



Editorial

Diabetic Capital Punishment: Time for Amnesty

Raúl Juan Molines-Barroso *, Mateo López-Moral and José Luis Lázaro-Martínez

Diabetic Foot Unit, Clínica Universitaria de Podología, Facultad de Enfermería, Fisioterapia y Podología, Universidad Complutense, Instituto de Investigación Sanitaria del Hospital Clínico San Carlos (IdISSC), 28040 Madrid, Spain

* Correspondence: rmolines@ucm.es; Tel./Fax: +34-913-942-203

Discussion

A study has shown that 19–34% of patients with diabetes will develop a foot ulcer in their lifetime [1], and close to 50% of these patients will die within 5 years [2,3]. A total of 22% of diabetes patients with ulcers are more likely to die than patients with diabetes who never develop ulceration [4].

Healthcare professionals have made significant efforts to treat ulcers. Recent findings show that ulcer healing time has been reduced, thereby lowering the associated complications [5,6]. However, it is estimated that 40% of patients will experience ulcer recurrence within 1 year after ulcer healing, almost 60% within 3 years, and 65% within 5 years. This issue consequently increases morbidity, reduces quality of life, and increases health care costs [7]. Thus, these patients are considered in a state of remission rather than being healed [1].

The “Pareto Principle”, also known as the 80/20 rule, states that 80% of outputs come from 20% of inputs [8]. In the context of health care, this rule suggests that 80% of resources are assigned to treat 20% of patients with ulceration, and 20% of the available resources are allocated to treat 80% of patients at high risk of ulceration. Thus, more implications by the industry must avoid the first and recurrent ulceration.

Each ulceration involves new debridement or surgical interventions, long-term immobilization, prolonged times hospitalizations, and multiple antibiotic treatments. Moreover, many patients may require partial amputation, contributing to increased morbidity and the risk of death [8]. As more amputation and surgical interventions are carried out for a patient, more biomechanical disturbances, and sometimes more difficulty in avoiding recurrent ulceration through conservative treatments, emerge, which can lead to a “hard-to-prevent” patient.

It is well-established that the primary and secondary preventions of foot ulcers are foot screening, stratifying patient categories based on the foot ulceration risk, the routine wearing of appropriate footwear, treating pre-ulcerative signs of foot, and providing patient and family education in foot self-care [9].

Several risk factors of ulceration have been identified, which include neuropathy, excessive plantar pressure, age, sex, BMI, or HbA_{1c} [10,11]. However, studies have shown a paucity of evidence regarding the predictive efficacy of the early diagnosis of symptoms [10,12]. Thus, developing models of clinical prediction, as well as the design and validation of high-quality randomized controlled trials (RCTs), is vital for identifying patients at high risk of ulceration across different health care settings [13].

Therapeutic footwear and the self-monitoring of foot skin temperatures are important interventions to prevent recurrent plantar diabetic foot ulcers [14]. These therapeutic strategies and the treatment of modifiable risk factors, such as regular callus removal, are vital for relapsing recurrent plantar ulcers [15]. However, a recent study has shown that patients have a low adherence to some of these preventive interventions, which may undermine the effectiveness of this approach [16]. The prevention of first ulcers and nonplantar ulcers has not been practically investigated [14].

Citation: Molines-Barroso, R.J.; López-Moral, M.; Lázaro-Martínez, J.L. Diabetic Capital Punishment: Time for Amnesty. *J. Clin. Med.* **2022**, *11*, 6562. <https://doi.org/10.3390/jcm11216562>

Received: 31 October 2022

Accepted: 3 November 2022

Published: 4 November 2022

Publisher's Note: MDPI stays neutral with regard to jurisdictional claims in published maps and institutional affiliations.



Copyright: © 2022 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (<https://creativecommons.org/licenses/by/4.0/>).

Other interventions are sometimes widely applied. Although surgical interventions are recommended to reduce ulcer recurrence, studies have not demonstrated sufficient evidence to support the prevention of ulcer recurrence [14,15].

Surgical offloading is effective in managing plantar pressure and relieving the effect of the ulcer site. These treatments should be a proper indication in patients in remission because the efficacy of preventative treatments could be insufficient in 1 out of 4 patients at high risk of developing an ulcer [17,18]. Thus, surgical offloading is a treatment for recalcitrant ulcers [19]. After surgical offloading, recurrent ulceration at other sites is different from the initial ulceration, and this contributes to transferring syndrome [20]. Thus, comparative studies will benefit surgical decision-making remission in patients by avoiding recurrence, defining time points, and protecting against irretrievable tissue loss/re-ulceration through surgical offloading [19].

Patient and family education is vital for improving adherence to treatments, protecting the feet, increasing the implication of foot self-care, and identifying problems associated with prevention programs. However, patient education alone is not sufficient to prevent recurrence and amputation [21]. Thus, more integral structured programs of education are recommended as a tool for reducing the recurrence rates [14].

Adherence to prescribing treatments is vital for patients with a loss of protective sensation in the feet. Two RCTs with a very low risk of bias have shown that partial adherence results are insufficient in protecting high-risk patients from developing recurrent ulcers [17,18]. This problem is higher during patient daily life (when they are not observed in a RCT framework), and adherence to prevention measurements could be reduced. It has been reported that nearly 50% of patients do not use adequate footwear when they are outdoors [22], and nonadherence increases when patients are indoors. Suboptimal adherence is more evident over time (after 6 months of footwear use) [23]. Economic reasons or problems with design could explain suboptimal adherence in some patients [23]; however, the refusal to use footwear is also common, even among patients who receive footwear for free every 6 months. Unfortunately, the term “patient in remission” is not adopted by them, and this is considered a behavior that causes preventative measures to be neglected [24].

Since patient education has not been effective in reducing ulcer recurrence, it should be guided toward a model of identifying human response that cause harmful behavior in high-risk patients. Future studies should focus on how behavioral changes could be used to reduce recurrent ulceration. Moreover, educational programs should include these new findings to improve adherence. Furthermore, the industry should collaborate in the design and development of supplementary tools and computerized intelligent systems for the monitoring and surveillance of high-risk feet. More investigations are needed to identify models of high-risk patients and hard-to-prevent patients so that they may benefit from surgical off-loading. The goal is to reduce the recurrent ulceration without precipitate transfer lesions. These recommendations will resolve the lack of evidence related to the prevention of first foot ulcers and nonplantar foot ulcers. Further investigations must prevent “diabetic capital punishment”, which entails the first occurrence of ulcers in patients with diabetes.

Author Contributions: Conceptualization, R.J.M.-B., J.L.L.-M. and M.L.-M.; methodology, R.J.M.-B. and M.L.-M.; software, R.J.M.-B. and M.L.-M.; validation, R.J.M.-B., J.L.L.-M. and M.L.-M.; formal analysis, R.J.M.-B., J.L.L.-M. and M.L.-M.; investigation, R.J.M.-B. and M.L.-M.; resources, R.J.M.-B., J.L.L.-M. and M.L.-M.; data curation, R.J.M.-B., J.L.L.-M. and M.L.-M.; writing—original draft preparation, R.J.M.-B.; writing—review and editing, R.J.M.-B., J.L.L.-M. and M.L.-M.; visualization, J.L.L.-M.; supervision, J.L.L.-M.; project administration, R.J.M.-B., J.L.L.-M. and M.L.-M.; funding acquisition, J.L.L.-M. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Conflicts of Interest: The authors declare no conflict of interest.

References

1. Armstrong, D.G.; Boulton, A.J.M.; Bus, S.A. Diabetic foot ulcers and their recurrence. *N. Engl. J. Med.* **2017**, *376*, 2367–2375. <https://doi.org/10.1056/NEJMr1615439>.
2. Morbach, S.; Furchert, H.; Gröbblinghoff, U.; Hoffmeier, H.; Kersten, K.; Klauke, G.T.; Klemp, U.; Roden, T.; Icks, A.; Haastert, B.; et al. Long-term prognosis of diabetic foot patients and their limbs: Amputation and death over the course of a decade. *Diabetes Care* **2012**, *35*, 2021–2027.
3. Walsh, J.W.; Hoffstad, O.J.; Sullivan, M.O.; Margolis, D.J. Association of diabetic foot ulcer and death in a population-based cohort from the United Kingdom. *Diabetes Med.* **2016**, *33*, 1493–1498.
4. Saluja, S.; Anderson, S.G.; Hambleton, I.; Shoo, H.; Livingston, M.; Jude, E.B.; Lunt, M.; Dunn, G.; Heald, A.H. Foot ulceration and its association with mortality in diabetes mellitus: A meta-analysis. *Diabetes Med.* **2020**, *37*, 211–218.
5. Edmonds, M.; Lázaro-Martínez, J.L.; Alfayate-García, J.M.; Martini, J.; Petit, J.M.; Rayman, G.; Lobmann, R.; Uccioli, L.; Sauvadet, A.; Bohbot, S.; et al. Sucrose octasulfate dressing versus control dressing in patients with neuroischaemic diabetic foot ulcers (Explorer): An international, multicentre, double-blind, randomised, controlled trial. *Lancet Diabetes Endocrinol.* **2018**, *6*, 186–196.
6. Game, F.; Jeffcoate, W.; Tarnow, L.; Jacobsen, J.L.; Whitham, D.J.; Harrison, E.F.; Ellender, S.J.; Fitzsimmons, D.; Löndahl, M.; Dhatariya, K.; et al. LeucoPatch system for the management of hard-to-heal diabetic foot ulcers in the UK, Denmark, and Sweden: An observer-masked, randomised controlled trial. *Lancet Diabetes Endocrinol.* **2018**, *6*, 870–878.
7. van Acker, K.; Léger, P.; Hartemann, A.; Chawla, A.; Siddiqui, M.K. Burden of diabetic foot disorders, guidelines for management and disparities in implementation in Europe: A systematic literature review. *Diabetes Metab. Res. Rev.* **2014**, *30*, 635–645.
8. Juran, J.M. *The Non-Pareto Principle. Mea Culpa*, 8th ed.; McGraw-Hill: New York, NY, USA, 1975; pp. 8–9.
9. Bus, S.A.; Lavery, L.A.; Monteiro-Soares, M.; Rasmussen, A.; Raspovic, A.; Sacco, I.C.N.; van Netten, J.J.; on behalf of the International Working Group. Guidelines on the prevention of foot ulcers in persons with diabetes (IWGDF 2019 update). *Diabetes Metab. Res. Rev.* **2020**, *36* (Suppl. S1), e3269.
10. Crawford, F.; Inkster, M.; Kleijnen, J.; Fahey, T. Predicting foot ulcers in patients with diabetes: A systematic review and meta-analysis. *QJM* **2007**, *100*, 65–86.
11. Monteiro-Soares, M.; Boyko, E.J.; Ribeiro, J.; Ribeiro, I.; Dinis-Ribeiro, M. Predictive factors for diabetic foot ulceration: A systematic review. *Diabetes Metab. Res. Rev.* **2012**, *28*, 574–600.
12. Monteiro-Soares, M.; Boyko, E.J.; Ribeiro, J.; Ribeiro, I.; Dinis-Ribeiro, M. Risk stratification systems for diabetic foot ulcers: A systematic review. *Diabetologia* **2011**, *54*, 1190–1199.
13. Crawford, F.; Cezard, G.; Chappell, F.M.; Murray, G.D.; Price, J.F.; Sheikh, A.; Simpson, C.R.; Stansby, G.P.; Young, M.J. A systematic review and individual patient data meta-analysis of prognostic factors for foot ulceration in people with diabetes: The international research collaboration for the prediction of diabetic foot ulcerations (PODUS). *Health Technol. Assess.* **2015**, *19*, 1–207.
14. van Netten, J.J.; Raspovic, A.; Lavery, L.A.; Monteiro-Soares, M.; Rasmussen, A.; Sacco, I.C.N.; Bus, S.A.; International Working Group on the Diabetic Foot. Prevention of foot ulcers in the at-risk patient with diabetes: A systematic review. *Diabetes Metab. Res. Rev.* **2020**, *36* (Suppl. S1), 84–98.
15. van Netten, J.J.; Sacco, I.C.N.; Lavery, L.A.; Monteiro-Soares, M.; Rasmussen, A.; Raspovic, A.; Bus, S.A. Treatment of modifiable risk factors for foot ulceration in persons with diabetes: A systematic review. *Diabetes Metab. Res. Rev.* **2020**, *36* (Suppl. S1), e3271.
16. Rovers, F.J.; Van Netten, J.J.; Busch-Westbroek, T.E.; Aan de Stegge, W.B.; Bus, S.A. Adherence to at-home monitoring of foot temperatures in people with diabetes at high risk of ulceration. *Int. J. Low Extrem. Wounds* **2022**, *Online ahead of print*.
17. Bus, S.A.; Aan De Stegge, W.B.; Van Baal, J.G.; Busch-Westbroek, T.E.; Nollet, F.; Van Netten, J.J. Effectiveness of at-home skin temperature monitoring in reducing the incidence of foot ulcer recurrence in people with diabetes: A multicenter randomized controlled trial (DIATEMP). *BMJ Open Diabetes Res. Care* **2021**, *9*, e002392.
18. Bus, S.A.; Waaijman, R.; Arts, M.; De Haart, M.; Busch-Westbroek, T.; Van Baal, J.; Nollet, F. Effect of custom-made footwear on foot ulcer recurrence in diabetes: A multicenter randomized controlled trial. *Diabetes Care* **2013**, *36*, 4109–4116.
19. Ahluwalia, R.; Maffulli, N.; Lázaro-Martínez, J.L.; Kirketerp-Møller, K.; Reichert, I. Diabetic foot off loading and ulcer remission: Exploring surgical off-loading. *Surgeon* **2021**, *19*, e526–e535.
20. Molines-Barroso, R.J.; Lázaro-Martínez, J.L.; Aragón-Sánchez, J.; García-Morales, E.; Beneit-Montesinos, J.V.; Álvaro-Afonso, F.J. Analysis of transfer lesions in patients who underwent surgery for diabetic foot ulcers located on the plantar aspect of the metatarsal heads. *Diabetes Med.* **2013**, *30*, 973–976.
21. Dorresteyn, J.A.N.; Kriegsman, D.M.W.; Assendelft, W.J.J.; Valk, G.D. Patient education for preventing diabetic foot ulceration. *Cochrane Database Syst. Rev.* **2014**, *2014*, CD001488.
22. Barwick, A.L.; Hurn, S.E.; van Netten, J.J.; Reed, L.F.; Lazzarini, P.A. Factors associated with wearing inadequate outdoor footwear in populations at risk of foot ulceration: A cross-sectional study. *PLoS ONE* **2019**, *14*, e0211140.
23. Luo, B.; Cai, Y.; Chen, D.; Wang, C.; Huang, H.; Chen, L.; Gao, Y.; Ran, X. Effects of special therapeutic footwear on the prevention of diabetic foot ulcers: A systematic review and meta-analysis of randomized controlled trials. *J. Diabetes Res.* **2022**, *2022*, 1–10.
24. Formosa, C.; Borg, A.; Papanas, N.; Mizzi, S. Adherence to therapeutic footwear in type 2 diabetes in Malta. *Exp. Clin. Endocrinol. Diabetes* **2020**, *128*, 244–245.