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Patterns of Care for Non-Small Cell Lung Cancer Treatment -The Impact of Increased Consultant Site Specialisation; Quality vs Availability

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Abstract: Consultant site specialisation in clinical oncology is accompanying increased decision making within a multi-disciplinary forum. Using retrospective audit in the periods before and after site specialisation, this study examines patterns of care and compliance with NICE chemotherapy recommendations and local radiotherapy protocols. A retrospective review of patients' notes was conducted in a London teaching hospital tertiary cancer centre. The outcome measures assessed were patient characteristics, waiting times for radiotherapy and compliance with the newly instituted guidelines in year 2. Three hundred NSCLC patients received radiotherapy to their primary lung lesion; 127, patients year 1 (1.1.00-31.12.00) and 163, patients year 2 (1.8.01-31.7.02). The number of patients treated increased by 28% from year 1 to year 2. The median waiting time for radiotherapy increased significantly from 13.5 to 27 days (p = 0.0237). In year 2, 130 (80%) of patients were treated according to the new radiotherapy guidelines. 92% (35 of 38) of chemotherapy regimes were prescribed within the guidelines in year 2. Consultant site specialisation resulted in significantly greater uniformity of care with excellent compliance to radiotherapy and chemotherapy guidelines. Increased consistency of treatment had a positive impact on patients' care and treatment outcome. However, the increased waiting times compromise tumour curability and cost benefit.

Key words: COIN guidelines, NICE guidelines, non-small cell lung cancer, radiotherapy, waiting time

Introduction

Lung cancer is the leading cause of cancer death in the UK (Hansen, 2002). Non-Small Cell Lung Cancer (NSCLC) represents 80% of new lung cancer diagnoses (Hansen, 2002). NSCLC has an 8-14% five-year survival rate (Hansen, 2002) with median survival of approximately 12 months (Carney and Hansen, 2000). Recent clinical trials proved that both chemotherapy and/or radiotherapy improve overall symptom control, local tumour control and survival benefit (MRC Lung Cancer Working Party, 1991; NSCLC Collaborative Group, 1995; MRC Lung Cancer Working Party, 1996).

In June 2001, the National Institute for Clinical Excellence (NICE) issued guidelines for chemotherapy use in patients with NSCLC in the UK (www.nice.org.uk). Local chemotherapy protocols were based on these guidelines. At the same time, local protocols for radiotherapy were instituted. The Royal College of Radiologists (RCR) recommended that consultant clinical oncologists sub-specialise in treatment of specific tumour sites. The audited Trust (Hammersmith Hospitals NHS Trust-HHNT) initially had only one clinical oncologist treating lung cancer as a primary specialty site. Changes were made in July 2001 to enhance clinical oncology consultant site specialisation throughout the Trust. Now there were three full time clinical oncologists responsible for lung cancer treatment, as a primary site (2) and a secondary site (1). To complement this, multidisciplinary teams were formed at all referring hospitals to discuss each new case in clinico-pathological conferences.

A retrospective audit was performed of all new NSCLC radiotherapy patients in the year prior to the implementation of the changes to assess patterns of care and patient characteristics. Following this audit, recommendations were made for future practice and the audit loop was closed with a further retrospective audit the following year. Local practice was compared to the national recommendations laid out in the Clinical Oncology Information Network guidelines (COIN, 1999). This audit process was approved by the Clinical Audit Department at Hammersmith Hospitals NHS Trust.

Materials and Methods

A retrospective analysis was performed on the notes of all NSCLC patients treated with radiotherapy to the primary lung lesion between January 1, 2000 and December 31, 2000 (year 1) at a London teaching hospital trust tertiary cancer centre (HHNT). Treatment details were obtained from radiotherapy simulator diaries, planning referral forms, treatment cards, the computerised treatment system and medical notes. Radical radiotherapy was defined as a total dose of 60 Gray in 30 fractions (or equivalent) or greater. The date of entry into the audit was defined as the date of referral for radiotherapy. This date was chosen to analyze waiting times for treatment in a consistent manner. In the case of missing or undated planning request forms, the date of radiotherapy simulation was used as the date of entry into the audit. Therefore, overall waiting time could not be assessed on this subset of patients.

Using the information gained from the year 1 audit and national guidelines, four targets were set for the department to attain by the year 2 audit:

- To enhance consultant site specialisation.
- To prescribe according to local lung radiotherapy protocols wherever possible, aiming for at least 80% compliance. This figure was chosen to allow expected treatment variations for individual patient needs such as retreatment of a previously irradiated area.
- To implement NICE chemotherapy guidance where appropriate.
- To treat patients receiving a single palliative fraction of radiotherapy on the day of radiotherapy simulation with 100% compliance.

The audit loop was then closed. Similar collection methods were used as in year 1 to collect patients' data from August 1, 2001 to July 31, 2002 (year 2). Statistical analysis was performed on waiting times using the Wilcoxon's rank sum test and on single fraction treatments using chi squared analysis (Neter *et al.*, 1983).

Results

Patients characteristics are shown in Table 1. In year 1, eight consultants treated 127 NSCLC patients with lung radiotherapy. In year 1, prior to the enhanced consultant site specialisation, there was only 1 lung cancer site specialist. Only six consultants treated 163 patients in year 2, 95% (152) of these were treated by the three lung cancer site specialists. The patients were referred from 11 hospitals in both years, though the proportion referred from individual hospitals varied with changes in the local Cancer Network.

The median overall wait for radiotherapy increased from 14 days in year 1 (range 0-70 days, interquartile (IQ) range 6-21 days) to 27 days in year 2 (range 0-107 days, IQ range 14-48 days) p = 0.0237 (Table 2). This was divided into the wait for palliative radiotherapy increasing from a median of 13 days (range 0-33, IQ range 6-19 days) to 20 days (range 0-70, IQ range 11-33 days) p<0.0001 and the wait for radical radiotherapy increasing from a median of 26 days (range 6-70, IQ range 20-39 days) to 54 days (range 12-107, IQ range 43-63 days) p<0.0001. The overall waiting time was unknown for 26 patients in year 1 (20%) and 24 patients in year 2 (15%). 80% (130/163) of patients were treated according to the newly approved radiotherapy protocols in year 2 (Table 3). Table 4 shows the number of patients treated by each consultant in year 2 and the proportion of deviations from protocol, which ranged from 14% (13/94) of treatments to 100% of treatments (though the consultant in this situation only treated one patient).

Five patients (3%) in year 2 had treatment prescribed according to protocol but received less due to illness or death; these were not counted as protocol deviations. There were 14 different dose fractionation schemes used in the protocol deviation treatments. Examples of common reasons for protocol deviation include post-surgical radiotherapy for positive margins and previous irradiation.

The proportion of single fractions of radiotherapy treated on the day of treatment simulation dropped from 81% (21/127) in year 1 to 48% (25/163) in year 2, p = 0.032 (Table 5). The number of patients receiving palliative treatments in five fractions or less increased from 75% (78/104) in year 1 to 82% (90/110) in year 2.

Table 1: Patient characteristics for year 1 and 2

	Year 1	Year 2
Number	127	163
Male	91 (72%)	101 (62%)
Median age	70 (range 40-89)	70 (range 29-95)
Radical treatment given	23 (18%)	53 (33%)
CT planned	12 (7%)	44 (27%)
Patients receiving single fraction of RT	21 (17%)	25 (15%)

Table 2: Overall wait for radiotherapy from date of decision to treat with radiotherapy to commencing radiotherapy

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	<1	1-2	3-4	5-6	7-8	9-10	11-12	>12	Total
No. of cases in Year 1	26	28	40	5	1	1	0	0	101
No of cases in Year 2	12	25	35	24	23	13	3	4	139

Table 3: Patients receiving radiotherapy by protocol in year 2

	LU-1	LU-2	LU-3	LU-4	LU-5	Protocol deviation
No. of patients	25 (15%)	52 (32%)	18 (11%)	16 (10%)	20 (12%)	32 (20%)
Protocol dose	10 Gy in	20 Gy in	30 Gy in	54 Gy in	60 Gy in	
	1 fraction	5 fractions	10 fractions	20 fractions	30 fractions	

Table 4: Radiotherapy protocol deviation rate per consultant in year 2

		No. of protocol	Proportion of protocol
Consultant	Overall No. of cases	deviations	deviations (%)
A	20	5	25
В	4	1	25
C	1	1	100
D	39	12	31
E	94	13	14
F	5	1	20

Table 5: Time between planning and treatment for single fractions for year 1 and 2

Year 1 Time between planning and RT (days) No. of Patients		Year 2 Time between planning and RT (days) No. of patients		
3	1 (5%)	1	4 (16%)	
5	1 (5%)	5	1 (4%)	
7	1 (5%)	6	4 (16%)	
Unknown	1 (5%)	14	1 (4%)	
	. ,	15	1 (4%)	
		16	1 (4%)	
		Unknown	1 (4%)	

Table 6: Chemotherapy regimes used in year 2

Chemotherapy regime	No. of patients	Total (%)
Vinorelbine	2	5
Concurrent Cisplatin	1	3
Vinorelbine Cisplatin	7	18
Gemcitabine Carboplatin	25	66
MVP (Mitomy cin-C, Vinblastine, Cisplatin)	1	3
MIC (Mitomy cin-C, Ifosphamide, Cisplatin)	1	3
Docetaxel	1	3

Percentages may not sum 100% due to rounding

Thirty-eight patients in year 2 received chemotherapy in addition to radiotherapy, either neo-adjuvantly or adjuvantly (Table 6) 92% (35/38) of these regimes followed NICE guidelines. Of the non-protocol regimes, 2 patients (5%) received neo-adjuvant chemotherapy that was started before the NICE guidelines were issued and commenced radiotherapy within the audited period.

Discussion

The impact of consultant site specialisation on treatment was marked and closely follows RCR guidelines. These guidelines state that tumour site sub-specialisation by oncologists is now not just encouraged, but expected, by both the RCR and the Department of Health (RCR, 2003a). The guidelines also state that sub-specialised consultants in clinical oncology should not normally offer care outside their subspecialty competence, but consultants are nevertheless expected to retain a broad competence in general clinical management. In year 2, the three consultants specialising in lung cancer treated 95% of patients, demonstrating good implementation of these guidelines.

There was good adherence generally to radiotherapy protocols in year 2 and a protocol deviation rate of 15-20% per consultant was considered acceptable. This allows for prescribing tailored to unusual clinical situations such as retreatment of a previously irradiated field. Fifty Gray in 20 fractions was a regimen commonly used following surgery and will be put forward as a new protocol.

When the NICE guidelines were issued, it was estimated that 4-16% of NSCLC patients would receive chemotherapy. This audit showed that 23% of patients did. The increase above the expected figures could have marked cost implications, though the move away from inpatient regimens may have a cost-saving effect. Many of the patients received chemotherapy in an endeavour to prevent turnour growth whilst awaiting a start date for radical radiotherapy. It is possible that as radiotherapy waiting times decrease, the number of patients receiving chemotherapy may also decrease.

The national guidelines for waiting times recommend that palliative treatments be started within 14 days of referral (Joint Council for Clinical Oncology, 1993); the median wait in this audit was 14 days in year 1, increasing to 27 days in year 2. The same national guidelines also recommend that radical treatments should start within 28 days of referral, the audited median increased from 26 days to 54 days. Such a significant increase in waiting times may be partly due to the increase in workload of 28% but also due to the increased time taken for planning radical treatments including the waiting time for a planning CT scan. There was no dedicated CT scanner to plan conformal radiotherapy at the time of the audit. Therefore there were limited spaces and long waits on the diagnostic imaging CT scanner. There was also a lack of treatment planners to plan the more complex radical treatments.

Long overall waits for radiotherapy are an increasing problem in the UK. This could have dramatic implications on tumour curability. In 1998 an RCR national audit of waiting times for all tumour sites showed that 32% of patients waited more than four weeks to start radical radiotherapy (RCR, 1998a). In 2003, the RCR showed that this figure had increased to 72% of patients (Ash *et al.*, 2004). A recent audit of head and neck patients showed that 59% of patients waited over four weeks to start radical treatment (James *et al.*, 2003). An audit of 29 lung cancer patients showed that 25 patients (86%) waited more than four weeks for radical radiotherapy. Six patients (21%) had such tumour growth during the waiting period that they were reclassified as unsuitable for radical treatment and therefore incurable (O'Rouke and Edwards, 2000). Similar situations occur in other disease sites, for example, a retrospective audit of 644 patients with squamous cell carcinoma of the tonsil showed an 8% loss of local control for every four weeks delay in treatment start (O'Sullivan *et al.*, 1998).

The 1997-2002 RCR audit of radiotherapy practice in the UK showed that the national radiotherapy department workload increased by 16% with only a 10% increase in linear accelerator (LinAc) provision over this time (RCR, 2003b). However, this was an improvement over the 1992-1997 RCR audit, which showed an increase in workload of 18% with a corresponding increase of treatment capacity of only 3.6% (RCR, 1998b). The RCR recommended that each department should have 4 LinAcs per million population served, nationally the average was 3.53 per million in 2002 (RCR, 2003b). The audited department had 5 LinAcs and a population of 2.2 million served, a provision of 2.27 LinAcs per million population.

The workload for NSCLC cancer patients increased by 28% over the audit period, possibly due to the effect of increased awareness of the service and increased referral by multi-disciplinary teams. The increase in the number of patients receiving longer radical treatment regimes may also have an adverse impact on waiting times.

Where possible, palliative cases were treated in five fractions or less. This strategy may have decreased waiting times but perhaps at the cost of an adverse impact on survival as studies have shown improved median survival for higher performance status NSCLC patients with longer courses of palliative treatment (Schaafsma and Coy, 1998).

The significant drop in the ability to treat single fractions on the day of planning was felt to be due to two factors. Treatment planning protocols were changed within the department during year 2 for all tumour sites requiring 24 h between simulation and treatment to allow for Quality Assurance (QA) checks to be completed. This had unforeseen consequences on this palliative group of patients. Also, hospital transport often brought patients to the department too late in the day to allow treatment on the same day. When considering treatment for palliative patients, a balance must be made between timely therapy and safe effective QA checks. Therefore for palliative single fractions, departmental policy has been changed to allow same day treatment by planning the patient early in the day. These changes will be re-audited after one year.

Conclusions

The modern era has seen massive scientific advances and sweeping treatment changes in cancer care. However, health care funding in the UK has lagged behind these innovations resulting in equipment deficits and lack of treatment personnel. An invigorated renewal of health service funding and machine provision is required to keep pace with the advances in modern oncology treatment.

The marked increase in waiting times over the audit period reflected a national trend, which may have serious implications on the curability of lung tumours. The installation of a CT simulator dedicated to conformal radiation planning within the department should help to decrease waiting times for radical treatment. Initiatives are also in place to recruit and retain radiographers to maximize the use of available LinAcs.

The increase in consultant site specialisation was carried out quickly and effectively. The radiotherapy protocols were followed well with an acceptable protocol deviation rate. The NICE guidelines were followed closely with a higher than nationally predicted number of patients receiving chemotherapy. This shows that radiotherapy and chemotherapy protocols can be devised and instituted with good compliance. However, the increase in workload may have profound effects on waiting times for treatment.

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