

CLINICAL STUDY, AXTAIR AUTOMORPHO MOTORISED AIR SUPPORT (1) – TABULATED SUMMARY

ITEM	DESCRIPTION
Product studied	AXTAIR AUTOMORPHO motorised air support
Type of study	Comparative, prospective, non-interventional, observational, and controlled Clinical Study.
Date of study	June 2005 to June 2006
Objective of the study	<p><u>Aim</u>: assess the improvement in the service expected from the AXTAIR AUTOMORPHO motorised air support, integrated into the care strategy on help in preventing and / or treating bedsores implemented as part of homecare; determine its suitability in the homecare and institutional environments.</p> <p><u>Main objective</u>: affirm tolerance of the AXTAIR AUTOMORPHO support by patients and carers, and the improvement in quality of life of the person cared for (comparing the operation of an automatic compressor versus a manual compressor).</p> <p><u>Secondary objective</u>: assess the contribution to maintaining or improving the skin condition of persons with reduced mobility presenting an assessed risk of bedsores linked to disturbances to their state of health or constituted bedsores.</p>
METHOD	
Criteria for inclusion	<p><u>Criteria for inclusion</u> Adults, young people until they are “grown up”, presenting a medium to high risk of developing a bedsore whilst lying down, measured on the validated Norton scale, monitored by Home Care, receiving palliative care, or admitted to an EHPAD (Accommodation Establishment for Dependant Elderly People) Persons who are bed-ridden for more than 15 hours. Persons with one or more bedsores in the support area and unable to move alone, subject to clinical judgement.</p> <p><u>Criteria for exclusion</u> Patients who weigh more than 135 kg. Patients who are confined to bed, who are physically incapable of moving alone, who are not assisted by a helper, who have several bedsores in the support area, and for whom the clinical benefit of the product has not been assessed against a therapeutic alternative.</p>
Context and place of study	<p>Study carried out by the Réseau Ville Hôpital Plaies et Cicatrisations du Languedoc Roussillon (Languedoc Roussillon Community Hospital Network, Wounds and Healing). Home care / EHPAD balance: 20/80.</p>
Main judgement criterion	Tolerance: ergonomics, safety, environmental compatibility. Perception of Comfort and Wellbeing transposed to assessing Quality of Life.
Secondary judgement criteria	Maintaining and / or improving skin condition.
Sample size	N = 38
Randomisation method	Not applicable
Method of analysing the results	Descriptive analysis
RESULTS	
Number of subjects analysed	N = 34
Duration of monitoring	32 days
Patient characteristics (without group comparability)	<p>Sex ratio W / M: 2.77 Average age: 80 years [40 < 105] Average weight: 56 kg [29 < 110] Average height: 1.63 m [1.45 < 1.80] Initial average BMI: 20.82 [11.72 < 30.86]</p> <p><u>Distribution of patients by pathology</u>:</p> <ul style="list-style-type: none"> - Neurology N = 5: paraplegia (3), tetraplegia (2) - Pathology of aging N = 7 Change in general health with unlabelled loss of independence (1) neuro-degenerative <i>Alzheimer's disease or similar</i> (3), loss of independence, end of life (3) - Cancerology with palliative-care component N = 5 Neo prostate with bone-marrow involvement (1), intestinal tumour (1), melanoma (1), neoplastic brain

	<p>tumour (1), unidentified (1)</p> <ul style="list-style-type: none"> - Cardio-vascular N = 1 decompensated heart failure (1) - Pneumology N = 1 Severe respiratory disease and bedsores (1) - Dermatology N = 8 post-operative bedsore surgery (2), vascular wounds <i>arterial with multiple lesions</i> (2), bedsores (4) - Ortho-traumatology N = 3: Pelvic fracture <i>Road-Traffic Accident (RTA)</i> (1), non-operable fracture of the neck of the femur (1), non-operable dislocation of hip prosthesis (1) <p><u>Pathologies or related states identified:</u> 19 cases of malnutrition, 6 diabetics with peripheral neuropathy, 9 cases of obliterating arteriopathy of the lower limbs, 3 cases of respiratory insufficiency, (Sat O₂ < 92%), 8 cases of neuro-degeneration, 8 cases of associated cardiac insufficiency, 9 cases of cognitive deficiency.</p> <p>Average initial Norton score: 8.19 [5 < 12] Total number of bedsores: 74 Location of bedsores: sacrum N = 30 (41%), heels N 20 (27%), others N = 24 (32%): <i>trochanter, ankle, malleoli, scapula, tibia, ischia, spinal cord, calf, thigh</i> Seriousness of bedsores: Stage 1 N = 6 (8%), Stage 2 N = 11 (15%), Stage 3 N = 23 (31%), Stage 4 N = 27 (36%), not recorded N = 7 (9%)</p>
<p>Characteristics relating to professional practices</p>	<p>Average period spent bed-ridden: 20 hours / day [10 < 24; SD 3.9] Average position of bed-ridden persons (hours / day): half-sitting 1 hour / day, contra-lateral supine position 1 hours / day, sitting: 3 hours / day Average time sitting in a seat (persons raised at least once per day): 4 hours / day. Average daily number of times turned over: 4 Reduction in the number of times turned over from the 3rd day of the study Turning over maintained for 2 patients (4 times / day): 1 woman aged 95 with loss of independence, and 1 man aged 75 with a neuro-degenerative pathology.</p>
<p>Results inherent in the main judgement criterion</p>	<p><u>Level of tolerance by criteria</u> level of satisfaction</p> <ul style="list-style-type: none"> - Effectiveness: 94.22% - Compatibility with care actions: 90.08% - Safety: 87.77% - User interface: 84.58% - How easy the product is to install: 83.66% - Ergonomics: 84.33% <p><u>Level of quality of life estimated by patients</u> level of satisfaction</p> <ul style="list-style-type: none"> - Comfort: 9.11 / 10 - Wellbeing 8.70 / 10
<p>Results inherent in the secondary judgement criteria</p>	<p>Average Norton score: 8.00 [5 < 12] Total number of bedsores: 44 Location of bedsores: sacrum N = 20 (45.5%), heels N = 9 (20.5%), others N = 15 (34%) Seriousness of bedsores: Stage 1 N = 6 (14%), Stage 2 N = 10 (23%), Stage 3 N = 15 (34%), Stage 4 N = 9 (20%), not recorded N = 4 (9%)</p>
<p>Secondary effects</p>	<p>None Bedsore-prevention care was carried out at the same time as a validated medical protocol.</p>

SUMMARY

Results by seriousness of bedsores

	Initial assessment	Final assessment	Increase
Stage 1 / 2 bedsores	17	16	6%
Stage 3 / 4 bedsores	50	24	52%
Total recorded	67	40	40%
Not recorded	7	4	-
N bedsores	74	44	-

Results by location of bedsores

	Initial assessment	Final assessment	Increase
Sacral bedsores	30	20	33%
Heel bedsores	20	9	55%
Other locations	24	15	38%
Total number of bedsores	74	44	40%

The study carried out as part of care in the home enabled, by the gathering of periodic data, to bring out the usefulness of the AXTAIR AUTOMORPHO motorised air support as part of a care strategy for preventing and treating bedsores. Tolerance levels were judged to be satisfactory to very satisfactory, with a 94% rate for effectiveness in helping with care, 90% for compatibility with care actions, 88% for safety, 85% for the user interface, and 84% for ergonomics. Assessing quality of life by means of criteria based on comfort and wellbeing is estimated at 8.85 ($[1 < 10]$), with an initial Comfort / Wellbeing ratio of 1, and 1.02 at the end of the study. Monitoring using photographs and / or a colour scale and / or a digital scale allowed the highlighting of the contribution made by the support in improving the lesion environment. When included in the care provided to people with high risk of bedsores and / or constituted bedsores, the motorised air support contributed very favourably to improving the state of the wound and to the general state of the persons receiving care.

CONCLUSION

The level of tolerance for the AXTAIR AUTOMORPHO motorised air support is compatible with the service expected of the home-care facility. The automatic system was judged superior to the manual one with regard to difficulties in measuring the person's weight. The support's technical performance is of particular help in healing constituted bedsores of up to stage 4. The quality of life for most of the persons receiving care was improved.

Abbreviations

RTA: Road-Traffic Accident

EHPAD: *Établissement Hébergeant des Personnes Âgées Dépendantes* (Accommodation Establishment for Dependant Elderly People)

W / M: Women / Men (Sex ratio)

Sat: Saturation

SD: Standard Deviation