Reviewer's report

Title: A randomized clinical trial comparing hydrocolloid, phenytoin and simple dressings in the treatment of pressure ulcers

Version: 8 Date: 9 August 2004

Reviewer: James F Graumlich

Reviewer's report:

General

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

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

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Discretionary Revisions (which the author can choose to ignore)

I thank the authors for their thorough responses to the questions in my review.

Discretionary revision (which the author can choose to ignore)
Page 2-3, Abstract

Please perform a word count of the abstract. Some journal indexing services may truncate the abstract after 250 words. If your abstract has more than 250 words, I fear your conclusion statement will be truncated. If you are looking for a way to shorten the abstract, then I suggest you delete or shorten the following sentence: “Baseline demographic and clinical characteristics, including age, weight, duration of ulcer before treatment, size and stage were comparable in all groups (P>0.10).” If you do not need to shorten the abstract text on page 2, then no deletion is required.

Discretionary revision (which the author can choose to ignore)
Page 3, Abstract

Current text
We deduced that HD is a more effective method of treatment for stage I and II pressure ulcers.

New text
We deduced that HD is a more effective method of treatment for stage I and II pressure ulcers in paraplegic young men.

Discretionary revision (which the author can choose to ignore)
Page 3, line 18

Current text
U.K.

New text
United Kingdom

Minor essential revision
Page 3, line 21
Page 6, line 7, 8, 11
Page 11, line 3
Page 14, reference 12

Current text
“debridment”

New text
“débridement”

Minor essential revision
Page 5, line 9-10

Current text
(e.g. diabetes mellitus or frank vascular disease, like Berger’s disease.

New text
(e.g. diabetes mellitus or frank vascular disease, like Buerger’s disease).

Minor essential revision
Page 5, line 14

Current text
Thus, the eligibile study population was 83 patients with 91 pressure ulcers in ischial, sacral or gluteal areas.

New text
Thus, the study sample was 83 patients with 91 pressure ulcers in ischial, sacral or gluteal areas.

Discretionary revision (which the author can choose to ignore)
Page 5, line 17
Page 7, line 8

Current text
…blocked randomization...

New text
…stratified randomization...

Explanation:
The definitions for blocked and stratified randomization that I use come from the following text: Meinert CL, Tonascia S. Clinical Trials Design, Conduct, and Analysis. 1986, New York: Oxford University Press, pages 93-96.
If the randomization were blocked, then I would expect the authors to report the block size. If the block size were a fixed number, for example, 6, then there would be no allocation concealment for every sixth enrolled patient because the investigative team could predict the assignment in this open label trial. In order to use blocked randomization in an open label trial and maintain allocation concealment, the appropriate technique is a variable block size that is unpredictable by the investigative team. Blocked randomization is used when patient enrollment is likely to occur over an extended period of time and when interim analyses require balanced allocations to treatment groups. Since the present trial enrolled within a short time and since there was no interim analysis, I do not perceive a rationale for blocked randomization. I note the balanced allocation within ulcer location in Figure 2 and within ulcer stage in Figure 3. These balanced allocations lead me to the conclusion that the stratification variables might have been ulcer location and ulcer stage.

Minor essential revision
Page 6, line 11

Current text
Fortunately non

New text
Fortunately, none

Minor essential revision
Page 6, line 23

Current text
For sage II ulcers…

New text
For stage II ulcers…

Discretionary revision (which the author can choose to ignore)
Page 9, line 26

Current text
Using a random number table, we performed a second analysis considering only one ulcer per patient, which included 83 ulcers in 83 patients.

New text
We performed a second analysis that included 83 ulcers in 83 patients. We selected one ulcer patient by using a random number table.

Minor essential revision
Page 10, line 4

Current text
8.27

New text
8/27
Discretionary revision (which the author can choose to ignore)
Page 11, line 15

Current text
...rationale...

New text
...rational...

Minor essential revision
Page 11, line 27

Current text
...ischial...

New text
...ischial...

Minor essential revision
Page 12, line 13

Current text
...prelude...

New text
...preclude...

Minor essential revision
Page 13, reference 5
Fix missing space

Minor essential revision
Page 14, reference 12
Page 14, reference 13
Page 14, reference 14
Page 16, reference 34
Page 16, reference 35
Fix errors in capitalization

Minor essential revision
Page 15, reference 22
Fix spelling “Compbell MJ” versus “Campbell MI”

Minor essential revision
Page 15, reference 27
Current text
50c

New text
Soc

Discretionary revision (which the author can choose to ignore)
Page 16, reference 33
Check spelling

Minor essential revision
Page 18-19, page 19-20
Table 2 and table 4 have page breaks within the table. Please insert page breaks so there is one table per page.

Minor essential revision
Page 19, title for table 2

Current text
…pbenytoin…

New text
…phenytoin…

Discretionary revision (which the author can choose to ignore)
Page 20, table 4
Please check for typographical error in hydrocolloid row and mean ulcer size column.

Minor essential revision
Figure 2 overlies and obliterates the title for figure 2.

Minor essential revision
Figure 3 overlies and obliterates the title for figure 3.

What next?: Accept after minor essential revisions

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

 Statistical review: No

Declaration of competing interests:
None