Community acquired pneumonia in the elderly: the *P*neumonia in *I*talian *A*cute *C*are for *E*lderly units (PIACE) study protocol by the Italian Society of Hospital and Community Geriatrics (SIGOT)

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Abstract

Pneumonia is a frequent cause of hospital admission in elderly patients. Diagnosis of pneumonia in elderly persons with comorbidity may be challenging, due to atypical presentation and complex clinical scenarios. Community-acquired pneumonia (CAP) arises out-of-hospital in subjects without previous contact with the healthcare system. *Healthcare associated pneumonia* (HCAP) occurs in patients who have frequent contacts with the healthcare system and should be treated with empiric broad spectrum antibiotic therapy also covering multi-drug resistant (MDR) pathogens. Recent findings, however, have questioned this approach, because the worse prognosis of HCAP compared to CAP may better reflect increased level of comorbidity and frailty (poor functional status, older age) of HCAP patients, as well as poorer quality of hospital care provided to such patients, rather than pneumonia etiology by MDR pathogens. The *P*neumonia in *I*talian *A*cute *C*are for *E*lderly units (PIACE) Study, promoted by the *Società Italiana di Geriatria Ospedale e Territorio* (SIGOT), is an observational prospective cohort study of patients consecutively admitted because of pneumonia to hospital acute care units of Geriatrics throughout Italy. Detailed information regarding clinical presentation, diagnosis, etiology, comprehensive geriatric assessment, antibiotic therapy, possible complications and comorbidities was recorded to identify factors potentially predicting in-hospital mortality (primary endpoint), 3-month mortality, length of hospital stay, post-discharge rate of institutionalization and other secondary endpoints. This paper describes the rationale and method of PIACE Study and reviews the main evidence on pneumonia in the elderly.

Introduction

Pneumonia is a major health problem among elderly persons.[1,2] The rate of pneumonia is increased in the elderly compared to younger populations[1,2] and the short-term prognosis of older persons after a pneumonia episode may be poor,[3] mainly because of comorbid diseases which contribute to death.[1,2] Thus, timely identification and appropriate treatment of pneumonia in elderly persons are crucial clinical issues.[1,2]

There are 3 types of pneumonia.[4-7] Community-acquired pneumonia (CAP) is the typical form of pneumonia arising out-of-hospital in subjects without previous contact with the healthcare system.[1,2] Hospital acquired pneumonia (HAP) is defined as pneumonia occurring 48 hours or more after hospital admission.[4] Healthcare associated pneumonia (HCAP) is contracted outside the hospital, but it occurs in high-risk patients having frequent contacts with the healthcare system.[5-7] In the original formulation proposed by the American Thoracic Society (ATS)/Infectious Diseases Society of America (IDSA) in 2005,[5] HCAP can be diagnosed in the presence of at least 1 of the following conditions: i) hospitalization for 2 or more days in the 90 days before the onset of pneumonia; ii) intravenous antibiotic therapy, chemotherapy, or wound care in the last 30 days; iii) residence in a nursing home or long-term care facility; iv) having attended (past 30 days) a hospital or hemodialysis clinic. The HCAP categorization is an attempt to identify more severe pneumonias caused by multi-drug resistant (MDR) pathogens and deserving more aggressive empiric antibiotic therapy.[8] Accordingly, the ATS/IDSA guidelines suggest treating HCAP with broad-spectrum antibiotics taking into account MDR pathogens,[5] such as extended spectrum β-lactamase (ESBL)-producing or carbapenem-resistant *Enterobacteriaceae*, *Pseudomonas aeruginosa* and *methicillin-resistant Staphylococcus aureus (MRSA)*. Indeed, most studies reported a higher rate of MDR pathogens and poorer outcomes in HCAP compared with CAP.[6-10]

It has been argued, however, that up to 75% of HCAP episodes (as calculated in the cohort of patients with etiological microbiological diagnosis) may not be caused by MDR pathogens[9-11] and that the use of guideline-concordant empiric therapy for MDR bacteria may not improve prognosis of HCAP,[12] leading to an overestimation of real risk and antibiotic resistance. Also, outcome of pneumonias (CAP and HCAP) is strongly affected by host and process factors, including older age,[13] failure of initial therapy,[9,13] comorbidity,[1,2,13] impaired mobility,[11] nursing home residency,[13] as well as by the severity of pneumonia[8-10,13] and the susceptibility to and adequate management of pneumonia-related complications (mainly acute respiratory failure and sepsis).[1] Consequently, even though older and frail patients frequently correspond to the ATS/IDSA definition of HCAP, it is plausible that the involvement of MDR pathogens or the presence of HCAP criteria do not entirely account for the increased incidence and severity of pneumonia in the elderly.[2] For instance, the value of comprehensive geriatric assessment (CGA) in predicting prognosis of pneumonia in the elderly compared with both disease-specific severity scores and HCAP criteria is an interesting applicative topic deserving further investigation.[14] Eventually, there are no studies that have investigated the microbiological pattern, clinical presentation and outcomes of patients admitted to acute care geriatric hospital wards for CAP/HCAP in the real world. Additionally, the approach of hospital geriatricians to this frequent disease also deserves to be investigated.

In order to address these and other issues, the Italian Society of Hospital and Community Geriatrics (*Società Italiana di Geriatria Ospedale e Territorio*; SIGOT) promoted and organized the *P*neumonia in *I*talian *A*cute *C*are for *E*lderly units (PIACE) Study. In the

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present paper, we describe the research framework, methodology and main aims of PIACE Study in the context of the revised recent evidence about pneumonia of older patients.

Materials and Methods

The PIACE Study design and study subjects

The PIACE Study is an observational prospective cohort study of patients consecutively admitted because of HCAP or CAP to hospital acute care units of Geriatrics throughout Italy. The study protocol was examined and approved by the Institutional Ethical Committee of the study-coordinating center (Unit of Geriatrics, Annunziata Hospital, Azienda Ospedaliera di Cosenza, Cosenza, Italy). The approved protocol was transmitted to all participating centers; the Institutional Ethical Committee of each center could ask for clarifications of the protocol. The PIACE Study group involved 22 acute care geriatric units in 12 Italian regions. Participating study units had to enroll a minimum of 12 consecutive patients, but they were allowed to exceed the minimum number of 12 patients by continuing the enrollment up to 12 months from the enrollment of the first patient. The first patient was recruited in February 2013.

Pneumonia was diagnosed as follows:[5,15] a new pulmonary infiltrate diagnosed by chest radiograph or thoracic computed tomography (CT) associated with ≥2 of the following criteria: i) new or increased cough; ii) new or increased sputum production; iii) fever (≥38°C); iv) new-onset or worsening dyspnea; v) either leukocytosis (>10,000/mm^3) or leukopenia (<4000/mm^3); vi) physical findings on chest examination compatible with pneumonia according to clinicians' judgment (rales or bronchial breath sounds).

HCAP was defined as follows:[8] i) hospitalization for 2 or more days in the last 90 days (before the onset of pneumonia); ii) intravenous therapy (including antibiotics and chemotherapy) or hemodialysis in the last 30 days; iii) residence in a nursing home or long-term care facility. In the absence of at least one of these criteria, a diagnosis of CAP was made. In the case of hospitalization in the previous 90 days, study physician had to report the main diagnosis of that hospitalization.

Patients' data were recorded in both a paper-based, written case report form (CRF) and a web-based electronic CRF (e-CRF), which reported the same data. The e-CRFs generated an electronic database.

Aims of the study

The PIACE study aimed to investigate etiology, clinical presentation, complications and outcomes of patients affected by CAP or HCAP and hospitalized in geriatric acute care wards in Italy. Participants underwent an accurate CGA for determining the role of *frailty* on outcomes in older patients presenting for pneumonia. Also, the role of antibiotic therapy in affecting prognosis represented another important goal of the study. The endpoints of the study are listed below: i) primary endpoint: in-hospital mortality; ii) secondary endpoints: length of hospital stay (number of days from the date of admission to the date of discharge or death), length of antibiotic therapy, functional status at discharge, rate of institutionalization after discharge, and 3-month mortality.

Collected data

The CRF (and the eCRF) included data belonging to 8 categories: i) baseline diseases and other baseline (before admission) patient's characteristics; ii) clinical presentation, laboratory values and imaging features at admission; iii) acute complications of pneumonia and concomitant acute illnesses; iv) bacteriological and etiological investigations; v) assessment of illness severity; vi) antibiotic therapy; vii) CGA; viii) follow-up and outcomes.

Baseline diseases and other baseline patient's characteristics

Data regarding the anamnestic presence of underlying chronic diseases were collected (Table 1). As shown in Table 1, the CRF includes the main important diseases, but researchers could add other diagnoses. In the eCRF, researchers were also asked to indicate the ICD9-CM (International Classification of Diseases, Ninth Revision, Clinical Modification) code for each disease. In the eCRF, each disease was associated with a categorical variable, which had 3 levels describing the diagnosis: i) main diagnosis; ii) present diagnosis, with current pharmacological treatment; iii) present diagnosis, currently monitored without treatment. A series of other possible pre-admission patient's characteristics (Table 1), including previous long-term home O_2 therapy, proton pump inhibitors therapy, flu vaccination and recent (last 30 days) antibiotic therapy, was also included in the CRF.

Clinical presentation, laboratory values and imaging

A series of clinical symptoms/signs and common laboratory measures, as observed or measured at hospital admission, was considered and reported in the CRF (Table 2). If available, the list also included an admission measurement of oxygen-hemoglobin saturation (SO_2) on room air from an arterial blood gas (ABG) sample, or non-invasively obtained through a finger pulse oximeter, for determining the severity of respiratory compromise due to pneumonia. In any case, an ABG analysis needed to be performed at admission in all patients, and the researchers were asked to specify whether the arterial sample was obtained on room air or during O_2 therapy.

The CRF required information concerning the radiological features of the pulmonary infiltrate/s (location, extension, presence of pleural effusion or cavitation), the imaging

Table 1. Baseline diseases and other important clinical features.

Baseline comorbid conditions
Renal failure
Chronic obstructive pulmonary disease (specify if clinical or spirometric diagnosis)
Type 2 diabetes mellitus
Dementia
Heart failure
Atrial fibrillation
Previous ischemic stroke or cerebral hemorrhage
Coronary artery disease
Obesity
Cancer (specify the type of cancer)
Blood disease (specify the disease)
Interstitial lung disease (specify the disease)
Other relevant baseline diseases (specify)
Chronic liver disease or cirrhosis (specify etiology)
Immunosuppressive therapy (specify the drug and the disease for which it is used)
Leukopenia (specify last WBC count before pneumonia)
Alcoholism
Other baseline clinical features
Nasogastric tube for enteral nutrition
Therapy with H2-inhibitors or proton pump inhibitors
Recent surgery (last 30 days)
Flu vaccination
Therapy with inhaled bronchodilators (specify the class of drugs)
Long term oxygen therapy (specify how many hours per day)
Presence of intravascular access devices, including cardiac pace-makers (specify the type of device and the date of placement)
Recent orotracheal intubation (last 30 days)
Presence of tracheostomy (specify the date of placement)
Antibiotic therapy in the last 30 days (specify the class of antibiotics)
Periodontitis
Other conditions

WBC, white blood cells.

tool that was used [chest X ray, computed tomography (CT) or both, other tools], the date of the first imaging demonstration, whether or not a complete or partial resolution of the infiltrate was demonstrated and the date of such complete or partial resolution.

Complications of pneumonia and concomitant acute illnesses

A list of 4 medical acute complications that may be observed during the hospital stay (acute coronary syndrome or myocardial infarction; stroke or transitory ischemic attack; deep vein thrombosis and/or pulmonary embolism; acute heart failure) were reported in the CRF. The researcher, however, could add up to 6 ICD9-CM diagnoses of other acute diseases observed during the hospital stay (for instance sepsis and acute respiratory failure). As described above, a 3-level categorical variable [i) main diagnosis; ii) present diagnosis, with current pharmacological treatment; iii) present diagnosis, currently monitored without treatment] was associated with each ICD9-CM diagnosis. Thus, because pneumonia may not be the main acute disease addressed during the hospital stay, researchers had to report the level 1 (main diagnosis) if they believed that one of these illnesses was the main disease managed during the hospital stay in the study ward, with pneumonia being only a component of a complex clinical scenario. In the same section, the researcher had to report whether or not the patient was treated with non-invasive mechanical ventilation during the hospital stay.

Table 2. Clinical presentation and laboratory or clinical values at admission.

Clinical presentation
Dyspnea
Tachypnea
Fever (>38°C)
Leukocytosis
Leukopenia
Cough
Sputum production
Thoracic pain
Altered state of consciousness
Acute mental confusion
Acute renal dysfunction
Cyanosis
Increased C-reactive protein
Increased erythrocyte sedimentation rate
Hemoptysis
Laboratory and clinical values at admission
Blood pressure
Heart rate
Body temperature
Respiratory rate
Blood urea nitrogen
Serum creatinine
Hemoglobin, hematocrit, platelet, white blood cells, neutrophils (%)
Total bilirubin
Albumin
Sodium, potassium
Fasting blood glucose
C-reactive protein, fibrinogen
Troponin I, NT-pro BNP, D-dimer (if measured)
AST, ALT
pO_2 , pCO_2, HCO_2, pH, osmolality (from arterial blood gas analysis)
SO_2
Body mass index (if measured)

NT-pro BNP, N-terminal pro-hormone of brain natriuretic peptide; AST, aspartate transaminase; ALT, alanine transaminase; pO_2, partial pressure of oxygen; pCO_2, carbon dioxide partial pressure; SO^2, oxygen-hemoglobin saturation, measured on room air (if available) by arterial blood gas analysis or non-invasively by pulse oximetry.

Bacteriological and etiological investigations

Data regarding the etiological investigations performed during the hospital stay were reported in the CRF, including microscopic examination and culture of blood, sputum, pleural fluid, bronchoalveolar lavage (BAL) fluid and tracheobronchial aspirate, serology (immunoglobulin G and M) for *Mycoplasma pneumoniae* and *Chlamydophila pneumoniae* and urinary antigens for *Streptococcus pneumoniae* and *Legionella pneumophila*. In the case of negative blood culture, it was requested to indicate whether or not blood samples were drawn while the patient was undergoing antibiotic therapy and to report the class of antibiotics. Also, the researcher could describe in the CRF any other additional investigation performed to determine the etiology of pneumonia and a copy of any positive microbiological report had to be uploaded in the e-CRF. The etiology of pneumonia was considered definite if 1 of the following result was obtained:[8,10] positive blood culture in the absence of any apparent extra-pulmonary infection; positive bacterial culture of pleural fluid; positive urinary antigen for *L. pneumophila* or *S. pneumoniae*; a bacterial yield in cultures of valid sputum (>25 polymorphonuclear cells and <10 epithelial cells per power field) of ≥ 10^6 CFU (colony forming units)/mL; tracheobronchial aspirates of ≥10^5 CFU/mL; BAL fluid of ≥10^4 CFU/mL; protected specimen brush cultures of ≥10^3 CFU/mL; occurrence of seroconversion [a 4-fold rise in immunoglobulin G (IgG) titers for *C. pneumoniae* (1:512) or a rise in immunoglobulin M (IgM) titers for *C. pneumoniae* (1:32) and *M. pneumonia* (any titer)]. When at least 2 of these etiological criteria were found, a polymicrobial infection was diagnosed; patients for whom no etiological investigation was performed, or those with negative results, were considered to have pneumonia of unknown etiology.

Assessment of illness severity

The severity of clinical conditions was assessed by the *sequential organ failure assessment* (SOFA) score, which also includes a measurement of respiratory impairment [partial pressure of oxygen/fraction of inspired oxygen ($pO_2/FiO)_2$ ratio].[16] The severity of pneumonia was measured by the pneumonia severity index (PSI).[17] The PSI divides patients into 5 classes of disease severity according to a series of variables, including age, sex, the presence of coexisting diseases, vital sign alterations, and laboratory and radiographic abnormalities.

Antibiotic therapy

The dates on which, respectively, the first and the last dose was administered, the resulting duration of therapy (in days), the mean daily dose, the reason for therapy interruption (completion of therapy, side effect or refusal, death) for each specified antibiotic that was administered during the hospital stay were reported in the CRF.

Comprehensive geriatric assessment

Comprehensive geriatric assessment was carried out within the first 2 days of hospital stay by the multidimensional prognostic index (MPI), a well-validated instrument for predicting mortality in hospitalized elderly.[18] MPI results from the score of 7 tools exploring 7 different domains, as follows: functional status was studied by the activities of daily living (ADL),[19] measuring the ability in the basic activities of daily living (bathing, toileting, feeding, dressing, continence and transferring from bed), and by the instrumental activities of daily living (IADL),[20] which assesses the ability in more cognitively and physically demanding instrumental tasks (managing finances, taking medications, using telephone, shopping, using transportation, preparing meals, doing housework and washing); cognitive status was investigated by the 10-item short portable mental status questionnaire (SPMSQ);[21] comorbidity by the cumulative illness rating scale (CIRS),[22] measuring the severity of illness in 13 systems; nutritional status by the short form of the mini nutritional assessment (SF-MNA);[23] the risk of developing pressure sores by the exton-smith scale (ESS);[24] eventually, we considered: the number of drugs taken by the patient within the first 2 days of hospitalization; and co-habitation status, *i.e.*, living with family, institutionalized or living alone. The

results of these scales were included in a software (www.mpiage.eu) for the calculation of the final MPI score, ranging from 0 to 1. MPI categorized patients as having low (MPI value ≤0.33), moderate (between 0.34 and 0.66), and severe risk (>0.66) of mortality in the follow-up.[18] In order to study the effect of pneumonia on the functional trajectory around hospitalization, ADL was also measured at hospital discharge (or the day before) and a third ADL value referring to about 2 weeks before admission was retrospectively measured at admission by asking patients (or their care-givers) about patient's functional status as it was 2 weeks before admission, *i.e.*, prior to the onset of the acute illness.

Follow-up and outcomes

The date of discharge from the study ward and the type of discharge [in-hospital death; discharge to home, discharge with home-based program of care, discharge to long-term care facility, rehabilitation facility or nursing home; transferred to another acute care unit or to intensive care unit (ICU)] were reported in the CRF. When a patient died in the study ward or was moved to another hospital unit or ICU, the main disease accounting, respectively, for in-hospital death or transfer was reported in the CRF. After at least 3 months from the discharge, vital status was assessed during an outpatient visit or by contacting patients or their relatives *via* telephone. For patients who died during the follow-up, if the cause of death could be reliably identified, it was reported in the CRF. For patients who were discharged alive from the study ward, the CRF also requested to report the list of medications, with daily doses, prescribed by discharging hospital physicians for post-hospital treatment.

Statistical analysis and sample size

Considering that former studies showed a mortality rate of about 10% among hospitalized older patients with pneumonia,[3] we planned to enroll 330 patients in order to achieve 0.80 statistical power with α=0.05 for identifying a 10% mortality rate. Comparison between groups will be carried out using chi-square test for categorical variables and t-test of Mann-Whitney for continuous ones, as appropriate. The association between study variables and primary/secondary endpoints will be investigated by using Kaplan-Meier curves and Cox multivariate regression models or logistic regression analysis when appropriate.

Discussion

Community-acquired pneumonia is a leading cause of morbidity and mortality in older patients.[1,2] We can identify 3 main important challenges that hospital clinicians may be called to face while managing older patients with suspected pneumonia contracted outside the hospital (CAP or HCAP): i) early diagnosis and timing of first antibiotic administration; ii) choice of empiric therapy according to the probability of underlying MDR pathogens; iii) choice of empiric therapy according to pneumonia severity and the baseline characteristics of patients.

It was found that a reduced time between patient's presentation and the first antibiotic administration may be associated with decreased in-hospital mortality.[25,26] A shorter time to first antibiotic dose, however, may not have a direct causative effect on survival, being only a proxy of overall better standard of care (less crowding of the emergency services, prompt identification and treatment of pneumonia-related complications), which, in turn, may be the true responsible for the improved outcomes.[25,26] In addition, a delayed administrations of antibiotics may be frequent in elderly patients with comorbidity and atypical presentation (for instance altered mental status), which usually have worse outcomes irrespective of quality of care and pneumonia severity.[26] Thus, the actual, obvious recommendation is to start antibiotic therapy as soon as pneumonia is diagnosed. This sends back to the difficulty in diagnosing pneumonia in elderly patients with comorbid diseases and complex clinical scenarios, due to atypical clinical presentation, low sensitivity of chest radiograph for detecting pulmonary infiltrates, poor correlation between radiological evolution of pulmonary infiltrates and actual clinical conditions.[1,25-27] For instance, it is not always easy to ascertain that a pulmonary infiltrate is new or changed so that it can be unequivocally attributed to a recent-onset pneumonia, rather than to a previous pulmonary infection, congestive heart failure, pulmonary fibrosis or other lung diseases.[25,27]

The second issue is the identification of patients who may have MDR pathogens as pneumonia etiology. Current guidelines recommend to treat hospitalized patients with either a respiratory fluoroquinolone alone or with a combination of a third-generation cephalosporin plus a macrolide.[5,15,25] When patients exhibit risk factors for the presence of MDR pathogens, however, it was suggested to treat patients with an empiric scheme usually dedicated to patients with HAP, including dual coverage for *P. aeruginosa* (an antipseudomonal β-lactam such as cefepime, ceftazidime or piperacillin/tazobactam, or an antipseudomonal carbapenem, *plus* either a fluoroquinolone or an aminoglycoside), *plus* vancomycin or linezolid if MRSA is suspected.[5,25] Since studies of patients with positive cultures have proved that HCAP is characterized by a higher prevalence of MDR pathogens and worse outcomes than CAP, criteria for HCAP may indeed contribute to identify patients with increased risk for MDR pathogens who should receive this broad-spectrum therapy.[6-10] However, there is increasing recognition that the value of HCAP criteria in identifying pneumonias caused by MDR pathogens is limited, given that many HCAP patients do not have MDR pathogens, with the result of overtreatment without improving outcomes if a broad-spectrum therapy is indiscriminately offered to all HCAP patients.[11,12,25] Thus, recent studies have tried to develop new scoring systems to help recognizing pneumonias due to MDR pathogens and the subsequent indication for broad-spectrum empiric therapy.[8,10,28,29] While confirming the predictive role of most HCAP criteria (prior hospitalizations, residence in long-term care facilities, hemodialysis, recent antibiotic use), these studies have proved the value of some typically *geriatric* features, such as poor functional status, comorbidity, and impaired renal function in identifying patients with MDR pathogens.[8,10,28,29] In older pneumonia populations, a more extensive geriatric assessment, such as that performed in the PIACE study, may help determining the predictive role of other unexplored yet important factors, such as poor nutrition and cognition.[1,14] At the moment, however, the criteria for determining the initial empiric antibiotic therapy in patients with pneumonia are controversial and the choice is left to clinicians' judgment and evaluation of the possible conditions promoting MDR infections.[25]

The third issue is the choice of empiric antibiotic therapy and overall hospital management according to baseline clinical characteristics and to pneumonia severity. In a single-center experience of patients affected by bacteremic pneumonia with the same etiology (Streptococcus pneumonia), patients with the HCAP criteria displayed lower survival than CAP counterparts.[30] In the absence of any role for bacterial etiology, the excess mortality of HCAP patients was attributed to their older age, higher comorbidity burden and lower rate of ICU treatment despite more severe pneumonia at admission.[30] In general, patients with the 2005 HCAP criteria often correspond to frail and older patients with increased number of comorbid diseases and poorer functional status.[9,11,29] These features, together with more severe presentation of pneumonia,[10,11] may determine outcome much more than the etiology of pneumonia.[1,2,10,11,30] Thus, in geriatric patients clinical attention should focus not only on selecting initial antibiotic therapy, but also on trying to improve the quality of hospital care, which should include a CGA-based treatment plan, appropriate management of comorbidities and prompt recognition and treatment of complications, especially sepsis and acute respiratory failure.[1,2,14,25]

Conclusions

Pneumonia in the elderly is a major health problem whose management is still burdened with a number of controversies regarding diagnosis, empiric antibiotic therapy and outcomes, in part due to the evolving and complex patients' clinical features. It is hoped that the *geriatric point of view* of PIACE study may shed some new light on this disorder.

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