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CLINICAL STUDY – ALOVA OVERLAY TABULATED SUMMARY

ITEM	DESCRIPTION
Product studied	ALOVA overlay
Type of study	Non-interventional prospective clinical study – observational type
Date of study	1998
Objective of the study	Assessing the performance of the ALOVA overlay when caring for Persons at Risk of Bedsores (PRBs) or Persons Suffering from Bedsores (PSBs)
METHOD	
Criteria for inclusion	Persons admitted to hospital and presenting a risk of the appearance of bedsores or suffering from one or more bedsores rated from stages 1 to 4 on the Waterlow scale
Context and place of study	Establishments - APHP (Assistance Publique – Hôpitaux de Paris – Paris Hospital System) Charles Foix Hospital Ivry sur Seine (Val de Marne département), L'Orbe Pavillon head of study: Dr. S. Meaume - Dr. Bouffard-Vercelli Functional Rehabilitation Centre Cerbère (Pyrénées Orientales département), head of study: Dr. Enjalbert -Paul Coste Floret Functional Rehabilitation Centre Lamalou les Bains (Hérault département), head of study: Dr. B. Garlenq and Docteur H. Ginglinger
Main judgement criterion	Maintaining or improving the person's skin condition
Secondary judgement criteria	Healthcare staff assessing the ease of use of the support Patient's willingness to retain the support at the end of the study
Sample size	N = 61
Randomisation method	Not applicable
Method of analysing the results	Descriptive analysis
RESULTS	
Number of subjects analysed	N = 61
Duration of monitoring	15 days
Patient characteristics (without group comparability)	Sex ratio W / M: 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 different pathologies, 6 main types *Paraplegias, tetraplegias, hemiplegias, dementia and depressive syndromes, orthopædic and rheumatic problems, cardiopathies and chronic obliterating arteriopathies of the lower limbs* 57.4% of the population studied had spinal-cord injuries Average initial Waterlow score: 18.3 [10 < 33] Waterlow score: at risk N = 15 (24.6%), at high risk N = 24 (39.3%), at very high risk N = 22 (36.1%) PRB N = 61 (100%), including: PRB without bedsores N = 43 (70.5%), PSB N = 18 (29.5%) Total number of bedsores: N = 21 Seriousness of bedsores: Stage 1 N = 2 (9.5%), Stage 2 N = 12 (57.1%), Stage 3 N = 4 (19%), Stage 4 N = 3 (14.3%) Location of bedsores: Sacrum N = 9 (42.9%), Heel N = 5 (23.8%), Ischium N = 2 (9.5%), Trochanter N = 1 (4.8%), Foot N = 2 (9.5%), Buttock N = 1 (4.8%), back N = 1 (4.8%) Patients in pain N = 26 (42.6%), including: N = 6 PSB (33.% of PSBs), N = 2- PRB (46.5% of PRB with no bedsores) Pain intensity by verbal analogy scale: Weak N = 17 (65.4%), Average N = 7 (26.9%), Intense N = 2 (7.7%)
Characteristics relating to professional practices	Average time spent in bed / 24 hours: 15 hours [9 < 24] Average time spend seated / 24 hours: 6.7 hours [0 < 14] Turning over: 29.5% Average time required to turn over: 9.16 minutes [5 < 15] Average frequency of turn-over / 24 hours 6 [2 < 10] Number of personal hygiene sessions per patient / 24 hours 1.6 [1 < 5] Physiotherapy session: 90.2%

	Average length of physiotherapy session per 24 hours: 85.45 minutes [15 < 90]
	Average frequency of Physiotherapy sessions / 24 hours 2.27 [1 < 4]
	Specific regimes: 34.4% (19% diabetic, 61.9% high-protein, 4.8% high-calorie, 4.8% high-carbohydrate, 4.8% hepatic, 4.8% intra-jejunal feeding
	Therapeutic protocol in case of bedsores: application of a hydrocolloid dressing 44.4%, tulle gras dressing 16.7%, iodoform wick dressing 5.6%, enzymatic detersion 16.7%, none 16.7%
	Care time for prevention and / or treatment: 57.4% less than 1 hour, 36.1% 1 hour to 2 hours, 6.5% over 2 hours
Results inherent in the main judgement criterion	1 exit from the study, Number of subjects analysed by Day 15 N = 60
	Waterlow score by Day 15: at risk N = 14 (23.3%), at high risk N = 25 (41.7%), at very high risk N = 21 (35)%
	PRB N = 60 (100%), including: PRB with no bedsores N = 49 (81.7%), PSB N = 11 (18.36%)
	Total number of bedsores: N = 14
	Seriousness of bedsores: Stage 1 N = 0 (0%), Stage 2 N = 7 (50%), Stage 3 N = 3 (21.4%), Stage 4 N = 4 (28.6%)
	Location of bedsores: Sacrum N = 7 (50%), Heel N = 3 (21.4%), Trochanter N = 1 (7.1%), Foot N = 2 (14.3%), back N = 1 (7.1%)
	Patient pain N = 14 (23.3%), including N = 3 PRB (27.3% of PRBs), N = 11 PRB with no bedsores (22.4% of PRBs with no bedsores)
	Pain intensity by verbal analogy scale: Weak N = 8 (57.1%), Average N = 4 (28.6%), Intense N = 2 (14.3%)
	Presentation of Results
	Very good: improvement of a pre-existing bedsore
	Good: non-occurrence of bedsores, stability of a pre-existing bedsore
	Average: aggravation of a pre-existing bedsore
	Poor: occurrence of a bedsore
	Overall results (total population)
	Very good N = 11 (18%)
	Good N = 46 (75.4%)
	Average: N = 1 (1.6%)
	Poor: N = 3 (4.9%) including 1 exit from the study
	Results by initial Waterlow score (total population)
	Patients at risk: Very good or good N = 14 (93.3%), Poor N = 1 (6.7%)
	Patients at high risk: Very good or Good N = 23 (95.8%), Average N = 1 (4.2%)
	Patients at very high risk: Very good or Good N = 20 (90.9%), Poor N = 2 (9.1%)
	Results for the population suffering from bedsores on Day 0
	Very good N = 11 (61.1%)
	Good N = 5 (27.8%)
	Average N = 1 (5.6%)
	Poor N = 1 (5.6%)
	Results by presence or absence of initial pain
	Patients in pain: Very good 16%, Good 76.9%, Poor 4%
	Patients not in pain: Very good 20%, Good 74.3%, Average 2.9%, Poor 2.9%
	Results by intensity of initial pain
	Weak Pain: Very good 70.5%, Good 23.5%, Poor 5.9% (2 exit from the study)
	Average Pain: Good 100%
	Intense Pain: Good 50%, Poor 50%
	Development of the state of pain in the population
	Patients in initial pain: favourable development 57.7%, state maintained 38.5%, 1 exit from the study
	Patients with no initial pain: state maintained 91.4%, unfavourable development 8.6%
	Results by age
	[20-59 years]: 100% very goof or good
	[60-79 years]: 90% very good or good, 5% average, 5% poor
	[80-99 years]: 88.2% very good or good, 11.8% poor

	Results by BMI BMI less than 21 (32.8%): 95% very good or good, 5% average BMI of 21 to 27.5 (50.8%): 90.3% very good or good, 9.7% poor BMI of 27.5 to 31.7 (14.8%): 100% good BMI above 31.7 (1.6%): 100% good **Results based on 6 main pathologies** Paraplegias (19.7%): 91.7% very good or good, 8.3% poor Tetraplegias (9.8%) 100% very goof or good Hemiplegias (27.9%): 100% good Dementia and depressive syndromes (13.1%): 100% very goof or good Orthopædic and rheumatic pathologies (19.7%): 91.7% very good or good, 8.3% poor Cardiopathies, chronic obliterating arteriopathies (11.5%) 85.7% very good or good, 14.3% poor **Results based on time spent lying down** Bed-ridden < 12 hours (19.7%): very good 8.4%, good 83.2%, poor 8.4% Bed-ridden [12-18 hours] (55.7%) very good 11.8%, good 85.3%, average 2.9% Bed-ridden [18-24 hours] (24.6%) very good 40%, good 46.7%, poor 13.3% **Results by time spent seated** Seated [0-6 hours] (50.8%) very good 22.6%, good 67.7%, poor 9.7% Seated [6-12 hours] (45.9%) very good 14.3%, good 82.1%, average 3.6% Seated > 12 hours (3.3%) good 100% **Results based on turning over** Regular (29.5%): very good 50%, good 38.9%, poor 11.1% Not done (70.5%): very good 7%, good 88%, average 2.5%, poor 2.5% **Results by daily physiotherapy time** Less than or equal to 1 hour (56.4%): very good 25.8%, good 64.5%, poor 9.7% 1 to 2 hours (27.3%): very good 20%, good 80% More than 2 hours (16.3%): good 100% **Results by diet** Diabetic diet N = 4: very good N = 1, good N = 2, poor N = 1 High-protein diet N = 15: very good N = 4, good N = 10, average N = 1 Hepatic diet N = 1: good N = 1 Intra-jejunal feeding N = 1: good N = 1 **Results by time spent daily in providing preventive care or treatment** Less than 1 hour (57.4%) very good 14.3%, good 82.8%, poor 2.9% 1 to 2 hours (36.1%): very good 18.5%, good 68%, average 4.5%, poor 9% More than 2 hours (6.5%): very good 50%, good 50%
Results inherent in the secondary judgement criteria	**Assessment of the support by staff** Ease of use: yes 90.2% **Assessment of the support by patients** The patient wishes to keep the pillow: yes 88.5%, no response 4.9%, no 6.6%
Secondary effects	None Bedsore prevention care was given at the same time.

The role of age: 100% of average or poor results were obtained from subjects aged 60 or over, with no linear correlation with age. The use of the support with elderly subjects was not brought into question.

BMI: not preponderant in the determinism of the results. 100% of results were good in subjects considered obese. The support seemed to be a useful alternative in cases of excess weight.

Associated pathology: the support showed effectiveness comparable across the various categories, so it can be used with extremely varied pathologies

Waterlow score: no significant difference in result by level of bedsore. The ALOVA overlay is positioned amongst supports with good preventive effectiveness, well above standard foam supports.

The presence of pre-constituted bedsores: does not seem to be a contra-indication for the use of this type of support. The preventive effect on risk areas remains excellent, the curative effect on areas with lesions seems very good, with reduction or stabilisation of bedsores in 88.9% of cases, regardless of stage.

Pain: non-determining element, the very good or good results were significantly associated with favourable developments in respect of pain.

Time spent lying down and seated: not significantly determinant. The majority of poor results were concentrated in subjects who were bed-ridden for between 18 and 24 hours and / or seated for between 0 and 6 hours, illustrating the influence of lying down in the causation and aggravation of bedsores.

Turning over: no significant difference noted between subjects who were turned over and those who were not. The practice must be tailored to each case, based on the level of risk of the subject to whom care is provided.

Daily length of physiotherapy session: appears determinant, since 100% of subjects who receive it for more than 1 hour per day record very good or good results, whereas 100% of average or poor results come from patients who do not receive it or who receive it for less than 1 hour per day. That confirms the essential role of mobility in preventing bedsores.

Diet: an important criterion, 94.1% of very good or good results in patients with an enriched diet, in particular high in protein. The case of diabetes should be looked at separately. The high-carbohydrate diet is an integral part of treating the illness, but it cannot be used alone to protect the patient from the risk of bedsores.

Daily care time spent in preventing or treating bedsores: proportional to risk. Subjects receiving care time of more than 2 hours obtain good or very good results.

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TABULATED RESULTS

Population by Waterlow index

	Initial assessment	Final assessment
Population at risk	15	14
Population at high risk	24	25
Population at very high risk	22	21
Population Total	**61**	**60**

Population by presence or risk of bedsores

	Initial assessment	Final assessment
PRB with no bedsores	43	49
PSB	18	11
Population Total	**61**	**60**

Results by seriousness of bedsores

	Initial assessment	Final assessment	Increase
Stage 1 / 2 bedsores	14	7	7
Stage 3 / 4 bedsores	7	7	-
Total number of bedsores	**21**	**14**	**7**

Results by location of bedsores

	Initial assessment	Final assessment	Increase
Bedsores – sacrum	9	7	2
Bedsores – heels	5	3	2
Bedsores – ischia	2	0	2
Bedsores – trochanter	1	1	-
Bedsores – foot	2	2	-
Bedsores – buttock	1	0	1
Bedsores – back	1	1	-
Total number of bedsores	**21**	**14**	**7**

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Selective results

Results		Very good	Good	Average	Poor
Overall		18%	75.4%	1.6%	4.9%
Bedsores	PRB at risk	93.3%		0	6.7%
	PRB at high risk	95.8%		4.2%	0
	PRB at high risk	90.9%		0	9.1%
	PSB	61.1%	27.8%	5.6%	5.6%
Pain	Patient in pain	16%	76.9%	0	4%
	Patient not in pain	20%	74.3%	2.9%	2.9%
	Weak pain	70.5%	23.5%	5.9%	0
	Average pain	0	100%	0	0
	Intense pain	0	50%	0	50%
Age	Elderly patient [20-59]	100%		0	0
	Elderly patient [60-79]	90%		5%	5%
	Elderly patient [80-99]	88.2%		0	11.8%
BMI	Patient with BMI < 21	95%		5%	0
	Patient with BMI [21-27.5]	90.3%		0	9.7%
	Patient with BMI [27.5-31.7]	0	100%	0	0
	Patient with BMI > 31.7	0	100%	0	0
Pathologies	Paraplegia	91.7%		0	8.3%
	Tetraplegia	100%		0	0
	Hemiplegia	0	100%	0	0
	Dementia and depressive syndromes	100%		0	0
	Orthopædic, rheumatic	91.7%		0	8.3%
	Cardiopathy, chronic obliterating arteriopathy	85.7%		0	14.3%
Lying down	Bed-ridden < 12 hours	8.4%	83.2%	0	8.4%
	Bed-ridden [12-18 hours]	11.8%	85.3%	2.9%	0
	Bed-ridden [18-24 hours]	40%	46.7%	0	13.3%
Sitting position	Seated [0-6 hours]	22.6%	67.7%	0	9.7%
	Seated [6-12 hours]	14.3%	82.1%	3.6%	0
	Seated > 12 hours	0	100%	0	0
Turning over	Turning over regularly	50%	38.9%	0	11.1%
	No turning over	7%	88%	2.5%	2.5%
Physiotherapy	Daily session ≤ 1 hour	25.8%	64.5%	0	9.7%
	Daily session [1 to 2 hours]	20%	80%	0	0
	Daily session > 2 hours	0	100%	0	0
Diet	Diabetic	25%	50%	0	25%
	High-protein	27%	67%	7%	0
	Hepatic	0	100%	0	0
	Intra-jejunal feeding	0	100%	0	0
Care time spent in prevention and / or treatment	Daily time < 1 hour	14.3%	82.8%	0	2.9%
	Daily time [1-2 hours]	18.5%	68%	4.5%	9%
	Daily time > 2 hours	50%	50%	0	0

SUMMARY

Essential risk factors:

- age over 60
- the existence of change in general health and / or an intercurrent pathology
- poor compliance with treatment

The effectiveness of the ALOVA overlayer has been established as a preventive tool and as a tool to help with healing, which sets it clearly apart from standard foam supports and justifies a specific classification in the hierarchy of supports.

Ease of use and maintenance, and ease of providing nursing care are largely emphasised by healthcare staff (90.2% satisfaction rating). Difficulties encountered are mainly in relation to obese patients who can only be moved with difficulty; those difficulties had only a little effect on the effectiveness of the support.

Finally, patient acceptance is also excellent, since 88.5% of patients wish to retain the support, and 93.5% did so. 3 patients were not able to express their preference. 4 patients judged it uncomfortable.

CONCLUSION

Of that sample of 61 cases, which represents the population usually admitted to a medium-term geriatric rehabilitation centre, it appears that the ALOVA overlayer is an effective support in helping with prevention of bedsores. Regardless of the Waterlow risk score, that effectiveness is at a comparable level, which makes the ALOVA overlayer one of the best supports, very clearly superior to standard foam supports That is confirmed by its role as a support in helping with healing observed in subjects suffering from bedsores.

Its ease of use by healthcare staff and the comfort that it gives to patients constitute other determining arguments for its indications.

ABBREVIATIONS

PRB: Person(s) at Risk of Bedsores
PSB: Person(s) Suffering from Bedsores