Pressure ulcer prevention using an alternating-pressure mattress overlay: the MATCARP project

Objective: The primary objective was to assess the incidence of pressure ulcer (PU) in patients at high risk of PU and lying between 15–20 hours per day on an alternating-pressure mattress overlay (APMO). Secondary objectives were the patient's satisfaction with the comfort of the APMO, patient acceptance of its sound level, and the care team's assessment of its use and the moisture level.
Method: This prospective observational study was conducted in three rehabilitation centres and two nursing homes between June 2016 and March 2017. To be included, patients should not have PU at baseline and present a high risk of PU (Braden score between 10–15). The primary endpoint was the percentage of patients in whom a PU developed over a 35-day period.
Results: A total of 83 patients were included in the study. Neurological disease was responsible for the reduced mobility of 44 (53.7%) patients, 10 patients (12.0%) dropped out (one patient for a serious adverse event (femoral neck fracture) considered not to be related to the APMO, four patients for adverse events, two of which were considered to be related to APMO and five for other reasons, including, in one case, discomfort with the APMO. These patients were considered in the analysis. Over the study period, 1.2% (1/83) (95% confidence interval (CI): 0.03 to 6.53) of patients developed a PU. Patient satisfaction with the comfort of the APMO, patient acceptance of its sound level, and the care team's assessment of its use were considered satisfying for most patients.
Conclusion: Based on the findings of this study of a low incidence of PU in participating patients, the use of an AMPO is recommended in high-risk patients lying for between 15–20 hours a day.
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alternating-pressure mattress overlay • beds • life support system • pressure ulcer • prevention

A pressure ulcer (PU) is a localised injury to the skin and/or underlying tissue, usually over a bony prominence, as a result of pressure, or pressure in combination with shear and friction.[1] PUs are also named pressure injuries,[2] bedsores, pressure sores and decubitus ulcer.

Tissue hypoxia, secondary to excessive and prolonged pressure, is recognised as one of the main causes.[2] The prevention of PUs, which have a multifactorial pathology, requires a global approach.[3–5] In patients with reduced mobility who are in bed or seated for prolonged periods, interventions should aim to reduce both the intensity or duration of pressure.[3–5]

The National Pressure Ulcer Advisory Panel (NPUAP) has proposed a classification for support surfaces for PU prevention.[6] Schematically, the supports can be classified as:

- 'Reactive support surface (air, low-air-loss, foam, air-fluidised, fibre, gel, water): powered or non-powered support surface with the capability to change its load distribution properties only in response to an applied load
- Active support surface: powered support surface, with the capability to its load distribution properties with or without an applied load
- Integrated bed system: a bed frame and support surface that are combined into a single unit whereby the surface is unable to function separately.'[6]

'Non-powered means the support surface does not require or use external sources of energy for operation. Powered means the support surface requires or uses external sources of energy to operate. An overlay is an additional support surface designed to be placed directly on top of an existing surface. A mattress is a support surface designed to be placed directly on the existing bed frame.'[6]

Among the powered active air surfaces, numerous alternating pressure air mattresses or mattress overlays are commercially available for patients who are in bed for prolonged periods (>10 hours per day) and at risk of PU. Cell thickness, flow and inflation/deflation cycle, and physical properties determine their effectiveness.[6,7]

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In a meta-analysis,[7] only two randomised controlled trials (RCTs) comparing dynamic air mattresses with alternating pressure versus standard mattresses were identified. In a fixed effect model, the risk of PU was reduced by an estimated 69% with the alternating pressure dynamic mattress versus standard mattress (risk ratio [RR]=0.31% CI: 0.17 to 0.58). The authors indicate that the risk of methodological bias is considered high. The advantages of alternating-pressure (AP) devices versus constant low-pressure (CLP) devices remain unclear.[7]

The relative effects of different support in reducing PU incidence have been determined in a network meta-analysis (NMA);[8] 65 RCTs enrolling 14,332 patients with all types of support surfaces were included. Even this NMA has some limitations, powered active air surfaces demonstrate statistical superiority on PU incidence with standard mattress (risk ratio=0.42 (CI: 0.29 to 0.63) (moderate certainty of evidence) and with non-powered reactive foam surfaces (risk ratio= 0.64 (CI: 0.42 to 0.96) (low certainty of evidence).[8]

Aim

To meet the requirements of the French authorities, application for reimbursement by national health insurance for a medical device (such as mattresses, cushions), intended for the prevention of PU and help in its treatment, must be supported by observational clinical data.[9] It was in order to meet this requirement that this study was put in place with patients using a specific alternating-pressure mattress overlay (APMO).[9]

The primary objective was to assess the incidence of PU in patients without a PU at baseline, at high risk of PU and lying between 15–20 hours per day on an APMO. Secondary objectives were the patient's satisfaction with the comfort of the APMO, patient acceptance of its sound level, and the care team's assessment of its use APMO and the moisture level.

Method

Design

This was a prospective, non-comparative, observational study with a 35-day follow-up. It was conducted in three rehabilitation centres and in two nursing homes between June 2016 and March 2017. The protocol was written according to the recommendations of the French authorities responsible for medical assessment for reimbursement.[9]

Patients

To be included patients had to fulfil the following criteria:

- At least 18 years-of-age
- At medium to high risk of PU (Braden score between 10 and 15)[10]
- Without PU at the baseline visit
- Sitting in a chair during the day for at least four hours, lying between 15–20 hours per day on an APMO
- Weighing between 40–160kg (manufacturer's specifications).

The patient (or a trusted third party) was informed of the study and gave their consent to participate. Patients were not included if:

- Estimated life expectancy was <6 months
- They presented with malnutrition, defined as follows: for adults <70 years-of-age, weight loss ≥5% in one month, or ≥10% in six months or body mass index (BMI) ≤18.5kg/m^2 (excluding constitutional weakness); for adults ≥70 years-of-age, weight loss ≥5% in one month, or ≥10% in six months, or BMI ≤21kg/m^2, or the Mini Nutritional Assessment (MNA)[11] score was ≤17 (out of a maximum of 30) or albumin <35g/l.[12]

The exclusion of patients presenting with malnutrition has been selected to meet the requirements of the French authorities for reimbursement by national health insurance.[9]

Data collection

The physician assessed the patient at baseline, after which the care team monitored the patient, including his/her skin condition, at least once a day throughout the 35-day follow-up period. A final visit was scheduled on day 35±5 days (or before in the case of drop-out) to record any onset of PU over the 35 days (or before, in the case of drop-out) and findings with regards to the secondary objectives.

At the baseline visit information was collected on: patient demographics (age, sex, weight, height); patient's place of residence (rehabilitation centre, nursing home, long-term care unit); comorbidities (high blood pressure, diabetes, urinary incontinence); medical condition responsible for the situation involving risk of PU; duration of sitting time per day; time spent on the APMO; bed installation (e.g. use of cushions, use of orthotics, use of medical devices for patient positioning); seating (e.g. use of pressure-relieving cushion); patient activity level (no exercise, low, moderate, or high); nursing protocol set-up; number of position changes per day; maximum time between position changes; use of medical devices to prevent PU, and number of bed sheets changes per day.

At the end of the study (day 35), the incidence of PU was recorded (location, area, category according NPUAP classification).[2]

Using a five-point rating scale, secondary objectives were recorded, including patient satisfaction with the general comfort and stability of the APMO, patient acceptance of sound level, and assessment by the care team of the set-up, ease of cleaning, ease of turning the patient, and ease of use in terms of lying-to-seating of the APMO. At the end of the study, the moisture level (using the Braden scale), adverse events, and technical incidents were also recorded.

Pressure-relieving support and management of patients

All patients were lying on an APMO (PM100A EVO, Pharmaouest Industries, France), a low-pressure

Table 1. Baseline characteristics of patients

Characteristics (n=83)	**n (%)**
Age, year, mean (SD)	71.8 (20.3)
Male gender, n (%)	51 (61.5%)
Urinary incontinence, n (%)	80 (96.4%)
Body mass index, kg/m^2, (n=72), mean (SD)	23.7 (5.2)
Braden score, mean (SD)	12.7 (2.1)
Urinary incontinence (n=80)	**n (%)**
Intermittent	12 (15.0%)
Total	63 (78.8%)
Unspecified	5 (6.2%)
Hours in bed per day (n=83)	**n (%)**
15–16	55 (66.3%)
17–18	16 (19.3%)
19–20	12 (14.5%)
Level of activity (clinical judgment) (n=83)	**n (%)**
No exercise	8 (9.6%)
Low	36 (43.4%)
Mild	32 (38.5%)
High	7 (8.4%)
Hours of mobilisation per day (n=40), mean (SD)	0.9 (0.7)
Installation in bed (n=83)	**n (%)**
Use of cushions	52 (62.7%)
Use of orthotics	5 (6.0%)
Medical device for patient positioning	21 (25.3%)
Seating authorised	77 (92.8%)
Using a pressure-relieving cushions when seating (n=77)	74 (96.1%)
Number of changes of position per day (n=77), mean (SD)	4.0 (2.6)
Time between two changes of position (n=61), hours, mean (SD)	5.0 (2.0)
Number of linen changes per day (n=79), mean (SD)	0.6 (0.7)
Disease responsible for condition (n=83)*	**n (%)**
Injury	10 (12.2%)
Multifactorial	20 (24.4%)
Neurologic	44 (53.7%)
Others	12 (14.6%)
History of surgery for pressure ulcer (n=82)	30 (36.6%)

SD—standard deviation; *Three patients had two diseases responsible for their condition

dynamic air mattress overlay, made up of 18 interchangeable and removable cells. The cells are equipped with a low air-loss system to limit condensation and maceration. The mattress overlay is supplied with air by a compressor, which has two modes of operation: dynamic (12-minute alternating cycle) static (for care). Pressure is adjusted manually by adapting the potentiometer to the patient's weight. The compressor is equipped with a pressure sensor that limits the pump operating time to improve patient comfort.

Patients and care teams were instructed in the use of the APMO. The health-care team determined the PU prevention care plan including the general rules on preventing PUs and specific instructions for each patient.

Outcomes

The primary endpoint was the percentage of patients in whom a PU (sacrum, ischium, spine and heels) developed over a 35-day period, of at least category II (according to the National Pressure Ulcer Advisory Panel (NPUAP) classification).[1] At the time of production of the final version of the protocol (dated 28 May 2015), the revised NPUAP, European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (PPPIA) PU category system was not yet published.[2,13]

The secondary endpoints were patient satisfaction with the comfort of the APMO, patient acceptance of the sound level of the APMO, and the care team's assessment of the use of the APMO and the moisture level. Safety was analysed by description of adverse events and technical incidents.

Sample size

Based on the literature data,[14–18] we hypothesised that 7% of patients would develop a PU (sacrum, ischium, spine, heels) at least of category II between day zero and day 35 of the study. With this assumption, we needed 80 patients to demonstrate, with a power of 80%, an upper limit of <20% of the bilateral 95% confidence interval (95% CI) of the percentage of patients with at least one PU (sacrum, ischium, spine, heels) at least of category II. This upper limit of 20% was considered reasonable for an acceptable level of prevention on the basis of the literature data. We therefore planned to include 80 patients.

Statistical considerations

All patients assessed at baseline and with at least a second assessment of their skin condition were considered for analysis. The exact 95% CI was calculated for the primary endpoint. In the case of premature discontinuation of the study, a full assessment of the patients was made and all data collected up until the point of leaving the study, including data for patients who did not complete the study, was used in the final analysis at day 35. This means that the analysis was conducted in intention-to-treat. Secondary endpoint analyses were descriptive.

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Table 2. Patients' opinion on the comfort and sound of level of the alternating-pressure mattress overlay at end of the study (n=83)

	General comfort	Stability	Sound level
	n (%)		
Not at all satisfactory	4 (4.8%)	3 (3.6%)	2 (2.4%)
No satisfactory	8 (9.6%)	9 (10.8%)	3 (3.6%)
Neither satisfactory nor no satisfactory	8 (9.6%)	12 (14.5%)	6 (7.2%)
Satisfactory	57 (68.7%)	57 (68.7%)	46 (55.4%)
Very satisfactory	6 (7.2%)	2 (2.4%)	26 (31.3%)

Table 3. Care teams' opinion on using the alternating-pressure mattress overlay (n=83)

	Set-up	Ease of cleaning (n=83)	Ease of use in terms of patient turnaround (n=82)	Ease of use in terms of lying to seating
	n (%)			
Not at all satisfactory	0	0	0	0
No satisfactory	0	0	5 (6.1%)	0
Neither satisfactory nor no satisfactory	9 (10.8%)	4 (4.8%)	59 (71.1%)	20 (24.1%)
Satisfactory	68 (81.9%)	79 (95.1%)	18 (21.9%)	63 (75.9%)
Very satisfactory	6 (7.2%)	0	0	0

Table 4. Evolution of moisture degree at baseline and at the end of the study assessed by care team (n=83)

Degree to which skin is exposed to moisture (according to Braden scale score)	Baseline	Day 35 (or end of follow-up)
	n (%)	
Constantly moist	35 (42.7%)	36 (43.4%)
Moist	13 (15.6%)	13 (15.6%)
Occasionally moist	22 (26.5%)	15 (18.1%)
Rarely moist	13 (15.6%)	19 (22.9%)

Ethical and regulatory approval

The protocol was approved in July 2015 by the ethics committee CCTIRS [Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé] in accordance with French Law.

Results

Enrolment and baseline characteristics

In total, 83 patients were included in the study. Of these, 10 patients (12.0%) dropped out (one patient because of a serious adverse event (femoral neck fracture) considered unrelated to the APMO, four patients for adverse events (AEs), two of which were considered as related to the APMO, and five patients for other reasons, including, in one case, discomfort with the APMO). Patient participation lasted a for mean of 33.2 days (SD: 10.0). Table 1 summarises the demographic and clinical characteristics at baseline. Patients presented with urinary incontinence in 96.4% of cases (n=80). The physicians considered all patients to be at high risk of PU and gave them scores of between 10–15 on the Braden scale, with the exception of six patients (the Braden score was eight in one patient, nine in one patient, 16 in three patients, and 17 in one patient). All the patients who presented with a minor deviation from inclusion criteria were kept in the analysis (six patients outside Braden scale range, four with malnutrition).

Primary end point

Over the study period of 35 days, 1.2% (1/83) (95% CI: 0.03 to 6.53) of patients developed a PU, at least of category II. A category II sacral PU (1.5cm in diameter) occurred at day 21 in a 78-year-old man suffering from level D12 paraplegia, with a baseline Braden score of 12/23 and who lay on the bed for 19 to 20 hours per day. When the patient dropped out of the study at day 27, the PU was still present. The health-care teams have reported no PU in other locations, such as in the trochanteric area.

Secondary end point: performance

Patients reported a high level of satisfaction concerning the comfort of the APMO. In >80% of cases, patients were 'very satisfied' or 'satisfied' regarding the sound level of the APMO (Table 2). The setting up and ease of cleaning the APMO, as assessed by the care team, showed a good level of satisfaction (Tables 3). Ease of turning the patient was considered as neither 'satisfactory' nor 'unsatisfactory' for 71.9% of patients. The care team considered the changing of the patient's position from lying to sitting as satisfactory in 75.9% of cases. At the end of the study, the moisture component of the Braden scale (ranging from one, 'constantly moist' to four, 'rarely moist') did not change between baseline and the end of the study (Table 4).

Secondary end point: adverse events (AEs)

There were five AEs in five patients over the 35 days:

- A total of three were considered as related to the APMO by the physicians: one with worsening of the patient's general state with the occurrence of a sacrum PU (stage II) leading to drop-out at day 27; one with lower back pain in a patient with a history of lumbar fusion, leading to drop-out at day four; and one patient with back pain caused by the APMO on a dorsal scar leading to drop-out of the patient at day one
- Another two patients were considered as unrelated to the APMO by the physicians: one patient had back and costal pain leading to drop-out at day two; one patient with a femoral neck fracture at day eight

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leading to hospitalisation. The latter was considered as a serious AE.

Secondary end point: technical incidents

A minor technical incident—dysfunction of the APMO that was not rectified for administrative reasons—was reported by the patient and led to drop-out at day 25.

Discussion

There was a low incidence (1.2% (1/83) of PU over the 35-day study. The upper limit of the 95% CI of the percentage of patients with a PU (sacrum, ischium, spine, heels) was less than the pre-specified 20% in the sample calculation, meaning that the main objective was reached.

Comparison of these results with literature data is difficult since the prevalence and incidence of PU depend on the residence of the patients, their degree of disability, the course of disability (acute or chronic stage), prevention methods, and evaluation methods.[19] In the PARESTRY study[17] in high-risk patients using a motorised alternating pressure air mattress in the prevention group, only one in 30 patients (3.03%; 95% CI: 0.54 to 15.32) developed a category II PU. Other comparisons could be made using data on inpatients and data from tests of good methodological quality.[3] In a comparative study in hospitalised patients at risk of PU, the incidence of PUs at 60 days was 10% (10/982) in the group using an alternating pressure mattress.[14] In a study conducted in Belgium in hospitals and in patients using an alternating pressure mattress, the incidence of PUs at 20 weeks was 15% (34/222).[15] In another study in 32 patients with a Braden score <16 (high risk) in a general hospital, the incidence of PUs was 15.8% in patients lying on a double layer air cell support with alternating active inflation, 19.2% in patients coated with a single layer of air cells operating with alternating active pressure, and 37% in patients lying on a standard mattress.[20] In the literature review by Vanderwee et al,[16] all studies considered were conducted in hospitals or in institutions. Depending on the location, the risk of occurrence of PUs, the type of prevention strategy, the type of mattress used as a preventive measure, and the prevalence of PUs varies from 1% to 54%. In patients with spinal cord injuries, the incidence of PUs varies between 25–66%. High spinal cord lesions are more likely to be associated with PUs than low spinal cord lesions.[21]

Although our results are encouraging, it is important to keep in mind that any indirect comparison should be interpreted with great caution, particularly in this context where many factors may influence the occurrence of a PU.

Limitations

The interpretation of our results is subject to some limitations. Firstly, the absence of a control group limits the appreciation of a link of causality between use of the APMO and the occurrence of PU. The high level of risk of PU used to select patients and literature data[14–18] on this type of patient nevertheless suggest that without this type of support the incidence of PU would have been higher.

Secondly, the level of risk of PU and the number of hours spent in bed per day fixed in the participation criteria correspond to the indications laid down by the French authorities in order for this type of APMO to be eligible for reimbursement, in particular for home use.[9] Thirdly, the study could be considered too short in duration, but in high-risk patients a PU can appear in a few hours and a follow-up period of 35 days seemed long enough, although it is likely that there would have been a higher incidence of PU over a longer period. Fourthly, among the study participation criteria, at the request of the national authorities,[9] patients showing signs of malnutrition and/or with a life expectancy of <6 months could not be included, and so patients at particular risk of PU were probably excluded and this may constitute a bias. So, the association of the use of this alternating mattress with low PU incidence occurs in people without malnutrition and this is a limitation to the generalisability of the results.

Conclusion

The data from this study indicate a low incidence of PU in high-risk patients lying for between 15–20 hours a day on an APMO, use of which is therefore recommended in these patients. JWC

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Reflective questions

- Why would you use an alternating-pressure mattress overlay in patients at high risk of pressure ulcer?
- Will the findings presented in this paper change your practice for the management of patients at high risk of pressure ulcer?
- How has this work modified your opinion for your future research in pressure ulcer prevention?

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