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Limb salvage therapy in septic diabetic foot ulcer in patients unwilling to undergo amputation

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Limb salvage therapy in septic diabetic foot ulcer in patients unwilling to undergo amputation

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ABSTRACT A clinical decision report appraising

Shojaiefard A, Khorgami Z, Larijani B. Septic diabetic foot is not necessarily an indication for amputation. *J Foot Ankle Surg*. 2008;47(5):419-423. https://doi.org/10.1053/j.jfas.2008.05.005

for a patient with a septic diabetic foot.

Keywords: *septic diabetic foot, amputation, salvage*

Clinical-Social Context

David Adams (pseudonym), a 45-year-old gentleman, with no documented past medical history presented to the emergency room with his father with a complaint of increasing right foot pain secondary to large foot ulcer. He denied having any history of diabetes or hypertension; he has not seen a doctor for more than 10 years. On presentation, the ulcer on his foot was draining fluid with dried blood on the sole of his foot. He states that he has had the ulcer for the past two years but continued to walk on it despite the pain. He denied having any neuropathy in his right foot. He reports that the passing of his mother approximately two years ago has left him and his father devastated. Given the death of his mother, he hid the ulcer from his father so that his father would not have to worry about his son's health. The father states that he noticed the ulcer while watching TV a couple hours prior to rushing his son to the emergency.

After his labs showed a severely elevated glucose levels of 305 mg/ dL as well as HgbA1C of 9.7, the patient was informed that he had a right-sided septic diabetic foot; a lengthy amount of time was spent discussing recommendations of an amputation to prevent further serious complications. Given the extent of his ulcer, it was strongly recommended that Mr. Adams undergo a below-the-knee amputation. Mr. Adams, however, expressed his fears and anxiety about the surgery. He worried what his life would be with a prosthetic leg. He believed that he would constantly receive strange "looks" wherever he goes. He feared that others will believe he is not capable of completing simple tasks. And soon that fear consumed him. He began to wonder if he would be able to complete simple tasks: walking up and down the stairs or cleaning the house. With this newfound distress, Mr. Adams anxiously asked if it was possible to salvage his leg with continued monitoring and care outside of the hospital. He acknowledged the seriousness of his condition and would agree to strict diabetic controls and follow-ups if this could prevent an amputation.

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Clinical Question

Can a septic diabetic foot be salvaged by means of aggressive medical and surgical treatment in patients reluctant to proceed with amputation?

Research Article

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Description of Related Literature

A search of the MEDLINE database via PubMed was conducted using the terms “septic diabetic foot ulcer [All Fields]” AND “amputation [All Fields]” AND “salvage [All Fields].” Using these variables yielded 10 results that were screened to determine their relevance to Mr. Adams’ case. Of these 10 articles, 8 were removed from selection since they had no relevance to the clinical question at hand. Three of the articles were removed since they either focused on treating lower limb critical ischemia[2], analyzed whether heparin-induced extracorporal LDL precipitaion (HELP)[3] can be used in the treatment of diabetic foot syndrome, or only evaluated the results of 65 lower-extremity amputations and thus did not pertain to our question.[2-4] Another was conducted in the tertiary care center of Tehran University of Medical Sciences in Tehran, Iran and was thus omitted given the concern that our patient would not fit the patient population of the study.[5] The one written by Gesslein M and Horch RE was omitted since it was a case report.[6] Shatnawi NJ et al. wrote a study that focused on determining the ability of redefined clinical spectra of diabetic foot syndrome (RCS-DFS) but was omitted as it was not relevant to our patient’s case.[7] While a study written by Rauwerda JA investigated how aggressive management can lead to limb salvage, it was not selected for appraisal given the retrospective nature of the study.[8]

A study by Bom Soo Kim et al. investigated the use of negative pressure wound therapy (NPWT) on 45 patients with septic diabetic feet. NPWT was used on patients for a median time of 26.2 +/- 14.3 days. The results of the study demonstrated 14 patients (31%) not needing any amputation but 30 patients (67%) needing partial foot amputations. While the study shows that NPWT is a possible treatment option, it did not apply to our patient. Other reasons why this study was removed from appraisal included the retrospective nature of the study, lack of control group, and Mr. Adam’s age differed than the age distribution of the study, which was 59.9 ± 12 years.[9]

A search was repeated on PubMed using the keywords “Diabetic foot [ALL FIELDS]” “ulcer [ALL FIELDS]” “limb salvage [ALL FIELDS]” AND “septic or sepsis [ALL FIELDS]”, which resulted in 9 articles. Three of the articles were repeats from the previous PubMed search. Of the remaining six articles, one of the articles written by Goudie et al. described a retrospective study in patients who underwent a distal bypass surgery followed by a partial calcanectomy, intra-operative negative pressure wound therapy (NPWT) placement, and recombinant platelet-deribed growth factor treatment. The results of the study demonstrated a 76% total limb salvage rate at a follow-up of two years. This study, however, was ultimately omitted from appraisal as partial calcanectomy was not an option for our patient and the small sample size used for the study.[10] The remaining five articles were excluded from appraisal for the following reasons. Two of the studies were omitted from appraisal due to concerns that our patient would not fit the patient population used for the studies.[11,12] Another study focused on the economic burden diabetic foot complications have on patients and was thus omitted.[13] Another study focused on the value of skin perfusion pressure measurement in diagnosing critical limb ischemia.[14] Finally, the last article was omitted as it was a case report.[15] Also, Google Scholar was used searching the article of interest and clicking “Related Articles”, resulting in 101 articles. Titles were scanned and all were excluded as they did not address limb salvage in patients with diabetic foot ulcers.

From the initial PubMed search, there was an article published by Shojaiefard et al. in 2008 of a prospective cohort study that investigated the effectiveness of a treatment protocol aimed at limb salvage of 139 diabetic patients with and without septic feet over two years. The treatment protocol consisted of blood glucose control, IV antibiotic therapy, controlling comorbidities, revascularization, ulcer drainage and irrigation, systemic debridement, dressing changes and wound care, and amputation if necessary. The primary outcome of interest was limb preservation; the secondary outcomes of interest were amputation and level of amputation. Of the 139 patients with diabetic foot, 31 developed septic feet. This study was chosen for appraisal studies the

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clinical question of interest and directly applies to our patient.[1] This article was chosen for appraisal based on the large sample size and direct application to our patient. Using SORT criteria, the quality of this publication can be considered as Grade-B Strength of Recommendation given the limited quality studies.[16] There was an article in my initial search that commented on the results of this study and was thus omitted for appraisal.[17]

Critical Appraisal

The article by Shojaiefard et al. is a prospective cohort study to investigate limb salvage in diabetic patients with and without serious foot infection. Eligible participants in the study included diabetic patients who required hospital admission to manage diabetic foot wounds. Each patient was evaluated the endocrinology and surgical teams. The vascular surgery team was then consulted to evaluate the extent of vascular surgical evaluation and treatments. Admission criteria to the hospital and thus for the study included: 1) ulcer or gangrene of the foot that required drainage, debridement, and IV antibiotics, 2) gangrenous toe, foot, or part of a foot that required amputation, 3) ischemic diabetic foot requiring revascularization after assessment and appropriate imaging studies, or 4) septic foot with deep soft tissue infection and necrosis, with or without ischemia. No exclusion criteria were mentioned in the article. In the end, the study recruited a total of 139 diabetic patients with or without septic feet. A statement on effect size was not mentioned nor any financial disclosure was reported.

Once admitted, patients were administered empiric IV ceftriaxone (1 g every 12 hours) and clindamycin (600 mg every 8 hours) for 3 to 28 days with or without drainage, debridement and/or amputation; the regimen was adjusted accordingly to culture results. Following discharge from the hospital, each participant continued oral ciprofloxacin (500 mg every 12 hours) and clindamycin (300 mg every 8 hours) for 7 to 21 days; patients with osteomyelitis continued the regimen for 4 to 6 weeks. All patients were followed weekly or twice per week for over two years; no patients dropped out of the study. After data collection and analysis, two groups were formed: one group consisted of septic diabetic foot and one group with nonseptic diabetic foot. Table 1 in the article demonstrated the results comparing the two groups.

Patients that were selected for the study were similar enough in comparison to our patient; there were some differences though. Within the 31 patients who had a septic diabetic foot, the average age was 59 +/- 10.2; this puts our patient below 1 standard deviation of the mean. Additionally, 74.2% of the patients with septic feet, presented with neuropathy, whereas Mr. Adams denied having any neuropathy in his foot. However, Mr. Adams did have an admissions glucose level greater than 300, which was the case in 45.2% of the patients with septic diabetic feet.

The primary outcome of the study was limb preservation. Of the 139 patients with a diabetic foot, 31 of them was diagnosed with septic feet. All 31 patients with a septic diabetic foot underwent multiple incision and drainage procedures to remove all necrotic tissues combined with IV antibiotic therapy and dressing changes. This treatment protocol resulted in 22 limb salvages (71%). However, with a 95% confidence interval, the findings of the study were not statistically significant ($p > 0.05$). It was noted that some patients that had multiple drainages and debridement developed foot edema, most likely due to lymphedema and decreased venous drainage. But this despite this side effect, these patients stated that they were still pleased with their limb salvage as they could still walk on their feet. Only one patient with a salvaged septic foot underwent a below-the-knee amputation due to recurrent sepsis and gangrene, which developed during the follow up period. In the end, the study suggested that aggressive medical and surgical treatment can salvage a septic diabetic foot, preventing the need for a prosthetic foot.

Other outcomes reported in the study included lower extremity amputation and amputation level. As mentioned above, 22 patients were successfully treated to prevent an amputation of their feet during initial treatment. But for the remaining nine patients (29%) with septic diabetic feet who had an amputation, four underwent a below-the-knee amputation (12.9%), three underwent a transmetatarsal amputation (9.7%), and two underwent a toe amputation (6.4%). It was noted that four of patients underwent a major amputation due to extensive arterial occlusive disease that were not treatable with surgical bypass, antibiotics and surgical debridements; the article did not specify which of the nine patients these were.

Several weaknesses of this study are worth noting. Given the prospective nature of the study, no randomization was performed and introduces biases of the results. In particular, the outcome measurements reported in the results were determined by the participating authors. This introduces subjective measurements that can vary with each evaluator. Another potential weakness of

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the study is the inclusion criteria since some could have been unreliable and difficult to accurately establish. While Mr. Adams' diabetic foot met the inclusion criteria, there were some differences between our patient and the results of the study.

Overall strengths of the study include a large sample size, generalizability of the study population and treatment protocol, and strict close follow-ups with patients. According to the SORT criteria, the quality of this publication is level 2 based on lower quality diagnostic cohort study.[16]

Clinical Application

Mr. Adams wanted to avoid a below-the-knee amputation given his concerns about the social impact it would have on his life. The article by Shojaiefard et al. suggests that aggressive treatments via medical and surgical methods can salvage a septic diabetic foot without the need of an amputation. Although his age differed than the patient population in the study, this paper possessed strong external validity. Thus, we felt that this study by Shojaiefard et al. could be applied to Mr. Adams' situation in making an appropriate, sound medical decision. However, there were still some limitations of applying this study to our patient. Given the prospective nature of the study, no randomization was performed and introduces biases of the results. In particular, the outcome measurements reported in the results were determined by the participating authors. This introduces subjective measurements that can vary with each evaluator. Another potential weakness of the study is the inclusion criteria since some could have been unreliable and difficult to accurately establish.

Our patient was reluctant in proceeding with the amputation of his limb. And while the study demonstrated strong internal validity for aggressive medical and surgical methods in lieu of limb amputation, a lengthy discussion regarding the application of the study to Mr. Adams' situation was discussed. Patients in the study followed a strict weekly or twice weekly follow-up schedule that ranged from 12 to 30 months. We informed him that he can return to our outpatient clinic at a weekly basis. However, this proved to be a challenge as Mr. Adams shared that he would not have a reliable way to make it to scheduled appointments due to his work schedule and lack of a car. He stated that if he were to avoid an amputation, he would do his best to comply with follow-up.

After careful consideration of the patient's wishes to avoid amputation versus aggressive medical and surgical methods to treat his septic ulcer, it was ultimately determined that the patient proceed with a below-the-knee amputation as soon as possible. We heavily considered difficulties he may have with complying to follow-up care to ensure that his foot was healing properly. Thus, the risk of the patient's infection worsening, which increased his chances of more serious complications, outweighed the potential of salvaging his foot. It is important to note that the fears that Mr. Adams had were not ignored as we answered any questions he had and provided emotional support. Thus, while his fears did not completely disappear, he appreciated the time the team took to respect his concerns with amputation and provide individualized care.

New Knowledge Related to Clinical Decision Science

Mr. Adams expressing fear and anxiety about the thought of undergoing a below-the-knee amputation was warranted. And given the seriousness of a septic diabetic foot, the amputation of the limb was also warranted. However, as clinicians, do we really take the time to think about the immense impact this procedure would have on the life of our patients? As critical as it is for us to present all available options for our patients, it is as critical for us to look beyond the hospital setting and see the social and emotional impact our treatment plans have on our patients. As in Mr. Adams' case, the team approached the severity of his situation open communication to address his fears of feeling less human as well as his concerns for completing daily tasks. The prospective cohort study by Shojaiefard et al. showed that Mr. Adams' foot did not necessarily have to be amputated. However, given that he may not comply with weekly follow-ups due to lack of reliable transportation, the decision to proceed with an amputation was made to prevent the risk of worsening complications.

Knowing his fears with the procedure, we discussed with him along with his father regarding ways to adapt to the new change in his life. Although he stated that he would have difficulties with outpatient follow-up, we discussed the option of conducting telemedicine calls to maintain a therapeutic relationship and follow his recovery process. Additionally, we scheduled for at-home

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physical therapy visits to assist him in learning how to walk with a prosthesis after he was fitted for one. We also provided phone numbers to local support groups for amputees. We assured him that we wanted to provide any assistance so that he can move forward with his life.

In the end, the team felt that the decision to proceed with an amputation was the right decision for Mr. Adam, a 45-year-old patient. If he had been an avid athlete, however, this would have dramatically impacted his life. Even though many individuals have been successful after receiving a prosthesis, the negative social and emotional impact an amputation would have on Mr. Adams' life if he were an athlete could not be ignored. Integrating clinical evidence with the social context of a patient highlights the complex decisions on a daily basis by clinicians. But by doing so, an effective therapeutic alliance be established.

Conflict Of Interest Statement

The author declares no conflicts of interest.

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