Clinical Audit on Diagnostic Accuracy and Management of Respiratory Failure in COPD

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BACKGROUND: The aim of the study was to evaluate the adequacy of diagnosis and management of respiratory failure (RF) in COPD. METHODS: Retrospective analysis of the hospital discharge forms of COPD patients hospitalized for RF from January 2007 to June 2008. Using the clinical audit tool, the primary end point was the accuracy of RF diagnosis. The secondary end points were mortality, re-hospitalization rate, length of hospital stay, accuracy of long-term oxygen therapy (LTOT) prescription, and agreement of the treatments with the Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2008 guidelines. Statistical analysis used Pearson and Spearman correlation test and the Cohen kappa for degree of agreement. Differences in demographics and clinical parameters were analyzed with the chi-square test, *t* test, or the Fisher test, as appropriate. RESULTS: We studied 130 patients , 81 males (62%), mean ± SD age 76.6 ± 9.1 years. Arterial blood gas analysis (ABG) was performed in 118 patients (90.8%), and in 77 (81%) a P_{aO_2} < 60 mm Hg was found at admission. Of these, 42 cases (54.5%) had no diagnosis of RF, despite a P_{aO_2} < 60 mm Hg. In 18 (19%) P_{aO_2} was ≥ 60 mm Hg; of these, 6 cases (33.3%) received an incorrect RF diagnosis. At discharge 8.1% of patients did not receive a diagnosis of RF, despite a compatible ABG. The highest mortality was found in the medicine departments (14.7%). The re-hospitalization rate at 90 days was 19.5%. Adherence of the treatment to the GOLD guidelines during hospitalization was confirmed in 75.8% of patients. In 41.1% of cases LTOT was prescribed at discharge; in 24 out of 27 cases P_{aO_2} values were < 55 mm Hg. CONCLUSIONS: Agreement between diagnosis of RF and ABG values was found to be insufficient in about half the cases. Among secondary end points, adherence of the treatment to guidelines and LTOT prescription were, however, found to be good. Data showed significant inaccuracies in the management of RF at our institution. *Key words: audit; respiratory failure; COPD; long-term oxygen therapy.* [Respir Care 2012;57(12):2067–2073. © 2012 Daedalus Enterprises]

Introduction

Management of respiratory failure (RF) from COPD is complex and requires strict application of the international guidelines, without ignoring the overall condition of the patient, who often shows multiple comorbidities. Clinical

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audit is a process used by healthcare professionals to carry out a regular and systematic review of clinical practice, comparing actual with well defined standard criteria, and modifying these as required.[1] It therefore becomes possible to measure the quality of healthcare and to identify the areas with scope for improvement with periodic feedback.

Very few studies have been published in the field, given the complexity of the subject. Two important clinical audits coordinated by the British Thoracic Society were published in 2001 and 2006,[2,3] after the release of the British guidelines on management of COPD.[4] The aim was to evaluate adherence to the above-mentioned guidelines in the United Kingdom hospitals and to identify differences, if any, between pulmonology and internal medicine departments. The results showed the best performances for patients followed by pulmonologists.[3] Another audit published by Stone et al in 2009,[5] which followed up the first study of 2003,[3] showed significant improvements of several indicators, such as average hospitalization, mortality, and re-hospitalization rate.

The primary aim of the study was to evaluate the accuracy in the diagnosis of acute or chronic RF in relation to international recommendations, and to make a comparison among the different departments involved. In this context, arterial blood gas analysis (ABG) is essential to have a correct diagnosis of RF. As secondary aims, the following indicators were evaluated: in-hospital mortality and rate of re-hospitalization, average hospital stay, accuracy in the prescription of long-term oxygen therapy (LTOT) at discharge, and accuracy of pharmacologic treatment during hospitalization, using the Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2008 guidelines[6] as standard.

QUICK LOOK

Current knowledge

Management of respiratory failure following an exacerbation of COPD is complex and requires strict application of the international guidelines. Accurate diagnosis and categorization are essential in implementing quality improvement measures based on clinical audits.

What this paper contributes to our knowledge

There are consistent discrepancies in the current hospital management of acute respiratory failure and the proposed international guidelines. These discrepancies include the accurate diagnosis of respiratory failure and the prescription for long-term oxygen therapy. Accurate recording is essential for tracking process and outcome indicators.

Methods

We planned a retrospective clinical audit to evaluate the adherence to the application of diagnostic-therapeutic protocols for RF in COPD in a large hospital. We took into account the departments in our hospital to which these patients are generally referred (ie, the pulmonology, 2 internal medicine, and infectious diseases departments). A retrospective analysis was carried out of hospitalization of patients with COPD and RF throughout the global process of care, from diagnosis to treatment and outcome evaluation.

The process indicators and outcomes were identified, to be compared with the reference standards, some obtained from literature, others defined at a local level, as of expert consensus. Some standards not found in the literature will have to be validated by means of continuous monitoring for a longer period. A set of quality indicators (see the supplementary materials at http://www.rcjournal.com) was identified to satisfy these objectives.

Study Population

The reference population was identified among patients hospitalized at the Arcispedale Santa Maria Nuova in Reggio Emilia, Italy, during the period from January 2007 to June 2008 with diagnosis of RF resulting from COPD. The cases were selected from the database of the hospital discharge forms, with the following International Classification of Diseases IX-CM codes: 491.21 obstructive chronic bronchitis with exacerbation, associated with 518.81 acute respiratory failure and 518.84 acute and chronic respiratory failure. The population included new diagnoses as well as known cases of RF. Patients without historical spirometric data obtained within the previous 12 months and consistent with COPD (ie, $FEV_1/FVC < 0.7$) were excluded. Spirometry records were checked for quality performance in accordance with guidelines, and severity staging was classified according to the GOLD criteria.

Data Collection and Statistical Analysis

A random sample was studied, reflecting the proportion of cases in each department. The formula for population sampling survey was used, placing it in the worst hypothesis, namely, that the expected frequency of the factor under study is 50% (software used, Epi Info, Centers for Disease Control and Prevention, Atlanta, Georgia). According to the sample size calculation, 130 cases were needed.

An electronic case record form was created containing all the information needed for measuring the prefixed indicators (see the supplementary materials at http://www.rcjournal.com). The case record form includes the

personal data of the patient, the International Classification of Diseases code, the admission and discharge department(s), the diagnosis at admission, comorbidities, treatment during hospitalization and at the time of discharge, ABG and spirometric data, oxygen therapy, and noninvasive ventilation (NIV). This chart was constructed using statistics software (SPSS, SPSS, Chicago, Illinois), which made it possible to enter data via the Internet.

The diagnosis at admission was defined as the medical diagnosis on the front page of the clinical record, to be considered as the reason for hospitalizing the patient. This diagnosis is usually recorded by the emergency department doctor. The principal diagnosis at discharge is also indicated on the front page of the clinical record and represents the main disorder accounting for the clinical activities and resource consumption during the hospitalization.

The data were analyzed with statistics software (SPSS 18.0, SPSS, Chicago, Illinois). The significance level was set at .05. The variables in the chart are of the nominal, ordinal, and quantitative types, and the results are therefore expressed as absolute terms, percentages, and mean ± standard deviation, as appropriate. Bivariate tables are reported to evaluate the correlation between the most significant diagnostic and clinical parameters.

Statistical analysis used Pearson and Spearman correlation test and the Cohen kappa for degree of agreement. Differences in demographics and clinical parameters were analyzed with the chi-square test, *t* test, or Fisher test, as appropriate.

Ethics of Investigation

This study was conducted in accordance with the ethical standards of the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. The study was approved by the local institutional review board.

Results

During the period of study, the total number of cases of hospitalization with the above-mentioned discharge codes was 374, treated mainly (approximately 83%) in the pulmonology, 2 internal medicine, and infectious disease departments.

A random sample of 130 hospitalization cases were selected, distributed by department as follows: 70 records (55%) came from pulmonology, 18 (13%) from infectious diseases, and the remaining 42 (32%) from the 2 internal medicine departments. Among patients hospitalized in the infectious diseases department, 43.8% were transferred to and then discharged from the pulmonology unit. Patients transferred from an internal medicine department to pulmonology accounted for a 14.6% of the cases reviewed.

Table 1. Baseline Characteristics

Male	81(62.0)
Female	49 (38.0)
Smoker	27 (20.8)
Non-smoker	9 (6.9)
Former smoker	47 (36.2)
Data not available	47 (36.2)
Age, mean ± SD y	76.6 ± 9.1
Post-bronchodilator FEV_1, mean ± SD % predicted (range)	43 ± 18.4 (17–78)
Post-bronchodilator FEV_1/FVC, mean ± SD % predicted (range)	40.7 ± 9.2 (29–61)

Values are number and percent unless otherwise indicated.

Table 2. Respiratory Failure Diagnosis at Admission and at Discharge

	Respiratory Failure at Discharge		Total
	Yes	No	
Respiratory failure at admission			
Yes	48	10	58
No	72	0	72
Total	120	10	130

The random case series of 130 patients showed a mean age of 76.6 ± 9.1 years (range 49–98 y), with a prevalence of males (62%). Twenty-seven patients were smokers (21.4%), and 47 ex-smokers (37.3%). It must be noted that in 34% of the cases, data regarding smoking habits were not present in the record (Table 1).

The mean ± SD value of post-bronchodilator FEV_1 was 43 ± 18.4% of predicted (range 17–78%), while the mean ± SD value of FEV_1/FVC absolute percentage was 40.7 ± 9.2% (range 29–61%) (see Table 1). Given spirometry data, the severity classification according to GOLD was 23% stage 2, 32% stage 3, and 45% stage 4.

Diagnosis at Admission and at Discharge

In 72 cases (55.3%) RF was diagnosed at discharge but was not identified at admission; in 10 patients (7.7%) only at admission and not confirmed at discharge; and in 48 (37%) it was present both at the time of admission and at discharge (Table 2). From these data there seems to be little agreement between the 2 moments of diagnosis (kappa = −0.15, 95% CI −0.15 to −0.08).

Arterial Blood Gas Analysis Parameters

Of the 130 cases of hospitalization analyzed, an ABG was performed in 118 (90.8%). Patients on LTOT at the

Table 3. Agreement Between Admission P_{aO_2} and Respiratory Failure Diagnosis at Admission

	Respiratory Failure at Admission		Total
	Yes	No	
P_{aO_2} at admission, mm Hg			
< 60	35	42	77
≥ 60	6	12	18
Total	41	54	95

Table 4. LTOT Prescriptions*

	n/N
Prescribed LTOT	44/107
Performed at least 1 ABG	40/44
ABG on room air	27/40
$P_{aO_2} < 55$ mm Hg	24/27 (88.9%)

* Excludes 23 patients already on long-term oxygen therapy (LTOT).
ABG = arterial blood gas analysis

time of admission and for whom the diagnosis of RF was therefore already known (23) were excluded from the analysis (Table 3):

- Seventy-seven (81%) had ABG on admission with $P_{aO_2} < 60$ mm Hg. Of these, in 42 cases (54.5%) there was no diagnosis of RF, although the ABG indicated this condition.
- Eighteen (19%) had a $P_{aO_2} \geq 60$ mm Hg. Of these, in 6 cases (33.3%) RF had been diagnosed incorrectly.
- According to the above data there is a poor agreement between ABG and RF diagnosis at admission (kappa = 0.07, 95% CI −0.09 to 0.19).
- For patients with $P_{aO_2} < 60$ mm Hg and a diagnosis of RF at admission to hospital (35/77 = 45.5%), the care regimen was adjusted in the appropriate setting (pulmonology or non-respiratory departments), according to the severity of RF. The proper treatment included therapy for exacerbation of COPD, oxygen therapy, and possibly NIV.
- ABG at discharge was repeated in 61.8% of the cases (73/118). Among patients with $P_{aO_2} < 60$ mm Hg at discharge, in 34/37 (91.9%) the diagnosis of RF was confirmed, while 3 (8.1%) were cases of inappropriate diagnosis.

New Prescriptions for LTOT

After exclusion of patients already on LTOT at admission, LTOT was prescribed in 44 patients (41.1%), in 90.9% of these cases the prescription being correctly supported by ABG data. In this subgroup, the ABG was carried out on room air in 27 patients (67.5%), 24 (88.9%) of whom showing a $P_{aO_2} < 55$ mm Hg (Table 4).

Patients With Hypercapnic Respiratory Failure

Of the 78 cases with $P_{aCO_2} > 45$ mm Hg (67.8% of all cases with ABG data, mean value of 69.7 ± 15.15 mm Hg, range 48–121 mm Hg), 19 (24.4%) received NIV during hospitalization, 10 of them in the pulmonology department. Two patients were discharged with a prescription for NIV at home.

Analyzing only the non-ventilated patients, the mean values of P_{aCO_2} and pH were 60 ± 12.2 mm Hg (range 45.4–121 mm Hg) and 7.35 ± 0.007 (range 7.21–7.48), respectively. Regarding patients undergoing NIV, the mean values of P_{aCO_2} and pH were 66.48 ± 17.7 mm Hg (range 54.6–127 mm Hg) and 7.22 ± 0.016 (range 7.07–7.37), respectively. Differences of P_{aCO_2} and pH values between ventilated and non-ventilated patients appeared to be statistically significant, with *P* values of .04 and .02, respectively.

Comorbidities and Duration of Hospitalization

Of the 130 cases examined, 118 (90.8%) showed at least one comorbidity. The main disorders were cardiovascular in 104 cases (88%), followed by neurological diseases in 32 cases (27.1%), and diabetes mellitus in 24 cases (20.3%).

The overall average hospitalization period of the global series was 13.5 ± 10.6 days, range 1–97 days. In detail, mean hospitalization was 10.8 days (range 1–20 d) in the infectious disease department, 15.9 days (range 5–97 d) in the internal medicine departments, and 12.5 days (range 1–47 d) in the pulmonology department, respectively. There were no significant differences of average stay among the 3 departments ($P = .24$).

The global mortality of our series was 10.9% (13 patients), distributed as follows: 11% (1 patient) in infectious diseases, 14.7% (5) in internal medicine, and 8.3% (7) in pulmonology, respectively. These differences are not statistically significant, for the low number of cases.

In order to determine the causes of the higher mortality rates in the medicine departments, we evaluated comorbidities, ABG values, and mean age, using univariate analysis. A greater presence of concomitant diseases and a statistically higher mean age was observed in the medicine departments, as compared to the pulmonology group. In detail, the mean age was 79.7 years in internal medicine, 81.5 years in infectious diseases, and 74.8 years in pulmonology ($P = .006$). A greater prevalence of concomi-

tant disorders observed in the medicine departments did not appear to be statistically significant ($P = .27$). A comparison of ABG parameters did not reveal significant differences, but the number of observations was considered inadequate for a correct statistical analysis. Twenty-five patients (19.5%) had to be re-hospitalized at least one time within 90 days.

Treatment

An analysis of the treatments carried out during hospitalization demonstrated that for 86 patients (75.8%) there was a substantial agreement with the GOLD 2008 guidelines. In detail, regarding drugs prescribed during hospitalization, systemic steroids were administered in 79.5% of patients (101), inhaled corticosteroids in 68.5% (87), β_2 agonists in 85.8% (109), antibiotics in 86.6% (110), anticholinergics in 64.6% (82), and other classes in 50.4% (64).

Discussion

RF is a condition in which the respiratory system fails in one or both of its gas exchange functions: oxygenation and CO_2 elimination. In clinical practice, it may be classified as either hypoxemic or hypercapnic.[7] Hypoxemic RF is characterized by a P_{aO_2} lower than 60 mm Hg with a normal or low arterial P_{aCO_2}. In hypercapnic RF P_{aCO_2} is higher than 45 mm Hg.

RF may be also classified as either acute or chronic. Although acute RF is characterized by life-threatening alterations in arterial blood gases and acid-base status, the clinical manifestations of chronic RF are less dramatic and may not be as readily apparent.[7]

Our audit was planned to evaluate the accuracy of diagnosis and management of patients suffering from COPD with acute or acute on chronic RF, and to take advantage of results to improve hospital management. The data showed differences in the standards of care among the departments analyzed (in particular concerning the duration of the hospitalization), but with a global substantial agreement with the GOLD 2008 guidelines.[6]

In Italy, in the last few years, considerable effort has been put into defining institutional programs for the management of RF in pulmonology departments, with the identification of quality indicators to conform to the Requisiti Specifici per l'Accreditamento Delle Strutture di Pneumologia.[8]

The general evaluation of medical records showed a relative lack of attention to smoking history: even lower than that found by other authors[9] Therefore, the audit has called attention to this point of weakness that must be improved.

For the purpose of our study, we accepted for diagnosis good quality spirometries performed in the previous 12 months, since airways obstruction in COPD is nonreversible by definition.

Analysis of the data shows that ABG to support the diagnosis of RF was performed in 90.7%. Unfortunately, there was a high discrepancy between the diagnosis of RF and the ABG data, since a diagnosis of RF was made also in patients with $P_{aO_2} \geq 60$ mm Hg, but, most importantly, 42 out of 77 cases with $P_{aO_2} \leq 60$ mm Hg did not receive a diagnosis of RF at admission. Analysis of the records did not allow an exact evaluation of the causes.

Diagnosis of RF at the time of hospitalization was done correctly in less than half the patients (45.5%); to the best of our knowledge, there are no data in the literature for comparison. Such a degree of misdiagnosis may have important consequences in the correct identification and local organization of clinical pathways. As a matter of fact, an incorrect evaluation performed in the emergency department may cause delays in the referral of the patient to the most appropriate treatment setting (eg, intensive care or respiratory intensive-care unit). The clinical audit tool was adopted to improve management of RF according to international standards and to allow an optimization in the use of healthcare resources.

LTOT was prescribed in 41.1% of the hospitalized patients: a figure higher than that in a study on a large scale[3] reporting a prescription of LTOT in 18% of the patients discharged; however, this study did not consider only patients with RF.

The prescription was supported by the performance of ABG in 90.9% of the cases. Of these, almost 90% of the cases considered had a P_{aO_2} value < 55 mm Hg in a clinical stability phase (ie, consistent with the American Thoracic Society/European Respiratory Society guidelines.[10] LTOT prescription in patients with P_{aO_2} of 55–60 mm Hg was allowed in the case of right heart failure or polycythemia.

There are few studies evaluating the accuracy of LTOT,[11–16] which showed that only a small percentage of the prescriptions were appropriate. Interestingly, a prospective re-audit by Dodd et al pointed out a distinct improvement of the performances in LTOT prescription occurring before and after the introduction of a prescription chart[13] (77% accuracy, against 7% identified in the first audit). Another audit, performed in New Zealand in 2006, showed how 75% of the prescriptions for oxygen treatment at home did not fulfill the guideline recommendation.[16]

An explanation for cases without further ABG for confirmation could be the choice of performing noninvasive monitoring of the oxyhemoglobin saturation in normocapnic patients; another possible interpretation could be related to clinical improvement of the patient, making additional ABG unnecessary. Finally, data on repeated ABG or oxygen flow were not always included, because they were unavailable in most records, for lack of a standard moni-

toring protocol and frequent noninvasive monitoring with pulse oximetry. In any case, failure to perform ABG at the time of discharge and at a later stage with the patient in a clinically stable condition is a drawback that must be corrected in order to avoid the possibility of diagnostic and prescription inaccuracies.

The satisfactory results highlighted by our study are probably the consequence of an organizational innovation made by our hospital in 2007, since an expert pulmonologist was appointed to check and certify the appropriateness of the LTOT prescriptions.

Among patients with ventilatory failure, those undergoing NIV had levels of hypercapnia and acidosis significantly worse than those not receiving NIV. Larger-scale studies show that 35% of patients with hypercapnia and acidosis at the first ABG did not receive additional ABGs, and only 13% had been ventilated.[3]

The overall data concerning re-hospitalization within 90 days (19.5%), appear to be acceptable, as compared to the international literature, but findings need to be reproduced in a larger series. The audit carried out by Price et al in the United Kingdom[3] showed a rate of 34%, which is much higher than that shown by our study, but it must be noted that the average hospitalization in the United Kingdom is much shorter than in Italy, and this might explain in part the higher rate of re-hospitalization.[16]

The highest percent mortality was registered in the medicine departments (14.7% of the cases), but the comparison with the other departments was not statistically significant, due to the low number of cases. These patients were, on average, older than those hospitalized in pulmonology, and also suffering from comorbidities in a higher percentage: cardiovascular disorders in particular.

For reasons related to the small sample size, we collected and reported only the categories of comorbid illness, and not the individual disorders. Probably a better discrimination of diseases would have resulted in a more accurate correlation with mean hospital stay and mortality rates for each department.

In infectious diseases, with an even higher mean age as compared to internal medicine, the mortality percentage was intermediate between that of medicine and pulmonology; the lower mortality could partly be explained by the fact that a large number of patients (over 43.8%) hospitalized in this department were transferred to pulmonology, where the indicators evaluated in this study, namely stay and mortality, denote a better quality of care.

Average hospitalization was found to be higher in internal medicine, followed by pulmonology, with stays (especially in the first case) longer than those in the literature (8 and 11 d on average in the United Kingdom and Italy, respectively).[17–19] Again, older age and comorbidities probably had an important role.

The analysis of the adherence of current in-hospital treatments for COPD exacerbations to the GOLD guidelines showed quite a good agreement (75.8%), but leaving large space for improvement.

Limitations of our study were mainly the fact that diagnostic data were not always present in medical records (eg, smoking history) and the limited sample size, making a comparison among departments unreliable.

Conclusions

In conclusion, from this retrospective audit a consistent discrepancy emerges between current and international standards in the hospital management of RF, with important differences among various departments. The small number of subjects did not allow more detailed inferential analyses, to better understand causal factors. Following the audit cycle, a prospective phase will be planned for continuous monitoring of improvement actions (accuracy of RF diagnosis and prescription of LTOT, and adherence of treatments to the guidelines) by means of appropriate process and outcome indicators.

For this purpose, healthcare programs within hospitals must be implemented in such a way as to apply uniformly recognized diagnostic criteria for RF, beginning from the emergency department as the starting point of clinical pathways, in order to assure patients with RF a suitable setting for best clinical results.

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