

ORIGINAL ARTICLE

Prevention of pressure ulcers with a motorized air support in at-risk patients hospitalized in rehabilitation departments

APAM + an observational prevalence study with historical control and incidence study

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ABSTRACT

BACKGROUND: The main study was a cross-sectional multicenter study of the prevalence of pressure ulcers in rehabilitation services (RS) where Axtair Automorpho® Plus mattresses were made available *ad libitum*. The primary objective was to enable comparison with prevalence as observed in the national PERSE study (historical control) in similar departments using a variety of prevention aids.

METHODS: This cross-sectional prevalence study was combined with a prospective study of the incidence of pressure ulcer occurrence in the high-risk target population whose beds were systematically equipped with the studied support.

RESULTS: On the day of the prevalence study, 18 of the 456 patients presented pressure ulcers which occurred during the period when Axtair Automorpho® Plus supports were made available to the departments. This corresponds to a prevalence of 3.9% [2.4, 6.2] which is significantly lower than those recorded in the PERSE study: 11.8% [10.8; 12.8] $p < 0.0001$. The ulcer incidence study covers 57 patients who were hospitalized on a bed with an Axtair Automorpho® Plus support because of their risk of contracting pressure ulcers. One pressure ulcer occurred in 3 patients and 3 pressure ulcers occurred in another patient, i.e. 4 out of 57 corresponding to an incidence of 7.0% [2.0; 17.0].

CONCLUSIONS: The results of the pressure ulcer prevalence study in rehabilitation departments where Axtair Automorpho® Plus supports were available as well as results of the study of pressure ulcer incidence in patients bedridden on Axtair Automorpho® Plus, confirm the expected benefit provided to patients in terms of prevention.

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KEY WORDS: Pressure ulcers - Incidence - Prevalence - Prevention- Axtair Automorpho® Plus.

Pressure ulcers are lesions of the skin or the subcutaneous tissues located over bony prominences resulting from the application of pressure, or pressure combined with shear forces.¹

For more than 20 years, the PERSE Study has been conducting major national surveys in France of the prevalence of pressure ulcers and these have become benchmarks in the field.²⁻⁵ The most recent survey conducted in 2015⁶ up-

dated the data on the national prevalence of pressure ulcers, *i.e.* for all hospital departments and by type of department. It covered 776 hospital departments and 21,538 patients, 12,752 (59.2%) of whom were women and 8786 (40.8%) men. The survey shows that the prevalence of pressure ulcers was 8.1%, 95% CI = [7.7; 8.5] (N.=1753). This figure breaks down to 7.8%, 95% CI = [7.3; 8.3] (N.=997) in women and 8.6%, 95% CI = [8.0; 9.2] (N.=756) in men

($P=0.0381$). In rehabilitation services, this prevalence was 11.8%, 95% CI = [10.8; 12.8]. Reducing the occurrence of pressure ulcers is a public health issue with respect to avoiding a major cause of deterioration in patients' quality of life and cutting the healthcare expenses they induce (2.7). In addition to the cost of care that they require in terms of medical supplies and nursing time, their occurrence is responsible for lengthening the average hospital stay by an estimated 9.8 days.⁷⁻¹⁰ Pressure ulcers also require nursing care when patients return home, which in many places is not easy to arrange due to the shortage of nurses.

The onset of pressure ulcers can be prevented by identifying the risk factors presented by patients and by reducing the interface pressure between the skin and supporting surfaces.² Prolonged bed rest should be avoided by different methods, including patient mobilization, the use of different positions for bed and chair rest, the elimination of shear forces, and the use of items for preventing and treating pressure ulcers such as cushions, mattresses, and mattress toppers. As part of this prevention, the use of pressure relief mattresses is one of the five best practices with a major impact on risk management. Motorized air supports are considered to be of prophylactic and therapeutic value for patients at risk of developing moderate to severe pressure ulcers. Axtair Automorpho® Plus is a motorized air support consisting of a network of 18 air cells, 12 cm high, arranged on a 5 cm foam base and connected to a compressor. The compressor inflates the cells (one out of two) alternately and automatically regulates the inflation pressure. The alternation of pressures and the system for relieving pressure on the heels applied to four cells helps to prevent the prolonged vascular compression that may lead to tissue hypoxia causing the onset of pressure ulcers. To evaluate the contribution to reducing pressure ulcer prevalence and incidence from using this equipment in daily practice, we conducted an observational study with historical control in at-risk patients in rehabilitation services. The study method was approved beforehand by experts from France's national health evaluation authorities. This paper presents the results of the study which ran from 1 February to 30 June 2017.

Materials and methods

Experimental plan and primary objective

The main study was a cross-sectional multicenter study of the prevalence of pressure ulcers in rehabilitation ser-

vices (RS) where Axtair Automorpho® Plus mattresses were made available *ad libitum*. The primary objective was to enable comparison with prevalence as observed in the national PERSE Study (historical control) in similar departments using a variety of prevention aids. This cross-sectional prevalence study was combined with a prospective study of the incidence of pressure ulcer occurrence in the high-risk target population whose beds were systematically equipped with Axtair Automorpho® Plus mattresses.

Secondary objectives

The secondary objectives were to describe the evolution of pre-existing pressure ulcers and of those occurring in patients during the study period, the satisfaction of the nursing staff, patient comfort, and the safe use of the support.

Scientific committee of the study

Prior to the study, a scientific committee was appointed specifically to advise WINNCARE FRANCE on any medical or scientific issues arising during the study, on the exploitation of data, the drafting of the study report, and the publication of the results.

Selection of RS centers

The study was conducted in rehabilitation services so that the population would be structurally similar to the elderly population maintained at home. The size of the sample required for the historical comparison meant that these centers had to be large enough to conduct a prevalence study on 330 patients and recruitment was conducted competitively in the various centers according to their size. All departments participating in the study were required to have existing pressure ulcer prevention nursing protocols which remained unchanged during the study.

Patient inclusion criteria

In every rehabilitation service all incoming patients were to be included in the study except those who, after being informed, declined or could not consent because they were under 18 years of age or had severely impaired cognitive functions (MMSE Score <15), or because of a medical contraindication to the studied support. All patients were described in a screening log. The prevention equipment under study was Axtair Automorpho® Plus and patient beds were fitted with this equipment in line with the medical practitioners' decisions as and when patients were included in the study.

Evaluation criteria

The primary endpoint was the occurrence or not of a pressure ulcer as defined by stages 1 to 4 of the NPUAP (National Pressure Ulcer Advisory Panel). This criterion was analyzed in terms of prevalence in the general population of hospitalized patients and in terms of incidence in the population of patients without pressure ulcers upon inclusion and meeting the severity criteria defined by the health authorities.

The secondary criteria were:

- the characteristics of pre-existing pressure ulcers and of ulcers that occurred in patients who were free of them when first hospitalized in the department;
- nursing staff satisfaction with the noise level of the prevention support, the ease of maintenance, and the ease of use in terms of turning patients and sitting them up;
- patient comfort and patients' opinions about the noise level of the equipment;
- product safety and in particular any adverse events and technical incidents with the product.

Conduct of the study and data collection

General organization of the study

The study included a cross-sectional prevalence survey of all patients in services on the 60th day and 120th day after the start of the study plus a prospective survey of incidence over 5 months.

A register of all patients entering the services was maintained. It described their demographic characteristics, the reason for their stay, their risk factors for pressure ulcers, their skin condition and in particular the presence of pressure ulcers (location and description), patient's mobility, the assessment of the risk of pressure ulcers on the Braden scale, any contraindication to using Axtair Automorpho[®] Plus, whether or not the selection criteria were met, the patient's non-opposition to participating in the incidence study, and on completing the registration form, the decision whether or not to include the patient in the incidence study.

Conduct of the cross-sectional study: prevalence assessment

The prevalence study was conducted on all patients in the department on the 60th day and 120th day after the start of the study. The 60-day threshold was set because the average length of stay in these services was 31 days. By taking 60 days, save very few exceptions, all patients meeting the inclusion criteria had had the opportunity to benefit

from Axtair Automorpho[®] Plus prevention if the caregivers had deemed it necessary. For the same reason, it was very likely that by the 120th day all the patients in beds equipped with Axtair Automorpho[®] Plus would be different from those included in the 60-day prevalence analysis.

A specific observational register was completed for the assessments of the prevalence study. It described the number of men and women hospitalized, and the number of men and women with at least one pressure ulcer, regardless of its stage, and included a form for each patient describing their age, sex, reason for hospitalization, risk factors of pressure ulcers, pressure ulcer prevention supports, existence of pressure ulcers and their number, plus the stage and location of the most severe of them.

Conduct of the prospective cohort study: incidence evaluation

After verifying the patient's non-opposition to the collection of their personal information and validation of their selection criteria, the practitioner filled out an inclusion sheet on D0 describing the patient's demographic characteristics, the existence of any pressure ulcers and their description: location, length, width, severity, and clinical stage. The practitioner also took a standardized picture where applicable. For the evaluation of the incidence, the cutaneous state of the patients was reported on D15 and on D31, and also in the event of the occurrence of a pressure ulcer the day of its occurrence. Any pressure ulcers were described and photographed according to the same protocol as at the inclusion visit. The standardized photographic protocol required the picture to be taken 20 cm from the pressure ulcer with a colorimetric and centimeter scale. If the patient left the hospital before D31, a form was completed on the day of discharge.

A record was made at each visit, or in the event of transfer or discharge from the service before D31, of:

- an assessment of the risk of occurrence of the pressure ulcer (Braden scale);
- the maceration of the skin on a Likert scale from 0 to 5;
- unexpected events and possible technical incidents related to the Axtair Automorpho[®] Plus support;
- the evolution of any pressure ulcer that appeared;
- the patient's opinion about the comfort and noise level of the Axtair Automorpho[®] Plus support.

Evaluation of the opinion of caregivers and patients

On D15, the investigator recorded on a special form the caregivers' opinion of the Axtair Automorpho[®] Plus mo-

torized air support and their level of satisfaction with its use: noise level, ease of implementation and maintenance, ease of use in terms of turning patients and getting them to sit up evaluated on 5-point Lickert scales. Patient opinion and satisfaction with the comfort and noise level of Axtair Automorpho® Plus were also reported.

Evaluation of tolerance

Any adverse events were recorded on the follow-up questionnaire completed by the practitioners.

Statistical analysis

Populations studied

In each rehabilitation service, all patients were included in the study except those who, after being informed, declined or could not consent because they were under 18 years of age, or had severely impaired cognitive functions (MMSE<15), or a medical contraindication.

Populations for the prevalence study included:

- all the patients present in the services at the end of the 60th and 120th day, and presenting a moderate to high risk of pressure ulcers defined by a Braden score of 17 or less,^{11, 12} who were up out of bed during the day, bedridden more than 15 hours, and who did not have any pressure ulcers on admission to the service;
- and all patients hospitalized in services present at the end of the 60th and 120th day.

Populations for the incidence study included:

- all patients hospitalized in departments whose beds were equipped with an Axtair Automorpho® Plus, having a hospital stay of at least 29 days, presenting a moderate to high risk of pressure ulcers defined by a Braden score of 17 or less, bedridden more than 15 hours, and not presenting any pressure ulcers on admission to the service;
- and all patients hospitalized in the service meeting the inclusion criteria whose beds were equipped with an Axtair Automorpho® Plus.

Description of the statistical analysis

DESCRIPTION OF THE POPULATIONS

Demographic and clinical characteristics of patients included in the prevalence and incidence populations were described by means and standard deviations for the quantitative variables and by numbers and percentages for the qualitative variables.

PREVALENCE AND INCIDENCE OF PRESSURE ULCERS

The prevalence of pressure ulcers in the rehabilitation services was described by number, frequencies, and 95% confidence intervals and compared to the current reference rate of the 2015 PERSE Study⁶ by a χ^2 test. The stage and location of pressure ulcers were also described and compared. The incidence of pressure ulcers at 31 days was described by the same parameters in the general population described previously.

SECONDARY CRITERIA

The stage (NPUAP) of pressure ulcers, their location, caregiver satisfaction with the use of Axtair Automorpho® Plus supports as well as patients' opinions of bed rest comfort, and any adverse events were described by numbers and frequencies. The evolution of the Braden score in the incidence population was described and compared by Student's tests on repeated series.

SOFTWARE USED

The data was recorded on Clinsight and analyzed with SAS version 9.3 software in the department of medical biostatistics of Cen Biotech. The significance level was set at $P < 0.05$.

SAMPLE SIZE

The latest national PERSE survey of 21,538 patients evaluated the current prevalence of pressure ulcers in rehabilitation patients at 11.8%. The number of cases required to compare it in a bilateral situation, with an alpha risk of 5% and a power of 80%, to the expected rate of 7.0% of pressure ulcers when using Axtair Automorpho® plus, according to the "Historical control studies" design is 290 patients¹⁰ rounded up to 330 to allow for 10% of patient drop-out.

Information to individuals and informed consent

In line with the legislation, the consent of the person or of a trusted third party was obtained after the practitioner had given them an explanatory letter and answered their questions. People under 18 years of age or with an impaired cognitive state characterized by an MMSE <15 could not participate in the study. The study was approved by the CCTIRS on 15 June 2016 and authorized by the CNIL (DR-2017-025).

Prevalence study

All patients present in each department 60 days and 120 days after the start of the study were included in the prevalence population, respectively 231 and 225 patients, making a total of 456 patients. The objective of this observational prevalence study with historical control was to determine whether a significant decrease in the prevalence of pressure ulcers could be achieved by providing Axtair Automorpho® Plus supports for all patients for whom the caregivers considered it necessary.

These 456 patients, of whom 58.8% were female, were 72.3±15.6 years old: 21.9% of patients under 60 years, 40.1% aged 60 to 80 years, and 37.9% over 80 years old. The risk factors for pressure ulcers included malnutrition (11.4%), urinary and/or fecal incontinence (25.9%), hemiplegia or paraplegia (20.7%), bone fracture (23.5%), obesity (BMI >= 30 kg/m²) (23.7%), diabetes (21.9%), peripheral neuropathies (3.1%), and psychotropic medication (33.8%).

The beds of 21.5% (N.=98) of these patients were equipped with Axtair Automorpho® Plus supports and the reasons why the others were not equipped were mainly because caregivers considered they did not require it (80.7%). Other reasons related to contraindications (1.4%) and especially to the fact that the patient was already in the department before the start of the study (15.1%). The supports used for the other patients were static mattresses to help prevent bedsores (74.3%), standard mattresses (22.6%), and other motorized air mattresses (3.1%).

Primary endpoint: total prevalence of pressure ulcers and historical comparison

On the day of the prevalence study, 18 of the 456 patients presented pressure ulcers which occurred during the period when Axtair Automorpho® Plus supports were made available to the departments. This corresponds to a prevalence of 3.9% [2.4, 6.2]. This figure is significantly lower than those recorded in the PERSE Study⁶ chosen for the historical comparison: 11.8% [10.8; 12.8] P<0.0001 (Table I).

TABLE I.—Comparison of the prevalence of patients with pressure ulcers to the prevalence described in the national Perse Study.

Pressure ulcers	CEN 1462		CI 95%	PERSE Study	
	N.	%		N.	%
No	438	96.1	[93.8 ; 97.4]	3324	88.2
Yes	18	3.9	[2.4; 6.2]	444	11.8
Total	456	100.0		3768	100.0

$\chi^2=25.641$, P value: <0.0001; significance: <0.0001.

These 18 patients were 71.2±17.7 years old. Twelve (66.6%) were female and presented a high risk of pressure ulcers with a Braden score on admission to the service of 15.7±3.2. They presented numerous risk factors favoring the occurrence of pressure ulcers and in particular 50.0% presented urinary, fecal or mixed incontinence, 44.4% psychoactive drug intake, 38.9% a paralytic syndrome (hemiplegia or paraplegia), 33.3% a fracture, 27.8% diabetes, 27.8% obesity, and 11.1% under-nutrition. Among them, six patients (33.3%) already had a pressure ulcer.

These 18 patients presented a total of 21 pressure ulcers that occurred despite the prevention policy. These pressure ulcers were located at the heels (52.4%, N.=11), sacrum (28.6%, N.=6), the feet other than the heels (9.5%, N.=2), ischion (4.8%, N.=1), and scrotum (4.8%, N.=1). Of the 11 heel pressure sores, there were 1 stage I, 6 stage II, 2 stage III, and 2 stage IV ulcers. Among the pressure ulcers on the sacrum, there were 2 stage I, 2 stage II, and 2 stage III pressure ulcers. The pressure ulcer on the feet other than the heel were 1 stage II and 1 stage III. The pressure ulcer of the ischium was stage II and that of the scrotum also. A total of 14.3% (N.=3) of pressure ulcers were stage I, 52.4% (N.=11) stage II, 23.8% (N.=5) stage III, and 9.5% (N.=2) stage IV. These stages were not statistically different from those found in the PERSE Study because of the small number of pressure ulcers that reduced the power of the statistical test, but stage II sores were factually more frequent than in the PERSE Study⁶ 52.4% vs. 38.3% and conversely stage III and IV sores less frequent 33.3% vs. 44.3%. As for the locations, the same lack of statistical power was present, but it was noticeable that although the locations on the heels occurred with comparable frequency (52.4% vs. 58.6% in the PERSE Study), the locations on the sacrum were less numerous (28.6% vs. 43.3%).

Prevalence in the moderate and high-risk subpopulation

An analysis was conducted in moderate to high risk patients targeted, *i.e.* patients without a pressure ulcer on admission to the ward, with a Braden score of 17 or less, bedridden over 15 hours, and up out of bed during the day. In 70 patients in this subpopulation, no pressure ulcers occurred.

Prevalence in the moderate and very high-risk subpopulation

In addition, an analysis was carried out in patients with a moderate to very high risk defined by patients with a Braden score of 17 or less, bedridden for more than 15

hours, but who may already have a pressure ulcer and who are not up out of bed during the day. Of the 89 patients concerned, two had a pressure ulcer, *i.e.* a prevalence of 2.2% [0.3; 7.9]. Patient PASO082, was an 83-year-old woman, with hemiplegia, on psychoactive drugs, with a Braden score of 12, and presenting two pressure ulcers; one stage III located on the heel and one stage III on the foot other than the heel. She already had 2 stage II pressure ulcers upon being admitted to the ward, one on the other heel and one not on the heel. Patient PAST015 was a 59 year old man who was quadriplegic, taking psychoactive drugs, and with a Braden score of 11. He had a stage II ulcer located on the heel. He already had one stage II pressure ulcer on the heel of the other foot upon admission to the service.

Incidence study

Of the 679 patients admitted to the four wards participating in the study within the five months of inclusion, 57 patients were included in the ulcer incidence study and were hospitalized on a bed with an Axtair Automorpho® Plus support because of their risk of contracting pressure ulcers.

Of these 57 patients, 16 left the study prematurely for the following reasons: four returned home (25%), one was intolerant of the support (6.3%), one presented a contraindication to the support (6.3%), one was considered as no longer requiring prevention with the support (6.3%), seven were transferred to another department (43.8%), and two died (12.5%). Their skin condition was described on the form before leaving the department.

These patients were 79.1±11.7 years old and 57.9% were women. Among their risk factors for pressure ulcers were malnutrition (42.1%), urinary and/or fecal incontinence (38.6%), hemiplegia or paraplegia (33%), bone fracture (26.3%), obesity (BMI≥30 kg/m²) (17.5%), diabetes (19.3%), peripheral neuropathy (8.8%), and psychoactive medication (7.0%).

Two-thirds of these patients (66.7%) were bedridden for more than 15 hours a day and one-third were continuously in the chair during the day. Their Braden score was 14.4±3.0 and 82.5% of them had a Braden score of 17 or less.

Of these patients, 40.4% (N.=23) had at least one pressure ulcer and the average number of pressure ulcers presented by the patients with pressure ulcers was 2.5±2.1, ranging from 1 to 9: 1 for 43.5% of patients, 2 for 21.7%, 3 for 13.0%, and 4 and more for 21.7%. In total, these patients had 58 pressure ulcers.

TABLE II.—Description of the pressure sores that occurred during the incidence study.

Patient N.	Heel	Foot other than the heel	Total
PASO126		1 stage II	1
PASO129	1 stage II	2 stage I	3
PAST165		1 stage I	1
PAST2019	1 stage I		1
Total	2	4	

These 58 pressure ulcers were located on the pelvis for 32.8% (N.=19) of them, on the heels for 13.8% (N.=8), on the ischions for 1.7% (N.=1), on the occiput for 1.0% (N.=1). Other localizations included the foot but not the heel for 31.0% (N.=18), the upper limb for 5.2% (N.=3), the lower limb (knee, calf) for 5.2% (N.=3), the genitals (testes and penis) for 3.4% (N.=2), the face for 3.4% (N.=2), and the back for 1.7% (N.=1).

These pressure ulcers were stage I for 27.6% (N.=16), stage II for 43.1% (N.=25), stage III for 15.5% (N.=9), and stage IV for 13.8% (N.=8). It was noted that half of the stage I pressure ulcers were located elsewhere than on the pelvis, heels, and occiput and in particular were located on the foot other than the heel.

One pressure ulcer occurred in 3 patients and 3 pressure ulcers occurred in another patient, *i.e.* 4 out of 57 (Table II) corresponding to an incidence of 7.0% [2,0; 17,0].

These pressure ulcers occurred in:

- patient PASO126, an 83-year-old man, hemiplegic, with mixed incontinence, a Braden score of 13, and a bed rest period >15 hours who presented a stage II ulcer located on the foot other than the heel;
- patient PASO129, an 83-year-old woman, hemiplegic, with mixed incontinence, a Braden score of 12 and bed resting time > 15 hours, who presented 3 ulcers: 2 stage I on the foot other than the heel and 1 stage II ulcer on the heel;
- patient PAST165, a 59-year-old man, quadriplegic, with mixed incontinence, Braden score of 11, and bed rest >15 hours, who had a stage I ulcer on the foot but not the heel;
- patient PAST219, an 80-year-old woman, with Guillain Barré syndrome, with mixed incontinence, Braden score of 13 and bed rest > 15 hours, who presented a stage I pressure ulcer located on the heel.

This patient description highlights that:

- pressure ulcers were stage I for four of them (66.7%) and stage II for the other two (33.3%);
- three patients had stage I pressure ulcers, and two had stage II pressure ulcers, which allows us to evaluate the incidence of stage I pressure ulcers as 3 out of 57 patients, *i.e.* 5.2% [0.1; 14.6], the incidence of stage II pressure ul-

cers as 2 out of 57 patients, *i.e.* 3.5% [0.1, 12.1] and that due to the lack of stage III and IV, the incidence of stages III and IV is 0;

- of the six pressure ulcers that occurred, four occurred on the foot other than the heel (66.0%) and two on the heel, and of the four patients, two presented only localizations on the foot other than the heel and two occurred on the heel, corresponding to an incidence of 3.5% [0.1, 12.1];
- these pressure ulcers all occurred in high-risk patients presenting pathologies with paralysis.

In the subpopulation of reference, namely the 18 patients whose hospital stay exceeded 29 days, who had a Braden score of ≤ 17 , and who were bedridden more than 15 hours per day and free of pressure sores upon admission to the department, a pressure ulcer occurred in only 1 of them, *i.e.* an incidence of pressure ulcers of 5.6% [0.1, 27.3]. This pressure ulcer occurred in Patient PASO126, an 83-year-old, male, hemiplegic (right hemiplegia), with mixed incontinence, a Braden score of 13, and bed rest >15 hours and he presented a stage II pressure ulcer located on the right foot other than on the heel.

In addition, the frequency of patients with at least one pressure ulcer fell significantly during the study from 40.4% [27.6, 54.2] at inclusion to 22.4% at D15 [11.8, 36.6] and 19.5% [8.8, 34.9] at D31 (Figure 1).

At day 15, 11 patients had a total of 22 pressure ulcers.

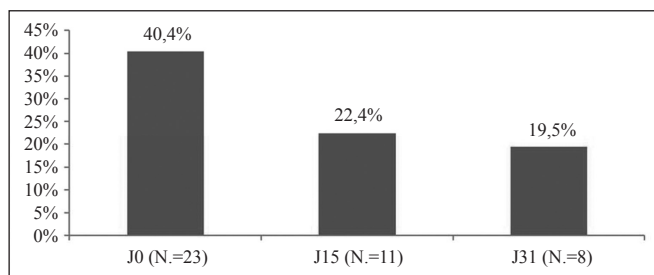


Figure 1.—Patients presenting one or more pressure sores at the different visits.

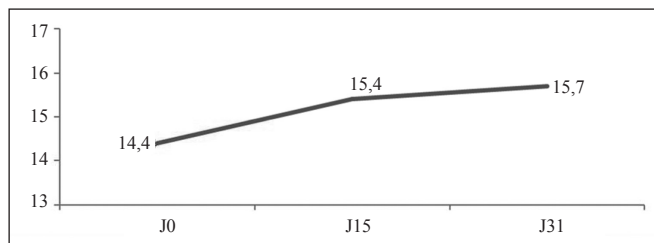


Figure 2.—Evolution of the Braden Score. $\Delta J0/J15$, *t*-test: P value: 0.0003 Significance: <0.001 $\Delta D0/D31$, *t*-test: P value: 0.0005. Significance: $P<0.001$.

These 22 pressure ulcers were located on the pelvis for 22.7% (N.=5) of them and 27.3% on the heels (N.=6). The other 11 locations concerned in particular the foot other than the heel for 22.7% (N.=5), the upper limb for 9.1% (N.=2), the lower limb (knee, calf) for 9.1% (N.=2), the face for 4.5% (N.=1), and the back for 4.5% (N.=1). These pressure ulcers were stage I for 31.8% (N.=7) of them, stage II for 40.9% (N.=9), stage III for 13.6% (N.=3), and stage IV for 13.6% (N.=3).

At D31, eight patients still had a total of 17 pressure ulcers located on the heel for 29.4% (N.=5) and on the pelvis for 11.8% (N.=2). As previously, the most frequent locations were the foot other than the heel for 47.1% (N.=8) and the upper limb for 11.8% (N.=2). These pressure ulcers were stage I for 17.6% (N.=3) of them, stage II for 35.3% (N.=6), stage III for 23.5% (N.=4), and stage IV for 23.5% (N.=4).

There was also an improvement in the Braden score throughout the follow-up period, which evolved from 14.4 ± 3.0 at D0 to 15.4 ± 3.1 at D15, and 15.7 ± 3.4 at D31 (<0.001) corresponding to an average increase of 1.3 ± 2.7 points (Figure 2).

The percentages of patients whose skin did not present maceration also increased from 51.1% at inclusion to 63.3% at D15 and 73.2% at D31 ($P<0.001$) (Figure 3).

The opinions of the patients and of the caregivers were also collected for each patient monitored in the incidence study. More than two-thirds of the patients (70.4%) rated the Axtair Automorpho® Plus mattress comfortable or very comfortable at day 15, and in particular, 90.9% of patients rated the noise level as low or very low.

Axtair Automorpho® Plus supports were also rated very positively by caregivers at D15. All the caregivers found the noise level of the support “low or very low”, 90.9% judged that the support was easy or very easy to set-up and maintain, and 86.4% found it made it very easy to turn patients and sit them up.

In terms of materiovigilance, five patients experienced

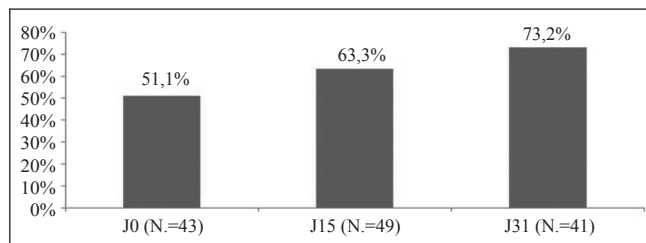


Figure 3.—Patients without maceration at the different follow-up visits.

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eight adverse events, which were all serious adverse events but none of them were considered to be attributable to the Axtair Automorpho® Plus support. These serious adverse events were five deaths, one of which was preceded by three hospitalizations leading to death. The reasons for death were: subdural hematoma following a fall (patient ETIE037), heart failure (patient HCOL012), acute dehydration (patient HCOL045), and respiratory distress (patients PAST060 and PAST176).

Results

The results show that no pressure ulcer occurred on the sacrum where the support acts strongly and that two-thirds of the pressure ulcers described in the study were only stage I, which also demonstrates how effective prevention was. They also show that two-thirds of pressure ulcers were located on the foot other than the heel, where the Axtair Automorpho® Plus support is the least likely to act.

This increased awareness also made for more thorough reporting of pressure ulcers during the follow-up of the study. Half of the incidence is represented by patients with stage I sores and localized on the foot other than the heel. This has to be given consideration because most studies attribute little importance to stage I pressure ulcers and ignore pressure ulcers occurring elsewhere than the occiput, sacrum, or heels. If this type of non-exhaustive assessment had been conducted in this study, the incidence of stage II to IV pressure ulcers would have been 3.5%. These elements must be compared with the results of the incidence of stage II to IV pressure ulcers resulting from a systematic review of the literature concerning 13 studies evaluating the effect of prevention with static air mattresses¹³ and which shows an average incidence of 7.8% when using such supports. Under these conditions, the ratio of stage II to IV incidences with Axtair Automorpho® Plus and with static support is 0.44 (3.5%/7.8%) and corresponds to the ratio of 0.42 of the incidence of pressure sores with motorized air structures and with classical supports calculated by C. Shi¹⁴ in a meta-analysis of 65 studies.

It is also noticeable that all these pressure sores occurred in severely paralyzed patients. In the subpopulation of high risk patients, the incidence falls to 5.6% [0.1; 27.3] and corresponds to one high risk patient of 83 years old who was hemiplegic, with mixed incontinence, a Braden score of 13, and bed rest of >15 hours per day. In this patient, again, the pressure ulcer was located on the foot other than the heel and no pressure ulcer was described on the occiput, sacrum, or heels.

In addition to information about the rate of pressure ulcer occurrence, the global incidence study also provides information about the evolution of pressure ulcer occurrence in this population of bedridden patients on Axtair Automorpho® Plus. It appears that not only the number of incidents of pressure ulcers is low, but that, far from increasing, the proportion of patients with a pressure ulcer decreases significantly in this population placed on the Axtair Automorpho® Plus support from 40.4% [27.6; 54.2] at inclusion to 22.4% [11.8; 36.6] at day 15, and 19.5% [8.8; 34.9] at day 31, *i.e.* it is halved. During this follow-up period, the percentages of maceration-free patients also increased from 51.1% at inclusion to 63.3% at day 15 and 73.2% at day 31, while the Braden scores rose over the follow-up period. These indications suggest that not only does the patient's use of Axtair Automorpho® Plus prevent the occurrence of pressure ulcers but that it contributes, in conjunction with the other measures implemented in the service and a probable improvement in the patients' health, to an improvement in those sores already present when patients were first put on this support.

Discussion

The prevalence of 3.9% [2.4, 6.2] observed in the study for all RS patients where Axtair Automorpho® Plus supports were available is statistically lower than that observed for RS services in the PERSE Study⁶ chosen for the historical comparison: 11.8% [10.8, 12.8] ($P < 0.0001$) and demonstrates the effectiveness of the prevention afforded by Axtair Automorpho® Plus supports. This quantitative efficiency is reflected qualitatively with 11.0% fewer stage III and stage IV pressure ulcers and 14.7% fewer sacrum locations.

In moderate to very high-risk patients, the prevalence is 2.2% [0.3; 7.9]. This lower prevalence among subjects with a moderate to very high risk than in the general population should not be viewed as paradoxical but as the effect of the prevention tools and of the careful monitoring of the patients at risk. It should be noted that the two patients in whom pressure ulcers occurred were patients at very high risk. One was hemiplegic, the other quadriplegic, taking psychoactive drugs, with Braden scores of 11 or 12 and who already had one or more pressure ulcers and one of them also had mixed incontinence.

The incidence study focuses exclusively on patients whose beds were equipped with Axtair Automorpho® Plus supports because of the risk of pressure ulcers and it shows an incidence of 7.0% [2.0; 17.0]. It is important to underline that in the context of this study, caregivers were

made very much aware of the need to declare stage I ulcers and pressure ulcers occurring at locations other than those most commonly described in literature such as on the foot other than the heel. This is reflected in the results of the study and confirms the evaluation of the preventive effect of the Axtair Automorpho® Plus support.

Conclusions

The results of the pressure ulcer prevalence study in rehabilitation departments where Axtair Automorpho® Plus supports were available and its comparison with results described in the PERSE national population study in rehabilitation services, as well as results of the study of pressure ulcer incidence in patients bedridden on Axtair Automorpho® Plus, confirm the expected benefit provided to patients in terms of prevention.

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