Misoprostol, Phenytoin and Aloe Vera (PCCA Poloxamer Gel)

Diabetic Foot Ulcers

SUMMARY: Diabetes is one of the leading causes of death in the United States. Complications include poor circulation, peripheral neuropathy and dry skin, which commonly result in foot problems. Two patients with diabetic foot ulcer infections were prescribed a compounded poloxamer topical gel including misoprostol, phenytoin and aloe vera. Both patients showed visible improvements after a short period of treatment. This case series demonstrates the important role of compounding pharmacists in wound management, in particular diabetic foot ulcer infections.

Submitted by: Jack Dunn, R.Ph., Owner of Jasper Drug Store, Jasper, Georgia, USA.

Introduction:

Diabetes is one of the leading causes of death in the United States (U.S.), with 1.5 million new patients diagnosed every year. Diabetes complications include poor circulation, peripheral neuropathy and dry skin, which commonly lead to foot problems. An ordinary wound in a diabetic foot may easily develop into a chronic ulcer and, if untreated, to infections and amputations. In 2018, there were 130,000 hospital discharges related to lower-extremity amputations in diabetic patients [1]. Early diagnosis and effective treatment of diabetic foot ulcers play an important role in reducing morbidity and mortality of these patients. Conventional treatments include wound care (e.g., debridement) and oral antibiotic therapy [2]. However, because of its complexity, the management of diabetic foot ulcers represents a major therapeutic challenge worldwide [3].

Case Series:

Two patients suffering from diabetic foot ulcers reached out to their local compounding pharmacist for help. Upon discussion with the prescribing doctors, both patients were prescribed a topical compounded medication including misoprostol, phenytoin and aloe vera in PCCA poloxamer topical gel. The formula for patient 1 also included pentoxifylline, as shown in Table 1 (PCCA formula 13638). Informed consent was obtained for the publication of this case series.

Rx	
Misoprostol	0.0024%
Phenytoin	2%
Pentoxifylline	3%
Aloe Vera	0.2%
Base, PCCA Poloxamer Gel	

Table 1. *PCCA formula 13638: compounded poloxamer topical gel*

Patient 1

A 50-year-old male with diabetes presented with an ulcerous wound on his left big toe caused by direct trauma from standing on an object in bare feet. The patient was instructed to apply a compounded poloxamer topical gel (Table 1) to his wound every other day. The patient was also taking supplements (zinc, vitamin D) and hyaluronic acid. Due to his lack of self-care, the patient was educated to drink plenty of water and to maintain a balanced protein rich diet. The total duration of treatment was 4 months.

Patient 2

A 71-year-old female with diabetes, living in a care home, presented with two ulcerous wounds located between toes on her right foot. Previous history showed that the patient had two toes amputated on her right foot; the toe next to the big toe and the one next to the small toe, leaving the middle toe hanging (Figure 1). The ulcers developed between the remaining toes. The patient was instructed to apply the same compounded poloxamer topical gel as patient 1, with the exception of pentoxifylline (PCCA formula 13637), to her wounds every other day. During treatment it was observed that the wounds were infected. An additional compounded medication was prescribed including an antibacterial (mupirocin 2%) and an antifungal (metronidazole 2%) to the original formulation. This treatment was continued for one month before switching back to the original formulation. The total period of treatment was five months. The overall treatment was overseen by staff at the care home who gave her additional supplements (zinc, vitamin D) and hyaluronic acid.

Figure 1. *Patient 2: right foot with amputated toes.*

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Results and Discussion:

Patient 1 responded well to the compounded poloxamer topical gel, as shown by the visible wound healing in Figure 2b. According to the physician, the patient's wound was completely healed following one additional week of topical treatment. The inclusion of pentoxifylline in his formulation (Table 1) aimed to increase circulation to the affected area and thus improve the wound healing process. This patient required self-care education since he was not fully compliant at the beginning of the treatment, and did not realize the dire consequences of poor diet and lack of personal care in the management of diabetic foot ulcers.

Figures 2a and 2b. *Patient 1: ulcerous wound before treatment (left) and one week prior to the end of the treatment (right).*

Patient 2 also responded well to the compounded poloxamer topical gel, as shown by the complete healing of the area closest to the big toe (Figure 3b). The area next to the small toe took a little longer to heal, which was to be expected since this area presents a more closed environment (Figure 4b). It is assumed that the physician did not include pentoxifylline in the formula because the patient was well taken care of by the staff at the care home, as opposed to patient 1.

Diabetic foot ulcer infections are a major concern in diabetic patients. In this case series, both patients recovered well from their diabetic foot ulcers following treatment with a compounded poloxamer topical gel. The important role of compounded medications is highlighted in this study. Compounded medications may be tailored to specific individual patient needs and have the flexibility to incorporate novel bases and alternative formulations as needed.

Figures 3a and 3b. *Patient 2: ulcerous wound (1) before treatment (left) and after treatment (right).*

Figures 4a and 4b. *Patient 2: ulcerous wound (2) before treatment (left) and after treatment (right).*

References:

1. Centers for Disease Control and Prevention (2020) *National Diabetes Statistics Report*. Available at: https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf (Accessed: 14 June 2021).

2. Lipsky, B.A. (2004) 'Medical Treatment of Diabetic Foot Infections', *Clinical Infections Diseases*, 39 (2), p. S104-S114.

3. Game, F.L., Hinchliffe, R.J., Apelqvist, J., *et al.* (2012) 'A systematic review of interventions to enhance the healing of chronic ulcers of the foot in diabetes', *Diabetes/Metabolism Research and Reviews*, 28 (1), p. 119-141.

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