IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

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Negative pressure wound therapy[1]

Executive Summary

[1] Executive summary of the final report "Vakuumversiegelungstherapie von Wunden" (Version 1.0; Status: 13.03.2006). Please note: This document is provided as a service by IQWiG to English-language readers. However, solely the German original full report is absolutely authoritative and legally binding.

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Executive summary

Background

The Federal Joint Committee commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to conduct a benefit assessment on negative pressure wound therapy (NPWT).

NPWT is mainly used to treat chronic wounds and consists of an open-cell foam dressing covered with an adhesive drape. The dressing is connected to a vacuum pump that creates and maintains a negative pressure.

Research question

On the basis of the published literature on this theme, the objectives of the present investigation are (with regard to patient-relevant therapy goals)

– the benefit assessment of NPWT compared with conventional forms of wound care

and

– the benefit assessment of different forms of NPWT compared with each other

in patients with acute or chronic skin wounds of any cause or localisation.

This benefit assessment is based on a comparison and consideration of the desired and undesired effects of NPWT.

Methods

Search strategy

Full-text articles on clinical trials investigating NPWT in patients with acute or chronic wounds were searched for in MEDLINE, EMBASE, CINAHL, and the Cochrane Central Register of Controlled Trials. Trial registries (www.clinicaltrials.gov and www.nrr.nhs.uk) were also screened to identify ongoing trials. Search strategies were adapted and broadened according to the specific structure of each database in order to identify all published non-RCTs. In addition, the Cochrane Library (CDSR, DARE, and HTA) was searched to identify systematic reviews on NPWT. All searches were last updated in October 2005. Furthermore, the US Food and Drug Administration (FDA), other health agencies, clinical experts, and the manufacturers of NPWT devices (Kinetic Concepts, Inc. [KCI], San Antonio, TX; Blue Sky Medical, La Costa, CA) were asked to provide published and unpublished data. Detailed information on the search strategies is available in the full report (see below).

Selection criteria

Studies were considered eligible if they investigated the effects of NPWT vs. conventional wound therapy on wound healing. The study types included were randomised controlled trials (RCTs) as well as non-RCTs with a concurrent control group. Abstracts were screened independently by 2 reviewers. Abstracts were excluded only if classified as clearly not relevant by both reviewers or if unavailable as full-text publications. An English-language title was required. No language restrictions were otherwise imposed. If an English-language title or abstract indicated the potential relevance of a foreign-language text, the text was obtained and translated.

Quality assessment and data extraction

Each study was assessed with regard to study design and conduct (e.g., allocation concealment, blinding of outcome evaluators, sample size calculation, quality of statistical analyses, reporting of withdrawals, and reporting of adverse events). In addition, the sponsor of each study was determined. Data from the trials included were extracted using standardised forms and were summarised independently by 2 reviewers. If inconsistencies in study data were detected, the authors of the publications were contacted for clarification, and if appropriate, their responses were considered in the assessment.

Statistics

Meta-analyses for all primary outcomes were planned, but due to the lack of data, only one such analysis was possible (for changes in wound size).

Results

Search results

The systematic search in bibliographic databases identified 20 relevant published studies including 9 RCTs; 17 studies (7 RCTs), were finally included in the evaluation.

(Partial) outpatient use of NPWT, mostly in specialised centres, was only described in 3 studies. The follow-up period in most studies did not exceed the actual duration of treatment, with a maximum of 1 year. The number of patients in the studies was low (the RCTs included a total of 371 patients).

Study quality

The quality of the studies and publications investigated was poor. One of the RCTs [Armstrong 2005] was superior to the others because of the greater number of patients included (N = 162) and the better quality.

Outcomes

There was evidence in favour of NPWT for the following patient-relevant therapeutic goals:

- Shortening of the wound healing time: These results are difficult to interpret, as there was either no blinding of outcome evaluation, or this was not fully implemented. However, the results on wound healing time were supported by results on a surrogate parameter (changes in wound size).

- Reduction in (re-)amputation rates in patients with diabetes mellitus and status after partial foot amputation: Data on this outcome were mainly obtained from a comparatively large (N = 162) RCT [Armstrong 2005] that was of better methodological quality than the other studies, but this outcome was not statistically significant (p = 0.06).

- Reduction in the mortality of patients with open abdomen following peritonitis: Data on this outcome are essentially based on a non-RCT with a very small number of patients in the control group (N = 5) and an inadequate description of the methods; an unambiguous interpretation is accordingly not possible.

- Shortening of the time spent in hospital: This outcome was only described in non-RCTs which were, moreover, unblinded. Therefore no unambiguous interpretation is possible.

The results on the occurrence or avoidance of adverse events or complications are inconsistent. In 1 RCT, wound infections were substantially more frequent in the NPWT group (with similar overall rates of adverse events); however, these were classified by the responsible physicians as not being related to NPWT. In any case, a classification of this sort must be regarded with a great deal of reservation, particularly if the evaluation was conducted in a non-blinded manner. In contrast, 1 other RCT and 1 non-RCT found much higher complication rates in the control group.

Essentially no relevant differences between the treatment groups could be established for any other patient-relevant therapeutic goal – or these outcomes were not even considered in the studies. The number of dressing changes was lower for NPWT in all studies in which this information was reported. However, this was either due to the methods used or to the procedures defined in the study protocol. It was reported in 1 RCT that more time was required to change the dressing in the NPWT group than in the control group.

The search for unpublished RCTs showed that we can expect a large number of publications on further randomised trials in the next few years. We can expect these to include more patients and to be of better methodological quality.

Conclusion

There are at present no results of adequate reliability which provide proof of the superiority of NPWT in comparison with conventional therapy, and which would justify broad use of this method outside clinical trial settings. It would be advisable to re-examine this question in 2 to 3 years.

References

Armstrong DG, Lavery LA: Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial. Lancet. 2005, 366: 1704-1710.

Please note:

1) The full report (English translation) is available under

http://www.iqwig.de/download/N04-03_Final_report_Negative_pressure_wound_therapy.pdf

2) An IQWiG rapid report on NPWT (Commission N06-02) has since been published (search period: May 2005 to December 2006). The full rapid report (German version) is available under: http://www.iqwig.de/index.535.en.html

3) The following journal articles related to the IQWiG report on NPWT are available:

1. Gregor S, Maegele M, Sauerland S, Krahn JF, Peinemann F, Lange S. Negative pressure wound therapy: a vacuum of evidence? Arch Surg. 2008; 143: 189-96.
2. Peinemann F, McGauran N, Sauerland S, Lange S. Disagreement in primary study selection between systematic reviews on negative pressure wound therapy. BMC Med Res Methodol. 2008; 8: 41.
3. Peinemann F, McGauran N, Sauerland S, Lange S. Negative pressure wound therapy: potential publication bias caused by lack of access to unpublished study results data. BMC Med Res Methodol. 2008; 8: 4.