Pressure Relief With Visco-Elastic Foam or With Combined Static Air Overlay? A Prospective, Crossover Randomized Clinical Trial in a Dutch Nursing Home

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Abstract: *Objective*. Evidence of the best mattress for preventing pressure ulcers is not conclusive. In a single center, prospective, crossover trial on pressure ulcer incidence in nursing home residents, a static air overlay mattress, without a pump, on top of a visco-elastic foam mattress was compared with a visco-elastic foam mattress alone. *Methods*. The study was performed using a randomized crossover design. Forty-one patients with a score of 19 or lower on the Braden scale, but with no pressure ulcer at the start, were divided into 2 groups; 21 patients received a visco-elastic foam mattress (control group) and 20 patients a static air overlay on top of a visco-elastic foam mattress (intervention group) for a period of 6 months. In the second (crossover) period of 6 months, 19 patients participated in each group. Patients were checked weekly and, only when signs of development of a pressure ulcer were present was treatment altered to reposition patients according to the nursing home pressure ulcer protocol. No statistically significant differences were noted between the 2 groups with regard to age, gender, or Braden scale score. *Results*. Of 41 patients, 3 died and were unable to participate in the crossover period, 8 patients (22.2%) developed a category 2 or higher pressure ulcer on a visco-elastic foam mattress (control group) and 2 (5.2%) on a static air mattress (intervention group)($P = 0.087$). There was a difference regarding pressure ulcer incidence between patients with a very low Braden score between 6 and 12, and patients with a mean score between 13-19. Out of 8 patients, in the 2(25%) who developed a pressure ulcer on a foam mattress, the ulcers showed no signs of healing. In the static air group all pressure ulcers healed by normal treatment according to a standardized pressure ulcer treatment protocol. *Conclusions*. In this small study, static air overlay mattresses provided a better prevention than visco-elastic foam mattresses alone (5.2% vs 22.2%). The Braden scores of the patients in both groups did not change during the 6-month test. The decision to use repositioning only when there were signs of a pressure ulcer is acceptable when a static air overlay is in position. The 22.2% incidence of pressure ulcers in the foam group, however, may stress the need to continue repositioning when using this type of mattress.

Key words: prevention, pressure ulcer, visco-elastic foam, static air overlay

Pressure-relieving mattresses are commonly used for prevention and treatment of pressure ulcers (PUs). To reduce the risk of PUs, clinicians and nurses may use support surfaces to redistribute pressure over a larger surface area of the patient's body. Despite their widespread use in daily practice, there is, in fact, little scientific evidence supporting the use of these systems, except expert opinion. By 1984, it was already suggested that a cold foam mattress provides better PU prevention than a standard hospital mattress.[1-3] Therefore, for many years, in a number of clinics and long-term care settings, standard 120-130 mm thick hospital mattresses (density foam 40kg/m2) were replaced by cold foam mattresses.[1-3]

In 2002, the Dutch Institute for Healthcare Improvement (CBO) guideline *Prevention and treatment of pressure ulcers* was revised.[4] Based on studies by Defloor,[5] the guideline advised to change the standard of care to a visco-elastic foam mattresses instead of a cold foam mattress.

Cold foam mattresses are made of polyether foam, an elastic foam composed of many very small closed air cells, that recovers its original shape quickly after compression. Visco-elastic foam mattresses are made of polyurethane foam, an elastic foam that consists of many open-air memory cells. When a patient is in the supine position the foam transforms its shape in a few seconds, which is called envelopment.

Until 2002 the authors of this study used a cold foam mattress in De Naaldhorst, a nursing home in Naaldwijk, The Netherlands. The mattress was used mostly in combination with a static air overlay (Repose, Frontier Therapeutics Ltd, Blackwood, South Wales) when there was a nonblanchable redness present on a patient for more than 6 hours. This time period allowed for a more accurate diagnosis of a category 1 PU. After the Dutch guideline was published in 2002, the new recommendations concerning the type of basic pressure-relieving mattress were implemented. Additionally, guidelines from the National Institute for Health and Care Excellence (NICE), the European Pressure Ulcer Advisory Council (EPUAP), the National Pressure Ulcer Advisory Panel (NPUAP), and the CBO guideline, state that using only a preventive mattress is not enough for adequate PU prevention. Universal guidelines also promote repositioning in bed every 3 hours (day time) or every 4 hours (night time) as a standard procedure for patients at risk.[6-8] In the PU protocol of De Naaldhorst however, repositioning is only started after development of a PU of category 1 or higher. This is because the workload of repositioning is very high and there is less evidence for a standard inclusion of repositioning. In a nursing home, PU prevention is important not only because of the frailty of the population, but also because PUs considerably reduce residents' quality of life. Unfortunately, more than 20% of patients in Dutch nursing homes still develop a PU during their stay.[9] Therefore, in the Netherlands, the prevalence of PUs has become an official indicator of quality of care in nursing homes.

Every April since 1998, Maastricht University (Maastricht, The Netherlands) conducts the International Prevalence Measurement of Care Problems (LPZ), including PUs in hospitals, nursing homes, and home care organizations.[9] The nursing home De Naaldhorst participates structurally in this LPZ measurement. At the time of the present study, 150 patients resided in De Naaldhorst, with a mean age of 83 years, and were admitted due to complex somatic and/or psycho-geriatric problems. After changing the PU protocol and introducing the standard visco-elastic mattresses (Duosmart, Kabelwerk Eupen, Eupen, Belgium) between 2002-2004, the prevalence of PUs category 2 and higher rose 4.1% to 12.4%. During the same period, the nursing home was involved in a randomized clinical trial of the effectiveness of a cold foam mattress vs the same mattress combined with a static air overlay. Data analysis of this study showed a better result for patients lying on the overlay (4.8% vs 17.1%, category 2 or higher).[10] Data of the LPZ also showed that repositioning is used as a standard of care in only 18%-20% of nursing homes in the Netherlands, due to the increased work load of the nursing staff and the wish to avoid the disturbance of patients during their sleep. In the aforementioned study,[10] repositioning was also only performed after development of a PU and it appeared that, even then, a low percentage of PUs occurred when patients were lying on a static air overlay.

Taking into account the issues of an observed increase of PU prevalence after the start of using visco-elastic mattresses alone and the strategy regarding the application of repositioning, the authors wanted to study the efficacy of additional static air overlay mattresses upon visco-elastic mattresses. It is not possible to change from a visco-elastic mattress to a static air mattress alone because static air mattresses are only available as an overlay type.

Just before the start of this study, an additional search in Medline and CINAHL from January 2001-September 2006 was performed, using the following Mesh terms:

Keypoints
- More than 20% of patients in Dutch nursing homes develop a PU during their stay.[9]
- Therefore, in The Netherlands, the prevalence of PUs has become an official indicator of quality of care in nursing homes.
- The aim of this study was to evaluate the clinical efficacy of a combination of a standard 15 cm visco-elastic foam mattress (Duosmart, Kabelwerk Eupen, Eupen, Belgium) with a static air overlay mattress (Repose, Frontier Therapeutics Ltd, Blackwood, South Wales) vs a standard 15 cm visco-elastic foam mattress alone in preventing PUs.

"prevention of pressure ulcers," "pressure ulcer," "visco-elastic foam mattresses," and "static air mattresses." No studies comparing visco-elastic foam mattresses and static air overlay mattresses were found. Moreover, it was expected that, by using a static air overlay, the frequency of repositioning might be lowered in this case as well. Therefore, the aim of this study was to evaluate the clinical efficacy of a combination of a standard 15 cm visco-elastic foam mattress with a static air overlay mattress vs a standard 15 cm visco-elastic foam mattress alone in preventing PUs.

Methods

A single center, prospective, crossover, randomized clinical trial was performed. The crossover design was based on the aim to perform the total study in 1 nursing home so that all data could be collected by 1 researcher. Moreover the authors wanted all patients to receive the same treatments for the same time periods. This type of design has 2 advantages: 1) the influence of confounding covariates is reduced because each crossover patient serves as his or her own control, 2) crossover designs are statistically efficient and so require fewer subjects than noncrossover designs. Selected patients were asked to participate for 1 year (6 months on each type of mattress).

The first cohort started for 6 months on a visco-elastic foam mattress only (control group) and for the next 6 months on a static air overlay mattress placed on top of a visco-elastic foam mattress (intervention group). The second cohort started for 6 months on a static air overlay mattress placed upon a visco-elastic foam mattress, and for the next 6 months on a visco-elastic foam mattress only.

Inclusion criteria for patients were: age > 65, a Braden score between 6 and 19, and informed consent of the patients or their representatives in case of dementia or other mental disorder. Patients were only excluded if they had an existing PU. Forty patients were required to detect a clinically relevant reduction of the incidence of PUs from 12% to 4% with an α of 0.05 and a power of 0.80. The Braden scale was used to assess the risk of PUs.[11] This scale measures PU risk by assigning scores from 1 to 4 regarding mental and physical condition, activity, mobility, and incontinence. (Each category is rated on a scale of 1 to 4, excluding the 'friction and shear' category, which is rated on a 1-3 scale, for a possible total of 23 points.) The maximum score of 23 indicates no risk of PU development, and the minimum score of 7 indicates a high risk of PU development. A score of 13-19 indicates a medium risk for PUs, and a score of 7-12 indicates a high risk.[11]

Patients were randomized into 2 groups using numbered envelopes. Group A was the control group, receiving a standard visco-elastic foam mattress, and group B was the intervention group, receiving a combination of a standard visco-elastic foam mattress with a static air overlay.

When out of bed, all patients sat on a static air pillow. In compliance with standard PU protocol at De Naaldhorst, study participants did not receive repositioning at night unless a category 1 PU developed. Patients' skin was inspected weekly to assess the possible occurrence of a skin lesion. Patients were evaluated using the Braden scale at the beginning of the study and after 6 months. During the intervention period, the primary outcome parameter was the development of category 2, 3, or 4 PUs (EPUAP-classification[7]). Category 1 was excluded because of the inconconclusiveness of the diagnosis.

In this crossover design, transfer to another type of mattress was carried out after a period of 6 months. All included patients, except 3 who died, participated in the second part of the study. Subsequently, both groups

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Table 1. Demographics of all patients.

Characteristics at baseline	Control Group (n = 21)	Intervention Group (n = 20)	*P*-value
Age in years	80.8	79.1	$P = 0.243$
Gender (females)	18	14	$P = 0.224$
Disease (dementia)	18	16	$P = 0.697$
CVA	3	4	
Braden first period score 6-12	14	11	$P = 0.530$
score 13-19	7	9	
Died in first period*	2	1	$P = 1.00$
Died in second period	0	2	$P = 0.486$
Braden second period score 6-12	13	10	$P = 0.508$
Braden second period score 13-19	6	9	

*Only 1 of the deceased patients developed a pressure ulcer during participation.
Table 1 shows no significant differences were found between both groups, although in group 1 more patients were female, and more patients had a very low Braden score, indicating that in the intervention group there were more pressure ulcer-prone patients.

of included patients were followed for a period of 12 months. The Medical Ethical Committee of the Reinier de Graaff Hospital in Delft, The Netherlands approved the study. At that time there was no obligation to take up the study in the trial register.

Statistical Analysis

All statistical analyses were performed using SPSS 17.0 for Windows (SPSS Inc, Chicago, IL). Differences were tested with a 2-sided Fisher exact test for categorical variables and Student's *t* test for continuous variables. Patients who died during the first period were included in the analysis of the first 6-month period but not of the second. Patients who died during the second 6-month period were included in the analysis of the second period.

Results

Forty-one patients were included at the start of the study, of which 38 were able to participate in the second crossover part of the study. The baseline characteristics of the patients are shown in Table 1. In total, 5 patients died during the study period (3 in the first 6-month period, and 2 in the second). In all cases, the patient's death had no relation with the study activities. Only one of the patients developed a PU, but died acutely of a heart attack. The causes of death of the other 4 patients during the trial were dehydration (n = 3) (caused by patients' refusal to drink fluids while still in the nursing home), and pneumonia (n = 1).

Keypoints

- Eight patients in group A developed a PU, 5 of which were in the heel region.
- In group B one ulcer occurred in the pelvic region and 1 on the heel. The majority of the PUs (n = 8) developed when patients had a Braden score lower than 14; the other 2 patients had scores of 14 and 15.
- All PUs that developed during the first 6-month study period were healed before the mattress was changed for the second 6-month period.

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All PUs that developed during the first 6-month study period were healed before the mattress was changed for the second 6-month period. Two patients using viscoelastic foam mattresses developed category 3 PUs and had to be transferred onto a low air loss bed, according to protocol, due to deterioration of their wounds. There was no reason to change the mattresses for all other patients. Wound healing was successful after starting standard wound care protocol. Because of nonblanchable redness, repositioning was started in group A for 9 (22.5%) patients and in group B for 1 (2.5%) patient ($P = 0.014$). Confidence interval related to the difference between the 2 groups was 1.325% till 91.887%.

Table 2. Incidence of pressure ulcers (category 2 and higher) per condition.

		Visco-elastic foam mattress (n = 40)*			Visco-elastic foam mattress with a static air overlay mattress (n = 39)**			*P*-value
Total amount of pressure ulcers		8	Location		2	Location		
			Pelvic Region	Heel		Pelvic Region	Heel	
Category	2	6	2	4	2	1	1	*P* = 0.087
	3	2	1	1	0	0	0	
	4	0	0	0	0	0	0	
Repositioning (yes)		8			1			*P* = 0.014

*21 first period and 19 second period of the study
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Table 2 shows that the PU incidence in the intervention group was lower than in the control group (2 vs 8 [5.2% versus 22.2%]; *P* = 0.087). The confidence interval related to the difference between the 2 groups was 0.92% till 23.4%.

Keypoints

- Current international and national guidelines advise repositioning every 3 or 4 hours.[4-7]
- The results of this study support the policy to use a static air overlay mattress without repositioning.
- However, the results of the control group confirmed the necessity of repositioning when using a visco-elastic foam mattress, which stresses the importance of following the international guidelines.[4,6-8]

Discussion

The aim of this study was to evaluate the clinical efficacy of a combination of a standard 15 cm visco-elastic foam mattress alone vs a standard 15 cm visco-elastic foam mattress with a static air overlay on the incidence of PUs in nursing home residents. In this study, a visco-elastic foam mattress resulted in a higher risk for developing a PU (22.2%) than when this mattress was combined with a static air overlay (5.2%). In spite of the power analysis, there was not a statistical significance ($P = 0.087$).

When signs of nonblanchable redness are evident, the results demonstrate a reduction in the development of category 2 or higher PUs when using a static air mattress on top of a visco-elastic foam mattress as opposed to the use of a visco-elastic foam mattress alone. An explanation for this difference may be the way of reduction of the perpendicular and tangential component of force at the contact area. On the static air, overlay both strengths (ie, the reduction in the development of category 2 PUs and the reduction of the perpendicular and tangential component of force) are less than on foam. Air mattresses are also able to realize more immersion and envelopment which may result in a better contact of the mattress over a larger skin area.[12]

In 2012, a study by Vermette et al[13] looked at the effects of using an alternating system (one for patients < 200 pounds and one for patients > 200 pounds) vs a static air overlay.[13] Patients were followed for a period of 2 weeks, had a Braden score < 14, and received repositioning every 2 hours. In the alternating group, 6 patients (12%) developed a PU and in the static air overlay group 2 patients (4%) developed a PU. Despite a total of 105 participating patients, no statistic significance was reached ($P = 0.1269$), but the trend is comparable, and in agreement with the current study.

The question that remains is when does repositioning by protocol need to be included? Current international and national guidelines advise repositioning every 3 or 4 hours.[4-7] This recommendation is based on 2 studies with patients lying on a visco-elastic foam mattress.[5,14] There are no randomized controlled trials on other types of mattresses available. A systematic review of pressure ulcer prevention strategies found insufficient evidence to support a specific regimen like a change of position every 2 or 4 hours.[15] It was concluded that an effective repositioning regimen will be indicated by the absence of persistent erythema over bony prominences. If persistent erythema occurs, this may require more frequent repositioning, or as decided in the authors' strategy, only repositioning when there are signs of nonblanchable redness. The results of this study support the policy to use a static air overlay mattress without repositioning. However, the results of the control group confirmed the necessity of repositioning when using a visco-elastic foam mattress, which

stresses the importance of following the international guidelines.[4,6-8]

Limitations

The limitations of this study are mainly related to the crossover design. First, there is the issue of "order" effects, because it could be possible that the order in which the mattresses were used, may have affected the outcome. Second, there could have been a "carry-over" effect between both interventions, which may have confounded the estimates of the intervention effects. Third, because the study in fact was underpowered, replication with a larger number of patients will be necessary to confirm the conclusion that a static air overlay on top of a visco-elastic foam mattress results in a much better prevention of PU than a visco-elastic foam mattress alone.

Conclusion

In this small study, a visco-elastic foam mattress with a static air overlay provided better prevention than a visco-elastic foam mattress alone (5.2% vs 22.2%). The Braden scores of the patients in both groups did not change during the 6-month test. The decision to use repositioning only when there were signs of a pressure ulcer is acceptable when a static air overlay is in position. The 22.2% incidence of pressure ulcers in the foam group, however, may stress the need to continue repositioning when using this type of mattress.

After this study, and also based on the results of a cold foam vs static air mattress study,[10] the institution where the study was conducted chose to make use of a static overlay mattress as part of its standard PU prevention protocol. For every at-risk patient lying on a cold foam or visco-elastic foam mattress, the static air overlay was added as a second step instead of repositioning at De Naaldhorst nursing home.

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