Cancer of the Lung and its Response to Non-Surgical Treatment

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Summary. From July 1969 to December 1972 a clinical trial was carried out to determine the effects of radiotherapy and chemotherapy individually or in combination on lung cancer. During the first three years of the study 53 of 234 patients underwent curative resection. 111 of the remaining patients were inoperable and were suitable for inclusion in the study. The patients were randomly assigned to four groups: 1) observation only, 2) chemotherapy (Hydroxyurea) only, 3) radiotherapy only, or 4) combination chemotherapy and radiotherapy. There were no differences in survival in any of the treated groups.

Introduction

Most patients with lung cancer are not suitable for attempts at cure by surgery (Fig. 1). About one half, in fact, are not even suitable for exploratory thoracotomy because of the presence of metastases or poor pulmonary function. The overall cure rate by surgery is about 10% of all patients seen, leaving the vast majority to be treated by non-surgical means. Combining different modalities of treatment has been a recent development in cancer management and therefore in July 1969,

Fig. 1. Usual fate of patients with lung cancer

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the Departments of Surgery and Radiology of Wayne State University instituted
a study to determine the effect of radiotherapy and chemotherapy alone or in
combination on lung cancer. The drug chosen was Hydroxyurea (Fig. 2), and the
choice was based on two studies. One of these indicated that Hydroxyurea alone
had some effect on lung cancer (Kaung, 1968). The other indicated that the
combination of radiotherapy and Hydroxyurea was effective in the management
of epidermoid cancers of the head and neck (Lerner et al., 1969).

![Fig. 2. Structural formula of hydroxyurea](image)

**Methods and Materials**

The total number of patients entered in the lung tumor registry during the three year
period of July 1, 1969 to June 30, 1969 was 234. Of these 53 underwent curative resection.
An additional 111 were found to have inoperable lung cancer and were suitable for inclusion
in the study. The responsible physicians made the decision concerning suitability for inclusion
in the study on the basis of the patient's ability to withstand a combination of radiotherapy
and chemotherapy if that were the group to which he was assigned.

The patients who had undergone curative resection were randomly assigned to four groups:
1) observation only, 2) Hydroxyurea only, 3) radiotherapy only, and 4) radiotherapy and
chemotherapy. The Hydroxyurea consisted of a dose of 80 mgs per kilogram of body weight by
mouth every third day. The radiotherapy consisted of 5000 RADS tissue dose delivered to the
mediastinum via Telecobalt at 60–80 SSD in a five week period starting one month following
surgery. It was specified that no more than 2.0 cm of the opposite main bronchus be included
in this treatment and a narrow 5.0 mm × 2.5 cm lead shield was placed posteriorly to reduce
the dose to the spinal cord (Fig. 3).

The inoperable patients who were without symptoms were also randomly assigned to four
groups: 1) observation only, 2) radiotherapy only, 3) chemotherapy only, and 4) combination
radiotherapy and chemotherapy. There were forty such patients in the study. If the patients
had symptoms referable to their primary tumors or mediastinal metastases, they were randomly
assigned to radiotherapy alone or in combination with chemotherapy. This was done to
provide the most rapid palliation of the patient's symptoms rather than to wait for an effect
from chemotherapy which might be delayed for several weeks. If the patient were assigned to
chemotherapy alone or radiotherapy alone the Hydroxyurea or radiotherapy was started on
the Monday following the Lung Tumor Conference at which the decision was made. If the
patient were assigned to combination chemotherapy and radiotherapy, the radiotherapy was
started on the Monday following the first week of Hydroxyurea.

The radiotherapy was given as follows. For patients whose tumors were described by the
pathologist as poorly differentiated or undifferentiated (the equivalents of Grades III and IV),
radiotherapy was directed to the primary tumor and entire mediastinum. A tissue dose of
2000 RADS was delivered in a two weeks period beginning on a Monday. If the patients'
tumor was described by the pathologist as fairly well or well differentiated (the equivalent of
Grades I and II), or if the diagnosis was made on cytology alone, the radiotherapy was directed
at the primary tumor, the hilus of the lung, and the adjacent mediastinum, and 3000 RADS
was delivered in a two week period beginning on a Monday. All treatment was carried out
with Telecobalt devices, operating at 60–80 SSD.

Following each of these courses of therapy a two week period was allowed to elapse and a
new X-ray done on the Friday of the second week of the "rest period". If the patient’s general
condition permitted, and there was no sign of progression of the tumor or distant metastases,