Clinical Rehabilitation 2003; 17: 488-492

The Use Of A New Overlay Mattress In Patients With Chronic Pain: Impact On Sleep And Self-Reported Pain

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Objective: To evaluate the use of an air flotation mattress overlay in patients with chronic pain. **Design:** Four-week prospective AB design. **Setting:** The mattress overlay was used in a community setting. **Subjects:** Adult patients attending an outpatients clinic in a department of rheumatology, with chronic pain plus sleep problems, or pain sufficient to disturb sleep. **Interventions:** An inexpensive low-pressure inflatable mattress overlay (Repose[™]), which is readily portable and has no electrical supply, was introduced to the patients. They were encouraged to use the support surface every night. **Main outcome measures:** The primary outcome was measured by self-reported changes in sleep quantity and frequency of sleep disturbance. Secondary outcomes were self-reported changes in pain and use of analgesia, verified by medical notes. **Results:** Nineteen female patients (mean age 61 years) completed the study. At baseline, mean length of sleep time was 3.8 h, with mean of 4.9 interruptions of mean 25.3 min: week 4, mean sleep time = 6.4 h, with a mean of 2.3 interruptions for mean 14.2 min (all measures p < 0.001). At baseline, median pain during the day was 6 and at night-time was 7; by week 4 a reduction in pain was reported both for the day (median = 5) and the night (median = 5) (both p < 0.001). Thirteen patients reported a reduction in the use of analgesia during the study. **Conclusions:** In this pilot study of a new mattress overlay, statistically significant improvements in sleep and pain were noted over a four-week period.

Introduction

Individuals with chronic pain can experience a range of additional symptoms including depression, fatigue and decreased overall physical functioning but sleep disturbance has been cited as a major problem.¹ The prevalence of sleep disturbance has been reported to be very high in patients with chronic pain (70% complaining of sleep problems)² with disturbance due to pain the most important sleep problem they encounter.³ The relationship between pain and sleep is complex and bi-directional. Pain slows the onset of sleep and contributes to sleeping badly or not at all,⁴ while the consequences of insufficient sleep can have a negative effect on pain management.⁵,6 For those with rheumatoid arthritis (RA) the consequences of living with pain and disturbed sleep may be poor functional ability,7 whilst their health status and quality of life is known to be 'substantially impaired.'8

The cumulative effect of chronic pain and disability affects not only the individual but also their partners/carers.⁹ Patients live with a range of additional symptoms related to their condition(s), for example, those with RA are confronted with far reaching physical problems that can threaten independence.¹⁰ For many of the elderly population living in

the community, pain in the joints and locomotor disability are common problems^{11–13} often caused by osteoarthritis^{12,14}

This condition is not curable, and most elderly people with symptoms are told that they have to 'learn to live with it.'9 In terms of behavioural management, advances in technology that can result in a range of aids to daily living are welcomed by those living with chronic pain.¹5 One potential method to reduce pain that has been investigated in patients with back pain¹6 is to provide an optimal mattress. This study evaluates the use of an air flotation mattress overlay over a four-week period in patients suffering from chronic pain.

Method

This was a four-week prospective, single-centre, 20-patient, AB design using an air flotation overlay in a community setting. The sample size was not determined statistically as the results of this evaluation will be used to calculate appropriate power for a subsequent study. The participants provided data based on their recent experiences with their own mattress (A), and in the second section (B), participants used the overlay provided every night for four consecutive

RESEARCH

weeks. Assessments were completed at weekly intervals by the same occupational therapist who issued the overlays. Sequential patients who met the inclusion criteria attending an outpatient clinic in the Department of Rheumatology were invited to participate, and written informed consent was obtained. Specific inclusion criteria were: aged 18 years or above, with stable disease, identified as having chronic pain, sleep problems and/or pain sufficient to disturb sleep as noted in their medical notes, with no change in analgesia prescription in the previous month and able to give informed consent. Each participant agreed to use the new overlay on a nightly basis for four consecutive weeks and complete the study data forms.

Mattress Overlay Details

The system used in the evaluation consisted of a low-pressure inflatable mattress overlay, which is inexpensive to purchase, readily portable, needs little maintenance and no electrical supply (Repose™, Frontier Therapeutics Ltd, Blackwood, South Wales). The mattress overlay was developed by the occupational therapy department of the University Hospital of Wales, Cardiff and Vale NHS Trust. The characteristics of the mattress overlay are related to specialized polyurethane materials from which the overlay is made. These materials have multidirectional stretch, are vapour permeable, waterproof and X-ray translucent.

Outcome Measures

Participants were required to complete a short questionnaire at baseline and at weekly intervals on their sleep patterns: usual length of sleep time (in hours), frequency of waking (number of times), length of time usually awake (in minutes), cause of waking (reasons). Pain VAS data were recorded at baseline and at weekly intervals. The VAS scales were anchored with a description that 0 represented no pain, and 10, the maximum, unbearable pain. These validated scales^{17,18} were used to describe pain during the day, during the night, the 'worst' and 'best' levels of pain experienced.

Each patient was asked to list the full range of medication taken with related daily dosage, which was checked against their medical notes, at each assessment. There was no restriction on patients requesting changes to their medication during the study.

At the end of the study period patients were asked to complete a comment sheet that allowed them the opportunity to comment on their experiences using the air flotation overlay.

Statistical analysis

The data were analysed using SPSS version 7.5. Analysis was completed using nonparametric tests, as many of the data were ordinal and skewed from a normal distribution. Analyses included nonparametric one-way ANOVA (Freidman Test). All analyses were two-sided and the 5% level was considered 'significant' in accordance with usual practice.

RESULTS

Study Conduct

A total of 20 patients were successfully recruited to the study. Only one patient did not complete the full four-week evaluation. This particular patient had lived with the consequences of polio for many years, and had adapted to her pain levels by sleeping in a sitting position. After three weeks, her discomfort in sleeping in a bed rather than in a chair resulted in her asking to be withdrawn from the evaluation.

Sample Characteristics

Unusually, all patients included in the study were female: mean age = 61 years (SD 14.24), ranging from 29 to 87 years. Fourteen patients presented with rheumatoid arthritis as the main diagnosis; other conditions were ankylosing spondylitis, cerebral palsy, osteoarthritis, lower back pain, polio and syringomyelia.

Sleep Patterns

At initial assessment, the average length of sleep time per night was 3.76 h, with a mean of 4.89 interruptions for an average of 25 min per interruption. Over the period of the study these figure changed significantly (p < 0.001). The average length of sleep time at week 4 was 6.37 h, with a mean of 2.26 interruptions for an average of 14.21 min (*Table 1*). Patients were asked to identify the reasons for waking during the night. At baseline, all 20 patients listed pain as a reason, either in isolation (n = 8) or in addition to other reasons. At week 4 only eight patients identified pain as a reason for waking.

Pain

Median daytime pain at baseline was 6, median pain at night-time was slightly higher at 7, with median 'worst' levels at 8.5 and median pain levels 'at best' at 5. By Week 4 the median scores on all four measures were statistically significantly lower, with median daytime pain = 5.00, median pain at night-time = 5, median 'worst' pain = 7 and median pain 'at best' = 4 (*Table 1*).

Medication

For 13 of those who completed the study there were changes in the use of analgesia. The reduction in analgesia represented a change of dosage in most cases (e.g., from eight paracetamol per day to six paracetamol per day). The full significance of these data is unclear, as there may be other reasons for the changes that were not noted during the study.

Qualitative Data

Qualitative comments were provided by 18 of the patients who were involved in the study. The most consistent comment related to changes in sleep patterns, reflecting longer periods of sleep without disturbance and the associated benefits to themselves (and in some cases their partners) in terms of energy during the day. One month after the completion of the study, 17 patients had continued to use the overlay of their own volition.

Table 1 CHANGES IN SLEEP AND PAIN SCORES

	Length of sleep (hours) ^a	Frequency of interruptions ^b	Frequency of interruptions (min) ^c	Pain (daytime) ^d	Pain (night-time) ^e	Pain (worst) ^f	Pain (best) ⁹
	Mean (standard deviation)			Median (range)			
Baseline	3.8 (2.1)	4.9 (2.1)	25.3 (13.6)	6 (4-9)	7 (3-9)	8.5 (6-10)	5 (3-6)
Week 1	4.2 (1.7)	4.3 (1.8)	20.8 (13.6)	6 (3-8)	6 (3-8)	8.5 (6-10)	4.5 (3-6)
Week 2	5.3 (1.5)	3.0 (1.4)	16.3 (13.6)	5 (3-7)	5 (3-8)	7.5 (5-10)	4 (3-6)
Week 3	5.8 (1.6)	2.7 (1.5)	15.3 (9.6)	5 (3-7)	5 (3-7)	8 (5-10)	4 (3-6)
Week 4	6.4 (1.7)	2.3 (1.3)	14.2 (9.8)	5 (3-6)	5 (3-7)	7 (4-10)	4 (3-5)

^aANOVA = 52.67, df = 4, p < 0.0009.

b
ANOVA = 48.77, df = 4, p < 0.0009.

e
ANOVA = 49.71, df = 4, p < 0.0009.

 9 ANOVA = 12.18, d^{f} = 4, p = 0.016.

Discussion

This study represents a pilot evaluation of the use of an air flotation overlay in a community setting to aid with sleep disturbance and related pain. The data collected from patients with known pain and sleep problems suggest that this mattress overlay made a substantial difference to many of the patients, with a statistically significant change in sleep patterns and fall in self-reported pain scores. The results from this study will be used to calculate the appropriate sample size for a larger, multicentre trial.

Caution is needed in the interpretation of the data at this stage. Those who participated had experienced chronic pain and related sleep disturbances for many years; the introduction of the mattress overlay to those desperate to change their experience of symptoms could have resulted in either a placebo or Hawthorne effect (as the visits themselves may have resulted in improvements), although the extent of the changes in scores and the reduction in consumption of analgesia indicated that, even if this were the case, the benefits were substantial.

Clinical messages

- Providing this overlay, together with weekly visits, was associated with an increase in sleep and a reduction in self-reported pain.
- Improvements in sleep, reduction in self-reported pain and use of analgesia could impact on health care services at relatively low cost.

Future studies should include more detailed data related to the management of the patients' condition during the study period, in order to be clearer about the attribution of the changes in scores to the mattress overlay rather than any other changes in management that may have brought about similar effects. The use of a validated sleep questionnaire will also be included in the next stage, as well as a more detailed health-related quality of life assessment. Inclusion of male participants in future studies should also be encouraged to help in investigating the generalisability of the findings. Patients living with chronic pain resulting from conditions

such as rheumatoid arthritis and osteoarthritis often rely solely on medication to manage their pain symptoms, although physiotherapy and nutritional status can help in some circumstances. Sustained improvements in sleep could include a reduction in the burden of illness, a reduction in analgesia usage with its associated side-effects, and an increase in length of sleep time. The results from this preliminary work suggest that this mattress overlay may have a role to play in allowing individuals with such symptoms to improve the quantity and quality of their sleep, with an associated reduction in pain, and reduce the risk of side-effects from medication at relatively low cost.

Acknowledgement

The study was funded by Frontier Therapeutics, which manufactures the Repose overlay; royalties are paid to the University Hospital of Wales, Cardiff and Vale NHS Trust where the mattress was first designed. None of the authors have any financial interest in the overlay or its production.

^dANOVA = 37.88, $d^f = 4$, p < 0.0009.

 $^{^{}f}$ ANOVA = 47.48, d^{f} = 4, p < 0.0009.

 $^{^{}c}$ ANOVA = 38.13, d^{f} = 4, p < 0.0009.

RESEARCH

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