
Non-Interventional Study Report

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Epidemiological study to describe NSCLC clinical management patterns in MENA. Lung-EPICLIN/ Gulf

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LIST OF ABBREVIATIONS

Abbreviation or special term	Explanation
AE	Adverse event
AZ	AstraZeneca
CT-scan	Computerized Tomography Scan
EWB	Emotional well-being
FACT-L	Functional Assessment of Cancer Therapy - Lung
FNAB	Fine Needle Aspiration Biopsy
FWB	Functional well-being
ICF	Informed Consent Form
MENA region	Middle East North Africa region
NSCLC	Non-Small Cell Lung Cancer
PWB	Physical Well-Being
PET	Positron Emission Tomography
PRO	Patient Reported Outcomes
PS	Performance Status
QoL	Quality of Life
RECIST	Response Evaluation Criteria in Solid Tumours
SCLC	Small Cell Lung Cancer
SWB	Social Well-Being

STUDY REPORT SUMMARY (ABSTRACT)

Epidemiological study to describe NSCLC clinical management patterns in MENA. Lung-EPICLIN/ Gulf

Study Design

This is a multinational, multicentre, non-interventional, prospective cohort study that was carried out in a representative selection of hospitals in order to assess lung cancer management in countries throughout MENA region.

Number of patients, sites and Countries (planned) in the study

A total of 25 patients, from three sites; 1 from each country (UAE, Bahrain, Qatar).

Background

Lung cancer is one of the leading causes of death worldwide. Of the 7.3 million deaths caused by cancer every year, 17% are due to Lung Cancer. Histopathologically confirmed lung cancer is essential for optimal management of the individual patient and must be secured before chemotherapy and radiotherapy are initiated. Furthermore, resources available for obtaining correct diagnosis and TNM classification are likely to differ among centres, exemplified by the lack of resources for PET examination in many sites throughout MENA region. The lack of good, updated, organized and accessible local epidemiological data, clinical management data and knowledge of how to use healthcare resources in view of the many different treatment regimens available, all leads to an underestimation of the actual burden of lung cancer and associated unmet medical needs, with consequences for payers and health decision makers, at the national and the MENA region level, as well as for patients and society. There are only a few current studies on how patients are managed in real life practice. In view of this it would be very useful for physicians to be informed of treatment strategies used around MENA region and also to have information on the impact of these treatment options on overall costs and patient outcomes, in order to determine the best management pattern for each type of patient.

Rationale

The EPICLIN study is designed to provide information on the clinical effectiveness of existing products, on health care resources that are associated with existing therapy and on patients' quality of life. This study is the first study to look at the treatment regimens of all lines of treatment across several MENA (Middle East North Africa) countries to identify patterns of care that may be similar or different across the region, to make comparisons among treatments and countries and help to determine effective and cost-effective treatments in the real practice. The EPICLIN study will provide accurate and reliable scientific information on NSCLC clinical management across MENA region, in order to detect unmet medical needs connected to this disease.

Overall Aim for this Non-Interventional Study (NIS):

To provide accurate, reliable information on NSCLC clinical management across MENA (Middle East North Africa) countries in order to detect unmet medical needs of this disease in terms of:

- Patient characteristics.
- Diagnostic and treatment approaches: initial and subsequent.
- Follow-up patterns in clinical management.
- Outcomes: symptoms, death, functionality, quality of life.
- Use of resources and burden on patients and health care systems.

Methodology

The inclusion period lasted from the 1st February 2012 till 30th February 2015. All patients attending the responsible department of treating this type of patients for the first time during this period should be included in the study.

For inclusion in the study, patients must meet all of the following criteria:

1. Confirmed NSCLC diagnosis (e.g. bronchoscope or FNAB), all stages, men and women, attending the responsible department of treating this type of patients for the first time between February 1st, 2012 and February 30th, 2015.
2. For PRO sub-sample: ability to read and write since they will be asked to participate in the PRO part of the study. Selection will not be based on the disease stage of each patient, in order to avoid a selection bias.
3. 18 years of age or more.

Information regarding patients and disease characteristics as well as clinical management approach (diagnostic methods, treatments and follow-up patterns) and final outcomes will be taken from the medical record at each evaluation visit. These visits will be performed according to normal clinical practice.

Functional status and Quality of Life (QoL) questionnaires will be collected directly from the patients when obtaining informed consent.

Statistical Analysis

A descriptive analysis approach will be used to analyse NSCLC population, clinical management, clinical outcomes and use of health care resources.

Statistical analysis Objectives

Descriptive objectives: Regarding the patient and the disease, clinical management of the disease.

Analytical Objectives: To assess the differences in patient characteristics, disease stage (differentiating between non-advanced disease, locally advanced disease, metastatic disease), and in clinical management across MENA countries. To detect differences in clinical outcomes and related factors among countries. To identify factors associated with clinical outcomes (patient, disease stage –see above- and clinical management related factors): predictive modelling for improved patient outcome.

Results

The majority of the patients in our sample had locally advanced or disseminated disease at diagnosis (72% stage IV). The most common histology and primary tumor location for NSCLC patients in our sample was adenocarcinoma and the upper right lobe respectively. The most common symptoms at first visits of NSCLC patients were coughing, dyspnoea and weight loss.

X-ray and CT-Scanners were used mostly as imaging techniques for NSCLC patients. The most common type of therapy used was chemotherapy, and specifically first line chemotherapy. At all visits, nearly half of the sample required 1 day hospital admission for chemotherapy administration. Moreover, among patients under chemotherapy, very few reported any sort of adverse event or severe adverse event.

NSCLC patients that are males, older age and ex-smokers are inversely associated with using RECIST criteria for judgement purposes. Having a histology of adenocarcinoma bronchioloalveolar is significantly associated with RECIST criteria in the positive direction. Patients with adenocarcinoma bronchioloalveolar are more likely going to have RECIST criteria for evaluation purposes than patients with squamous cell carcinoma (OR: 16).

Males and ex-smokers have greater odds of clinical criteria as the type of judgement. Patients with a histology of Adenocarcinoma are 7 times more likely to have a clinical criteria judgement then patients with squamous cell carcinoma. Patients with PS2 are less likely going to have clinical criteria as the type of judgement to make a clinical evaluation (when compared to PS0).