IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

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Negative pressure wound therapy (rapid report)[1]

Executive Summary

[1] Executive summary of the rapid report "Vakuumversiegelungstherapie von Wunden" (Version 1.0; Status: 29.01.2007). 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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Background

IQWiG's final report on negative pressure wound therapy (NPWT) was published in May 2006 (status: March 2006). (In the following text, this report is referred to as "final report 2006".) On the basis of the literature published on this topic, the aims of the former assessment were 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. The main focus of the assessment was on patient-relevant outcomes.

Research question

The aim of the present report is to determine whether any substantially new evidence has been published since the final report 2006, evidence that could decisively change the final report's conclusion so that a new assessment of NPWT would be recommended.

Methods

The methods applied were based on those of the final report 2006.

Study types to be included in the assessment were randomised controlled trials (RCTs). Non-randomised intervention studies and observational studies with a concurrent control group were also to be considered.

Study outcomes used were those that permitted an evaluation of patient-relevant outcomes, such as wound healing time, wound recurrence or the need for revision surgery, amputations, mortality, health-related quality of life, pain caused by the wound or by wound care, the necessity of hospital admissions and duration of hospital stays, as well as adverse effects and complications of therapy.

The systematic literature search was performed in 4 electronic databases (MEDLINE, EMBASE, Cochrane Library, and CINAHL) and covered the period from May 2005 (first search conducted for the final report 2006) up to December 2006. In addition, the reference lists of primary and relevant secondary publications (such as systematic reviews and HTA reports) were searched.

The literature screening was performed by at least 2 reviewers independently of each other. After an assessment of the quality of the relevant studies to be included in the report (also conducted independently by 2 reviewers), the results of the individual studies were collated according to outcomes and summarised.

Results

The main result of the rapid report was the detection of several further studies on NPWT. The number of randomised and non-randomised studies that could be suitable for a benefit assessment increased from 7 and 10 in the final report 2006 by 5 and 6 studies respectively. This resulted in a total number of 12 randomised and 16 non-randomised studies reporting on 596 and 486 patients respectively. The overall number of patients increased from 602 (final report 2006) by 480 (rapid report) to 1082.

Overall, the newly identified studies confirmed the indications described in the final report 2006 of a beneficial impact of NPWT on wound healing time and, associated with this outcome, a possible reduction in the length of hospital stays through the use of NPWT. However, the data still showed inconsistencies and the unchanged low quality of the studies remains a major problem. As the newly identified studies were conducted in an inpatient setting, no new evidence from a controlled setting was obtained with respect to the use of NPWT in outpatients.

Only one of the randomised studies achieved an acceptable level of quality, whereby open questions regarding the analysis still remain. The other studies showed a lack of clarity concerning randomisation. For non-randomised studies, due to the clear imbalances at baseline (or imbalances that cannot be certainly excluded), the validity of the comparison between the intervention and control group can hardly be assessed. Most studies did not present information on the parallelism of groups, so that it is unclear whether the studies in fact may have had a design with historical controls, which actually would have been an exclusion criterion for the assessment. Therefore, the data obtained from non-randomised studies prove to be insufficiently valid for conclusions based on them to be justified.

Overall, the interpretation of data was made more difficult by the fact that a wide range of wounds was investigated in the various studies. In view of the differences in aetiology and pathophysiology, it is questionable whether the evidence from the studies can be summarised and assessed in a meaningful manner at all.

Furthermore, it can be assumed that at least 18 randomised studies on NPWT are still ongoing and/or unpublished. As a matter of principle, the potential impact of publication bias also needs to be considered. If an update of the report is performed, it would seem meaningful to consider only randomised studies as relevant. The concern that it is not possible to conduct RCTs in many areas must by now be seen as unfounded. Only in areas where rare diseases are investigated or where the conduct of a study is made difficult due to an emergency situation and/or the inability of a patient to give consent, could it also be meaningful to consider non-randomised studies as an alternative.

Conclusion

Since the completion of the final report on NPWT in 2006, several additional randomised and non-randomised studies on the topic have been published. However, the findings show that

these studies do not provide evidence of sufficient quality and quantity that necessitates a change in the conclusions drawn in the final report and a new assessment of NPWT.

Key words: negative pressure wound therapy, negative pressure, wound therapy, split-thickness skin, wound infection, ulcus cruris, diabetes mellitus, systematic review.

Please note:

1) The following journal articles related to IQWiG's work 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.

2) The IQWiG final report 2006 (full English version) is available under

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