

Preventing the occurrence of pressure ulceration in hospitalised elderly patients

- **Objective:** To determine which factors contribute to the development of pressure ulcers and to evaluate the role of topical agents in preventing their occurrence.
- **Method:** An observational, prospective survey covered 36 care of the elderly wards and involved 1121 patients at high or very high risk of pressure ulceration. The patients, of whom 667 (59.6%) received a gentle application of a topical agent to at-risk areas, were followed up for eight weeks.
- **Results:** Of the patients, 15.7% developed a pressure ulcer. The use of a corpitinol 60-based topical agent (Sanyrène/Corpitol) significantly reduced the incidence of pelvic pressure ulcers ($p=0.04$) when used with recognised prevention strategies. This was identified by undertaking a logistic regression analysis. The resulting odds ratio of 0.61 indicates that the intervention helped to reduce the number of pressure ulcers by 40%.
- **Conclusion:** The results of this observational study can provide a useful guide to the design of further randomised controlled trials.
- **Declaration of interest:** Sponsored by Laboratoires Urgo (France).

pressure ulcers; topical agents; elderly care

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Pressure ulcers are frequently associated with age-related diseases, so prevention must include not only their treatment but also the use of pressure-relieving devices, and regular patient repositioning.¹ Bony prominences are no longer 'massaged' in France, but it has been suggested, even in the absence of clinical data to support this practice,² that gentle application of a topical agent to these areas may have a beneficial effect.³

To enhance epidemiological knowledge of pressure ulcers in the elderly-care environment, and explore the usefulness of applying preventive topical agents to at-risk areas, we undertook a prospective, longitudinal, observational study designed by a scientific committee comprising four expert pressure ulcer physicians.

Materials and method

Study design

The study was conducted in 36 elderly-care wards and long-term care units that had a pressure ulcer group or committee.

- Patient were included in the study if they:
- Were aged over 60 years
 - Had been in hospital for at least eight days and were expected to remain there for at least a further two months
 - Were free from pressure ulcers on the pelvis or heels
 - Were assessed as being at high or very high risk of developing pressure ulcers.

Patient were excluded if they had:

- Grade IV arteriopathy of the lower limbs (Leriche classification)⁴
- Diabetes and distal trophic disorders of vascular origin because these enhance the risk of pressure ulceration.⁵

Objectives

The study aimed to establish the incidence of pressure ulcers and the role of topical agents in preventing their occurrence. Pressure ulcers were graded using the National Pressure Ulcer Advisory Panel (NPUAP) classification.⁶ We also wanted to identify the risk factors associated with pressure ulcer development, and potential at-risk areas.

Data collection

At the initial visit the investigating physician recorded the patients' demographic data, medical/surgical history and general physical condition (Table 1). The risk score and preventive measures used for each patient were also recorded. These included:

- The type of preventive support
- Repositioning schedule
- The type of chair cushion
- The topical agent used on at-risk areas
- Any nutritional supplementation.

Additional biological parameters were available for some patients, who had undergone the relevant tests before entering the study (Table 1).

This was an observational study, so the investiga-

tors did not influence any of these routine interventions. The only difference between the participating centres was whether or not they used a topical agent on the at-risk areas. All centres used a validated pressure ulcer prevention and treatment protocol, in compliance with the recommendations of the French Consensus Conference² and provided an appropriate support surface for each patient (this was monitored during the study).

Patients were observed for eight weeks. At each visit, the physician checked their pelvis and heels for signs of pressure-ulcer development.

Statistical analysis

Mean and standard deviation for quantitative parameters, and frequency histograms for qualitative variables were used to describe the patients' demographic and clinical characteristics at the outset of the study.

Analysis described the incidence of pressure-ulcer development in the entire patient population.

Comparisons were performed by analysis of variance for quantitative variables and by chi-square tests for qualitative parameters.

Items that appeared to be significant after these univariate analyses were introduced into a logistic regression multivariate model to identify the major determinants for pressure-ulcer occurrence or non-occurrence. This type of analysis can determine the role played by each factor after adjusting for the presence or absence of factors likely to increase risk. This was first performed for all pressure ulcers, then for those on the pelvis and heels alone.

SAS software running on a Unix operating system was used to analyse the data. Statistical significance was set at $p=0.05$.

Results

A total of 1121 patients were involved. Baseline demographic data are outlined in Table 1.

The risk assessment scales used across the 36 units are listed in Table 2. Overall, 65.1% of patients were considered to be at 'high risk' of pressure ulcer development and 34.9% at 'very high' risk.

Table 3 shows the prevention strategies used and the division of patients according to topical agent intervention. Of the patients, 15.3% received heel relief (foams, boots [Medaboot, Medassist], or cushions under the calf).

Treatment received by the patients was determined by the protocols followed in each investigating centre. Of the patients:

- 451 (40.4%) received no topical agents
- 281 (25.1%) received a cream or a skin barrier. More than 10 different products were used across the wards. This wide variation reflects the lack of consensus on the use of topical agents in pressure ulcer prevention

Table 1. Baseline data and concomitant disease

Gender (female/male)	77%/23%
Age (years)	84.7 ± 8.1 (62; 101)
Body mass index (kg/m ²)	22.6 ± 4.7 (11.4; 38.2)
Cardiovascular disease	63.4%
Neuropsychiatric disease	88.8%
Diabetes	10.4%
Incontinence (Yes/No)	91.6%/8.4%
• Urinary incontinence	14.6%
• Double incontinence	77%
Plasma albumin (g/l) (n=672)*	
• < 22g/l	0.9%
• 22–30g/l	27.4%
• ≥30g/l	71.7%
Plasma pre-albumin (mg/l) (n=402)*	
• < 110mg/l	28.9%
• 110–160mg/l	13.4%
• ≥160mg/l	57.7%
C-reactive protein (mg/l) (n=654)*	
• < 6mg/l	35.6%
• 6–50mg/l	55.5%
• ≥50mg/l	8.9%

*Biological parameters recorded before the study took place

Table 2. Risk scales and mean risk assessment score used during the study

	Frequency	Mean value
Norton ¹⁸ (Patient at risk if <14)	39.7%	10.7 ± 2.1
Angers ²⁶ (Patient at risk if >13)	18.3%	18.8 ± 2.6
Gonesse ²⁶ (Patient at risk if >9)	12.1%	9.9 ± 2.1
Braden ¹⁹ (Patient at risk if <16)	11.8%	11.6 ± 2.4
Waterlow ²⁷ (Patient at risk if >10)	10.3%	18.9 ± 4.2
Others	7.8%	—

- 386 (34.5%) received corpitinolol 60 (Laboratoires Uργο). This is licensed for use in pressure ulcer prevention as Sanyrène in France and the Netherlands^{7,8} and as Corpitol in Spain. A UK licence for Sanyrène is being sought.

Table 3. Prevention strategies used

	Study population
Type of mattress	
Static support:	93.3%, of which:
• Foam	75.4%
• Water	12.4%
• Other	5.5%
• Dynamic (alternating) air support	6.7%
Frequency of repositioning	
In bed (for 24 hours)	2 (0, 8)
Sitting in a chair?	
Yes	95.9%
• Number of times in a day	1.3 ± 0.6
• Longest period each time (hours) (%)	6.3 ± 2.7
Cushion on chair (gel, foam or air cushion)?	
Yes	47.8 %
Nutritional supplementation	
Yes	41.6%
• High-calorie diet	21.9%
• High-protein diet	39.4%
• Vitamin/trace-element supplementation	6.4 %
Use of topical agents*	
• No topicals	40.4% (n=451)
• Corpitolinol 60	34.5% (n=386)
• Other topicals (cream/skin barriers)	25.1 % (n=281)

* Data were missing for three patients

Data on the treatment received are missing for three patients. This reasons for this are unknown, but we do not believe this affected the results. The proportion of patients at high risk and very high risk was similar in all three groups.

A total of 41.6% of the entire sample received additional nutrition (high-calorie, high-protein diet and/or vitamin or trace-elements supplements).

Pressure ulcer incidence

A total of 1028 patients were followed up for eight weeks. Ninety-three did not complete the study — 41 died, 24 were transferred to another ward/hospital and 28 returned home or to a nursing home. Nevertheless, the presence or absence of a pressure ulcer was documented and the overall final calculation of incidence took these patients into account: if all the patients are included, the mean follow-up duration per patient was 53.9 ± 9.0 days.

At the end of the study, 15.7% had developed a

pressure ulcer: 10.6% on the pelvis and 7.1% on the heel (2% had pressure ulcers on both areas).

Clinical factors affecting pressure ulcer occurrence

In terms of biological factors and pressure-relieving interventions, all patients were comparable. However, there was a difference in incidence between patients with different risk factors, namely:

- Those at ‘very high risk’ had an incidence of 20.6% compared with 13.2% in those at ‘high risk’ (p<0.001)
- Patients with double incontinence had an incidence of 17% compared with 9.9% in those with urinary incontinence alone (p<0.02)
- Patients who were not seated in a chair had an incidence of 26.7% compared with 15.3% in those who were seated (p=0.04)
- Those receiving other topical agents or no topical agents on their pelvic area had an incidence of 16.3% and 15.6% respectively, as opposed to 7.3% in the corpitolinol 60 group (p=0.04)
- Those who used a chair cushion had an incidence of 18.0% compared with 12.8% in patients seated without one (p<0.02)
- Patients receiving nutritional supplementation had an incidence of 18.4%, as opposed to 13.5% in unsupplemented patients (p<0.04).

The latter two results are surprising as these patients were receiving more preventive measures.

Effect of topical agents on incidence

• **Multivariate analysis** To evaluate the specific benefit of using topical agents on ‘high risk’ areas, the statistical analysis took account of all other factors likely to impact on ulcer incidence. A logistic regression model was used into which co-factors — all the items identified in the previous univariate analysis as statistically related to pressure ulcer development — were introduced. Analysis was performed for all pressure ulcers, and then separately for pelvic ulcers and for heel ulcers.

When all pressure ulcers were considered, the only factor that appeared to predict incidence was the initial risk assessment, but this result was at the very limit of statistical significance (p=0.05), with an odds ratio of 1.43 (1.00–2.05) (Table 4).

By contrast, when only pelvic pressure ulcers were considered, the corpitolinol 60 factor significantly reduced occurrence (p=0.04), with an odds ratio of 0.61 (0.38–0.98) (Table 5), suggesting that corpitolinol 60 reduced the likelihood of patients developing pelvic pressure ulcers by about 40%, independently of other factors, particularly those identified at the start of the study.

No such effect was noted for heel ulcers, and their incidence appeared to be independent of the factors previously taken into account in the analysis.

Discussion

No study limitations were identified for this study.

A large majority (93.3%) of the patients were nursed on a static support surface, and the rest on alternating mattresses. The full affect of this variable on outcomes is unknown as the relative merits of alternating and constant low-pressure devices are unclear, as are the effects of the different alternating pressure devices on patient outcomes.⁹

Patient selection was dictated by the need to determine whether patient management methods affected ulcer development and the need to ensure that the study evaluated environments in which nurses work every day.

The overall incidence of pressure ulcers, including grade I ulcers, was 15.7%. This underlines the progress that remains to be made, even in wards where staff are motivated to use preventive measures, and highlights the need to identify high-risk patients. Previous studies of general institutionalised elderly patients have reported either a higher¹⁰⁻¹² or lower incidence, where grade I ulcers were discounted,¹³ so correlating these findings with our figures is difficult as we specifically included patients at high or very high risk.

The effectiveness of preventive interventions needs to be considered. There may have been a relative lack of resources, notably preventive support systems were static rather than dynamic, in most cases owing to economic restrictions.

The higher incidence observed in patients given more preventive measures (chair cushions and nutritional supplements) may reflect the fact that they were at 'very high' risk of ulceration.

This situation is not acceptable — sufficient resources should be available to meet the needs of all at-risk patients, regardless of their level of risk, particularly since the cost of prevention is lower than treatment.^{14,15}

Further education of medical and nursing staff is also required.^{16,17}

The mean values of the Norton¹⁸ and Braden¹⁹ scales, which are widely used in older people because of their sensitivity (83%), specificity (63%) and predictive value (37%), accurately reflected the high risk of pressure ulcer occurrence in the study participants.^{1,20}

Double incontinence, reported here as a veritable risk factor, has not always been clearly identified as such in other studies.^{21,22} It would be prudent to consider this as a risk factor and to introduce appropriate preventive measures.¹

Topical agents

While a randomised double-blind clinical trial would have produced a more conclusive outcome regarding the effect of topical agents, the scientific committee considered such an approach to be

Table 4. Logistic regression analysis: pressure ulcers, all areas

	Significance	Odds ratio	Confidence interval
Topicals versus no topicals	0.62	0.90	0.58–1.38
Corpitolinol 60 versus no topicals	0.64	0.91	0.61–1.35
No incontinence versus double incontinence	0.67	0.86	0.44–1.69
Urinary incontinence versus double incontinence	0.15	0.66	0.38–1.16
Support versus no support	0.08	1.37	0.96–1.94
Very high risk versus high risk	0.05	1.43	1.00–2.05
Nutritional supplements versus none	0.27	0.82	0.58–1.16

Table 5. Logistic regression analysis: pelvic pressure ulcers

	Significance	Odds ratio	Confidence interval
Topicals versus no topicals	0.45	0.83	0.52–1.34
Corpitolinol 60 versus no topicals	0.04	0.61	0.38–0.98
No incontinence versus double incontinence	0.70	0.86	0.40–1.86
Urinary incontinence versus double incontinence	0.24	0.68	0.36–1.29
Support versus no support	0.15	1.35	0.9–2.03
Very high risk versus high risk	0.27	1.27	0.84–1.93
Nutritional supplementation versus none	0.37	0.83	0.56–1.24

removed from routine practice and harder to undertake due to the changes in practice that would have been required.

Furthermore, post-study calculations showed that demonstrating the benefits of a topical agent in a randomised study would have required 1124 patients in each of the three groups (or a total of 3372 patients). This would have presented difficulties in obtaining informed consent as many of the patients recruited had cognitive disorders. (Consent was not required from these patients as this was an observational study, although all patients were informed about the study at its outset.)

The use of corpitolinol 60 gave an odds ratio of 0.61 for the occurrence of ulcers in the pelvic area, or a reduction of 40% in incidence compared with those who did not have the topical agent after adjusting for other factors likely to affect incidence.

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It is important to note that although significant risk factors in the univariate analysis were no longer significant when introduced into the logistic model, they nonetheless figure in ulcer determination. Therefore, corpitinolol 60 neutralised the effect exerted by these factors, and it is possible to conclude that this topical treatment had a positive effect, with all other factors being equal and constant.

These results concur with those of Colin,⁷ who reported that application of topical corpitinolol 60 to the pelvic area kept TcPO₂ values stable when compared with a control group (which received no topical agent), in whom a decrease of the TcPO₂ level was observed (p=0.014).

The positive effect of corpitinolol 60 on the cutaneous microcirculation could be explained by the composition of the product, which is rich in linoleic essential fatty acid and peroxidised substratum of the ω₆ family, which are involved in cutaneous trophicity.^{23,24} In addition, the product reinforces skin resistance and improves the mechanical and elastic cutaneous properties of the skin, preventing friction and shear.²⁵

Conclusion

The multifactorial analysis of indicators likely to promote or reduce the development of pressure

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Box 1. The scientific committee involved in the study

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ulcers in patients at high or very high risk showed that the incidence on the pelvic area was reduced by 40% in patients who received a local application of corpitinolol 60, particularly when this was combined with conventional preventive strategies.

Only the provision of preventive treatment of pressure ulcers through validated prevention protocols and further education of health-care professionals will reduce the incidence of pressure ulcers in patients at high risk.

Economic arguments, combined with ethical considerations, provide a strong case for adopting a more stringent preventive approach, particularly in the elderly care environment. ■