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Scientific Article

A comparison of interfraction setup error, patient comfort, and therapist acceptance for 2 different prostate radiation therapy immobilization devices

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Abstract

Purpose: Our purpose was to investigate interfraction setup error of the immobilization device required to implement transperineal ultrasound compared with the current, standard immobilization device. Patient comfort and radiation therapist (RT) satisfaction were also assessed.

Methods and materials: Cone beam computed tomography images were acquired before 4069 fractions from 111 patients (control group, n = 56; intervention group, n = 55) were analyzed. The intervention group was immobilized using the Clarity Immobilization System (CIS), comprising a knee rest with autoscan probe kit and transperineal ultrasound probe (n = 55), and control group using a leg immobilizer (LI) (n = 56). Interfraction setup errors were compared for both groups. Weekly questionnaires using a 10-point visual analog scale were administered to both patient groups to measure and compare patient comfort. RT acceptance for both devices was also compared using a survey.

Results: There was no significant difference in the magnitude of interfraction cone beam computed tomography–derived setup shifts in the lateral and anteroposterior direction between the LI and CIS ($P = .878$ and .690, respectively). However, a significant difference ($P = .003$) was observed in the superoinferior direction between the 2 groups of patients. Patient-reported level of comfort and stability demonstrated no significant difference between groups ($P = .994$ and .132). RT user acceptance measures for the LI and CIS were ease of handling (100% vs 53.7%), storage (100% vs 61.1%), and cleaning of the devices (100% vs 64.8%), respectively.

Conclusions: The CIS demonstrated stability and reproducibility in prostate treatment setup comparable to LI. The CIS device had no impact on patient comfort; however, RTs indicated a preference for LI over the CIS mainly because of its weight and bulkiness.

Conflicts of interest: None.

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Introduction

Robustness of immobilization systems and devices in radiation therapy has always been an imperative aspect in patient positioning and setup. Because of the desire to reduce setup errors to a negligible level, a wide range of commercialized immobilization devices have been designed. In prostate radiation therapy, variations in practice exist between different hospitals, ranging from the use of a simple device such as a leg immobilizer (LI) or thermoplastic shell, to a more sophisticated, multicomponent body-fix device. At the other end of the spectrum, others use invasive options such as endorectal balloons.[1-5] Several factors, such as ease of and time taken for setup, storage, and robustness, in addition to residual setup errors, are usually considered before clinical implementation of an immobilization device.[6,7]

In our center, we traditionally use a simple foam cushion LI (Civco Medical Solutions, IA) for positioning of prostate patients during radiation therapy. In 2011, Siow et al reported interfraction mean setup errors of 0.1 mm (range, −2.3 to 1.2), 0.1 mm (range, −2.3 to 1.7) and 0.1 mm (range, −1.3 to 1.5) in the right-left (x), anteroposterior (y), and superoinferior (z) directions, respectively, for 36 patients treated in our hospital between 2006 and 2008 using an empty bladder protocol and orthogonal imaging.[8] Since 2013, however, all prostate patients have been treated with a full bladder protocol because of the advantage of small bowel displacements and reduced gastrointestinal and genitourinary side effects. Additionally, their position is now verified using daily 3-dimensional cone beam computed tomography (CBCT).

Recently, our department has placed more emphasis on the accuracy and consistency of the treatment setup position because of our interest in the use of hypofractionation and dose escalation for prostate radiation therapy. The application of real-time imaging using the 4-dimensional (4D) Clarity transperineal ultrasound (TPUS) system (Elekta AB, Stockholm, Sweden) to monitor prostate motion during treatment has become increasingly popular in the literature, with reliable system accuracy and potential in achieving better treatment outcomes.[9-12] More recently, Trivedi et al has further demonstrated the capability of the Clarity TPUS system in achieving comparable accuracy compared with the fiducial-based CT localization of the prostate gland.[13] Before adopting this system, however, radiation therapists (RTs) needed to implement a more elaborate immobilization device for separating the patients' legs to facilitate the positioning of the ultrasound probe. To our knowledge, this is the first paper to evaluate the usability of the Clarity Immobilization System (CIS) from the perspective of patients and the RTs. This study aims to investigate the level of comfort and stability of treatment position using CIS as perceived by patients. More importantly, the interfraction setup errors between the 2 immobilization devices (LI vs CIS) will be compared and RT perspectives on the handling, storage, and cleaning will be assessed.

Methods and materials

This was a prospective, nonrandomized study to compare treatment setup between 2 immobilizing devices. Ethics approval was obtained from the SingHealth Centralised Institutional Review Board in November 2014, and informed consent was obtained from each participant. The study is registered on the National Institutes of Health (NIH) clinical trial registry (ID: NCT02408497). From March 2015, this study enrolled 111 patients who were treated in 2 groups (55 patients in the intervention group and 56 in the control group) for 12 months. All patients were prescribed radical volumetric modulated arc therapy (74 Gy in 37 fractions) to the prostate (±seminal vesicles and pelvic nodes). Patients treated in the intervention group were part of an ongoing prospective study to evaluate the use of real-time tracking of the target volume in prostate radiation therapy using the noninvasive Clarity TPUS system. Patients in the intervention group were immobilized with the CIS, and patients in the control group were immobilized with the LI, which is used traditionally in the department (Fig 1). Patients immobilized with the CIS were treated with the TPUS probe in place. The TPUS probe position was guided and reproduced daily by an optical camera that detected the fiducial markers mounted on the probe. The setup and placement of the TPUS probe was completed by the same group of trained RTs throughout the study. Exclusion criteria included postprostatectomy and stereotactic body radiation therapy prostate cases.

Imaging protocol

Patients were instructed to follow a full bladder preparation protocol. After initially emptying their bladder 30 minutes before the radiation therapy session, patients

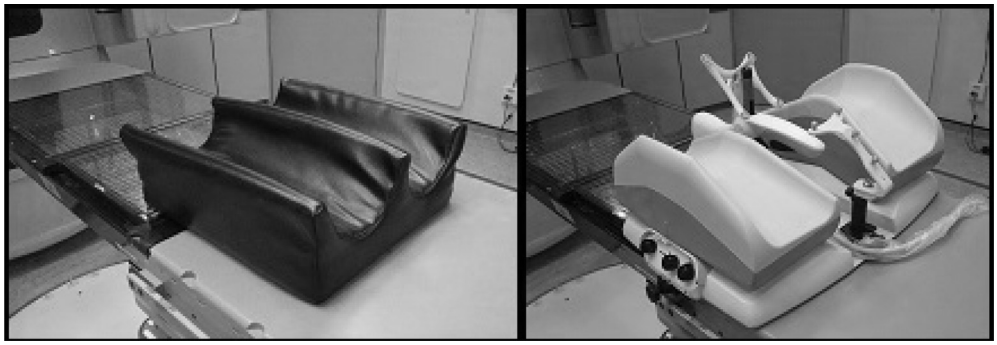

Figure 1 Illustrates the leg immobilizer (left) and Clarity Immobilization System (right) used in the control and intervention groups, respectively.

were then required to drink 2 cups of water (400 mL). No specific bowel emptying protocol was given, but all patients were encouraged to evacuate their bowels before the treatment. Pretreatment CBCT images were acquired for all patients (115 kV, 80 mA; 15 ms) on a daily basis using the on-board imager, version 1.5, using a half-fan bowtie filter on a Varian Trilogy Linac (Varian Medical Systems, PA). Each CBCT contributed approximately 17.7 mGy imaging dose.[14]

During online image registration, automatic matching within a region of interest was performed using the on-board imager bony matching algorithm. Bladder and rectal volumes (including rectal content) were visually assessed for consistency against the planning CT. Manual fine-tuning based on soft-tissue coregistration was then completed by the RTs using a coned down region of interest including the prostate and seminal vesicles for coverage by the primary planning target volume. For large-field treatments including pelvic nodes, this manual registration was limited to maximum deviation of $\leq$5 mm from the initial bony match to ensure nodal volume coverage. The 2 different immobilization devices were assessed based on the magnitude of daily interfraction CBCT-derived setup errors during prostate radiation therapy.

Patient and RT satisfaction survey

To investigate the comfort level of each setup position from the patients' perspective, a 2-question questionnaire using a 10-point visual analog scale (scale, 1-10) was administered once per week to both patient groups (Appendix E1, available as supplementary material online only at www.practicalradon.org). A 10-point rating scale was used because it contained multiresponse points without the complication of words.[15] The questionnaire was adapted from the validated questions previously used by Nutting et al and Howlin et al.[16,17] The shift toward a higher score would imply an increase in discomfort and lack of stability in position during treatment. The population mean (μ) and standard deviation (σ) score for each question will be reported.

Additionally, an evaluation of each device by the treating RTs was conducted using a visual analog scale and analyzed (Appendix E2). For each patient, the user perspectives from the RTs were taken into account to consider multiple factors such as ease of handling, storage, and cleaning. Table C1 (in Appendix E3) details the different requirements related to each of these factors for the 2 immobilization devices. Unstructured comments from the questionnaires were analyzed in Excel for each group, and numbers of positive and negative comments were counted.

Statistical analysis

An independent-samples *t* test was performed using PASW for Windows, version 18.0 (SPSS Inc, Chicago, IL) to compare the individual mean interfraction setup errors between the 2 groups of patients treated. Patient and the RT satisfaction in terms of comfort level and the use of the positioning devices were also analyzed accordingly.

Results

Interfraction setup shifts

A total of 4069 fractions from 111 patients (ie, control group [n = 56] and intervention group [n = 55]) was analyzed. Table 1 summarizes the mean and standard deviation of the interfraction setup shifts derived using CBCT for both control and intervention groups. A smaller mean setup error was observed in the superoinferior (z-plane) for the intervention group compared with the control group.

An independent-sample *t* test was conducted to compare the individual mean CBCT-derived setup shifts between the 2 groups of patients immobilized using either the LI or CIS. Table 2 illustrates the results of the independent-sample *t* test. There was no significant difference in the CBCT-derived setup shifts in the lateral (x-plane) and anteroposterior (y-plane) direction for LI and

Table 1 Comparison of interfraction setup shifts for control versus intervention groups

	Control group (LI) (n = 56)		Intervention group (CIS) (n = 55)	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
Right-left (x-plane)	−0.1	1.7	−0.1	1.9
Anteroposterior (y-plane)	2.4	2	2.2	2.8
Superoinferior (z-plane)	1.1	1.5	0	2

CBCT, cone beam computed tomography; CIS, Clarity Immobilizer System; LI, leg immobilizer; SD, standard deviation.

Table 3 Population scores for the patient satisfaction survey on comfort level of treatment position and the ability to maintain treatment during treatment delivery

	Control group (LI) (n = 56)		Intervention group (CIS) (n = 55)	
	Overall mean	SD	Overall mean	SD
Comfort level of immobilizer	1.3	0.58	1.3	0.46
Ability to stay still and maintain treatment position during treatment delivery	1.2	0.42	1.4	0.5

See Table 1 for abbreviations.

CIS (P = .878 and .690, respectively). However, there was a significant difference observed in the superior/inferior (z-plane) direction between the 2 groups of patients, with a larger μ setup error observed in the control group versus intervention group (P = .003).

Patient perspectives

The population μ (σ) score for patient comfort level of treatment position and the ability to stay still and maintain treatment position during treatment delivery were comparable between the 2 groups. Both the control and intervention groups have achieved a relatively low overall mean score of less than 1.5 of 10. The population scores for the patient satisfaction survey on comfort level of the treatment position and the ability to maintain treatment during treatment delivery is summarized in Table 3. Patient-reported level of comfort and stability demonstrated no significant difference between groups (P = .994 and .132). Table 4 illustrates the result of independent-sample t test for perceived comfort level and stability of the immobilizer devices by 2 groups of patients (LI vs CIS).

RT perspectives

Table 5 summarizes the responses from RT perceptions and evaluation of the immobilizer devices for both control and intervention groups (ie, LI vs CIS). Five different aspects of using the setup devices were investigated. After accounting for missing data (1 survey form was left empty in each patient group) the LI outperformed CIS (100% vs 51.9% to 64.8%). Similarly, overall ratings in terms of stability of the patients immobilized on the devices gathered 100% vs 57.7% as the LI is preferred over the CIS (3 missing data for the intervention group). Table C2 (in Appendix E3) summarizes the responses of the RTs' perceptions and evaluation about the overall stability of the immobilizer devices for both groups.

Of the 55 RT questionnaires in the intervention group, there were 32 positive and 38 negative comments about the CIS, compared with 28 positive and 4 negative comments about the LI. The comments were categorized into themes with some comments contributing in different themes. Positive comments in the intervention group included "easy to use and stable" (43.8%) and "legs were well rested on knee rest" (21.7%). Negative comments

Table 2 Independent-sample t test for the comparison of CBCT-derived setup shifts for the 2 groups of patients (LI vs CIS)

Independent-samples test						
	Levene test for equality of variances	t test for equality of means				
	Sig.	Sig. (2-tailed)	Mean difference	SE Difference	95% CI of the difference	
					Lower	Upper
x						
Equal variances assumed	0.93	0.88	0.00528	0.03417	−.06244	.07299
y						
Equal variances not assumed	0.005	0.69	−0.01821	0.04556	−.10863	.07220
z						
Equal variances assumed	0.12	0.003	−0.10079	0.03313	−.16646	−.03511

CI, confidence interval; sig., significance. See Table 1 for other abbreviations.

Table 4 Result of independent-sample *t* test for perceived comfort level and stability of the immobilizer devices by 2 groups of patients (LI vs CIS)

Independent-samples test						
	Levene test for equality of variances	*t* test for equality of means				
	Sig.	Sig. (2-tailed)	Mean difference	SE difference	95% CI of the difference	
					Lower	Upper
Comfort level						
Equal variances assumed	0.41	0.99	−0.00078	0.10090	−.20076	.19920
Stability						
Equal variances assumed	0.36	0.13	−0.13542	0.08922	−.31225	.04141

SE, standard error. See Tables 1 and 2 for abbreviations.

were categorized into 2 main themes: "heavy" (55.3%) and "knee rest was not indexed and reproducibility issue" (47.4%). On the other hand, positive comments in the control group were categorized into 2 main themes: "easy to use and stable" (89.3%) and "lightweight" (21.4%). All the negative comments captured in the control group can be represented in a single theme; "LI not indexed and reproducibility issue."

Discussion

Interfraction setup shifts

This study found that the CIS is a stable immobilization device for daily treatment positioning and is able to achieve high reproducibility compared with the LI. It was also notable that the population overall μ interfraction setup errors in the z-plane (ie, superoinferior) were relatively smaller compared with the LI.

These findings were in agreement with the previous paper by Palombarini et al,[18] who reported mean interfraction prostate motion to be 2.7 mm (±0.7 mm) in the anteroposterior direction and <1-mm shifts in the lateral and superoinferior directions. From the comparison of the CBCT-derived setup shifts between the 2 groups of patients, it is apparent that the intervention group has achieved an acceptable stability and demonstrated reliability in prostate treatment setup. The results of the improved reproducibility in the superoinferior plane for the intervention group that used the CIS may be attributed to the placement of the TPUS probe at the perineum (indexed on the autoscan probe kit), which potentially restricted motion in the longitudinal plane during daily treatment setup.

Patients' perspectives

All patients reported a favorable experience with the use of the CIS in terms of comfort level and their ability to maintain position during treatment. Most important, the

Table 5 Summary of RTs perceptions and evaluation about immobilizer devices for both the control and intervention groups (LI vs CIS)

	Ease of handling	Ease of storage	Ease of cleaning	Achieving patient comfort	Ease of setup
Control group (n = 56)					
Very easy (%)	70.9	69.1	65.5	54.5	58.2
Easy (%)	29.1%	30.9%	34.5%	45.5%	41.8
Difficult (%)	0.0%	0.0%	0.0%	0.0%	0.0
Very difficult (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Missing (n)	1	1	1	1	1
Very easy + easy (%)	100.0	100.0	100.0	100.0	100.0
Difficult + very difficult (%)	0.0	0.0	0.0	0.0	0.0
Intervention group (n = 55)					
Very easy (%)	20.4	14.8	20.4	9.3	16.7
Easy (%)	33.3	46.3	44.4	51.9	35.2
Difficult (%)	42.6	38.9	35.2	33.3	42.6
Very difficult (%)	3.7	0.0	0.0	5.6	5.6
Missing (n)	1	1	1	1	1
Very easy + easy (%)	53.7	61.1	64.8	61.1	51.9
Difficult + very difficult (%)	46.3	38.9	35.2	38.9	48.1

comfort level and satisfaction of this new device was not inferior to the traditional LI. The high level of acceptance of the CIS by the patients also postulates that the patients are receptive toward the application of the TPUS probe during treatment.

RTs' perspectives

There were mixed responses among the RTs, with 55.3% of the negative comments highlighting that the CIS was "heavy and bulky" to handle or transfer (especially for female RTs). In addition, 18 (47.4%) negative comments commented that the CIS made it "difficult to reproduce" the knee rest position on the autoscan probe kit because of a lack of indexing and was "difficult to use," compared with only 4 negative comments related to the LI. Despite that, 43.8% of the positive responses from the RTs in the intervention group perceived that the device was "easy to clean and set up" and "benefits the US workflow" by allowing more accurate treatment delivery (ie, considering the intrafraction tracking capability). A further 21.9% of the positive comments indicated that the knee rest may be more comfortable because patients' legs were slightly bent. Nonetheless, the weight and bulkiness of the CIS was 1 of the main issues elicited from the RT evaluation. On the other hand, 89.3% of the positive comments in the control group found that the LI was "easy to use" and "stable" and 21.4% commented the LI was "lightweight." Interestingly, both groups captured negative comments about the potential difficulty of reproducing the leg position because of the lack of indexing for both the LI and knee rest on the CIS.

Summary of advantages and disadvantages and future research

Considerations before the introduction of a new immobilization device are multifaceted. In our investigation, we reported high acceptability of the CIS compared with the LI by patients in terms of comfort level and perception of stability of the device. Table C3 (in Appendix E3) summarizes the overall advantages and disadvantages of using the CIS. Although the RTs preferred the LI, the superior setup results indicate that the CIS has a clinical application. To overcome the apparent negativity expressed by RTs toward the CIS, and to minimize occupation safety risk with handling bulky devices, workflow processes should be reviewed and feedback provided to the Clarity manufacturer.

Now that the acceptability of using CIS has been established, future work will focus on analyzing the potential planning target volume margin reductions achievable, particularly in the superoinferior direction, when using the real-time tracking capability of the CIS instead of daily CBCT for pretreatment setup corrections. Additional work is also under way to analyze and evaluate the most important capability of the Clarity 4D TPUS, intrafraction tracking, with a view to publishing these works in the near future.

Conclusions

The CIS demonstrated stability and reproducibility in prostate treatment setup comparable to the use of LI. Patients were receptive to its use during treatment; however, RTs indicated their preference for the LI over the CIS mainly because of its weight and bulkiness.

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Supplementary data

Supplementary material for this article (http://dx.doi.org/10.1016/j.adro.2017.02.001) can be found at www.practicalradonc.org.

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