Pressure ulcers prevention efficacy of an alternating pressure air mattress in elderly patients: E²MAO a randomised study

Objective: Our aim was to compare Axtair One, an alternating pressure air mattress (APAM), with a viscoelastic foam mattress (VFM) in elderly patients at moderate to high risk of developing pressure ulcers (PUs).
Method: A randomised, controlled, superiority, parallel-group, open-label, multicentre study, was conducted, between February 2012 and March 2015, in nine French, medium- and long-term stay facilities. Eligible patients were aged 70 and over, had no PUs on enrolment, were bedridden for at least 15 hours per day, had reduced mobility, an absent or minimal positioning capability, a Braden score <14, a nutritional status score >12 and a Karnofsky score <40%. The primary endpoint was the appearance of PUs over a 30-day monitoring period. The primary objective was to demonstrate a 50% reduction in instantaneous risk of PUs in the APAM versus the VFM group. Secondary objectives were to determine if preventive care was less frequent in the APAM group, the instantaneous relative risk of PUs (hazard ratio) was constant over time and the comfort experienced was higher in the APAM group and to verify the uniformity of the preventive benefit of an APAM, regardless of the level of exposure to major risk factors for PUs.
Results: We randomised 76 patients (39 in the APAM group and 37 in the VFM group). The groups were comparable on enrolment and throughout the study. The cumulative risk of PUs was estimated at 6.46% [95% confidence interval (CI): 1.64; 23.66] in the APAM group and at 38.91% [95% CI: 24.66; 57.59] in the VFM group, p=0.001 (log-rank test). The adjusted hazard ratio according to the Cox model with four prognostic factors for the appearance of PUs was 7.57 [95% CI: 1.67; 34.38, p=0.009]. Preventive care proved to be equivalent in both groups. The only risk factor significantly associated with an increased risk of PUs was the type of mattress (VFM). The comfort and tolerance perceived by the patients were both high and similar in the two groups. The constancy over time of the preventive benefit of an APAM could not be verified because of the lack of a sufficient number of events (appearance of PUs) in the APAM group.
Conclusion: The APAM was superior to a VFM for preventing PUs in elderly patients, bedridden for more than 15 hours per day, severely dependent, at moderate- to high-risk of PUs, with an instantaneous risk for the appearance of PUs 7.57 times greater in the VFM group than in the APAM group. This study provides descriptive information and evidence for practice.
Declaration of interest: The authors report no conflicts of interest.

pressure ulcers • elderly patients • viscoelastic foam mattress • alternating pressure air mattress

A European study reported a hospital prevalence of category I–IV pressure ulcers (PUs) at 18.1%.[1] A US study conducted for three months on more than 1500 residents of long-stay units reported an appearance rate of category I–IV PUs of 29%; the patients had no PUs on enrolment but were at risk for developing one (Braden score ≤17).[2] Advanced age is identified as a predictive risk factor for PUs and the cumulative presence of risk factors places the elderly person at high risk.[3,4] PUs not only increase morbidity but also mortality in elderly and frail patients. They cause pain and discomfort, cause significant impairment of quality of life and increase health expenditure.[5–10] High-impact preventive measures are recommended, such as assessing and reassessing the risk according to validated scales, adapting prevention to the level of risk (choice of support and frequency of mobilisations), performing skin care, improving nutrition and hydration, training professionals and educating patients.[3,11] Reduction of applied pressure is achieved by either static media (mattress or mattress overlays made of air, water, gel, foam or combined), or dynamic media (alternating pressure air mattress (APAM), mattress overlay, low-air-loss mattress or air-fluidised mattress).[11] International guidelines recommend the use of a viscoelastic foam mattress (VFM) combined with a protocol of turning every four hours to effectively

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prevent PUs for patients in palliative care[3,12] and use of a dynamic medium when it is not possible to intervene by frequent manual repositioning.[3] The French National Health Authority considers that the category of air support has incomplete defined minimum technical specifications and recommends the use without distinction of an APAM with more than 10cm thickness of air or a VFM for patients at medium to high risk of PUs (depending on clinical judgment and scales), who get up during the day, but are bedridden for more than 15 hours.[13] The benefits of an APAM versus the standard mattress and/or static mattresses for PU prevention are not clearly demonstrated. Randomised controlled studies are needed to justify their benefit.[4] The E²MAO study objective was to demonstrate the efficacy of the Axtair One APAM compared with the VFM in the prevention of PUs in elderly patients with moderate to high risk of PUs, in accordance with good professional practice rules.

Methods

Study design

This randomised, controlled, superiority, parallel-group, open-label, multicentre and survival type study was conducted from February 2012 to March 2015 in nine French medium- and long-stay facilities.

Patient eligibility

Eligible patients were males and females aged 70 and over, bedridden for at least 15 hours per day, with reduced mobility due to medical problems (such as malnutrition, low blood pressure, urinary incontinence, neurological diseases and sensory disorders), a low to zero positioning capability, a Karnofsky score ≤40% and a planned period of hospitalisation of at least two weeks. They had no PUs at the time of enrolment but had a medium to high risk for developing PUs, as defined by a Braden score ≤14.[14] Exclusion criteria were a weight >120kg, body mass index (BMI) <12kg/m², a nutritional status score <12 according to the Mini Nutritional Assessment (MNA), uncompensated nutritional insufficiency and ongoing participation, or within 15 days before, in another clinical research study.

Randomisation

Patients were randomised in a 1:1 ratio to receive either an APAM or a VFM. Randomisation was centralised (RANDLIST software v1.2) and globally balanced intra-centre with random block sizes established from two possibilities (2 and 4).

Pressure redistribution support

The APAM (Axtair One, Asklé Santé, Nîmes, France) consisted of therapeutic air cells with a height of 12cm, supplied by a compressor, which adjusts the pressure based on the patient's weight and whose mode of operation allows alternating inflation of one out of two cells, with a six-minute cycle time. The VFM (ALOVA mattress, Asklé Santé, Nîmes, France) was composed of a base made of high resilience foam (density >34kg/m^3) and an upper layer of viscoelastic foam (density>75kg/m^3). Both medical devices have been certified compliant with special requirements for safety, performance and efficacy by a recognised Independent Accredited Test Laboratory (FCBA, France). Health-care professionals were trained in the use of these devices. PUs preventive care had to be performed in compliance with validated care protocols compliant with Good Professional Practice Recommendations;[3,15] this was a prerequisite in the selection of centres.

Data collection

Patients were assessed daily in order to record their skin condition, the appearance or not of PUs (time to appearance and stage), the duration of bed rest, the duration of sitting in a chair, the frequency of preventative interventions (repositioning, relational massages and re-education), any therapeutic change (medical, paramedical) and any serious or non-serious adverse event occurring during the study. Weekly evaluations of the level of risk of PUs according to the Braden Scale were performed (sensory perception, moisture, activity, mobility, nutrition, friction and shearing) and the perception of patient comfort was collected on days 8, 15, 22 and 30 via a satisfaction questionnaire (skin–mattress contact, feeling of warmth, discomfort due to motor noise and disturbed sleep).

Patients were followed for a maximum of 30 days depending on their length of hospitalisation, the occurrence of a PU or a withdrawal from the study decided by the investigator or the patient. The protocol was reviewed by the internal ethics committees of all participating institutions, and the study was approved by a national ethics committee (CHU Limoges). The study was conducted in accordance with the recommendations of Good Clinical Practice, the Helsinki Declaration and current legislation relating to biomedical research. All enrolled patients or their representatives received written information and gave written informed consent.

Primary objective

The population selected for the main analysis were all randomised patients in intention-to-treat (ITT). The primary endpoint criterion was the appearance of PUs during a period of 30 days after randomisation. A survival analysis consisting of comparing the time to appearance of PUs in both groups was performed (log-rank test), and a Kaplan Meier table was presented by treatment group for descriptive purposes. The instantaneous relative risk (hazard ratio) of PUs was estimated by the Cox model and confidence interval (CI). The Cox model explored the relationship between the duration without PUs and four explanatory variables (covariates): type of mattress (APAM or VFM), the Braden scale score, the daily duration of bed rest and body mass index (BMI) on enrolment. The follow-up period of each patient was not to exceed 30 days in accordance with the protocol

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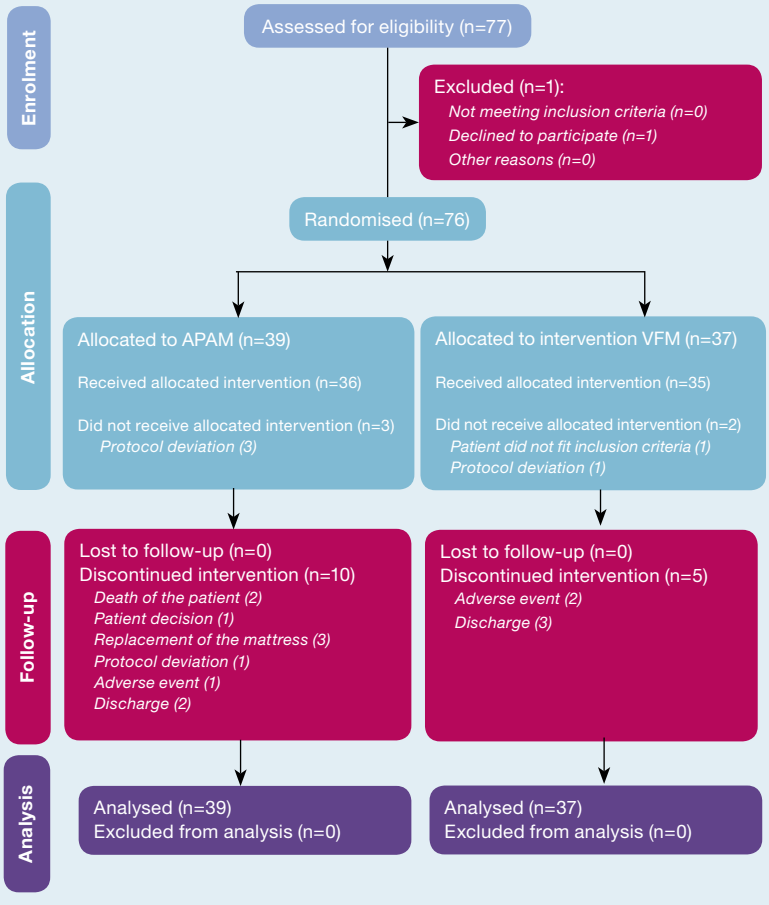
Table 1. Patient characteristics on enrolment

Intention-to-treat (ITT) population n (%)	APAM, n=39 (100%)	VFM, n=37 (100%)
Males, n (%); Females, n (%)	13 (33.3%); 26 (66.7%)	9 (24.3%); 28 (75.7%)
Age (years): mean ± SD (minimum; maximum)	86.03 ± 5.49 (73; 98)	84.59 ± 6.68 (71; 99)
Weight (kg): mean ± SD (minimum; maximum)	64.61 ± 14.37 (42; 103)	64.45 ± 15.81 (35; 88)
Height (cm) mean ± SD (minimum; maximum)	159.46 ± 9.99 (140; 180)	158.86 ± 8.33 (141; 174)
Body mass index (BMI) (kg/m²): mean ± SD (minimum; maximum)	25.47 ± 5.76 (15.4; 39.2)	25.49 ± 5.85 (15.6; 39.3)
Number of comorbidities (diagnosed, mean ± SD (minimum; maximum)	6.49 ± 2.19 (2; 10)	6.35 ± 2.36 (2; 10)
Karnofsky score (%): mean ± SD (minimum; maximum)	30.00 ± 5.06 (20; 40)	30.81 ± 4.86 (20; 40)
Braden score: mean ± SD (minimum; maximum)	11.77 ± 1.27 (8; 13)	12.08 ± 1.26 (8; 13)
Mini nutritional assessment (MNA): mean ± SD (minimum; maximum)	17.02 ± 4.07 (4; 28)	17.11 ± 4.00 (9.5; 27)
Bed rest duration (hours/day): mean ± SD (minimum; maximum)	17.49 ± 3.04 (8; 24)	18.16 ± 2.88 (15; 24)

SD–standard deviation; APAM—alternating pressure air mattress; VFM—viscoelastic foam mattress. The minimum MNA score of 4, reported in a patient in the APAM group, seems to result from a partial assessment of nutritional status. The second MNA score minimum value in this group is 10. The minimum bed rest duration value of 8 is reported for an unique patient in the APAM One group. The second bed rest duration minimum value in this group is 15.

Fig 1. Distribution of patients (CONSORT 2010 Flow Diagram)



Secondary objectives

The first secondary objective was to determine whether preventive care for onset of PUs was less frequent on average in the APAM group. The frequencies were compared between the two groups by a non-parametric Mann-Whitney test.

The second secondary objective was to determine if the relative instantaneous risk of PUs was constant over time and, if not, to determine in what time window the decrease in the instantaneous risk of PUs with APAM was most relevant. Non-proportionality of risk was tested by the likelihood ratio of two nested models: the Cox model and the Cox fragmented model. In case of significance, the instantaneous relative risk was calculated over three time intervals (each corresponding to one-third of the total number of events of interest). The optimal window, assuming a 50% higher risk for VFM as compared with APAM, was the time range in which the instantaneous relative risk was less than 0.666.

The third secondary objective was to determine if the comfort felt by patients in the APAM group was superior to that of patients in the VFM group via a quality of life questionnaire. The mean satisfaction rates were compared between the groups by a Mann-Whitney test.

The fourth secondary objective was to identify the most important risk factors for PUs, to determine if the preventive benefit contributed by the APAM was consistent regardless of their level and if it was not, to define the subpopulations of patients in whom the APAM had a marked advantage over the VFM. Risk factors to be tested in the regression model were demographic data (age, BMI), clinical data collected on enrolment (MNA score, Braden score, daily duration of bed rest, Karnofsky score, blood pressure—systolic and diastolic, heart rate) and the treatment group (type of mattress: APAM or VFM). The method used for selection of candidate variables was a backward selection with a probability of inclusion in the model equal to 0.05, in order to retain the variables significantly contributing to the risk of PUs. The interaction between risk factors and the type of mattress should be tested to determine if the treatment effect depended on the level of the factors. For significant interactions, the level at which the effect of the APAM became favourable should be determined.

Statistical hypothesis and number of required events

The power of this study was dependent on the number of events to be observed (occurrence of PUs in patients at

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Table 2. Braden risk scale criteria on enrolment (APAM/VFM)

Patients evaluated (n)	Sensory perception (% patients)	Moisture (% patients)	Activity (% patients)	Mobility (% patients)	Nutrition (% patients)	Friction and shearing (% patients)
	Very limited to completely limited	Very to constantly moist	Confined to chair to bed	Very to completely immobile	Probably inadequate to very poor	Potential problem to apparent problem
39/37	54/65	59/62	95/97	92/86	74/65	100/95

Table 3. Exposure to risk of pressure ulcers during the study

Treatment group	APAM	VFM
Braden score: mean ± SD (minimum; maximum)	12.39 ± 2.24 (8;18)	13.00 ± 2.52 (8;22)
Bed rest duration (h/day): mean ± SD (minimum; maximum)	17.86 ± 3.26 (5;24)	17.66 ± 2.83 (8;24)
Time spent in chair (h/day): mean ± SD (minimum; maximum)	5.88 ± 3.03 (0;14)	6.05 ± 2.75 (0;15)
Number of turnings per day: mean ± SD (minimum; maximum)	1.42 ± 2.02 (0;7)	1.68 ± 2.17 (0;7)
Number of massages per day: mean ± SD (minimum; maximum)	0.25 ± 0.63 (0;3)	0.05 ± 0.22 (0;1)
Number of re-educations per day: mean ± SD (minimum; maximum)	0.14 ± 0.39 (0;2)	0.07 ± 0.44 (0;4)
Concomitant treatments: mean ± SD (minimum; maximum)	9.51 ± 3.14 (2;15)	8.76 ± 2.55 (3;13)

SD—standard deviation; APAM—alternating pressure air mattress; VFM—viscoelastic foam mattress; Duration expressed in hours, tenths and hundredths of an hour

Table 4. Braden risk scale criteria during the study (APAM/VFM)

	n	Sensory perception (%)	Moisture (%)	Activity (%)	Mobility (%)	Nutrition (%)	Friction and shearing (%)
	Patients evaluated (n)	Very limited to completely limited	Very to constantly moist	Confined to chair or bed	Very to completely immobile	Probably inadequate to very poor	Potential problem to apparent problem
D8	36/31	53/48	56/61	89/90	83/74	67/61	97/94
D15	33/27	42/56	55/59	85/85	79/78	64/41	97/93
D22	28/21	57/48	57/62	89/86	75/81	71/38	93/90
D30	24/17	63/59	63/71	83/94	75/88	75/35	92/100

APAM—alternating pressure air mattress; VFM—viscoelastic foam mattress

risk, not having a PU on enrolment) and not the number of patients to be included. The desired effect was a 50% reduction in instantaneous risk of PUs in the APAM group versus the VFM group. In order to achieve a study power of 80% with an alpha risk of 5%, assuming a risk ratio of two, 72 events had to be observed. A sequential test composed of nine interim analyses at equal intervals of approximately seven events was planned to allow for an end to the study if the APAM proved more effective than expected.

Results

Distribution of patients on enrolment and withdrawal from the study

We enrolled 76 consenting patients who were randomised: 39 (51.3%) in the APAM group and 37 (48.7%) in the VFM group (Fig 1). The serious adverse events (SAEs) reported in the APAM group were two deaths, a massive septic shock with acute pulmonary oedema and a decompensation of an insulin-dependent diabetes. No SAE was reported in the VFM group. There were 20 adverse events reported in each group, including two discomforts in the APAM group and one hyperalgesia in the VFM group. The other events did not involve the mattresses.

Patient characteristics on enrolment

The study population consisted of 71.1% females, 28.9% males and had a mean age of 85.3 years. Both groups of patients were found to be comparable at the baseline visit in terms of demographic characteristics, general condition and level of PU risk (Table 1). The median Karnofsky score was 30% in both groups, corresponding to full disability requiring hospitalisation without imminent risk of death, the patients being at best disabled, requiring care and special assistance (maximum reported score of 40%). The patients were confined to bed more than 63% of the day (bedridden for more than 15 hours and up to 24 hours per day). Analysis of the Braden risk scale criteria confirmed a high level of risk exposure for skin impairment (Table 2). Randomisation produced the expected comparability.

Level of exposure to risk of pressure ulcers in patients during the study

Daily exposure to the risk of PUs and the severity of the patients' conditions during the study were maintained similar in the two groups (Table 3). Analysis of the Braden risk scale criteria confirmed maintenance of a high level of risk exposure for skin impairment (Table 4).

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Primary analysis

The principal efficacy analysis was conducted after the appearance of 15 PUs (Table 5). The cumulative risk for the occurrence of PUs during the 30-day period was estimated at 6.46 % [95% CI: 1.64–23.66] in the APAM group and 38.91% [95% CI: 24.66–57.59] in the VFM group, p=0.001 (log-rank test), corresponding to six times the risk of PUs in the first 30 days in the VFM group than in the APAM group, or a decrease of 83.4% in the risk of PUs in the APAM group. The Kaplan-Meier curves show that the probability of being free from PUs decreases more rapidly in patients in the VFM group (Fig 2). The hazard ratio adjusted according to the Cox model was 7.57, corresponding to an instantaneous risk of PUs 7.57 times higher in the VFM group than in the APAM group [95% CI: 1.67–34.38], p=0.009. The type of mattress (APAM or VFM) having been the only factor significantly associated with an increased risk for the occurrence of PUs, a Cox model including this single covariate was readjusted and the hazard ratio rose to 7.94 [95% CI: 1.79–35.21], p=0.006.

Secondary analyses

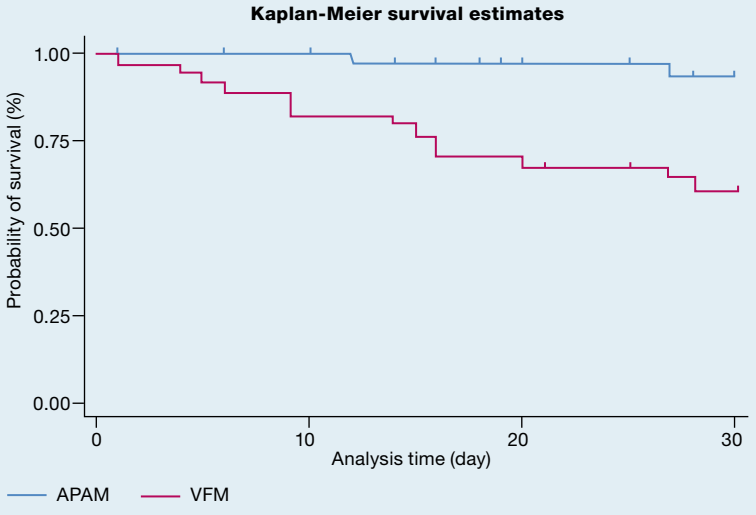
The preventive care for the occurrence of PUs proved similar in both groups, with an average of 0.60 physical interventions (turnings, relational massages and re-educations) daily per patient in each group (preventive intervention difference between the two groups not significant, p=0.78) (Table 3). The Kaplan-Meier approach indicated that the appearance of PUs in the APAM group was late but the number of events was insufficient for verifying if the instantaneous relative risk of PUs was constant over time (Table 5). The results of all evaluated quality-of-life criteria indicated a high satisfaction rate, which was comparable between the two mattresses (difference in satisfaction between the two groups not significant, p=0.21) (Table 6). Finally, among the ten risk factors for PUs tested, the type of mattress was the only factor significantly contributing to an increased risk of PUs, with a hazard ratio of 5.96 [95% CI: 1.69–20.99], p=0.005.

Table 5. Number of events (first appearance of pressure ulcers)

Pressure ulcer category	APAM (n=39)	VFM (n=37)	Total
I	1	7	8
II	1	5	6
III	0	1	1
Total	**2**	**13**	**15**

APAM—alternating pressure air mattress; VFM—viscoelastic foam mattress

Fig 2. Kaplan-Meier curves



APAM—alternating pressure air mattress
VFM—viscoelastic foam mattress

Discussion

The E²MAO study showed the superiority of a APAM over a VFM in reducing of the risk of PUs. The literature reviews and meta-analyses carried out on the effectiveness of the pressure redistribution media warn about the methodological bias of the studies and draw cautious conclusions. They report that APAMs are likely to be more effective than standard hospital mattress; the comparison of the effectiveness of different APAMs, on the other hand, showed no tendency in favour of one or the other.[4,16] A randomised study (n=447 patients),[17] mentioned in 2012 in the French guidelines,[18] compared the efficacy of an APAM without a turning protocol with that of a VFM with a turning protocol every four hours. This study reported a similar incidence of category II–IV PUs in the two groups (15.3% APAM and 15.6% VFM), with more severe PUs in the APAM group. The duration of bed rest and the preventive care provided daily to patients are variables that can impact the assessment results of the efficacy of the devices. In order that these factors do not affect the time to appearance of PUs, they should be similar in the two groups, or to the detriment of the group whose support is considered more effective. Similarly, when the risk of PUs proves equivalent in both groups, necessary preventive care should be reduced in one of the groups in order to demonstrate a prophylactic benefit and/or related to the number of interventions. In the E²MAO study, preventive interventions were similar in both groups and were less than the Good Professional Practice Recommendations. The elderly person who is unable to reposition themselves independently must have their position changed regularly.[3] If there is no consensus on the frequency of change of position, it is advisable to reposition patients in palliative care at least every four hours on a VFM or every two hours on a simple mattress. Despite the existence of validated protocols within the nine centres assessed in the study, carers were not able to perform the position changes appropriately. The results of the E²MAO study would thus strengthen the international recommendation to use an active support of the APAM type for patients at high risk of developing PUs when frequent manual repositioning

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is not possible,[3] and analysis of the E²MAO survival curves shows the benefits of using an APAM early in the management of this type of patient in home care, where the frequency of PU prevention interventions is lower than what is possible in institutions. The low incidence of reported PUs in the APAM group would suggest that the frequency of repositioning on the appearance of PUs for this type of patient should be separately investigated in another study.

In France, the National Support Agency for the Performance of Health and Medico-Social Establishments (ANAP [Agence Nationale d'Appui à la Performance]) has estimated the cost of screening and prevention for patients at risk of PUs at €1.15 and €56.59 respectively per patient and per day, and the additional treatment costs depending on the severity of the PUs at €3.90 for category I, €7.89 for category II, €28.80 for category III and €52.97 for category IV.[19] The duration of the treatment up to healing depends on many factors and on the severity of the PU. A first approach to the additional cost of therapeutic management of PUs was modelled on a minimum and maximum treatment duration (ANAP); 7/14 days for category I, 42/112 days for category II and 210/252 days for a category III to IV. The additional cost takes into account human resources (hospital) and direct and indirect costs. The homogeneity between patient groups and preventive care practices allows us to consider that prevention costs were equivalent throughout the duration of patient follow-up. The total additional cost of prevention failure by the mattress was 12 to 20 times higher in the VFM group than in the APAM group according to the duration considered (min/max) (Table 8).

Finally, PUs are the cause of physical and psychological pain for the patient who already has them and/or is at high risk of PUs. By extrapolating the results of the Briggs study[20] to those of the E²MAO study, we could consider that six patients, among whom one was suffering from PUs, had complained of pain in the APAM group compared with nine patients, among whom six had PUs, in the VFM group. If the difference in satisfaction with the quality-of-life criteria assessed appears to be insignificant, a pain assessment would have been relevant.

Limitations

The limit of the E²MAO study was its premature termination. The principal analysis was planned, according to the establishment of a sequential test, on the occurrence of 22 events (third interim analysis). The recruitment difficulties did not objectively allow continuing the study beyond the 15 PUs occurrences and reaching the required number of events. In fact, according

Table 6. Patient satisfaction (APAM/VFM)

	n	Skin-mattress contact: Good to very good (%)	Feeling of warmth: Good to very good (%)	Ease of movement: Easy to very easy (%)	Discomfort caused by noise of the motor: Unimportant to non existent(%)	Sleep disturbance: Unimportant to non existent(%)
D8	36/31	92/97	94/94	67/74	97/NA	94/97
D15	33/27	91/100	97/100	70/93	94/NA	94/100
D22	28/21	100/100	96/100	82/86	93/NA	96/100
D30	24/17	96/100	96/94	88/100	92/NA	100/100

NA—not applicable; APAM—alternating pressure air mattress; VFM—viscoelastic foam mattress

Table 7. Total number of pressure ulcers by severity and location

Study population	APAM (n=39)			VFM (n=37)		
Site	**Sacrum**	**Heel**	**Total**	**Sacrum**	**Heel**	**Total**
Pressure ulcers category I	1	2	3	5	6	11
Pressure ulcers category II	1	0	1	4	2	6
Pressure ulcers category III	0	0	0	0	1	1
Total pressure ulcers	**2**	**2**	**4**	**9**	**9**	18

APAM—alternating pressure air mattress; VFM—viscoelastic foam mattress

Table 8. Additional costs associated with the treatment of pressure ulcers

Population	APAM (n=2)				VFM (n=13)			
Additional costs	**Pressure ulcers**	**Day (€)**	**Total Min (€)**	**Total Max (€)**	**Pressure ulcers**	**Day (€)**	**Total Min (€)**	**Total Max (€)**
Treatment category I	3	11.70	81.90	163.80	11	42.90	300.30	600.60
Treatment category II	1	7.89	331.38	883.68	6	47.34	1,988.28	5,302.08
Treatment category III	0	0.00	0.00	0.00	1	28.80	6,048.00	7,257.60
Total incremental costs	4	19.59	413.28	1,047.48	18	119.04	8,336.58	13,160.28

APAM—alternating pressure air mattress; VFM—viscoelastic foam mattress

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to the principal investigator, in an open-label study, regarding the classification of diseases and patient risk factors, the observed superiority of APAM versus VFM was causing the slowdown of enrolments. For ethical reasons the study stopped based on the appearance of PUs when the researchers were convinced of the benefits of APAM over VFM.

A validity limit for the results was the non-compliance with the recommendation of good clinical practice to distinguish frequency of the patient repositioning in bed depending on the type of prescribed support for the prevention of PUs. The protocols observed in the investigating centres consisted of their actual practices. The results of the E²MAO study are valid for patients benefiting from a repositioning protocol similar to that observed. They are not generalisable to more frequently repositioned patients. Patients enrolled in the E²MAO study were randomised to a comparable initial state of distribution; different care practices after randomisation would have been a source of bias.

Conclusion

The E²MAO study showed the superiority of APAM over VFM in elderly patients who were severely dependent, unable to care for themselves, bedridden more than 15 hours and up to 24 hours a day and at high risk of PUs, evaluated under conditions of similar daily practices. The risk of onset of PUs was 7.57 times greater in the VFM group than in the APAM group.

Reflective questions

- What should be the frequency of effective repositioning to objectively reduce the occurrence of pressure ulcers (PUs) on the viscoelastic foam mattress (VFM) for the type of patients concerned?
- Could the karnofsky limit be considered useful in making the decision to prescribe an alternating pressure air mattress versus (APAM) a VFM in addition to the Braden scale?
- What would be the most appropriate method to validate the predictive criteria for choosing the right surface and the relevant duration?

These results suggest the need to consider at the initial management of this type of patients their capacity to reposition themselves efficiently and/or the availability of personnel who can perform repositioning day and night at a frequency of at least every four hours for a patient on a VFM. In the event that these conditions are not fulfilled, APAM has shown that it is an effective alternative in the management of these patients. This study provides descriptive information and evidence for practice, showing that the establishment of studies with robust methodologies is possible to evaluate this type of medical device. This research must be continued in order to help the caregivers in the detection, assessment, advocacy and prescription of the right support at the right time for the right patient. **JWC**

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