



Original Article

Stereotactic Ablative Body Radiotherapy Versus Radical Radiotherapy: Comparing Real-World Outcomes in Stage I Lung Cancer

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Abstract

Aims: Stereotactic ablative body radiotherapy (SABR) is now considered the standard of care for medically inoperable stage I non-small cell lung cancer (NSCLC). The English National Cancer Registration and Analysis Service (NCRAS) collects data on all patients diagnosed with lung cancer, including information on treatment. We wanted to compare outcomes for patients with stage I NSCLC treated with radical radiotherapy with either SABR or fractionated radiotherapy. **Materials and methods:** All patients diagnosed with stage I NSCLC in 2015 and 2016 were identified from the NCRAS dataset, validated by the National Lung Cancer Audit, and their treatment data were collated. For patients who received radiotherapy, those receiving radical dose fractionations, including SABR, were identified through linkage to the national Radiotherapy Dataset. Clinical outcomes for those receiving SABR or more fractionated radical radiotherapy were compared using univariate and fully adjusted Cox proportional hazards models.

Results: In total, 12 384 patients with stage I NSCLC were identified during the study period; 53.5% underwent surgical resection, 24.3% received no documented treatment, 18.6% received radical radiotherapy and 3.5% received other non-curative-intent treatments. For those receiving radical radiotherapy, 69% received SABR and 31% received fractionated treatment. The hazard ratio of death for the 1587 patients who received SABR was 0.69 (95% confidence interval 0.61–0.79) compared with 717 patients who received radical fractionated radiotherapy; this benefit was seen for both stage Ia and stage Ib disease. The median overall survival was also longer for SABR versus radical radiotherapy (715 days versus 648 days). Exploratory travel time analysis shows that compared with stage I NSCLC patients receiving SABR, those receiving fractionated radiotherapy and those receiving no active treatment would have to travel longer and further to reach their nearest radiotherapy SABR centre.

Conclusion: This study adds to the data that SABR has a survival benefit when compared with fractionated radical radiotherapy. Although the use of SABR increased in England over this study period, it has still not reached levels of use seen in other countries. This study also highlights that one quarter of stage I NSCLC patients overall received no active treatment.

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Key words: Radical radiotherapy; SABR; stage I NSCLC

Introduction

Internationally, stereotactic ablative body radiotherapy (SABR) has become the standard of care for medically inoperable early stage non-small cell lung cancer (NSCLC) [1–3].

When compared with radical fractionated radiotherapy, SABR delivers a higher biological equivalent dose, in fewer

highly focused doses in a shorter treatment time. SABR has a high local control rate [4]. The largest published UK cohort has a local control rate of more than 95% at 3 years [5]. To date, SABR has only been directly compared with radical radiotherapy in two small randomised controlled trials, both containing about 100 patients. The SPACE trial showed similar survival in both cohorts, despite more adverse risk factors in the SABR cohort; it also showed lower toxicity rates and a lower loss of quality of life in the SABR cohort [6]. The CHISEL trial reported that SABR improved local control and overall survival compared with fractionated radical radiotherapy [7]. Alternative methods of analysis reported in the

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literature also suggest improved outcome for SABR compared with fractionated radiotherapy and accelerated hyperfractionated radiotherapy [8–10]. With advancing technology, improved local control, increased convenience and lower toxicity, SABR was commissioned for use in England at selected radiotherapy centres in 2013 [11].

SABR is potentially accessible to all patients in England, but not necessarily at their nearest radiotherapy centre. Many patients who receive any form of radical radiotherapy, rather than surgery, do so because of comorbidities, as they are older and less fit. They may not wish to or be able to travel to a more distant radiotherapy centre to receive SABR treatment. Referring patients to a tertiary centre adds an inherent delay to starting treatment, as patients need to be reviewed by a second oncology team; this delay may affect outcomes. This is consistent with the findings of the UK Royal College of Radiologists' audit of radical radiotherapy for lung cancer, which identified that older patients are less likely to get optimal treatment, possibly because of travel times [12].

During the analysis period in this study, patients were receiving both SABR and radical fractionated radiotherapy for stage I lung cancers in England. This 'delay or lag' as use of SABR continues to rise, offers a 'real-world' opportunity to compare the outcomes of the two different radiotherapy treatment strategies in use at the same time.

Materials and Methods

Study Population and Databases

Data for this study are based on patient-level information collected by the National Health Service as part of the care and support of cancer patients. The data are collated, maintained and quality assured by the National Cancer Registration and Analysis Service (NCRAS), which is part of Public Health England.

Data on all individuals in England aged 18–99 years diagnosed with a first primary lung cancer (International Classification of Diseases code 10 C34) between 1 January 2015 and 31 December 2016 were used, validated via the National Lung Cancer Audit. We excluded individuals with a small cell morphology (M8041–45) and all individuals who were not diagnosed with stage I disease [13].

Treatment Definitions

The treatment rates among all stage I NSCLC patients were analysed. Treatments were included from –30 to +183 days from the date of diagnosis. Surgery was identified using OPCSv4 codes for major resection, as previously described by the National Lung Cancer Audit; radical radiotherapy, including SABR, was identified from the Radiotherapy Dataset using derived treatment intent, total prescribed dose and prescribed number of fractions [14]. SABR was defined as 50 Gy or more in eight or fewer fractions; fractionated radical radiotherapy was defined as 50 Gy or more delivered in over 10 fractions.

Travel Times

Travel times (by private transport) for patients who received radiotherapy treatment were calculated from the patient's postcode of residence to the postcode of the nearest radiotherapy centre, the treating radiotherapy centre and to the nearest radiotherapy centre commissioned to deliver SABR in 2015. Travel times were computed using ArcGIS by Norwich Medical School [15]. Road speeds were taken from Jones *et al.* [16], with adjustments for walking speed for off-road locations using the methodology set out in Bateman *et al.* [17]. Full details are described in Sen *et al.* [18]. Theoretical travel times to the nearest radiotherapy SABR centre were similarly calculated for the stage I NSCLC patients who had no record of treatment.

Statistical Analysis

We compared gender, age, stage and performance status between patients who received SABR and those who received radical fractionated radiotherapy and carried out univariable and multivariable logistic regression modelling.

Survival time was calculated from the start of radiotherapy treatment until death or censored at the end of the follow-up period on 18 September 2018.

Kaplan–Meier survival estimates were calculated to compare survival between patients receiving SABR and those receiving radical fractionated radiotherapy. Because we observed a difference between receiving radical radiotherapy treatment modality by stage, we ran the analysis separately for stage Ia and stage Ib. Two patients were only recorded as having stage I disease, these were coded as stage Ia.

Finally, after checking that the hazards were proportional, we ran univariable and multivariable Cox proportional hazards models to assess the association between SABR and survival, overall and by stage while accounting for potential confounding by age, gender and performance status.

Results

Overall

In the study period, 12 384 patients were diagnosed with stage I NSCLC. The most common treatment was surgery (53.5%); the second largest proportion of the cohort was the 24.3% who received no documented treatment. Full details can be found in Table 1. Radical radiotherapy as a single treatment modality was delivered to 18.6% (2304) of cases.

Radical Radiotherapy (Single Modality)

For the 2304 patients treated with radical radiotherapy alone, 31% (717) received fractionated radical radiotherapy and 69% (1587) of patients received SABR.

This cohort had an almost even distribution of men and women. Forty-six per cent of patients had a histological

diagnosis of NSCLC and 54% were treated with a radiological diagnosis of primary lung cancer. The proportion of patients receiving SABR versus radical fractionated radiotherapy increased from 64% in 2015 to 73% in 2016. Performance status was worse in the SABR group, with higher numbers of performance status 2 patients than the radical radiotherapy group. However, trend analysis for performance status and age between the cohorts was not statistically significant ($P = 0.15$ and $P = 0.54$, respectively) on multivariable analysis. **Figure 1** compares performance status and age at treatment for those receiving SABR and radical fractionated radiotherapy. In terms of the details of the radiotherapy prescription, the most common radical fractionated regimen was 55 Gy in 20 fractions (79%); the most common SABR regimen was 55 Gy in five fractions (70%).

Clinical Outcome

When comparing clinical outcomes for radical radiotherapy, the hazard ratio for death for those receiving SABR was significantly lower at 0.69 (95% confidence interval 0.61–0.79). **Figure 2** shows that this improvement in survival occurred independently in both smaller stage Ia tumours (hazard ratio 0.71, 95% confidence interval 0.58–0.84) and, perhaps surprisingly, in larger stage Ib tumours (hazard ratio 0.68, 95% confidence interval 0.56–0.82), as well as in the whole cohort.

Radiotherapy Travel Times

Figure 3 shows that patient access to SABR may affect who receives it. It shows that the proportions of patients having to travel 45 min or more to access treatment, both SABR and fractionated treatment, were approximately equivalent (8% versus 9%). However, if those receiving fractionated radiotherapy were to theoretically travel to receive SABR, then this proportion increases to 41%. It is similar for those patients receiving no treatment; theoretically, 45% of untreated patients would have had to travel more than 45 min to attend their nearest SABR centre.

Discussion

This is the first time it has been possible to comprehensively analyse the use of radical radiotherapy for stage I

NSCLC in England using real-world registry data, since the commissioning of SABR in 2013.

During the 2015–2016 time period analysed, we show that 18% of stage I NSCLC patients received radical radiotherapy and, of these, 69% received SABR.

For the whole cohort, the hazard ratio for death was significantly less for patients receiving SABR when compared with those receiving fractionated radical radiotherapy (hazard ratio 0.69, 95% confidence interval 0.61–0.79). This improved outcome was also seen when the analysis was run separately for stage Ia and stage Ib disease. This real-world data confirm the conclusions of the recently published small randomised CHISEL trial showing that SABR has improved outcomes compared with fractionated radiotherapy and should be the standard of care for all those patients who are suitable, as recommended in the new National Institute for Health and Care Excellence (NICE) guidelines [3,7].

Although it is encouraging to see that the proportion of stage I NSCLC radiotherapy patients treated with SABR in England increased from 64% in 2015 to 73% in 2016, these proportions still lag behind other comparable countries where SABR is more established, such as the USA and the Netherlands, where over 90% of radical radiotherapy in this patient group is delivered as SABR [8,19]. Data from the National Lung Cancer Audit also identifies wide regional variation in the use of SABR over fractionated radical radiotherapy across England (46–91%) [12].

In countries where SABR is well established, not only is the use of more fractionated radical radiotherapy very low, the proportion of stage I NSCLC patients receiving no curative-intent treatment at all is also low, including older patients and those with comorbidities, such as severe Chronic Obstructive Pulmonary Disease (COPD) [8,20,21]. Previous published data have shown that as the proportion of patients receiving SABR increases, so do both the proportion of patients receiving a radical treatment and the overall survival of the cohort [19].

It is well recognised that the UK and England have lower rates of lung cancer survival compared with the rest of Europe or other countries around the world [22,23]. In view of the fact that outcomes for stage I lung cancer patients treated with fractionated radical radiotherapy and SABR in England are comparable with other reported series [8,19], and the use of surgery is similar, a major factor probably adversely influencing overall stage I lung cancer survival data for England is the fact that, during this time period,

Table 1

Documented treatment of patients with stage I non-small cell lung cancer (NSCLC) in England in 2015–2016

Treatment modality	Number of patients	Percentage of cohort
Surgery	6631	53.5
No documented treatment	3010	24.3
Radical radiotherapy (Stereotactic ablative body radiotherapy)	2304 (1587)	18.6 (12.8)
(Conventional radiotherapy)	(717)	(5.8)
Non-curative treatment	439	3.5
Total	12 384	99.9

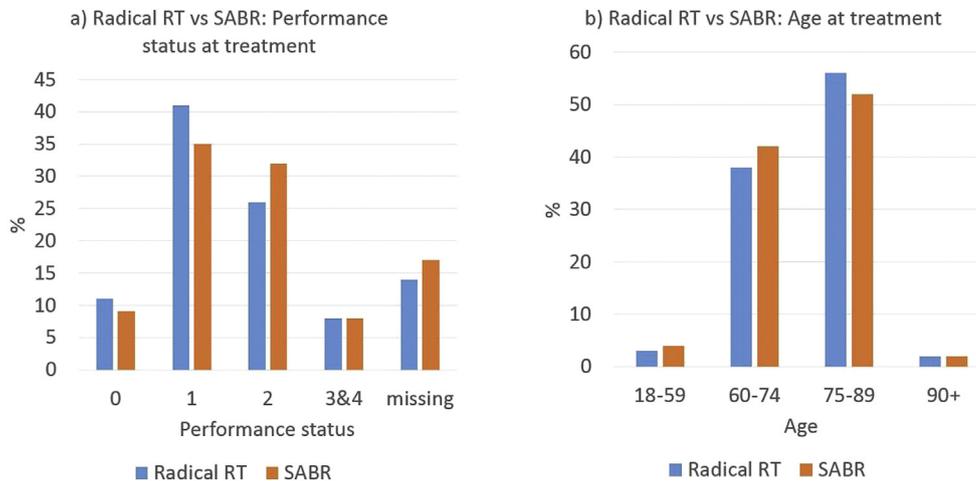


Fig 1. Comparing age and performance status at the time of treatment in patients receiving stereotactic ablative body radiotherapy (SABR) or radical radiotherapy. More patients receiving SABR were performance status 2. *P* values for a multivariate trend analysis for SABR in older and less fit patients were 0.54 and 0.15, respectively.

almost one quarter of patients with stage I NSCLC in England received no active treatment at all, in particular patients over the age of 80 years.

Although not all stage I NSCLC patients will be appropriate for surgery or radical radiotherapy, as SABR is a very well-tolerated treatment, requiring a small number of hospital visits, it is potentially feasible to deliver this to more people within this older, frailer group [19]. Dutch data have shown that survival of the lung cancer cohort as a whole improves when an increased number of older patients receive SABR. This is because more patients receive a radical treatment option [19].

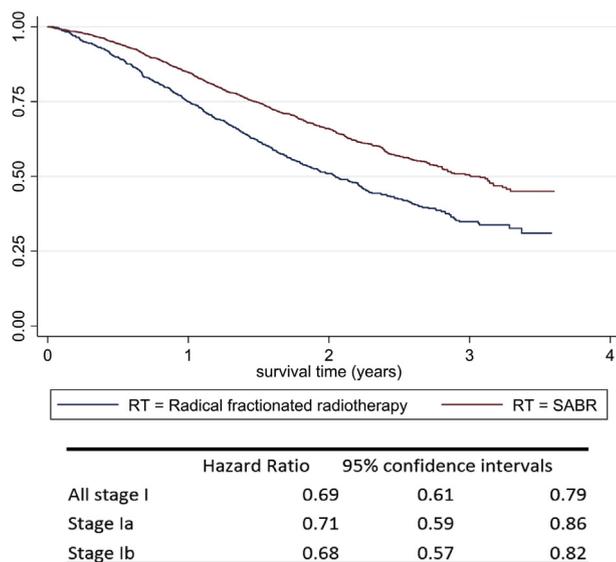


Fig 2. Kaplan–Meier curve of stereotactic ablative body radiotherapy (SABR) versus fractionated radiotherapy. The hazard ratio for death for all stage I patients was 0.69 (95% confidence interval 0.61–0.79). The hazard ratio for death for stage 1a and 1b was calculated using the Cox model adjusted for age, gender and performance status.

During the analysis period, SABR was commissioned in 17 radiotherapy centres across England and this number was increased to 24 in 2017.

Our exploratory travel time analysis shows that those patients receiving fractionated radical radiotherapy would have had to travel for longer to receive SABR and a similar theoretical travel time analysis for untreated patients shows the same, with over 40% of these groups needing to travel for over 45 min to reach a SABR centre.

The Independent Cancer Task Force Report, ‘Achieving world class cancer outcomes: a strategy for England 2015–2020’ [23], highlights that differences in treatment are a contributing cause for poorer outcome and greater access to cutting-edge radiotherapy treatment, such as SABR, would allow more patients to receive a radical treatment, when surgery is not suitable [23]. For medically inoperable patients, delivering such effective treatment locally, has the potential to avoid delays related to referral to a tertiary centre, which could have an effect on outcome.

Lung SABR provision will probably need to increase further, with additional radiotherapy centres commissioned to deliver lung SABR to improve access and reduce travel times, through the new radiotherapy networks to encompass the growing need; a repeat analysis on 2017–2018 data is planned to assess this [24]. A recent survey by Beasley *et al.* [25] suggests that 36 centres in the UK deliver SABR. Six non-commissioned centres in England delivered SABR in the survey period. ESTRO-ACROP have published a step by step guide to developing a linear accelerator delivered SABR service [26]. This suggests that SABR provision in England is not sufficient and that it should be deliverable in a centre with adequate equipment. SABR has been a specialist service because of the need for a set level of image guidance and because treatment is delivered in fewer, larger fractions, meaning treatment accuracy is even more important than in fractionated radiotherapy. As the use of image-guided radiotherapy and SABR extends beyond lung

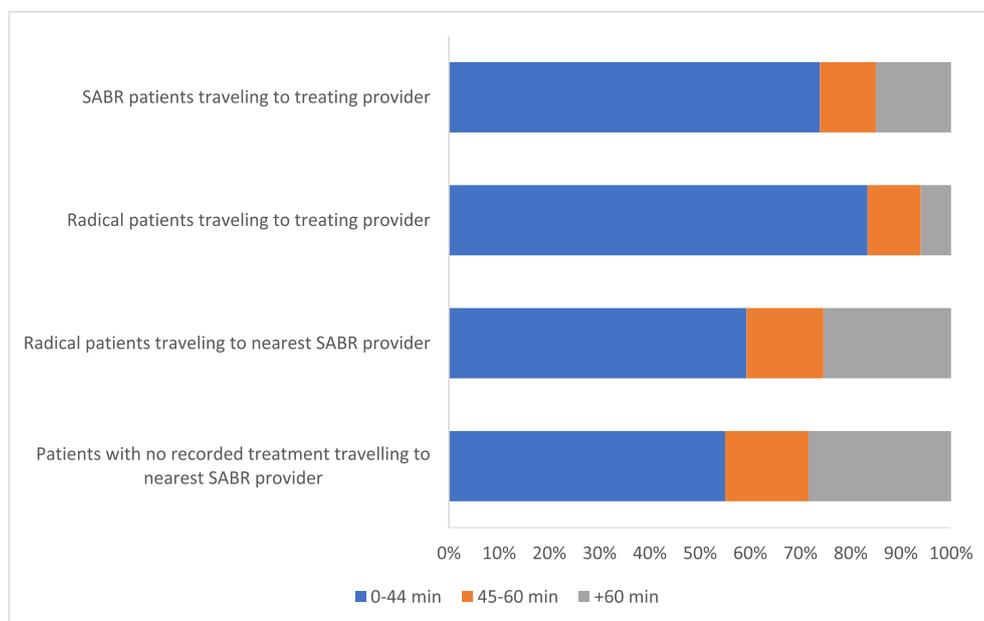


Fig 3. Travel times for patients receiving radical radiotherapy in England. For those receiving stereotactic ablative body radiotherapy (SABR) and radical fractionated radiotherapy, most patients travelled 44 min or less (92 and 91%, respectively). However, if those patients receiving radical fractionated radiotherapy were to travel to their nearest SABR provider, only 60% of patients would have travelled 44 min or less, suggesting that the distance to travel to access treatment may be an issue in an older, frailer population.

SABR, the technical skills and equipment are more widely available than when the lung SABR service was initially commissioned.

As well as a wider provision of lung SABR, there needs to be appropriate support for treating oncologists in terms of education and peer review. Currently, SABR clinical trials and the SABR treatment of oligometastases through the Commissioning Through Evaluation programme are run in conjunction with a national Radiotherapy Trials Quality Assurance (RTTQA) framework and UK SABR consortium guidelines [27]. It is important to ensure that as more radiotherapy centres are commissioned to deliver SABR for stage I NSCLC, to improve access and to increase the number of patients offered this treatment, that they do so with appropriate quality assurance and radiotherapy network support. Although further sites are initiating lung SABR, there is a potential ethical issue in ensuring clinicians in non-SABR centres are offering access to SABR using robust, efficient referral pathways. One way of potentially allowing greater access to SABR could be reducing the number of visits for treatment, by further investigating delivering SABR in a single visit [28].

The numbers of patients who may benefit from lung SABR could increase further over the next few years. First, the increased use of medical imaging means that more incidental early stage lung tumours will be identified. Second, the number of cases of lung cancer in the over 60s is rising, particularly in those aged 81 years or older, where cases have risen by nearly 1.5 times from 446 per 100 000 in 2004 to 666 per 100 000 in 2012 and comorbidities and performance status may preclude surgery [29]. Third, the development of a national lung cancer screening programme in high-risk individuals, based on the European

NELSON study and the American NLCT study, may increase the proportion of patients presenting with stage I disease [30,31].

Strengths and Limitations

The main strength of this real-world study is the completeness and quality of the data, validated via the National Lung Cancer Audit and with linkage to the national Radiotherapy Dataset within the NCRAS. The registry data include all reported lung cancer cases and, hence, gives a clear denominator when looking at the proportion of patients with stage I NSCLC receiving optimal management.

One limitation is the retrospective nature of non-randomised real-world data, which means that even with adjustment it may be subject to confounding or selection bias. Second, although the Radiotherapy Dataset captures every radiotherapy exposure delivered within National Health Service trusts in England, allowing SABR treatments to be clearly identified, it does not capture data on tumour location within the lung or detailed tumour size measurements beyond TNM staging or record contraindications to SABR, such as the presence of interstitial lung disease. However, the information presented here provides valuable insight into current treatment patterns, and under treatment in particular, which can be used to drive improvements in practice.

Conclusion

This study is the first to show that treating stage I NSCLC with SABR reduces the risk of death, when compared with

the commonly used fractionated radical radiotherapy in England. It also identifies that although the use of SABR in England is increasing, it has still not reached the levels in European countries, where SABR is well-established. It is a major concern that almost one quarter of stage I lung cancer patients do not receive any active treatment at all. This supports recommendations that greater access to SABR is required nationally.

Improving SABR access through provision in more centres has the potential to positively impact the overall survival of patients with stage I NSCLC, particularly in those who are older or less fit.

Conflict of interest

The authors declare no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.clon.2019.07.013>.

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