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Seek, and ye shall find:

Efficacy of proactive screening for diabetic foot ulceration in the community autonomously performed by nurses

Diabetic foot ulceration (DFU) is a severe complication of diabetes mellitus associated with a high morbidity and mortality rate, whose treatment requires considerable financial costs.

This paper describes a test of the efficacy of proactive screening – autonomously managed by nurses in a community setting – in detecting patients at high risk of DFU, as an integrated part of a chronic care model strategy.

Keywords:

diabetic foot ulcer; screening; community nurses; prevention; amputation

ABSTRACT

Objective

Our aim was to test the efficacy of proactive screening – autonomously managed by nurses in a community setting – in detecting patients at high risk of Diabetic Foot Ulcer (DFU), as an integrated part of a chronic care model strategy.

Research design and methods

In a community setting in northwest Tuscany, where 421,382 people live in a mixed urban/rural area around the hospital of the University of Pisa, we trained 324 nurses according to the International Working Group on the Diabetic Foot guidelines for the screening of ulcerative risk. Nurses committed to screening the population of known diabetic patients, who were referred by their general practitioners, for DFUs annually.

Patients at high risk or with active DFUs were

promptly referred to our specialised diabetic foot clinic; all patients received education on prevention. The results of the screening were retrospectively collected and analysed for the years 2014-2016.

Results

During the study period we observed an increased number of screenings performed (+18.8% and +36.1% during the first and second year of follow-up, respectively; $p < .05$) and therefore an increased number of high-risk patients detected (+0.5% during the first year and +1.3% during the second year of follow-up; $p < .05$). Also, the number of patients with undiagnosed active foot ulceration significantly increased (+0.1% and +0.4% in the first and second year of the study, respectively; $p < .05$).

Conclusions

In this study we demonstrate that increasing the rate of subjects actively screened increases, in parallel, the

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likelihood of finding patients at high risk of and with active DFUs. The improvement of this screening programme could favour an early detection of DFU cases to promptly intervene in and possibly interrupt the progression of the disease.

Key messages

The prevalence of patients at-risk for foot ulceration is still underestimated among patients with diabetes

A proactive screening is effective in sorting out patients at risk and patients with active lesions

Nurses, once adequately trained, can effectively autonomously perform this activity

INTRODUCTION

Diabetic foot ulceration (DFU) is a severe complication of diabetes mellitus associated with a high morbidity and mortality rate, whose treatment requires considerable financial costs.^{1,2} The prevalence rates of DFU are 19-34%, with an annual incidence of 2%³ and a recurrence rate up to 65% within 3 years after healing. More than 85% of non-traumatic limb amputations originate from DFUs.^{4,5} Major amputations are more frequent in people with diabetes – about 10-30 times more than the general population – and mortality increases up to 80% at 5 years after amputation.^{6,7}

Due to a global rise in both diabetes and life expectancy, a parallel global increase in DFU cases is expected in the future. Therefore, DFU has been compared to some forms of cancer for its general features: frequency, severity, chronicity and social cost.³

One of the criteria aspects of the management of DFU is related to the late referral of high-risk patients or patients with a DFU in the early phases of its evolution, which has been indicated as one of the most important determinants in the progression of its pathology towards the late and non-critical phases.⁸ For this reason, we need to implement a multidisciplinary, integrated approach for adequate treatment and prevention.

From a clinical point of view prevention and prophylactic foot care have been emphasised to reduce patient morbidity and the risk of amputations.^{9,10} The implementation of preventative programmes, including patient education, intensive podiatric care and the identification of risk factors^{7,11,12} have been shown to be cost-effective and cost saving.¹³

International guidelines¹⁴ recommend a multilevel healthcare network¹⁵ in which diabetic patients might be referred without delay from a primary to secondary or tertiary level, according to the grade of complexity of the pathology; whereas the primary level is represented by the general practitioners (GPs), the secondary one by non-specialised diabetologic services, while the tertiary level is identified by the specialised diabetic foot clinic.

According to these recommendations, the Tuscany Local Health Authority has adopted this organisation for DFU management since 2003, with further implementation in 2016.^{16,17} To date, despite these recommendations, as confirmed by recent data reported in the regional healthcare agency database of Tuscany¹⁸, only 27% of type 2 diabetic patients are managed by specialised outpatient clinics; consequently, in the majority of cases, GPs play a crucial role in disease management, at least in the early phases.

Since 2009 a specific project for chronic diseases, including diabetes mellitus, BPCO, hypertension and stroke, has been implemented and financed by the Tuscany Health Authority following the Chronic Care Model (CCM).¹⁹ A network of GPs and nurses (1 nurse per 10,000 inhabitants) has been structured and committed to actively screening and managing these pathologies and their complications, including DFU.

MATERIALS AND METHODS

In 2013, in the northwest of Tuscany, we trained 324 nurses on the CCM according to the International Working Group on Diabetic Foot (IWGDF) guidelines for the screening of ulcerative risk in DFs. The nurses received a 4-hr module of specific training on physiopathology, natural history, clinical presentation and diagnostic approach to DFs, integrated with a 4-hr practical training delivered by the diabetic clinics active in the area. The structure of the course and training was delivered and supervised by the diabetologists and podologists of the DF section of the University Hospital of Pisa, which is the third-level centre for DFs in northwest Tuscany.

At the end of the course, the participants underwent an assessment of adequacy according to pre-defined criteria, taking into consideration both knowledge and skills.



TUSCANY-NORTH-WEST-AREA
SCREENING FOR LOWER-LIMB COMPLICATIONS IN DIABETIC PATIENTS

DATE ___/___/___

NAME _____ DATE OF BIRTH ___/___/___

CITY OF RESIDENCE _____ GP _____

INSPECTION	RIGHT FOOT	LEFT FOOT
Previous ulcer or amputations	Yes___ No___	Yes___ No___
Active ulcers/Necrosis	Yes___ No___	Yes___ No___
Deformity	Yes___ No___	Yes___ No___
Hyperkeratosis/Onicopathies		
/Fissures	Yes___ No___	Yes___ No___
Odema/Erythemo	Yes___ No___	Yes___ No___
Cyanosis	Yes___ No___	Yes___ No___
PALPATION		
Font cold	Yes___ No___	Yes___ No___
Thermal tresho	Yes___ No___	Yes___ No___
Absence of posterior tibial pulse	Yes___ No___	Yes___ No___
Absence of dorsalis pedidis pulse	Yes___ No___	Yes___ No___
MONOFILAMENT		
Lack of perception	Yes___ No___	Yes___ No___
OUTCOME	Negative _____	Next control _____
	Positive _____	Refer to _____
OPERATOR _____		

TUSCANY-NORTH-WEST-AREA
SCREENING FOR LOWER-LIMB COMPLICATIONS IN DIABETIC PATIENTS

DATE ___/___/___

NAME _____ DATE OF BIRTH ___/___/___

CITY OF RESIDENCE _____ GP _____

DOPPLER CW	RIGHT FOOT	LEFT FOOT
Absence of posterior tibial	Yes___ No___	Yes___ No___
Absence dorsalis pedis	Yes___ No___	Yes___ No___
Claudicatio intermittens	Yes___ No___	Yes___ No___
Rest pain	Yes___ No___	Yes___ No___
OUTCOME	Negative _____	Next control _____
	Positive _____	Refer to _____
OPERATOR _____		

Figure 1. Screening questionnaire completed by nurses

After their training, the nurses started annually screenings of a population of known diabetic patients, who were referred to them by the patients' GPs. Patients were examined in a dedicated ambulatory setting on a daily schedule, and each examination was performed by trained nurses, without direct involvement or supervision by doctors or podologists, and took 30 minutes.

Consequently, this screening protocol has become an integrated part of a CCM strategy, in a community living in an urban/rural area near Pisa of about 421,382 people.

For each patient screened, nurses were able to determine the class of risk for DFU by using a simple questionnaire shown in Figure 1. In that questionnaire nurses reported anamnestic risk factor data, detectable alterations with the inspection and palpation of the patient's feet, vascular examination with ankle brachial index calculation and the presence of suspected neuropathy with the Semmes-Weinstein monofilaments evaluation. The questionnaire was based on the American Diabetes Association's screening tool for at-risk diabetic feet²⁰, and it was validated on a significant sample of admitted patients before the beginning of the study.

All patients screened by nurses, irrespective of the level of risk, received information on prevention – the

importance of daily foot inspection and hydration, of wearing adequate shoes and socks and other general recommendations on self-protecting behaviours. The aim of this study was to evaluate the outcomes of the screening programme for the years 2014, 2015 and 2016.

For the purpose of this study, the general database of GPs for northwest Tuscany was retrospectively consulted to sort out the number of diabetic patients and to calculate the prevalence of the disease in the general population. The screening questionnaires, performed by nurses, were collected and examined to calculate the number of patients screened, the number and prevalence of high-risk patients and the number and prevalence of active DFUs intercepted.

These data were validated by direct telephone contact with the patients, after the screening, double-checking if they were actually screened and if the conditions at the moment of the screening were actually those reported in the questionnaires.

The number of patients screened, their prevalence among diabetes population and the number of high-risk patients and active DFUs were calculated for the three areas where the programme was implemented.

Continuous data are presented as means (SDs) or medians (ranges), as appropriate for each variable.

Figure 2. Increase of the number of patients screened during study period

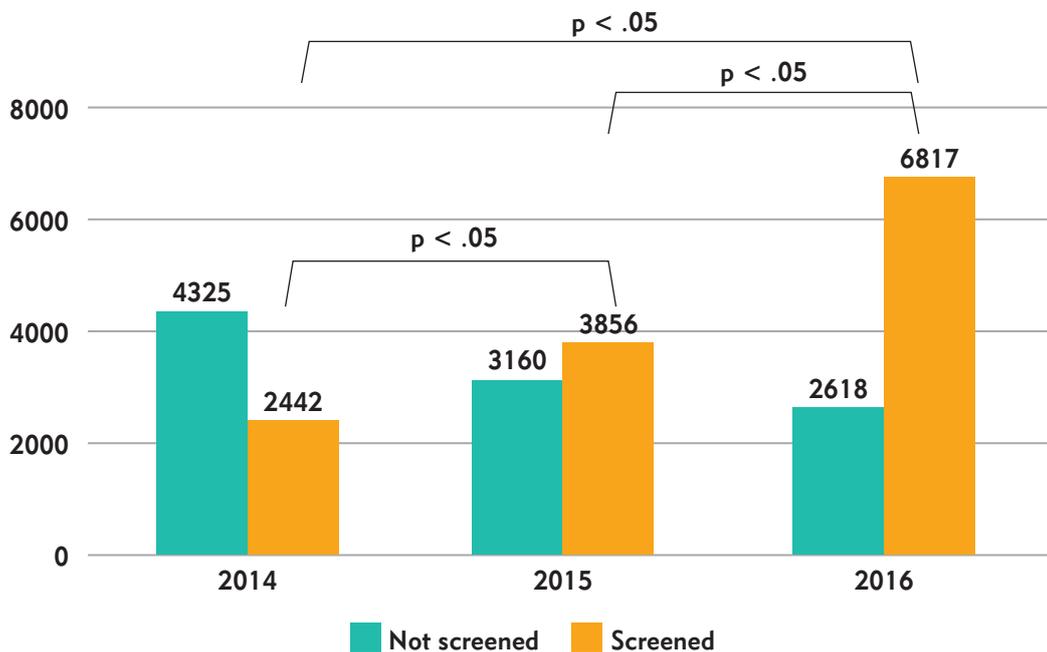
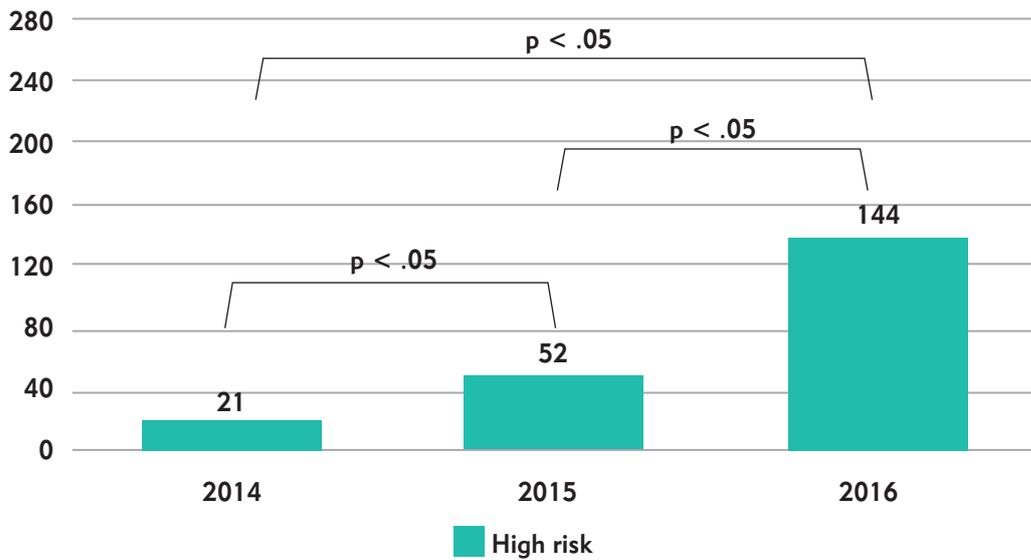


Figure 3. Increase of the number of high-risk patients detected during study period



A Chi-square test was applied for the comparison of the study groups.

The statistical analyses were performed using a commercial software, StatView vers. 12.0 (SAS Institute, Gary Ill), on an iMac computer.

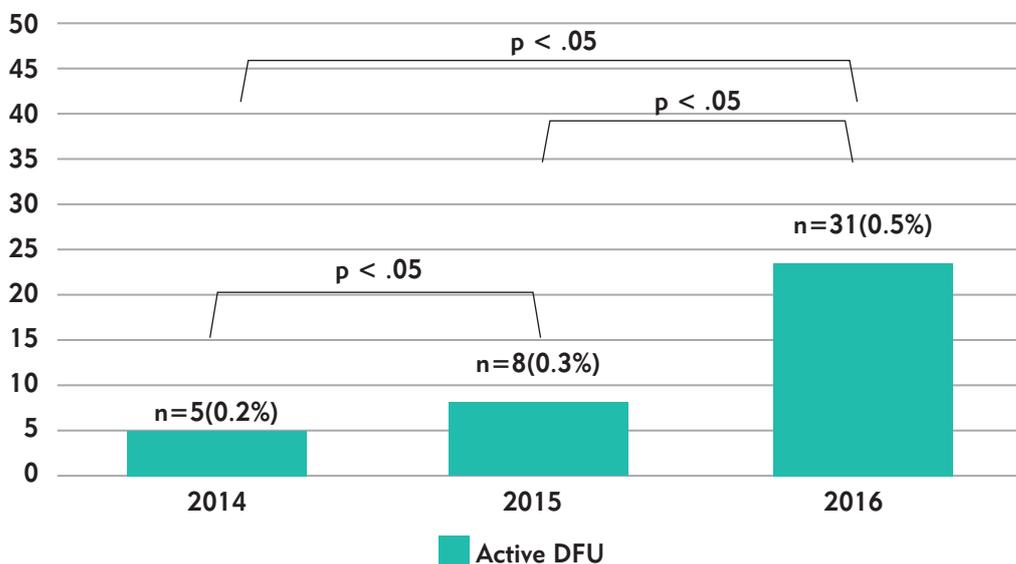
RESULTS

Data from northwest Tuscany's register of GPs revealed that the number of patients affected by diabetes increased over the three years of follow-up in the study population, with a total of 6,767/421,382 (1.6%), 7,016/421,382 (1.7%) and 9,435/421,382

(2.2%) patients for 2014, 2015 and 2016, respectively.

In the first year of the study we observed 2,442/6,767 (36.1%) patients screened (1,587 females and 855 males), with a mean age of 64.3 ± 13.4 years affected by type 2 diabetes. In the following years we observed 3,856/7,016 (54.9%) patients screened in 2015 (2,313/1,543 females/males), with a mean age of 66.5 ± 12.9 years and 6,817/9,435 (72.2%) patients screened in 2016 (4,090/2,727 females/males), with a mean age of 65.7 ± 14.3 years. No significant demographic differences were found between the groups.

Figure 4. Increase of the number of active DFU patients detected during study period



During the three years of the study we observed a statistically significant increase of the patients-screened percentage: 2442/6767 (36.1%), 3856/7016 (54.9%) and 6817/9435 (72.2%), $p < .05$ (Figure 2).

As reported in Figure 3, we also observed a statistically significant increase in the number of patients classified as high risk for DFU, according to the IWGDF guidelines: 21/2442 (0.8%) patients in 2014, 52/3856 (1.3%) in 2015 and 144/6817 (2.1%) in 2016 ($p < .05$). High-risk patients were referred to the specialised clinic for adequate second-level examination and education on DFU prevention.

Moreover, in parallel to the increase in the number of high-risk DFU patients detected we observed a significant increase in the identification of the number of active DFU patients during the study follow-up (Figure 4). This group of patients in the acute DFU phase, previously undiagnosed, was promptly referred to our hospital and consequently managed in a timely manner.

DISCUSSION

Our data confirm the efficacy of a proactive screening programme to detect DFU patients at an early stage in order to adequately and in a timely manner refer them to specialist care. Our findings strongly support the beneficial effect of proactive screening for the interception of DFs in a heterogeneous, at-risk population. The increase in rates of both high-risk patients and active DFUs detected, in the period in which the screening was performed, is an indirect confirmation of the presence of the pathology in the population.

The importance of DFU screening was underlined in the previous guidelines on DFs and confirmed by the most recent ones published in May 2019.¹³ Screening is aimed at identifying patients with the risk of developing ulcers in order to apply adequate prevention. Screening also has a crucial importance in the identification of patients with pre-ulcerative or ulcerative lesions in the active phase that could not otherwise being recognised in order to promptly treat the disease and thus prevent its progression.

Therefore, by implementing suitable prevention, the aim of screening is to reduce the rate of hospitalisation for DFU and the long-term rate of lower-limb amputations.

However, clear-cut data that confirm the impact of screenings on DFU outcomes are not yet available.²¹⁻³²

According to recent guidelines, a multidisciplinary approach to the prevention and treatment of DFU, involving GPs, podiatrists and diabetologists, is the best choice for the patient. In fact, the prompt application of adequate multidisciplinary treatment has been shown to result in a 50% reduction of major lower-limb amputation, especially in high-risk patients.³³

Therefore, an integrated intervention including healthcare professionals' education and healthcare systems' programmes that can identify the level of risk for DFU development early and limit the progression of disease, with the aim of reducing ulceration and the lower-extremity amputation rate, has the greatest influence on DF outcomes.

The direct involvement of nurses, specifically trained on DF, in a low-cost screening project make it possible to reach a large number of patients otherwise not intercepted, also giving them the occasion to get adequate information on DF and how to prevent it.

Many previous randomised, controlled diabetes studies evaluating the efficacy of foot care education for healthcare professionals report an improvement in foot care processes, an increase in the foot examination rate^{23,34-38} and an increase in the number of patients appropriately referred to a podiatrist.^{23,36} A concomitant increase in patient education^{23,36} and increased requests for protective footwear^{23,39} was also observed. An improvement in healthcare professionals' diabetic foot knowledge is also reported in DF studies that have used medical education and a pre-test/post-test study design.^{22,39}

An increased foot examination rate is also observed in a more recent non-randomised, stepped-wedge design, evaluating a single education session of nurses in a haemodialysis unit.⁴⁰

A previous study from the Netherlands reports a significant reduction of lower-extremity amputations as an effect of the increasing number of podiatrists and multidisciplinary teams.⁴¹ In this study, during a period of about 10 years of implementation of the management of diabetes-related lower-limb complications, the incidence rate of diabetes-related, lower-

extremity amputation decreased in both men (36%) and women (38%), and the duration of hospitalisation decreased over time.

Another, more recent study shows that the discontinuation of podiatry care from Medicare in the US⁴² resulted in an increase in the number of hospitalisations for diabetic foot disease, consequently with an increase in health cost.

Both studies offer indirect evidence regarding the potential importance of healthcare organisation in DF care, including ulcer prevention.

Other authors demonstrate that by educating healthcare workers in a primary healthcare clinic it is possible to obtain an increase in the number of diabetic patients screened and, consequently, a significant quality improvement in the management of the disease.³⁰ Similar results were obtained from a nurse-driven educative intervention on diabetic patients' foot screening performed in four UK National Health Service dialysis units.⁴⁰

We are aware of the limitations of this study, which is single centre, retrospective and without a control group.

However, this is the first interventional screening study with the aim of improving a large-scale screening programme for DFU reported in the literature.

Because of the short-term follow-up of the study we

have no data about the possible favourable impact of the screening programme on the long-term reduction of the major-amputation rate.

Moreover, since major-amputation rates are related to the whole Tuscany region, it was not possible to connect our findings to this outcome.

However, we have to underline that a screening programme alone is not sufficient for adequate management of DFU. In fact, to obtain better long-term outcomes, we need, as strongly suggested by recent guidelines, a multilevel organisation composed of primary, secondary and tertiary care.

Although possibly biased, this study shows how increasing the rate of subjects actively screened in the population of known diabetic patients also increases the rates of high-risk patients and active DFUs detected; thus it is possible to detect them early and to promptly intervene, interrupting the progression of the disease.

CONCLUSIONS

Our study demonstrates how an organised screening programme of diabetic patients, performed by nurses in the community, is effective in intercepting high-risk and ulcerated patients in an early phase of the clinical course of the disease, then addressing them to specialist care and giving preventive education on DF, eventually reducing the progression of the disease towards the later, more critical stages.



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