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## Original research article

# Prospective evaluation of anxiety, depression and quality of life in medically inoperable early stage non-small cell lung cancer patients treated with stereotactic ablative radiotherapy



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## ABSTRACT

**Aim:** The aim of this prospective study was to evaluate the level of anxiety, depression, and quality of life (QoL) in medically inoperable patients with early stage non-small cell lung cancer (NSCLC) treated with stereotactic ablative radiotherapy (SABR).

**Background:** Prolonged survival is equally important as maintaining high QoL and good psychological functioning during the treatment of lung cancer. Nowadays available SABR has markedly changed clinical care and outcomes in the group of medically inoperable patients. To our knowledge, analysis of QoL and psychological state has not been performed in Polish patients with early NSCLC treated with SABR.

**Materials and methods:** Research group consisted of medically inoperable, early NSCLC (T1-2aN0M0) patients qualified to SABR. Patients were asked to complete Polish versions of the European Organization for Research and Treatment of Cancer Quality of Life – Core Questionnaire (EORTC QLQ-C30) with the Lung Cancer Questionnaire (LC13) and Hospital Anxiety and Depression Scale (HAD). These questionnaires were repeated 2 weeks and then 3 months after treatment completion.

**Results:** We enrolled 51 patients who met the inclusion criteria. SABR did not deteriorate QoL and psychological functioning. On the contrary, clinically meaningful improvement was observed in emotional functioning, level of insomnia, anxiety and depression. Significantly worse improvement was shown in patients with chronic obstructive pulmonary disease (COPD).

**Conclusions:** Our results confirm that SABR is well tolerated and does not have a deleterious effect on QoL and psychological state. Results of our study indicate the importance of additional psychological care in the group of patients with COPD.

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## 1. Background

Lung cancer is considered to be a lifestyle disease, unfortunately with extremely poor prognosis. Radical surgical treatment has been regarded the first choice treatment in early stage of non-small cell lung cancer (NSCLC) for many years. In fact, lobectomy with lymphadenectomy has been the only potentially curable method.<sup>1</sup> Unfortunately, this approach puts patients at high risk of severe toxicity. Due to the global aging of the population, about 20% of all stage I NSCLC patients are medically ineligible for surgery.<sup>2,3</sup> Increased risk of treatment-related complications is unacceptable in this group of older patients with multiple comorbidities. Instead, the best supportive care (BSC) has been the only treatment option, because it does not negatively impact the patients' quality of life (QoL). Unfortunately, BSC does not prolong survival. In the past few years stereotactic ablative radiotherapy technique (SABR) has evolved as a consequence of radiobiological concept of higher efficacy of extremely hypofractionated radiotherapy in many tumors, including lung cancer.<sup>4–6</sup> Phase II multicenter clinical trials addressed to medically inoperable patients with early stage NSCLC showed 90% of 3-year cancer specific survival and above 60% of 3-year OS.<sup>7,8</sup> SABR has a low toxicity rate and seems to be well tolerated.<sup>9,10</sup>

Prolonged survival is equally important as maintaining high quality of life and good psychological functioning during the last years. QoL of lung cancer patients depends on several factors related to the neoplastic disease as well as other concomitant diseases and treatment characteristics.<sup>11</sup> Among many available questionnaires, the European Organization for Research and Treatment of Cancer Quality of Life – Core Questionnaire (EORTC QLQ-C30) with the Lung Cancer questionnaire (QLQ LC13) was found to be well developed, reliable, and validated.<sup>12</sup> Psychological problems are more difficult to assess. A very good tool like Hospital Anxiety and Depression Scale questionnaire (HAD Scale, reserved for psychologists, allows accurate evaluation of psychological functioning.<sup>13</sup>

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## 2. Aim

The aim of our study was to prospectively assess the level of anxiety and depression, and QoL in medically inoperable patients with early stage NSCLC treated with the stereotactic ablative radiotherapy technique.

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## 3. Materials and methods

### 3.1. Patients

Recruited patients received information about the project before any treatment procedures. Only those were eligible who provided written informed consent for participation in the study.

Research group consisted of medically inoperable, early stage NSCLC patients qualified to SABR in the Department of Clinical Oncology and Radiotherapy, University Clinical Centre in Gdansk by the local multidisciplinary tumor board. Inclusion criteria were: at least 18 years of age, cytopathological

or histopathological proof of NSCLC, PET/CT-confirmed early (T1-T2aN0M0) stage of the disease, cognitive status sufficient to understand and complete questionnaires.

Exclusion criteria included other synchronic malignancy, stage IV chronic obstructive pulmonary disease, severe asthma, other ongoing or a history of previous anti-cancer treatment (chemotherapy, radiotherapy, small molecule therapy, immunotherapy), active infection or inflammation, cognitive impairment.

### 3.2. Research methods

Study protocol and procedures were approved by the local bioethical committee and conducted in accordance with the 1964 Helsinki Declaration and its subsequent amendments. After providing a written informed consent included patients were asked to complete a baseline assessment using Polish versions of validated questionnaires EORTC QLQ-LC30, QLQ LC13 and HAD scale. The same questionnaires were repeated 2 weeks after accrual and then 3 months after treatment completion. Functional and cognitive status, symptoms, psychological distress, and overall QoL were assessed three times. The timeframes were selected based on the expected incidence of acute treatment-related toxicities. At the time of study, the medical staff, other than the treating physician, assisted patients with poor eyesight or those who did not understand questions. EORTC QLQ-C30, QLQ-LC13 and HAD scale questionnaires were evaluated with the support of psychologist.

Medical chart audits were conducted to obtain key demographics, clinical and system resource use characteristics.

### 3.3. Questionnaires

#### 3.3.1. EORTC QLQ-C30

This questionnaire is composed of multi-item scales: five functional scales (physical, role, cognitive, emotional, and social), three symptom scales (fatigue, pain, and nausea/vomiting), global health and quality of life scales and several single items assessing the most common symptoms of cancer patients (dyspnea, appetite loss, sleep disturbance, constipation, and diarrhea).<sup>14</sup>

#### 3.3.2. EORTC QLQ-LC13

This is a supplementary questionnaire dedicated for lung cancer patients. It contains 13 parameters defining characteristic lung cancer associated symptoms as cough, hemoptysis, dyspnea, pain, treatment related side-effects as hair loss, neuropathy, sore mouth and dysphagia.<sup>15,16</sup>

Hospital Anxiety and Depression (HAD) scale is dedicated to measure anxiety and depression in patients with somatic disease. The questionnaire contains 14 parameters for self-assessment.<sup>17</sup>

### 3.4. Raw results calculation

In accordance with EORTC recommended algorithm, data were converted to linear parameters in the range from 0 and 100. Score between 60 and 100 was considered as high level of

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