

Clinical and Financial Implications of Wound Care Management Across the Care Continuum

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Summary

Healing wounds is an expensive endeavor for managed care. Because the population is aging and diabetes prevalence is on the rise, this problem is going to continue to grow. When all the costs related to wound care are examined from a real world perspective, advanced therapies such as negative pressure wound therapy are cost effective. To maximize cost effectiveness, advanced therapies should be applied in a timely manner to those patients most likely to benefit.

Key Points

- Wound care using both conservative and advanced therapies is expensive.
- Given the aging of our population and the explosion of diabetes, the number of patients with wounds is growing.
- Advanced therapeutics such as negative pressure wound therapy and artificial skin do not appear to be over-utilized at this time.
- Advanced therapeutics are started late in most cases.
- Early use of advanced therapies appears to result in significant cost savings.
- Early use of negative pressure wound therapy saves the cost of failed conservative care and may also improve the effectiveness.

VENOUS STASIS ULCERS, PRESSURE ULCERS, and diabetic foot ulcers are all common wounds that require medical care. Venous stasis ulcers may be the most common chronic wounds. About one percent of the population has venous insufficiency and around two percent develop ulceration. They are 10 times more common when peripheral arterial disease is present. Five hundred thousand venous stasis ulcers develop annually and they recur eighty percent of the time. These ulcers are estimated to cost between \$2,000 and \$10,000 per incidence. The total costs are estimated at five billion dollars annually.

Pressure ulcers are a \$12 billion-a-year problem. Two-and-a-half million patients are treated annually in U.S. acute care facilities for pressure ulcers. The average additional charge per case of pressure ulcer is \$40,381. Pressure ulcers incidence is increasing by 5 percent annually because of the increasing long-term care population.

There are 15.7 million people in U.S. with diabetes. About 15 percent of diabetics have a foot ulcer at some time. Diabetic foot ulcers are the most common reason for hospitalization of patients with diabetes.

Over 56,000 amputations resulting from diabetic foot ulcers are performed yearly. After a first amputation, there is a 10 percent per year contralateral amputation rate. Less than 50 percent of amputees over 65 years ever ambulate again. The five-year survival rate after major amputation is dismal at less than 30 percent. The rate is even worse with concomitant renal failure with less than 14 percent of patients surviving at the five-year point. Diabetic foot ulcers account for approximately 80 percent of wound care spending.

Other wounds come from arterial ulcers, non-healing surgical wounds, non-healing traumatic wounds, and ulcers of other etiologies such as vasculitis, cancer, and infections. In total, there are six million chronic wound patients in the U.S. yearly. Eight-and-a-half billion dollars are spent annually for wound care products and services and over \$20 billion for wound treatment.

Efficacy refers to whether an intervention can be successful when it is properly implemented under controlled conditions. Efficacy is best determined by prospective, controlled, randomized clinical trials. There are three clinical models utilized for wound

Exhibit 1²: Cost, Resource Utilization and Outcomes in Diabetic Amputated Foot Wounds

Patient Group	Average Cost V.A.C.® Therapy	Average Cost MWT	Difference
Achieved Complete Healing	\$25,954	\$38,806	\$12,852
Patients Treated > 8 weeks	\$27,270	\$36,096	\$8,826
All Patients Treated	\$26,972	\$36,887	\$9,988

healing randomized controlled trials (RCTs): venous stasis ulcerations, well-vascularized neuropathic diabetic foot ulcerations, and pressure sores. There are almost no studies examining treatments in diabetic foot ulcers with concomitant arterial venous disease. To avoid a beta error in which study design causes a product to appear to be ineffective, patients with significant co-morbid conditions are excluded from nearly all wound-healing studies. Thus, only wounds that are likely to be healed in relatively healthy patients are included in most wound healing studies.

In contrast to efficacy, effectiveness is the capability of producing an effect. It refers to whether the intervention

typically is successful in actual practice in patients with multiple comorbidities and difficult to heal wounds.

Cost-effectiveness analysis is a form of economic analysis that compares the relative expenditure (costs) and outcomes (effects). Typically the cost-effectiveness analysis is expressed in terms of a ratio where the denominator is a gain in health from a measure and the numerator is the cost of the health gain. The best-cost effectiveness data come from studies in real world populations.

Electronic searches conducted on PubMed for the years 1996 to 2006 using the MeSH terms venous stasis ulceration, diabetic foot ulcer, pressure sore, and

Exhibit 2²: Average Treatment Cost Per Procedure/Patient*

Procedure	N	V.A.C.® (n=63)	N	MWT (n=72)
Surgery	8	19	3	152
Amputation	2	417	7	684
Cost of Stay (any)	25	38,794	22	46,617
Antibiotics (all)	29	9,096	31	24,845
Dressing Change Material (primary)	63	6,022	70	7,321
Dressing Change (Personnel)	63	1,244	70	3,395
Debridement (post-BL)	22	423	38	470
Outpatient Clinic Visits	24	681	17	1,762
Overall Total Per-Patient Average Cost	63	\$27,270	72	\$36,096

*Subjects completing 50% of study visits

Exhibit 3³: Early Use of NPWT Associated with Reduced Length of Therapy and Length of Home Care Service for Patients with Pressure Ulcers

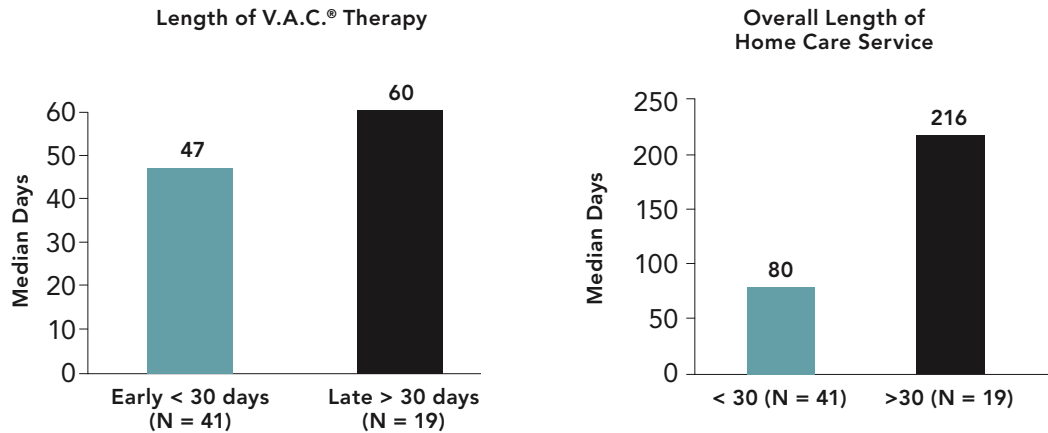
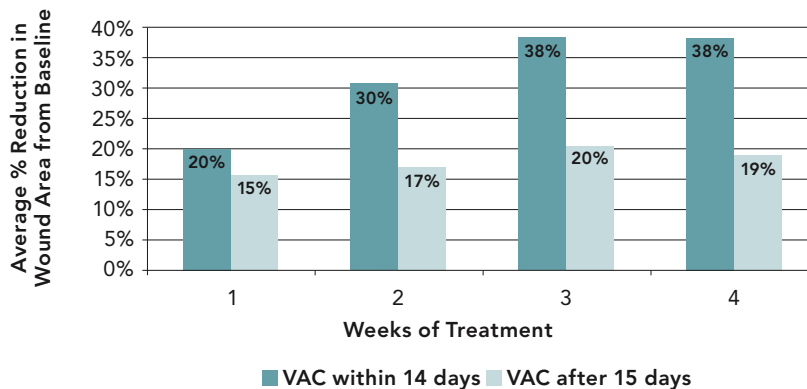


Exhibit 4⁴: Differences in Percent Wound Reduction Over Time with Early vs. Late Initiation of V.A.C.® Therapy



* Indicates $p < 0.05$ from a two-sample t-test.
 (Please note that the sample sizes decrease over time due to patient's healing, being discharged and missing data.)

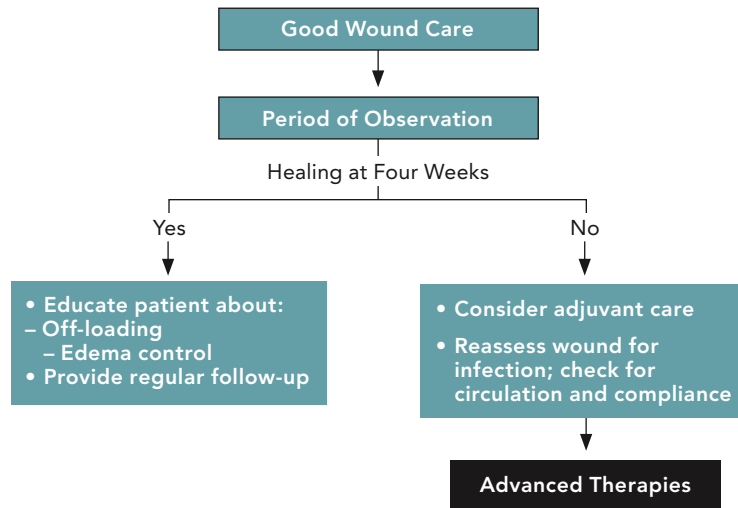
wound healing (English-only, RCT) found an initial set of 3,000 abstracts. After eliminating duplications and poorly done trials, seventeen RCTs over the past 10 years evaluating advanced wound healing technologies were found. Exclusion criteria were compared by wound-care model (venous, diabetic foot, and pressure ulcer) to patients in the Intellicure Research Consortium (IRC). The IRC consists of de-identified, pooled data obtained from the electronic medical records of patients seen at outpatient wound centers in 11 states. Among 8,611 wound center outpatients, greater than 50 percent would have been excluded from the wound-related RCTs at the “first pass” based on exclusions on the basis of comorbid conditions, previous surgeries or medications, even before further tests are performed.¹ Because relative-

ly healthy people are the only subjects included in wound-care RCTs, we know virtually nothing about the efficacy of various treatments in the sick patients in which these treatments are utilized. In 2005, the Medicare carrier advisory committee called for a review of wound-healing practices. The committee recognized there was a need for real world data.

Wound-care electronic medical records (EMRs) can be used for cost-effectiveness research. With an EMR, the physician does documentation in the room while interviewing the patient. One hundred percent of medical information, wound documentation, tests, and treatments are collected in the EMR. The EMR generates all necessary documents, including nursing notes, follow up letters, procedure notes, and home nursing orders. The EMR calculates the physician

Exhibit 5: Use of Advanced Technology in Wound Healing

Look for and Measure the Healing Rate Within the First 4 Weeks of Therapy to Decide on Alternate Approaches



and the facility level of service, tracks all procedures, orders lab tests, and generates nursing orders detailing all dressing products used). The Intellicure Research Consortium (IRC) collects data contained in the EMR of wound centers from 18 states for facility benchmarking and cost effectiveness research.

Using the wound center data, the usual care of chronic wounds was determined. Records for 8,611 patients were examined. There were 1.8 wounds per patient resulting in 112,000 patient visits. The average patient age was 60.4 years (1 - 104). The mean wound size was 8.3 cm². The average wound duration or wound age at initial wound center consultation was 189 days. This is a long time before patients get referred to a specialty center.

Patients in this data set had an average of six comorbid conditions. Thirty two percent had diabetes, 16 percent had coronary artery disease, and 10 percent were smokers. Additionally, 8.4 percent were on steroids, seven percent had heart failure, and six percent had peripheral vascular disease. Interestingly, 26 percent of the wounds, which were not specifically diabetic foot ulcers, were in patients who had diabetes. Thirty nine percent of patients developed a new wound during their course of care.

In another analysis of 15,499 wounds in the database, the goal of therapy was listed as palliative care in two percent of patients. Amputation resolved 3.7 percent of wounds. Eleven percent of patients (n= 955) died during treatment or within 3 months of the last clinic visit. Overall, 90.8 percent of all wounds were healed. Overall, specialized wound

care centers are seeing sick patients with significant comorbid conditions who have long standing wounds that are eventually being healed.

The real question is how are the wound care centers managing to heal such a large percentage of long-standing wounds? Moist wound care (MWC) with sophisticated dressings was employed exclusively in 71.0 percent of wounds. Other non-wound specific therapies such as improved nutrition and controlling underlying diseases are being done at same time. Advanced therapies were used in 29 percent of wounds. Negative pressure wound therapy (NPWT) was used in 5.81 percent and hyperbaric oxygen in 9.48 percent of wounds. Bioengineered skin was used in 3.26 percent and becalpermin (Regranex[®]) in 10.49 percent.

The average time to heal for moist wound care patients was 68 days. The average lag time to initiating NPWT for all wounds in all categories is 115 days. Thus, the average lag time to starting NPWT is longer than the average time to heal with moist wound care. Even at these expert centers, clinicians waited until after a wound should have healed before initiating an advanced therapy. Unfortunately, moist wound care is usually required to fail before advanced therapy is begun.

In another study, the costs of conservative care between January 1, 2006 and December 31, 2007 were assessed at 14 hospital-based outpatient wound centers in 10 states. Data from 5,571 patients with 13,880 wounds with 76,095 visits was examined. Patients had a mean of 57.5 visits. The majority of these patients were Medicare beneficiaries. The cost of care components included were billed facility fee, billed

physician fee, prescribed home health (estimated visit charges), facility dressing change cost, product cost for planned dressing changes before next visit, and billed procedures at the facility. The total cost of care for these 5,571 patients was \$38,500,517.24. Across all facilities, the cost of care per patient was a mean of \$6,923.90. This ranged from a minimum of \$53.43 to \$223,378.07 per patient. There were 23 patients who had care totaling over \$100,000 per patient. In other words, even conservative care is relatively expensive, especially if it goes on for a long time.

Several cost-effectiveness studies of NPWT using V.A.C.[®] Therapy have been conducted. One study was a retrospective analysis of a prospective, randomized, 16-week, 18-center controlled trial comparing NPWT with moist therapy in diabetic amputated foot wounds. The cost analysis, in 2005 costs, included all patients enrolled for a minimum of 8 weeks. The V.A.C.[®] Therapy group showed reduced number of days to wound healing (NPWT 52 days vs. MWT 64 days). This group also had a greater percentage that achieved healing and lower direct treatment cost. On average, NPWT used fewer treatment resources than MWT.² NPWT lowered average direct cost per patient and average procedure costs compared to MWT (Exhibits 1 and 2).² The conclusion of this study was V.A.C.[®] Therapy is a cost-effective intervention for post-operative diabetic foot ulcer patients.

Since it is known that advanced therapy use gets delayed, there are significant costs to the wasted conservative care. The costs of early versus delayed use of NPWT in patients with stage III and IV pressure ulcers have been compared.³ This study was a retrospective comparison study of time to initiation of NPWT using data from a Centers for Medicare and Medicaid Services (CMS) database. This study looked at episodes of home health care and service utilization. Early therapy was initiation of NPWT within the first 30 days of home health care initiation. Late therapy was initiation after 30 days. In the regression analysis, each one-day delay in V.A.C.[®] Therapy initiation lead to a 1.5 day increase in total length of home care service (Exhibit 3).³ Patients treated with early therapy had fewer days of NPWT and fewer days of home health service. The costs were one-third less for emergent care and hospitalizations due to wound-related problems in the V.A.C.[®] Therapy group (\$995) compared with MWT group (\$3,265). The cost of care per episode for Stage IV Pressure Ulcers was also significantly less with V.A.C.[®] Therapy (\$911 vs. \$4,152). This study showed that time and resources are wasted when advanced therapy is initiated at a late date.

In a study in a long term care population with pressure ulcers, even after four weeks of NPWT

there was still a difference in healing rates in early initiators (within 14 days of admission) versus late initiators (Exhibit 4).⁴ Early initiation of V.A.C.[®] Therapy within the first 14 days of admission was associated with a reduction in length of stay of 20.2 days ($p < 0.0001$).

Biochemical differences between chronic and healing wounds may account for the difference in benefits with early versus late use of advanced therapeutics. In the healing wound, there is a balance of pro-inflammatory cytokines and their natural inhibitors, whereas in the chronic wounds there are increased levels of the pro-inflammatory cytokines.⁵ The longer a wound persists in a non-healing state, the worse the biochemical changes that occur.

Rapid identification of patients who are unlikely to respond to conventional care will allow for earlier interventions with advanced therapies. Initial healing rates (at four weeks) with conservative therapy predict overall healing rates. Initial healing rates of greater than 0.1 cm per week correlate with healing with conservative care. If a patient is not achieving this rate of healing at four weeks, then advanced therapies should be considered (Exhibit 5).

Conclusion

Wound care is expensive and the population of patients who need it is growing. When examining overall costs, conservative care is not inexpensive. Advanced therapies do not appear to be over-utilized at this time. However, advanced therapies are started late in most cases. The early use of advanced therapies seems to result in significant cost savings. This is in part because it saves the cost of failed conservative care but it may also improve the effectiveness of NPWT. **JMCM**

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