



# Dalbavancin and Moleculight: A New Paradigm for Wound Diagnosis and Treatment

A Pandemic-time solution allowed a NJ acute care center to bullet rather than buckshot their wound therapy regimen.

BY WAYNE J. CAPUTO, DPM, GEORGE FAHOURY, DPM, DONALD BEGGS, MD, AND PATRICIA MONTEROSA, RN, BSN

## Introduction

Clara Maass Medical Center is a fully accredited acute care 342-bed facility in Belleville, Essex County, New Jersey. It offers a full array of services, including an outpatient cancer center, dedicated breast health and disease management, broad scope cardiac services, and comprehensive wound care, including parenteral infusion, full podiatric services, vascular and plastic surgery, as well as hyperbaric oxygen therapy and infectious diseases management.

The COVID-19 pandemic and its associated waves and surges, as well as its multiple symptoms, required our institution to re-evaluate our multi-disciplinary approach to patient care. In 2023, the United States was expected to spend \$4.7 trillion on healthcare, or 18 percent of the national economy.<sup>1</sup> The annual market value for successful wound treatment exceeds over \$50 billion US dollars<sup>2</sup>

Chronic wounds affect millions of individuals in the United States. Wounds of the lower extremity affect between 2.5 and 4.5 million people, including 3% to 5% of those 65 years or older<sup>3</sup>. Chronic non-healing ulcers, such as diabetic foot ulcers and venous stasis ulcers, have a major impact on healthcare. Infections of these ulcers remain pervasive. Prevention of infection is imperative. Every day, 10,000 Baby Boomers turn 65; and 15% of all Medicare beneficiaries are subject to non-healing wounds. This translates into 6.5 million patients annually. The estimated costs of treating a diabetic foot ulcer were \$28,000 in a 1999 U.S. study; and a 2000 Swedish study reported costs as \$18,000 (with no amputation)<sup>4</sup> and \$34,000 (with amputation)<sup>5</sup> Mortality following amputation ranges from 13% to 40% at a year, 35% to 65% at 3 years, and 39% to 80% at 5 years—worse than for most malignancies.<sup>6</sup>

## Moleculight and Dalbavancin

The Moleculight Imaging Device is a one-of-a-kind wound management system. Cardinal signs of inflammation (rubor, tumor, calor, loss of function, dolor)<sup>7</sup> often go undetected and may be muted in high bacterial wounds. This device, with its use of fluorescence imaging, provides an objective method to detect the presence of bacteria. It assists with overall wound treatment decision-making. Clinical outcomes are improved with the addition of information previously un-

available to wound care clinicians. Visualization of bacteria is quick, safe, and easy when the imaging device is employed.

The use of dalbavancin (Dalvance), a long half-life lipopeptide, allowed streamlined care, decreased selected admissions, decreased patient time in the facility's outpatient department, and decreased need for central line access for antibiotic therapy<sup>8</sup> while still maintaining excellent patient care with a 30-minute one-dose intravenous infusion. Dalbavancin provides a new paradigm in the use of antibiotics.

Dalbavancin is indicated to treat acute bacterial skin and skin structure infections (ABSSSI). Its long half-life allows for a full course of complete therapy. Most bacteria, because of their porphyrins, fluoresce red. Pseudomonas species, because of their pyoverdines, fluoresce a cyan color.

## Methods

Our institution's use of the fluorescence imaging device and dalbavancin concurrently to diagnose and treat infected wounds began soon after COVID-19 was declared a pandemic. The joint use of the imaging device and dalbavancin remains a mainstay to diagnosis and treat wounds in the Outpatient Department/Wound Care Center at our facility.

Patients with lower extremity cellulitis or infected foot and ankle ulcers were included in the study. Those patients with three or more cardinal signs and symptoms of inflammation were included, as were those patients with > 2 cm of associated cellulitis. Those with one predom-

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## New Concepts and Studies

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inant sign of inflammation were also included. Patients were seen one time, utilizing the fluorescence imaging device. Patients with positive results received dalbavancin.

The cost for day-stay emergency room visits in New Jersey is estimated to be \$3,087 per patient.<sup>9</sup> The shift from emergency department day-stay to outpatient department/wound care center, with an estimated cost savings of \$2,850 per patient, helped to significantly decrease our emergency room pandemic burden and inpatient impasse. 631 cases were treated in this manner during the COVID-19 lockdown. Clinical follow-up occurred via telephone conversations at day 8 for a two-dose protocol (two doses of dalbavancin), or on day 11 for a one-dose protocol (one dose of dalbavancin).<sup>10</sup> Outside of vascular insufficiency, no complications were noted in the 631 patients treated with the fluorescence imaging device and dalbavancin.

The Moleculight Imaging Device has received Food and Drug Administration (FDA) approval. Medicare established a CPT (Current Procedural Technology) code for this device, making reimbursement a seamless process. In addition, the Moleculight Imaging Device was awarded Top Innovation in Wound Care, 2022 from *Wound Management and Prevention*.

The fluorescence imaging device is the only point-of-care modality that will enhance clinicians' decision-making ability and augment their clinical intellect. It provides immediate bedside diagnosis of both the presence and degree of harmful bacterial burden in real time. It allows for the visualization of significant bacterial burden by the use of fluorescence in a quick, easy, and safe manner. Reliance on clinical signs and symptoms as an assessment is not sensitive. This can lead to the misuse of antimicrobials.<sup>7</sup>

The fluorescence imaging device is hand-held and mobile. It is both MAC and PC-compatible. It does not require a contact or coupling agent. The device can be used repeatedly without harming the patient, unlike an x-ray. It is non-invasive. The device utilizes safe violet light, not ultra-violet light (UV). It does not produce enough energy to damage skin or eyes. The violet light is absorbed by wound tissue and emits a fluorescence.

## Antimicrobial Stewardship Plans (ASP)

The Joint Commission (a global quality improvement organization that accredits and certifies hospitals in the United States) mandates that all outpatient departments that prescribe antimicrobials have an antimicrobial stewardship plan (ASP) in place.<sup>11</sup>

Observational prescription of antimicrobials/antibiotics often results in both under- and over-prescribing antimicrobials/antibiotics. This can impede wound healing. It also hinders the Antimicrobial Stewardship Plan (ASP).

Evaluation of clinical signs and symptoms with criteria at >3 signs and symptoms or one predominant symptom were considered. CSS results in antibiotic misuse.<sup>7</sup> Inconsistency in prescribing can be related to certain co-morbidities (i.e., diabetes, steroid use, autoimmune disease).

The use of these two products, dalbavancin and the Moleculight Imaging Device, allowed us to bullet rather than buckshot our therapeutic regimen. Our tailored treatment allowed us to decrease admissions, reduce length of

stay, and neutralize complications. A central line was not required, and this significantly reduced cost.

## Cost-Effectiveness and Patient Satisfaction

The average annual expenditure of diabetic foot care in the United States is \$8,659 per patient. The total medical cost for the management of diabetic foot disease ranges from 9-13 billion dollars.<sup>5</sup>

In our study patient care was optimized. We were able to control and lower expenses using dalbavancin and the fluorescence imaging device together. These techniques helped streamline care and decrease patient time in the facility's Emergency Department, while maintaining excellent patient care.

Patient satisfaction is the extent to which patients are happy with their healthcare, both inside or outside the doctor's office<sup>12</sup> or medical setting. As a measure of the quality of care, patient satisfaction gives providers insight into various aspects of medicine.<sup>12</sup>

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## The Moleculight Imaging Device is a one-of-a-kind wound management system.

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Conversations with patients via telemedicine indicated that those who received dalbavancin were satisfied with this protocol. Efficient use of the antibiotic in conjunction with the fluorescence imaging device was important to patients and their families, as it limited time spent in the hospital. This was always important to patients, but even more so during the Pandemic.

The use of dalbavancin and the fluorescence imaging device in tandem alleviated the need for additional supplies. The impasse in the emergency department and both general and intensive care units was resolved. By improving efficiency with the use of dalbavancin and the imaging device, patient care was optimized, expenses were lowered, and the burden on the staff was eased.

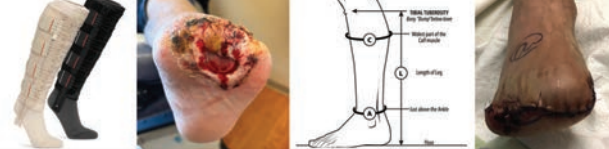
## Results

No control group was established due to the infectious component of the COVID-19 Pandemic. Reduction in admission was accomplished by day-stay admission utilization in kind to same-day surgery. Length of stay was reduced to day-stay status. No complications were noted in our study of 631 patients, outside of vascular insufficiency. Cost reduction was significant. Deflecting the Emergency Room burden to the Outpatient department management resulted in savings. If these 631 patients were seen in the Emergency Room Department for treatment, costs could spiral to almost \$2 million dollars.<sup>8</sup> No correlation studies were completed to compare the fluorescence imaging device with microbial diagnostic lab results. No re-admissions were noted in the study.

## Discussion

During the pandemic, our hospital encountered many logistical problems including scheduling, organization of

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facilities, transportation issues, and trafficking problems. Nursing staff reductions became monumental. Staff responsibility had to be dealt with accordingly. Isolation issues were paramount. Our staff bore the brunt of these difficulties. Mundane issues such as laundry, food service, pharmacy, trash removal, and special handling of specimens required particular precautions.

The cooperation of our staff was integral in the handling of the challenges brought on by the COVID-19 Pandemic.

The use of the fluorescence imaging device and dalbavancin tailored our antibiotic therapy for the patients. Our staff was open to utilizing these two therapies in new and different ways.

The fluorescence imaging device provides point-of-care detection of elevated bacterial burden. With its fluorescence, the device allows for an early start of treatment. There is no waiting on PCR (polymerase chain reaction) or culture swabs. It allows for a more targeted treatment. Its direct fluorescence measures wounds, and reveals the location of harmful bacteria. The device has been proven to diminish both clinical and economic burdens.

The COVID-19 pandemic influenced medical services and assets, as our study demonstrated. This unpredictable crisis had a significant impact on healthcare workers, facilities, and patients. Some of the deleterious effects included staff burnout, psychological stress, high rates of infection, stressors related to known and unknown information, and the fear of uncertainty regarding the continuing impact of COVID-19. Any emotional issues faced by the staff were handled by in-house referrals.

Despite the challenging situation, our healthcare workers realized that it is part of their duty to care for affected patients. We saw our staff willing and ready to coordinate efforts, and accept changes in protocols to better serve patients' needs. This demonstrated immense dedication to their profession.

## Limitations

Our study had some limitations. The manifestation/destination of the patients was terribly separated from initial check-in time to the time patients received treatment. This included patients being exposed to hospital staff during movement.

The logistics of moving patients from the Emergency Department to the outpatient department/wound care center was a challenge. It would have been better to have all units regarding antibiotics at the same area at the same time. No heterogeneity was necessary. One of the problems we encountered with spot-treatment was that patients were not cohort and were taken "catch as catch can" (cohort meaning patients shared certain characteristics, i.e., all diabetic). We could have saved time, and costs could have been further reduced, by cohorting the patients instead of "catch as catch can."

## Conclusion

Our goal was to deflect and ease the burden on the emergency department. Making the shift from emergency department/inpatient admissions to the outpatient depart-

ment/wound care center was a key factor in relieving the staff's stress. These changes provided a significant cost savings to our facility. **PM**

## References

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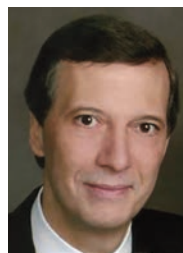
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<sup>11</sup> The Joint Commission R3 Report Issue 8: New Antibiotic Stewardship Standards <https://www.jointcommission.org/standard>.

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**Dr. Caputo** is the Chief of Podiatry at Clara Maass Medical Center in Belleville, New Jersey. He is a Diplomate, American Board of Podiatric Surgery.



**Dr. Fahoury** is the Chief of Podiatry at Monmouth Medical Center in Long Branch, New Jersey. He is a Diplomate, American Board of Podiatric Surgery.



**Dr. Beggs** is an infectious diseases physician and Chair of the Infection Control Committee at Clara Maass Medical Center. He is a Diplomate, American Board of Internal Medicine and Diplomate, American Board of Infectious Diseases. Additionally, Dr. Beggs is a Fellow of the American College of Physicians, Certified in Tropical and Travel Medicine, and is an HIV Specialist, American Academy of HIV Medicine.