EVALUATION OF AXTAIR AUTOMORPHO® AXENSOR® AT15 MATTRESS - TABULATED SUMMARY UPDATED ON 01/03/2017

DESCRIPTION	
Study Title	Clinical follow-up after the marketing of the Axtair Automorpho® Axensor® alternating pressure air mattress (AT15) integrated to the care strategy for prevention and treatment aid of pressure sores implemented in intensive care units.
Type of study	Observational, Non-Interventional, Prospective, Single-Centre Study.
Framework, place of the study	Intensive Care Unit, Unit 4, Marie Curie Hospital, CHU (Centre Hospitalier Universitaire [University Hospital Centre]) of Charleroi, Lodelinsart, Belgium.
Investigators	Michèle Pachioli, nurse head of department, Intensive Care Unit, CHU of Charleroi, Maïté Delpire, ICU 4 head nurse of Marie Curie Hospital, CHU of Charleroi.
Study Date	January to March 2016.
METHOD	
Inclusion criteria	Adult patient (age > 18 years old) meeting the indications listed in the instructions for use: prevention and treatment aid of stage 1 to 4 established pressure sore(s) (according to medical opinion) for patients with high risk evaluated based on a validated scale and clinical judgement, raised during the day and bedridden more than fifteen hours or bedridden 24/7 who cannot be raised.
Non-inclusion criteria	Patient aged less than eighteen years old and for whom the product is contraindicated as mentioned in the instructions for use: weight above 180 kg, use of compression chamber, stretcher use.
Primary objective	- Evaluate the efficacy of AT15 in helping prevent pressure sores: onset or not of pressure sore(s).
Secondary objectives	- Evaluate the efficacy of AT15 in helping treat pressure sores: progress of the pressure sores existing at the time of enrolment, - Evaluate the safety of AT5 [sic: AT15]: onset or not of safety adverse event(s) related to AT15, - Evaluate the comfort of AT15: comfort felt by the patient, skin-mattress contact, ease of movement, discomfort created by the motor noise, disturbed sleep.
Sample size	N=19
Randomisation	Not applicable
Analysis of the results	Descriptive analysis. Data processing and analysis operated by the sponsor's medical service (Winncare).
RESULTS	
Subjects analysed	N=19
Follow-up period	- Average follow-up period: 9,61 ± 7.42 days (2; 31) - Qualification of stops: 37% Death (n=7), 63% Discharge from the department (n=12), 0% Technique
Patients' characteristics at the time of enrolment	- Female/Male distribution: 1.4 - Average age: 70.42 ± 13.34 years (41; 93) - Average weight: 80.73 ± 21.51 kg (51.5; 148) - Average height: 1.68 ± 0.08 m (1.56; 1.90) - Average BMI: 28.54 ± 6.01 (19.62; 41) - Recent abnormal weight loss*: 0% yes, 95% no (n=18), 5% NR (n=1) - General condition: 53% Poor (n=10), 42% Average (n=8), 5% Good (n=1) - Peripheral artery disease: 10.5% Severe (n=2), 16% Moderate (n=3), 10.5% mild (n=2), 63% nil (n=12) - Daily bed-confinement period: 89% not raised (n=17), 11% >15 hours (n=2), 0% 10 to 15 hours, 0% < 10 hours - Neurological disorder: 26% Severe (n=5), 21% Moderate (n=4), 37% Low (n=7), 16% Nil (n=3) - Average Norton score: 8.05 ± 1.99 (5; 11) - Physical condition: 26% Very poor (n=5), 63% Poor (n=12), 11% Average (n=2), 0% Good - Mental condition: 52.5% Stupor (n=10), 37% Confusion (n=7), 10.5% Apathetic (n=11), 0% Alert - Activity: 100% Bedridden (n=19), 0% Armchair-confined, 0% Walks with help (n=0), 0% Mobile - Mobility: 37% Immobile (n=7), 42% Very limited (n=8), 21% Slightly limited (n=4), 0% Complete - Incontinence: 31.5% Bladder and bowel (n=6), 58% Bladder (n=11), 10.5% Occasional (n=2), 0% Continent - Established pressure sores: 0 *HAS (Haute Autorité de Santé [French National Authority for Health]) opinion of CNEDIMTS (Commission Nationale d'Evaluation des Dispositifs Médicaux et des Technologies de Santé [National Committee of Medical Devices and Health Technologies]) of 22/12/2009: ≥ 5% in 1 month or ≥ 10% in 6 months Acronyms: HAS: Haute Autorité de Santé [French National Authority for Health]; CNEDIMTS: Commission Nationale d'Evaluation des Dispositifs Médicaux et des Technologies de Santé [National Committee of Medical Devices and Health Technologies]; NR: No Response; BMI: Body Mass Index
Professional practices	- Frequency of daily turn-overs: 0% Nil, 21% Less than 3 (n=4), 79% More than 3 (n=15) - Use of Posture Technical Aid Devices: 10.5% yes (n=2), 79% no (n=15), 10.5 % NR (n=2) - Number of daily skin massages: 0% Nil, 68% Less than 3 (n=13), 32% More than 3 (n=6)
Primary endpoint	- Number of pressure sores that appeared: 4 - Number of patients with pressure sores: 3 - Sites: 1 sacral pressure sore, 3 heel pressure sores - Severity: 4 stage 1 pressure sores
Secondary endpoints	Clinical progress - Average weight: 81.57 ± 23.45 kg (52; 146) - Average BMI: 28.84 ± 7.04 (19.93; 45.55) - Average Norton score: 10.16 ± 4.18 (5; 18) - Physical condition: 37% Very poor (n=7), 16% Poor (n=3), 42% Average (n=8), 5% Good (n=1) - Mental condition: 37% Stupor (n=7), 5% Confusion (n=1), 42% Apathetic (n=8), 16% Alert (n=3) - Activity: 79% Bedridden (n=15), 16% Armchair-confined (n=3), 5% Walks with help (n=1), 0% Mobile - Mobility: 42% Immobile (n=8), 5% Very limited (n=1), 53% Slightly limited (n=10), 0% Complete - Incontinence: 10% Bladder and bowel (n=2), 58% Bladder (n=11), 16% Occasional (n=3), 16% Continent (n=3)

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	- Progress of physical condition: 47% Improvement (n=9), 32% Stabilisation (n=6), 21% Deterioration (n=4) - Progress of mental condition: 63% Improvement (n=12), 32% Stabilisation (n=5), 5% Deterioration (n=1) - Progress of Activity: 21% Improvement (n=4), 79% Stabilisation (n=15), 0% Deterioration - Progress of Mobility: 37% Improvement (n=7), 47% Stabilisation (n=9), 16% Deterioration (n=3) - Progress of incontinence: 42% Improvement (n=8), 53% Stabilisation (n=10), 5% Deterioration (n=1) Progress of the skin condition: Not applicable (no established pressure sore at the time of the patients' enrolment) Progress of safety: No safety adverse event related to AT15 Evaluation of the comfort felt by the patient ▪ Censored results (no response): 37% of the patients (n=7) ▪ Usable results (responses): 63% of the patients (n=12) - Comfort: 67% Good to very Good (n=8), 33% Unpleasant (n=4) - Skin-mattress contact: 100% Good to very Good (n=12), 0% Unpleasant - Ease of movement: 75% Very Easy to Easy (n=9), 25% Difficult (n=3) - Discomfort due to the motor noise: 83% Non-existent to minor (n=10), 17% Significant (n=2) - Disturbed sleep: 83% Non-existent to minor (n=10), 17% Significant (n=2)
Side effects	No side effect. Pressure sore prevention care was continued simultaneously.

PRIMARY ANALYSIS - characteristics for the three patients with pressure sores

Table 1 - Progress of the BMI, Norton's score and skin condition

Patients	Follow-up (days)	BMI D0/DEND	Norton D0/DEND	Pressure sores DEND Sites/Stages
009	5 (discharge)	19.62 / 19.93	10/13	1 sacrum / stage 1
016	4 (discharge)	41.00/40.44	11/18	1 heel/stage 1
018	NR (death)	28.41/28.41	6/6	2 heels/stage 1

Table 2 - Risk factors for pressure sores at the time of enrolment according to CNEDIMTS, France

Patients	General condition	Neurological disorder	Daily bed-confinement	Daily movement	Daily massage
009	Average	Mild	Not raised	> 3	< 3
016	Average	Mild	> 15 hours	> 3	> 3
018	Poor	Severe	Not raised	< 3	< 3

No recent abnormal weight loss, peripheral artery disease and use of DATP (dispositifs d'aide technique au positionnement [positioning technical aid devices])

Table 3 - Progress of risk factors for pressure sores according to Norton's scale

Patients	Physical condition D0/DEND	Mental condition D0/DEND	Activity D0/DEND	Limitation of mobility D0/DEND	Incontinence D0/DEND
009	Poor/Average	Confused/Apathetic	Bedridden/Armchair	Mild/Mild	Bladder/Bladder
016	Poor/Average	Apathetic/Alert	Bedridden/Armchair	Strong/Mild	Occasional/None
018	Very poor/Idem	Stupor/Stupor	Bedridden/bedridden	Total/Total	Bladder/Bladder

SECONDARY ANALYSIS - characteristics for the five patients who were not satisfied with 1 or more criteria

Table 4 - Levels of patient satisfaction

Patient	Overall comfort	Skin-mattress contact	Ease of movement	Discomfort caused by the noise	Disturbed sleep
004	Unpleasant	Good	Easy	Non-existent	Minor
008	Unpleasant	Good	Difficult	Minor	Significant
011	Unpleasant	Good	Difficult	Significant	Minor
013	Unpleasant	Good	Easy	Significant	Significant
016	Good	Good	Difficult	Non-existent	Non-existent

Table 5 - Progress of risk factors for pressure sores according to Norton's scale

Patient	Physical condition D0/DEND	Mental condition D0/DEND	Activity D0/DEND	Limitation of mobility D0/DEND	Incontinence D0/DEND
004	Poor/Average	Confused/Apathetic	Bedridden/bedridden	Mild/Mild	Double/Occasional
008	Average/Good	Apathetic/Alert	Bedridden/Assisted walking	Strong/Mild	Bladder/None
011	Very poor/Average	Stupor/Apathetic	Bedridden/bedridden	Total/Mild	Double/Occasional
013	Poor/Average	Stupor/Apathetic	Bedridden/Armchair	Strong/Mild	Double/Occasional
016	Poor/Average	Apathetic/Alert	Bedridden/Armchair	Strong/Mild	Occasional/None

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DISCUSSION

In 2008, Defloor et al (1) measured the hospital prevalence of pressure sores in Belgium at 12.1%. The prevalence of stage 2 to 4 pressure sore lesions was 7%. The percentage of patients with maceration lesions (stage 1) was 5.7%. As far as the care units are concerned, the authors noticed more frequent pressure sore lesions in the intensive care units (ICU) and in geriatrics, units that have the highest number of patients at risk. In ICU, this study reports a stage 1 to 4 pressure sore prevalence of 19.9% (13% of stage 2 to 4) with 37% of stage 1 pressure sores. The use of adapted preventive care was more frequent in these units. The incidence rate of pressure sores varies considerably from one study to another. In 2009, Nijs et al. (2) show a cumulated pressure sore incidence (stage 2-4) appeared at least 48 hours after the admission of the patients to the ICU, of 20.1%. Another study conducted in 2009 (3) shows a pressure sore incidence (stage 1-4) in the ICU of 14.3%, of which 74% was stage 1. The average period of onset of a pressure sore was 10.4 ± 1.85 days and among the most influential risk factors was the length of stay and the level of activity.
The observational, prospective, single-centre study *AT15* was conducted in the Intensive Care Unit 4 of Marie Curie Hospital (CHU of Charleroi) for three months and included 19 patients aged on average 70.42 years old (41; 93), without pressure sores but at high risk to develop them (average Norton score at enrolment 8.05 ± 1.99 (5; 11)), bedridden between more than 15 hours to 24 hours a day, with a moderate-to-poor general condition, mostly linked to neurological disorders. Four pressure sores appeared on three patients. All pressure sores were stage 1 with sacral (n=1) and heel (n=3) localisation. The cause of hospitalisation, the main pathology and the related comorbidities, the history, the date of onset of the pressure sore, are missing elements to objectify the analysis.

Primary endpoint

Two heel pressure sores appeared in a patient evaluated to be at very high risk of pressure sores, in critical general condition (Norton 6 with severe neurological disorders reported); this patient died during the evaluation, despite the preventive measures used in order to reduce the support in the risk areas. A sacral pressure sore appeared in a patient whose risk level progressed favourably during his hospitalisation (Norton D0-DEND: 10-13); bladder incontinence was reported and he was placed in an armchair during the day, but there is insufficient data to identify the cause(s) that triggered the onset of this stage 1 pressure sore. The absence of photography makes it impossible to distinguish the presence or absence of Incontinence-Associated Dermatitis (IAD). A stage 1 heel pressure sore appeared in a patient with moderate-to-high risk level at the time of enrolment and nil at the time of discharge (length of stay: 4 days); this patient presented with class III (massive) obesity and was moved more than three times a day. It was not reported if the discharge function of the heel area, embedded in the mattress was used by the carers.
Nijs et al. (2) have shown that the ICU patients have additional risk factors besides those evaluated in other units and require evaluation and a special prevention protocol. The conduct of a new incidence study, integrating the collection of special risk factors of all the patients hospitalised in the unit, recording the primary and related pathologies of the patients, accurate data on the cardiorespiratory, neurological and vascular condition, could objectify the analysis of the results obtained and prove the prophylactic interest of the support.

Secondary endpoints

Twelve patients were able to cognitively answer the evaluation questionnaire for the comfort felt with AT15, of which seven patients felt good-to-very good comfort without reservations and five patients expressed at least one dissatisfaction. Among the patients who were the least tolerant to the support, one man stated difficulty moving, which could be due to his massive obesity. A second patient noticed overall discomfort, but satisfaction with respect to all the other quality-of-life criteria evaluated; the related factors of this patient were a BMI higher than 35 and an apathetic state. The last patient reported having disturbed sleep due to the significant motor noise.
The tolerance level of the device was deemed mostly “good to very good”.
No safety adverse event related to the use of the motorised air support was reported.

CONCLUSION

The population observed is heterogeneous in its characteristics, there is no historic check, the sample is low to deem the statistical result significant. The results show that the preventive measures implemented demonstrated the onset of a number of pressure sores and a severity less than the data reported in the literature studied. The pressure sore prevention aid support belongs to the five good high-impact practices. In this study, the Axtair Axensor AT15 alternating pressure motorised air support showed a prophylactic interest associated to the preventive measures validated and implemented in the intensive care unit, with the purpose of improving the care of patients with moderate-to-very-high risk of pressure sores. The tolerance level of the device was deemed mostly “good to very good”.

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