Evaluating the Quality of a Negative Pressure Wound Therapy Device

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Introduction

Negative Pressure Wound Therapy (NPWT) has become an established method of treatment for problematic acute and chronic wounds. However in the past, the high cost of this therapy may have prevented its use in some care settings. The introduction of lower-priced systems in the UK has enabled many clinicians to access this treatment, although it has been observed that there may be concerns of its effectiveness.

Method

In order to address these concerns a non-comparative product evaluation of one of the newer NPWT devices* was undertaken on a range of patients with different wound aetiologies and in different care settings. Clinicians wishing to participate in the evaluation worked within a simple protocol and used a structured data capture tool. The process was submitted for ethical approval, but the response was that as a product evaluation it was not required. However, the participants were encouraged to gain approval for the project through their local governance regulations. Issues such as patient consent and data protection were also addressed and maintained. Completed data capture forms were returned to the sponsor and entered into a database for analysis.

The aim of the project was to demonstrate that this system was suitable for use in a range of care settings on different wound types. Therefore a number of parameters were measured including wound progress, patient acceptability, clinician acceptability, incidence of complications and cost.

Outcomes

The product was evaluated on 50 patients and data has been analysed on 30 individuals to date with 140 dressing changes being undertaken.

Patient Population

- 47% were male (n=14): 53% female (n=16)
- The age ranged from 29 years to 87 years (median 70 years)
- 73% of patients had existing medical conditions which may influence healing.
- 27% of patients were taking antibiotics for a wound related infection at the initial assessment
- 50% of patients reported pain in the wound at the initial assessment but only 40% were taking analgesia for wound related pain.

Wound Assessment

Aetiology and Duration

- 16 surgical wounds
- 12 pressure ulcers
- 1 leg ulcer duration
- 1 diabetic foot ulcer

Wound Location (see Table 1)

Location	No. of Patients
Abdomen	8
Buttock	7
Sacrum	5
Leg	6
Foot	3
Chest	1

TABLE 1

Exudate Level at Initial Assessment

- High - 12 patients
- Moderate - 15 patients
- Low - 2 patients
- No data - 1 patient

Dressing Change Information (see Table 2)

The clinical decision to evaluate the NPWT device was as follows:-

- 60% to promote wound healing
- 30% for exudate management
- 10% for other reason (not specified)

Location	Total no. of dressing changes	Initial Assessments		All dressing applications	
Hospital	72	Hospital (in-patient)	16	Ward	62
				ICU	4
		Clinic	3	Clinic	6
Community	68	Patient's Home	7	Patient's Home	38
				Community Clinic	4
		Nursing Home	4	Nursing Home	26

TABLE 2

Pressure Settings

- The minimum pressure setting recorded on application and removal was 60mmHg
- The maximum pressure setting recorded on application and removal was 110 mmHg
- The median pressure setting recorded on application and removal was 80 mmHg

Patient Acceptability

Patient acceptability was recorded at each dressing change, which demonstrated a high level of satisfaction.

- Patients expressed discomfort during the procedure at only 6% of all dressing changes
- Only 1% of responses identified patient discomfort during the therapy
- 0% of responses demonstrated that patients were unable to mobilise with the device in situ. (This was recorded on patient who were mobile.)
- Noise of the pump was identified as disturbing the patient at night in only 6% of responses.

Clinician Acceptability

The experiences of the clinician in using the device were recorded at each dressing change.

Application of Dressing

- 81% of dressing changes were assessed as "easy"
- 14% of dressing changes were assessed as "average"
- 5% of dressing changes were assessed as "difficult"

In 60% of the assessments where "average" or "difficult" were recorded, staff added comments that this was due to wound related factors.

Removal of Dressing

- 94% of dressing removals were assessed as "easy"
- 1% of dressing removals was assessed as "difficult"
- No data was recorded in 5% of responses

Ease of Use of Pump

- 99% of responses identified the pump to be "easy" to use
- 1% identified it to be "average" to use

Number of Staff Required to Change Dressing

- 1 clinician changed the dressing in 79% of changes
- 2 clinicians were required in 21% of changes

Wound Outcomes

Condition of Periwound Skin Pre and Post

A breakdown of periwound skin changes is demonstrated in Table 3.

Condition	Pre	Post
Normal	18	25
Macerated	4	1
Inflamed	4	1
Dry	4	3
Other	0	0
Not documented	0	0

TABLE 3

Reduction in Devitalised Tissue

- 43% improvement on the wound bed necrotic tissue
- 90% improvement on the wound bed sloughy tissue

Increase in Viable Tissue

- 12% improvement on the wound bed granulation tissue
- 85% improvement on the wound bed epithelial tissue

Wound Complications Pre- and Post-

A breakdown of wound complications is demonstrated in Table 4.

Wound Types	Pre NPWT	Post NPWT	% Improvement
Wound Cavity	23	19	17
Undermining / Tunnelling	12	6	50
Fistula Present	4	3	25
Wound Infection	5	2	60
Wound Painful	15	3	80
Average Pain Score	5	1	80

TABLE 4

Discussion

The clinical outcomes of the evaluation are very positive and provide relevant information to the participating clinicians on which they can base their clinical decision making. However, this is not a clinical trial and the information should be considered within the context of a product evaluation

The process identified that the evaluation device was highly acceptable to patients, being comfortable during procedure and wear, and there was minimal disturbance from the noise of the pump. Clinicians generally found it easy to use both in application and removal.

Within the evaluation process consumables and addition products within the wound and extra fixation were recorded at each dressing change. At the end of the analysis to date the average cost (excluding that of the pump) across all wound aetiologies was reported to be £30.10 per dressing change.

Summary

The evaluation to date demonstrated that this system provided relevant information on the evaluation device*. This process provides clinicians with an opportunity to observe the outcomes from a large product evaluation.

*Evaluation device – Venturi™ (Talley Group Ltd)

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