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CLINICAL STUDY

Pressure relief, cold foam or static air? A single center, prospective, controlled randomized clinical trial in a Dutch nursing home

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KEYWORDS
Foam;
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Abstract *Objective:* At present, the evidence regarding the type of mattress that is the best for preventing pressure ulcers is not convincing. In a single center, prospective, controlled trial we compared a static air overlay mattress (no electric pump needed) on top of a cold foam mattress with a cold foam mattress alone on pressure ulcer incidence in nursing home residents.
Methods: 83 Patients were included in the study with a score lower than 12 points on the Norton scale and no pressure ulcer at the start of the study. 42 Patients received a cold foam mattress and 41 patients received a static air overlay on top of that cold foam mattress. Out of bed we standardized the pressure reduction in sitting position by using a static air cushion in both groups. Patients were checked weekly in both groups for pressure ulcers.

Only when there were signs of developing a pressure ulcer grade 2 or higher, repositioning by our nursing home pressure ulcer protocol (PU protocol) was put into practice.
Results: Seven patients (17.1%) on a cold foam mattress and two (4.8%) on a static air mattress developed a pressure ulcer grade 2 or more. There was no difference regarding pressure ulcer incidence between patients with a high risk (Norton 5—8) and patients with a medium risk (Norton 9-12). In 5 out of 7 patients who developed a pressure ulcer on a foam mattress the ulcers showed no healing using our PU protocol. In the static air group all pressure ulcers healed by regular treatment according to our PU protocol.

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Conclusions: In this study, static air overlay mattresses provided a better prevention than cold foam mattresses alone (4.8% versus 17.1%). The Norton scores of the patients in both groups did not change during the 6 month trial period. Our decision to use repositioning only when there were signs of a pressure ulcer seems to be acceptable when a static air overlay is in position. However, the score of 17.1% development (incidence) of pressure ulcers in the foam group may stress the need of repositioning when using only this type of mattress.
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Introduction

Pressure relieving systems are commonly used for prevention and treatment of pressure ulcers. To reduce the risk of pressure ulcers support surfaces can be used to redistribute pressure over a larger surface area of the patient's body can be used. The mostly used systems for prevention and treatment of pressure ulcers are: cold foam mattresses, visco-elastic foam mattresses, alternating air mattresses, static air mattresses with or without an electric pump and air fluidized beds. Despite their widespread use in daily practice, there is in fact little scientific evidence supporting the use of these systems except expert opinion. It is suggested that a cold foam mattress is better than a standard hospital mattress [1–3]. Therefore in many clinics and long-term care settings, already for years, standard 12–13 cm thick hospital mattresses (density foam 40 kg/m^2) have been replaced by cold foam mattresses [1–3].

Cold foam mattresses are made of polyether foam. This is an elastic foam consisting of many very small closed air cells. After compression it recovers very quickly its original shape. The foam shows no "memory" behavior like the foam used for visco-elastic foam.

The quality of the mattress depends on the specific gravity of the foam. This can vary from 20 till 55 kilogram/cubic meter. Manufacturers can produce different types of stiffness.

Cold foam mattresses were also used in our nursing home De Naaldhorst in Naaldwijk, the Netherlands.

After1994 no other studies are available about the use of cold foam mattresses to prevent pressure ulcers [4].

Moreover, it is stated that using only a preventive mattress is ineffective for adequate pressure ulcer prevention. Therefore in addition, universal guidelines (NICE [5], EPUAP [6], NPUAP [7], Dutch CBO guideline [8]) promote repositioning in bed every three hours in day time or for four hours at night.

In most guidelines there also is attention for relieving pressure and friction when patients are sitting in (wheel) chairs. Defloor studied which type of pressure reducing chair cushion showed the lowest maximum contact pressure. Static air cushions (Waffle®, Repose®) scored the best in a laboratory test [9].

In nursing home residents prevention of pressure ulcers is very important; not only because of the frailty of this population but also because pressure ulcers considerably reduce quality of life.

Since 1998, the University Maastricht conducts a national prevalence measurement of care problems (called LPZ-measurement), including pressure ulcers, in hospitals, nursing homes, homes for the elderly and home care organizations [10]. These annual measurements have clearly revealed that pressure ulcers in Dutch nursing homes are a relevant and important problem. Therefore, the prevalence of pressure ulcers has become an indicator of quality of care in Dutch nursing homes [11].

Nursing home De Naaldhorst participates structurally in the yearly LPZ-measurement and showed in the period of 1999–2001 a mean overall prevalence of grade 2, 3 and 4 pressure ulcers of 15%.

In this nursing home 150 patients reside, who mostly are very old (mean age 83 years) and have complex somatic and/or psycho geriatric problems.

In the period 1994–2001 all patients were lying on a standard 15 cm cold foam mattress (Silhouette®, Comfortex, Winoma USA).

Furthermore, a pressure ulcer prevention protocol (PUprotocol) was used, mainly based on the Dutch guidelines for prevention of pressure ulcers [8]. Standard in this protocol is a daily check of the condition of the skin, if needed followed by appropriate measures to reduce pressure, e.g. the use of pressure relieving devices at the first signs of nonblanchable redness, extra attention for nutritional status and comorbidity.

However, contrary to the national guidelines, in our pressure ulcer prevention protocol (PUprotocol) repositioning every 3 hours at daytime and every 4 hours at night is not structurally incorporated, because of 2 reasons. First: the interference

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in sleep during night time diminishes the quality of the residents' sleep and second: the associated higher workload of the nursing staff results in higher costs.

Only when other preventive measures like using another type of mattress/cushion and when there are signs of nonblanchable erythema reposition is standard in our PUprotocol.

Siderenko et al. looked at the effects of using a static air overlay on sacral and heel pressure ulcers in a clinical population [12]. One of the conclusions was a 5% development of pressure ulcers, when patients were laying on a static air mattress contrary to a standard hospital mattress (15% on a water mattress and 25% on an alternating mattress).

Based on the study of Sideranko et al and the study of Defloor (both mentioned above) we were very interested to perform a study looking at the efficacy of additional static air overlay mattresses.

The main aim of our study was:

- To evaluate the clinical efficacy of combining a standard 15 cm cold foam mattress with a static air overlay mattress versus a cold foam mattress alone in preventing pressure ulcers.

Methods

A single center, prospective, controlled randomized clinical trial was performed in De Naaldhorst in the period March 2002 until October 2004.

All patients living in our nursing home with a Norton score below 13 at the start or during the study were asked to participate.

Inclusion criteria for patients were: age >65, a Norton score between 5-12 and informed consent of the patients or their representatives in case of mental disorders. The only exclusion criterion was a pressure ulcer in the previous 6 months.

To detect a clinically relevant reduction of the incidence of pressure ulcers from 10% to 2.5% with a statistical safeguard of α 0.05 and a power of 0.80, we calculated that 38 patients were needed in each group.

The Medical Ethical Committee of the Reinier de Graaf hospital in Delft approved the study.

To assess the risk of pressure ulcers we used the Norton scale [13]. This scale measures pressure ulcer risk; scores range from 1 to 4 regarding items like mental and physical condition, activity, mobility and incontinence. The maximum score is 20 (no risk at all) and the minimum score is 5. A score lower than 14 indicates patients at risk for pressure ulcers. (a score of 9—12 indicates a medium risk and 5—8 a high risk).

Randomization into two groups was performed after informed consent using numbered envelopes:

A. a control group receiving a standard cold foam mattress.
B. an intervention group receiving a combination of that mattress with a static air overlay.

When out of bed, all patients were sitting on a static air pillow following the institutional PUPP. At night, nobody received repositioning conform this PUprotocol.

Subsequently, both groups of included patients were followed for a period of 6 months.

A weekly inspection of the skin to assess the possible occurrence of a skin lesion was done by an independent nurse. The Norton scale was registered for every patient at the start and the end of the observation period.

During the intervention period, the primary outcome parameter was the development of grade 2, 3 and 4 pressure ulcers (EPUAP-classification [9]) at the heel or in the sacral/hip region. No repositioning was allowed before development of a grade 2 pressure ulcer.

Statistical analyses

All statistical analyses were performed using SPSS 15.0 for Windows (SPSS Inc., Chicago, IL USA).

Results

Eighty-three patients were included, 41 received a cold foam mattress (control group) and 42 a static air overlay mattress upon the cold foam mattress (intervention group). The baseline characteristics of the patients in both groups are shown in Table 1.

In total 9 patients died (5 in the cold foam group and 4 in the static air group) during the study period. In all cases, there was no relation with the study activities. None of the patients who died developed a pressure ulcer.

Table 1 shows that at the start of the study more patients in the static air group had a very low Norton score, indicating that in the intervention group there were more pressure ulcer prone patients. No further relevant differences were encountered between both groups.

Table 2 shows that the pressure ulcer incidence in the intervention group was lower than in the control group (2 versus 7; $p = .088$ Fisher's Exact Test). The confidence interval related to the difference between the two groups varied from 1.3% to 25.9%.

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Table 1 Demographics of all patients ($N = 83$).

Patients	Cold foam (control group) (41)		Static Air + Cold foam (intervention group) (42)	
Characteristics at start study	N	N%	N	N%
Age in years (mean ± SD)	83.1 ± 7.86		81.1 ± 8.37	
Gender (females)	34	82.9%	33	78.6%
Norton 5-8 at start of study	22	53.7%	26	61.9%
Norton 9-12 at start of study	19	46.3%	16	38.1%
Diagnoses				
Dementia	31	75.6%	31	73.8%
CVA	4	9.8%	8	19.0%
Rheumatoid arthritis	0	0.0%	1	2.4%
Encephalopathy	1	2.4%	0	0.0%
m. Parkinson	1	2.4%	1	2.4%
Diabetes	1	2.4%	0	0.0%
Arthrosis	1	2.4%	0	0.0%
Hip fracture	1	2.4%	1	2.4%
COPD	1	2.4%	0	0.0%
Died during study[a]	5	12.2%	4	9.5%
Norton 5—8 at end of study	21	58.3%	26	68.4%
Norton 9—12 at end of study	15	41.7%	12	31.6%

[a] None of the died patients developed a pressure ulcer during participation.

Five patients on the cold foam mattress showed progression of the ulcers to grade 3 or 4 pressure ulcer and had to be transferred onto another type of bed (low air loss), while two patients with a grade 3 were treated by standard care by PUprotocol on the cold foam mattress with a good healing after standard care with additional repositioning every 3—4 hours.

The 2 on the static air mattress were both treated successfully as well with standard care by protocol on the static air mattress including additional repositioning every 3—4 hours.

Discussion

The main aim of this study was to evaluate the clinical efficacy of a combination of a standard 15 cm cold foam mattress with a static air overlay mattress versus that cold foam mattress alone on the incidence of pressure ulcers in nursing home residents.

Table 2 Number of patients who developed a grade 2, 3 or 4 pressure ulcer in the six month observation period.

	Cold foam (control group)		Static air + cold foam (intervention group)	
Norton	5—8	9—12	5—8	9—12
Grade 2	0	2	0	1
Grade 3	4	1	1	0
Grade 4	0	0	0	0

In this study 4.8% pressure ulcers occurred in the static air group and 17.1% in the cold foam group, which means that the cold foam mattress only appears to be associated with a higher risk for development of a pressure ulcer than combining a foam mattress with a static air overlay.

The results suggest a rather clear relationship between the type of mattress and the pressure ulcer risk, which was significant at $p > .10$.

After our study we performed an additional search in Medline and Cinahl over the period January 2001—September 2009 to look for studies comparing cold foam mattresses and static air overlay mattresses (Mesh terms: prevention, pressure ulcer, cold foam mattresses, static air mattresses). No studies were found.

Therefore we advise to perform a larger study to assess the reproducibility and significance of our findings.

Taking every individual patient into account, it is very difficult to make a choice for a special type of pressure relieving mattresses. In the last Dutch guideline of 2002 no special advises for different types of patients are recommended as well. One of the most important reasons for this is the fact that the effects of pressure reduction are based on studies with mainly young and healthy people [8].

In the recently published guidelines of the NPUAP/EPUAP (September 2009) again no special advises are stated that help us to make a tailor-made choice [14]. Hopefully future studies will provide more specific guidance on this.

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An interesting finding of our study was that the results seem to support our policy to use a static air overlay mattress without repositioning at day or night time.

Of course it remains an ethical question whether we may take up in our PUprotocol: *no repositioning*.

Especially because most international PU guidelines as well as our own national guideline incorporate repositioning as an essential preventive measure. But there is more. Measurements for prevention are based on two items: relieving pressure by limiting the time of pressure, but maybe even or more important relieving pressure by enlargement of the area. If we look to the evidence for the effect of repositioning, most evidence is based on studies by Defloor and Vanderwee [9,15].

They showed that even when repositioning is used, 9–16% of the patient developed a pressure sore grade 2 or more.

In this study we found an incidence of 4.8% without repositioning. Maybe our choice for just using enlargement is enough on this type of static air mattresses. Nevertheless further studies are required to conform our preventive strategy in patients laying on static air mattresses and to provide more evidence for the value of using repositioning during the use of different types of mattresses.

Moreover, the results of the control group in our study in fact stressed the necessity of embedding continuous repositioning again in our PUprotocol when using a cold foam mattress alone.

Based on this study, however, we decided to change our PUprotocol in another way. When non-blanchable redness of the skin is noticed by the nursing staff, additional pressure relief by using a static air overlay has become a standard procedure now.

This study was performed without conflicts of interest.

We thank the director as well as the medical and nursing staff of the Naaldhorst in Naaldwijk for making this study possible.

Conflicts of interest

The study and writing of the article is done without any financial support by a company. The companies are not informed before, during or after the study and writing of the article.

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