Fifty-patient evaluation of the Venturi™ NPWT device

Undertaking an evaluation of a new product is an essential part of the decision-making process when considering implementing a new therapy or dressing. This project describes a process whereby clinicians can undertake this in a structured manner providing them with data on outcomes and cost. It involves completing an evaluation form, in which an initial patient and wound assessment is undertaken, followed by recording the outcome of each dressing changed. This information is then collated and analysed, giving the evaluation site access to a structured report which they may use to support the decision-making process.

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KEY WORDS
Product evaluation
Negative pressure wound therapy (NPWT)
Measurable outcomes

Negative pressure wound therapy (NPWT) is an accepted form of treatment for the management of complex wounds. Historically, its use has generally been restricted to the most complex wounds, mainly because of the cost. However, with lower price alternative systems becoming available, this therapy is being offered to more patients.

As with any new technology, it is important that evidence is available to support its use in clinical practice. Although the gold standard is the multi-centre randomised controlled trial (RCT), it takes time and high levels of funding to produce a study which is worthy of scientific merit. Therefore, other forms of evidence are produced which aim to demonstrate that the device meets the expectations of the user, including non-comparative evaluations and case reports (Trinder and Reynolds, 2000).

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While they have limited scientific value, case reports are the quickest and most common way to provide information about the use of a product and the clinical outcome in a specific indication (Gomm et al, 2000). They capture the patient's experience, and show the skill of the clinician in managing a particular wound type. They can be a useful educational tool, but the information they provide is restricted to a single patient in a specific wound care setting, and the results should not be considered as representative of the outcomes if the therapy were used in a cohort of patients.

Clinical evaluations are more reliable in providing information on the outcomes of a therapy in a pre-determined population of patients with specific clinical indications. Investigators work within the parameters of a protocol which determines which patients should be included and excluded, and can also stipulate the length of time the therapy should be used. Non-comparative evaluations can provide good qualitative and quantitative information on a product within specific indications.

However, as with RCTs, the patient population is subject to inclusion and exclusion criteria, and one criticism may be that the more difficult to manage patients may not be included. Clinical evaluations and randomised controlled trials should be submitted for ethical approval.

While there is no substitute for good quality clinical evidence, when a new product is introduced into clinical practice this may not be available to support the manufacturer's claims. Many clinicians will review the available evidence, and where this is limited, risk assess whether to proceed with their own evaluation. These evaluations are classed as 'product evaluations', and,

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being uncontrolled, should not be considered as scientific evidence.

Evaluating a therapy is an essential part of the procurement process. It enables the clinician to experience the positive and negative aspects of the technology, its acceptability to patients and other clinical staff and any budgetary impact its adoption may incur. Many clinicians will undertake their own evaluation of a product before making a decision as to whether to implement it into their own sphere of practice. While this is a good opportunity to experience the therapy first hand, it may be restricted for a number of reasons including time, availability of appropriate patients, and the possibility that the patient may be transferred from one setting to another – cutting the evaluation short or losing the patient to follow up.

A good data capture tool is an integral part of the process. Some evaluations are undertaken as part of large procurement contracts, so the information which is collected should objectively inform the project of the expected clinical outcomes, the impact of its use on clinicians and, if possible, give an indication of cost. While the views of the 'evaluators' are important, these should support, not replace, quantitative data.

The adoption of NPWT into clinical practice is seen by many budget holders to be an additional expense for which there is often no funding identified. The cost of this therefore has to be found within existing budgets, or through other means of procurement.

Venturi™ (Talley Group Ltd) product evaluation

As the Venturi™ system was launched into clinical practice, Talley recognised the need for clinicians to be able to undertake a product evaluation of the device in a structured manner. This would demonstrate its impact in their own area of practice and give them the opportunity to collate these results with those of other evaluations to get a wider range of information. A written report of clinical outcomes, acceptability of the device to patients and other staff, and ultimately the cost of care per patient were of use to Talley.

The process

The project enabled clinicians in both hospital and community settings to participate in a structured, non-comparative product evaluation using the Venturi NPWT device. They were provided with a simple protocol, which supported them in working within the best practice guidelines for gauze-based NPWT, and a data capture form which they completed on each patient evaluated.

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The data collection process required the clinicians to:

1. Complete an initial patient and wound assessment.
2. Record information at each dressing change on wound progression and the patient's pain and comfort experience at dressing change and during wear time.
3. Record their opinion on the ease of use of the device.

This would give a simple but comprehensive data set which reflected the outcome of the evaluation. There was no set time for the evaluation period, which was finished when the patient no longer required the therapy.

There were some initial discussions around whether ethical approval was required for the project, but after consulting with the National Research Ethics Service (NRES) it was considered to be a product evaluation and therefore ethical approval was not required. However, clinicians were encouraged to submit the project through their local research governance organisation for approval and advice.

Patient identity was protected within the data collection process, as no personal information was collated other than age and sex. Before starting the project, clinicians were requested to sign a copy of the protocol to confirm that they had sought local approval, and that they had a process in place for product evaluations in which they obtained consent from the patient.

At the end of the evaluation period the data collection forms were sent to Talley Group Limited, who returned them for independent analysis.

In return, participating clinicians were offered a report of the outcome of their evaluation, which included the cost of treating their patients with the Venturi system. It was anticipated that this would be useful in procurement situations, where there is a set budget or an estimated cost of care is required.

Data management

All completed evaluations were returned to Talley who then forwarded the forms to an independent source for analysis. The information was entered into a database which had been designed for the project, after which the results were reviewed and reported. The reports were site specific, and where clinicians had given permission, the information was entered into a central database so that an outcome of larger numbers of evaluations could be available.

The patient was registered using data taken from the initial assessment, which also provided the baseline information. Data recorded at each subsequent visit was also entered, so that at the end of the evaluation period there was information on which the progression could be measured.

Three specific patient outcomes were measured:

- Reduction in wound complications: this included wound pain, infection, and the presence of a cavity, sinus or undermining. As some patients were observed to have a combination of wound cavity, sinus or undermining, the data was analysed as a collected reduction at the end of the evaluation period
- The percentage reduction in devitalised tissue over all of the evaluations: at each dressing change clinicians were asked to assess the percentage of devitalised tissue and document this as a percentage of the total wound bed tissue, in comparison to granulation and epithelial tissue. This was expressed as an 'overall % improvement' across the patient population. Any patient-specific deteriorations were also reported
- The percentage increase in healthy tissue: as described above, this was assessed and documented at each dressing change.

This information was collated with the responses recorded by the evaluating clinician on the ease of use of the device, as well as the opinion of the patient. This formed the basis of the report.

In addition, the total number of dressing changes, the number and cost of the consumables (dressing packs and canisters) and any other products used within the wound bed or surrounding tissues was automatically calculated to give an overall cost of managing this patient population.

Results

The evaluations were undertaken over a 12-month period by clinicians in 10 trusts who were interested in evaluating the Venturi system. To date, 50 patient evaluations have been undertaken using this process, where the initial assessment was undertaken as follows

- 54% (n=27) on in-patients
- 14% (n=7) from an out-patient clinic

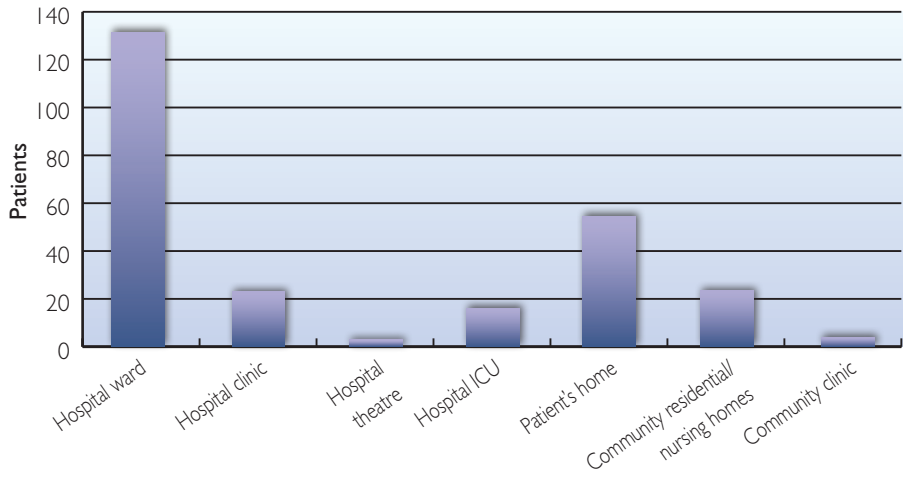

Figure 1. Clinical setting of NPWT applications.

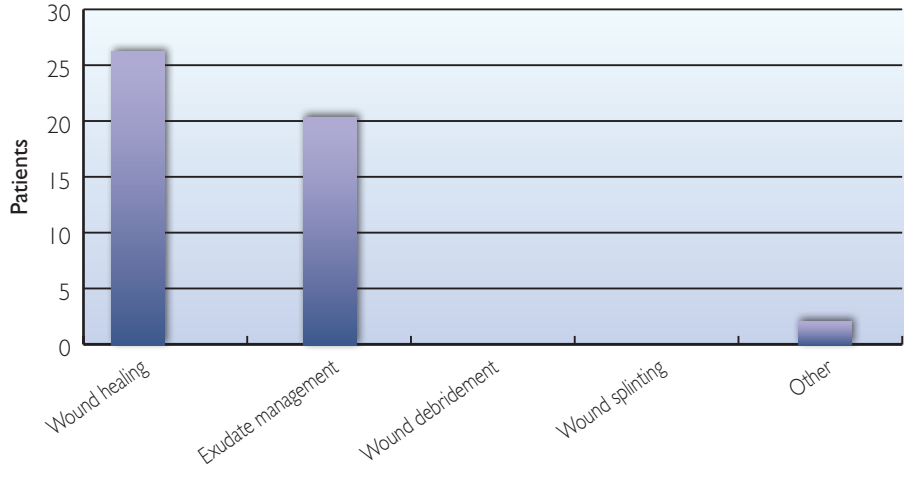

Figure 2. Clinical reason for the use of NPWT.

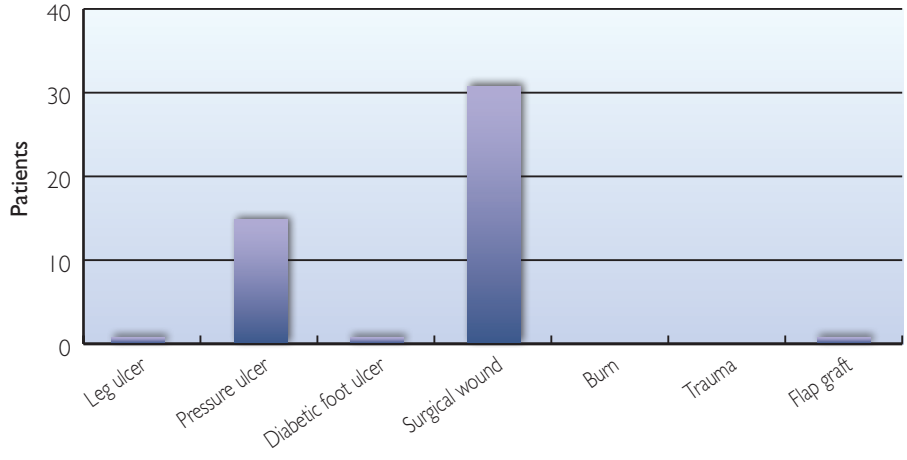

Figure 3. Range of wound types on which clinicians used the Venturi system.