EVALUATION OF ALOVA MULTI-SUPPORT MATTRESS TOPPER (1998) - TABULATED SUMMARY UPDATED ON 01/03/2017

DESCRIPTION	
Study Title	Evaluation of efficacy of ALOVA mattress topper in the treatment of People at Risk for Pressure Sores or with Pressure Sores.
Type of Study	Observational, Non-Interventional, Prospective, Multicentre Study.
Study Date	1998.
Evaluation Departments	APHP (Assistance Publique Hôpitaux de Paris [Public Assistance Hospitals of Paris]), Ivry sur Seine (92), Orbe Wing, Dr S. MEAUME Dr Bouffard-Vercelli Functional Rehabilitation Centre, Cerbère (66), Dr ENJALBERT Paul Coste Floret Functional Rehabilitation Centre, Lamalou les Bains (34), Dr B. GARLENQ and Dr H. GINGLINGER
METHOD	
Inclusion criteria	Hospitalised patients at risk for pressure sores evaluated according to the Waterlow scale and/or with current stage 1 to 4 pressure sores.
Primary objective	Preservation or improvement of the patients' skin condition.
Secondary objectives	Opinion of the carers: ease of use of the support. Opinion of the patients: willingness to keep the mattress at the end of the study.
Sample size	61
Randomisation	Not applicable.
Analysis of the results	Descriptive analysis: the descriptions are conducted by averages, minimum and maximum values for the quantitative variables and by numbers and percentages for the qualitative variables. Data processing and analysis operated by the sponsor's medical service.
Abbreviations	ND: Not Documented. M: Male; F: Female
RESULTS	
Subjects analysed	61 (one trial withdrawal analysed)
Follow-up period	15 days
Characteristics of the patients At the time of enrolment	F/M distribution: 0.64; Average age: 60.03 years (20; 99); Average weight: 64.77 kg (31; 100); Average height: 1.67 m (1.50; 1.93) Average BMI: 23.11 (15.6; 39.1) 23 pathologies, of which 6 primary: paraplegia, tetraplegia, hemiplegia, dementia and depressive disorders, orthopaedic and rheumatic problems, heart disease and chronic peripheral artery disease; 57.4% of the patients have spinal cord injuries 21 Special diets: 4 diabetic, 13 high protein, 1 high calorie, 1 high carbohydrates, 1 hepatic, 1 enteral nutrition Daily bed-confinement: 15 hours on average (9; 24). 12 patients < 12 hours; 34 patients between 12 and 18 hours; 15 patients between 18 and 24 hours Daily sitting: 6.7 hours on average (0; 14). 31 patients between 0 and 6 hours; 28 patients between 6 and 12 hours; 2 patients > 12 hours Initial average Waterlow score: 18.3 (10; 33) Risk level of the entire population: 15 patients at risk, 24 at high risk, 22 at very high risk Classification of patients according to their skin condition: 43 with no pressure sores, 18 with one pressure sore Total number of pressure sores: 18 Severity of pressure sores: Stage 1 (2), Stage 2 (10), Stage 3 (4), Stage 4 (2) Location of the pressure sores: 9 Sacrum, 4 Heel, 5 others (2 ischium, 1 trochanter, 1 foot, 1 buttock) 26 patients with pain: 6 pain related to the pressure sore, 19 related to the illness, 1 ND
Professional practices	

	Practice	Period/patient/day	Frequency/patient/day
Cleaning	61 patients	-	1.6 (1; 5)
Turn-overs	18 patients	9.16 min (5; 15)	6 (2; 10)
Physiotherapy	55 patients	85.45 min (15; 90)	2.27 (1; 4)

Local treatment of the pressure sores: 8 hydrocolloid, 3 Sofra-Tulle, 1 iodoform gauze, 3 enzymatic debridements
Carer time in prevention and/or treatment: 35 patients < 1 hour, 22 patients between 1 and 2 hours, 4 patients > 2 hours
Daily physiotherapy time: 31 patients ≤ 1 hour; 15 patients between 1 and 2 hours; 9 patients > 2 hours

Primary endpoint

	Prevention total population	Prevention for Patients at risk without pressure sores	Treatment of Patients with pressure sores
Number on D0	61	43	18
Efficacy of ALOVA mattress overlay	**57 (93%)**	**42 (98%)**	**15 (83%)**
Favourable progress	11	NA	11
Stationary status	46	42	4
Unfavourable progress	1	0	1
Onset of pressure sore	2	1	1
Study withdrawal	1	0	1

1 unfavourable progress
Incidence: 1.6% of the total population
Result: high risk of pressure sore between D0 and D15; 1 pressure sore on D0 (sacrum, stage 1); 1 pressure sore on D15 (sacrum, stage 2)
Risk factors: 63 years old, BMI 19.3, amyotrophic lateral sclerosis, high-protein diet, painless
Daily protocol: bed confinement 12 hours, seated between 6 and 12 hours, carer time between 1 and 2 hours, 1 cleaning, without turn-over or physiotherapy
2 onsets of pressure sore
Incidence: 3.3% of the total population
Patient 1:

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	Result: very high risk of pressure sore between D0 and D15; 1 pressure sore on D0 (foot, stage 4); 2 pressure sores on D15 (foot, stage 4 and sacrum, stage 4) Risk factor: 88 years old, BMI 25.3, multiple sclerosis and arteritis, diabetic diet, intense pain related to the pressure sore, septicaemia Daily protocol: not raised, carer time between 1 and 2 hours, 1 cleaning, 8 turn-overs, 2 physiotherapy sessions Care of the pressure sore: enzymatic debridement on D0; hydrocolloid dressing on D15 Patient 2: Result: very high risk of pressure sore on D0 and D15; no pressure sore on D0; 1 pressure sore on D15 (sacrum, stage 2) Risk factor: 68 years old, BMI 26.1, paraplegia, diabetic diet, pain Daily protocol: not raised, carer time between 1 and 2 hours, 1 cleaning, 8 turn-overs, 2 physiotherapy sessions Note: turn-over frequency decreased on D15 (patient's refusal) Care of the pressure sore: eosin and antimycotic treatment (sacral mycosis) **1 study withdrawal** Patient at risk for pressure sore, without pressure sore on D0 Risk factors: 94 years old, BMI 25.3, unsteadiness of gait with diffuse osteoarthritis, mild pain (osteoarthritis), no diet Daily protocol: bed confinement 11 hours, seated for 6 hours, carer time < 1 hour, without turn-over, 1 cleaning
Secondary endpoints	Personnel's opinion regarding the support: ease of use: yes 90.2% (55 cases) Patient's opinion regarding the support: 54 wish to keep the mattress (88.5%), 3 do not state their opinion (4.9%), 4 no (6.6) Patient in pain on D15: 14
Side effects	No side effect. Pressure sore prevention care was continued simultaneously.

CONCLUSION

ALOVA mattress overlay appears to provide effective support in the prevention and treatment of pressure sores, in this sample of 61 cases, representative for the population usually admitted to rehabilitation and geriatric medium-term stay centres, irrespective of the level of risk for pressure sores evaluated according to the Waterlow validated scale, with an **efficacy noted in 93% of the total population**, 98% of the population at risk without pressure sores and 83% of the population at risk with pressure sores. The main risk factors retained are age older than 60, deterioration of the general condition and/or an intercurrent pathology, and well as poor treatment compliance. The ease of use, maintenance and nursing care are extensively stressed out by the carers (90.2% satisfaction). The difficulties encountered pertain essentially to obese patients, patients with difficulty in moving, but had only little effect on the efficacy of the support. 88.5% of the patients say they wish to keep the support and 93.5% actually kept it. 3 patients could not express their wish. 4 patients deemed it uncomfortable.

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EVALUATION OF ALOVA MULTI-SUPPORT MATTRESS (2004) - TABULATED SUMMARY UPDATED ON 01/03/2017

DESCRIPTION	
Study Title	Evaluation of efficacy of ALOVA mattress in the treatment of People at Risk for Pressure Sores or with Pressure Sores.
Type of Study	Observational, Non-Interventional, Prospective, Multicentre Study.
Study Date	2004.
Evaluation Departments	30% Medicine (n=12), 32.5% Spec. medicine (n=13), 20% Long-term stay (n=8), 12.5% Surgery (n=5), 5% ICU (n=2).
METHOD	
Inclusion criteria	Hospitalised patients at risk for pressure sores (according to the validated scale and clinical judgement) and/or with current pressure sores.
Primary objective	Evaluate the efficacy of the Alova mattress: onset or not of pressure sores.
Secondary objectives	Evaluate the opinion of the carers: ease of installation, comfort, efficacy, stabilisation, patient's movement, bed remake, Evaluate the opinion of the patients: satisfaction, tolerance and safety.
Sample size	N=40
Randomisation	Not applicable.
Analysis of the results	Descriptive analysis: the descriptions are conducted by averages, minimum and maximum values for the quantitative variables and by numbers and percentages for the qualitative variables. Data processing and analysis operated by the sponsor's medical service.
Abbreviations	ND: Not Documented. M: Male; F: Female
RESULTS	
Subjects analysed	N=40
Follow-up period	Average follow-up period: 25.27 days (1; 50)
Characteristics of the patients At the time of enrolment	M/F distribution: 0.86; Average age: 71.38 years (28; 95); Average weight: 69.47 kg (36; 90); Average height: 1.63 m (1.48; 1.82) Average BMI: 16.25 (10.3; 25.3) Average daily bed confinement: 18.17 hours/day (6; 24) Mobility: 35% Yes (n=14), 10% Average (n=4), 50% no (n=20), 5% ND (n=2) Conscience: 52.50% Good (n=21), 3% Average (n=14), 10% Poor (n=4), 0% Coma, 2.5% ND (n=1) Continence: 35.5% Yes (n=13), 57.50% No (n=23), 10% ND (n=4) Nutrition: 20% Good (n=8), 52.50% Average (n=21), 25% Poor (n=10), 2.5% ND (n=1) Pain: 37.5% Yes (n=15), 50% No (n=20), 12.50% ND (n=5) Pressure sores: 10 of the patients without risk (n=4), 30% at risk (n=12), 50% with pressure sores (n=20), 10% ND (n=4) 24 established pressure sores: 56% stage 1 (n=14), 20% stage 2 (n=5), 12% stage 3 (n=3), 12% stage 4 (n=3)
Professional practices	Number of daily turn-overs: 2.8 (0; 10) Indication of the support considered by the carer: 67.50% prevention (n=27), 7.50% curative (n=3), 17.50% preventive and curative (n=7), 7.50% prevention and comfort (n=3)
Primary endpoint	No onset of pressure sores
Secondary endpoints	<u>Evaluation of the equipment</u> Installation: 92.50% easy (n=37), 0% complicated, 5% heavy (n=2), 2.5% ND (n=1) Comfort: 65% very good (n=26), 25% Good (n=10), 2.50% Average (n=1), 7.50% ND (n=3) Efficacy: 35% very good (n=14), 50% Good (n=20), 5% Average (n=2), 10% ND (n=4) Maintenance: 95% Easy (n=38), 2.50% Difficult (n=1), 0% Heavy, 2.50% ND (n=1) Patient's movement: 90% Easy (n=36), 5% difficult (n=2), 5% ND (n=2) Bed remake: 95% Easy (n=38), 2.50% Difficult (n=1), 2.50% ND (n=1) <u>Patient's satisfaction</u> Properly installed: 67.50% Yes (n=27), 5% No (n=2), 27.50% ND (n=11) Sleeps better: 30% Yes (n=12), 20% No (n=8), 50% ND (n=20) Does not slide in bed: 45% Yes (n=18), 15% No (n=6), 40% ND (n=16) <u>Patient's tolerance</u> Is not in pain: 42.5% Yes (n=17), 17.50% No (n=7), 40% ND (n=16) Has a relaxed face: 57.50% Yes (n=23), 42.50% ND (n=17) Has healthy skin: 62.50% Yes (n=25), 15% No (n=6), 22.50% ND (n=9) Has normal sweating: 65% Yes (n=26), 2.50% No (n=1), 32.50% ND (n=13) <u>Patient's safety</u> Moves in bed without risks: 72.50% Yes (n=29), 10% No (n=4), 17.50% ND (n=7)
Side effects	No side effect. Pressure sore prevention care was continued simultaneously.
CONCLUSION	
ALOVA multi-support memory foam mattress proves to be effective in helping prevent pressure sores. No onset of pressure sores has been noted, on the contrary, the pre-existing lesions have stabilised or progressed favourably. The carers are content with the equipment and the patient's tolerance is good.	

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