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"To Determine If Atherectomy Using The TransluminalEndarterectomy Catheter (TEC) Is An Effective Endoluminal Therapy For Infrainguinal Occlusive Disease Rather Than Conventional Open Endarterectomy"

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Abstract
Background: *Leg ulcers affect probably millions of persons in the Bangladesh, and their prevalence is likely to rise as the population ages. They cause considerable disability, limb or part of limb loss, and the cost of treating these chronic wounds is enormous.*
Objective: *The purpose of this study was to assess the financial, social, and psychological Implications of leg ulcer on overall quality of life.*
Methods: *Data were collected by standardized personal interviews with 69 patients with chronic leg ulcers. The interview covered several domains that were selected to determine the Impact of a leg ulcer on overall quality of life.* ***Results:*** *A significant number of patients had moderate to severe symptoms, principally pain, related to the leg ulcer. Seventy two percent believed that their mobility was adversely affected by the ulcer; the dominant predictor of impaired mobility was swelling of the leg. For younger, working patients, leg ulceration was correlated with time lost from work, job loss, and adverse effects on finances. Fifty-six percent of patients found caring for the ulcer burdensome. There was a strong correlation between time spent on ulcer care and feelings of anger and resentment. Seventy-two percent of patient reported that the ulcer had a negative emotional impact on their lives, including feelings of fear, social isolation, anger, depression, and negative self-image.*
Conclusion: *Leg ulcers pose a substantial threat to a variety of dimensions of a patient's quality of life.*
Keywords: *Psychological Implications, Severe Symptoms, Principally Pain, Leg Ulcer.*

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I. Introduction

The prevalence of leg ulcers is probably between 0.18% and 1 % of the population"! And is likely to increase as the average age of the population rises. Leg ulcers are a common presentation in the elderly population associated with a negative impact in the quality of life. Several factors including venous and arterial insufficiency, immobility and obesity all contribute to an increased incidence in this age group.Bangladesh, a retrospective cohort study conducted by Samira, Sayeed, Lahiry, and Ali (as cited in Paul andcolleagues' work) in a diabetic hospital, the BIRDEM (Bangladesh Institute of Research Rehabilitation in Diabetes, Endocrine and Metabolic Disorders); found that the prevalence of DFU was 2.8% [1]. The cost of treating chronic wounds is enormous." The working capacity of the patient is often reduced; in our society no data is available but approximately 2 million work days are lost annually in the United States because of leg ulcers but in our country we have no specific data or papers like that. In addition, there are numerous psychosocial squeal. In this study, we attempted to assess the overall impact of leg ulceration on the patient's quality of life with regard to physical, functional, psychological, and financial domains. Many adults with vascular disease and/or diabetes suffer with chronic leg or foot ulcers, leading to loss of functional ability, poor quality of life and long term ill-health. Studies on patients with chronic leg ulcers have reported the average duration of these ulcers is around 12–13 months, around 60–70% of patients have recurring ulcers, 24% of patients are hospitalized because of the ulcers

and most people suffer from the condition for an average of 15 or more years in western world. Care for chronic wounds is reported to cost 2-3% of total health care spending in developed countries and these costs are set to rise with ageing populations. Treatment in the U.S. costs over 3 billion $US and the loss of over 2 million workdays a year. Similarly, Harding quotes a cost of £400 million each year in the U.K. In Australia, wound dressings are the second most frequent procedure in General Practitioner practice and chronic wound care accounts for 22–50% of community nursing time in the UK and Australia. In addition to direct health care costs, chronic wounds are associated with hidden burdens on the community resulting from loss of mobility, decreased functional ability, social isolation and loss of participation in the workforce and society. Foot ulceration is the common major end point among diabetic complications. Proper foot care and early recognition and management of risk factors prevent foot ulcer of diabetic patient. It is estimated that the developing countries will bear the brunt of diabetes epidemics in the 21stcentury [1, 2].Despite reports of improved healing and reduced recurrence rates following the introduction of evidence based guidelines and coordinated care, a significant evidence-practice gap has been reported around the world in appropriate assessment of chronic leg ulcers and timely use of best practice treatments. For example, around 70% of chronic leg ulcers are caused by venous disease and compression therapy is the gold standard treatment, yet a U.S. study found only 17% of patients with venous leg ulcers received compression, and Australian studies found 40–60% of venous leg ulcers in Australia did not receive adequate compression. A number of reasons have been identified as contributing to this evidence-practice gap, including lack of information and skills, difficulties with access to evidence based guidelines, the costs and lack of reimbursement associated with specialist wound care and treatments such as compression bandaging, limited access to specialist multidisciplinary teams, poor communication and limited evidence on effective assessment, referral and treatment pathways of care to manage this chronic condition. Coyer et al. found clients were confused as to whom to access for care (whether general practitioners, community clinics, pharmacists, outpatient departments, vascular specialists, skin specialists); and health professionals themselves often find it difficult to manage care across disparate levels (community nurses, general practitioners, vascular/endocrine/wound care specialists, allied health professionals) in health care systems which lack models of service delivery that integrate chronic disease primary care and focus on health promotion, illness prevention and early intervention. In the area of wound healing many practitioners are involved in the trajectory of care. The absence of wound care as a medical specialty and dispersion of responsibility for wound care among a variety of health care providers often results in poor continuity of care across the health service continuum and a lack of consistent, evidence-based care and long-term preventative care. Effective and economic care of venous leg ulcers, combination of standard surgical procedures including perforator and sapheno-femoral ligation with long saphenous stripping and standard physio-pharmacotherapeuticcare is essential [3].Chronic leg ulcer is defined as a defect in the skin below the level of knee persisting for more than six weeks and shows no tendency to heal after three or more months. Chronic ulceration of the lower legs is a relatively common condition amongst adults, one that causes pain and social distress. The diversity of budgets and financial climate of cost control means that there is extraordinary complexity in the funding and provision of wound care and preventive care in the community. Up-front costs for long term wound care (wound dressings, bandages, costs of health care service providers) and follow-up preventative care have been identified as a barrier to implementing evidence based practice. The potential benefits of specific health service pathways for chronic leg ulcer management and facilitation of evidence based wound care are not clear from current research. A few studies have demonstrated improved clinical outcomes following the introduction of evidence based protocols; however, the relative benefits (both in patient outcomes and effective use of health resources) of alternative models of care are not well evaluated. This area of translational research is important in addressing gaps between research findings and wide-spread implementation of new information to improve patient outcomes.

II. Objective of the study

General objective:

a) To explore the implication of leg ulcers on quality of life and to find out the alternative health service pathways of care for patients with leg ulcers.

Specific objective:

a) To observe the chronic leg ulcer as a health hazard in our society
b) To observed implication leg ulcer on financial, physiological, psychological and social life.
c) To find out the major etiological factors which leads to chronic leg ulcer

III. Methods of the Study

Study Design: This is a descriptive type of cross sectional study

Study place: The study has been carried out at Cardiovascular OPD, Bangabandhu Sheikh Mujib Medical University.

Study period: The study has been carried out during the period from January 2014 to April 2014
Study population: The study has conducted with the patients both male and female attending cardiovascular OPD, BSMMU with leg ulcer

Inclusion criteria:
Patient presenting with ulcer in cardiovascular OPD, BSMMU.

Exclusion criteria:
•Prisoner who are referred from jail
•Exclusion criteria included insulin-dependent diabetes
• Current known psychiatric illness, a diagnosis of AIDS
• Inability to speak and not to give Informed consent.

Sample size: Data were collected from 69 respondents
Sampling techniques: A purposive sampling technique was used for sample selection.
Data collection techniques: A semi structured questionnaire used as data collection instrument for this study.

Data processing and analysis: The data collected from the patients with leg ulcer attending cardiovascular OPD, BSMMU has been entered into SPSS 16. The data have been checked for their completeness and consistency. Incomplete and inconsistent data have been corrected if it is possible, otherwise removed. The processed data has been presented as in percentage (%). The result has been verified as logical and accurate as per filled up questionnaire.
The data processing involves the following steps:

- ❖ Questionnaire making
- ❖ Data collection and cross checking
- ❖ Data editing
- ❖ Data entry and entry verifying
- ❖ Entering data as per questionnaires structure in SPSS 16
- ❖ Verifying the logic and accuracy of the data as per filled up questionnaire
- ❖ Inputting data into SPSS work sheet
- ❖ Tabulating as per objective and requirement in quantum
- ❖ Program development as per analysis plan
- ❖ Report generation

Ethical consideration: Permission will be taken from the concern departmental academic and technical committee and also from the central ethical committee in order to undertake the study. All patients enrolled in this study will be explained about the nature and purpose of the study and an informed written consent will be taken from them.

IV. Result of the Study

I interviewed 73 patients from the patients with leg ulcer attending cardiovascular OPD; BSMMU of them 69patients fulfilled the inclusion criteria. There were 61(88.4%) male and 08(11.6%) female whose ages ranged from 15to 75 years (mean, 42 years). The mean duration of ulceration was 2.4 years (range, 3 week to 6 years).

Table1. Distribution of respondents by their socio-demographic characteristics (n = 69)

Variables	Frequency (n)	Percentage (%)
Age		
15-25 years	05	07.2
26-35 years	18	26.1
36-45 years	14	20.3
46-55 years	17	24.6
56-65 years	11	15.9
66-75 years	4	5.8
Mean±SD (years)	42.0±13.0	
Gender		
Male	61	88.4
Female	08	11.0
Marital status		
Married	68	98.6
Unmarried	0	0
Divorced	1	1.4

Educational level		
Illiterate	16	23.2
Primary	20	29.0
Secondary	14	20.3
Higher secondary and above	19	27.5
Occupational status		
Service holder	17	24.6
Business	25	36.2
Day Labor	15	21.7
Housewife	6	8.7
Others	6	8.7
Family type		
Nuclear	67	97.1
Joint	2	2.9
Building	26	37.7
Tin shed	43	62.3
Others	0	0
Monthly household income		
5000-10000Tk	27	39.1
10001-20000 Tk	20	29.0
>20000 Tk	14	20.3
No income	8	11.6

The mean age of the respondents was 42.0±13.0 years. The age of the majority respondents was more than 32 years where only 21.6% had the age below 32 years and the majorities of the respondents were male (88.4%) and married (98.6%).About one third of the respondents (36.0%) had higher secondary and above level of education followed by secondary (20.3%), primary (29.0%) and illiterate (23.2%).More than one-thirds of the respondents (39.2%) were business followed by service holder (24.6%), day labor (21.7%), housewife (8.7%) and others (8.7%).About ninety percent of the respondents (97.1%) came from nuclear family and rest are from joint family and in regards to housing condition, more than half of the respondents had Tin shed (62.3%) followed by Building (37.7%). More than one-thirds (39.1%) of the respondents had monthly household income in between 50000tk to 10000tk followed by 10001-20000 Tk (29.0%),>20000 Tk (20.3%) and no income (11.6%) as shown in [Table 1].

Table 2: Leg ulcer relatedsymptoms of the respondents (n=69)

Variables	Frequency (n)	Percentage (%)
Pain in leg ulcer		
Mild pain	36	52.2
Moderate pain	12	17.4
Severe pain	17	24.6
No pain	4	5.8
Discharge from leg ulcer		
Discharge present	33	47.8
No discharge	15	26.8
Duration of leg ulcer		
1-3 months	6	8.7
3-5 months	29	42.0
5 months – 1years	30	43.5
>1years	4	5.8
Itchingin leg ulcer		
Itching present	22	31.9
Itching not present	47	68.1
Edema in leg ulcer		
Edema present	19	27.5
Edema absent	50	72.5

The majority of the respondents (94.2%) had the complain of pain and The physical domain encompasses numerous aspects of pain as well as swelling (27.5%), discharge (47.8%), itching(27.5%) and various aspects related to mobility. With regards to pain, including pain intensity mild(52.2%) moderate(17.4%) and severe(24.6%), the influence of pain on physical activities, sleep, analgesic therapy, and the coping strategies used to reduce pain are described. About half (49.9%) of the respondents were found duration of leg ulcer5months -1 years which are venous type as shown in [Table 2].

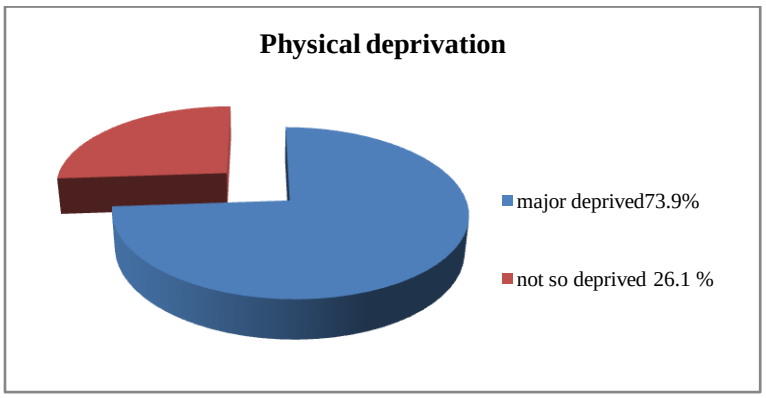

Figure 1: Physical deprivation due to leg ulcer (n=69)

According the [Figure 1], about half of the respondents (73.9%) reported their mobility was adversely affected due to leg ulceration followed by (26.1%) not much affect like that.

Table 3: Impact of leg ulceration on the several domains in quality of life (n=69)

Variables	Frequency (n)	Percentage (%)
Degree of effect on dailyjob		
Severely affected	13	18.8
Moderately affected	24	34.8
Mildly affected	26	37.7
Not affected	6	8.7
Effect on income due to leg ulcer		
Affected	54	78.3
Not affected	15	21.7
Any chance of limb or part of limb loss		
Yes	35	50.7
No	34	49.3
Effect on treatment due to economic condition		
Yes	52	75.4
No	15	21.7
Social problem due to leg ulcer		
Yes	63	91.3
No	6	8.7
Type of social problem due to leg ulcer		
Personal problem	24	34.8
Familial problem	26	46.4
Social ignorance	17	24.6
Others	1	1.4
Status of co-morbid condition		
Yes	19	27.5
No	50	72.5
Co-morbid conditions		
Diabetes mellitus	10	14.49
Hypertension	7	10.14
Both	2	2.8

As shown in [Table 3], more than two-thirds of the respondents (78.3%) reported unable to their daily job due to leg ulcer followed by severely affected (18.8%), moderately affected (34.8%), mildly affected (37.7%) and not affected(8.7).%. In terms of affected treatment for decrease earning money respondents (75.4%) and not involve (21.7%).Half of the respondents (50.7%) thinks that they might have a chance of total or part of limb loss due leg ulcer and(49.3%)not thinks like that (table 3). Of total, 91.3% of the respondents had history of social problem due to leg ulcer followed by (8.7%); don't have any social problem as shown in table 3. About one-thirds of the respondents (34.8%) reported that they have personal problem, Family problem (34.8%), social ignorance (24.6%), others (1.4%) for leg ulcer.About near one-thirds of the respondents (27.5%) reported the existence of co-morbid conditions, among them, diabetes mellitus was reported by 14.4% respondents, hypertension (10.14%) and both (2.8%) as shown in [Table 3].

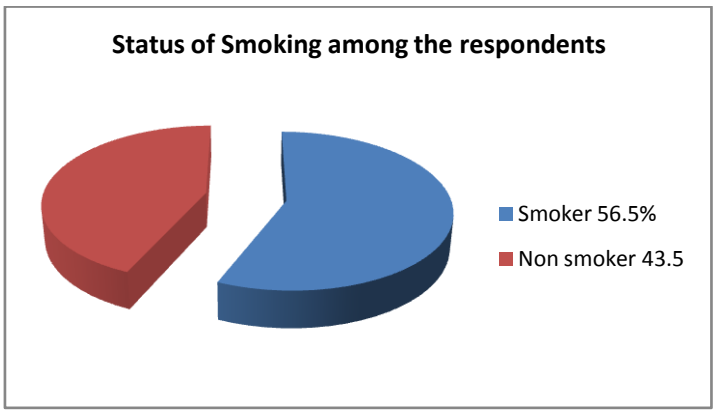

Figure 2: The status of smoking among the respondents

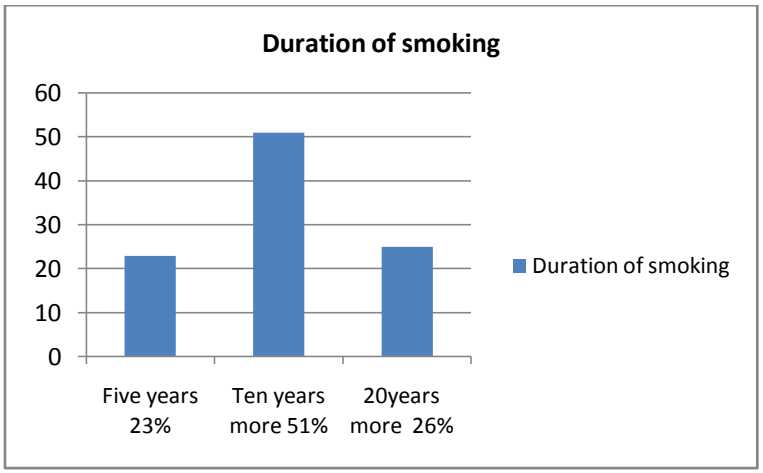

Figure 3: The duration of smoking among the respondents who smoke

More than half of the respondents were smokers 56.5% and among then 51.0% reported that they smoked for more than 10 years 26% for more than 20 years as shown in [Figure 2 and 3].

Table 4: Additional information only for female respondents (n=8)

Variables	Frequency (n)	Percentage (%)
Duration of marital life		
≤ 5 years	2	25
>5 years	6	75
Number of children		
1-2 children	3	37.5
>2 children	5	62.5
History of huge swelling of leg during pregnancy		
Yes	0	0
No	8	8

Of total married women (n=8), more than two-thirds were found to have their marital life more than 5 years and 62.5% of women had more than two children. They majority of women reported that they had no history of huge swelling of their leg as shown in [Table 4].

V. Discussion

Quality of life has been investigated in patientswith leg ulcers with associated diseases. In my studyalthoughmany studies have focused on the epidemiological factors, cause, and treatment oflegulcers, relativelyfewhave examinedthequalityof lifein patientswiththis chronic wounds [4]. But unfortunately in our country we have no research papers found like thisstudy. From the point of view of the patient, quality of life is crucial in assessing the effectiveness of medical treatments with daily and social life. Morbidity from leg ulcers can substantiallyreducemanyaspects of a patient's qualityof life.In this study some interesting and important findings comes out which are different statistical information than other studies, like (78.3%) respondents

reportedthat they are affected to do their daily job decrease the income status led to poor quality of life. This condition becomes more pathetic in illiterate day labor have arterial ulcer smoker who is the only earning member of the family.The majority of the respondents (94.2%) had the complain of pain and The physical domain encompasses numerous aspects of pain as well as swelling (27.5%), discharge (47.8%), itching(27.5%) and various aspects related to mobility.Because of high price of medicine medical equipment and dressing material these chronic wound become more burdensome on their life this happen in venous ulcers mainly. In UK and USA there areseveral supports for ulcer care.Ulcer care was frequentlygiven by a visiting nurse at considerable federal expense, which may amount to almost $40,000 peryear per patient in USA [5].In my study female respondent is (11.4%) than male (88.6%) which is unusual than other research finding this may be due to female are nonsmoker and not doing long standing work the most potential risk factor for developing leg ulcer [6].Thus, in patients withleg ulcers and leg edema, reductionof swelling maybe important in improvingquality of life. This finding is especially importantbecause ofthe generally highfailure rate of surgicalintervention in patients with venous ulcers [5],avariety of simplemodalities could be used to alleviate limb edema, including compression bandages, graduated compression elastic stockings. We have a large number of lymphatic edema patient specially filariasis less in western society. The prevalence of arterial disease in this study is significantly increased (42.0%) than other study's because of large number of smoker (56.5%) patient was observed most of them are young male low income group .'! Fiftysixpercent of patients had a previous history of smoking [4]. The majority of patients had severe pain and deemed their leg ulcer theirmost significant problem despite other important medical problems. This factor is probably underestimated byphysician'swho willoften judges a chronic wound as non-life-threatening as and therefore less important to the patient than other medical conditions.According to the Wound Healing Society, about 15% of older adults in the US suffer from chronic wounds, including predominantly venous stasis ulcers, pressure ulcers (bedsores), and diabetic (neuropathic) foot ulcers. Every year 2 to 3 million more Americans are diagnosed with various types of chronic wounds [7]. Estimate of annual incidence of leg ulcer in the UK and Switzerland are 3.5 and 0.2 per 1000 individuals, respectively. The prevalence of vascular ulcer in the US is estimated at 500,000 to 600,000 and increases with age [8].According to the study in Ireland the prevalence was 0.12% but it was 1.03% in the patients aged 70 years and over. Women were twice as likely to be affected. Venous disease accounted for 81% of ulcers and arterial disease for 16.3%, while ulceration due to diabetic neuropathy and rheumatoid vasculitis was unusual. Leg ulcers are an important source of morbidity in our ageing population [9].In Brazil, a study conducted in Botucatu, São Paulo, reported a 35.5% prevalence of varicose veins and 1.5% prevalence of severe chronic venous insufficiency with an ulcer or ulcer scar [10]. The peripheral artery disease, the circulatory disease commonly associated with no healing wounds, affects about 8 million Americans and 12–20% of Americans of age group 65–72 years. It is estimated that there are over 7.4 million pressure ulcers in the world where estimation was possible, that is, excluding the vast number of developing countries [11].In Western Australia (WA) in 1994, leg ulcers were found to affect 1.1 per 1000 population (0.11% point prevalence). This study demonstrated that 24% of the ulcers were present for 1 year, 35% had a problem of ulceration for 5 years, 20% had experienced 10 or more episodes of ulceration, and 45% of sufferers were housebound [12].According to a study carried out in Germany, venous insufficiency was the dominating causative factor in 47.6% and arterial insufficiency in 14.5%, and 17.6% of ulcers were due to combined arterial and venous insufficiency. Rarer causes included vasculitis (5.1%), exogenous factors (3.8%), andpyodermagangrenosum (3.0%) [13].Foot ulceration is the common major end point among diabetic complications. Proper foot care and early recognition and management of risk factors prevent foot ulcer of diabetic patient. Venous ulcers represent a common and debilitating condition associated with significant financial loss for the patient as well as the society. It affects 1-2% of the population, often with a protracted course of delayed healing and multiple recurrences. Though demographic data of patients with venous leg ulcers in developing country like Bangladesh is not available, still there is quite large number of patients. The condition affects 1% of the adult population and 3.6% of people older than 65 years. Leg ulcers are debilitating and greatly reduce patients' quality of life. The common causes are venous disease, arterial disease, and neuropathy. Less common causes are metabolic disorders, hematological disorders, and infective diseases. As many factors lead to chronic lower leg ulceration, an interdisciplinary approach to the systematic assessment of the patient is required, in order to ascertain the pathogenesis, definitive diagnosis, and optimal treatment.

VI. Conclusion

There are a number of potential social and economic national benefits to be gained from improving health service coordination for this population in country like Bangladesh where resource is limited very difficult to manage these chronic wound patient. Increased implementation of evidence based care in venous case try to control venous hypertension by providing health education and arterial case try to remove the risk factors like smoking, dyslipidemia which significantly less use of health services. The outcomes include improved health, well-being and decreased pain for young adults suffering with this condition. A cost

effectiveness analysis should be done and expected to specifically demonstrate the savings to the health care system with prevent lower limb disability.

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