

Investigating the role of 3D goggles in optimising time during deep-inspiratory breath-hold radiotherapy: A randomised study

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Keywords: breast cancer; radiotherapy; deep-inspiratory breath-hold; audio-visual feedback; 3D goggles

Received: April 09, 2026

Accepted: August 06, 2026

Published: September 24, 2026

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ABSTRACT

Background: Deep-inspiratory breath-hold (DIBH) is a widely adopted cardiac-sparing technique but is associated with longer treatment times than free breathing. This non-blinded, randomised, parallel-group superiority study evaluated whether 3D goggles improve treatment efficiency in patients undergoing DIBH radiotherapy.

Methods: Ninety-four patients with breast cancer or lymphoma who were planned for DIBH radiotherapy were randomised (computer-generated randomisation) to receive either audio-only feedback (standard arm) or audio-visual feedback using 3D goggles (test arm). Patients in both arms underwent dedicated DIBH training 1–2 weeks before simulation. Total treatment time (primary endpoint), beam-on time, imaging time, setup time, and breath-hold counts were recorded and compared.

Results: The overall treatment time did not differ significantly between the test arm ($N = 43$) and the standard arm ($N = 51$) (22.4 minutes vs. 23.4 minutes; $p = 0.205$). Treatment durations on day 1, days 1–3, and from day 4 onward also showed no significant differences between the two arms. Breath-hold counts and treatment interruptions were also compared. However, the test arm had a longer average setup time (test arm: 7.3 vs. standard arm: 6.5 minutes; $p = 0.005$). The mean treatment time for the entire study cohort was 25.6 minutes during the first three sessions, reducing to 21.5 minutes thereafter, which was statistically significant.

Conclusions: With efficient patient counselling and training, DIBH can be performed effectively without the need for video feedback. The use of goggles did not offer a significant advantage in reducing treatment time. The trial was registered in the Clinical Trials Registry of India. (CTRI/2022/06/043212) on June 13, 2022.

Funding: TRAC/0822/3467/01 dated August 3, 2022; Minimal intramural funding, does not cover the publication charges.

INTRODUCTION

Recent advancements in cancer therapeutics have significantly lowered cancer-specific mortality rates [1] and contemporary radiation therapy (RT) is a vital part

of this success. Modern radiation therapy techniques focus not only on effective cancer treatment but, more importantly, on improving the therapeutic ratio, thereby leading to longevity of life span with improved quality of life.

Over the years, numerous technological advancements have emerged in the field of radiotherapy, including 3D Conformal Radiotherapy (3DCRT), Intensity-Modulated Radiotherapy (IMRT), Image-Guided Radiotherapy (IGRT), Stereotactic Body Radiotherapy (SBRT), and particle therapy [2]. Motion management techniques such as Deep-expiratory Breath-Hold (DEBH), Deep-inspiratory Breath-Hold (DIBH), Active Breathing Control (ABC), Tumour Tracking, and Surface Guided Radiotherapy (SGRT) have brought a paradigm shift in improving the therapeutic ratio [3]. These innovations enhance not only the treatment precision by improving dose conformity to the tumour but also minimize tumour motion thereby protecting the surrounding organs at risk (OAR). This is particularly relevant in certain cancer sites like breast, hepato-biliary, pelvic malignancies, and mediastinal lymphomas where critical structures are presented in close proximity to the target volumes.

Deep-inspiratory breath-hold is an attractive technique of motion management in which the patient inspires to a certain threshold and holds the breath, resulting in flattening of the diaphragm and expansion of the lungs that pulls the heart down and away from the chest wall. This offers the dual advantage of decreasing the radiation dose to the OARs as well as reducing the motion of the chest wall. Nonetheless, effective patient training and motivation are crucial to ensure proper understanding of the procedure, allowing patients to consistently perform adequate breath holds.

At our institute, we use the Real-time Position Management (RPM) system from Varian Medical Systems, which operates without integrated visual feedback. Patients are typically guided through audio instructions delivered via the treatment console. However, some patients face difficulty in following these instructions due to factors such as hearing impairment, language barriers, or lower educational levels. To overcome these challenges, we introduced visual feedback using 3D goggles (ITVGoggles, Los Angeles, CA, USA Model FPView3D).

The integration of 3D goggles provides patients with simultaneous audio and visual feedback, enabling real-time visualization of their breathing patterns. Patients can monitor their respiratory waveforms throughout various phases and accurately identify the optimal breath-hold window. This real-time feedback enhances patient comfort and facilitates improved compliance and precision during the procedure.

Our present study addresses the unmet need of improving the compliance to DIBH procedure in our patient population. In a high-volume clinical environment, where time and cost are critical factors, our study aims to investigate whether incorporating advanced aspects into the routine DIBH technique offers any demonstrable benefits in terms of treatment time.

Objectives

This randomised controlled trial evaluates the difference in overall treatment time (primary objective) between the use of audio-only feedback and combined audio-visual feedback via 3D goggles during the DIBH procedure among patients of breast cancers and lymphomas receiving radiotherapy between July 1, and January 15, 2024. Various demographic and clinical factors impacting the treatment time were analysed as the secondary endpoint. Some of the secondary outcomes like patient compliance to goggle usage and patient satisfaction between both the groups, will be published later.

RESULTS

The mean age of the entire cohort was 46 years and history of co-morbidities was noted in 18% (17 patients), primarily type II diabetes and hypertension, both controlled with oral medications. The Table 1 below depicts the demographic features in patients of both arms. Various time components involved in administering DIBH radiation therapy across both study arms is outlined in Table 2.

The overall treatment time did not differ significantly between the arm with goggles compared to the standard arm (22.4 minutes vs. 23.4 minutes, p -value: 0.205). There was also no statistically significant difference in treatment times between the two arms for Day 1, Days 1–3, or Day 4 to the last fraction. The total number of breath-holds, or interruptions also were not statistically different between the two arms. The average set up time however was longer in the test arm (7.3 minutes) compared to the standard arm (6.5 minutes) ($p = 0.005$). The average treatment time of all patients was recorded as 25.6 minutes in the first 3 days which reduced to 21.5 minutes for the subsequent fractions.

Various parameters were analysed by univariate analysis for their impact on the treatment time (Table 3). Gender was the only parameter significantly associated with overall treatment time, with men having a mean treatment time that was 3.5 minutes shorter than that of women ($p = 0.024$).

The positional reproducibility also remained consistent across both the groups, with no notable variation between goggle users and non-users.

DISCUSSION

Thoracic radiotherapy for breast, lung, esophageal cancers and lymphomas exposes heart and its substructures to a variable extent. This poses them to a risk of developing cardiac morbidity which can manifest as coronary artery disease, cardiomyopathy, valvulopathy, arrhythmias, and pericardial disease [4].

Darby et al. identified a linear association between the mean heart dose (MHD) and the incidence of major

Table 1: Patient and treatment related parameters in both arms

Variable	Level	ARM		<i>p</i> -value
		Standard arm (DIBH) (<i>n</i> = 51)	Test arm (DIBH with Goggles) (<i>n</i> = 43)	
Age (Years)	<50	34 (66.6)	21 (48.8)	0.08
	>50	17 (33.3)	22 (51.2)	
Performance score	Fully active	43 (84.3)	40 (93.0)	0.19
	Restricted	8 (15.7)	3 (7.0)	
Gender	Male	6 (11.8)	2 (4.7)	0.38
	Female	45 (88.2)	41 (95.3)	
Comorbidities	No	43 (84.3)	34 (79.1)	0.69
	Yes	8 (15.7)	9 (20.9)	
Diagnosis	Breast	44 (86.3)	41 (95.3)	0.25
	Lymphoma	7 (13.7)	2 (4.7)	
Laterality	Right	2 (4.1)	2 (4.7)	0.95
	Left	42 (85.7)	38 (88.4)	
	Bilateral	3 (6.1)	2 (4.7)	
	Midline	2 (4.1)	1 (2.3)	
Histology breast	Ductal	43 (97.7)	40 (97.6)	0.96
	Others	1 (2.3)	1 (2.4)	
Education level	Literate	44 (86.3)	37 (86.0)	0.97
	Illiterate	7 (13.7)	6 (14.0)	
Radiotherapy Technique	3DCRT	2 (3.9)	1 (2.3)	0.66
	IMRT	49 (96.1)	42 (97.7)	

Abbreviations: 3DCRT: 3-dimensional radiotherapy; IMRT: Intensity modulated radiotherapy.

Table 2: Various aspects of time and number of breath holds recorded during DIBH treatment

Variable		ARM		<i>p</i> -value
		Standard arm (<i>n</i> = 51)	Test arm (<i>n</i> = 43)	
Total treatment time (minutes)	Mean (SD)	22.4 (3.7)	23.4 (3.9)	0.20
DAY 1 – Total treatment time		30 (26,37)	31 (25,38)	0.80
DAY 1–3 Total treatment time		25.3 (23.6,30.3)	26 (23.3,32)	0.31
DAY 4-last fraction total treatment time		21.1 (19.2,23.8)	21.8 (18.75,25.6)	0.38
Imaging time(minutes)	Median (IQR)	6.5 (2.5, 7.6)	6.8 (4.7, 8.4)	0.48
Setup time(minutes)	Median (IQR)	6.5 (5.7, 7.2)	7.3 (6.4, 9.0)	0.005
Beam on time (minutes)	Median (IQR)	8.2 (7.0, 10.2)	7.5 (6.7, 8.9)	0.15
Day 1 Beam on time (minutes)	Median (IQR)	9 (7, 10)	8 (6,10)	0.14
Day 1-3 Beam on time (minutes)	Median (IQR)	8.3(7.0,10.3)	8.0(6.6,9.6)	0.49
Day 4-last fraction Beam on time (minutes)	Median (IQR)	8.0(6.8,9.9)	7.4(6.0,8.9)	0.14
Number of breath-holds during radiation	Median (IQR)	2.9 (2.6, 3.3)	2.8 (2.4, 3.4)	0.52
Number of breath-holds during CBCT	Median (IQR)	3.2 (2.7, 3.8)	3.2 (2.5, 3.8)	0.53
Total number of breath-holds	Mean (SD)	11.8 (3.4)	11.7 (4.3)	0.98
Total number of interruptions	Mean (SD)	10.9 (3.6)	10.5 (4.2)	0.68

Abbreviations: SD: standard deviation; IQR: Interquartile range; CBCT: Cone beam computed tomography.

Table 3: Univariate analysis of various patient and treatment related factors

Factor	Criteria	N	Median (IQR)	P-value
ECOG	0	83	22.3 (20.1, 25.2)	0.185
	1	11	25.2 (20.6, 26.7)	
Gender	Male	8	19.1 (17.7, 21.1)	0.024
	Female	86	22.6 (20.5, 25.6)	
Co-morbidities	No	77	22.6 (20.1, 25.5)	0.451
	Yes	17	21.8 (21.2, 24.0)	
Diagnosis	Breast	85	22.6 (20.2, 25.6)	0.159
	Lymphoma	9	20.4 (19.7, 23.6)	
Education	Literate	81	22.1 (20.2, 25.4)	0.705
	Illiterate	13	23.7 (20.1, 26.5)	
Technique	3DCRT	3	18 (16.8, 20.8)	0.083
	IMRT	91	22.5 (20.2, 25.5)	

Abbreviations: ECOG: Eastern co-operative oncology group, 3DCRT: 3-Dimentional radiotherapy; IMRT: Intensity modulated radiotherapy.

coronary events, with a 7.4% increased risk per Gray (95% CI: 2.9 to 14.5, $P = 0.001$) observed within 20 years after radiation therapy for breast cancer [5]. This finding was supported by Bogaard et al, who reported a 16.5% relative increase in acute coronary events per Gray within 9 years following treatment [6]. In addition, a systematic review by Taylor et al. indicated an excess relative risk of 0.11 for early lung cancer per Gray of whole lung dose, and an increase of 0.04 for cardiac mortality per Gray of whole heart dose [7]. Hence, the utilization of cardiac-sparing techniques is imperative in thoracic radiotherapy to minimize radiation exposure to the heart and its critical substructures. Several studies in the past have established DIBH as an effective method of cardiac sparing for chest radiotherapy [8, 9]. It reduces not only the mean heart dose but also doses to the critical substructures like the left ventricle and left anterior descending artery (LAD) [10, 11].

In a recent prospective Indian study [12], 100 breast cancer patients undergoing adjuvant radiotherapy were planned with both DIBH and free-breathing scans. DIBH significantly reduced mean doses to the heart (2.5 vs. 4.4 Gy), left ventricle (3.3 vs. 6.6 Gy), right ventricle (3.7 vs. 6.8 Gy), and LAD (8.89 vs. 21.14 Gy) compared with free-breathing plans.

However, the DIBH procedure involves several breath-holds and interruptions during treatment verification and delivery. This increases the overall treatment time and affects machine throughput. Many times, audio coaching with verbal instructions alone are not fully understood by the patient due to language barriers or ineffective communication.

Hence commercial solutions like SGRT based DIBH, visual navigation with video scalers, 3D Goggles, frame-based tactile feedback etc., are being implemented [13–15].

To our knowledge, this randomised study is the first to compare 3D goggles-based DIBH radiotherapy with a conventional verbal feedback approach. In the present study, we compared the conventional audio-only feedback to audio-visual feedback using 3D Goggles. However, the study did not demonstrate any additional benefit with 3D goggles. There was no significant difference in either the overall treatment time (22.4 vs. 23.4 minutes; $p = 0.205$) or the beam on time (8.2 vs. 7.5 minutes; $p = 0.15$). Rather, the usage of 3D goggles showed statistically significant increase in the set-up time (6.5 vs. 7.3 minutes; $p = 0.005$) as the goggle we used required manual setup to connect the goggles before each radiation fraction. We analysed treatment times across fractions to assess whether DIBH performance improved with increasing patient familiarity and reduced anxiety. The treatment time and beam-on time of day 1, days 1–3, and day 4 to the last fraction, were also compared between both the arms. Although, we noticed a trend in the decrease in total treatment time from day 1–3 and day 4-last fraction (25.6 minutes vs. 21.5 minutes; $p = 0.001$), there was no statistically significant change between the two arms.

These findings are in contrast with several earlier studies, which reported a significant reduction in treatment time with the use of 3D goggles [13, 14].

Cradley et al. [14] showed that 3D Goggles-based DIBH was highly efficient and reproducible. The actual time for 3D goggles-based-DIBH treatment delivery, compared to no DIBH treatment, was within 13.5 seconds in 10/10 fractions. In 9/10 fractions, the patient completed each treatment field with a single DIBH. Only 5 patients were used for comparison between DIBH with audio-visual feedback and free-breathing unlike our study that had 94 patients comparing audio-only to audio-visual feedback in patients receiving DIBH radiation.

Dolezel et al. [13] evaluated an audio-visual feedback system using video scalers to display RPM signals during DIBH. Patients receiving audio-visual navigation ($N = 10$) had significantly shorter treatment times than those receiving voice instructions alone ($N = 10$) (92.3 vs. 68.1 seconds/field and 170.2 vs. 133.8 seconds/100 MU). However, the study included a small cohort of 20 DIBH patients and 10 free-breathing patients. Among patients receiving audio-visual guidance, breath training showed no additional benefit (68.1 vs. 66.1 seconds/field and 133.8 vs. 132.5 seconds/100 MU). However, coaching the patients for DIBH was an important pre-requisite in our study. Our DIBH team of technologists started training all patients at least a week before the start of simulation. The use of spirometers aided to improve the lung capacity of patients. The assigned technologists monitored the practice sheets weekly to keep a track of patients' daily practice. We consider breath training to be an important factor of finding no difference in treatment time or the beam on time between the two arms. In a resource limited setting with high patient burden, DIBH with breath training is a reasonably good and cost-effective alternative to other sophisticated methods like SGRT, frame based DIBH or the use of 3D goggles. Moreover, most studies that compared treatment time with visual aids only considered the beam-on time and not the overall treatment time. There is a considerable amount of time lost in setting up patients with the 3D goggles as is shown in our study where there was a statistically significant difference in the set-up time between both the arms. (6.5 vs. 7.3 minutes, $p = 0.005$). However, this disadvantage can be overcome by using battery-operated 3D goggles.

Our study is one of the few that throws light on the overall time taken to perform DIBH and not just the per-field time. The count of interruptions and breath-holds determines the machine's throughput and additional time required with DIBH, compared to free-breathing (FB) delivery. Though we have not compared the treatment time with those treated in FB, the results highlight the need for thorough assessment of each patient before radiotherapy to check their eligibility and extent of additional benefit offered by DIBH.

Patients who were unable to perform DIBH were directly excluded from the study. We could not successfully train the non-compliant patients using 3D Goggles to see if they became compliant. While treatment time is an important factor to track, evaluating the number of patients who transitioned from non-compliant to compliant due to the use of goggles would have provided valuable insights. It would offer a clearer picture of the added benefits of 3D goggles beyond just the efficiency of treatment.

We used a pair of 3D goggles with an adapter and extension set up. Battery-operated 3D goggles usage would have saved more time and there could have been a significant reduction in the treatment time.

DIBH is the simplest and effective way of cardiac sparing. The findings from our study suggest that structured pre-treatment coaching alone may be sufficient to achieve efficient DIBH delivery in routine clinical practice, without the need for additional audiovisual augmentation.

MATERIALS AND METHODS

Patient population

Patients aged > 18 years, treated for breast cancer and lymphomas who required radiotherapy using DIBH technique for cardiac sparing, were eligible for the trial. Written informed consent was taken from all the study subjects. The accrual period was from July 1, 2022, to January 15, 2024. Patients were randomised by the central research secretariat, ensuring allocation concealment without access to the principal investigator or any other study team member. A computer-based random number generator was used for patient allocation. Patients were stratified according to disease site (breast vs. lymphoma) and presence of comorbidities (yes/no). Of the 106 patients initially enrolled, 12 were excluded due to various reasons including disease progression prior to initiation of radiotherapy, non-compliance with the DIBH protocol after RT planning, or transfer to another facility due to machine downtime at our institute. The final cohort comprised 94 patients, with 51 in the no-3D goggles arm and 43 in the 3D goggles arm. The sample estimation for the current trial has been shown in Supplementary Materials as Appendix 1 and the consort diagram is presented in Figure 1.

Patients accrued in both the arms were sent for DIBH training to a dedicated team of technologists in our hospital at least 1–2 weeks before the planned simulation. The technologists thoroughly demonstrated the DIBH technique and provided instruction on the use of a spirometer, which was given to patients to help enhance their lung capacity. As per the institutional protocol, patients were instructed to practice the technique at home daily, performing at least five sessions per day, and to record their inspiratory volumes and breath-hold durations on designated practice sheets (Figure 2). Weekly review of the practice sheet was done by the technologists who motivated patients for complying with the instructions all throughout the period from simulation to treatment conclusion.

Patients were simulated in the supine position with arms above the head and head turned to the opposite side in cases of supraclavicular fossa (SCF) radiation. An RPM camera was placed on the couch and the system was calibrated using a frame with an infrared marker above it (Figure 3A–3C). A free-breathing (FB) scan was taken before the DIBH scan with the RPM marker box placed 2 cm below xiphisternum. All patients received verbal

feedback from the console for performing DIBH. Figure 3 illustrates the various steps involved in patient simulation and treatment using Deep-inspiratory Breath-Hold (DIBH) with the aid of 3D goggles.

Treatment

Breast cancers patients received 40 Gy in 15 fractions as adjuvant therapy while lymphoma patients were treated with 25.2 to 45 Gy over 14 to 25 fractions. Patients in the test arm wore 3D goggles to visualise their breathing pattern in addition to the verbal feedback from the technologist at the console (Figure 3D–3F). Verification of the patient position was done with cone beam computed tomography (CBCT) performed before the start of treatment. Positional deviations between CBCT

and simulation CT were documented, and any shifts greater than 5 mm required repositioning.

Treatment time calculation

Total Treatment Time: refers to the duration from the patient's entry into the treatment room to their exit, averaged across the total number of fractions. This metric was calculated for all fractions, as well as specifically for Day 1, Days 1–3, and Day 4 to the final fraction.

$$\text{Total treatment time} = \frac{\sum(\text{Room exit time} - \text{room entry time})}{\text{Total number of fractions}}$$

Setup Time: refers to the interval measured from the patient's entry into the treatment room to the initiation of Cone Beam CT (CBCT) averaged across the total number

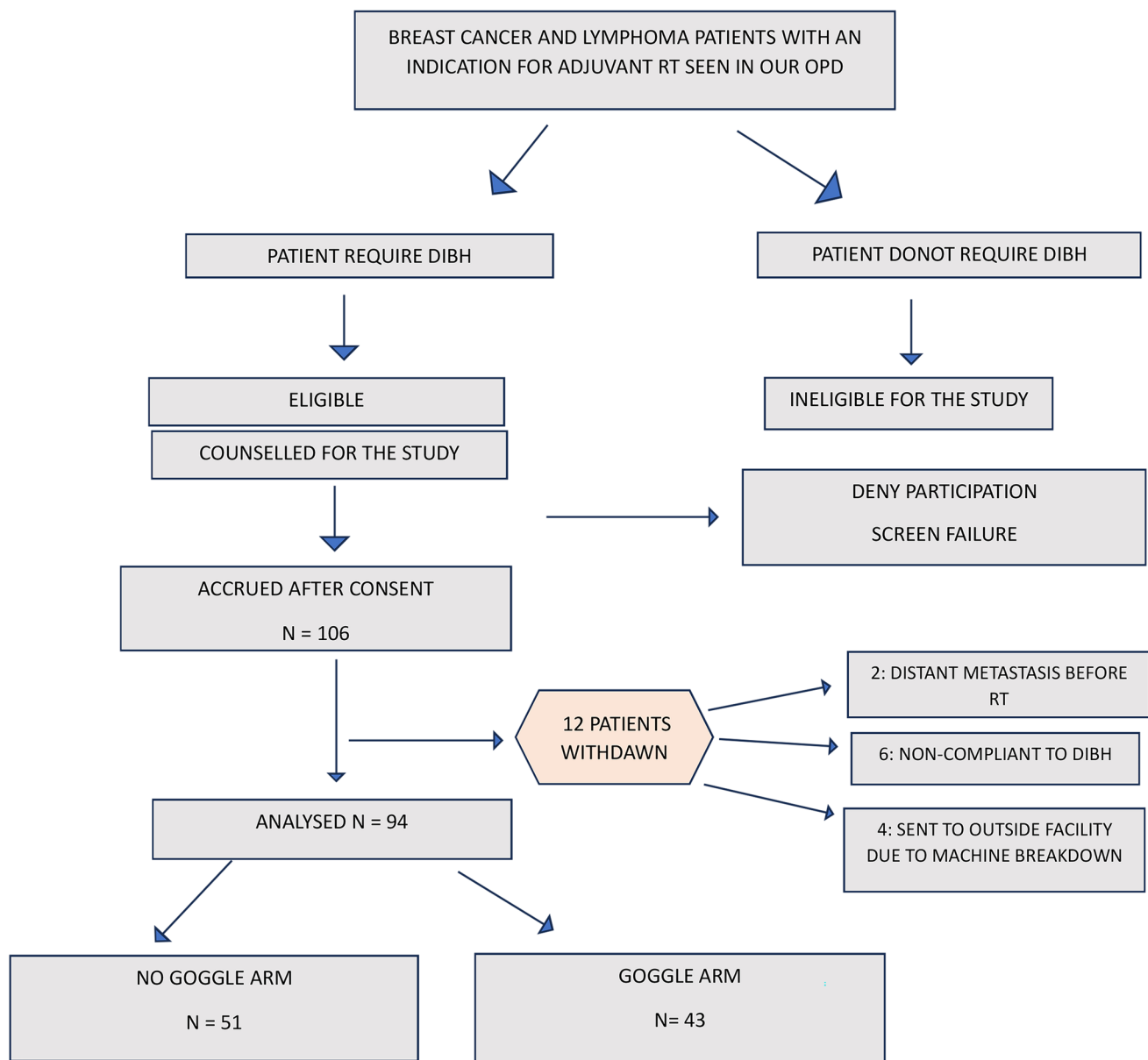


Figure 1: Consort diagram. Abbreviations: OPD: outpatient department; DIBH: Deep-inspiratory breath-hold.

of fractions. This period included time taken for patient positioning on the couch, laser alignment, and 3D goggles placement (for test arm patients) among other setup activities.

$$\text{Set up time} = \frac{\sum(\text{Room exit time of CBCT initiation} - \text{patient entry time into treatment room})}{\text{Total number of fractions}}$$

Imaging Time: refers to the total CBCT acquisition time averaged across all the fractions, recorded from the console workstation (ARIA). It was calculated from start time of CBCT till the end and included the image matching time.

$$\text{Imaging time} = \frac{\sum(\text{CBCT end time} - \text{CBCT start time})}{\text{Total number of fractions}}$$

PART C: DAILY PRACTICE RECORD

TRIAL ID: _____ SIMULATION DATE: _____ STARTING DATE: - _____ DATE OF CONCLUSION: _____
CASE NO: _____ MOBILE NOS: _____ PATIENT AGE: _____

PRACTICE TO BE DONE IN LYING DOWN POSITION WITH BOTH ARMS ABOVE HEAD AS INSTRUCTIONS GIVEN
SPIROMETER TRAINING DONE: A) YES B) NO ARM: A) STANDARD B) GOGGLE

S NO	DATE	SESSION (1) Pre-breakfast		SESSION (2) Post-breakfast		SESSION (3) Post lunch		SESSION (4) Evening		SESSION (5) Night		WEEKLY COMPLIANCE SCORE
		SPIROMETER READING (ML)	BH TIME (SEC)	SPIROMETER READING (ML)	BH TIME (SEC)	SPIROMETER READING (ML)	BH TIME (SEC)	SPIROMETER READING (ML)	BH TIME (SEC)	SPIROMETER READING (ML)	BH TIME (SEC)	
												---- / 35
1	28/8/23	Unwell										
2	29/8/23	Unwell										
3	30/8/23	Chemo										
4	31/8/23	4200	28.0	4100	28.3	4300	29.1	4400	29.2	4300	29.4	
5	01/9/23	4100	27.9	4200	28.1	4300	29.4	-	-	-	-	
6	2/9/23	4300	27.3	4200	29.0	4200	29.9	np	-	4200	29.1	
7	3/9/23	4200	28.2	4100	28.7	4300	29.0	4300	28.5	4400	28.2	17 / 35
8	4/9/23	4200	28.7	4400	26.7	4400	28.3	-	-	4400	28.2	
9	5/9/23	4300	28.3	4100	29.6	4200	26.9	-	-	4200	27.6	
10	6/9/23	chemo										
11	7/9/23	4100	29.0	4200	29.3	4100	29.1	4400	28.9	4200	29.2	
12	8/9/23	4300	29.1	4400	29.5	4400	30.1	-	-	-	-	
13	9/9/23	4400	30.3	4100	28.3	4200	29.4	-	-	-	-	
14	10/9/23	4200	29.7	4500	29.8	4400	31.3	4000	30.8	4100	29.8	24 / 35
15	11/9/23	4000	29.5	4300	30.4	4200	28.2	4200	30.2	4300	29.8	
16	12/9/23	4400	28.6	4100	29.6	4500	30	-	-	-	-	
17	13/9/23	chemo										
18	14/9/23	Fatigue	-	-	-	-	-	-	-	4200	29.9	
19	15/9/23	4300	30.1	4100	29.8	4400	30.3	4100	31.2	4200	28.6	
20	16/9/23	4000	30	4200	30.1	4200	30.8	4100	29.9	-	-	
21	17/9/23	4100	30.8	4200	29.9	4300	30.1	4000	30.1	4400	30.0	23 / 35
22	18/9/23	Travel										
23	19/9/23	Hospital										
24	20/9/23	Hospital										
25	21/9/23	4000	30.1	4400	30.3	4300	30.1	4400	30.3	4100	30.1	
26	22/9	Travel										
27	23/9	4100	30.1	4100	31.1	4300	29.6	4200	30.4	4100	30.7	
28	24/9	4100	32.3	4300	30.4	4200	30.3	* Palpitation & nausea due to Bism	30.8	4300	31.0	14 / 35
29	25/9	4400	30	4100	31.1	4200	31.1	4200	30.8	4300	31.0	
30	26/9	4300	30.4	4200	32.3	4200	30.3	4100	31.3	4400	30.5	
31	27/9	4100	30.1	4100	29.8	4400	29.9	4000	31.3	4400	30.1	
32	28/9	Travel								4300	31.0	
33	29/9	Hospital								4400	30.0	
34	30/9	Hospital								4100	30.6	
35	01/10	4100	32.1	4200	32.0	4300	31	4400	29.8	4300	29.6	25 / 35

(If practices 5 times/day for 7 days i.e 35 times- Excellent, If practices 6 out of 5 days i.e 30 sessions- Good, Anything <30- Poor)
RTOG reactions: Skin _____ Esophagus: _____

Figure 2: Daily practice sheet. The patient is instructed to practice five times daily. Compliance is scored at one point per session, with a weekly maximum of 35 points (100%) for full adherence.

Beam-On Time (Radiation Time): calculated by summing the radiotherapy beam delivery durations of all the beams obtained from ARIA and averaged across the total number of fractions. This was also recorded for all fractions, as well as specifically for Day 1, Days 1–3, and Day 4 to the final fraction.

$$\text{Beam on time} = \frac{\sum(\text{Beam 1 time} + \text{beam 2 time} + \dots \text{beam } n \text{ time})}{\text{Total number of fractions}}$$

Total interruptions: refers to the average number of times the treatment or imaging process was automatically paused because the patient's breathing moved outside the predefined respiratory threshold. These interruptions were recorded during both CBCT imaging and radiation delivery.

$$\text{Interruption rate\%} = \frac{\text{Total number of automatic interruptions}}{\text{Total number of imaging and treatment sessions}} \times 100$$

Figure 3G, 3H shows the images of the waveforms appearing on the console screen while taking CBCT and treatment, which were used for obtaining various aspects of the time calculations mentioned above.

All these parameters were then compared between both the treatment arms for any significant time difference

as the primary outcome. Several demographic and clinical factors, such as age, gender, performance status, cancer type (breast or lymphoma), cancer stage, and educational level, were analysed and compared between the 3D goggles and no-3D goggles arms to assess their potential impact on the overall treatment time.

The set-up reproducibility and positional variations of the patients during the treatment were also recorded and compared between both the arms.

Statistical methods

Descriptive statistics were calculated, including the mean, median, and standard deviation (SD) for continuous variables, and frequencies with percentages for categorical variables. The relationships between various time-related parameters were analysed using either the independent *t*-test or the Mann-Whitney *U*-test, based on the normality of the data. To examine the correlation between treatment-related factors and overall treatment time, the Chi-square test or Fisher's exact test was applied for categorical data, while Pearson's correlation coefficient was used for continuous data. All statistical analyses were performed using SPSS version 29 and R Studio 2024.04.1.

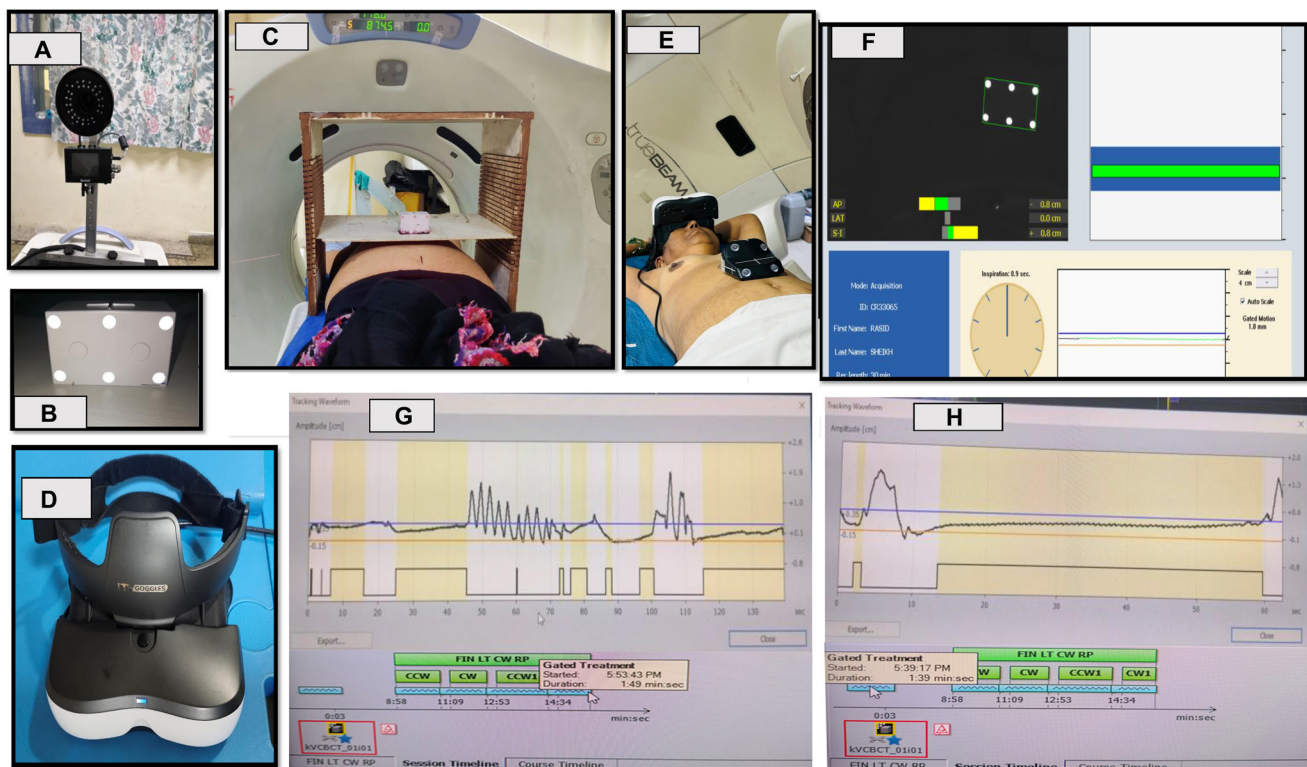


Figure 3: Various phases of planning and treatment. (A) Infrared camera mounted on the CT couch, (B) Surrogate marker box with 6 metallic reflectors, (C) Patient on CT couch with frame to calibrate the respiratory threshold, (D) 3D Goggles. (E) Patient on treatment couch with 3D goggles, (F) Patient's chest wall position falling within the threshold set by the help of Infrared camera and the IR marker, (G, H) Waveform of breath-holds and interruptions seen during CBCT and radiation delivery; used to calculate various phases of treatment.

Data availability statement

Research data are stored in an institutional repository and not available for public sharing.

AUTHOR CONTRIBUTIONS

Study conception and design: Tabassum Wadasadawala. Patient recruitment and data collection: Naseera Syeda, Tabassum Wadasadawala, Jayant Goda, Chetana Vartak, Vrushal Sonawane, Priyanka Parab, Rajesh Thigale, Gaurika Pokale, Himani Kamble, Walmik Deshmukh, Swati Hase, Sonali Shingte, Maruti Bhoir. Statistical analysis: Sreelal Velloden. Manuscript writing: Naseera Syeda. Review of manuscript: All authors. Final manuscript: Tabassum Wadasadawala.

CONFLICTS OF INTEREST

Authors have no conflicts of interest to declare.

ETHICAL STATEMENT

This a non-blinded, randomised, parallel group superiority study, conducted at Tata Memorial Centre, Mumbai, India, after the approval by the institutional ethics committee. The research work was carried out in accordance to the declaration of Helsinki, the International Council of Harmonisation guidelines for good clinical practice. The trial was also registered in the Clinical Trials Registry of India on June 13, 2022. (CTRI/2022/06/043212). This study was conducted and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

CONSENT

Written informed consent was taken from all the participants of the study.

FUNDING

TRAC/0822/3467/01; dated 3 August 2022.

Minimal intramural funding, does not cover the submission charges.

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Investigating the role of 3D goggles in optimising time during deep-inspiratory breath-hold radiotherapy: A randomised study

SUPPLEMENTARY MATERIALS

APPENDIX 1

Sample size calculation

	Average treatment time		Difference	Standard deviation	Sample size	Alpha	Power
	Without 3D Goggles	With 3D Goggles					
Day 1	45	35	10	15	74	5%	80%
	35	25	11	11	34	5%	80%
	23	15	8	6	20	5%	80%

In above table sample size calculation was done for day 1, day1 to day3 and day 4 - last fraction treatment time. We have considered the largest sample size. As per historical data, the overall treatment time on day 1 without 3D Goggles is 45 mins, as assumption it will be reduced with 3D Goggles to 35 mins. It is also anticipated that the standard deviation of the overall treatment time to be approximately 15 mins. To detect a difference of 10 minutes with 80% power and a 5% level of significance, a total of 74 patients would be required. After accounting for a 20% dropout rate, a total of 94 patients would be required, with 47 patients in each arm. Assuming about 40–50 patients undergo DIBH annually, the study is expected to be completed within 3 years.