

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form ([see an example](#)) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Randomized Controlled trial evaluating the Efficacy of Wrap Therapy for Wound Healing Acceleration in NPUAP Stage II and III Pressure Ulcer Patients
AUTHORS	Seiji Bito, Akihiro Mizuhara, Sandai Onishi, Kensuke Takeuchi, Masatsune Suzuki, Kazuhiro Akiyama, Kazuyo Kobayashi and Kayoko Matsunaga

VERSION 1 - REVIEW

REVIEWER	Yoshiki Miyachi Professor and Chairman Department of Dermatology Kyoto University JAPAN NO COI
REVIEW RETURNED	05/09/2011

GENERAL COMMENTS	<ol style="list-style-type: none">1. The basic concept of the wrap therapy is "moist wound healing", which is comparable to the modern dressing techniques. So, this reviewer was not surprised to find the results, since food wraps may have the similar effects on moist wound healing in pressure ulcers. Because of the difficulty for controlled studies, even the modern dressings have poor clinical evidence, though they are approved and covered by health insurance.2. The major ethical problem is those wrap therapies uses food wraps which are not approved by health insurance, and, furthermore, the manufacturers are opposed to using their products for pressure ulcers. However, wrap therapy is very popular among nursing homes as well as home medical care in Japan, because it is inexpensive. Good news is that some wraps are modified for clinical uses and approved by Ministry of Health, Labor and Welfare.3. Under these situations, the major clinical problem is that wrap therapy is widely used by non-specialists as an almighty tool for any kind of pressure ulcers. This is why JSPU released a statement that wrap therapy should be used by well-trained physicians under the informed consent of the patients if modern dressings cannot be used due to the limited medical expenses.4. Taking these conditions into consideration, this reviewer finds that this article is a well organized prudent RCT evaluating the so-called "wrap therapy", though this is a small study with weak statistical power and impossibility of blindness of the treatment.5. This reviewer would like to ask the authors to discuss 1) the ethical issues of wrap therapy which I pointed out above, 2) the clinical indications and advantages of wrap therapy if modern dressings are available and covered by health insurance, and 3) the limited situations for wrap therapy.6. Since modern dressings have developed various other devices
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	<p>such as antiseptic activities using Ag and reduced pain during dressing techniques, one may infer that modern dressings may have additional advantages for QOL of patients. I am wondering how the authors evaluate the evolution of modern dressings.</p> <p>7. I am wondering if the similar data are already accepted for publication in a Japanese Journal.</p>
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REVIEWER	<p>---</p> <p>Xiaofeng Wang, Ph.D. wangx6 at ccf dot org Associate Member and Professor of Biostatistics, Lerner Research Institute Cleveland Clinic Foundation, 9500 Euclid Ave/JJN3, Cleveland, OH 44195, USA</p> <p>-----</p> <p>No conflict of interest.</p>
REVIEW RETURNED	17/10/2011

The authors present a study to evaluate if ‘wrap therapy’ using food wraps is not inferior when compared to guideline adhesion treatments. The primary end point was the period until the pressure ulcers were cured. The secondary end point was a comparison of the speed of change in the Pressure Ulcer Scale for Healing (PUSH) score. Sixty-four of the 66 patients were analyzed. However, there is no statistical significant finding in this study.

The paper is well written. However, I disagree their conclusion “It might be possible to recommend wrap therapy as an effective treatment in primary care settings as an extremely simple and inexpensive dressing care.”, since no statistical test is significant. The paper lacks the scientific findings based on the formal significant statistical results.

The authors tried to make some significant conclusions based on non-significant statistical results. For example, Page 10, the second paragraph, it is not reasonable to draw the (significant) scientific conclusions only based on the “visual” survival graphics (when your tests were not significant).

The sentence “No statistical significance, however, was presented due to insufficient statistical power” could be misleading. The reader might understand that the nonsignificant results were due to the power of the statistical methods, but not from your data.

Some statements in the paper are too overwhelming. For example, Page 11, line 6, “The conclusion obtained will greatly influence pressure ulcer care methods in the further.”

Minor comments:

- (1) Table 1, please statement what kind of statistical tests you used (t-test, chisqre test?)
- (2) Tabel 2, keeps the format as the same as Table 1.
- (3) Figure 2-2, the legends are out of bounds.
- (4) Please give detailed descriptions of y-axis in Fig 3-2 and Fig 3-3.

VERSION 1 – AUTHOR RESPONSE

- 1 I added some sentences according to CONSORT non-inferiority and equivalence trial model. I added details of random allocation and PROBE method.
- 2 I stated all co-authors meet ICMJE authorship criteria
- 3 According with the first reviewers comments, I wrote "practical application" section in discussion that include ethical and social aspects of wrap therapy, the clinical indications and advantages of wrap therapy if modern dressings are available, and actual situations for wrap therapy.
- 4 I totally agree with the second reviewers comments. I have rewritten my representations concerning the interpretation of results. Though I also change minor comments that the second author pointed out, I initially do not have "figure2-2". I think it was my mistake.

VERSION 2 – REVIEW

REVIEWER	Yoshiki Miyachi Professor and Chairman Department of Dermatology Kyoto University JAPAN NO COI
REVIEW RETURNED	

THE STUDY	Grammatical erros in English should be improved. For example: "..did not showed..."
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REVIEWER	Xiaofeng Wang, Ph.D. Cleveland Clinic Lerner Research Institute Cleveland Clinic Lerner College of Medicine Cleveland, OH 44195, USA
REVIEW RETURNED	08/12/2011

GENERAL COMMENTS	The presentation of the paper have been improved, however, my main comments have not been taken into consideration. For example, there is no statistical significant finding in this study. The figures need to be reproduced for scientific publications. The authors did not even give point-by-point responses to the reviewers' comments. The English grammar still needs to be checked in this revised paper. Due to the minor revision of the manuscript, I'm not sure that the paper meets the standards of BMJ Open.
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