

Provision of assistive devices for people with diabetes at risk of mobility impairment

Authors

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Abstract

Whilst diabetes is a growing global health problem, diabetic foot disease is one of the most expensive complications of diabetes leading to significant morbidity and mortality in the adult population. Previous research has clearly highlighted the limitations of currently available diabetic foot screening guidelines; which aim to identify patients at risk of foot complications, such as ulcerations and amputations, and who therefore may require mobility assistive devices. Also, there are differences between screening guideline recommendations at the national level and this contributes to the differences in national diabetic foot disease outcomes and associated burden. There is also a lack of high quality evidence on which these guidelines are based which is responsible for the current gaps between guidelines, standard clinical practice, and development of complications. Whilst indicating that diabetes is associated with a clear increase in the risk of physical disability, studies have called for efforts to promote healthy ageing and strategies for mitigating this risk through prevention and management. In addition, reports showcase that diabetes related lower extremity complications are one of the leading causative factors in the global burden of disability. This study focussed on publicly available datasets to retrieve relevant information relating to physical disability as a result of diabetes. It also examined the national guidelines for screening and their relationship to global guidelines. Whilst publicly available datasets highlight and host up to date information on the global burden of the diabetes, it has little or no information relating to the complications resulting from diabetes and in particular no data on amputations or mobility related assistive devices. There is a clear need for collecting structured data during screening at a primary care level. This, in addition to helping to reduce the complications of the disease will help to understand the assistive technology needs of these patients.

Keywords

Orthoses; Assistive Devices; Diabetic Foot

Introduction

The worldwide diabetic population is expected to grow from 171 million to 381 million by 2030 posing a serious international challenge. Reports highlight that there has been a clear increase in the age standardised diabetes prevalence in adults since 1980. When this is coupled with the growth in population and the effects of ageing, the number of adults with diabetes has nearly quadrupled. In addition, the reported data suggests that this growth has increased faster in low-income and middle-income countries than in high-income countries (1).

Diabetic foot disease is one of the most expensive complications of diabetes and leads to significant morbidity and mortality in the adult population with a prevalence of 9.7%. The lifetime risk of diabetic foot ulcers (DFUs) is 15% to 25%. 15% of these DFUs result in amputation, which amounts to 85% of all lower-limb amputations (2). Following a first amputation, the likelihood of the need for a subsequent amputation for people with diabetes is twice as likely as people without diabetes. After a diabetic foot ulceration or amputation mortality rates are high; within 5 years of having an amputation up to 70% of people will die and within 5 years of developing a DFU around 50% will die (3). As the incidence of diabetes and the resulting complications are on the increase, we need a step change in all aspects of prognosis, diagnosis and prevention. In addition, more sustained efforts are needed to understand not only the progression of the disease but also the resulting complications. Whilst assistive technology, in the form of orthoses, footwear, is pivotal in the clinical management of people with diabetic foot disease, there is a clear paucity of structured information and research evidence to inform the clinical management of this population (4). Assistive technology to aid mobility are vital to prevent and treat DFUs. They combat the exclusion of people with disabilities from the workplace, enabling them to participate in education, work and social activities. Without them, people can be isolated increasing the impact of disease on them, their families, and society (5).

Whilst general healthcare support for people with diabetes is still not uniform both within and between countries, it is particularly evident for diabetic foot disease and its complications. Previous research (6,7) has clearly highlighted the limitations of currently available diabetic foot screening guidelines; which aim to identify patients at risk of foot complications, such as ulcerations and amputations, and who therefore may require mobility assistive devices. Also, there are differences between screening guideline recommendations at the national level and this contributes to the differences in national diabetic foot disease outcomes and associated burden. There is also a lack of high quality evidence on which these guidelines are based which is responsible for the current gaps between guidelines, standard clinical practice, and development of complications (6). Even in the countries who have established guidelines, our previous work (8) identified 3 key themes highlighting barriers to the implementation of diabetes foot screening guidelines. Although this data was local to Malta, the results might be applicable to other countries.

Our findings clearly highlight the need for change in current practices if effective diabetic foot screening is to be offered and ultimately, to reduce the mortality rates.

As a first step to tackle some of the issues, there is a need for structured epidemiological data on lower limb amputations related to diabetes and its complications. One of the recent reports (9), whilst showing that a significant variation exists in the incidence of lower extremity amputations, clearly highlights the variation in reporting methods and calls for standardised reporting methods. Although ethnicity and social deprivation might play a significant role in these amputations, the role of diabetes and its complications cannot be ignored and based on existing data, it is most profound. Diabetes and its complications are associated with a clear increase in the risk of physical disability and studies have called for efforts to promote healthy ageing and strategies for mitigating this risk through prevention and management (10). In addition, reports (11) showcase that diabetes related lower extremity complications are one of the leading causative factors in the global burden of disability.

Despite improvements in morbidity and mortality levels, general health inequalities remain. This is particularly prevalent in the management of chronic conditions such as diabetes and its complications. It is important to develop a version of Global Quality and Outcomes Framework (QOF) on trends in diabetes management and inequalities in care with a focus on musculoskeletal and mobility issues. The Quality and Outcomes Framework is a system designed within the National Health Service (NHS) in the United Kingdom, to encourage high quality care and cost-effective management of medical condition, using an evidenced based checklist (12). This scheme was established by NICE in the United Kingdom and research has shown this system has been associated with improved care in multiple conditions, including diabetes (13). Whilst indicating that the QOF led to modest improvements in diabetes care within the NHS, this report concluded that the healthcare providers should look at other alternatives (13).

In the context of this paper, the QOF is used as a reference point to highlight the need for a structured screening, reporting and management system rather than a system for financial compensation. Given that there is a pledge to achieve universal health coverage by 2030, and that the healthcare organisations and departments are currently negatively subjected to various resource implications, the quality of services can only be improved by structured recording and analysis of appropriate information. Whilst commitment from the politicians and policy makers to provide universal health coverage is a step in the correct direction, one of the previous papers (14) have synthesized the lessons learnt from the NHS that provides a universal health coverage, free at the point of care for over 70 years. This report identified that: 1) the development of a coherent strategy to improve quality, 2) to boost public health as a measure to reduce disease burden, 3) to adopt evidence-based priority setting methods that ensure efficient spending of financial resources, 4) to introduce an independent way of inspecting and regulating providers, and finally, 5) to allow for task-shifting, specifically in regions where staff retention is low as main factors to consider.

The overall experiences of Thailand, where QOF similar to the United Kingdom was adopted in 2013 with an objective of strengthening the quality of primary health care by introducing financial incentives and quality indicators for measuring health care service performances have been positive. Evaluations and research reports of the initial pilot show that some of the main barriers for the QOF program include budgetary constraints, lack of evidence-based quality indicators, lack of involvement from key stakeholders and the incompatibility of policies between the ministries of public health and the health service provision. This meant an increase in burden for health workers in the primary care sector and poor communication between various stakeholders. Based on these findings a new set of indicators were developed, implemented and evaluated. Although long term effects are yet to be reported, the initial indicators show that the QOF in Thailand is a promising intervention despite its many challenges (15–17).

It is generally accepted that the development of quality indicators using a specific screening and guideline-based approach is a useful way of generating evidence to support the effective implementation of a health policy program. There have been some research reports which provides a framework for insurance and cost implications in improving health care quality in low resource settings. This framework bridges the gap in literature between strategic designs for system improvement and narrower discussions of the technical methods to influence the quality by the organisations and departments which make the payments (18).

The main purpose of this work is to explore the available data on the global burden of diabetic foot disease and to review the research and clinical literature to explore what information is needed to develop a structured framework. This should give us an understanding of the level of health inequalities in the provision of assistive devices for people with diabetes at risk of mobility impairment and to establish a protocol for basic requirements to mitigate the risk of further physical disabilities.

Methods

In addition to a thorough literature search relating to diabetic foot screening guidelines(6,8), publicly available datasets (19–22) were explored in a systematic way to retrieve any relevant information relating to physical disability as a result of diabetes. We also examined the national guidelines for screening and their relationship to global guidelines.

In terms of the quantitative data, as we wanted to focus on developing and under developed regions of the world, the dataset from the Demographics and Health Services (DHS) program was first explored to see how many surveys included questions on diabetes. The next step was to synthesize the data available from the World Bank. A particular focus was given to the prevalence rate of diabetes. The third step was to look at individual country profiles on diabetes and related data published by the World Health Organisation (WHO). Finally, we approached the International Diabetes Federation (IDF) for any available data.

Results

Within the DHS out of the reports from multiple years (2002-2018), 21 full country reports were available which consisted of survey answers based on questions on diabetes. These questions related to the general prevalence of diabetes and did not have any specific data related to causative factors or complications resulting from diabetes.

The data from the World Bank showcased the prevalence of diabetes (% of population ages 20 to 79). This dataset showed a weighted average data of people who have type 1 or type 2 diabetes. This data indicates that diabetes is an important cause of ill health and a risk factor for other diseases in developed countries and is spreading rapidly in developing countries. Although it is highest among the elderly, the prevalence rates are rising among younger populations in developing and under-developed regions of the world. Data on a total of 217 countries and territories has been reported and the diabetes prevalence ranges between 0.99-30.53%. Out of these 72 countries reported a prevalence rate between 10.08-30.53%. The data were also grouped by the following regions: East-Asia & Pacific, Europe and Central-Asia, Latin America & Caribbean, Middle-East & North-Africa, North-America, South-Asia, Sub-Saharan Africa and by the following income groups: low, lower-middle, upper-middle, high.

In terms of the dataset from the WHO, country profile reports published in 2016 were scrutinised to understand the data relating to the complications resulting from diabetes. In addition to the prevalence data, the profile includes data on: 1) mortality, 2) risk factors, 3) the country's plans and policies on: 1) monitoring and surveillance; 2) primary prevention, 3) treatment and availability of medicines and, 4) basic technologies and procedures. Out of the 72 countries identified with diabetes prevalence of over 10% from the World Bank data, 34 countries had profiles within the WHO dataset. Although the IDF has data on prevalence, they do not collect data on amputations and specific data related to the complications of diabetes.

In summary, although the publicly available datasets highlight and have up to date information on the global burden of the diabetes, it has little or no information relating to the complications resulting from diabetes and in particular no data on amputations or mobility related assistive devices. In addition, there is little information within the scientific literature on the potential clinically viable outcome measures for documenting and assessing physical disability in people with diabetes. A critical evaluation of available foot screening guidelines highlights the need for culturally competent, nationally relevant guidelines.

Discussion

The purpose of looking at publicly accessible datasets is to make sure that this data could be used by local policy makers who might not have access to specific research datasets. In addition, although one could argue that these large surveys normally provide superficial

data and not individual, highly scientific and quantifiable data, it gives a global trend and provides pointers to scientists and policy makers on the direction to follow.

The results and the synthesis of available reports highlight that availability of health data is limited. It is not only a major constraint in the assessment of any health indicators in the developing and underdeveloped regions of the world but also impedes the development of policies and procedures to alleviate the issues relating to any particular non-communicable disease. Whilst this report focused on diabetes, its complications and assistive technology, the analyses of data sets show that there is a paucity of data relating to important public health issues. In addition to this, the reports also highlight the fact that some of the estimates relating to disease incidence and prevalence are either incomplete or unreliable.

Recognising the global burden, in 2016 the WHO released the first global report on diabetes along with a series of country profiles to highlight the status of diabetes prevention and control in each member state. These profiles provide a comprehensive information which could support further focused work. Although the data presented within these profiles were derived from a variety of sources, the mortality and risk factor data were estimated using standard methods to maximize cross-country comparability. Whilst these may not represent true values and official statistics of member states, it provides a clear picture of the growing burden in various parts of the world.

A report (1) on the global burden which used the data from 751 studies (4372000 adults) showed that global age-standardised diabetes prevalence increased from 4.3% in 1980 to 9.0% in 2014 in men, and from 5.0% to 7.9% in women. This means that the approximate total number of adults with diabetes across the world increased from 108 million in 1980 to 422 million in 2014. Other reports (23) highlight that the burden of musculoskeletal (MSK) diseases also increased significantly between 2000 and 2015. It is universally accepted that foot screening is important in diabetic patients as it is recognised as the basis to save a high-risk foot. For this screening to be effective it must be performed correctly. The skills required to complete this screening is complicated and needs appropriate training. Our research within the reported literature show that a range of healthcare sector workers from a variety of specialities perform this screening with little training. This possibly needs to change if the screening has to be effective in saving limbs (8). Our previous work highlights the need for appropriate assessment of ABPI (24,25), the need for structured screening within the primary care (26,27) and accurate evaluation of footwear (28). In addition our work on the critical analysis of the current foot screening guidelines developed by various organisations and policy makers (6) shows a clear disparity and inconsistencies in areas with regards to tools and methods for effective screening and the diagnosis patients at an early stage of their disease. Based on 10 complete diabetes foot screening guidelines (out of which 6 of them included the full-process guidelines recommended by the IDF) our analysis showed that most of the recommendations within many of these guidelines are either poorly evidenced or based solely on an 'expert opinion'. There is a clear need to create a network of clinical practitioners and health policy experts who would look at these

guidelines in a clear and structured fashion taking into consideration the technological developments for clinical assessment and cultural differences across the world, to develop appropriate screening tools which are fit for purpose. This will no doubt have a substantial impact not only in reducing ulcerations and amputations but also in improving the quality of life of people with diabetic foot disease.

Previous research conducted in a primary care setting in Malta where the prevalence rate is high, showcases the importance of structured observation coupled with strengthening of existing screening protocols and introducing clinical guidelines with regards to biomechanical assessment of the feet in a primary care setting. This report concluded that this has the potential to reduce the incidence of diabetes foot complications (29). Although various scientific and clinical publications indicate that peripheral vascular disease (PVD) is strongly associated with type 2 diabetes, the assessment and diagnosis of PVD are often neglected within primary care. Another report on the same population showed that a significant proportion of these patients with type 2 diabetes who visit primary care have vascular insufficiency. The paper called for the use of Ankle Brachial Pulse Index as an added measurement in order to facilitate early detection and treatment and reduce the burden of PVD in this high-risk population (26). Finally, the demographics within this population showed that, whilst metabolic outcomes such as hypertension and dyslipidaemia were present in most subjects, peripheral vascular disease, peripheral sensory neuropathy and foot deformities were also common. The report indicated that 26 per cent of the participants had to be referred for further vascular assessment following this screening program due to their critical vascular status (30).

Based on some of these findings, it is important that structured screening is carried out at a primary care level. The WHO country profiles do provide some insight into the technologies available at the primary care. These technologies and the facilities could be strengthened to include some of the quantitative outcome measures to facilitate structured screening. In terms of the profiles themselves, out of the 34 countries which were looked at in detail, only 4 were from the low-income countries and the rest were from middle or high-income countries. One could easily attribute this to change in socio-cultural and dietary habits. Only 18 of these countries report to have a diabetes registry. Given that this situation is there to stay some urgent measures are needed to tackle the situation.

Inequalities to access healthcare are preventable and have a huge socio-economic impact because they result in people who are disadvantaged having poorer health and quality of life. This is amplified in people living with chronic health conditions such as diabetes. The complications of diabetes result in physical disabilities. To improve health outcomes and to help with mobility issues relating to diabetic complications appropriate actions, strategies and interventions are required.

These include not only the development of clinical protocols but also the development of appropriate technology. United Nations Sustainable Development Goals (SDG) (31) clearly outline the need for effective, innovative, and affordable medical devices. This is a critical

component of any effective healthcare intervention and to achieve the WHO goal of 3 billion lives saved as stated in the 13th General Programme of Work. It is clear that lack of access to quality, affordable medical devices is most apparent in low – and middle – income countries and contributes to global health inequalities.

Whilst the WHO statistics series (32) provides an annual snapshot of the state of the world's health and contains data for 36 health-related SDG indicators, there is a gap in knowledge in terms of complications resulting from diabetes. To address this gap and as a first step, there is a need to design and employ measures to collect data in a structured way across the world on diabetes and more importantly on its complications. Our exploratory work clearly highlights that there is no global data on amputations and the level of amputations relating to diabetes. Also, there is a clear paucity of information on the assistive technology needs for this population. This data is essential to policy makers, healthcare providers and commercial organisations to develop a quality provision of AT to people with diabetes.

Various reports clearly highlight that inequalities in access to healthcare exist across different socio-demographic groups across the world both for financial and non-financial reasons. To ensure universal access to care, an effective screening program followed by evidenced based clinical management is paramount. Reports (11) analysing the global burden of disability highlight the need for policymakers to prioritise the development of policies that will improve evidence-based care for people with diabetes complications. This will no doubt influence the reduction of the largest cause of lower limb amputations and the global burden of disease.

Limitations of currently available guidelines and lack of evidence on which the guidelines are based are responsible for the current gaps between guidelines, standard clinical practice, and development of complications. For the development of standard recommendations and everyday clinical practice, it will be necessary to pay more attention to both the limitations of guidelines and the underlying evidence. In addition to this, one needs to consider the fact the AT needs of a patient with diabetes will be different to a patient with other MSK conditions and other disease complications. Collecting structured data during screening at a primary care level can lead not only to reduce the complications of the disease but also to understanding the AT needs of these patients. The results of these findings will also help the policymakers to prioritise policies that will improve evidence based screening and clinical management of people with diabetes and mobility impairment. This might also help us develop a QOF which will help not only in improving the standards for the provision of care but also structured data to identify investment needs for the government and non-governmental agencies.

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