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Pressure injury progression and factors associated with different end-points in a home palliative care setting: a retrospective chart review study

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**Title:** Pressure injury progression and factors associated with different end-points in a home palliative care setting: a retrospective chart review study.

Running head: Pressure ulcer course in palliative home care.

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#### Abstract

#### Context

Patients with advanced illnesses show the highest prevalence for pressure ulcers. In the palliative care setting the ultimate goal is injury healing, but equally important is wound maintenance, wound palliation (wound-related pain and symptom management), and primary and secondary wound prevention.

#### Objectives

To describe the course of healing for pressure ulcers in a home palliative care setting according to different end-points, and to explore patient and caregiver characteristics and specific care activities associated with their achievement.

#### Methods

Four-year retrospective chart review of 669 patients cared for in a home palliative care service, of those 124 (18.5%) patients had at least one pressure ulcer with a survival rate  $\leq 6$  months.

#### Results

The proportion of healed pressure ulcers was 24.4%. Of the injuries not healed, 34.0% were in a maintenance phase, while 63.6% were in a process of deterioration. Body Mass Index (p=0.0014), artificial nutrition (p=0.002), and age <70 years (p=0.022) emerged as predictive factors of pressure ulcer complete healing. Artificial nutrition, age, male caregiver (p=0.034) and spouse (p=0.036) were factors significantly associated with a more rapid pressure ulcer healing. Continuous deep sedation was a predictive factor for pressure ulcer deterioration and significantly associated with a more rapid worsening.

#### Conclusion

Pressure ulcer healing is a realistic aim in home palliative care, particularly for injuries not exceeding Stage II occurring at least two weeks before death. When assessing pressure ulcers, our results highlight the need to also pay attention to artificial nutrition, continuous deep sedation, and the caregiver's role and gender.

# Pressure injury progression and factors associated with different end-points in a home palliative care setting: a retrospective chart review study

#### Background

Patients with advanced illnesses cared for by palliative care services are estimated between 30 and 400 million worldwide (1,2). They are defined as patients suffering from diseases no longer responsive to specific therapies and whose life prognosis is usually not exceeding six months (3).

During their illness trajectory, patients in palliative care are exposed to several comorbidities that contribute to the progressive loss of their physiological functions and autonomy (2,4-7). Approaching end of life, antalgic obliged positions and sedative therapies gradually lead these patients toward a bedfast condition (5,8-10) that dramatically increases their risk of pressure injuries (6,10,11). Immobility, skin moisture, and poor nutritional status are among the most relevant risk factors for pressure injuries in patients with advanced illnesses (4,12), who are the population showing the highest prevalence for developing them (3,10,13). Furthermore, although pressure injury prevention represents a crucial goal, wound care specialists unanimously suggest that not all injuries are avoidable (2,5,6,15,16) mainly due to the extremely frail conditions of patients approaching death (13,17,18).

In palliative care settings, the management of pressure injuries requires a holistic and integrated approach. In particular, in home palliative care the patient's outcomes mainly come from the joint activities of professionals and home caregivers, who become to all effects members of the care team (19). Home palliative care professionals continuously take into consideration wishes and needs of the patient/caregiver dyad (5,22), to develop well-negotiated care planning (23) able to achieve the highest levels of acceptance and adherence of the health plan by both patient and caregiver (8,14,20,21).

Considering the constantly evolving conditions of these patients, the pressure injury management plan might include different goals during the illness course (4,5,24–28). The preferred aim of the palliative care team is injury healing. When this becomes unrealistic, the goal shifts toward achieving maintenance and stabilization, avoiding deterioration (25) with a main focus on wound palliation (4,5,26).

There is paucity of data about the pressure injury healing process in palliative care. The available evidence, referred to a mixed home/hospital context, reveals healing rates of 18.9% for Stage I pressure injuries, and ranging from 9.4–10.4% among Stage II injuries (25,29). A study conducted in hospice reports a proportion of 8.4% (all stages) of healed injuries (30). Specific data

about the course of pressure injuries in the home palliative care setting and the factors associated with the different management goals are lacking.

#### Aims

The primary aim of the study was to describe the proportion of healed pressure injuries in a home palliative care service in Italy and the progression characteristics of those not healed. The secondary aim was to explore pressure injury different end-points and their predictive/associated factors in relation to caregiver and patient characteristics, and selected care activities.

#### Methods

#### Study design

A retrospective chart review was undertaken. The research report was written according to STROBE recommendations (31).

#### Setting

The study was conducted in a home palliative care setting in a largely rural area of a northeastern region of Italy. Nurses, physicians, psychologists, and nurse assistants of the home palliative care team provided their integrated services at patients' homes. The home caregivers guaranteed continuity of care (23,32,33); therefore, they were considered essential members of the team, which shared with them realistic pressure injury treatments and goals (4,25). As preventive strategies, nurses provided caregivers with information about pressure injury prevention activities (34) in accordance with worldwide-accepted guidelines, and provided all patients with a high specification pressure redistribution device (6). When healing represented a realistic aim the most appropriate treatment strategies were provided in accordance with the principles of wound bed preparation (35–37). In addition, wound palliation was considered a priority for pain relief, management and control of exudate and odor.

Nurses also ensured education and provided training to the home caregivers, performing the recommended care activities with them until they achieved adequate skills and competencies. During every home access, nurses guaranteed individualized pressure injury assessment and caregiver support (6). The frequency of the home accesses varied from once per week to more daily visits, depending on the patient's overall conditions and the needs of the home caregivers (5,22).

#### Participants and sample size

The research team considered the electronic clinical records of all patients admitted in home palliative care from 1 January 2013 to 31 December 2016. All records of patients were included who: a) showed at least one pressure injury; b) survived  $\leq 6$  months (3); c) died either in home palliative care or were transferred elsewhere and died within 7 days. Considering the exploratory nature of the study and the lack of previous data in the same setting, the calculation of sample size was not undertaken.

#### **End-points**

The main end-point of the study was the proportion of healed pressure injuries. In accordance with Maida and colleagues (25), the healing of Stage I pressure injuries was defined as the remission of a non-blanchable erythema and of any changes in sensation, temperature, or firmness, while injuries of Stages II–IV were considered healed with the complete re-epithelialization of the skin.

Possible intermediate end-points of unhealed pressure injuries at the time of death/discharge included: improvement towards healing, maintenance and deterioration (25). Any changes of the wound conditions over time were assessed and scored using the PUSH tool (38,39) based on three wound characteristics: length x width (0-10), exudate amount (0-3) and tissue type (0-4) (40). Scores lower than the previous ones identify injuries improving towards healing, static scores identify injury maintenance and increased scores indicate deterioration.

#### Data collection

The data collected about pressure injuries were: stage (from I to IV) according to the National Pressure Ulcer Advisory Panel (NPUAP) (6), anatomical site (description) and days of permanence (number). Literature and clinical experience guided the research team in the choice of the following explanatory variables. The patients' data retrieved at time of admission were: gender (male vs. female), age (years), diagnoses (cancer vs. non-cancer), Body Mass Index (41) (score), Braden Scale (42) (score) and Karnofsky Performance Status (KPS) (percentage). The KPS demonstrates a significant correlation with the Palliative Performance Scale (PPSv2), the internationally most used measure of performance status in palliative care, and therefore they can be used interchangeably (43). Data about the care activities provided included home artificial nutrition (parenteral or enteral) (44–46), continuous deep sedation (47), and urinary catheter or ostomy (6,11). The variables related

to home caregivers included number of caregivers for each patient, family role (spouse vs. nonspouse), gender (male vs. female) and age (years) of the main caregiver.

#### **Bias**

To minimize selection bias, all electronic charts of patients admitted in the home palliative care service during the study period were reviewed; moreover, to balance any distorting effects, the sample was stratified based on the propensity score (48).

In order to limit detection bias, home palliative care professionals were specifically trained with homogeneous procedures for pressure injury detection and assessment: (1) early identification and staging of pressure injuries according to the NPUAP classification, (2) assessment of pressure injury complete healing, and (3) evaluation of improvement, maintenance, or deterioration of unhealed pressure injuries at the time of death/discharge. Moreover, any pressure injury changes were double-checked by two home palliative care trained nurses (49,50).

#### Data analysis

The normality of distribution of continuous variables was preliminarily tested with the Kolmogorov–Smirnov test. The proportion of healed pressure injuries was calculated as the percentage of injuries showing complete healing during the study period. To examine the patient, caregiver, and pressure injury variables, descriptive statistics and 95% Confidence Intervals (95% CI) were calculated.

Logistic regression models for surveys were used to analyze the factors associated with complete healing of pressure injuries or with the achievement of intermediate end-points. Since injury events were intra-patient dependent, patients were treated as clusters, and the pressure injury episodes were considered as random samples within the clusters. Moreover, a sampling weight was added as 1/(number of pressure ulcers within a patient), so that the sum of the weights for a patient was 1 (51). Odds ratio (OR) results of logistic regression were used as relative risk estimators.

To analyze the relationship between the explanatory variables and the time needed for complete pressure injury healing or for the achievement of an intermediate end-point, Cox proportional hazards models (52) (Hazard ratio – HR) were used. Propensity score analysis was performed by using the matching radius algorithm using calipers of width equal to 0.2 of the standard deviation of the logit of the propensity score (53). Assumption of proportional hazards was tested using the tests of the non-zero slope according to Therneau and Grambsch (54). A p value  $\leq 0.05$  was accepted.

The analyses were conducted using the IBM SPSS Statistics (Version 22.0. Armonk, NY: IBM Corp).

#### Ethical issues

The General Director of the Local Health Unit approved the study (Deliberation Nr. 1005/2015). Data anonymity was guaranteed by using fully de-identified database records. Patients or family caregivers provided verbal informed consent before data collection.

#### Results

#### **Participants**

One hundred and twenty-four (18.5%) out of 669 patients who received home palliative care during the study period met the inclusion criteria. The majority of patients were female (68, 58.4%), with a mean age of  $75.8\pm11.7$  years. At the time of admission, participants showed an average KPS index of  $29.8\pm5.9$ . Twenty-one (16.9%) of them, according to BMI score, were severely thin or obese, while 89 (71.8%) were at risk of developing pressure injuries according to the Braden score. Out of 124 patients, 29 (23.4%) received home artificial nutrition, 35 (28.2%) a continuous deep sedation, and 34 (27.4%) had a urinary catheter or ostomy (Table 1).

Most participants (66, 53.2%) had a single caregiver, who was principally (77.4%) a spouse or a daughter/son. The main home caregiver was predominantly female (79.8%) with a mean age of  $60.4\pm12.6$  years. Most participants (73, 58.9%) were cared for at home until their death for an average of  $50.6\pm41.0$  days.

#### Pressure injury characteristics and progression

One hundred and fifty-six pressure injuries were detected in 124 patients (Table 2), with more than one injury in 29 (23.4%) patients. During home palliative care stay, 53 (34.0%) pressure injuries did not exceed Stage I, while 55.8% (n=87) reached Stage II. Fifteen patients (9.6%) experienced a Stage III injury, and only one (0.6%) reached Stage IV. The most affected anatomical site was the sacrum/coccyx (94, 60.3%) and the average time of pressure injury permanence was  $21.2\pm23.2$  days.

During the study period 38 (24.4%) pressure injuries completely healed. The injuries not healed at the time of death/discharge were 118 (75.6\%), of which three (2.5%) were improving towards healing, 40 (33.9%) were in a phase of maintenance, and 75 (63.6%) were deteriorating. Data on the achievement of different end-points by stage (Table 3) showed that a complete healing occurred

only in favor of Stage I (37.3%) and Stage II (20.7%). Stage III and IV injuries were present only in relation to the intermediate end-points.

Table 4 shows the distribution of pressure injuries according to the time of occurrence from the patient's death. None of the injuries developed during the last week of the patient's life healed completely, and 85% of them were deteriorating at time of death. Eleven (19.3%) pressure injuries developed during the second or third week from death and healed completely, while 40.3% and 38.6% were in a phase of maintenance or deterioration, respectively. Beyond three weeks from death, 38% of the injuries showed a complete healing, while 40.9% switched toward a progressive deterioration.

# Odds ratio and Hazard ratio of participant and caregiver characteristics at different pressure injury end-points

#### Complete healing

In the univariate logistic regression model regarding pressure injury complete healing (Table 5), patients' age, provision of home artificial nutrition, and BMI score showed a significant OR. Being younger than 70 years (OR=2.634, p=0.022), receiving artificial nutrition (OR=3.886, p=0.002), and being obese or severely thin (OR=3.316, p=0.014) were predictive factors of a complete healing process at any stage during home palliative care.

The Cox proportional hazards univariable model (Table 5) suggested that artificial nutrition, patients' age, gender, and role of the main caregiver might be associated with a more rapid healing. In fact, the probability (hazard) of experiencing a more rapid pressure injury complete healing was more than two times higher for patients who were younger than 70 years (HR=2.169, p=0.021) and increased to 88.2% (HR=1.882, p=0.050) for those who received artificial nutrition. Furthermore, to be assisted at home by a male caregiver (HR=2.155, p=0.034) and by the spouse (HR=2.009, p=0.036) increases the hazard rate in both cases more than double.

#### Deterioration, maintenance, and improving toward healing

In the univariate logistic regression model (Table 6), only continuous deep sedation showed a significant association and was predictive of pressure injury deterioration during home palliative care (OR=2.287, p=0.033). The Cox proportional hazards univariable model suggested that continuous deep sedation might be associated also with a more rapid deterioration, with an increased likelihood of 65% (HR=1.647, p=0.038).

The univariate logistic regression and Cox proportional hazards showed that none of the explanatory variables were predictive factors or showed a significant association with the injury maintenance.

Considering the very small number (n=3) of injuries that were improving toward healing, no regression analysis was conducted for this outcome.

#### Discussion

Very few studies on the course of pressure injuries in palliative care are available, among which the most important was conducted in hospital and community (29). Therefore, our study represents one of the first attempts (55) to analyze progression, outcomes, and associate factors of pressure injuries in patients with advanced illnesses cared for in home palliative care. The old age, the poor performance status at admission, and the high risk of pressure injury development of our sample were comparable to those of prior palliative care studies (3,30,56).

Data on pressure injuries were collected prior to current international guidelines, therefore the injuries now defined as 'unclassified/unstageable' and 'deep tissue injury', in this study were staged as IV (6). Although the challenging task of detecting Stage I pressure injuries is well documented (6,57), they were included in the statistical analysis for two main reasons. First, without appropriate management, Stage I pressure injuries have an increased risk of progression to open wounds (49,58). Second, patients already at Stage I might experience bothersome symptoms (6,59). The patients included in the study were all Caucasian and this probably facilitated home palliative care nurses in detecting Stage I pressure injuries (6).

A complete healing was only achieved by pressure injuries of Stage I and II. The healing percentages of both stages were higher than those found by studies conducted in comparable settings (25,29). Our findings showed that a complete healing process might be considered a realistic goal for pressure injuries occurring at least in the second week before the patient's death.

A patient's younger age and artificial nutrition emerged as predictors of complete and more rapid pressure injury healing. During the first home visit, the majority of patients showed a normal BMI, but during the nearly two-month stay in home palliative care, they suffered a progressive loss of appetite and weight, so that almost a quarter of them received artificial nutrition. This percentage was higher than that reported in previous studies conducted in home palliative care, even if not exclusively with patients showing pressure injuries (60,61). Although artificial nutrition might cause an additional burden for patients and home caregivers (62), the strong positive effects observed on pressure injuries cannot be underestimated (63).

Obesity (iatrogenic) or severe thinness at time of admission emerged as predictive factors for a complete healing. This result, which requires further investigation, may be reasonably explained by the fact that providing care for individuals in such risky conditions for pressure injuries forced the home palliative care team to pay higher attention and to require greater home caregiver involvement.

The last predictor for injury healing, although with a borderline significance, was the presence of a urinary catheter or ostomy. Despite their unpleasant consequences, the proper use of catheterization or ostomy might have a role not only as a preventative measure, but also in the healing process of injuries (12).

Two main family compositions at a patient's home emerged from this study, confirming the existing literature (64). Over half of the patients were cared for by a single caregiver, so that a clear patient/caregiver dyad was shaped (22). The other half was assisted by a support network (65,66) consisting of at least two caregivers, not necessarily relatives, who were actively involved in the home caregiving (23). New findings from this study were precisely related to the caregiver characteristics and, therefore, proved to be pivotal in the home palliative care setting. Although care provided by a spouse or a male did not emerge as predictive factor of complete healing, it demonstrated a significantly greater likelihood of its more rapid achievement. While our results about spousal home caregivers confirmed previous studies (2,67), those related to gender differences in providing care diverge from several researches showing that female spouses coped better as caregivers than males (68,69), and provided better care for their loved one during illness progression (19,67,70). Therefore, considering the limited number of male caregivers involved in our study, these results deserve further exploration and should be used with caution.

Our results about the pressure injuries not being healed at the time of death/discharge showed that maintenance could be a realistic goal in each phase of the home palliative care trajectory, even until the last week of the patient's life. A reasonable explanation for this may be connected to wound management strategies (26) that were able to avoid the worsening of some injuries. However, the majority of unhealed injuries, regardless of their stage or time of occurrence, were in a phase of progressive deterioration consistently reflecting the patient's end-of-life condition. It is worth noting that none of the pressure injuries occurring in the last week of the patient's life healed completely, rather the majority of them were in a deterioration phase at time of death. Previous literature suggests that pressure injuries occurring at the end-of-life phase can be considered unavoidable (14,15). Our findings also point out that the same pressure injuries (last week of life/<8 days from death) were not curable at all, probably due to the extremely compromised patient conditions, and to the short period left to live.

Our sample showed a higher proportion of patients receiving continuous deep sedation compared with those observed in other studies in various palliative care settings (71–73). From our results, continuous deep sedation emerged as a predictive factor for pressure injury deterioration and showed a higher probability of a more rapid worsening process. Continuous deep sedation is mainly used to manage refractory symptoms and leads de facto to a state of patient immobilization and unconsciousness. In such a situation, despite the increased risk of pressure injury development, it is expected that both home palliative care professionals and home caregivers tend to reduce the activities commonly performed to manage the injuries (such as repositioning), as those activities might cause additional unpleasant consequences (30).

This study has some limitations. First, the retrospective design adopted is subject to a higher potential error, data underestimation, and incompleteness than prospective studies (74,75). Particularly, the timeliness of pressure injury detection and staging could have been impaired when the frequency of the nurses' home accesses was not daily. Second, the results are based on a relatively small sample from a single home palliative care service and may not be generalizable to other patient populations. Last, our limited sample size did not allow performing the statistical analyses on some of the pressure injury end-points.

#### Conclusion

The significant percentage of pressure injuries healed proves that healing is a realistic outcome in home palliative care, especially for injuries occurring at least two weeks before death and not higher than Stage II. When complete healing was not possible, a third of the cases showed evidence that the pressure injury management reached the intermediate objective of their maintenance, typical of palliative care, while about half of all injuries inevitably deteriorated during the illness trajectory. In particular, our results showed the incurability of the injuries occurring in the last week of life, and reasonably they represent injuries recognized as unavoidable.

Patients with a BMI at risk, older than 70 years, and undergoing continuous deep sedation require enhanced measures to prevent new pressure injuries and to ensure that existing wounds do not deteriorate.

This study provides the home palliative care team with valuable information to target efforts toward realistic goals of care and appropriate management strategies. Future prospective and multicenter research needs to confirm the gender association in order to help home palliative care nurses tailor educational interventions for home caregivers.

The not negligible proportion of pressure injury healing and maintenance suggests the need to always maintain a high attention to this issue, to contribute to the highest possible well-being for patients in home palliative care.

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Gender		
Female	68 (54.8)	
Male	56 (45.2)	
Age		
Years		75.8 (73.7-77.9)
Race		
Caucasian	124 (100.0)	
No Caucasian/Other	- (-)	
Diagnoses		
	120 (96.8)	
Non-cancer	4 (3.2)	
	+ (3.2)	
KPS (index)		
Percentage		29.8 (28.7-30.8)
BMI (score)		22.1 (21.1-23.1)
Normal (>15 and <30)	103 (83.1)	
Severe thinness (<16) or obesity (>29)	21 (16.9)	
Braden (score)		13.3 (12.6-14.0)
Not at risk (>15)	35 (28.2)	
At risk (≤15)	89 (71.8)	
Home artificial nutrition	~ /	
	20 (22 4)	
Yes	29 (23.4)	
No	95 (76.6)	
Continuous deep sedation		
Yes	35 (28.2)	
No	89 (71.8)	
Urinary catheter or Ostomy		
Yes	34 (27.4)	
No	90 (72.6)	
Home caregiver(s) number		
1	66 (53.2)	
2	47 (37.9)	
3	10 (8.1)	
4	1 (0.8)	
Main caregiver role		
Spouse	54 (43.5)	

## Table 1. Participants' characteristics (n=124)

			Table 2. Pressure ulc
	N (%)	Mean (95% CI)	
Patients with pressure ulcers			
Yes	124 (18.5)		
No	545 (81.5)		
Number of pressure ulcers' per patient			
1	95 (76.6)		
2	27 (21.8)		
3	1 (0.8)		
4	1 (0.8)		
Pressure ulcers			<u>.</u>
	156 (100.0)		
Highest stage reached			
I	53 (34.0)		
П	87 (55.8)		
Ш	15 (9.6)		
IV	1 (0.6)		
	1 (0.0)		
Anatomical site	04 (60.2)		
Sacrum/coccyx	94 (60.3)		
Trocanther	14 (9.0)		
Gluteus	12 (7.7)		
Heel	10 (6.4)		
Dorsal spines	6 (3.8)		
Malleolus	6 (3.8)		
Ischium	5 (3.2)		
Ear	5 (3.2)		
Foot	3 (1.9)		
Knee	1 (0.6)		
Days of pressure ulcers permanence			
Average (95%CI)		21.2 (17.5-24.9)	
Healed pressure ulcers			
Yes	38 (24.4)		
No	118 (75.6)		
Non healed pressure ulcers (n=118): Progression at time of discharge/death			
Improvement toward healing	3 (2.5)		
Maintenance	40 (33.9)		
Deterioration	75 (63.6)		

#### Table 2. Pressure ulcers' characteristics (n=156)

Pressure ulcers'	Complete healing	Improving toward healing	Maintenance	Deterioration	Total	
stages	N (%)	N (%)	N (%)	N (%)	N (%)	
Ι	20 (37.7)	0 (-)	10 (18.9)	23 (43.4)	53 (100.0)	
II	18 (20.7)	2 (2.3)	23 (26.4)	44 (50.6)	87 (100.0)	
III	0 (-)	1 (6.7)	6 (40.0)	8 (53.3)	15 (100.0)	
IV	0 (-)	0 (-)	1 (100.0)	0 (-)	1 (100.0)	

## Table 3. Pressure ulcers' end-points by injury stages (n=156)

Days from pressure ulcers	Complete healing	Improvement toward healing	Maintenance	Deterioration	Total	
death	occurrence to death N (%) N		N (%)	N (%)	N (%)	
≤7*	0 (-)	0 (-)	4 (14.3)	24 (85.7)	28 (100.0)	
>7 and ≤21	11 (19.3)	1 (1.8)	23 (40.3)	22 (38.6)	57 (100.0)	
>21	27 (38.0)	2 (2.8)	13 (18.3)	29 (40.9)	71 (100.0)	

#### Table 4. Pressure ulcers' end-points by time of occurrence before death (n=156)

\*Considering only patients who died within home palliative care

#### Table 5. OR and HR for a pressure ulcer' complete healing

	Logistic Regression Model				Cox Proportional Hazards Model			
	OR		959	%CI	HR		95%	CI
	UK	р	Lower	Upper	HK	p	Lower	Upper
Home artificial nutrition* (no vs. yes)	3.886	.002	1.689	8.938	1.882	.050	1.001	3.585
BMI at risk (normal weight vs. obese/cachectic)	3.316	.014	1.279	8.595	.624	.094	.900	3.872
Patients age (≥70 vs.<70)	2.634	.022	1.153	6.014	2.169	.021	1.122	4.193
Urinary catheter/Ostomy (no vs. yes)	2.661	.054	.982	7.213	.664	.138	.807	4.675
Main caregiver role (non spouse vs. spouse)	1.867	.126	.836	4.166	2.009	.036	1.048	3.852
Main caregiver gender (female vs. male)	.538	.175	.219	1.323	2.155	.034	1.060	4.383

#### Table 6. OR and HR for a pressure ulcer' deterioration

	Logistic Regression Model			Cox Pr	Cox Proportional Hazards Model			
	OR p		959	%CI	HR	n	95%CI	
	<b>U</b> K	р	Lower	Upper	ш	p.	Lower	Upper
Continuous deep sedation (no vs. yes)	2.287	.033	1.070	4.890	1.647	.038	1.027	2.641