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ORIGINAL RESEARCH

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Elderly individuals with diabetes and foot ulcer have a probability for healing despite extensive comorbidity and dependency

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ABSTRACT

Background: Limited scientific evidence for prevention and treatment of diabetic foot ulcers in elderly with comorbidities.
Aim: To explore patient-related factors and outcomes in patients ≥75 years with diabetes and a foot ulcer.
Method: Sub-analysis of consecutively presenting patients ≥75 years (N = 1008) from a previous study on 2,480 patients with diabetic foot ulcer treated in a multidisciplinary system until healing. Patient characteristics: age – 81(75–96); diabetes type 2–98.7%; male/female – 49/51%; living with a spouse – 47%; nursing home 16%; or with home nursing 64%.
Result: Primary healing was achieved in 54%, minor amputation 8%, major amputation 9%, auto-amputation 2%, and 26% of the patients died unhealed. Among the oldest (88–96 years), 31% healed without any amputation. Extensive comorbidities were frequent: neuropathy 93%, visual impairment 73%, cardiovascular disease 60%, cerebrovascular disease 34%, and severe peripheral disease in 29% of the patients. Out of patients (80%) living in institutions or dependent on home nursing, 56% healed without amputation, compared to 44% of patients living in their own home without any support from social services or home nursing.
Conclusion: Healing without major amputation was achieved in 84% of surviving patients ≥75 years, despite extensive comorbidity and dependency.

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KEYWORDS
Amputation; complications; diabetes mellitus; diabetic foot ulcers; healing; neuropathy; peripheral vascular disease; home nursing

1. Background

The number of older persons has increased substantially in recent years. The growth rate is likely to accelerate in the coming decades, with people aged 80 years or over projected to reach nearly 202 million by the year 2030 [1]. With improved health-care systems, the increasing prevalence of diabetes in the elderly will contribute to a higher number of patients with diabetic foot ulcers [2,3]. This situation is expected to increase health-care expenditures [3,4]. However, it has not been described previously how people 75 years and older (75+) with diabetes and a foot ulcer (DFU) are best taken care of, or what their expected outcome might be. In several guidelines about diabetes management in the elderly, the diabetic foot is hardly mentioned [5,6], despite its burden on the patient. The Swedish Agency for Health Technology Assessment confirms that the scientific evidence for the prevention and treatment of diabetic foot ulcers is limited [7]. However, a limited number of studies present prospective data on current outcomes and determinants of outcome in individuals with diabetic foot ulcers [8]. Further, most comparative studies regarding the treatment of DFU relate to younger populations [8,9]. Because the elderly population often has comorbidities and multiple medications, ulcer healing can be affected and bias to the studies introduced. A substantial number of the patients with DFU are de facto at end of life stages and subsequently dependent on others for their daily living [10–12]. It seems that research on the most vulnerable patients has been a neglected area. The aim of this study was to explore patient-related factors and outcomes in patients 75 years and older with diabetes mellitus and a foot ulcer.

2. Method

This is a retrospective analysis on prospectively collected data on patient-related factors and outcome of diabetic foot ulcers in persons 75 years and older. From a previous study [10] on 2,480 patients with diabetes mellitus and a foot ulcer, a sub-analysis was made on the included patients 75+.

2.1. Study population

Patients with diabetes presenting consecutively with a new foot ulcer (Wagner grade 1–5) below the ankle admitted to a multidisciplinary foot center.

2.2. Follow-up time

The patients were prospectively followed, treated, and recorded according to standardized protocol [10,13] until

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healing was achieved, or death, irrespective of time, by the multidisciplinary team both as in- and outpatients.

2.3. Setting

A multidisciplinary foot center at a university hospital. The core team consisted of a diabetologist, an orthopedic surgeon, an orthotist, a podiatrist, and a registered nurse educated in diabetes. Vascular investigation was carried out according to a prescheduled program by a vascular surgeon integrated into the team on a regular basis. Specially trained casting technicians provided continuous service for total contact casting. A specialist in infectious disease was available for consultations when required. The registered nurse coordinated the team, and performed care planning and patient education. Physical examination was performed at inclusion and regularly during the study by the multidisciplinary team. Outpatient treatment was conducted in collaboration with primary health care home nursing services. The team maintained daytime telephone service for support.

2.4. Definitions

2.4.1. Ulcer definition

At admission and during the study, all lesions were assessed after debridement by the same team and documented according to a pre-set standardized protocol [10,13]. One lesion below the ankle per patient and the most severe ulcer occurring during the observation period was selected as the index ulcer. In patients with more than one lesion, the one with the worst outcome was selected. *Multiple ulcers* were defined as three or more ulcers on the same foot. Lesions were classified at their worst according to Wagner (grade 1–5) [14], with the most superficial ulcer included being a full skin ulcer penetrating the subcutaneous layer.

Wound duration was defined as the estimated number of weeks from development of an ulcer until entry in the study.

Cardiovascular disease was defined as at least one of the followings: angina pectoris, myocardial infarction, coronary artery bypass surgery (CABG), congestive heart failure, or non-ischemic heart disease [13].

Cerebro-vascular disease was defined as all types of stroke and transient ischemic attack (TIA).

Smoking was defined as patients who self-reported having smoked regularly; this was recorded as *smoker*.

Visual impairment was defined as diabetes retinopathy after fundus photography or any other eye diagnosis that contributed to impaired vision [10].

Edema was defined as swelling of the foot as pronounced enough to leave a clear imprint after pressure by a finger.

Rest pain was defined as severe persistent pain localized to the foot and relieved by lowering of the foot.

2.4.2. Off-loading

All patients were offered off-loading equipment adjusted to their individual needs. Total contact casts, orthoses, insoles, specially made shoes, half shoes, or wheelchairs were used.

Healing was defined as full epithelisation intact for 6 months or as intact skin at time of death.

Time to healing was defined as the number of weeks from the first visit to the clinic until full epithelisation.

2.4.3. Outcome

Primary healed was defined as intact skin for 6 months or intact skin at time of death without any amputation. Minor amputation was defined as intact skin for 6 months, or intact skin at time of death after amputation of one or more toes or forefoot. Major amputation was defined as intact skin for 6 months, or intact skin at time of death after amputation below or above the knee [15,16]. Deceased was defined as death (from Census records) without healing, with or without any amputation. Other definitions have been presented in a previous publication [10].

2.5. Treatment pathway

Elderly patients with diabetes and complications meet health-care professionals at different settings of the health-care organization in Sweden: *primary health centers* constitute the backbone of Swedish primary care and are managed by the respective county council [17]. They are responsible for a geographically defined population or for a number of listed patients. General practitioners work together with district nurses and other health-care professionals, including diabetes nurses (registered nurses with education in diabetes nursing, 15 or 30 credits) [18,19]. The patients visit the diabetes responsible physician annually but meet the diabetes nurse more often [19]. Patients with a detected diabetic foot ulcer are referred to the diabetes foot center at the university hospital.

At the diabetes foot center, patients are offered medical treatment to improve metabolic control and to optimize treatment of comorbidity. Patients with deep abscesses or acute osteomyelitis are hospitalized and are treated with intravenous antibiotics and surgery for major revisions, and amputations when deemed necessary. A non-healing ulcer does not indicate that an amputation is necessary. Rather, the criteria would be progressive gangrene, intolerable pain, despite adequate analgesic medication, and septic and toxic conditions not responding to medical treatment. In between visits to the diabetes foot center, the patients with ongoing foot ulcers have their dressings changed in either the primary health center or at home by the home nursing staff if they are unable to travel. The diabetes foot center provides the patients with written prescriptions informing about the dressings to be used, off-loading strategies, and any changes in medication.

Family members of elderly patients with a deteriorated health status take on a significant amount of the caring responsibilities. However, they can receive support from the municipality's social care and home nursing service when the patients themselves are no longer able to come to the county council's facilities or to maintain their self-care [20,21].

The home nursing service differs in its organization both nationally and internationally, depending on local political and financial frames [22–28]. Patients in Sweden have an individual care plan created (due to reimbursement rules), and home nursing services are assessed and organized accordingly [21,28]. The highest medical competence in the municipalities' organization would be registered nurses working in collaboration with physicians from primary health centers. These registered nurses work under two different

legislations: the Health and Medical Service Act [17] and the Act of Social Service [21]. This entails that while the registered nurses are responsible for the nursing process, nurse assistants (with 3 years of secondary school education in social work and health promotion) [29] perform many of the activities, such as administration of pre-packed tablets (ApoDos®) and insulin injections, plasma glucose monitoring, and changing of ulcer dressings after a written delegation. However, due to a shortage of staff, a mix of educational background is common in many municipalities. As time to healing is often long, the registered nurses get to know the patients well and can identify early changes in their healthcare status.

2.6. Ethical approval

The study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Regional Ethical Board in Lund, Sweden.

3. Result

3.1. General characteristics

The cohort of included elderly patients with DFU (N = 1008) had a median age of 81 years: n = 518 were female (51.4%); n = 985 had diabetes type 2 (98,7%); and n = 755 of them had never smoked (75%). Regarding living conditions, n = 805 patients (80%) lived either in a nursing home (n = 164) or were dependent on social services and/or a home nursing (n = 641) at the time of first contact with the diabetes foot center (See Table 1).

There was a substantial comorbidity in the cohort, with a majority suffering from multiple conditions: n = 732 suffered from visual impairment (73%), n = 606 from cardiovascular disease (60%) and n = 340 from cerebrovascular disease (34%). Reduced renal function affected 116 patients (21%), either as nephropathy, n = 164 (16%), or as ESRD, n = 52 (5%).

The ulcers were mainly located on the toes (n = 574) or on the heels (n = 177). The most common reasons for ulceration were trauma from ill-fitting shoes and/or ischemia. Stress ulcers were less common, with n = 145 (14%). See Table 2.

Table 1. Demographic data on 1,008 patients 75+ with diabetes and a foot ulcer.

General characteristics		
Age (years)	81 (75–96)	
Male/female	490/518	48.6/51.4%
Diabetes type 1/2/other	17/985/6	1.7/97.7/0.2%
Hba1 c	7.2 (4,0–14.0)% MonoS	64 (31–136) mmol/mol
Ever a smoker	253	25%
Good compliance	949	94%
Comorbidities		
Neuropathy	938	93%
Cardiovascular disease	606	60%
Stroke/TIA	340	34%
Visual impairment (incl diabetes retinopathy)	732	73%
Nephropathy	164	16%
ESRD	52	5%
Extremities		
Edema	475	47%
Rest pain	341	34%
Toe pressure <30 mm/Hg	245	24%
Ankle pressure <50 mm/hg	113	11%
Severe PAD TP<30 OR AP <50	289	29%
Living conditions		
Living alone/with spouse	534/474	53%/47%
Home nursing & social service	641	64%
Living in nursing home	164	16%

Table 2. Foot-related factors.

	n	
Foot ulcer		
Big toe	242	24%
Other toes	174	17%
Plantar	115	11%
Mid foot	12	1%
Heel	177	18%
Multiple	158	16%
Other (malleol, between toes)	127	13%
Cause of ulcers		
Ill-fitting shoe	171	17%
Ischemia	171	17%
Stress ulcer	145	14%
External trauma	138	14%
Pressure ulcer	112	11%
Unknown	92	9%
Ingrown nails	57	6%
Fissure/cracked skin	46	5%
Podiatric care	34	3%
Miscellaneous	20	2%
Wound duration	6 (0–260) weeks	
Wagner score at inclusion		
W1 Superficial ulcer	613	61%
W2 Deep ulcer without abscess or osteomyelitis	234	23%
W3 Deep ulcer with abscess, osteomyelitis, or joint sepsis	79	8%
W4 Minor gangrene	69	7%
W5 Major gangrene	6	0.5%

3.2. Outcome

From a total of N = 1,008 patients, n = 542 (54%) healed without any amputation; n = 82 (8%) healed with minor amputation (toe(s) or fore foot); n = 93 (9%) healed with major amputation (above ankle); n = 20 (2%) healed with auto-amputation; and n = 266 (26%) died before healing, with or without any amputation. Five patients (0,5%) were lost to follow up. Of all *surviving patients*, 74% healed without any amputation, 10% healed with minor amputation and 14% with major amputation. See Table 3.

Patients with severe peripheral arterial disease (PAD) (toe pressure <30 mmHg and ankle pressure <50 mmHg) who healed without amputation were n = 92 (19.9% of all primary healed). Those who healed with amputation at any level were n = 89 (34.7% of all amputated).

A comparison of demographics between patients younger than 75 years and the patients included in the present study revealed that the older patients more often had diabetes type 2, macrovascular complications, and major gangrene, while the younger patients more often had diabetes type 1, microvascular complications, deep foot infection, and minor gangrene (See Table 4).

Table 3. Final outcome in patients 75+ with diabetes and a foot ulcer below the ankle.

Outcome	*N*	%	Time to healing
Healed without amputation	542 Home nursing/ nursing home: n = 304 Living independently: n = 238	54% 56% 44%	1–136 median 16
Healed with minor amputation	82	8%	3–108 median 35
Healed with major amputation	93	9%	4–131 median 26
Auto amputation	20	2%	21–197 median 44
Died before healing (n = 24 amputated but unhealed at time of death)	266 Home nursing/ nursing home: n = 211 Living independently: n = 55	26% 79.3% 20.7%	
Lost to follow-up	5	0.5%	

Table 4. Comparison of comorbidity of patients 18–74 compared to patients 75–96.

N = 2480	Age 18–74 (*n* = 1472)	Age 75–96 (*n* = 1008)	Pearson's Chi Square
Diabetes type 1/2	435/1031	17/985	0.000
Duration of diabetes >16 years	442 (30%)	143 (14%)	0.000
Any heart disease	477 (19.2%)	600 (24.2%)	0.000
CVD	234 (9.4%)	340 (13.7%)	0.000
Retinopathy	700 (28.2%)	328 (13.2%)	0.000
Other eye disease	295 (11.9%)	378 (15.2%)	0.000
Nephropathy	521 (21%)	164 (6.6%)	0.000
Uraemia	155 (6.3%)	52 (2.1%)	0.000
Previous amputation	80 (3.2%)	65 (2.6%)	0.291
W3 Deep foot infection	207 (8.5%)	107 (4.4)	0.000
W4 Minor gangrene	180 (7.3%)	157 (6.4)	0.000
W5 Major gangrene	38 (1.6%)	56 (2.3%)	0.000

In patients 82 years old or older (n = 500), n = 235 (47.2%) healed without amputation at any level, n = 75 (15%) healed after amputation of toe(s) or leg, n = 11 (2%) healed after auto amputation and n = 176 (35.4%) died unhealed.

Of the oldest patients, 88–96 years (n = 120), n = 37 (30.8%) healed without amputation, n = 5 (4.1%) healed with minor amputation and n = 11 (9.2%) healed with major amputation. Three patients healed with auto amputation, and n = 63 (52.2%) died unhealed. When comparing patients 89–96 years to those aged 75–81 years and 82–88 years, the oldest cohort died more often than the younger, and fewer of them healed without surgery compared to the younger two cohorts. However, the frequency of major amputation seems equivalent between the three cohorts, while very few of the oldest had a minor amputation. See Table 5.

Patients living in a nursing home or dependent on social care/home nursing healed without amputation (66%), but they died unhealed more often than patients living in their own home without any support from social services or home nursing, where 44% healed without amputation. See Table 3. A comparison of outcome and dependency on home nursing/institutional care for patients included before and after the year 2000 revealed no statistically significant difference between the two groups.

Table 5. Outcome divided in three age groups.

Outcome	**N = 1008**	**100%**	**Time to healing (weeks)**
	75–81 yrs n = 508	50.4%	
	82–88 yrs n = 380	37.7%	
	89–96 yrs n = 120	11.9%	
Healed without amputation	n = 542	53.7%	3–952 median 112
	75–81 yrs n = 311	61.2%	
	82–88 yrs n = 194	51%	
	89–96 yrs n = 37	30.8%	
Healed with minor amputation	n = 82	8.1%	22–757 median 245
	75–81 yrs n = 42	8.2%	
	82–88 yrs n = 35	9.2%	
	89–96 yrs n = 5	4.1%	
Healed with major amputation	93	9.2%	28–919 median 182
	75–81 yrs n = 55	9.8%	
	82–88 yrs n = 27	7.1%	
	89–96 yrs n = 11	9.2%	
Auto amputation	20	2%	150–1379 median 308
	75–81 yrs n = 9		
	82–88 yrs n = 8		
	89–96 yrs n = 3		
Died before healing	n = 266	26%	(n = 24 amputated but never healed)
	75–81 yrs n = 90	17.7%	
	82–88 yrs n = 113	29.7%	
	89–96 yrs n = 63	52.5%	
Lost to follow-up	n = 5	0.5%	

4. Discussion

This is one of the first large studies of patients with DFU aged 75 years and older that shows the vast majority of surviving patients healed without amputation.

Healing without major amputation was achieved in 84% of surviving patients, despite extensive comorbidity. Healing after amputation below or above the knee constituted 14% of the patients. One out of ten surviving patients healed with minor amputation or auto amputation of one or more toe(s) or a forefoot. Our treatment strategy was to try to save the foot, using the most distal amputation level possible, if the patient was ambulant [30]. However, the outcome was associated with a substantial long healing and treatment time. In the present study, the primary healing rate in the whole cohort without any amputation was 51%, and the mortality rate of unhealed patients was 26%. These findings are in agreement with some, but not all, previous studies. In mixed cohort

studies primary healing rates of 60% to 74% and amputation rates of 8% to 23% have been reported [8,31–33]. Comparisons between studies are difficult to make due to differences in design, settings, patient selection, definitions, follow-up time, and other confounding factors. Patients in the present study were substantially older than those in other published studies [13,34–43]. The findings from the present study indicate that even in the oldest patients healing can be achieved without a major amputation.

Age is described to be an important factor related to progress of PVD, neuropathy, and lower leg ischemia, as well as to probability of healing and amputation in DFU [44–46]. However, this is not the case in all studies, especially not in short-term observation studies of neuropathic foot [35,47–50]. In the present study, the patients had severe extent of comorbidity; and 26% of the patients in died unhealed. In large cohort studies [10,51], outcome has been related to duration of diabetes and comorbidity, ischemia and infection, rather than chronological age. Our study confirms these findings: that old age per se does not affect the outcome of foot ulcers in persons with diabetes mellitus and the impact that comorbidities have on the outcome. The majority of the patients in the present study had reached (and some even beyond) the average life expectancy in Sweden, which in 2016 was 84 years for women and 81 for men [52]. A foot ulcer in a patient with diabetes is frequently a sign of comorbidity, and it can sometimes be considered the first sign of the dying process [53,54]. Thus, it should be taken seriously as a warning sign of future deterioration in general health. But it has to be recognized that in the present study a third of all patients 88 years and older healed without amputation.

The majority of the patients in the present study were living in institutions or were dependent on home nursing, and had a less favorable outcome compared to those patients living in their own home without any support from social services or home nursing. The present study also showed that 56% of all patients dependent on registered nurses in a home nursing service or in nursing homes healed without any amputation. About half of the patients lived with a spouse or a partner at the time of ulceration. This indicates that family members carry some of the burden of assisted self-care for these often fragile patients with diabetes [20].

In the majority of the patients, an external precipitating factor for the development of a foot ulcer was seen, and impaired vision and edema were common in our cohort study. Foot ulcers caused by trauma might be a result of impaired vision, as well as impaired balance and mobility due to comorbidities. Impaired vision has been considered a risk factor for the development of foot ulcers as the patient is more prone to trauma [55] and cannot see an injury in the insensate foot. About half of the patients had lower leg edema from various reasons: cardiac failure, ESRD, DVT, or physical inactivity. Edema is a risk factor for both development of an ulcer as well of risk for an amputation in the presence of an ulcer [10].

This situation requires a shift in perspective for health-care organizations: from the treatment of ulcers to actively working with patient safety, identifying risk factors and quality of care with early detection of any deterioration in health, and applying active interventions to improve the health status of these patients [12,56,57]. Consequently, both family members and health-care staff in home nursing and nursing homes require education and active support to manage this situation together with the patient [20]. Existing guidelines to prevent pressure ulcers need to be implemented also in health-care settings outside of the hospitals [58,59]. Future position statements of diabetes care for the elderly [5,60] need to include the prevention and treatment of diabetic foot ulcers.

The most common direct causes of ulceration reported from the patients or their caregivers in this study were external trauma in combination with ill-fitting shoes and ischemia. Plantar stress ulcers were relatively few, compared to other studies where it has been reported as more common in populations of mixed ages [10,61]. The low rate of plantar stress ulcers might be explained by the fact that many of these patients do not walk long distances. These findings might indicate that the distribution of type of ulcers might be a bit different compared to younger patients with pure neuropathic foot ulcers, in which plantar for foot ulcers are reported between 25% and 30% in western populations [10,62] and even higher in nonwestern cohorts [8].

Healing after amputation below or above the knee constituted 14% of the patients. One out of ten surviving patients healed with minor amputation or auto amputation of one or more toe(s) or a forefoot. A minor amputation below the ankle enables walking capacity compared to major amputation, but the patient needs life-long surveillance of the feet in order to avoid new foot ulcers [51,62]. This surveillance requires systematic care planning and diabetes foot education of all persons involved in the patient's foot care [8]. An especially vulnerable patient group with a high risk for ulceration are patients with visual impairment and dementia, for which special attention is needed [6]. Major amputation in this fragile patient group often results in the patient being wheelchair-bound with a dependency on others for daily living [63]. Increased needs for assisted self-care interventions often result in the patient moving from their home to a nursing home, where the quality of care might vary [12,64]. Appropriate care for amputated patients in nursing homes needs to be explored further.

The present study revealed that more women than men with DFU survived past the age of 75. Studies with cohorts of younger DFU-patients commonly report a majority of male patients [10,36,44,51,53,65,66]. Our study indicates that male patients with DFU are severely ill and do not reach the average life expectancy of 81 years [52]. There could be various explanations for this. Genetic factors (different candidate genes increase the risk of late complications in diabetes) [67] and hormonal factors (with estrogen protecting women from vascular comorbidity and causing potential differences in immune competence) [68] may play important roles. Moreover, behavioral differences (smoking habits, risk-taking lifestyle, attitudes to health, and care-seeking behavior) [69] might change over time. Furthermore, differences in life expectancy depend on socio-economic and political factors [52]. This gender-related mechanism has, to our knowledge, not been fully explored and should be addressed in future studies.

We conclude that a foot ulcer in a person with diabetes mellitus might be a sign of deteriorated general health and an

indication that life is coming to its end. However, for half of the oldest patients (88–96 years), healing is achievable with or without amputation when they get their first foot ulcer. The result of our study indicates that outcome is related to comorbidity rather than to chronological age.

5. Limitations

This study is limited to a sub-analysis from a larger study from a diabetes foot clinic in a university hospital in southern Sweden. It might be possible that in the catchment area of 1.2 million inhabitants several persons with diabetes and a foot ulcer have been treated and healed elsewhere: in primary care or home nursing settings. However, no patients were amputated without the knowledge of the orthopedic ward at the same university hospital. They constitute a fundamental part of the multidisciplinary team. Another limitation is the insufficient systematic documentation of diabetes foot-related procedures that takes place within the home nursing service [11]. Some background variables might have been underreported due to flaws in a stressful clinical environment. However, the outcomes of the patients are well documented. Due to Sweden´s social registration system, almost all patients can be followed up within the public health-care organization.

6. Conclusion

Healing without amputation is achievable in the majority of patients 75 years and older with diabetes and a foot ulcer if treated in a multidisciplinary setting in close collaboration with primary care and home nursing organizations. For patients who do not die unhealed, 3 out of 4 heal without amputation. However, this patient group suffers from severe comorbidity and conditions that hamper self-care, which might delay healing and increase the risk of developing new foot ulcers. As they very much are in need of assisted self-care, registered nurses caring for patients with diabetes 75 years and older need appropriate theoretical and clinical training in foot ulcer prevention and treatment.

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