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BMJ 1995;310:1040-1041 (22 April)

Papers

Randomised clinical trial of ultrasound treatment for pressure ulcers

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One in four Dutch doctors and supervisory nurses in nursing homes thinks that ultrasound treatment is effective for pressure ulcers.[1] McDiarmid et al found positive results only in a subgroup of patients with infected ulcers.[2] We performed a placebo controlled trial of ultrasound treatment for pressure ulcers.

Patients, methods, and results

We randomly assigned 88 patients (median age 81) in 12 nursing homes, to genuine or sham (detuned) ultrasound treatment for stage II pressure ulcers (partial thickness skin loss or worse). Randomisation was done in blocks of four after stratification by nursing home and according to whether muscle was affected (16 patients, yes; 72, no) and ascorbic acid supplements were being given (43 patients, yes; 45, no).

The ultrasound devices had 20 codes randomly divided over the two treatment options. Each patient was assigned a treatment code and treated five times weekly over 12 weeks, or until

complete healing of the ulcer. The manufacturer checked the power output of the ultrasound devices every three months. The maintenance of double blind conditions was checked two and 12 weeks after randomisation. For each patient we chose one ulcer, preferably on the trunk. Patients taking systemic glucocorticoids were excluded. Nursing care consisted of identical water beds, three hour repositioning, and once daily gentle cleansing of the wound with saline, enzymatic or surgical debridement being performed when indicated. Ulcers were covered with paraffin and hydrophilic gauze. We measured 60 covariables, varying from age and mobility to serum zinc concentrations, at baseline. We took colour slides at baseline and after 1, 2, 4, 6, 8, 10, and 12 weeks. The trial was approved by the ethics committee of the University Hospital of Maastricht.

Mean weekly changes in outcome variables of ultrasound treatment for pressure ulcers (intention to treat analysis)

	Ultrasound* (n=45)	Sham (n=43)	Ultrasound minus sham	Adjusted difference (95% confidence interval)+
Surface reduction				
cm^2	0.18	0.31	-0.13	-0.12 (-0.30 to 0.06)++
%	22.91	13.82	9.09	8.27 (-4.34 to 20.88)
Healing velocity (cm)	0.18	0.13	0.05	0.05 (-0.05 to 0.15)
Volume reductionsection				
ml	-0.29	0.42	-0.71	-0.72 (-1.32 to 0.12)
%	-4.12	15.84	-19.96	-17.41 (-57.85 to 23.03)
Overall clinical assessments from slides:				
Improvement in report mark(parallel to)	0.71	0.46	0.26	0.22 (-0.21 to 0.64)
Clinical improvement (%)@	27.40	16.51	10.90	9.15 (-3.47 to 21.77)

*Frequency 3.28 MHz, pulse duration 2 ms, pulse repetition frequency 100 Hz, spatial average temporal average intensity 0.10 W/cm^2, beam non-uniformity ratio <4, effective radiating area 4 cm^2.

+Adjusted for 60 covariables clustered in eight clinically cogent clusters.[3]

++Power to detect weekly difference of 0.2 cm^2 or larger is 71% ((alpha)=0.05; one tailed test).

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^Measurements available for 11 and 14 patients in the ultrasound and
sham groups respectively.[4]
||Report marks were scored on a scale from 1 (bad) to 10 (excellent).
@Scored on a scale from -100% to 100%.
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The table summarises the trial outcomes. We used the slides to measure changes in surface area and in a clinimetric index rated by an expert panel. We avoided measurement bias by working blind to treatment and time of follow up. After 12 weeks 40% (18/45) of ulcers in the ultrasound group and 44% (19/43) in the sham group were closed. Wound survival analysis (Kaplan-Meier) did not show significant treatment differences (p=0.61, log rank test, one tailed). A per protocol analysis showed that outcomes were almost identical in a subgroup of 64 patients who had no other interventions, whose compliance with treatment was at least 80%, and whose measurements were unproblematic. Whether patients were to be excluded from the analysis was decided before the treatment code was broken.

The number of baseline prognostic covariables precluded the use of common multivariable techniques. We therefore grouped the covariables into eight clinically cogent clusters and used the clusters to control for confounding.[3] For example, wound status had three values (bad, normal, good) depending on whether muscle was affected, the age of the ulcer, the estimated time for closure, and the median report mark of the panel. Cut off points and the clusters were decided before the treatment code was broken. The influence of loss to follow up (11 patients) was estimated in a sensitivity analysis in which the trend of each drop out was extrapolated using the sham group trend (reported here), the patient's treatment group trend, and deletion (omitting such patients from the analysis).[5] Results of all analyses were almost identical.

Results in our subgroup of 75 patients with infected ulcers did not confirm the positive results of McDiarmid et al. For infected ulcers we found no treatment differences in surface reduction and the clinimetric index. After 12 weeks 39% (15/38) of ulcers in the ultrasound group and 41% (15/37) in the sham group were closed. Kaplan-Meier analysis did not show significant treatment differences (P=0.46, log rank test, one tailed).

Comment

A problem with testing ultrasound treatment is the large number of treatment characteristics. After consulting experts and reading published work we selected parameters with the highest chance of success, but we could not show that ultrasound treatment was clearly beneficial. This finding may also indicate the low therapeutic potential of other forms of ultrasound treatment for pressure ulcers.

This work was supported by a grant (900-561-036) from the Netherlands Organisation of Scientific Research. We thank Henriette van Houtem, Marleen Palland, Hilde Sielhorst, Ingeborg Poorterman, Pieter Wolters, Jan Meyers, Rob Castermans, Jan van der Heijden, Andre Knols, Els van der Meulen, Richard Allman, Lex Bouter, Martien van Dongen, Jo Houben, Frans Jongsma, Jos Kleijnen, and Annemie Mordant for their help and advice. We thank Uniphy (Eindhoven) and Lopital (Oisterwijk) for supplying the ultrasound devices and

the water beds respectively.

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(Accepted 31 January 1995)

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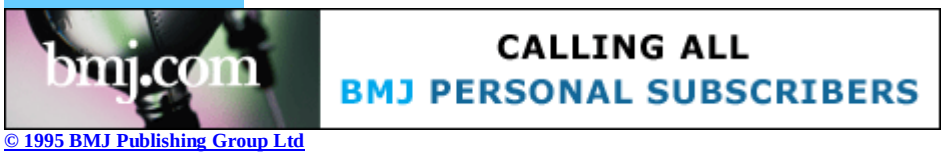

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