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Original Article

A prospective randomised controlled clinical trial to evaluate three immobilisation devices for intra-thoracic radiation therapy

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Abstract

Purpose: To determine the optimal of three immobilisation devices for lung radiotherapy in terms of set-up reproducibility, patient comfort, radiation therapists' (RTs) satisfaction and cost-effectiveness.

Materials and methods: A total of 30 lung CRT patients were randomised to one of three immobilisation techniques – Arm A, headsponge; Arm B, BreastBoard dedicated immobilisation device; and Arm C, LungBoard dedicated immobilisation device.

Results: Random errors were larger for Arm A versus C in all directions ($p < 0.05$). Random errors were larger for Arm A versus B for y and z directions ($p < 0.05$). When the data for the immobilisation devices (Arms B+C) were pooled and compared with Arm A (no dedicated device), the systematic errors were larger in the z direction for A ($p < 0.05$). Arm C was cheaper and was more comfortable for patients. Therapists preferred this device (Arm C) and treatment times were less ($p < 0.05$).

Conclusion: This is the first prospective randomised controlled lung immobilisation trial, based on 3-DCRT, that takes into account treatment accuracy, users satisfaction and resource implications. It suggests that the LungBoard immobilisation device is optimal.

Keywords

Conformal lung radiotherapy; set-up errors; lung immobilisation; treatment accuracy

INTRODUCTION

The ability to more precisely define the target volume and critical normal structures using conformal radiotherapy techniques (3-Dimensional Conformal Radiotherapy, 3-DCRT and Intensity Modulated Radiotherapy, IMRT) have major potential and proven clinical benefits in irradiating thoracic malignancies. An improved therapeutic ratio theoretically permits dose escalation and reduction of acute and/or long-term radiation-induced side effects.[1–9] Further improvements in the therapeutic ratio may be obtained by strategies aimed at reducing the safety margin added to produce the planning target volume (PTV). These account for geometrical uncertainties that are an inherent

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component of the treatment process of external beam radiotherapy.[4,5,10–15]

The increasing ability to measure set-up errors, the need to reduce PTV margins and the safe clinical application of conformal radiotherapy has lead to a growing number of studies.[10–12,16] Detailed quantitative studies about set-up accuracy, in which a separation between random and systematic set-up errors and the specification of the standard deviation (SD) of these errors in three directions (x, y and z) were made, are scarce in thoracic radiotherapy.[1,17–22] Published data suggest that the SD of the systematic (range 1.8–5.1 mm) and random errors (range 2.2–5.4 mm) is about equal and the SD of the systematic and random errors of $\leq$3.5 mm can be considered as "state of the art" for such treatment.[12] The use of a correction protocol results in a considerable reduction of systematic set-up errors.[4,16]

Optimal immobilisation is critical for patient set-up reproducibility in high-dose lung radiotherapy and various immobilisation devices aiming to reduce the daily set-up errors have been developed and reported. These include the T-bar,[21] expanded foam devices with and without a T-bar,[21] stereotactic body frame and abdominal pressing plate with T-bar,[22] headsponge with arms by side—(antero-posterior techniques),[1,20] headsponge with arms above head with armband or crossbar,[1,20] arms above head with and without alphacradle,[17] polyurethane foam cast,[19] and forearm support and knee-roll and instructions to breathe gently.[16] Devices providing stable arm-support are preferred, especially when prolonged immobilisation is required.[21] However, the optimal immobilisation technique and patient positioning have yet to be determined.

Analysis of set-up errors in the current trial

It is well accepted that each centre must evaluate its own immobilisation and techniques in terms of patient set-up errors. Published quantitative analyses are useful as a benchmark for comparisons but cannot be explicitly relied upon for the application of safety margins for set-up uncertainties. Before this trial, lung cancer patients were immobilised in the supine position on an *ad hoc* basis with a variety of devices and supports: headsponge, vacuum bag, BreastBoard, Kneefix or pillow. The majority were immobilised using the headsponge. In addition, patient set-up errors were not previously investigated in our institution. This is the first prospective randomised controlled clinical trial on lung immobilisation devices, based on 3-DCRT, that takes into account treatment accuracy, users satisfaction—patients and radiation therapists (RTs)—and resource implications.

MATERIALS AND METHODS

Patients were randomised to one of three immobilisation techniques available in our institution (Figure 1); Arm A: headsponge plus triangular sponge under head with arms unsupported above the head holding on to the opposite elbow and Kneefix (Kneefix cushion from Sinmed), Arm B: BreastBoard dedicated immobilisation device, positioned at the smallest possible angle (5°) with hands clasping the opposite poles (Carbon Fibre BreastBoard from MedTec). Each pole can be positioned in one of the four locations to suit the patient. The forearm and upper-arm supports are removed. It is not possible to use the Kneefix with the BreastBoard due to the length of the device; and Arm C: LungBoard-dedicated immobilisation device (Mamma CT-Step LungBoard from Innovative Technology Volp) with C-shaped supports for the forearm and upperarm and Kneefix.

The manufacturers and distributors of these products had no influence in the design, conduct, analysis or reporting of the results of this research.

Overall study endpoint

To recommend a specific immobilisation technique for conformal lung radiotherapy patients in our institution based primarily on an evaluation of set-up accuracy.

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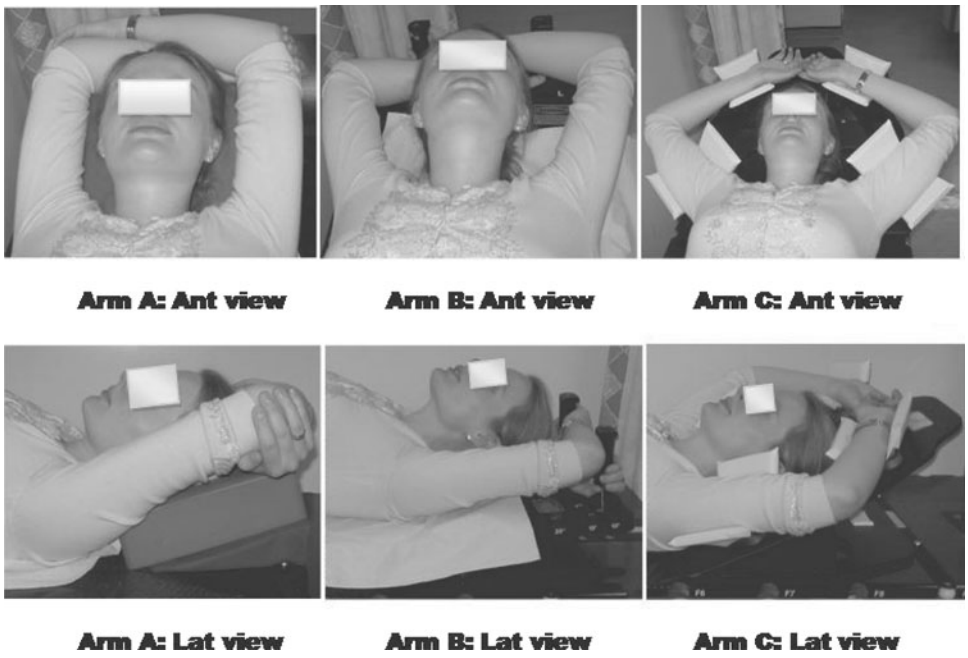

Figure 1. Anterior and lateral views of the immobilisation devices investigated—Arm A, headsponge; Arm B, BreastBoard; Arm C, LungBoard.

Primary objectives

- To evaluate and compare the treatment set-up accuracy of three immobilisation techniques using one-dimensional set-up error analysis.
- To determine and compare patients' comfort with the immobilisation techniques.

Secondary objectives

- To evaluate RTs' satisfaction with the immobilisation techniques.
- To examine and compare the cost effectiveness of the immobilisation techniques.

Inclusion criteria

- Histologically proven intra-thoracic malignancy: Non-small cell (NSCLC) and small cell (SCLC) lung carcinoma, oesophageal carcinoma, thymoma
- Treatment by 3-DCRT
- Age >18 years
- Provision of written informed consent in accordance with International Conference on Harmonisation guidelines for Good Clinical Practice (ICH-GCP).

Exclusion criteria

- Evidence of any significant clinical disorder that made it undesirable for the patient to participate or if it was felt by the research or medical team that the patient might not be able to comply with the protocol.

The trial was approved by the institution's Ethics and Medical Research Committee.

The methodology used for each study objective is described separately: treatment accuracy, patient comfort, RTs satisfaction, and cost effectiveness.

Treatment accuracy

All patients were CT scanned and treated by RTs in the supine position and breathed freely. The skin was tattooed at simulation. Scanned orthogonal simulator images (gantry at 0° and 90°/270°) were used as reference images,[22,23] because the direct transfer of digitally reconstructed radiographs (DRRs) to the electronic portal imaging (EPI) software—iViewGT—was not possible at the time of the study. All

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set-up parameters on the simulator exactly matched the CT, and the simulator images corresponded exactly to the DRRs from the treatment plan.[4] EPIs were obtained with an amorphous silicon flat panel EPID (Elekta).[24] Two orthogonal EPIs were obtained per imaged fraction during treatment. This method has been used by many investigators.[4,16,21,22] Three sets of orthogonal EPIs were obtained on week 1 of treatment and one set of images was obtained weekly thereafter, in line with published recommendations.[12,16] Set-up corrections were not applied to patient's treatment. A repeat image was requested if a discrepancy of >5 mm was detected on the EPI. If there was a discrepancy >5 mm in the repeated EPI, the patient underwent a check film procedure in the simulator.

When patients completed treatment, the field edge and bony anatomy were retrospectively outlined, by one RT, on reference images and EPIs.[21] Vertebrae were used as the rigid bony matching structures. The sternum was also used if it was visible on the images. Each EPI was electronically matched to the corresponding reference image,[21,22] by the RT using iViewGT match software. This RT was blinded regarding the patient's immobilisation device. A two-dimensional translational displacement of set-up error was automatically displayed on screen by the software. Set-up errors were reported in the x and y directions on the anterior images, and in the y and z directions on the lateral images. The y displacements were averaged for orthogonal image sets that were acquired on the same fraction. Therefore, set-up errors were evaluated in three orthogonal directions x, y and z for each immobilisation device. The measured set-up error also includes errors introduced by the generation of the reference image.[12] The accuracy of matching EPID images to reference images is of the order of 1 mm or 1°.[12] In addition, one patient's data was re-outlined and re-evaluated at a later date, to check the RTs repeatability. The systematic and random set-up errors (1 SD) were quantified using analysis of variance (ANOVA) for each orthogonal direction for each immobilisation device.[21,23] Significance of the differences between the treatment arms was determined using the F-test for equality of variances.[21]

Patient comfort

Patients scored their comfort using a Visual Analogue Scale (VAS) at the beginning and end of their radiotherapy course. Patients marked X on a 10 cm line ranging from ''very uncomfortable'' to ''completely comfortable'', immediately after their treatment session. This method is described by Cox 2005.[25] Comfort was also assessed objectively by the RT in the questionnaire.

RTs satisfaction

RTs satisfaction with the immobilisation techniques was investigated using a questionnaire. Because no relevant validated questionnaire exists, one was designed and piloted by RTs from the institution. The key features investigated were ease of patient set-up, overall patient stability, patient comfort, ease of cleaning and handling and storage.

Cost-effectiveness

The duration of daily treatment, number of repositions needed during daily treatment, number of check films required during the course of treatment and the cost of the individual devices were investigated.

RESULTS

Patient demographics are summarised in Table 1. A total of 62 patients were screened for eligibility before simulation during an 8-month period in 2005. In total, 16 patients were not eligible due to severe distress/anxiety ($n = 3$), negative experience with a clinical trial in another institution ($n = 1$), or treatment intention changed to palliative at simulation clinic ($n = 12$). The remaining 46 patients were recruited and randomised before their planning CT scan. However, 16 patients were subsequently withdrawn because their treatment changed to palliative before commencement of their radiotherapy. Thus, 30 patients who underwent a complete course of radical 3-DCRT were included in this trial. This sample size of 30 evaluable patients was chosen in

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Table 1. Patient demographics

Patient demographics		A: headsponge, $n = 10$	B: BreastBoard, $n = 10$	C: LungBoard, $n = 10$
Gender	Male/female	6/4	6/4	8/2
Age (years)	Range	48–75	42–80	46–74
	Median	61	64	66
Smoking status	Current/Ex-smoker	3/7	5/5	6/4
Diagnosis: lung Ca	NSCLC/SCLC	5/5	5/5	7/3
	IA and IB	2	2	1
	IIA and IIB	2	0	1
Stage NSCLC	IIIA and IIIB	0	1	5
	IV	1	1	0
	Data unavailable	0	1	0
Stage SCLC	Limited	All ($n = 5$)	All ($n = 5$)	All ($n = 3$)
		50 Gy/25#, $n = 1$	50 Gy/25#, $n = 1$	48 Gy/24#, $n = 1$
		60 Gy/30#, $n = 2$	60 Gy/30#, $n = 2$	50 Gy/25#, $n = 1$
Radiotherapy NSCLC	Dose/fractionation	66 Gy/33#, $n = 1$	60 Gy/28#, $n = 1$	56 Gy/28#, $n = 1$
		72 Gy/24#, $n = 1$	66 Gy/33#, $n = 1$	60 Gy/30#, $n = 3$
				66 Gy/33#, $n = 1$
Radiotherapy SCLC	Dose/fractionation	50 Gy/25#, $n = 5$	50 Gy/25#, $n = 5$	50 Gy/25#, $n = 2$
				54 Gy/27#, $n = 1$
Surgery NSCLC	Inoperable, post-op	$n = 5$ (1 refused), $n = 0$	$n = 4$, $n = 1$	$n = 6$, $n = 1$
Surgery SCLC	Inoperable, post-op	$n = 5$, $n = 0$	$n = 4$, $n = 1$	$n = 3$, $n = 0$
Chemotherapy NSCLC	Concom, Neo-adj, No	$n = 1$, $n = 3$, $n = 1$	$n = 3$, $n = 1$, $n = 1$	$n = 2$, $n = 5$, $n = 0$
Chemotherapy SCLC	Concom, Neo-adj, No	$n = 4$, $n = 1$	$n = 4$, $n = 1$	$n = 3$, $n = 0$

advance based on published studies investigating patient set-up that had sample sizes ranging from 5 to 30 patients.[1,5,12,17–23] Ten patients were randomised to each arm. Apart from being randomised to a specific immobilisation device, all other aspects of a patient's treatment were in accordance with institutional standard practice. The results are presented in the following four sections according to the study objectives.

Evaluation of set-up errors

A total of 462 EPIs were acquired on 30 patients. Of them, 29 EPIs were not evaluable due to poor image quality and metal couch bar visible in the EPI. Set-up errors were measured and reported on 433 EPIs, by one RT. The minimum usable EPI measurement in a patient was 20. The average was 28, 30 and 28 for Arms A, B and C, respectively.

Table 2 demonstrates the one-dimensional SDs of the random and systematic set-up errors for each of the three orthogonal directions—x, y and z, for each immobilisation device, calculated using ANOVA. The SDs of the one-dimensional set-up errors ranged from 1.26 to 4.92 mm for the systematic errors and 2.09–5.18 mm for the random errors (Table 2). The results in Table 2 indicate that there is some evidence that the SD of the set-up errors are higher in Arm A but the difference is not large enough to be statistically significant in all cases. The random errors are significantly larger for Arm A compared to Arm C for all (x, y and z) directions, $p = 0.004$, 0.017 and 0.027, respectively. The random errors are significantly larger for Arm A compared to Arm B for y and z directions, $p = 0.001$ for both. The statistical analyses indicated that Arms B and C were very similar. Therefore, Arm A (no immobilisation device) was compared with pooled Arms B+C (dedicated immobilisation devices). When data from Arms B and C are pooled, the random errors are statistically significantly larger for all directions—x, y and z for Arm A, $p = 0.023$, 0.001 and 0.001, respectively, and the systematic error is statistically significantly larger for the z direction $p = 0.044$.

The RT's repeatability in outlining match structures and determining the set-up errors was found, on average, to be <0.2 mm ($p = 0.29$). Published inter-observer variation in contouring the structures for matching was found to be 0.9

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and 1.3 mm (1 SD), respectively, in the lateral and longitudinal direction (AP images only).[20]

Because of the inconsistencies in the methods of analysing and presenting results of set-up inaccuracies in the published literature, analysis was also performed on 2D and 3D set-up error vectors for completeness in this study. The results in Table 3 indicate that there is some evidence that the displacements are higher in Arm A for both anterior and lateral images, but the difference is not large enough to be statistically significant in all cases. The random and systematic errors are significantly larger for Arm A compared to Arm B for the lateral images ($p = 0.001$ and 0.023, respectively). The random errors are significantly larger for Arm A compared to Arm C for the anterior images ($p = 0.011$). The difference between Arm A and pooled Arms B+C is statistically significant for the random errors on the anterior image, $p = 0.017$, and for both the random and systematic errors for the lateral images $p = 0.034$ and 0.007, respectively.

A 3D vector length was calculated to incorporate all three directions of set-up errors for each patient, i.e. x, y and z. The SD of the systematic and random set-up errors was calculated for each immobilisation device and is presented in Table 4. SDs of the 3D vector length set-up errors appear to be greater with Arm A. However, when statistical analysis of the SD was carried out, using the *F*-test for pair-wise comparisons, statistically significant differences between the three immobilisation techniques was identified for the random errors only.

Table 2. *Overall mean, random and systematic errors (1 SD) for x, y and z directions (mm), for each immobilisation device calculated using ANOVA, and the F-test P-values for pair-wise comparisons*

					***P* value (*F*-test)**			
1D set-up errors	**Arm A**	**Arm B**	**Arm C**	**Pooled B+C**	**A versus B**	**A versus C**	**B versus C**	**A versus B+C**
x Mean error	0.93	−0.64	0.13	−0.28				
x Systematic SD	2.37	2.21	1.92	2.05	0.842	0.541	0.679	0.566
x Random SD	3.06	2.63	2.09	2.40	0.228	**0.004**	0.073	**0.023**
y Mean error	0.38	−1.37	−1.21	−1.29				
y Systematic SD	2.31	1.26	2.39	1.83	0.085	0.923	0.070	0.370
y Random SD	3.52	2.39	2.62	2.50	**0.001**	**0.017**	0.433	**0.001**
z Mean error	−0.42	−0.26	0.54	0.14				
z Systematic SD	4.92	2.55	3.26	2.86	0.063	0.237	0.473	**0.044**
z Random SD	5.18	3.31	3.89	3.61	**0.001**	**0.027**	0.199	**0.001**

Significant results are in bold face.

Table 3. *Overall mean, random and systematic errors (1 SD) for 2D set-up error vectors (mm), for each immobilisation device, and the F-test P values for pair-wise comparisons*

					***P* value (*F*-test)**			
2D set-up errors	**Arm A**	**Arm B**	**Arm C**	**Pooled B+C**	**A versus B**	**A versus C**	**B versus C**	**A versus B+C**
Anterior image								
2D vector, mean error	5.49	4.33	4.17	4.26				
Systematic SD	1.64	1.52	0.90	1.22	0.819	0.087	0.133	0.265
Random SD	2.73	2.25	1.95	2.11	0.121	**0.011**	0.266	**0.017**
Lateral image								
2D vector, mean error	6.71	4.61	5.19	4.90				
Systematic SD	2.38	1.05	1.62	1.34	**0.023**	0.271	0.211	**0.034**
Random SD	4.02	2.67	3.31	3.00	**0.001**	0.128	0.087	**0.007**

Significant results are in bold face.

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Table 4. Overall mean, random and systematic errors (1 SD) for 3D set-up error vectors (mm), for each immobilisation device, and the F-test P values for pair-wise comparisons

3D set-up errors					*P* value (*F*-test)			
(*x*, *y*, *z*) 3D vector	Arm A	Arm B	Arm C	Pooled B+C	A versus B	A versus C	B versus C	A versus B+C
3D vector, mean error	7.65	5.49	6.06	5.76				
Systematic SD	1.67	1.36	1.86	1.59	0.555	0.744	0.362	0.820
Random SD	3.87	2.29	2.98	2.65	**0.000**	0.059	**0.047**	**0.001**

Significant results are in bold face.

Set-up error margins

Set-up error margins were calculated using the Van Herk Margin Recipe formula[11]: margin $= 2.5\Sigma + 0.7\sigma$ where the SD of the systematic error (Σ) and the SD of the random error (σ) were calculated for each direction based on 1D errors (x, y and z), for each immobilisation device (Table 5). It is clear that the headsponge Arm requires the largest margin for set-up errors when compared to the use of a specific immobilisation device.

Table 5. Set-up error margins (mm) for x, y and z directions for each immobilisation device, based on Van Herk's margin recipe

Direction	A: headsponge	B: BreastBoard	C: LungBoard
x	8	7	6
y	8	5	8
z	16	9	11

Patient comfort using VAS

The variability of comfort scores was smaller in Arm C than that in A and B. Therefore, the Kruskal–Wallis (K–W) non-parametric analysis was performed on the patients' comfort VAS. The Mann–Whitney (M–W) non-parametric test was used to perform pair-wise comparisons: A versus B, A versus C and B versus C. The median comfort scores and pair-wise comparisons at the beginning and end of radiotherapy are shown in Table 6. The analysis demonstrates statistically significantly higher comfort scores (more comfortable) for patients randomised to Arm C, at the beginning and end of treatment.

RT satisfaction survey

A total of 153 questionnaires were completed by RTs, on all patients, at each stage of their radiotherapy process; simulation ($n = 45$), planning CT-scan ($n = 45$), verification ($n = 33$) and treatment ($n = 30$). Questionnaires were completed on the patients who were withdrawn from the trial before starting treatment. Thus, the numbers of completed questionnaires exceeded 30 for the pre-treatment procedures. The LungBoard was the preferred device amongst RTs for ease of patient set-up, overall immobilisation stability, patient comfort, and ease of cleaning, handling and storage. Overall, the LungBoard was the recommended device for continued use in the department.

Cost-effectiveness

An economic analysis was not conducted on the three arms. However, some surrogate parameters are presented. Only one patient (Arm A) required a repeat simulation procedure (check film) because of discrepancies detected on the EPIs. Scanning simulation films, registering images, delineating match structures, matching EPIs and reference images, and recording results took on average 100 minutes/patient. In total, 755 daily treatment times were recorded on 30 patients. The treatment times were statistically significantly lower for Arm C compared to Arm B ($p = 0.045$) using the M–W non-parametric test (Table 7). The maximum treatment times were statistically significantly lower for Arm C when compared to either Arm A or Arm B ($p = 0.03$ and 0.001, respectively).

The number of repositions during 762 treatment sessions was recorded on 30 patients.

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Table 6. Analysis of patients' comfort scores at the beginning and end of radiotherapy (10-cm scale)

Arm	Median comfort score: Start RT	Pair-wise comparisons (M–W test)	Overall comparison (K–W test)
A: headsponge	5.5	A versus C, $p = 0.028$	
B: BreastBoard	4	B versus C $p = 0.006$	$p = 0.009$
C: LungBoard	9	A versus B $p = 0.290$	
Arm	**Median comfort score: End RT**	**Pair-wise comparisons (M–W test)**	**Overall comparison (K–W test)**
A: headsponge	7.8	A versus C, $p = 0.009$	
B: BreastBoard	7.0	B versus C, $p = 0.035$	$p = 0.022$
C: LungBoard	9.5	A versus B, $p = 0.910$	

Table 7. Mann–Whitney non-parametric analysis of the median and maximum treatment times for the three immobilisation devices

	Arm A	Arm B	Arm C	M–W pairwise comparisons
Median of median treatment times per arm	9.505	9.988	9.075	A versus B, $p = 0.43$ A versus C, $p = 0.38$ B versus C, $p = 0.045$
Median of maximum treatment times per arm	20.33	21.77	17.29	A versus B, $p = 0.73$ A versus C, $p = 0.03$ B versus C, $p = 0.001$

The results of comparisons of either the median or maximum number of repositions were not significantly different for any immobilisation device ($p > 0.05$). The actual costs to purchase the devices in the Republic of Ireland (including Value Added Tax) in 2006 are BreastBoard = €12,500, LungBoard = €2,250 and headsponge + triangular sponge €89.

DISCUSSION

Set-up errors must be evaluated in individual institutions because differences in working procedures, staff experience, treatment techniques, technology and immobilisation devices will cause different magnitude of errors.[12,23] Published set-up errors can be used as a benchmark but cannot be assumed to occur in an institution. Reporting set-up errors as SD of the random and systematic set-up errors for three orthogonal directions, as in this study, permits comparison of results with other institutions because this method of reporting errors is a commonly accepted method.[4,12,16] These results can also be used directly to calculate the set-up margin[11] and in the design of action level correction protocols.

By reference to the available literature the uncorrected set-up errors of lung 3-DCRT patients in this trial appear acceptable. Similarly the SDs (and range) of the random set-up errors are very similar to the SDs (and range) of the systematic set-up errors as reported by Hurkman et al.[12] Examples of SD of uncorrected systematic errors in the x, y and z directions in the literature are 3.3, 4.4 and 2.2 mm, respectively,[16] and 3.2, 3.6 and 1.7 mm, respectively.[4] The corresponding errors in this study for the LungBoard are 1.92, 2.39 and 3.26 mm, BreastBoard are 2.21, 1.26 and 2.55 mm, and headsponge are 2.37, 2.31 and 4.92 mm, respectively. The random and systematic errors in the z-direction seem larger for this study when compared with the published literature. One possible explanation for this is that Table-Top-Height is not used as a treatment set-up

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parameter in our institution. However, for the BreastBoard and the LungBoard, the magnitude of this z-direction set-up error is still within the 3.5 mm "state of the art" recommendation.[12] When the 1D set-up errors are analysed for each immobilisation device separately, it is clear that the errors are equivalent or less for patients randomised to an immobilisation device in comparison to no immobilisation device (headsponge). For the headsponge, the 1D systematic and random set-up errors (1 SD) are significantly larger in the z-direction ($p = 0.044$ and 0.001, respectively), and the random set-up errors (1 SD) are significantly larger in the x and y directions ($p = 0.023$ and 0.001, respectively).

The purpose of investigating possible displacements during treatment relative to the planned position is to define appropriate planning margins to account for set-up uncertainties, as well as to identify efficient methods to ensure or reduce these margins.[4,10–13,16,23] Numerous investigators have developed margin recipes. The published margin recipes that differentiate between random and systematic errors are well described by Van Herk and were used in this trial.[11] The margins derived reflect the impact of the specific immobilisation device on set-up accuracy (Table 5). It is clear that larger margins for set-up uncertainty are needed for the headsponge in comparison with either of the immobilisation devices investigated and the margins required for the BreastBoard and LungBoard are similar. The magnitude of systematic set-up errors and therefore margins can be reduced by the application of an off-line set-up correction protocol without changing the treatment technique itself.[4,11–13,16,20,22,23]

One shortcoming of the inherently 2D technique used in this trial is the failure to incorporate out-of-plane rotations that could deform the 2D projections.[23] However, out-of-plane rotations $<3°$ in general do not cause an important deformation of the projected anatomy in portal images and lead to acceptable accuracy of the 2D registration of set-up errors.[12,23] For lung cancer patients, the published rotational errors are 0.9 and 1.0° in the coronal and sagittal planes, respectively[21] and 1.6 and 1.3°, respectively.[4] Therefore, rotations were not taken into account in this and other similar studies and were assumed to be invariant under translation.[5,10] Analysis of intra-fraction variation in set-up would have required additional resources including radiation exposure to the patient and was beyond the scope of this trial. Another limitation was that patients were randomised to only one immobilisation device for treatment.

A comfortable treatment position in radiotherapy promotes patient stability and contributes to the best possible patient experience.[25] Patients may move if they do not feel comfortable, thereby reducing the accuracy of treatment. It is therefore essential when selecting a treatment position to know which is the most comfortable for the patient.[25] The analysis of patient comfort scores demonstrated that patients significantly preferred the LungBoard. Considering the fact that the treatment set-up accuracy qualities of the BreastBoard and the LungBoard devices are not different, it is imperative that patients' comfort should be the deciding factor when choosing the optimal immobilisation device. The data in Table 6 shows that patients seem to adjust to their treatment position during the course of treatment and they found the LungBoard more comfortable from the outset. The LungBoard was the immobilisation device of choice by both patients and staff in this trial.

Regarding resource implications, the daily treatment times were less for patients immobilised with the LungBoard and the cost of the LungBoard is very favourable in comparison with that of the BreastBoard. There was no difference between treatment Arms in terms of the numbers of check film procedures in the simulator.

CONCLUSION

This is the first prospective randomised controlled clinical trial on lung immobilisation devices, which is based on 3-DCRT and takes into account treatment accuracy, users satisfaction and resource implications. The LungBoard

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provides similar treatment accuracy in terms of set-up errors, compared to the BreastBoard and better accuracy compared to the headsponge. When compared to the BreastBoard and headsponge, the LungBoard is more comfortable for patients, easier for patients and RTs to use, and is considerably less expensive. Based on the evidence from this trial, the LungBoard is the immobilisation device of choice for lung 3-DCRT patients in our institution. The set-up error data analysed in this study permits a protocol for off-line correction of patient set-up to be devised for lung 3-DCRT in our institution, and allows for the appropriate PTV margins for set-up deviations to be applied. The proper implementation of an off-line correction protocol with decision rules based on set-up errors will ultimately permit reduction of the set-up errors and therefore reduction of the appropriate margins.

References

1. Essapen S, Knowles C, Norman A, Tait D. Accuracy of set-up of thoracic radiotherapy: prospective analysis of 24 patients treated with radiotherapy for lung cancer. Br J Radiol 2002; 75: 162–169.
2. Schwarz M, Alber M, Lebesque JV, Mijnheer BJ, Damen EM. Dose heterogeneity in the target volume and intensity-modulated radiotherapy to escalate the dose in the treatment of non-small-cell lung cancer. Int J Radiat Oncol Biol Phys 2005; 62: 561–570.
3. Grills IS Yan D, Martinez AA, Vicini FA, Wong JW, Kestin LL. Potential for reduced toxicity and dose escalation in the treatment of inoperable non-small-cell lung cancer: a comparison of intensity-modulated radiation therapy (IMRT), 3D conformal radiation, and elective nodal irradiation. Int J Radiat Oncol Biol Phys 2003; 57: 875–890.
4. de Boer HC, van Sörnsen de Koste JR, Senan S, Visser AG, Heijmen BJ. Analysis and reduction of 3D systematic and random setup errors during the simulation and treatment of lung cancer patients with CT-based external beam radiotherapy dose planning. Int J Radiat Oncol Biol Phys 2001; 49: 857–868.
5. Engelsman M, Remeijer P, van Herk M, Lebesque JV, Mijnheer BJ, Damen EM. Field size reduction enables iso-NTCP escalation of tumor control probability for irradiation of lung tumors. Int J Radiat Oncol Biol Phys 2001; 51: 1290–1298.
6. McGibney C, Holmberg O, McClean B, Williams C, McCrea P, Sutton P, Armstrong J. Dose escalation of chart in non-small cell lung cancer: is three-dimensional conformal radiation therapy really necessary? Int J Radiat Oncol Biol Phys 1999; 45: 339–350.
7. Armstrong JG. Target volume definition for three-dimensional conformal radiation therapy of lung cancer. Br J Radiol 1998; 71: 587–594.
8. Armstrong JG, Burman C, Leibel S, Fontenla D, Kutcher G, Zelefsky M, Fuks Z. Three-dimensional conformal radiation therapy may improve the therapeutic ratio of high dose radiation therapy for lung cancer. Int J Radiat Oncol Biol Phys 1993; 26: 685–689.
9. Rosenthal SA, Roach M 3rd, Goldsmith BJ, Doggett EC, Pickett B, Yuo HS, Soffen EM, Stern RL, Ryu JK. Immobilization improves the reproducibility of patient positioning during six-field conformal radiation therapy for prostate carcinoma. Int J Radiat Oncol Biol Phys 1993; 27: 921–926.
10. Schwarz M, Van der Geer J, Van Herk M, Lebesque JV, Mijnheer BJ, Damen EM. Impact of geometrical uncertainties on 3D CRT and IMRT dose distributions for lung cancer treatment. Int J Radiat Oncol Biol Phys 2006; 65: 1260–1269.
11. van Herk M. Errors and margins in radiotherapy. Semin Radiat Oncol 2004; 14: 52–64.
12. Hurkmans CW, Remeijer P, Lebesque JV, Mijnheer BJ. Set-up verification using portal imaging; review of current clinical practice. Radiother Oncol 2001; 58: 105–120.
13. van Herk M, Remeijer P, Rasch C, Lebesque JV. The probability of correct target dosage: dose-population histograms for deriving treatment margins in radiotherapy. Int J Radiat Oncol Biol Phys 2000; 47: 1121–1135.
14. McKenzie AL, van Herk M, Mijnheer B. The width of margins in radiotherapy treatment plans. Phys Med Biol 2000; 45: 3331–3342.
15. Stroom JC, de Boer HC, Huizenga H, Visser AG. Inclusion of geometrical uncertainties in radiotherapy treatment planning by means of coverage probability. Int J Radiat Oncol Biol Phys 1999; 43: 905–919.
16. Erridge SC, Seppenwoolde Y, Muller SH, van Herk M, De Jaeger K, Belderbos JS, Boersma LJ, Lebesque JV. Portal imaging to assess set-up errors, tumor motion and tumor shrinkage during conformal radiotherapy of non-small cell lung cancer. Radiother Oncol 2003; 66: 75–85.
17. Bentel GC, Marks LB, Krishnamurthy R. Impact of cradle immobilization on setup reproducibility during external beam radiation therapy for lung cancer. Int J Radiat Oncol Biol Phys 1997; 38: 527–531.
18. Van de Steene J, Van den Heuvel F, Bel A et al. Electronic portal imaging with on-line correction of setup error in thoracic irradiation: clinical evaluation. Int J Radiat Oncol Biol Phys 1998; 40: 967–976.
19. Ekberg L, Holmberg O, Wittgren L, Bjelkengren G, Landberg T. What margins should be added to the clinical

target volume in radiotherapy treatment planning for lung cancer? Radiother Oncol 1998; 48: 71–77.

20. Samson MJ, van Sörnsen de Koste JR, de Boer HC, Tankink H, Verstraate M, Essers M, Visser AG, Senan S. An analysis of anatomic landmark mobility and setup deviations in radiotherapy for lung cancer. Int J Radiat Oncol Biol Phys 1999; 43: 827–832.
21. Halperin R, Roa W, Field M, Hanson J, Murray B. Setup reproducibility in radiation therapy for lung cancer: a comparison between T-bar and expanded foam immobilization devices. Int J Radiat Oncol Biol Phys 1999; 43: 211–216.
22. Negoro Y, Nagata Y, Aoki T, Mizowaki T, Araki N, Takayama K, Kokubo M, Yano S, Koga S, Sasai K, Shibamoto Y, Hiraoka M. The effectiveness of an immobilization device in conformal radiotherapy for lung tumor: reduction of respiratory tumor movement and evaluation of the daily setup accuracy. Int J Radiat Oncol Biol Phys 2001; 50: 889–898.
23. Remeijer P, Geerlof E, Ploeger L, Gilhuijs K, van Herk M, Lebesque JV. 3-D portal image analysis in clinical practice: an evaluation of 2-D and 3-D analysis techniques as applied to 30 prostate cancer patients. Int J Radiat Oncol Biol Phys 2000; 46: 1281–1290.
24. O'Shea E, Thirion P, Downes A et al. ''Electronic Portal Imaging Devices''. J Irish Inst Radiogr 2002; 6: 166–168.
25. Cox J, Davison A. Comfort as a determiner of treatment position in radiotherapy of the male pelvis. Radiography 2005; 11: 109–115.

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