

Treatment Patterns and Outcomes Of Medicare Enrollees Who Developed Venous Leg Ulcers

WH Tettelbach, MD^{1,2,3,4,5*}; V Driver, DPM^{7,8}; A Oropallo, MD^{9,10}; MR Kelso¹¹, RN; JA Niezgoda¹²; MD; N Wahab, MD^{13,14,15,16}; JL De Jong, MS⁶; Brandon Hubbs, MS⁶; RA Forsyth^{6,17}; PhD; GA Magee, MD¹⁸

OBJECTIVE

The objective of this analysis was to retrospectively evaluate the comorbidities, treatment patterns and outcomes of Medicare enrollees who developed VLUs.

METHODS

Medicare Limited Data Standard Analytic Hospital Inpatient and Outpatient Department Files were used to follow patients who received medical care for a VLU between October 1, 2015 and October 2, 2019. Patients diagnosed with chronic venous insufficiency (CVI) and a VLU were propensity matched into four groups based on their treatment regimen (Figure 1). Episode claims were used to document demographics, comorbidities and treatments of Medicare enrollees who developed VLUs, as well as important outcomes, such as time to ulcer closure, rates of complications and hospital utilization rates. Outcomes were compared across key propensity-matched groups.

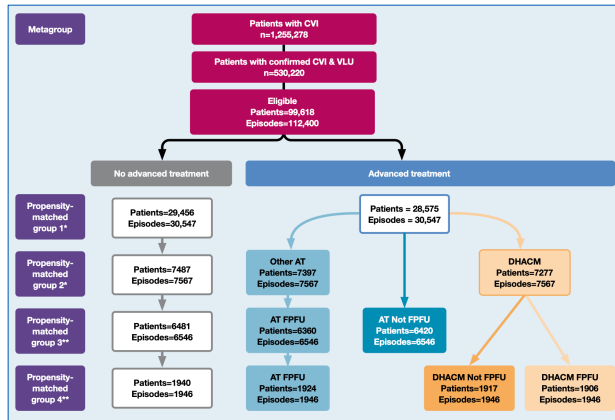


Figure 1: Consort diagram. AT—advanced treatment; CVI—chronic venous insufficiency; DHACM—dehydrated human amnion/chorion membrane; FPFU—following parameters for use; NAT—no advanced treatment; VLU—venous leg ulcer. *Propensity-matched groups 1 and 2 were matched using propensity model #1; **Propensity-matched groups 3 and 4 were matched with propensity model #2

Author Affiliations

1. Barrow Neurological Institute, Department of Neurosurgery, Brain & Spine, Phoenix, AZ, US
2. Restorix Health, Metairie, LA, US
3. Duke University School of Medicine, Department of Anesthesiology, US
4. Association for the Advancement of Wound Care, US
5. MIMEDX Group Inc., GA, US
6. American Professional Wound Care Association, US
7. Wound Care and Hyperbaric Centers at INOVA Healthcare, US
8. Wound Care Collaborative Community, US
9. Comprehensive Wound Healing Center, US
10. Hyperbarics at Northwell Health, US
11. Wound Care Plus, LLC, MO, US
12. AZH1 Wound & Vascular Centers, US
13. Wound Care Experts, WV, US
14. HCA Mountain View Hospital, US
15. Roseman University College of Medicine, US
16. Common Spirit Equity Hospitals, US
17. Department of Biology, San Diego State University, US
18. Keck School of Medicine, University of Southern California, US

DHACM = EPIFIX (MIMEDX Group, Inc., Marietta, GA, US)

*William Tettelbach corresponding author: tarpon@rxmission.com

Poster development supported by MIMEDX Group, Inc. & Restorix Health.

RESULTS

In total, 42% of Medicare enrollees with CVI (n=1,225,278), developed at least one VLU during the study, and 79% had their episode claim completed within one year. However, 59% of patients developed another VLU during the study period. This analysis shows that only 38.4% of VLU episodes received documented VLU conservative care treatment. Table 1 demonstrates the percentage of treatment modalities within each study group. Despite published clinical benefits and favorable cost-effectiveness data, axial venous closure procedures, such as venous ablations, remains underutilized in the treatment of hard-to heal VLUs. Propensity-matched groups (PMG) with episodes that received an advanced treatment or high-cost cellular, acellular, matrix-like product (CAMP) for a wound which had not progressed by 30 - 45 days demonstrated the best outcomes when their CAMP treatment was applied weekly or biweekly while following parameters for use (FPFU). Patients who developed a VLU also developed secondary complications, such as infections (28.2% of PMG4 NAT episodes) which can lead to visits to the ED or intensive care unit (ICU) and, potentially amputations. Patients who

Table 1: Percentage of treatment modalities within each study group

Treatment	Metagroup episodes, % Patients, n	NAT episodes, % 30,547	AT episodes, % 28,575
Debridement	17.3	74.0	79.4
Combination treatment	16.7	62.8	70.0
High compression bandage	16.4	61.9	69.2
Axial venous closure	0.5	2.0	2.1
Compression stockings	0.0	0.1	0.1
Advanced treatment	3.6	0.0	100.0
NPWT	0.5	1.4	3.1
Total contact cast	0.4	1.1	2.2

AT—advanced treatment; NAT—no advanced treatment; NPWT—negative pressure wound therapy. CPT codes for: debridement—11042-11047, 15002-15005, 97597, 97598, 97602; compression—A4490-A4510, A6530-A6541, A6544, A6545, A6549; axial venous closure—36465-36466, 36473-36479, 36482, 36483, 37700, 37718, 37722, 37735, 37760, 37761, 37768; high compression bandage—29580, 29581; NPWT—A9272, 97605-97606; total contact cast—29456

developed a VLU also developed secondary complications, such as infections (28.2% of PMG4 NAT episodes) which can lead to visits to the ED or intensive care unit (ICU) and, potentially, amputations. For patients with VLU episodes receiving NAT, 30.1% had at least one infection or an amputation. The total rate of complications dropped to 21.8% when VLU episodes were treated with DHACM FPFU, with significant reductions in cellulitis (p=0.00398), sepsis (p=0.00038), gangrene (p=0.03662) and amputation (p=0.0153) (Figure 2).

Following parameters for use (FPFU) to treat hard-to-heal wounds is defined as initiating a CAMP within 30 - 45 days of the initial claim submission and once initiated the CAMP is applied routinely within the range of every 7 to 14 days.

RESULTS

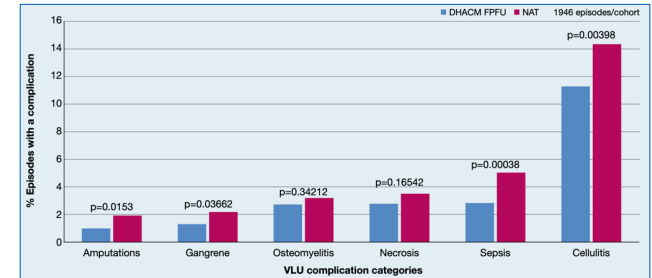


Figure 2: Rates of common episode complications from propensity-matched group 4. When episodes are treated with dehydrated human amnion/chorion membrane following parameters for use notable decreases in many infections and amputations were observed. NAT—no advanced treatment

VLU complications frequently lead to excessive healthcare utilization and >56% of patients with VLU episodes receiving NAT visited the ED. Patients receiving DHACM FPFU showed significantly lower claim rates for ED visits (45.8%; p<0.0001), admissions (21.6%; p<0.0001), readmissions (5.1%; p<0.0018) and ICU stays (7.4%; p<0.0062) (Figure 3).

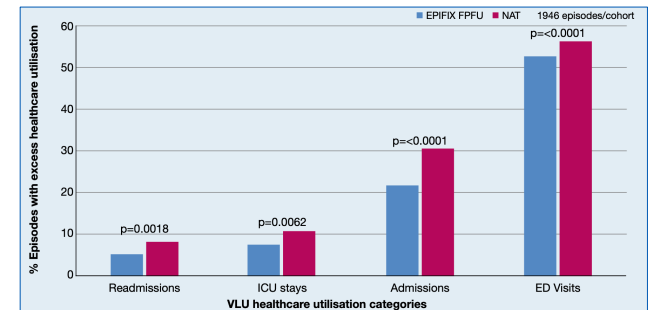


Figure 3: Healthcare utilization for propensity-matched group 4. Consistently, the lowest rates of hospital utilization (readmissions, intensive care unit (ICU) stays, admissions and emergency department (ED) visits) occurred when episodes were treated with dehydrated human amnion/chorion membrane (DHACM) following parameters for use (FPFU). NAT—no advanced treatment.

CONCLUSION

Medicare enrollees with CVI have diverse comorbidities and many do not receive sufficient management, which contributes to high rates of VLUs and subsequent complications. Medicare patients at risk of a VLU who receive early identification and advanced CAMP treatment demonstrated improved quality of life and significantly reduced healthcare resource utilization.