WINNCARE group

CLINICAL STUDY E²CTA TABULATED SUMMARY

ITEM	DESCRIPTION
Reference	E²CTA
Type of study	Non-interventional prospective clinical study –observational type
Date and length of the study	15/12/2013 - 9 months
Objective of the study	Assessment of the performance of the Axtair Automorpho axensor device in caring for Persons at Risk of Bedsores (PRBs) or Person Suffering from Bedsores (PSBs) (PSB).
METHOD	
Criteria for inclusion	Persons receiving care who are aged over 17, presenting a risk of occurrence of bedsores or suffering from one or more bedsores of stages 1 to 4 on the EPUAP* scale.
Context and place of study	Health and medico-social establishments on French territory, and Home Care.
Products studied	AXTAIR AUTOMORPHO motorised air support incorporating axensor technology.
Main judgement criterion	Maintaining or improving the person's skin condition.
Secondary judgement criterion / criteria	Ergonomics, MMI, safety, comfort – according to caregivers and care recipients.
Sample size	N = 31
Randomisation method	Not applicable
Method of analysing the results	Descriptive analysis.
RESULTS	
Number of subjects analysed	N = 29 (2 cases rejected), i.e. a total of 31 assessments carried out.
Duration of monitoring	Average: 25 days (min: 6 < max: 78); median 17, SD 17.25
Patient characteristics *(No group comparability)*	Sex ratio W / M = 2.2; Average age 81 years [18 < 96; median 84; SD 17,18]. Average weight 63kg [35 < 117; median SD 18.09]. Average height 1.62 m [1.5 < 1.89; median 1.6; SD 0,11]. Average BMI 24 [16 < 35; median 23.63; SD 6.29]. Average Norton 8 [6 < 11; median 8; SD 1.22]. Average time spent bed-ridden 20 hours [12 < 24; median 20; SD 3,1] including 29% continuous. Poly-pathological patients N = 11 (65%) Pathology types: Neurology N = 23, Cardio-vascular N = 10 Pneumology N = 8; Orthopædics N = 9; Endocrinology N = 6; Cancerology N = 4; Rheumatology N = 1. PRB N = 6; PSB N = 23 (Total number of bedsores: N = 34) Initial level of change in general health: Deteriorated N = 16; Stationary N = 11; Improved N = 2 Location of bedsores: Sacrum N = 16, Heel(s) N = 13 (PSB 2 heels N = 4) (Others N = 5) Seriousness of bedsores: Stage 1 N = 13 (37%), Stage 2 N = 11 (31,5%); Stage 3 N = 4 (11.5%); Stage 4 N = 7 (20%)
Characteristics linked to professional practices	Types of previous supports: simple mattress N = 5; egg-box N = 6; visco-elastic N = 1, motorised air N = 11. Number of changes in position (unit per day): average 3.6 per 24 hours [0 < 12; median 4; SD 1.49]. Number of times raised (unit per day): average 1.3 [0 < 6; median 1; SD 1.28]. Length of time raised (hours): average 3 hours [0 < 12; median 3; SD 2,86].
Results inherent in main judgement criteria	Number of occurrences of bedsores during the study: N = 0 Healing development of bedsores: Favourable N = 22, stationary N = 1 Improvement in general health upon exit Deteriorated N = 4 (2 DC); Stationary N = 9; Improved N = 16.
Results inherent in secondary judgement criterion / criteria	Ergonomics: Very satisfied [10.3], satisfied [13.3], Little satisfied [0], Unsatisfied [0] MMI: Very satisfied [5], satisfied [14.3], Little satisfied [1.5], Unsatisfied [0] Safety: Very satisfied [9.3], satisfied [11], Little satisfied [1], Unsatisfied [0] According to the assessors Comfort: Very satisfied [10], satisfied [10.3], Little satisfied [2], Unsatisfied [1]

	According to the person being treated Comfort: Very satisfied [3], satisfied [9], Little satisfied [0], Unsatisfied [1]
Secondary effects	None Bedsore prevention care was given at the same time.

SUMMARY

The AXTAIR AUTOMORPHO support with axensor technology shows its value through its contribution to the strategy of caring for poly-pathological PSBs and PRBs in establishments and at home. At the end of the study, no occurrence of bedsores was noted, with improvement in 96% of constituted bedsores, concomitantly with the improvement in the general health of 52% of patients. Users gave an overall "satisfactory" rating to compatibility with the care environment and the comfort of persons receiving care.

Abbreviations:

Statistics: average: Average; median: Median; SD.: Standard Deviation; min. minimum value; max.: maximum value;

MMI: Man-Machine Interface PRB: Patient(s) at Risk of Bedsores; PSB: Patient(s) Suffering from Bedsores EPUAP: European Pressure Ulcer Advisory Panel.

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Updated on 22 December 2013

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