Respiratory Distress Observation Scale Italian Version

Cultural-Linguistic Validation and Psychometric Properties

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Dyspnea can be assessed using self-rating scales but, as death approaches, self-reporting becomes difficult. The validated Respiratory Distress Observation Scale measures dyspnea distress. The aim of this study was to develop the Italian version of the Respiratory Distress Observation Scale and to examine its psychometric properties. This was a cross-sectional study, analyzing cultural and linguistic validation, content validity, and psychometric properties. Eighty-nine palliative care subjects were enrolled to validate the Italian version of the Respiratory Distress Observation Scale. Patients had an average age of 74.5 (SD, 11.6) years, and 52% (n = 46) were female. Fourteen experts in palliative care evaluated the Italian Respiratory Distress Observation Scale in terms of the content validity ratio and the content validity index (CVI). The Italian Respiratory Distress Observation Scale was reported with an internal consistency (Cronbach α value) of .72 and an overall substantial interrater reliability (Cohen κ method). The Italian Respiratory Distress Observation Scale achieved a scale-level CVI of 93%, an items-level CVI of greater than 86%, and a minimum content validity ratio value of 0.71. A weak positive correlation was found between the Respiratory Distress Observation Scale and the Dyspnea Visual Analog Scale scores (0.374; $P < .001$). The Italian Respiratory Distress Observation Scale showed good reliability and validity for patients in palliative care. The Respiratory Distress Observation Scale measured respiratory distress in patients nearest to death.

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Dyspnea was defined as "a subjective experience of breathing discomfort that consists of qualitatively distinct sensations that vary in intensity." The experience of dyspnea "derives from interactions among multiple physiological, psychological, social, and environmental factors and may induce secondary physiological and behavioral responses." Eighty-eight percent of heart patients and 95% of patients with chronic obstructive pulmonary disease (COPD) who die each year have dyspnea.[1] Dyspnea worsens before death,[2] when patients also begin to have difficulty in self-reporting it.[3] The period before death is characterized by cognitive decay and consciousness

reduction due to hemodynamic, blood gas, or metabolic disorders. The same physiological changes that cause dyspnea in patients with intact cognitive capacity produce respiratory distress even in patients with cognitive decline.[4,5]

As dyspnea is a symptom, that is, the perception of an abnormal or distressing internal state, it should be distinguished from signs that typically indicate the presence of respiratory distress, such as tachypnea, the use of accessory muscles, and intercostal retractions.[4-6]

Respiratory distress can be observed if the patient is unable to report it.[4,5] Patients who are unable to report dyspnea may be exposed to undertreatment.[6] Therefore, for an effective control of symptoms or signs, it is necessary for the clinic staff to carefully assess dyspnea or respiratory distress.[7,8] The Respiratory Distress Observation Scale is the only known tool for assessing respiratory distress and its intensity in patients who cannot report dyspnea.

The Respiratory Distress Observation Scale was developed from a biobehavioral framework by Dr Margaret L. Campbell.[4,9,10] Psychometric testing was performed for interrater and scale reliability, as well as construct, convergent, and discriminant validity.[5-7,11]

The Respiratory Distress Observation Scale has clinical utility for assessing respiratory distress across care settings, including the intensive care unit.[12] The Respiratory Distress Observation Scale is not valid with neonates, young children, patients with cervical spinal cord lesions producing quadriplegia, or patients with bulbar amyotrophic lateral sclerosis.[6] The Respiratory Distress Observation Scale has research utility as a dependent measure in efficacy trials.[12,13] The Respiratory Distress Observation Scale is in clinical use in more than 50 sites in the United States and in 11 countries.

To date, the assessment tools used in Italy for dyspnea are all for patients who are conscious, whereas in patients unable to express themselves, respiratory distress is not constantly or systematically monitored. Whereas the Respiratory Distress Observation Scale has been translated into French, Dutch, Chinese, Tamil, and Greek, no official Italian version is currently available.

Therefore, this study aimed to develop the Italian version of the Respiratory Distress Observation Scale and to examine its psychometric properties. Developing an Italian version of the Respiratory Distress Observation Scale could help clinicians objectively and systematically assess respiratory distress in patients not able to self-report it.

METHODS

The quality of a scale is based on its estimated psychometric properties, which comprise reliability and validity. Validity comprises cross-cultural validity, content validity, and convergent validity. Reliability comprises internal consistency and interrater reliability. The Italian version of the Respiratory Distress Observation Scale was developed according to the following validation stages: cultural and linguistic validation, test of content validity by involving a group of experts in palliative care, and test of psychometric properties on a larger sample of patients through a cross-sectional study. These measurement properties of the Italian version of the Respiratory Distress Observation Scale were determined along with feasibility and the floor/ceiling effect. Data were collected between February and December 2019 in three hospitals in northern Italy from trained nurses in the palliative care team.

Cultural and Linguistic Validation

Consent to the translation and validation of the Respiratory Distress Observation Scale into Italian was obtained by the author of the scale, Dr Margaret L. Campbell. The scale was translated using the back-translation method, in accordance with the guidelines.[14] The original Respiratory Distress Observation Scale (English version) was translated into Italian (forward translation) by 2 professionals conversant with both languages. One of the 2 translators, a nurse, ensured mastery of the professional terminology. The translators separately developed 2 versions of the questionnaire reporting the difficulties encountered.

During a second step, the 2 translators discussed the text with another nursing professional until a common version was reached. The translated version was submitted to a group of experts in palliative care who conducted a formal review of the forward translation, improving its linguistic and cultural comprehensibility for each item. The version was then translated into English (back translation) by a native English speaker and finally sent to the original author for verification.

Content Validity

Content validity is considered the first step in validating instruments, given that it identifies the degree to which the tool measures the construct that it is intended to measure, in our case respiratory distress.[15] Content validity can be expressed through 2 numerical indexes: the content validity ratio (CVR) and the content validity index (CVI). The translated Respiratory Distress Observation Scale was delivered to the group of experts in palliative care. Their first duty was to determine whether each individual item on the scale was: not necessary, useful but not essential, or essential. This information allowed us to calculate the CVR.

The CVR can vary between +1 (total agreement between evaluators to maintain the item) and −1 (null agreement). The minimum CVR value to consider an item relevant was set at 0.29 by 40 professionals and at 0.99 by 5. The minimum CVR value used in this study was set then at 0.51 by the 14 panelists.[15]

Second, the group of experts evaluated the Respiratory Distress Observation Scale items in terms of relevance (not relevant, somewhat relevant, quite relevant, relevant, very

relevant). The CVI was calculated both at the items level (I-CVIs) and at the scale level (S-CVI). The percentage of agreement on the relevance of each item was thus obtained; this index can vary between 0 and 1.[15]

Participants

The psychometric properties were tested by administering the evaluation scale to a group of terminally ill patients in hospice or home palliative care. The sample size was set in accordance with the criteria defined by the guidelines of COSMIN (COnsensus-based Standards for the selection of health Measurements INstruments).[16] According to the COSMIN checklist,[16] the sample size must specifically be 7 times the number of items on the scale; thus, in our study, we defined this to include at least 56 patients. The inclusion criteria were as follows: 18 years or older, intact cognition (score at Mini-Mental State Examination score >24),[17] diagnosis of advanced cancer or advanced stage chronic illness, and presence of dyspnea at enrollment and/or in the previous days so at risk of experiencing dyspnea. Expressly excluded were conditions of paralysis, amyotrophic lateral sclerosis, mechanical ventilation, and mental or cognitive disorders. Patients who did not speak Italian were also excluded.

Feasibility and Floor/Ceiling Effect

Feasibility considers whether there is any difficulty in completing the Respiratory Distress Observation Scale and the time required for clinicians to complete it. The time for administering the scale and the difficulties in comprehending the items by the nurses were recorded.

The floor effect was evaluated calculating the percentage of patients reaching the minimum score, whereas the ceiling effect took into consideration the number of patients reaching the maximum score. These effects were considered present if the percentages were greater than 15%. Assessment scales might be at risk of a floor or ceiling effect as many patients, despite varying levels of symptoms and disability, are likely to fall in the best or worst category, respectively.

Psychometric Properties

The internal consistency measure of reliability is a psychometric property evaluating the interrelatedness among the items of a scale. To effectively measure a phenomenon in the study, such as respiratory distress, the items on a scale must explore its different aspects and be consistent with each other. If this consistency is lacking, the items are likely to measure different things and therefore not to contribute to the measurement of the phenomenon being studied. Internal consistency can be evaluated by means of Cronbach α coefficient.

Cronbach α was determined using the data collected through administration of the Respiratory Distress Observation Scale; it was also determined seeing whether, upon deleting each item from the scale, the index and the correlation between the remaining items would improve without the deleted item (Cronbach α if the item was deleted and the corrected item-total correlation). A Cronbach α coefficient higher than .7 and corrected item-total correlations greater than 0.3 were considered adequate.

Interrater reliability represents the degree of correlation between the scores assigned to the same sample of patients by 2 or more independent evaluators using the same scale.

In our study, 2 raters evaluated the same patients separately. Cohen κ method was used to assess the interrater reliability. κ Values lower than 0.2 were considered poor agreement; 0.2 to 0.4, fair; 0.41 to 0.6, moderate; 0.61 to 0.8, substantial; and 0.81 to 1, perfect.

Interrater reliability was evaluated in a subgroup of 24 patients.

Convergent validity detects whether a scale that measures a certain concept is correlated with other tests that measure similar concepts. Convergent validity can be estimated using correlation analysis. In our study, Spearman correlation coefficient between the Respiratory Distress Observation Scale and the Visual Analog Scale–Dyspnea (VAS-D) score was calculated to assess whether the same construct was measured.

Statistical Considerations

The analyses were carried out using IBM SPSS Statistics 26 (IBM Corp., Armonk, NY). The sociodemographic data and clinical characteristics of the sample were analyzed through descriptive statistics. Continuous variables are presented as mean (SD), and categorical variables are presented as a percentage (absolute value).

Ethical Considerations

The study "Dyspnea in Palliative Care. Assessment, Quality of Life and Caregiver's Role" was approved by the ethics committee (number 491-102018, May 10, 2018). The participation of experts and patients was voluntary, and anonymity was ensured during the study. The patients were informed about the purpose and modalities of the study and gave their informed written consent. The study was conducted in accordance with Italian law and the principles of the Helsinki Declaration.

Measures

The Italian Version of the Respiratory Distress Observation Scale

Enrolled patients were assessed by the designated expert professionals according to the Respiratory Distress Observation Scale. The Respiratory Distress Observation Scale (Table 1) is an 8-item ordinal scale measuring the presence and intensity of respiratory distress in adults. It is intended for assessing the presence and intensity of respiratory distress when a patient is unable to report dyspnea. Each parameter is scored from 0 to 2 points, and the points are summed. Scale

TABLE 1 Results of the Content Validity, Internal Consistency, and Interrater Reliability Analysis of the Italian Respiratory Distress Observation Scale

	CVR	I-CVI	Cronbach α			κ	Asymptotic Standard Error
				Item Deleted	Item Correlation		
1. Heart rate per minute (Frequenza Cardiaca)	0.71[a]	0.86[a]	0.720	0.724	0.208	1	0[b]
2. Respiratory rate per minute (Frequenza Respiratoria)	1.00[a]	1.00[a]		0.722	0.282	1	0[b]
3. Restlessness: non purposeful movements (Irrequietezza: movimenti involontari)	1.00[a]	0.86[a]		0.687	0.502	0.739	0.139[b]
4. Paradoxical breathing pattern: abdomen moves in on inspiration (Quadro di respiro paradosso: movimenti addominali in inspirazione)	0.71[a]	0.93[a]		0.734	0.285	1	0[b]
5. Accessory muscle use: rise in clavicle during inspiration (Utilizzo della muscolatura accessoria: innalzamento della clavicola durante l'inspirazione)	0.86[a]	0.86[a]		0.692	0.466	1	0[b]
6. Grunting at end expiration: guttural sound (Presenza di suoni/rumori a fine espirazione: suono gutturale)	1.00[a]	1.00[a]		0.611	0.703	1	0[b]
7. Nasal flaring: involuntary movement of nares (Alitamento delle pinne nasali: movimento involontario delle narici)	0.71[a]	1.00[a]		0.706	0.361	1	0[b]
8. Look of fear (Sguardo impaurito)	0.71[a]	0.93[a]		0.615	0.692	1	0[b]
S-CVI		0.93					

Abbreviations: CVI, content validity index; CVR, content validity ratio; I-CVI, item content validity index; RDOS, Respiratory Distress Observation Scale; S-CVI, scale-level content validity index.

[a]*Relevant or adequate item (italic items in Italian language).*

[b]*P < .001.*

scores range from 0, signifying no distress, to 16, signifying the most severe distress.[6] The parameters estimated by the observer are heart rate, respiratory rate, use of accessory muscles, paradoxical breathing, restlessness, grunts at the end of the expiration, nasal flaring, and fearful facial expressions. The receiver operating characteristic curve analysis determined that a Respiratory Distress Observation Scale score of 0 to 2 suggests no respiratory distress; a score of 3, mild distress; scores of 4 to 6, moderate distress; and 7 or greater, severe distress, with an adequate cutoff point for assigning clinical significance at score 3.[10,18] A trend of increasing median Respiratory Distress Observation Scale scores was reported, leading to a new cutoff proposal of 4 or greater.[11] No difference was found in reliability and validity between diagnoses; thus, the Respiratory Distress Observation Scale authors assumed that these cutoff points are uniformly applicable.[5,6,9]

Other Measures

Demographic (age, gender), disease, and treatment data were collected. The Glasgow Coma Scale was administered. The intensity of dyspnea, based on patient self-reports, was also evaluated using the VAS-D, represented by a vertical 100-mm line at the ends of which the terms "no dyspnea" and "worst possible shortness of breath" were indicated.[19] Karnofsky Performance Status is an assessment conducted by a health care professional to assign a patient to 1 of 10 categories (from 0 "dead" to 100 "normal activity, no evidence of illness").[20]

RESULTS

Cultural and Linguistic Validation

The 14 experts' response rate was 100%. Thirteen experts were female (92.9%), and their average age was 50.7

(4.4) years. Sixty-four percent of the professionals were nurses (9), 14% with a master's degree in nursing science (2), and 22% were physicians (3) with a mean work experience of 13.2 years (7.8). The work setting was as follows: 22% hospice (3), 56% home palliative care (8), and 22% bachelor school of nursing (3) teaching nursing in palliative care. The members of the group examined each individual element of the translation, and consensus was obtained in the formulation of the individual items and the instructions for use.

The Italian translation contained no problematic elements or terms to translate. The author, Dr Margaret L. Campbell, confirmed that the back-translation from Italian to English is closely aligned with the original Respiratory Distress Observation Scale. The translated items are presented in Table 1.

Content Validity

As to content validity, all the items were deemed relevant as all CVRs are greater than 0.70 (Table 1).[15] The Italian version of the Respiratory Distress Observation Scale achieved an S-CVI of 93%, whereas each item presented an I-CVI of greater than 86% and a minimum CVR value of 0.71 for the items (Table 1).

Basic Data of Participants

Eighty-nine patients who met the inclusion criteria were enrolled and completed the questionnaires. The enrolled population characteristics are shown in Table 2. Patients had an average age of 74.5 (11.6) years, ranging from 45 to 94 years, and 52% (46) were female. Thirty-six percent of the patients had lung cancer (33), 16% had gastrointestinal cancer (14), 15% had urinary genital cancer (13), and 12% had breast cancer (11); the remaining sample had other diagnoses with lower percentages. Fifty-eight percent (52) of patients received opioids, 64% (57) received benzodiazepines, and 76% (68) received oxygen therapy. The whole sample presented a Glasgow Coma Scale score of 15 with best response. All patients showed dyspnea in the days prior to enrollment and had a terminal disease, with Karnofsky Performance Status of 40 or less for 62% of cases (n = 55). Comorbidities included COPD (25% [16]), heart failure (17% [15]), and other diseases. The sample presented metastases to the lung in 31% of cases (28), as well as to other sites.

As to administration of the Respiratory Distress Observation Scale, 10% of patients (9) presented respiratory distress with a score of 3 on the Respiratory Distress Observation Scale, and 33% (29) with a score in the range of 4 to 6 (mild to moderate distress). Fifty-seven percent (51) had a Respiratory Distress Observation Scale score of 7 or higher (severe distress); only 1 patient had the maximum score.[18] The average score on the scale was 7.8 (SD, 3.4).

TABLE 2 Patients Characteristics

Mean age, y	74.5 (±11.6)	
Gender	Male	48 (43)
	Female	52 (46)
Diagnosis	Lung cancer	36 (33)
	Gastrointestinal cancer	16 (14)
	Urinary genital cancer	15 (13)
	Breast cancer	12 (11)
	Heart failure	5 (4)
	COPD	2 (2)
	Others	14 (12)
KPS	20 = Very ill	9 (8)
	30 = Severely disabled	28 (25)
	40 = Disabled	25 (22)
	50 = Requires help often	21 (19)
	60 = Requiring some help	12 (11)
	70 = Caring for self	3 (3)
	80 = Normal activity with some difficulty	1 (1)

Abbreviations: COPD, chronic obstructive pulmonary disease; KPS, Karnofsky Performance Scale.

Continuous variables are presented as mean and SD and categorical variables as percentages.

Psychometric Properties

Feasibility

The time to administer the Respiratory Distress Observation Scale was 257.4 (SD, 63) seconds. None of the nurses experienced difficulty understanding the items.

Floor/Ceiling Effect

Only 1 patient reached the maximum value of the Respiratory Distress Observation Scale, whereas none of the patients reached the minimum value of the scale; thus, no floor or ceiling effects were present.

Internal Consistency

The results of the internal consistency analysis are presented in Table 1. Cronbach α calculated based on all the items was .720 (Table 1). Five of the corrected item-total correlations were greater than 0.3, and the other three were greater than 0.2.

Interrater Reliability

The interrater reliability results, in a subgroup of 24 patients, are shown in Table 1. The κ value related to item 3 was 0.739 (substantial interrater reliability).

Convergent Validity

The Spearman correlation coefficient between the Respiratory Distress Observation Scale and the VAS-D was 0.374 ($P < .001$), indicating a significantly weak positive correlation.

DISCUSSION

The study presented the cross-validated Italian version of the Respiratory Distress Observation Scale originally created by Dr Margaret L. Campbell[14] and assessed its content validity among experts in palliative care.[15]

Finally, its feasibility, internal consistency, interrater reliability, floor/ceiling effect, and convergent validity were tested in a large sample of patients with an advanced life-limiting disease. The Italian version of the Respiratory Distress Observation Scale was developed to be used in palliative nursing care, to assess respiratory distress in nonverbal patients, a frequent condition at end of life. The authors identified the need for an easy-to-manage tool for the assessment of dyspnea by palliative care nurses. According to the literature, the findings had shown a conceptual equivalence with the original version and good content validity for all the items.[15] Experts confirmed the absence of ambiguities or of items to amend, as reflected by high CVR values (all items were relevant) and high CVI scores (items feasible and semantically well organized). These results demonstrated that the Italian version of the Respiratory Distress Observation Scale was found to be an acceptable and practicable tool to assess respiratory distress in clinical practice. Evaluators, with or without experience in chest or respiratory care, had the possibility to use the Italian version of the Respiratory Distress Observation Scale. Standardized, advanced, and clinically usable tools for the evaluation of dyspnea are indispensable for patients who are unable to provide self-reports in palliative care.

The scale was also confirmed to be feasible on a large sample of patients recruited in 2 different palliative care settings, in hospices and at home. The average administration time, evaluated in this study for the first time, was slightly higher than 4 minutes and was considered adequate to ascertain respiratory distress. The rapidity with which an otherwise unobjective symptom can be assessed is worth emphasizing, as this translates into the most appropriate treatment for the benefit of the patient. The present study confirmed substantial interrater reliability in a subgroup of 24 patients, in line with previous studies.[6,7,11] This indicated that the Italian version of the Respiratory Distress Observation Scale, with 2 evaluators simultaneously evaluating the same patient, was considered stable, there being no conditioning due to the presence of different evaluators. In Dr Margaret L. Campbell and colleagues'[6] study in 2010 on the Respiratory Distress Observation Scale, interrater reliability was optimal between nurse data collectors. Chan et al[7] increased the number of subjects to 30, and Zhuang et al[11] to 50 palliative care patients with good interrater reliability. Evaluation with the Respiratory Distress Observation Scale is a registered nursing function; agreement between nurses in assessing the symptom is essential. The Cronbach α coefficients and the item-total correlations observed indicate good internal consistency, in line with the previous studies (Cronbach α coefficients range between .64 and .86).[6,7] As indicated in our study, the results showed adequate reliability and good content validity, providing solid support for the Italian version of the Respiratory Distress Observation Scale.

Convergent validity evaluates the extent to which 2 same-concept measurement methods are similar.[5] An instrument is compared with a criterion-standard instrument in order to determine convergent validity. The evaluation of dyspnea was significantly correlated to the severity of the disease.[7] There are no behavioral scales to measure dyspnea. The Respiratory Distress Observation Scale was compared with the patient's self-report on dyspnea using the VAS-D. In our study, the correlations between the Respiratory Distress Observation Scale total score and the VAS-D were moderately satisfactory for conscious patients in palliative care, in support of convergent validity.[21] This correlation, although weak, suggests that there was the same "respiratory distress" construct between the Italian Respiratory Distress Observation Scale and the VAS-D, confirming the conceptual association between respiratory distress and dyspnea and showing good convergent validity. The low correlation could be due to the fact that dyspnea is a symptom, distinct from signs that typically indicate the presence of respiratory distress. Low correlation indicates that respiratory distress is not exactly equivalent to dyspnea. Further validity and reliability studies are needed within the target Respiratory Distress Observation Scale population, that is, patients who are unable to self-report dyspnea.

In previous studies, convergent validity was determined by comparing the Respiratory Distress Observation Scale and dyspnea self-reports in different populations ($r = 0.38$-0.74).

A strong correlation ($r = 0.74$) was found in a population of healthy volunteers, postoperative pain patients, and COPD dyspneic patients.

Considering only patients with COPD, a mildly significant within-group correlation was found ($r = 0.38$).[5,6,10] In the study of Chan et al,[7] there was a high positive correlation ($r = 0.76$) among conscious patients who were critically ill. Comparing our results with previous studies, we obtained similar results to those of Dr Margaret L. Campbell regardless of conscious pulmonary rehabilitation patients.[5]

Our study showed mild to severe respiratory distress without floor/ceiling effects, comparable to previous studies,[5,10] despite the fact that the patients were receiving palliative care.

The complexity of patients was mirrored by a high use of benzodiazepines. Although benzodiazepines are not an evidence-based primary treatment for dyspnea, in our sample it was used frequently, which may account for the high perceived respiratory distress in our sample. In previous studies, dying patients had Respiratory Distress Observation Scale scores in the ranges of 0 to 14, 0 to 12,[6,13] and 0 to 13, with a median score of 4.8 in the last range.[18] As more than half of the near-death patients are known to be unable to answer about shortness of breath,[3] application of the Respiratory Distress Observation Scale in palliative care is important[6]; otherwise, this symptom could be overlooked. Previous studies showed that nurses underestimate patient dyspnea.[18,22] Despite this, Dr Margaret L. Campbell[6] reported a significant reduction in the Respiratory Distress Observation Scale score over time, corresponding to treatment in patients with terminal diseases. Chan et al[7] also highlighted the sensitivity of the Chinese Respiratory Distress Observation Scale to change when treatment is applied. Also, Zhuang et al[11] showed a significant difference in Respiratory Distress Observation Scale scores between patients with different severity of levels of dyspnea. The ability of the Respiratory Distress Observation Scale to detect clinically relevant changes in dyspnea over time provides an important contribution. Future studies are encouraged also for the Italian version of the Respiratory Distress Observation Scale.

Patients who, for a variety of reasons, are unable to report distress generated by symptoms may be at risk of overtreatment or undertreatment; indeed, the Respiratory Distress Observation Scale could help to guide assessment and care for patients with cognitive impairment or near death.[18] An observation scale is a valuable tool for the assessment of respiratory distress. Many chronically ill patients with lung disease are aware of their distress, and despite this, they deny it even in the presence of clear signs of pulmonary stress.

Behavioral evaluation with the Respiratory Distress Observation Scale is essential in the absence of any form of a dyspnea report. Another advantage in the use of the Respiratory Distress Observation Scale is the evaluation of patients during weaning from mechanical ventilation; this can be optimized by using the Respiratory Distress Observation Scale to measure patient distress based on signs of dyspnea. The Respiratory Distress Observation Scale may also be useful in determining which patients may benefit from oxygen therapy at end of life. The oxygen administered can help relieve dyspnea. It is frequently administered routinely to patients near death, regardless of their ability to report an experience of respiratory distress and/or in the absence of behavior indicating breathing difficulties. However, oxygen administration is not without negative effects. Previous studies in advanced and terminal disease produced contradictory results, and it is not possible to predict with certainty which patients may benefit from this treatment.[6] No previous studies included patients near death or patients who were unable to provide a self-report. The Respiratory Distress Observation Scale cutoff points permit the establishing of respiratory distress treatment regimens; oxygen may not be indicated for a dying patient with a Respiratory Distress Observation Scale score of less than 3 (no distress), whereas a rapid response is required with a Respiratory Distress Observation Scale score of 7 or greater (severe distress).[18] Cutoff points represent an objective and uniform semantic meaning,[23] therefore easily understood by service providers and thereby improving communication between them and care planning.

There is a gap in knowledge about the treatment of patients near to death because their inability to self-report dyspnea had excluded them from clinical studies. Increased distress was found in patients closer to death[6]; thus, further investigations are needed in this vulnerable population. The Respiratory Distress Observation Scale is useful as a research tool to assess respiratory distress and to allow the inclusion in palliative care studies of patients with cognitive and near-death problems. As suggested by Dr Margaret L. Campbell,[18] it should be interesting to investigate whether the Respiratory Distress Observation Scale can reveal how respiratory distress varies as death approaches. In the study by Campbell et al,[6] a high percentage was found of patients with respiratory distress who were not given opioids or benzodiazepines. This result supports the thesis that respiratory distress could be undertreated in near-death patients unable to self-report dyspnea. This result further supports the need for the Respiratory Distress Observation Scale to guide the assessment and treatment of patients with cognitive impairments. Dying patients have distressing symptoms,[24] such as dyspnea, and therefore need treatment and nursing care in order to ensure adequate comfort.[25]

In accordance with the author,[6] we recommend the Respiratory Distress Observation Scale as a clinical tool for the assessment of respiratory distress when patients cannot provide a self-report.

The study conducted had some limitations. The Italian version of the Respiratory Distress Observation Scale was compared with the patients' self-reported dyspnea using the VAS-D. This is not an ideal comparison, because dyspnea and respiratory distress are not entirely congruent phenomena. Patients were asked to report their degree of dyspnea and not their respiratory distress. Further research is needed to assess the applicability of the Italian Respiratory Distress Observation Scale to patients for all diagnoses and in all treatment settings, such as acute and

critical care. An important aspect to investigate remains the responsiveness and sensitivity to change of the Respiratory Distress Observation Scale. The Respiratory Distress Observation Scale may be useful to ascertain whether end-of-life patients benefit from oxygen administration.

CONCLUSIONS AND IMPLICATIONS FOR NURSING RESEARCH

Our study enriches the literature available, with the psychometric properties of the Italian Respiratory Distress Observation Scale being close to those of the original and the other cross-cultural validated versions. Its feasibility, internal consistency, interrater reliability, and validity are adequate for clinical practice. The Italian version of the Respiratory Distress Observation Scale is available to health care professionals as a useful tool to assess respiratory distress in life-limiting disease patients. The validated Italian version of the Respiratory Distress Observation Scale can be used in a larger sample to determine respiratory distress in patients with advanced disease and in palliative care. The proposed Italian version of the Respiratory Distress Observation Scale is the only known tool for behavioral assessment of respiratory distress in the Italian language. The tool is useful in clinical application, as a guide to patients' evaluation, in nursing care, and in the research field, to assess respiratory distress and to allow the inclusion of patients nearest to death in palliative care studies.

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