Author's response to reviews

Title: A randomized clinical trial comparing hydrocolloid, phenytoin and simple dressings in the treatment of pressure ulcers [ISRCTN33429693]

Authors:

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Version: 14 Date: 9 November 2004

Author's response to reviews: see over
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

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

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

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.

Authors response: The text was revised.

Discretionary revision (which the author can choose to ignore)

Page 3, line 18
Authors response: The text was revised.

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

Authors response: The text was revised.

Authors response: The text was revised.

Authors response: The text was revised.

Authors response: The text was revised.

Authors response: The text was revised.

Authors response: The text was revised.

Authors response: The text was revised.
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.

Authors response: The text was revised.

Minor essential revision
Page 6, line 11

Current text
Fortunately non

New text
Fortunately, none

Authors response: The text was revised.

Minor essential revision
Page 6, line 23

Current text
For stage II ulcers…

New text
For stage II ulcers…

Authors response: The text was revised.

Discretionary revision (which the author can choose to ignore)
Page 9, line 26
Using a random number table, we performed a second analysis considering only one ulcer per patient, which included 83 ulcers in 83 patients.

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

**Authors response:** The text was revised.

Minor essential revision
Page 10, line 4

Current text
8.27

New text
8/27

**Authors response:** The text was revised.

Discretionary revision (which the author can choose to ignore)
Page 11, line 15

Current text
…rationale…

New text
…rational…

**Authors response:** The text was revised.

Minor essential revision
Page 11, line 27

Current text
…ischial…

New text
…ischial…

**Authors response:** The text was revised.

Minor essential revision
Page 12, line 13

Current text
…prelude…

New text
…preclude…

**Authors response:** The text was revised.
Minor essential revision
Page 13, reference 5
Fix missing space
Authors response: The text was revised.

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
Authors response: The text was revised.

Minor essential revision
Page 15, reference 22
Fix spelling “Compbell MJ” versus “Campbell MI”
Authors response: The text was revised.

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

New text
Soc
Authors response: The text was revised.

Discretionary revision (which the author can choose to ignore)
Page 16, reference 33
Check spelling
Authors response: The text was revised.

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.
Authors response: The tables were revised.

Minor essential revision
Page 19, title for table 2

Current text
...phenytoin...

...phenytoin...
New text
…phenytoin…

*Authors response:* The text was revised.

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.

*Authors response:* The table 4 was revised.

Minor essential revision

Figure 2 overlies and obliterates the title for figure 2.

*Authors response:* The figure title was deleted from the figure file.

Minor essential revision

Figure 3 overlies and obliterates the title for figure 3.

*Authors response:* The figure title was deleted from the figure file.

*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