

## Research Article

### Validity and Reliability of the Behavioral Pain Scale (BPS) for Assessing Pain in Non-Communicative Chronically- Ventilated Patients

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#### Abstract

**Background:** The inability to express pain in non-communicative, chronically ventilated patients is a significant barrier to assess pain intensity. Behavioral Pain Scale (BPS) has been evaluated and validated as a tool for assessing pain among ventilated patients in intensive care units. This assessment tool has not been tested among chronically non-communicative ventilated patients. The aim of this study was to examine the reliability and validity of the BPS in this population.

**Methods:** This observational study included 48 non-communicative, chronically ventilated patients, at two different long term facilities. Each patient was assessed for pain by two assessors using the BPS score. Pain was evaluated during repositioning, venous puncture and tracheal suction. Each assessor, independently, assessed the BPS score before, during and after each one of the three mentioned procedures.

**Results:** 864 observations were conducted. Total BPS score showed a good internal reliability for repositioning, venous puncture and tracheal suctioning (Cronbach  $\alpha$  = 0.885, 0.868 and 0.693

respectively). Validity was approved by demonstrating significant increase from baseline to painful levels of BPS score and significant decrease from the painful levels to the post-procedure levels during all the three procedures ( $P < 0.001$ ).

**Conclusion:** BPS is a valid and reliable pain assessment tool for chronically, non-communicative ventilated patients.

#### Perspective

This article demonstrates that the Behavioral Pain Scale (BPS) is a valid and reliable pain assessment tool also for chronically, non-communicative ventilated patients. This validation may facilitate further research of assessing pain level and response to treatment. This tool may also improve pain management among this specific patients' population.

**Keywords:** Behavioral pain scale; Chronically ventilated; Pain assessment; Pain scale validation

#### Introduction

Pain can be a significant source of stress for non-communicative, mechanically-ventilated patients that experience pain at rest while hospitalized [1], with worsening pain during routine medical procedures (such as tracheal suctioning, venous puncture, repositioning etc.) [2-6]. Pain causes a reduction in the oxygen tension and perfusion to the tissues, and thus may inhibit wound-healing [7]. Pain is a subjective experience and currently there are no validated objective markers that can be recommended for its evaluation [8]. The ability of the medical staff to identify and diagnose pain among patients is critical for initiating and appropriately adjusting pain control treatments and for monitoring their effectiveness. Studies comparing patient-reported pain intensity to that assessed by personnel, have shown that medical staff tends to under-estimate patients' pain levels [9-11]. When possible, the gold standard for assessing pain level is patient reports [12], however, some patients are unable to express their pain by any means of verbal (speech, writing) or non-verbal (moving fingers or blinking) communication [13,14]. The inability to express pain among non-communicative ventilated patients is a significant barrier to accurate pain assessment. Therefore, these patients are at an increased risk for inappropriate analgesic treatment [15], such as under- or over-medication. In this context, it should be noted that the use of physiological indices has only little predictive significance, if any [2,15-18]. Although objective biomarkers for pain could support diagnosing pain, such reliable markers are scanty [19].

Thus, there is a need for adoption of pain assessment methods based on behavioral responses which are suitable for patients who do not communicate [14,20], that may help to identify pain, monitor the treatment, and improve the flow of information between caregivers [21,22]. This type of assessment tool is better suited for recognizing the existence of pain and assessing the response to therapy, rather than to the accurate evaluation of pain intensity.

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**Citation:** Kirshner D, Zheludkov S, Gharra N, Irina R, Bogoslavsky T (2020) Validity and Reliability of the Behavioral Pain Scale (BPS) for Assessing Pain in Non-Communicative Chronically- Ventilated Patients. J Gerontol Geriatr Med 6: 046.

**Received:** January 27, 2020; **Accepted:** February 10, 2020; **Published:** February 17, 2020

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Physicians bear the responsibility to use only high-quality, validated and reliable assessment tools that are appropriate for the training level of the nursing teams and are suitable for the specific target population [14]. It was demonstrated that the adoption of behavior-based pain assessment methods in the acute non-communicative patient, improved clinical outcomes and the proper use of pain management therapies [23,24]. While there is no single standard evaluation tool [25], there are several pain assessment tools geared towards non-communicative subjects, such as those with advanced dementia. Most pain assessment scales were not designed to evaluate non-communicative ventilated patients and as a result, do not include a component that refers to changes in the patient's pattern of respiration in response to pain.

The Behavioral Pain Scale (BPS) is a behavior-based pain assessment scale for intensive-care unit adult patients who are unable to express pain [16]. This evaluation tool can be implemented after a short training, its reliability has been confirmed [26,27] and its use has been shown to exert a positive impact on clinical outcomes [23]. The BPS was proposed in 2001 as a simple tool for evaluating pain levels in acute sedated ventilated patients in Intensive Care Units (ICU) and is comprised of three components: facial expression, upper limb movement and compliance with mechanical ventilation. Each component is graded from 1 (no stimulus response) to 4 (full response). The higher the index, the greater the level of pain experienced by the patient [28].

Another behavior-based pain assessment scale is the Critical-Care Pain Observation Tool (CPOT) which was developed by Gelinas et al., [29]. This tool was designed to detect pain in critically ill patients and includes 4 behavioural categories - facial expressions, body movements, muscle tension, compliance with a ventilator (for intubated patients) or verbalization (for extubated patients). As far as we know, there is no data about the use of pain assessment scales in chronically-non-communicative mechanically ventilated hospitalized patients. It is not known whether the accepted pain assessment tools for non-communicative ventilated patients in the acute setting, are also valid and reliable for assessing pain among chronically-ventilated non-communicative patients. The purpose of this study was to examine the validity and reliability of the behavioral based pain assessment tool, BPS, in pain detection among chronically-ventilated non-communicative patients.

## Methods

### Ethics approval

The protocol was approved by the hospitals' ethics committees. Informed consent of the surrogate decision maker of each enrolled patient was obtained. The study was funded entirely by the hospitals and the investigators have no conflict of interest to report.

### Patient population

The study took place in two long-term care facilities for chronically (30 days and above) ventilated patients. All consecutive hospitalized non-communicative mechanically and chronically-ventilated patients above 18 years of age were eligible for enrolment. Exclusion criteria were: quadriplegic paralysis, degenerative muscle disease, peripheral neuropathy or usage of medication for muscle paralysis.

### Conduct of the study

The documentation of the pain level was before, during and after

routine procedures known to cause pain [30]. Three routine procedures were chosen for the potential of stimulating a sensation of pain [3]: tracheal suction through the patients' tracheostomy, venous puncture for blood sampling and scheduled repositioning in bed. Observations were performed separately during each of the three procedures, at three different time intervals: a minute before, during (up to 30 seconds after completing the procedure) and 15 minutes after. During each procedure, the observations were carried out simultaneously by two independent assessors in each of the two hospitals. Two assessors in each hospital, who were physicians, were trained to use the BPS. Training material consisted of the study protocol and the paper versions of the BPS. In addition, a trial run of 1 week was performed, in which every assessor evaluated 10 patients to minimize the possible bias of a learning curve.

### Data collection

During the different time intervals of each procedure, the two assessors determined the BPS score which is determined by the sum of three components (facial expression, upper limb movements and compliance to the ventilation machine) and ranges between 3 (minimum pain) and 12 (maximum pain) [28]. Demographic and clinical data (primary cause of respiration, duration of respiration, breathing method, background diseases, analgesic drugs usage and laboratory measurements) were collected [Table 1].

Item	Description	Score
Facial expression	Relaxed	1
	Partially tightened	2
	Fully tightened	3
	Grimacing	4
Upper limbs	No movement	1
	Partially bent	2
	Fully bent with finger flexion	3
	Permanently retracted	4
Compliance with mechanical ventilation	Tolerating movement	1
	Coughing but tolerating ventilation most of the time	2
	Fighting ventilator	3
	Unable to control ventilation	4

**Table 1:** Patient time course.

### Statistical analysis

Data was described as numbers and percentage for non-metric variables and as mean and standard deviation for continuous parameters. Reliability refers to the extent to which assessments are consistent and was tested by a reliability procedure. Cronbach  $\alpha$  (measuring the strength of that consistency) was used for between-raters at each hospital and between hospitals. Validity refers to the accuracy of the assessment tool. Since there is no "gold standard" for evaluation of pain in non-communicative ventilated patients, the validity of the BPS was established by measuring the change in BPS score for each procedure, by each assessor at each hospital, during the three painful procedures.

The Chi-Square test was performed for qualitative data and t-test for continuous variables. Differences between rates were performed with Repeated Measures and paired t test.  $P < 0.05$  was considered a statistical difference. All analyses were done with SPSS-25.

## Results

48 non-communicative chronically mechanically ventilated patients, at two different long-term facilities for chronically-ventilated patients (24 patients at each center) were assessed. Two assessors from each facility participated in the evaluation of the BPS score. In total, 864 observations were taken (48 patients, 3 procedures, 3 time frames and 2 observers). The patients' characteristics are presented in table 2. The mean age was  $75.89 \pm 13.78$  years. Half of the patients were males. Most patients (87.5%) were of Jewish ethnicity. Causes of mechanical ventilation had been categorized to respiratory failure, cardiac failure, neurologic disease and patients were approximately equally-distributed between categories. The main comorbidity was hypertension, reported for 34 patients (70.8%) followed by diabetes mellitus (26 patients, 54.2%). The mean duration of ventilation was  $18.15 \pm 18.34$  months (minimum duration of ventilation was 1 month).

	Hospital A	Hospital B	Total	P-value
<b>No. of patients</b>	24	24	48	
<b>Age (years)</b>				
Mean $\pm$ SD	76.79 $\pm$ 15.69	75 $\pm$ 11.83	75.89 $\pm$ 13.78	p=0.657
Median (Range)	79.75	79.5	79.6	
	(23.9-96.3)	(43.0-92.0)		
<b>Gender</b>				p=0.148
Male	9 (37.5%)	15 (62.5%)	24 (50.0%)	
Female	15 (62.5%)	9 (37.5%)	24 (50.0%)	
<b>Ethnicity</b>				p=0.188
Jewish	19 (79.2%)	23 (95.8%)	42 (87.5%)	
Arabic	5 (20.8%)	1 (4.2%)	6 (12.5%)	
<b>Causes of ventilation</b>				p=0.263
Respiratory failure	7 (29.2%)	8 (33.3%)	15 (31.3%)	
Cardiac failure	5 (20.8%)	3 (12.5%)	8 (16.7%)	
Neurologic disease	9 (37.5%)	5 (20.8%)	14 (29.2%)	
Other	3 (12.5%)	8 (33.3%)	11 (22.9%)	
<b>Duration of ventilation (months)</b>				
Mean	15.75 $\pm$ 19.00	20.54 $\pm$ 17.72	18.15 $\pm$ 18.34	p=0.371
Median	9.00	18.00	11.50	
<b>Comorbidities</b>				
Heart failure	6 (25.0%)	10 (41.7%)	16 (33.3%)	p=0.221
Hypertension	16 (66.7%)	18 (75.0%)	34 (70.8%)	p=0.525
Chronic Obstructive Lung Disorder	4 (16.7%)	8 (33.3%)	12 (25.0%)	p=0.318
Diabetes Mellitus	10 (41.7%)	16 (66.7%)	26 (54.2%)	p=0.082
<b>Analgesic Use</b>				
Fentanyl	8 (33.3%)	15 (62.5%)	23 (47.9%)	p=0.043
Opioids	1 (4.2%)	1 (4.2%)	2 (4.2%)	p=1.000
Benzodiazepines	14 (58.3%)	10 (41.7%)	24 (50.0%)	p=0.248
Acetaminophen	11 (45.8%)	0 (0.0%)	11 (22.9%)	p=0.000
Dipyrone	3 (12.5%)	0 (0.1%)	3 (6.3%)	p=0.234

**Table 2:** Patient characteristics.

Analgesic consumption during the 72-hour period prior to the evaluation was recorded. Approximately half of the patients were recorded as administered fentanyl, or benzodiazepines (47.9%, and

50%, respectively). No significant statistical differences in patient characteristics were found between the two hospitals except for fentanyl and acetaminophen use.

## Reliability

Within each of the two hospitals there were no significant differences ( $p > 0.05$ ) in the mean scores given for each BPS component during each of the three painful procedures (Table 3). One exception was the assessment of 'compliance with mechanical ventilation' during tracheal suction in hospital A.

Procedure	Hospital	BPS component	Assessor	Mean	Standard Deviation	P-value
Repositioning	A	Facial expression	1	3.04	0.20	0.135
			2	3.25	0.61	
		Upper limbs	1	5.71	1.46	0.458
			2	5.46	2.25	
		Compliance with ventilation	1	3.25	0.53	0.083
			2	3.00	0.51	
	B	Facial expression	3	3.17	0.38	0.083
			4	3.04	0.20	
		Upper limbs	3	5.33	1.88	1.000
			4	5.33	1.83	
		Compliance with ventilation	3	3.13	0.61	0.328
			4	3.00	0.00	
Tracheal suction	A	Facial expression	1	3.13	0.34	0.575
			2	3.17	0.48	
		Upper limbs	1	8.08	2.50	0.809
			2	7.92	2.52	
		Compliance with ventilation	1	3.42	0.72	0.032
			2	3.13	0.34	
	Facial expression	Facial expression	3	3.04	0.20	0.445
			4	3.21	1.02	
		Upper limbs	3	6.04	2.05	0.170
			4	6.25	2.15	
		Compliance with ventilation	3	3.04	0.20	0.185
			4	3.17	0.48	
Venous puncture	A	Facial expression	1	3.08	0.41	0.664
			2	3.04	0.20	
		Upper limbs	1	4.83	2.08	0.679
			2	4.67	2.06	
		Compliance with ventilation	1	3.29	1.04	0.426
			2	3.21	0.66	
	B	Facial expression	3	3.00	0.00	
			4	3.00	0.00	
		Upper limbs	3	5.71	2.03	0.096
			4	5.92	2.04	
		Compliance with ventilation	3	3.00	0.00	
			4	3.00	0.00	

**Table 3:** Inter-rater differences within each hospital.

N of observations = 24 for all

Cronbach  $\alpha$  values demonstrated a very good internal consistency between the two assessors in each hospital for the total BPS score during each procedure's observation (Table 4). One exception was evaluation of total BPS score during tracheal suction in hospital A.

Procedure	Hospital	Cronbach $\alpha$
Repositioning	A	0.775
	B	0.981
Tracheal suction	A	0.201
	B	0.970
Venous puncture	A	0.715
	B	0.979

**Table 4:** Cronbach  $\alpha$  values demonstrating in-hospital consistency.

After demonstrating good inter-rater agreement between each pair of assessors within each hospital, the mean BPS scores of the two assessors in each hospital were combined. Thereafter, the combined assessor means in each hospital were compared between hospitals. No significant differences in the mean components of the BPS scores (for each of the three procedures) were found between the hospitals ( $p>0.05$ ; Table 5). Two exceptions were the BPS score during and after tracheal suction.

Cronbach  $\alpha$  values demonstrated internal consistency between the unified BPS scores of the two hospitals (Table 6).

### Validity

The BPS score showed significant increase from baseline to painful levels (scores measured one minute prior to the painful procedures and during the painful procedures, respectively). In addition, BPS score showed significant decrease from the painful levels to the post-procedure levels (scores measured during the painful procedures and 15 minutes after the procedures' cessation). The increases and decreases were demonstrated in all the 3 painful procedures. There

were no significant differences between the baseline and the post-procedure BPS scores (Table 7).

### Discussion

Clinical procedures may produce pain and anxiety, both of which should be assessed and addressed [31]. Adequate pain management should be based on reliable tools and indeed, accurate pain evaluation has been shown to be associated with better prognosis [16]. Chronically mechanically ventilated patients are often non-communicative. Since self-reporting of pain, which is considered to be the gold standard for evaluating pain, is not applicable for uncommunicative patients, behavior-based pain rating scales have been developed. BPS has been extensively reported in previous studies and was found valid for assessing pain among mechanically-ventilated patients in ICUs [2,18,28,32]. Elevated BPS scores are associated with poorer clinical outcomes among mechanically-ventilated patients [33].

Due to the lack of a gold standard tool for assessing pain in non-communicative patients, it is very difficult to establish and validate pain assessment tools for these patients. Our study examined the validity and reliability of the BPS as a tool for evaluating pain in chronically-ventilated, non-communicative patients. This tool has been proven to be valid and reliable in critically- ill ventilated patients in ICUs, but not in chronically-ventilated patient population which was evaluated in our study [28]. There is scarce data in the literature on pain evaluation among this specific ventilated patient population.

The population of chronically-ventilated patients differs from the population of critically-ill ventilated ICU patients in three major characteristics that are relevant to pain experience and its evaluation. The first main difference between the two populations is the continuous existence of acute illness among ICU patients.

Hospital		Repositioning			Tracheal suction			Venous puncture		
		Before	During	After	Before	During	After	Before	During	After
A	Mean BPS	3.04	5.71	3.25	3.13	8.08	3.42	3.08	4.83	3.29
	No.	24	24	24	24	24	24	24	24	24
	Std. Dev	0.204	1.459	0.532	0.338	2.501	0.717	0.408	2.078	1.042
	Median	3.00	6.00	3.00	3.00	7.50	3.00	3.00	4.00	3.00
	Minimum	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00
	Maximum	4	8	5	4	12	6	5	10	8
B	Mean BPS	3.17	5.33	3.13	3.04	6.04	3.04	3.00	5.71	3.00
	No.	24	24	24	24	24	24	24	24	24
	Std. Dev	0.381	1.880	0.612	0.204	2.053	0.204	0.000	2.032	0.000
	Median	3.00	5.00	3.00	3.00	6.00	3.00	3.00	5.00	3.00
	Minimum	3	3	3	3	3	3	3	3	3
	Maximum	4	10	6	4	12	4	3	10	3
Total	Mean BPS	3.10	5.52	3.19	3.08	7.06	3.23	3.04	5.27	3.15
	No.	48	48	48	48	48	48	48	48	48
	Std. Dev	0.309	1.676	0.571	0.279	2.487	0.555	0.289	2.081	0.743
	Median	3.00	6.00	3.00	3.00	7.00	3.00	3.00	5.00	3.00
	Minimum	3	3	3	3	3	3	3	3	3
	Maximum	4	10	6	4	12	6	5	10	8
P in t-test		0.163	0.444	0.454	0.306	0.003	0.018	0.323	0.147	0.177

**Table 5:** Inter-rater difference between the two hospitals.



Procedure	Cronbach $\alpha$
Repositioning	0.885
Tracheal suction	0.693
Venous puncture	0.868

**Table 6:** Cronbach  $\alpha$  values demonstrating between-hospital consistency.

ICU patients typically battle with a dynamic and aggressive medical condition that can cause pain in and of itself and may also require specific therapeutic and diagnostic procedures that cause additional pain. In chronically-ventilated patients, acute conditions occur relatively infrequently and most of the hospitalization time is characterized by a stable medical condition. In this context, it should be noted that the chronically-ventilated patients are ventilated through tracheostomy rather than through an endotracheal tubes.

The second major difference is the environment. While the hospitalization environment in the ICUs is unpredictable and highly active throughout most of the day, in the vicinity of hospitalization in chronic wards, there is a great deal of possibility to maintain a stable routine. These facts may also have an effect on the perception of pain that has not yet been examined in a controlled manner among chronically ventilated, non-communicative, hospitalized patients. Moreover, staff caring for these patient populations differs as well. The staff dealing with chronic hospitalization departments has more prolonged acquaintance with the patients. It is not known how this prolonged acquaintance affects the pain assessment of the team. It can be assumed that prolonged acquaintance will contribute to the accuracy of pain assessment, but it is possible that this may dull this assessment. Further studies are needed to answer this question.

The third difference is a potential difference in perception of the pain associated with routine procedures, which has yet to be examined. It is possible that over time, there is a decrease in the intensity of the pain experienced during performance of these procedures. It is possible that a kind of passivity develops, or alternatively, the threshold of pain and discomfort rises. Validating assessment tools for this population will enable further research into these possible changes.

In this study we showed that the BPS is a valid and reliable tool for assessing pain in the specific population of chronically-ventilated non-communicative patients. The validity of the tool was demonstrated

by the statistically-significant differences between the levels of pain before and during a procedure known to have a potentially painful effect. In addition, there was a statistically significant difference between the pain level during the procedure and a few minutes after it. Similar significant differences were reported in previous studies [27,34].

The inter-rater reliability of the BPS in our study was good (Cronbach's coefficient  $\alpha$  0.693 - 0.885), and in line with previous studies assessing the BPS in other settings/populations [28,32,34,35]. An analysis of the results revealed that there was good agreement among the evaluators within each hospital and between the hospitals. This consensus was observed in the majority of the sub-sections of the BPS and it contributes to the reliability of the measurement. A good reliability is very important in any pain evaluation among hospitalized patients since it is done by a large group of caregivers [10,32].

A difference in the mean BPS score during and after tracheal suctioning between the two hospitals was observed. One explanation for this particular discrepancy may be the difference in suctioning procedure between the two hospitals, as well as the difference between the equipment used in each one. In addition, the training of the two assessors in each hospital was done separately, a fact that may also influence the results, although no difference was found among the other two procedures. The reliability of the evaluations within each hospital during and after tracheal suctioning was high and statistically-significant. This discrepancy explains the relatively low Cronbach  $\alpha$  value of between-hospital consistency during tracheal suctioning compared to the other two procedures. Considering this data, it appears that the assessment of the patient's pain at the time of this specific procedure is more complex and its reliability may be lower. It is known that pain scales based on behavioral parameters are subjective and depend on staff education and training [24].

In the examined population, the baseline pain level, before and after painful procedure, was very low (mean BPS score of 3.09). This has also been observed in other studies and appears to be a sign of relatively good pain control among the evaluated patients [34,36]. It should be noted that although this level is low, it is not negligible - clear evidence that there is always room for improvement. One way for achieving an improvement is by having an accurate evaluation for pain.

Procedure	Timing of evaluation in relation	Mean of BPS score	No. Of observations	Standard deviation	p- Value Before vs. During	p- Value During vs. After	p- Value Before vs. After
Repositioning	Before	3.1	48	0.31	p<0.0001	p<0.0001	0.322
	During	5.52	48	1.68			
	After	3.19	48	0.57			
Tracheal suctioning	Before	3.08	48	0.28	p<0.0001	p<0.0001	0.07
	During	7.06	48	2.49			
	After	3.23	48	0.56			
Venous puncture	Before	3.04	48	0.29	p<0.0001	p<0.0001	0.375
	During	5.27	48	2.08			
	After	3.15	48	0.74			

**Table 7:** Differences in the BPS scores.

The results of the study further strengthen the importance of this evaluating tool and extend the patient population to which it can be applicable. As was proven previously among ICU patients, we demonstrated that non-communicative ventilated patients also experience pain during routine procedures [30]. This may improve the accuracy of pain assessment and enable better, more appropriate pain control for patients who cannot self-report or express pain. Appropriate evaluation of the pain level may also prevent unnecessary use of pain-relief medications [34].

Our study has some limitations. First, due to the characteristics of the study, among real patients in two different institutions with different pain treatment protocols and due to ethical issues, it was impossible to influence or change the chronic pain relief treatment prior to data collection. The use of pain medication was slightly different between the two hospitals. It should be noted that there was no difference in the background rate of the opioids and benzodiazepine use. In one hospital, the use of acetaminophen and dipyron was not part of hospital protocols. Additional limitation is the fact that the observers were not blinded to the noxious stimulus. By demonstrating the validity and reliability of the BPS in the examined population, the results of this study provide a basis for further studies in the field of identifying, characterizing and evaluating pain. It will also enable more appropriate treatment of pain for non-communicative chronically ventilated patients.

## Conclusion

Behavioral Pain Scale (BPS) is a valid and reliable tool for pain assessment among chronically ventilated non-communicative patients.

## Disclosures

The authors have no conflicts of interest to declare. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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