CORRESPONDENCE

Negative Pressure Wound Therapy

Systematic Review of Randomized Controlled Trials
by Dr. med. Frank Peinemann M.Sc., Dr. med. Stefan Sauerland MPH
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Poor Evidence Based Medicine

Even though the advantages of negative pressure wound therapy cannot be confirmed with any degree of certainty on the basis of the criteria of evidence based medicine (EBM), the procedure has greatly gained in importance in a wide range of surgical interventions, and rightly so. The advances prompted by this method are probably obvious only to those who experienced the time before it was introduced, which is longer than 20 years ago.

After 29 years' activity in the specialty I can honestly say that the development of negative pressure wound treatment constituted one of the largest advances in surgery during this time.

There is a multitude of wounds and defects in abdominal-trauma-vascular surgery and related disciplines that were almost unmanageable in the past without extensive aids and patient transfers to maximum care hospitals, but which nowadays can be managed successfully in any basic surgical ward. This makes the frequent, irritating problems with reimbursement of costs in the outpatient setting—because the effectiveness of the method has allegedly not been confirmed—even more irritating. No alternative treatment method is supported by better evidence, but none of them incur similar problems in terms of costs being covered.

This example illustrates the two weaknesses of the concept of pure EBM, at least in the way it is practiced in Germany. One is an inherent aversion to progress and advances in the system, the other is the fact that any novel procedure can be made into an instrument of financial politics.

To restrict EBM to a few randomized controlled trials, which means basing whole truths on such a sparse foundation, and to ignore the entire empirical proofs accumulated over time is not a satisfactory concept within surgery; neither does it reflect the original ideas of evidence based medicine. But this incomprehension of what EBM actually is provides politicians and health insurers with easy reasons to reject ideas.

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Conflict of interest statement
The author declares that no conflict of interest exists.

Objective Is Questionable

I can only underline the authors' conclusion—namely, that further studies are needed. I am a plastic surgeon working in reconstructive surgery, treating large defects after infections, trauma, and tumors on a daily basis, but I have doubts about the ultimate objective. It is not negative pressure wound therapy (NPWT) that needs to be evaluated as this procedure has an undisputed position in conditioning wounds right up to wound closure by a plastic surgeon, especially large wounds and those with a primary infection. Until the wound is closed, NPWT does not only increase patients' quality of life because of less frequently needed painful changes of dressings (intervals of up to seven days are entirely feasible), but it improves the wound after debridement so that we can close the wound more quickly and more safely. This does not relate to skin transplants only but also to coverage with pediculed and free microvascular flaps. Aspects of infection and vascularization of the wound (or limb) always need to be clarified before any procedure can take place. Admittedly, such an end point depends on clearly more (subjective) variables, but the fact that an end point is difficult to measure should not serve as a deterrent to defining an objective correctly. It would be regrettable for our patients if new studies again evaluated the wrong end point. In this context, reconstructive (plastic) surgeons should be included from the initial study design.

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Prof Fansa has received travel and hotel expenses from Pfizer.

Niche Use at Best

The current critical literature review shows that a method that is well rewarded within the system of diagnosis related groups is questionable; consequently so is its expensive financing. Reimbursement is done without any proof of success and thus stimulates demand. According to our decades of experience, wound healing in the long term—rather than granulation stimulated in the short term—almost entirely depends on local vascularization, and improving this should be the primary objective. Subsequently it is hardly relevant which method of wound closure is used or which dressing technique is applied for secondary healing, as long as the correct principles are applied for transplants or

moist wound healing. In my opinion, negative pressure wound treatment would be used in no more than a niche function without the considerable financial stimuli.

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In Reply:

We are pleased to read about Dr Thies's positive experiences with negative pressure wound therapy. Usually, clinical experience is not sufficient for drawing conclusions of nationwide validity, which apply to thousands of patients in inpatient and outpatient settings. Especially outpatient NPWT entails certain risks; and that the benefits of this therapy really should be well documented. The fact that the methods of evidence based medicine are primarily applied to expensive and risky treatment methods seems to us easy to understand. Members of health insurance schemes could hardly be expected to condone a situation whereby the German Federal Joint Committee (*Gemeinsamer Bundesausschuss*, G-BA) and the Institute for Quality and Efficiency in Health Care (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen*, IQWiG) spend a lot of time and resources evaluating interventions that hardly differ from one another in terms of their risk-benefit profile or cost.

We welcome the fact that Professor Fansa also identifies the need for further randomized studies. Wound closure by means of NPWT does not rule out the use of plastic-reconstructive methods. Perhaps a misunderstanding arose regarding this issue. In the studies starting in autumn, wound closure by reconstruction/plastic surgery is certainly an essential component within the treatment concept after appropriate conditioning of the wound areas. To avoid giving preference to one therapeutic group, photographic documentation and independent assessment of the wound should be used to ensure that the indication for plastic closure is defined dependent on local findings but independent of preceding wound treatment. The future studies will also investigate whether NPWT really reduces pain and improves quality of life.

We thank Professor Breuninger for his appreciation of the problems we identified in evaluating negative pressure wound therapy. We think this supports our methodological approach of using complete wound closure as the primary end point.

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