used to allocate the participant in to experimental and control group.

Allocation concealment mechanism: Sequentially numbered opaque sealed envelopes will be used to by investigator to allocate the subjects and to enrol the participant and also to assign participant to treatment.

Blinding (masking): Trial participant will be blinded after assignment to treatment.

Data Collection Methods: Official permission will be taken from authority to conduct study. Investigator will introduce herself with purpose of study to samples. Selection of sample will be as per inclusion criteria. Participant's informed consent will be taken before starting study. Sample will be allocated to experimental and control group. First all newly diagnosed diabetic patients under study will be assessed. Intervention will be given to experimental group and control group will receive routine skin care. Observation will be in 3 observations.

Pilot Study: Pilot study will be carried out. Necessary changes on the basis of observations of pilot study will be implemented in the protocol before final study.

2.6 Tool and Techniques

1. Semi structured questionnaire for demographic data
2. Skin assessment tool, [GI, Glammal score for xerosis, Visual Analogue Scale for pruritus, Questionnaire on erythema, hair and nail colour changes]
3. Self-reported practice checklist.

Validity: Content and construct validity of the tool and protocol will be done by subject experts.

Reliability: Split half method and interrater reliability

Data Management: Data collected will be prepared in master sheet with proper coding and it will be stored by investigator. Confidentiality of data will be maintained.

Statistical Methods: Descriptive analysis will be like frequency, percentage, mean and standard deviation. To determine effectiveness of Nursing skin care protocol t test will be utilized. Comparison between experimental and control group will be done by chi-square test or Fischer exact test whichever will be applicable. All analysis will be performed using SPSS software.

Monitoring of Data: Investigator will herself conduct the monitoring of data.

Auditing: Auditing of trial data will be carried out by investigator.

Protocol Amendments: Any changes in protocol will be informed to institutional ethical committee and clinical trial registry of India every six monthly.

Confidentiality: Code number will be assigned to enrolled participant to maintain confidentiality.

Declaration of Interests: No conflict of interest.

Access to Data: Investigator and statistician will have access to the data.

Post trial observation will be carried out for 6 months to all participant and will participant will be referred to physician and dermatologist if needed.

3. RESULTS

Investigator expects nursing skin care protocol will prevent the skin related problems like Redness, Dry skin, Itching, Wheal, Skin colour changes, Nail problem and Hair problem in newly diabetic patients. During trial if any of the study participant develop the skin disorder it will be identified early and prompt treatment will be initiated and number of times skin problems developed, types of problems, number of visits to

consultant, duration of treatment, severity of problems will be compared in both groups [10].

4. DISCUSSION

A research was conducted to rule out the effect of an emollient on diabetic patients. Forty patients with diabetes applied the emollient two times a day for a month on one arm and one leg, in normal conditions. A 1-month treatment with an emollient allows a similar skin hydration rate in diabetics to that in healthy people. Dry skin improvement was found with a significant reduction in pruritus and desquamation, and a significant improvement in the skin barrier function. Skin complications can be limited by use of emollient treatment in diabetes [10]. This study is suggestive of use of emollient to treat and prevent skin condition which is expected by investigator in current study.

A study with 100 diabetic patients with skin lesions, xerosis was found in 44% of the patients. Patients with kidney disease also frequently suffer from xerosis. The study suggested that consultation to a dermatologist is necessary for xerosis. Health care provider should educate patients about the importance of skin hygiene, with applying fragrance-free creams or lotions within 3 minutes of bathing to trap moisture within the skin. [11]. Study revealed that skin hygiene use of lotions are beneficial in dry skin care. In current study also investigator is including in protocol skin hygiene and use of lotion [11].

5. CONCLUSION

Nursing skin care protocol for newly diagnosed diabetic patients developed by investigator will be utilized by diabetic patients routinely to prevent skin related problems. Study will help to early detect skin related problems in diabetic patients and prompt action will be initiated.

CONSENT

Investigator will obtain informed consent with the help of consent form in participant own language.

ETHICAL APPROVAL

The study has been granted ethical approval by institutional ethics committee, Datta Meghe Institute of Medical Sciences (Deemed to be university) Sawangi (Meghe) Wardha. The investigator will be disseminate the study result and implication of the study via publication.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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ANNEXURE

Annexure-I

Schematic presentation of research design

Title: Efficacy of Nursing Skin Care Protocol on prevention of Skin related problems among newly diagnosed diabetic patients.

Research Design: Randomized controlled trial

Setting: Acharya Vinoba Bhave Rural Hospital, Wardha

Target population: Newly diagnosed Diabetic patients in selected hospitals

Sampling technique: Purposive sampling followed by randomization

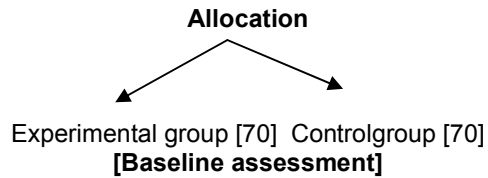
Sample Size :- 140

Inclusion criteria: Newly diagnosed Diabetic patients who are,

1. diagnosed within zero to one year
2. both male and female
3. in age group of 18 years and above
4. able to read and understand English, Marathi, Hindi
5. willing to participate

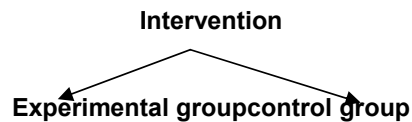
Exclusion criteria: Newly diagnosed diabetes patients who are,

1. critically ill
2. undergoing any skin treatment.
3. diagnosed with skin disorders
4. having thyroid disorder



Tool: 1. Semi structured questionnaire on, A] age, gender, education, occupation, religion, marital status, type of family, family income per month, dietary pattern, habit of exercise, information about skin care in diabetes. B] Clinical Variables, duration of diabetes, diabetes medicine, fasting blood sugar level, any other disease, any other medicine

2. Skin Assessment Tool
3. Self Report Practice Checklist



[Nursing Skin Care Protocol]	Routine skin care with coconut oil]
Consist of Daily skin inspection, Bathing Drying, clothing, Application of lotion Hydration, Injury prevention, Nail care and Hair care, Sugar control, Dermatological consultation and Physician consultation.	Diagnosed patients of this group will receive routine skin care with instructions to apply coconut oil only on skin as lotion follow up will be done as in experimental group

Post intervention observation

Sr. NO	Observation		
	1 Month	3 Month	6 Month

Follow up will be done on phone and as well as in person.

A checklist will be given to the patient for daily marking and it will be produce on follow up day to investigator for record.

Outcome

Prevention of skin related problems [Redness, Dry skin, Itching, Wheal, skin colour change, nail problem and hair problem]

Early detection and prompt action

Number of times skin problems developed, types of problems, number of visits to consultant, duration of treatment, severity of problems comparison in both group

Annexure-II

Schedule of event

Activity/Visit Visit period	Screening baseline 30 days	Treatment First day	Observation		
			1 Month	3 Month	6 Month
Selection of participant according to inclusion criteria, informed consent	→				
Assign code number	→				
Randomization	→				
Assessment of Demographic information	→				
Intervention experimental group [nursing skin care protocol		→	→	→	→
Control group [routine care with coconut oil application on skin		→	→	→	→

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