Establishing a Baseline for CTP Usage and Outcomes at a US Outpatient Wound Care Center

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Introduction

- Appropriate usage of cellular and tissue-based products (CTPs), or skin-substitutes, is necessary to protect the reimbursement of these advanced treatments.
- Cutting-edge technologies (e.g., fluorescence imaging, hydrosurgical debridement) can help ensure adequate wound bed preparation to improve CTP success, promoting more efficacious and thus rational use of these products[1].
- To understand the impact of enhanced diagnostics in pre-CTP wound bed preparation, we must first establish the characteristics of the patient population receiving CTPs and baseline CTP outcomes.

Objective: To describe baseline characteristics & healing outcomes for wound care patients receiving CTPs at Northwell Health Comprehensive Wound Care Healing & Hyperbarics.

Study Methods

- **Study design:** retrospective chart review
  - EMR data from all patients that received a CTP at Northwell Health outpatient wound clinic (New Hyde Park, NY) from Dec 2012 through Aug 2019
- **Exclusion criteria:**
  - Incomplete background and wound baseline information
  - No follow-up visits after CTP application
- **Follow-up period:** 12-weeks following the day of the first CTP application, most patients attended weekly care visits

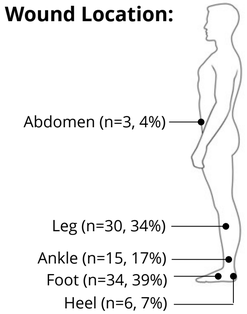
Results

88 patients

Wound Type:

- Venous leg ulcer (n=39, 44%)
- Diabetic foot ulcer (n=22, 25%)
- Pressure ulcer/injury (n=5, 6%)
- Arterial ulcer (n=3, 3%)
- Surgical wound (n=5, 6%)
- Other (n=14, 16%)

Wound Location:



Patient Age:

69 years, on average

Range = 33-73
Median=73

Patient Race:

- Asian (n=3, 3%)
- African American (n=27, 31%)
- Caucasian (n=48, 55%)
- Unknown/Not Reported (n=10, 11%)

Patient Sex:

- Male (n=54, 61%)
- Female (n=34, 39%)

Wound Area:

- 19.7 cm^2, on average
- Median = 6.6 cm^2, STDV = 31.8 cm^2

Comorbidities/Lifestyle:

- Former smoker (n=33, 38%), current smoker (n=4, 5%), non-smoker (n=41, 47%), unknown (n=10, 11%)
- Peripheral vascular disease or venous insufficiency (n=65, 74%)
- Diabetes Type 2 (n=49, 56%)
- Hypertension (n=58, 66%)
- Coronary artery disease/ myocardial infarction (n=29, 33%)

Usage Rates:

- 170 CTPs were applied across 88 wounds within 12-weeks.
- Average of 2 per wound (range=1-6, STDV=1)
- Brands used:
  - Apligraf (n=103, 61%)
  - Epifix (n=19, 11%)
  - Grafix (n=15, 9%)
  - Oasis (n=12, 7%)
  - Primatrix (n=7, 4%)
  - Purapply (n=14, 8%)

Healing outcomes:

- 15 patients (18%) had their wounds heal by 12-weeks (15/83, 5 patients were lost to follow-up).

For wounds that healed by 12-weeks:

- Average duration to healing was 6.1 weeks (range=1-11, SD=2.9)
- 73% of wounds healing by 12-weeks received only 1 CTP (n=11, range=1-6 CTPs applied)
- Only one wound experienced recurrence after ~3 months.

Day of CTP application (post-debridement)

8-weeks after CTP application

Discussion

- The patients who received CTPs were healing-challenged. They were mostly elderly with wound areas of 20 cm^2 on average and multiple comorbidities (65% with 3 or more), primarily diabetes, hypertension, vascular or arterial disease, and a history of smoking.
- The US Wound Registry (USWR) analyzed EMR from 236,352 patients treated at ~134 HOPD facilities from Oct 2015 through July 2018[2]. They found that an average of 3 CTPs were applied per wound, where the average time in service per wound (time to healing, including healing new wounds that develop) was 10 weeks and the average wound area at application was 22 cm^2. **Therefore, these data indicate a relatively low CTP usage rate per patient (avg=2) as compared to this national average.**
- The 12-week healing rate is susceptible for improvement, however the low number of CTPs applied per wound (73% received only 1) and the low rate of wound recurrence within the study period is promising.

Conclusion

These data provide a benchmark from which to compare patient population characteristics and CTP outcomes in future studies that evaluate the impact advanced diagnostic wound care technologies, such as bacterial fluorescence imaging.

References:

1 Serena TE, Harding K, Queen D. Point-of-care fluorescence imaging to optimise wound bed preparation prior to cellular and/or tissue-based product (CTP) application. Int Wound J. 2023 Nov;20(9):3441-3442. doi: 10.1111/iwj.14446.

2. Fife, C. A Peek at Real World Use of Cellular and/or Tissue Based Product (CTP) use – On the Eve of Episode-Based Payment. Available at: https://carolinefifemd.com/2020/02/19/a-peek-at-real-world-use-of-cellular-and-or-tissue-based-product-ctp-use-on-the-eve-of-episode-based-payment/