

Adverse events in diabetic foot infections: a case control study comparing early versus delayed medical treatment after home remedies

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Background: The aim of conventional medical therapy in diabetic foot infections is to control infection, thereby reducing amputation rates, infectious morbidity, and death. Any delay incurred during a trial of home remedies could allow an infection to progress unchecked, increasing the risk of these adverse outcomes. This study sought to determine the effects of delayed operative interventions and amputations in these patients.

Methods: A questionnaire study targeting all consecutive patients admitted with diabetic foot infection was carried out over 1 year. Two groups were defined, ie, a medical therapy group comprising patients who sought medical attention after detecting their infection and a home remedy group comprising those who voluntarily chose to delay medical therapy in favor of home remedies. The patients were followed throughout their hospital admissions. We recorded the duration of hospitalization and number of operative debridements and amputations performed.

Results: There were 695 patients with diabetic foot infections, comprising 382 in the medical therapy group and 313 in the home remedy group. Many were previously hospitalized for foot infections in the medical therapy (78%) and home remedy (74.8%) groups. The trial of home remedies lasted for a mean duration of 8.9 days. The home remedy group had a longer duration of hospitalization (16.3 versus 8.5 days; $P < 0.001$), more operative debridements (99.7% versus 94.5%; $P < 0.001$), and more debridements per patient (2.85 versus 2.45; $P < 0.001$). Additionally, in the home remedy group, there was an estimated increase in expenditure of US \$10,821.72 US per patient and a trend toward more major amputations (9.3% versus 5.2%; $P = 0.073$).

Conclusion: There are negative outcomes when patients delay conventional medical therapy in favour of home remedies to treat diabetic foot infections. These treatments need not be mutually exclusive. We encourage persons with diabetes who wish to try home remedies to seek medical advice in addition as a part of holistic care.

Keywords: diabetic foot infections, adverse events, medical treatment, home remedies

Introduction

Diabetic foot infections take a heavy toll on health care resources in the Caribbean. Each year, the Government of Trinidad and Tobago spends \$85 million US dollars solely to treat patients hospitalized with diabetic foot infections.¹ Despite this, these patients have poor clinical outcomes, with age-standardized amputation rates of 54 per 100,000 persons in the group aged 30–60 years.²

In an attempt to improve outcomes, the Government of Trinidad and Tobago implemented a “three-tiered approach” to limit the impact of diabetic foot infections: the first tier attempted to prevent foot infections by optimizing metabolic control and promoting healthy lifestyles;^{3–5} the second tier promoted early detection and prompt treatment of foot infections when they did occur;^{6–8} and the third tier facilitated research to make

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local data available for development of evidence-based treatment protocols suited to the local environment.^{9,10}

This multidisciplinary approach was designed to address all aspects of diabetic foot infections, but the caveat is that the patients must utilize the services. Any factor delaying access to these services will render the “three-tier approach” ineffective. Our anecdotal experience was that many persons with diabetes mellitus had a strong cultural belief that home remedies could cure diabetic foot infections. Consequently, our patients often presented late with advanced foot infections or systemic sepsis only after a trial of home remedies had failed.

We hypothesized that the delay incurred during a trial of home remedies could allow infections to progress unchecked, increasing the need for operative procedures and the risk of amputation. This study sought to determine the effect of the delay during a trial of home remedies on hospitalization and operative interventions in these patients.

Materials and methods

After securing approval from the local institutional review board, we performed an observational study following all consecutive patients with diabetic foot infections admitted to tertiary care hospitals in Trinidad and Tobago. In this environment, local institutional protocols called for admission and in-hospital management if any of the following were present: systemic signs of infection, evidence of deep tissue infection (osteomyelitis, gangrene, deep-seated collections), leukocytosis, metabolic derangements, critical limb ischemia, limited outpatient support, or any social circumstance that renders patients unable to adequately care for themselves.⁶

The patients were interviewed during hospital admission from January 1, 2012 to December 30, 2012. A questionnaire was used to collect data on patient demographics, the interval between detection of infection and presentation, use of home remedies, and details of these therapies.

The second part of this study was strictly observational. The patients were managed solely by attending clinicians following institutional protocols. We followed the patients throughout their hospital admissions and recorded the duration of hospitalization, and numbers of operative debridements and amputations performed.

Two groups of patients were defined. Patients who sought medical attention after detecting their infections were assigned to a medical therapy group. Those who detected infections and voluntarily delayed medical treatment in favor of home remedies were assigned to a home remedy group. Our study hypothesis was that the delay incurred by home

remedies would affect outcome measures, so we made no attempt to distinguish between the different types of home remedies utilized.

The primary aim was to compare the number of operative debridements, number of amputations, and duration of hospital stay between the medical therapy and home remedy groups. The data were analyzed using Statistical Package for the Social Sciences version 14 software (SPSS Inc., Chicago, IL, USA). Descriptive analyses were generated as appropriate and comparisons were made between the groups. A two-tailed *P*-value was calculated for variables of interest in each group using Fisher’s Exact test. The mean number of procedures in each group was compared using the paired *t*-test. A *P*-value <0.05 was considered to be statistically significant.

Results

There were 695 patients with diabetic foot infections admitted over the study period. After detecting their infection, 382 patients (55%) chose to consult a health care professional and 313 (45%) voluntarily chose to embark on a trial of home remedies. Significantly more men used home remedies (60% versus 40%; *P*=0.014). Otherwise, the groups were well matched (Table 1).

In the medical therapy group, 298 patients (78.0%) had been hospitalized previously for foot infections, during

Table 1 Characteristics of study groups

Parameter	Medical therapy group (n=382)	Home remedy group (n=313)	P-value
Sex			
Men	191	186	–
Women	191	127	
Age, years			
Mean ± SD (range)	59.1±12.6 (37–89)	56.5±12.6 (24–93)	0.43
Self-described ethnicity			
Afro-Caribbean descent	143 (37.4%)	141 (45.1%)	–
East Indian descent	219 (57.3%)	133 (42.5%)	
Mixed descent	20 (5.2%)	35 (11.2%)	
Chinese descent	0	4 (1.3%)	
Diabetes type			
1	12	21	–
2	358	292	
HbA _{1c} reading at admission, percent			
Mean ± SD (range)	7.94±1.54 (4.36–11.23)	7.89±1.55 (4.32–11.67)	0.1428
Interval between detecting infection and presentation to a health care worker (days)	3.7±5.2 (0–30)	8.9±5.6 (0–60)	<0.0001

Abbreviations: SD, standard deviation; HbA_{1c}, glycated hemoglobin.

which 64 (21.5%) had amputations and 112 (37.6%) had operative debridements.

In the home remedy group, 234 patients (74.8%) had been hospitalized previously for foot infections, during which 30 (12.8%) had amputations and 96 (41%) had operative debridements. The mean (\pm standard deviation) duration of the trial of home remedies was 8.9 ± 5.6 days. Multiple agents were employed for home remedies. Topical agents were applied to the wounds in 286 (91.4%) cases, most commonly with paraffin wax (60) honey (54), wonder of world (*Kalanchoe pinnata*) leaves (37), ichthammol ointment (34), and aloe vera (32). Unspecified oral therapies were used in 27 (8.6%) cases: nine patients purchased “pills” from informal vendors, eleven ingested “left-over pills” from uncompleted antibiotic courses previously prescribed for other persons to treat other diseases, and eight ingested unspecified herbal concoctions specifically to treat their foot infections.

Table 2 compares the main outcome measures between the groups. In the home remedy group, there was a statistically significant increase in the total number of patients treated with operative debridements, the mean number of operative debridements per patient, and the mean duration of hospitalization. There was also a trend toward more major amputations, although not attaining statistical significance.

Discussion

Diabetes mellitus affects 15% of the adult population in Trinidad and Tobago.¹⁰ In this setting, persons with diabetes have a 0.75% annual risk of developing foot infections.¹

Table 2 Comparison of outcomes in home remedy and medical therapy groups

Parameter	Medical therapy (n=382)	Home remedy (n=313)	P-value
Patients treated with operative debridements (n)	361 (94.5%)	312 (99.7%)	<0.001
Mean operative debridements, mean \pm SD per patient	2.45 \pm 1.3	2.85 \pm 1.2	<0.001, CI -0.59, -0.22
Mean duration of hospitalization (days), mean \pm SD	8.54 \pm 3.64	16.3 \pm 8.9	P<0.001, CI -8.75, -6.79
Patients treated with amputations (unselected, n)	133 (34.8%)	118 (37.7%)	0.475
Patients treated with minor amputations (n)	113 (29.5%)	89 (28.4%)	0.8012
Patients treated with major amputations (n)	20 (5.2%)	29 (9.3%)	0.0725

Abbreviations: CI, confidence interval; SD, standard deviation.

Although it is only one complication, diabetic foot infections consume a disproportionate amount of resources. This is evidenced by reports that the Government of Trinidad and Tobago spent 0.4% of the nation's gross domestic product in 2012 solely to treat diabetic foot infections.¹

Although the “three-tier approach” was implemented in an attempt to improve outcomes, its efficacy was attenuated because patients who used home remedies waited 9 days before seeking medical attention. This was disappointing since there were several mechanisms already in place to ensure that these patients had unimpeded access to health care: dedicated diabetes clinics were placed strategically at high traffic areas within the community for easy access;⁶ state-funded health care was available through a network of public facilities across the nation where no user fees were generated at the points of service;¹¹ a national referral policy was implemented to ensure that patients were routinely evaluated by specialists at tertiary hospitals; and clear treatment protocols were developed that were tailored to the local environment.¹⁻³ These would not provide the intended benefits unless patients access the services early, and that did not seem to be compatible with the home remedy philosophy.

There are many reports of persons with diabetes using alternative/home remedies to control glucose levels, originating from other Caribbean countries,^{6,12-14} India,^{15,16} Bangladesh,^{17,18} the People's Republic of China,¹⁹⁻²³ Malaysia,²⁴ Iran,^{25,26} Turkey,²⁷ and the African continent.²⁸⁻³¹ However, only a handful of reports have evaluated alternative/home remedies specifically to treat diabetic foot infections.³²⁻³⁶ These reports originate mostly from developing nations and none could definitively demonstrate any benefit from alternative/home remedies due to design flaws.

Despite the absence of supporting evidence, this practice was common in our setting but we were unable to compare the prevalence of home remedy use because the existing reports did not quantify the prevalence of these practices in their populations. Nevertheless, we were surprised that almost half of our patients voluntarily delayed medical treatment given that 75% were aware of the consequences of inappropriate treatment. These patients had first-hand experience of hospitalization for diabetic foot infections, during which 41% had operative debridements and 13% had lower limb amputations. The fact that many patients still chose to delay medical treatment puts the problem in context: in the Caribbean, these home remedies are usually “prescribed” by alternative healers who are revered by the general population, often superseding conventional medical practitioners in terms of their perceived importance. It is an

undeniable barrier to effective treatment of foot infections in persons with diabetes.

We demonstrated that the exclusive use of home remedies delays standard medical care and that leads to an increase in adverse events. These patients required significantly more operative debridements to control local sepsis, suggesting that more severe local infections were present in the home remedy group. Several other studies have demonstrated poor outcomes due to delays in medical therapy,^{37–40} although none have specifically studied this in relation to the use of home remedies.

The duration of hospitalization was also significantly longer in the home remedy group. On average, these patients spent an additional 7.8 days in hospital to control diabetic foot infections. We previously reported that the cost to treat in-patients with diabetic foot infections was estimated to be US \$1,387.40 per day in Trinidad and Tobago.¹ Therefore, we estimated that there was an additional expenditure of US \$10,821.72 US per patient in the home remedy group as a direct result of the prolonged hospitalization. Since health care is completely government-funded in this environment, the patients may not appreciate the increase in cost, but they would appreciate the requirement for more operative debridements, with the resultant loss in productivity and income. The trend toward a greater risk of major amputations in the home remedy group is also clinically important because amputees have poor postoperative outcomes, with significantly reduced quality of life, independence, and life expectancy.^{3,5,37}

Although the Government in Trinidad and Tobago has made several advances in policy development and service provision, barriers to effective care still exist. These barriers are different to those that exist in developed countries and require a modified solution tailored to the local environment. This is only one of several cultural nuances that exist in Caribbean countries that may make the management of foot infections different from that in developed countries. There have also been other Caribbean practices that have been recognized as contributors to foot infections, such as the use of flip-flops and the slipping slipper sign.⁵ It is time to tackle these cultural practices boldly. This is one way in which local data can alter the management of diabetic foot infections in the Caribbean, allowing us to strengthen our three-tiered approach to diabetic foot infections.

Study limitations

We acknowledge that there are limitations to this study. Firstly, the study design did not consider bias due to clinician variability. Although treatment guidelines existed in this

setting, attending surgeons could have made individualized management decisions that in turn may have affected the threshold for operative debridement and hospital discharge.

Additionally, the study did not control for possible confounders when the univariate analysis were undertaken, such as infection severity, associated vascular disease, and associated osteomyelitis. This could weaken our ability to make definitive conclusions.

Conclusion

When patients use home remedies exclusively to treat diabetic foot infections rather than standardized medical therapy, it results in prolonged hospitalization, an increased number of operative debridements, and an estimated increase in expenditure of US \$10,821.72 US per patient. These treatments need not be mutually exclusive. We encourage persons with diabetes who wish to try home remedies to seek medical advice in addition as a part of holistic care.

Author contributions

SOC conceived the study, participated in its design, and drafted the manuscript. PH participated in the study design, statistical analysis, and drafting of the manuscript. SI participated in data acquisition and helped to draft the manuscript. SB participated in data acquisition, study design, and drafting of the manuscript. SR participated in the study design, statistical analysis, and drafting of the manuscript. VN participated in data acquisition and helped in drafting the manuscript. All authors read and approved the final manuscript.

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