

BACKGROUND

- Chronic hypoxemia is a worsening condition that implies huge economic resources either for the therapy of stable disease at home either for the treatment of acute exacerbations in hospital setting.
- In Italy, there is no data on the prevalence and incidence of this condition nor a National Register on long-term oxygen therapy (LTOT). It has been estimated that 50.000-60.000 patients received LTOT with a global burden for the National Health System amounting to about € 250.000.000 per year [1,2].
- Worldwide, several hundred of thousands of patients receive LTOT, following the recommendation of international documents (Fig. 1) based on two landmark clinical trials (NOTT and MRC studies) published more than 25 years ago. LTOT when used for more than 15 hours/day has been shown to improve the survival in Chronic Obstructive Pulmonary Disease (COPD) patients with severe resting hypoxemia [4-9].

Figure 1 - Current guidelines for Long Term Oxygen Therapy in COPD

HYPOXEMIA	ATS-ERS ERJ 2004 [3]	GOLD AJRCCM 2007 [4]	NCCC-NICE Thorax 2004 [5]	Thoracic Society of Australia and New Zealand MJA 2005 [6]	AIPO Rass. Pat. App. Resp. 2004 [7]
Severe	PaO ₂ <55 mmHg or SpO ₂ <88%	PaO ₂ <55 mmHg or SpO ₂ <88%	PaO ₂ <55 mmHg	PaO ₂ <55 mmHg	PaO ₂ <55 mmHg
Moderate	PaO ₂ of 55 to 59 mmHg or SpO ₂ of 89% and at least one of the following criteria: Cor pulmonale, peripheral edema, hematocrit >55%	PaO ₂ of 55 to 59 mmHg or SpO ₂ of 89% and at least one of the following criteria: pulmonary hypertension, peripheral edema, hematocrit >55%	PaO ₂ of 55 to 59 mmHg or SpO ₂ of 89% and at least one of the following criteria: pulmonary hypertension, peripheral edema, secondary polycythemia, nocturnal desaturation >30% of sleep	PaO ₂ of 56 mmHg to 59 and there is evidence of hypoxic organ damage (right heart failure, pulmonary hypertension, peripheral edema, secondary polycythemia)	PaO ₂ of 55 mmHg to 60 and at least one of the following criteria: hematocrit >55%, signs of pulmonary hypertension, peripheral edema, signs of hypoxia (peripheral edema of right heart failure, mental decline) ischemic heart failure
None	PaO ₂ ≥60 mmHg or SpO ₂ >90% with severe nocturnal desaturation and lung-related dyspnea responsive to oxygen	No recommendation	No recommendation	Nocturnal oxygen may be indicate: desaturation (SpO ₂ <88%) >30% of sleep or in presence of hypoxia-related sequelae.	Intermittent oxygen may be indicate: desaturation (SpO ₂ <90%) >30% of sleep or in presence of exercise-related desaturation.

▲ This recommendation are not evidence based

RESULTS

From 1st October 2010 to 16th July 2014:

- 6925 patients were enrolled
- 6305 patients have been included in the data analysis
- 620 patients were not included for missing data

The patients' characteristics and the results about LTOT prescription are represented in the figures 3-9.

Figure 3 – Characteristics of patients at the start

	N. of pats	Mean	95% CI	SD	Median (min-max)
Sex M/F: 59/41%	6305				
Smoking: Yes: 8,1%, No:46 %,Ex:45,9%	6305				
Age, yrs	6305	75.35	75.09-75.61	10.52	77 (17-103)
Heart Rate (bpm)	3584	82.7	82.3-83.1	11.9	80 (50-140)
Respiratory Rate (cpm)	3512	18.5	18.34-18.63	4.3	18 (10-40)
PAP (mmHg)	788	46.6	45.35-47.8	17.3	45 (10-140)
Haematocrit (%)	1810	43.2	42.9-43.5	6.21	44 (25-64)
Charlson Index un-adjusted	6286	2.05	1.99-2.10	2.03	1 (0-16)
Charlson Index adjusted	6286	5.10	5.04-5.15	2.34	5 (0-20)
Exacerbations in the previous year	3488	1.39	1.34-1.44	1.34	1 (0-15)
Hospitalization in the previous year	3513	0.76	0.74-0.79	0.89	1 (0-11)

Figure 4 – N. of patients and rate of inclusion in the Register per year from the start (1/10/2010)

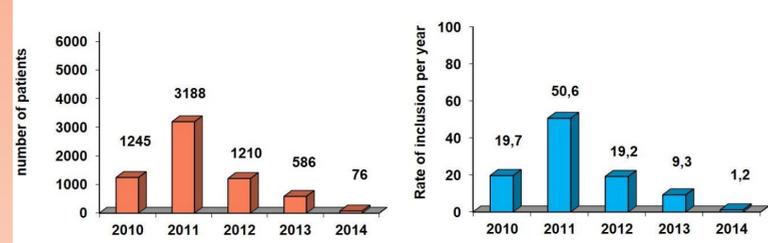


Figure 5 – Oxygen prescription

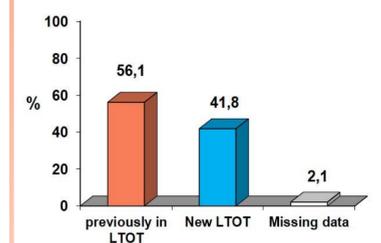


Figure 6 – Rate of inclusion in the Register per year in LTOT previously and new LTOT prescription

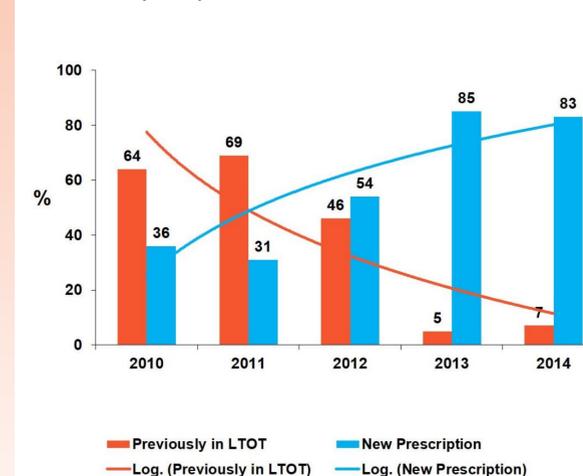


Figure 7 – Underlying disease: COPD (7A) and NO COPD (7B)

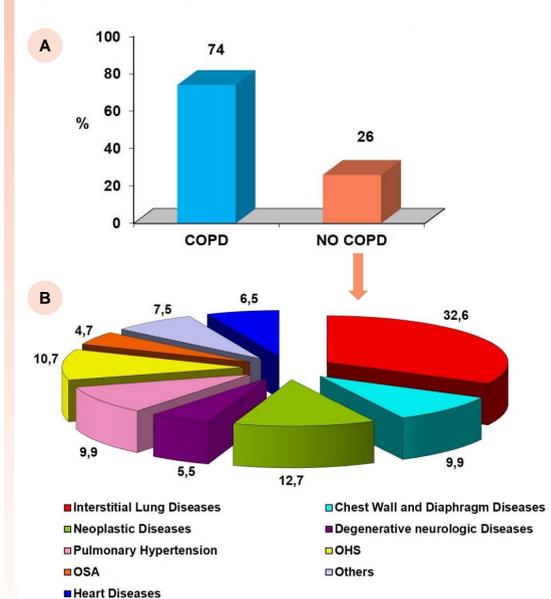


Figure 8 – Hypoxemia

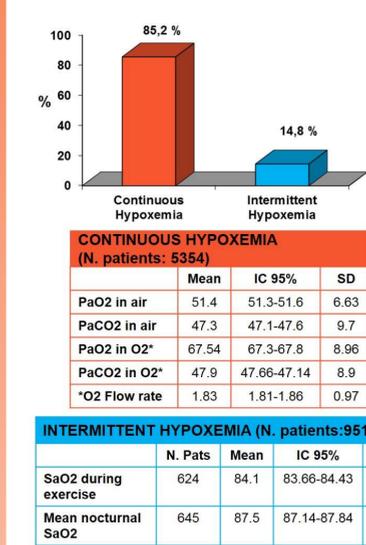
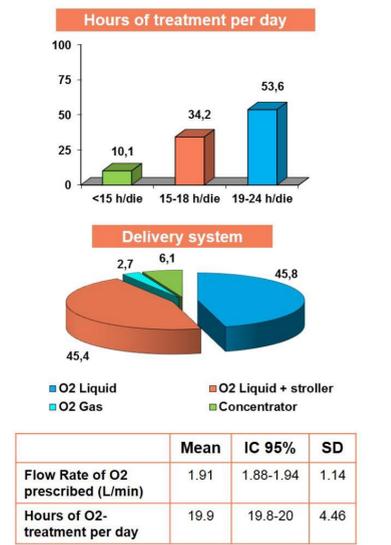


Figure 9 – LTOT prescription



OUTCOMES of patients with continuous hypoxemia:

- Oxygen was withdrawn in 63/5389 patients for improvement (correction of hypoxemia) after a median of 6 months (range 1-33)
- 173/5389 (3.2%) patients died after a median of 6 months (range 1-39) from the inclusion in the Register
- Years of oxygen treatment before the inclusion in the Register in patients who died:
 - median 0 (range 0-15)
 - mean 1.68 ± 2.59

CONCLUSION

- The data show that Italian clinicians prescribe LTOT mainly in COPD patients (74%)
- Oxygen therapy was prescribed in 85,2% of patients with severe chronic hypoxemia and in 14,8% of patients with intermittent Hypoxemia, even-though this last point is controversial according to different national and international guidelines
- Oxygen was prescribed in 87,8% of patients for more than 15 hours/day
- The majority of patients (91,2%) received liquid oxygen while the utilization of the concentrator, even though less expensive, pertained only 6,1% of patients.
- The oxygen prescription is almost in agreement to current guidelines.

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OBJECTIVES

The aims of the present study were to:

- collect epidemiological data on chronic stable and intermittent hypoxemia
- investigate the standards of LTOT prescription in Italy
- build up an electronic system as potential National Register of LTOT

METHODS

Study Protocol: observational, cross-sectional, non-interventional multicenter study promoted by AIPO-Associazione Italiana Pneumologi Ospedalieri.

From October 2010 to July 2014, 116 Italian Centers included patients in the Register (Fig. 2).

Data were collected through a central web-based system (e-CRF- electronic Case Report Form).

The protocol was approved by the local ethics committees of all the participating centers.

Inclusion criteria:

- Patients with chronic stable or intermittent hypoxemia
- Written informed consent to participate in the study



Figure 2 – Centers distribution