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Identification of palliative care needs and prognostic factors of survival in tailoring appropriate interventions in advanced oncological, renal and pulmonary diseases: a prospective observational protocol

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ABSTRACT

Introduction It is estimated that of those who die in high-income countries, 69%–82% would benefit from palliative care with a high prevalence of advanced chronic conditions and limited life prognosis. A positive response to these challenges would consist of integrating the palliative approach into all healthcare settings, for patients with all types of advanced medical conditions, although poor clinician awareness and the difficulty of applying criteria to identify patients in need still pose significant barriers. The aim of this project is to investigate whether the combined use of the NECPAL CCOMS-ICO and Palliative Prognostic (PaP) Score tools offers valuable screening methods to identify patients suffering from advanced chronic disease with limited life prognosis and likely to need palliative care, such as cancer, chronic renal or chronic respiratory failure.

Methods and analysis This multicentre prospective observational study includes three patient populations: 100 patients with cancer, 50 patients with chronic renal failure and 50 patients with chronic pulmonary failure. All patients will be treated and monitored according to local clinical practice, with no additional procedures/patient visits compared with routine clinical practice. The following data will be collected for each patient: demographic variables, NECPAL CCOMS-ICO questionnaire, PaP Score evaluation, Palliative Performance Scale, Edmonton Symptom Assessment System, Eastern Cooperative Oncology Group Performance Status and data concerning the underlying disease, in order to verify the correlation of the two tools (PaP and NECPAL CCOMS-ICO) with patient status and statistical analysis.

Ethics and dissemination The study was approved by local ethics committees and written informed consent was obtained from the patient. Findings will be disseminated through typical academic routes including poster/paper presentations at national and international conferences and academic institutes, and through publication in peer-reviewed journals.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The strengths of this study include its large sample size, the multiplicity of medical conditions and care settings evaluated, and the combination of NECPAL and Palliative Prognostic Score tools, which to the best of our knowledge has never previously been assessed.
⇒ The study concerns a multiplicity of medical conditions (advanced cancer and advanced chronic renal and respiratory failure) and care settings, making its findings applicable to a broad range of patients.
⇒ While this is an observational study based on routine clinical practice, meaning that the specialists' decisions were not taken in palliative care situations, an assessment such as this may offer guidance as to when the involvement of palliative care services may be appropriate.

INTRODUCTION

Many countries face an increasing prevalence of chronic health conditions. It is estimated that 69%–82% of those who die in high-income countries could benefit from palliative care (PC), many of whom are affected by advanced chronic conditions with limited life prognosis.[1]

Several organisational and policy frameworks have been developed to respond to these challenges, proposing the integration of the palliative approach for patients with all

advanced medical conditions, in all settings.[2] The global benefits of integrating the PC approach for all patients in general healthcare are evident in terms of coverage, equity and universal access to PC, as basic principles of a comprehensive and integrated public health approach. There are many benefits for patients in gradually introducing an active palliative approach focused on quality of life (QoL), including a multidimensional assessment, a review of the status of underlying conditions and treatment options, and the starting of advance care planning and a case management process.[2–4]

One of the most significant barriers for integrated early PC is reduced clinician awareness, and the difficulty of applying criteria to identify patients in need. Two systematic reviews of tools for the identification of such patients are available[5 6] but the implementation of these tools is still uncommon. A number of tools have recently been developed for use in specific patient populations and settings: the NECPAL CCOMS-ICO (NECPAL) has been designed to identify patient PC needs, while the Palliative Prognostic (PaP) Score has been designed to identify poor life expectancy.

The NECPAL contains an element known as the 'surprise question' (SQ). Developed more than a decade ago, the SQ has been suggested as a simple test to identify patients who might benefit from a PC approach,[7] and involves a clinician reflecting on the question 'Would I be surprised if this patient died in the next 12 months?'. The SQ has been designed to correct for a physician's tendency to overestimate prognosis, by asking the physician to consider whether death in the coming year is possible rather than probable, and alone has shown variable accuracy as predictor of mortality in patients with advanced cancer and in other chronic, end-of-life conditions. For Kim *et al*,[8] the SQ and temporal question are similar, with a low to moderate accuracy. Both have a number of limitations, and prognostic models may help to increase their clinical predictions of survival. In the systematic review and meta-analyses by White *et al*,[9] the SQ had a pooled accuracy level of 74.8% (95% CI 68.6% to 80.5%) with a C-index of 0.735, ranging from 0.512 to 0.822 across the studies. These meta-analyses reported a sensitivity of 67.0% and a specificity of 80.2%, with a pooled accuracy of 74.8%. More recently, a review by van Lummel *et al*[10] assessed 88 268 SQs, showing an estimated sensitivity of 71.4% (95% CI 66.3% to 76.4%) and a specificity of 74.0% (95% CI 69.3% to 78.6%).

The NECPAL tool[2 11] combines the SQ with additional clinical parameters for a more comprehensive assessment, proposing a quantitative–qualitative, multifactorial, indicative evaluation and not a dichotomous one, combining a subjective perception assessment (SQ) with the subjective and objective needs of the patient. While the original NECPAL tool was designed principally to assess PC needs, more recent versions of the tool (NECPAL CCOMS-ICO V.3.1 2017[12]) have been designed to identify a 2-year mortality prediction. Turrillas *et al*[12] reported this version as accurate and potentially useful in clinical practice, identifying three different populations, with a median survival of 38, 17.2 and 3.6 months. Gómez-Batiste *et al*[13] subsequently sought to identify a prognostic approach for patients with advanced chronic conditions based on the PC need items: their study found several parameters with prognostic value, and added them to the tool to permit early identification of the PC needs of patients with advanced chronic conditions in all care settings.

The PaP Score was developed in the 1990s[14] as the result of a series of prospective trials aimed at identifying clinical and biological factors related to the prognosis of patients with advanced cancer referred to hospice, and collating them to create a prognostic index. Univariate analysis of 36 clinical factors showed that age, performance status, physician prediction of the individual absolute survival (measured in weeks), certain treatment characteristics (hospitalisation, progestin use, corticosteroid use and blood transfusions) and various symptoms (pain, anorexia, dry mouth, dysphagia, weight loss and breathlessness) were associated with survival. These findings were inserted in a multiple regression model to produce the PaP Score, and the resulting tool contained only four criteria: two symptoms (anorexia and dyspnoea); performance status measured by the Karnofsky performance score;[15] White Blood Cells (WBC) abnormalities (high total WBC count and lymphopenia) and the physician's survival prediction, measured in weeks. Validated cut-off points based on the total PaP Score were established to classify the patients into the three prognostic groups for survival at 30 days: group A (more than 70% probability of 1-month survival)—0–5.5 points; group B (30%–70% probability of 1-month survival)—6–11 points and group C (less than 30% probability of 1-month survival)—11.5–17.5 points. The PaP Score has been validated by different authors[16 17] and its prognostic value has been highlighted in several international reviews on prognostic tools in the cancer population.[18]

Hui *et al*[19] identified new areas of research in which new tools and/or new prognostic factors, or a combination of these, were suggested as possible candidates for improving prognostic capacity. Tripodoro *et al*[20] subsequently looked for new prognostic factors in end-of-life patients, finding only three survival predictors: low response to treatment ($p<0.001$), Palliative Performance Scale (PPS) ≤50 ($p<0.000$) and condition (inpatients/outpatients) ($p<0.000$).

The overall purpose of this project is to introduce a palliative approach early in the trajectory of chronic incurable illnesses as a global healthcare priority, using a person-centred approach.

We believe that the combined use of the NECPAL and PaP Score tools constitutes a potentially valuable screening method to identify patients with limited life prognosis and a probable need for PC, suffering from advanced chronic diseases such as cancer, renal failure or respiratory failure. We therefore wish to verify whether the combined use of these tools can help clinicians develop a comprehensive and person-centred 'palliative approach',

one which combines the early detection of PC needs with appropriate interventions in an integrated, population-based, community-oriented care model. This model should focus on appropriateness, and should include a multidimensional assessment, a review of the patient's diseases and treatments, the start of an advance care planning process and case management for integrated care across settings.

Current study objectives

Our primary aim is to determine whether the combination of NECPAL and PaP Score succeeds in identifying patients with PC needs and/or reduced life span, so as to analyse the appropriateness and timeliness of a progressive PC approach in patients with advanced metastatic non-small cell lung cancer, advanced gastric or pancreatic adenocarcinoma, advanced chronic respiratory failure caused by chronic obstructive pulmonary disease (COPD) or idiopathic pulmonary fibrosis (IPF) and advanced chronic renal failure. The measure for this primary aim is the percentage of positive NECPAL tools and distribution of PaP Score values, and the longitudinal repetition of both scores shows any modifications over time.

As secondary aims, the longitudinal repetition of the NECPAL and PaP Scores will also show the 'optimal' moment of their prognostic capacity during the trajectory of the different diseases, based on the scores recorded. Finally, use of a panel of tools would permit clinicians to identify any associations and/or correlations between the two major scores assessed and the other scores of the panel.

METHODS

Study design

This multicentre, prospective observational study was conducted on three patient populations: cancer, chronic pulmonary and renal disease. It began in January 2021 and will run until September 2023, unless extended by the Italian Ministry of Health.

Trial centres

The trial centres are:

- Palliative Care Unit, IRCCS Istituto Romagnolo per lo Studio dei Tumori 'Dino Amadori' (IRST), Meldola, FC, Italy.
- Respiratory and Critical Care Unit and Nephrology, Dialysis and Transplantation Unit, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Policlinico 'Sant'Orsola-Malpighi', Bologna, BO, Italy.
- Nephrology and Dialysis Unit, AUSL della Romagna, 'Morgagni-Pierantoni' Hospital, Forlì, FC, Italy.

Patient and public involvement

Patients were not involved in the design of the study protocol nor in the conduction of this research; they were enrolled in the study as patients as per inclusion criteria.

Participants and inclusion/exclusion criteria

A total of 200 patients will be enrolled: 100 patients with cancer, 50 patients with chronic pulmonary failure and 50 patients with chronic renal failure.

Inclusion criteria for all patients

- Both sexes.
- All ethnic backgrounds.
- Age ≥18 years.
- Subjects who, in the opinion of the investigator, are able to understand this study and who are able to cooperate with the study procedures.
- Written informed consent.
- Patients who are not receiving care from the PC service.

Specific inclusion criteria for cancer population

- Diagnosis of inoperable locally advanced and/or metastatic non-small cell lung cancer, gastric cancer or pancreatic adenocarcinoma within the previous 8 weeks, any T, any N, M+ or T4 inoperable (neoadjuvant excluded).
- Life expectancy >2 months.

Specific inclusion criteria for chronic pulmonary failure population

Diagnosis of COPD with at least two of the following characteristics: age >70 years, Forced Expiratory Volume in the first second (FEV1) <30% predicted, oxygen-therapy dependency, >1 admission/year in hospital for COPD-exacerbated congestive heart failure and/or other comorbidity, weight loss/cachexia, reduced functional autonomy, increased dependence or an IPF diagnosis with at least two of the following characteristics: age >70 years, Usual Interstitial Pneumonia (UIP) histology pattern (if known), dependence on oxygen-therapy, 'honeycomb lung' radiological appearance on High-resolution Computed Tomography (HRCT) of the thorax, reduced functional autonomy or increased dependence.

Specific inclusion criteria for chronic renal failure population

- Diagnosis of advanced chronic renal failure with at least two of the following characteristics: age >75 years, advanced malignancy, severe malnutrition, cardiac or pulmonary pathology, terminal or multiple organ failure in intensive care.
- Life expectancy >2 months.

Study outcomes and assessment methods

The patients are assessed at baseline, then monthly or every 2 months, for a maximum of 12 months. If possible, additional assessments will follow at the time of evidence of instability (increase or sudden change in problems or symptoms of the disease) and at change of care setting (eg, at the time of an unscheduled new hospitalisation) until the patient's death.

While not PC specialists, patient recruitment and assessment are to be carried out by physicians, who are part of the research team.

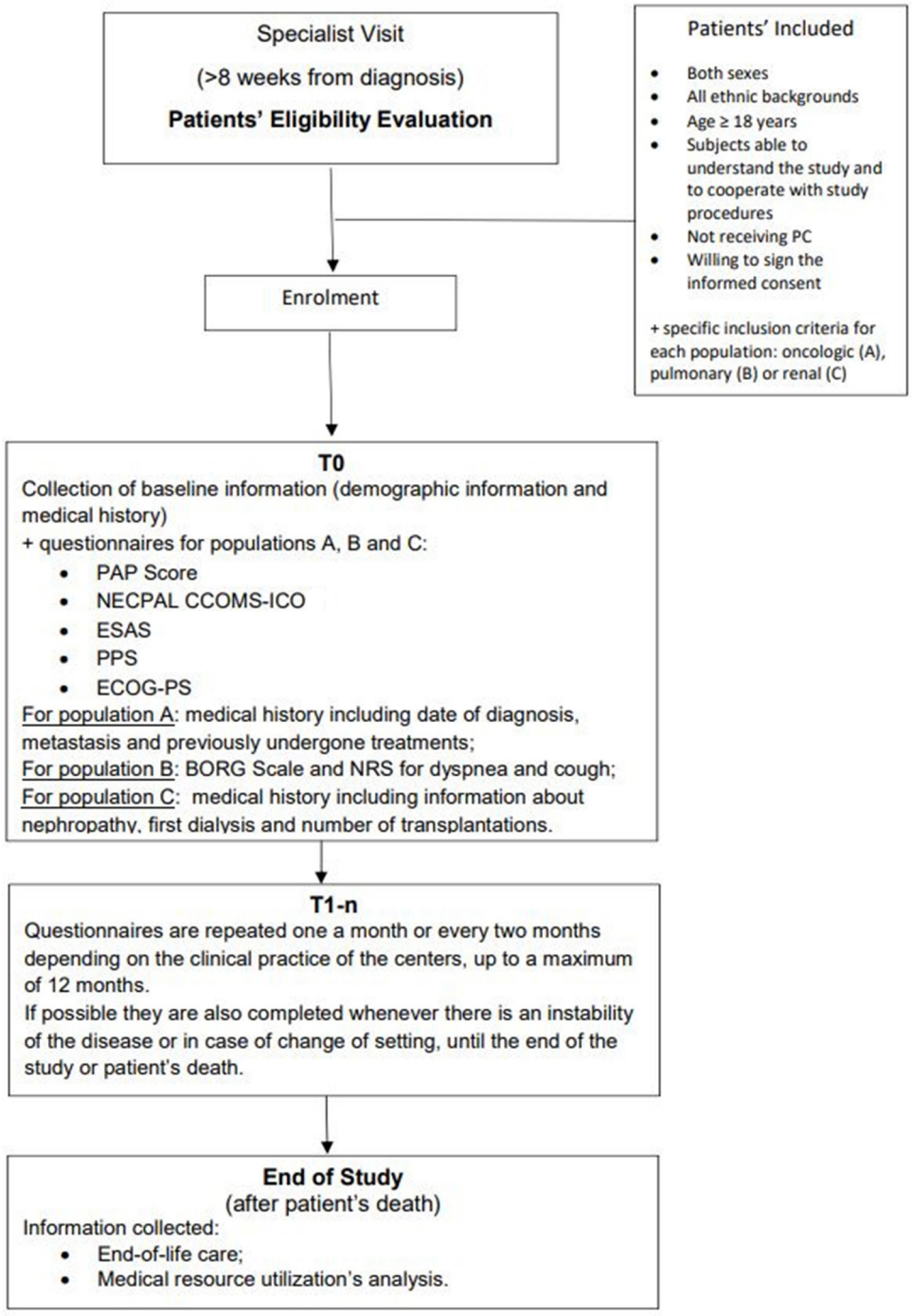

Figure 1 Study procedures. ECOG-PS, Eastern Cooperative Oncology Group-Performance Status; ESAS, Edmonton Symptom Assessment System; NRS, numeric rating scale; PaP, Palliative Prognostic; PC, palliative care; PPS, Palliative Performance Scale.

For all data to be collected, figure 1 and online supplemental table A1 show the assessment tools and the timing of the various assessments.

The following data will be evaluated:

- Demographic data (date of birth, sex and ethnic origin).
- PaP Score.[14]
- NECPAL CCOMS-ICO V.1.0.[18 19]
- Edmonton Symptom Assessment System (ESAS) Questionnaires.[21]
- PPS.[22]
- Eastern Cooperative Oncology Group (ECOG) Performance Status Scale.[23]
- Dyspnoea (using Borg scale[24]) and cough (using numeric rating scale from 0 to 10) for patients with pulmonary disease.
- Use of healthcare resources and death date and location.

The PaP Score, as previously described, is a prognostic tool, which includes six criteria to determine prognostic

survival: the Karnofsky Performance status;[15] clinical prediction of survival (in weeks); presence or absence of anorexia; presence or absence of dyspnoea, and WBC and lymphocyte percentage (laboratory values must be assessed ±7 days from PaP Score evaluation).

We are using version 1.0 of the NECPAL CCOMS-ICO, being the only version translated into Italian.

The ESAS is a questionnaire used to rate the intensity of nine common symptoms (pain, tiredness, nausea, depression, anxiety, drowsiness, appetite, well-being and shortness of breath) experienced by patients. At the time of assessment, the severity of each symptom is rated from 0 to 10 on a numerical scale, with 0 indicating the symptom is absent, and 10 indicating the worst possible severity.[21]

The PPS is a prognostic tool which measures the functional status of PC patients, and has been adopted and used in a variety of healthcare settings in different countries. Adapted from the Karnofsky Performance Scale[15] functional dimensions of ambulation and evidence of disease, the PPS adds self-care, oral intake and level of consciousness. The PPS is divided into 11 categories, with scoring performed from 0% to 100% in 10% increments. A PPS of 0% indicates absence of life, while a PPS of 100% indicates a patient who is mobile and healthy.[22] The ECOG Performance Status is a functional and prognostic tool created to measure how a disease impacts a patient's daily living abilities, known to physicians and researchers as a patient's performance status. It describes a patient's level of functioning in terms of daily activity, physical ability (walking, working and so on) and their ability to care for themselves,[23] using a 5-point score to assess performance status, and is considered a straightforward tool for daily clinical practice. All tools used are validated in Italian.

Use of healthcare services and end-of-life care will be assessed by a dedicated research nurse, and reported using a protocol-specific electronic case report form (eCRF) developed ad hoc. Hospice referral, inclusion in the local PC network, hospital admissions, emergency department visits, admissions to the intensive care unit and the date and location of death will be collected.

eCRFs will be created through use of a promoter-designated Electronic Data Capture (EDC) system, and sites will receive training and have access to a manual to aid in eCRF completion.

For the cancer population, additional information concerning the patient's medical history (date of diagnosis, metastases and treatments) will be collected from their electronic medical record.

For patients with pulmonary disease, dyspnoea and cough will be assessed (using the Borg scale[24] and a numeric rating scale from 0 to 10, respectively) at the same time as the other questionnaires.

For patients with kidney disease, details of the type of disease, the date they were taken into care due to advanced chronic renal failure, date of initial dialysis and number of previous transplants will be collected.

Additional data to be collected from the three populations are chemotherapy/immunotherapy treatments for patients with cancer, details of intubation with subsequent death or palliative extubation for the pulmonary population and details of severe haemodynamic instability which does not allow extracorporeal treatment for patients with renal.

Statistical analysis

All baseline data analyses will be presented with descriptive statistics: continuous variables as mean with SD, and categorical variables as frequency with percentages. To verify the correlation of the two tools (PaP and NECPAL) with patient status, we will assess both sensitivity and specificity, as well as positive and negative predictive values The binomial proportion CIs for these measures will be computed using a normal approximation, and the χ^2 test for equality of proportions will be used to compare mortality rates. The non-parametric survival curve estimation will be performed using the Kaplan-Meier method, and the log-rank test will be used to determine differences between survival curves. Finally, a semiparametric Cox proportional regression will be used to estimate risk of death.

Organisational issues

The study is being administered by the Unit of Biostatistics and Clinical Trials. This includes support for the preparation of all documents needed for EU submission of the study protocol for each participating centre, training of staff assigned to data collection, definition of monitoring procedures, development and administration of CRFs and monitoring of data quality. The results will be published in peer-reviewed journals, and authorship will be based on the Vancouver rules. All manuscripts will be prepared by the researchers, and the principal investigator will have access to all data. The access granted to researchers will be decided based on the actual need for access, and access to anonymised participant-level data sets will be granted based on journal policy.

Ethics and dissemination

Signed consent will be obtained from all participants by an investigator at each site, and the study is being carried out in accordance with ICH GCP and the World Medical Association Declaration of Helsinki (1964) and its subsequent revisions (Tokyo 1978, Venice 1983, Hong Kong 1989, South Africa 1996 and Edinburgh 2000). The study was approved by IRCCS Istituto Romagnolo per lo Studio dei Tumori (IRST) 'Dino Amadori' Medical Scientific Committee and then by both the Romagna Ethical Committee (CE-ROM) and the Central Emilia Wide Area Ethical Committee of the Emilia-Romagna Region (CE-AVEC). Informed consent will be obtained from patients in writing.

Findings will be disseminated through typical academic routes, including academic institutes, poster/paper

presentations at national and international conferences and publication in peer-reviewed journals.

DISCUSSION

The increasing prevalence of chronic illness conditions has prompted worldwide organisations to encourage an active and integrated palliative approach for patients with all types of advanced medical conditions, in all healthcare settings.[1 2] This approach consists of a number of different elements: effective symptom management; multidimensional assessment to improve QoL by boosting physical function; reviewing the status of underlying conditions and treatment options, and beginning advance care planning and a case management process.[2–4]

While the benefits of early integrated PC for patients are clear, there are still barriers to referrals, two of the most significant being reduced clinician awareness and the difficulty of applying criteria to identify patients in need.[2] Two systematic reviews of tools used to identify patients who potentially require an integrated PC approach are available.[5 6] Several additional tools have been developed, such as the NECPAL and the PaP Scores in specific patient populations or settings, but research shows that these tools are rarely used in clinical practice.[11 12 14 20] Analysing the appropriateness and timeliness of a progressive PC approach is the first step toward fulfilling the overall purpose of this project, which sees the introduction of a palliative, person-centred approach early in the trajectory of chronic incurable illnesses.

We believe that combined use of the NECPAL and PaP tools offers a valuable screening method to identify patients with advanced chronic disease such as cancer, chronic renal and respiratory failure who have a limited life prognosis and are most likely in need of PC. Identifying these patients will protect against medical overtreatment and needless diagnostic procedures, and will facilitate access to acute care facilities.

The strengths of this study include a large sample size, a multiplicity of evaluated medical conditions and care settings and the combination of NECPAL and the PaP Score tools, which to the best of our knowledge has never previously been assessed.

The limitations of this study lie in its observational nature, meaning that we report what happens in clinical practice. We hope that this study will encourage specialists to refer more patients to PC, and that these tools will prove educational for physicians, making them more aware of patient PC needs: indeed patients recruited for the study can be referred to PC during follow-up, should a specialist deem it necessary.

Another potential limitation of the study is our use of version 1.0 of the NECPAL CCOMS-ICO: the latest versions of the tool are the NECPAL CCOMS-ICO V.3.1 and NECPAL 4.0 PROGNOSTIC, however, these are not yet validated in Italian, requiring us to use version 1.0.

Our study is part of a nationally funded programme focusing on the recognition of and response to PC needs in patients suffering from various chronic illnesses, offering an excellent opportunity to raise nationwide awareness of the importance of PC integration in outpatient settings. Once finalised, the national programme will provide much improved guidance to the Italian Ministry of Health for the allocation of resources to implement and improve specialised PC services in acute hospitals.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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