Reviewer’s report

Title: A comparison in therapeutic effects of hydrocolloid dressing and phenytoin and simple dressing methods in healing pressure ulcers of spinal paraplegic patients.

Version: 1 Date: 17 November 2003

Reviewer: James F Graumlich

Reviewer’s report:

General

Discretionary Revisions (which the author can choose to ignore)

Minor Compulsory Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

Review

To the editors, BMC Dermatology

Subject: review of manuscript entitled
"A comparison in therapeutic effects of hydrocolloid dressing, phenytoin, and simple dressing methods in healing pressure ulcers of spinal paraplegic patients"

I received a title page (pdf) and 5 supporting documents.

The manuscript is a research article. The manuscript is not a Study Protocol, Case Report, Debate, Software or Database article. The authors describe a randomized, parallel group, controlled clinical trial. I employed the Consolidated Standards of Reporting Trials (CONSORT) during my review. My references for the CONSORT are below:


In addition to the CONSORT references, I also relied on information found in the following document: Guidance for Industry, Chronic cutaneous ulcer and burn wounds - developing products for treatment, U.S. Food and Drug Administration, June 2000. http://www.fda.gov/cder/guidance/3226df.htm
CONSORT item 1: Title and abstract "How participants were allocated to interventions (e.g., "random allocation," "randomized," or "randomly assigned")

Reviewer comment: The abstract describes the design as "simply randomized." The title does not mention random allocation. (Minor Compulsory Revisions)

CONSORT item 2: "Scientific background and explanation of rationale."

Reviewer comment: In the Introduction, the authors describe pressure ulcer prevalence, cost, and treatment. In most circumstances, the authors provide appropriate references for their text. However, the reference for cost (reference 5) is from 1987 and may be out of date. In the last paragraph of the Introduction, the authors assert morbidity and mortality associated with pressure ulcers. I ask the authors to provide references for their assertions regarding morbidity and mortality. The last sentence of the Introduction suggests extrapolation and generalization of the results to other surface wounds. I believe text about "generalizability" (external validity) of the trial findings belongs in the Discussion section (please see CONSORT item 21 below). (Minor Compulsory Revisions)

CONSORT item 3: "Eligibility criteria for participants and the setting and locations where the data were collected."

Reviewer comment: The authors described the eligibility criteria and setting for the trial.

CONSORT item 4: "Precise details of the interventions intended for each group and how and when they were actually administered."

Reviewer comment: Who administered treatment intervention? Who assured the treatment intervention was administered with comparable adherence in each treatment group? In Patients and Methods section, paragraph 4, the control therapy appears to be dry sterile gauze. Since maintenance of a moist wound environment is the standard of care, the dry sterile gauze group may not have received standard therapy. Comparisons to the dry sterile gauze group will need to emphasize any deviations from the standard of care that might exaggerate differences between treatment groups. (Major compulsory revisions)

CONSORT item 5: "Specific objectives and hypotheses"

Reviewer comment: The text does not contain precise statements of the primary and secondary objectives or hypotheses. My review of the Results section leads me to believe the primary objective was a comparison of complete healing rates between patients with pressure ulcers treated with hydrocolloid, phenytoin, or dry sterile gauze. I assume the secondary objectives were comparisons of complete healing rates within subgroups defined by ulcer stage and ulcer location. (Major compulsory revisions)

CONSORT item 6: "Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors)."

Reviewer comment: I could not find an explicit statement of the primary outcome in the Methods section. Was the primary outcome complete healing within 8 weeks? What was the definition of complete healing for Stage I ulcers? What was the definition of complete healing for Stage II ulcers? The authors calculated ulcer area. Was ulcer area a secondary outcome? (Minor Compulsory Revisions)
CONSORT item 7: How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules."

Reviewer comment: I did not find text in the Methods section to describe a rationale for the sample size. If the study did not have a formal sample size analysis, then it would be appropriate to call the study a "pilot study" in the title and methods and discussion. (Minor Compulsory Revisions)

CONSORT item 8: "Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification)."

Reviewer comment: I did not find text in the Methods section to describe the technique for random sequence generation. (Minor Compulsory Revisions)

CONSORT item 9: "Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned."

Reviewer comment: I did not find text in the Methods section to describe the presence or absence of allocation concealment. (Major Compulsory Revisions)

CONSORT item 10: "Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups."

Reviewer comment: I did not find text in the Methods section to describe the implementation of random allocation. (Minor Compulsory Revisions)

CONSORT item 11: "Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated."

Reviewer comment: The Methods section describes the study as "single blind." I could not find text to tell me who was blind. If outcome assessors were blind, then I would like to know if they were blind to treatment assignment when they assessed the primary outcome and/or secondary outcome. (Minor Compulsory Revisions)

CONSORT item 12: "Statistical methods used to compare groups for primary outcome(s)...."

Reviewer comment: The text does not state the primary outcome for analysis and does not state the method of analysis for the primary outcome. The text states ANOVA and chi-squared tests for "all data gathered from patient's preliminary and complementary questionnaire." The text does not give me enough information to assess fulfillment of CONSORT item 12. The authors analyzed 91 ulcers from 83 patients. When analysis involves more than one ulcer per patient, then there is a violation of the statistical assumptions of independence and of random sampling from the population. The statistical tests chosen by the authors do not permit more than one ulcer per patient. If the authors wish to analyze two ulcers per patient, then they need to have a matched design that will allow the use of appropriate tests like McNemar's test. (Major compulsory revision)

CONSORT item 13: "Flow of participants through each stage (a diagram is strongly recommended)."

Reviewer comment: I did not receive a flow diagram to review. I could not assess drop-outs or withdrawals. (Major compulsory revision)

CONSORT item 14: "Dates defining the periods of recruitment and follow-up."
Reviewer comment: I found the dates of spinal cord injury in the text. I did not find dates requested in CONSORT item 14. (Minor Compulsory Revisions)

CONSORT item 15: "Baseline demographic and clinical characteristics of each group."

Reviewer comment: I found these items in Table 1. The text does not state if the trial included men or women or both. Please note, Figure 1 and Figure 2 were distorted and were hard to read. I assume the distortion occurred during the process of uploading or downloading from the Internet. Either way, both Figure 1 and Figure 2 appear to be superfluous because they display baseline characteristics that belong in Table 1 or in the text. (Minor Compulsory Revisions)

CONSORT item 16: "Number of participants (denominator) in each group included in each analysis and whether the analysis was by 'intention to treat.' State the results in absolute numbers when feasible (e.g., 10 or 20, not 50%)."

Reviewer comment: The text does not state if the analysis was according to intention to treat. In the Results section, there are numerous examples of percentages that lack numerator and denominator data. In the abstract, there are p values without numbers of participants. Please note. The Results section mentions Table 2. I did not receive Table 2 in the documents submitted for review. (Minor Compulsory Revisions)

CONSORT item 17: "For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval)."

Reviewer comment: I did not find 95% confidence intervals in the text submitted for review. (Minor Compulsory Revisions)

CONSORT item 18: "Address multiplicity by reporting any other analyses performed, including subgroup analyses, indicating those prespecified and those exploratory."

Reviewer comment: I found subgroup analyses within ulcer stage and within ulcer location. The text does not state if these analyses were prespecified or exploratory. (Minor Compulsory Revisions)

CONSORT item 19: "All important adverse events or side effects in each intervention group."

Reviewer comment: I did not find adverse event data in the text submitted for review. (Minor Compulsory Revisions)

CONSORT item 20: "Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes."

Reviewer comment: The Discussion section mentions the mechanisms of action of phenytoin and hydrocolloid. The third paragraph contains several assertions about hydrocolloid that require references. The references at the end of the paragraph (25-27) do not appear to pertain to hydrocolloid. I could not check the references from the journal named HELIOS because this journal is not indexed by the National Library of Medicine (PUBMED) or by Science Citation Index. The authors did not address potential biases. I cannot tell from the text if there are biases related to randomization, execution of the blind, drop outs - withdrawals, generation of random numbers, or allocation concealment. (reference Moher D, Pham B, Jones A, Cook DJ, Jadad AR, Moher M, Tugwell P, Klassen TP. Lancet 1998; 352: 609-613 ) (Minor Compulsory Revisions)

CONSORT item 21: "Generalizability" (external validity) of the trial findings
Reviewer comment: In the Discussion, paragraph 6, the authors make generalizations and assertions regarding hydrocolloid cost and comfort. Since these outcomes were not measured in their trial, I ask the authors to provide reference citations to other trials. (Minor Compulsory Revisions)

CONSORT item 22: "General interpretation of the results in the context of current evidence."

Reviewer comment: I believe the authors achieved this criterion.

In my review of the manuscript, I considered the following seven points.

1. Is the question posed by the authors new and well defined?
Reviewer comment: The question is new. The question is not well defined. Please see detailed comment above. This is a major compulsory revision.

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?
Reviewer comment: The methods appear to be appropriate. However, there are several missing details required by the CONSORT. There are major and minor compulsory revisions.

3. Are the data sound and well controlled?
Reviewer comment: Yes

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
Reviewer comment: The manuscript does not adhere to the CONSORT standards. I describe major and minor compulsory revisions in the text above.

5. Are the discussion and conclusions well balanced and adequately supported by the data?
Reviewer comment: Yes

6. Do the title and abstract accurately convey what has been found?
Reviewer comment: The title and abstract require minor compulsory revisions. Please see CONSORT comments above.

7. Is the writing acceptable?
Reviewer comment: The manuscript contains many spelling and language errors and other errors that are not acceptable. However, I feel these errors are the easiest to remediate. Below is a partial list of minor compulsory revisions.

Disclosure
Insistence
Special posture
Dollars in year
60/000
calory
Non-probability
What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Not suitable for publication unless extensively edited

Statistical review: No

Declaration of competing interests:

none