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Efficacy of Shadow-Based Needle Positioning System in Performing CT Image-Guided Percutaneous Biopsy of Lung Lesions: Our Initial Experience

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Abstract

Context Computerized tomography (CT) is widely used for various interventions and there is a need for an effective navigation tool, for best outcomes.

Aim The study was performed to evaluate the efficacy of light- and shadow-based needle positioning assistance device, an innovative navigation tool over the conventional freehand technique, in performing CT image-guided percutaneous interventions.

Settings and Design This randomized control trial was performed among patients undergoing CT-guided percutaneous intervention for lung pathologies.

Methodology A total of 60 participants were randomized into an intervention group and a control group. The accuracy of needle insertion and other efficacy parameters were assessed for both groups. Post needle placement, CT images were used to evaluate the study endpoints.

Statistical Analysis Statistical analysis was performed using SPSS ver. 20 software.

Results The mean needle positioning accuracy was 2.1 mm in the experimental group compared with 7.2 mm in the control group freehand procedures. The average time to position the needle at the desired target location was 2.5 minutes in the assisted procedure as compared with 5.3 minutes in the freehand procedure ($p < 0.05$). The total number of check scans required to position the needle was 1.3 for assisted procedures and 1.9 for freehand procedures.

Conclusion The use of shadow-based assistance device for CT-guided interventions is proven to be efficient and safer with high needle positioning accuracy.

Keywords
- biopsy
- CT-guided intervention
- lung
- radiation exposure

Introduction

Computed tomography (CT) plays a key role in interventions such as tumor ablation, FNAC/FNAB, percutaneous block of the upper sympathetic chain, treatment of secondary pulmonary aspergilloma, and brachytherapy.[1] The procedures are user-dependent, and achieving accuracy is challenging. Several navigation tools have been innovated for CT-guided interventions[2]; however, drawbacks continue

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to exist. There is a need for a navigation tool with improved accuracy and one such is light and shadow-based needle positioning which consists of a light source for shadow, a camera, and a projected laser crosshair. The perceived advantages include simplicity, accuracy, and reduced intervention time. Comprehensive validation of this innovation will help in improving the outcomes of CT-guided interventions.

Objectives

This study was done to compare the efficacy of HigHNoon Navigation system to the conventional freehand method of operation in a clinical use case environment to compare parameters such as procedural accuracy, procedural efficiency (speed and radiation exposure (based on the number of check scans required). The study endpoints were:

(a) Accuracy (mm) at which the biopsy needle was placed at the target site with reference to the plan (calculated in terms of error [defined as the distance between the tip of the needle actually seen on the images from the planned target]).
(b) Number of skin punctures required to finally place the biopsy needle at the planned target point.
(c) Number of check scans required to place the biopsy needle at the planned target point.
(d) Time taken to place the biopsy needle at the planned target point (in min).

Methodology

Study Design and Setting

This study was performed as a randomized control study in a tertiary care hospital in India, for a period of 75 days between June and August 2019. This study consisted of two arms—The experiment arm consisting of patients undergoing shadow-based positioning and the control arm consisting of patients undergoing the intervention using the freehand technique.

Study Patients

During the study period, consecutive patients routinely booked for CT-guided interventions of the lung lesions, meeting the inclusion/exclusion criteria, were recruited into the study.

Inclusion Criteria

Only adults aged above 18 years, with focal lung lesions requiring CT-guided biopsy of lung lesions were included in the study. Contiguous cases referred for CT-guided lung biopsy were considered for the study. A minimum lesion size of 5 mm and a minimum trajectory window of 5 mm was a prerequisite for inclusion into the study to maintain patient safety. Only patients with adequate compliance to instructions and willingness to consent were recruited into the study.

Exclusion Criteria

There were no exclusion criteria for the study.

Sample Size Calculation

Assuming a mean difference of 2.5 mm, accuracy in reaching the target point (lung lesion) between the two groups with standard deviations of 3 and 2.5 in the two procedures, and with a level of significance of 5% and power of 90%, the sample size was calculated as 30 participants in each of the group, i.e., 60 patients for the study to evaluate the two groups.

Randomization and Blinding

The participants were randomly allocated into experiment and control groups using computer-generated random numbers. The intervention procedures in both groups were performed or supervised by the same operator.

Experimental Device Group

The device (HigHNoon) used in the experimental group is a light- and shadow-based instrument positioning device to be used by radiologists for CT-guided percutaneous interventions.

The device consists of a positioning unit and a planning station [►**Fig. 1**].

The positioning unit is assembled on a rail that is installed parallel to the CT system onto two pillars, erected on either side of the CT gantry. The positioning unit mounts the laser and light sources and the camera, which will be together used to guide the radiologist for instrument placement.

HigHNoon planning station allows the radiologist to plan instrument placement by marking the entry point and target points on the displayed digital imaging and communication in medicine (DICOM) images. Based on the plan, the instrument trajectory and insertion depth are automatically calculated and displayed on the screen. Once the plan is completed, the radiologist can command the positioning unit to be ready and align itself for the procedure.

Once the positioning unit is aligned, the laser and light-emitting diode (LED) light can be switched on to project the same in the planned angle. The radiologist can then manually align the needle to the projected light and continue needle insertion.

Intervention Procedure Using the Device

The clinical protocol and procedural steps for both experimental and control groups were the same for the only difference that instead of manual planning and placement of needles, the experimental group used the device assistance. The clinical workflow of CT-guided lung biopsy in the experimental arm is elaborated below (►**Fig. 2**, ►**Video 1**).

Video 1

Steps of performing the shadow-based needle positioning system in performing CT image-guided percutaneous biopsy of lung lesions. Online content including video sequences viewable at: https://www.thieme-connect.com/products/ejournals/html/10.1055/s-0041-1742243.

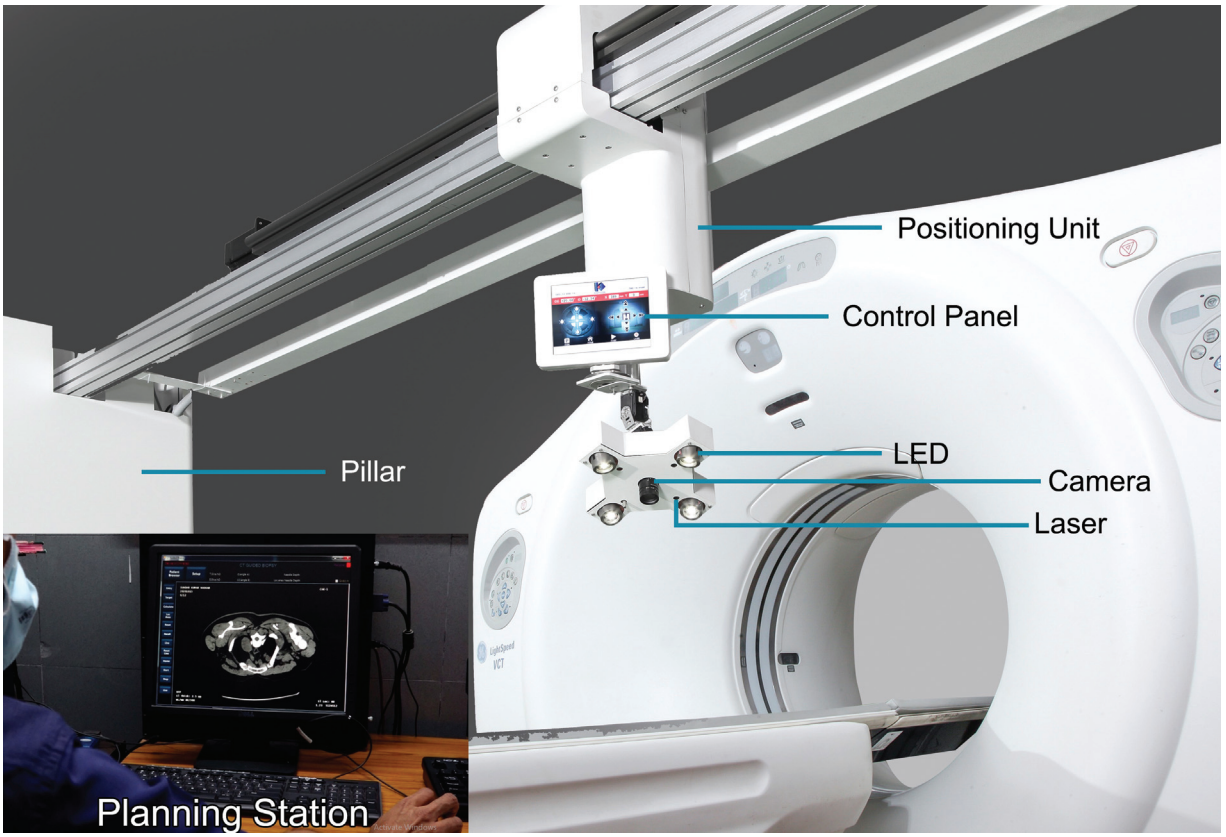

Fig. 1 HigHNoon, shadow-based assistance device.

Fig. 2 (**A-E**) HigHNoon biopsy procedure. Left posterior paravertebral lesion seen on pre-procedural CECT (**A**). Patient in prone position with a radiopaque marker (**B**). Desired entry (**C**) and target (**D**) points marked in HigHNoon console. The generated track is having 7.88 degree medio-lateral (XY axis) and 1.93 degree cranial tilt (Z axis). Device positions itself to the planned angle. Outer coaxial needle advanced aligning the center of the hub to the laser crosshairs (**E**). Check CT demonstrating cranially tilted needle tip matching the planned trajectory, suitable for coaxial Trucut biopsy (**F**).

The study participants were positioned on the CT table based on regular imaging protocol and the approach planned. A preliminary anteroposterior (AP) scout image was acquired for selecting the region of interest. To mark the entry point, a piece of the angiographic catheter was used as a radio-opaque marker, which was fixed on the skin with the help of a micropore plaster. Further CT scan images were generated in the area of interest. Based on CT images, an optimal entry point was finalized. CT distance tool was used to draw an optimal path from the desired entry point to the

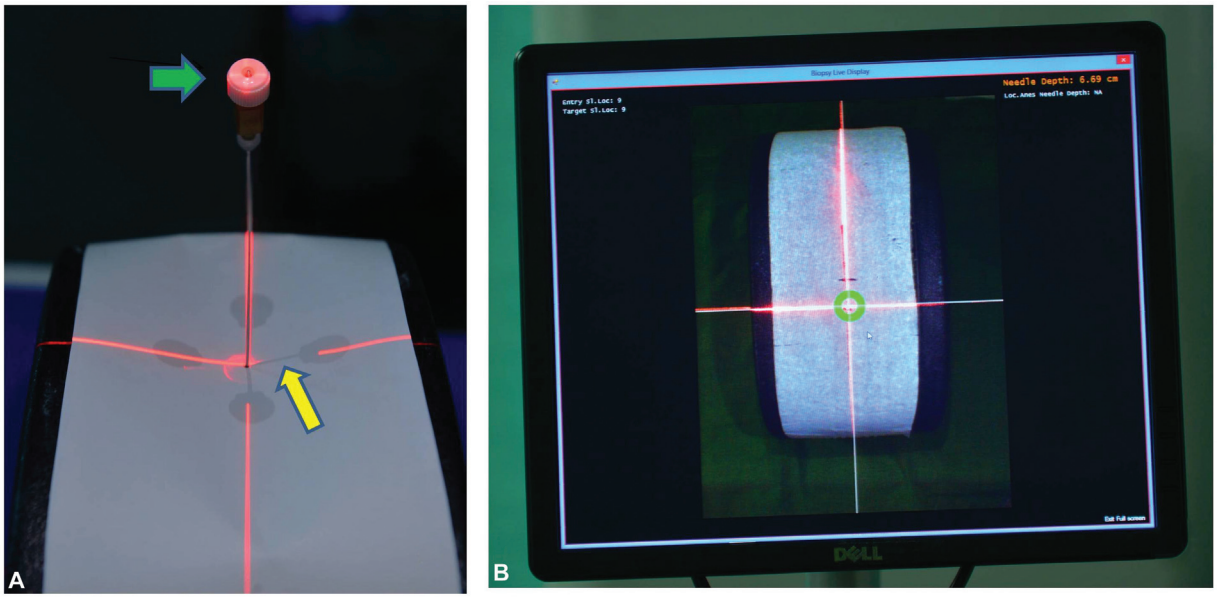

Fig. 3 (**A** and **B**) Three level conformation tool for needle placement accuracy. Level 1 (**A**) the laser crosshair centered on the instrument head (green arrow). Level 2 (**A**) the instrument shadows superimpose on the four limbs of the laser-cross hair (yellow arrow). Level 3 (**B**) the instrument head centered within the green circle displayed on the live monitor.

target point and also another line from the radio-opaque marker to the selected entry point, on the CT image. The distance and slice location of the entry point were documented. The CT table was then positioned at the level of the planned slice location and the CT crosshair was switched on. Using a marker pen, a transverse line was drawn along the cross-hair on the participant's body. The entry point was then marked at the measured distance from the radio-opaque marker.

Once the entry point was marked, the subsequently acquired CT scan of the patient was transferred to the HigHNoon planning station, where the radiologist drew the optimal trajectory from the marked entry point to the desired target. Once the plan is completed, the system automatically calculates the angle and depth of insertion.

The positioning unit was then initiated and moved to align the center of its laser crosshair onto the entry point. Local anesthesia was injected in and around the entry point. A check CT was performed to confirm the location of the skin entry site with the local needle in situ. Planned needle insertion depth, as displayed on the HigHNoon was physically marked on the outer coaxial needle, which was then introduced manually at the entry point aligning to the angles formed by the positioning unit light source. As the needle was being introduced, the precision of insertion was confirmed by radiologists by the three-level confirmation tools of the device [►**Fig. 3**].

The procedure was considered successful when the tip of the needle was placed as planned within the lesion, as confirmed on the CT, and tissue was obtained when a coaxial biopsy was performed [►**Fig. 4**]. A final check CT scan was performed after obtaining the biopsy and the removal of the needle to look for any complications like pneumothorax or hemorrhage.

Free Hand Control Group

In the control group of this study, the conventional free-hand method was used to perform CT-guided interventions. The overall clinical workflow from participant positioning to the final biopsy remains the same in both groups with the exception that no assistance device was used in this group.

Intervention using Freehand Method

Similar workflow steps were followed in the control group with a difference that the planning was done on the CT console. CT distance tool was used to draw an optimal path. The plan parameters such as CT slice number, the distance of entry point from the radio-opaque marker, angle of insertion, and required needle depth were physically noted and used to physically mark the entry point on the patient.

After injecting local anesthesia in and around the marked entry point, a check CT with the needle was performed to confirm the location of the skin entry site. Once the entry point was confirmed, the outer coaxial needle was introduced at the entry site, with the radiologists trying to maintain the needle trajectory at the planned angle. The needle insertion was completed in a required number of steps, with each step followed by a confirmatory CT check scan, making needle adjustments as required. Obtaining the biopsy and post-biopsy check CT scans were similar to the other group.

Data Collection

Data regarding the efficacy of the experiment over the control procedure were documented in a structured proforma. Data consisted of particulars regarding needle placement accuracy, the number of skin punctures required, the number of check scans required, and the

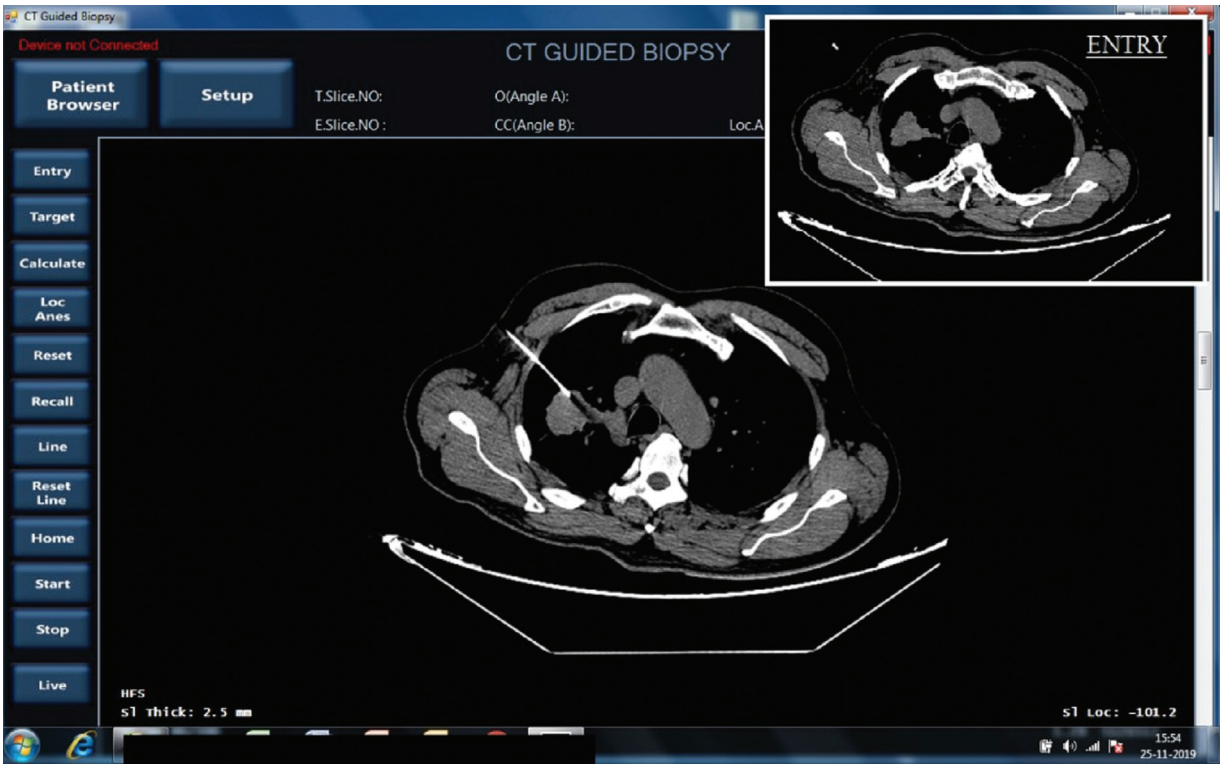

Fig. 4 CT-guided lung biopsy done with HigHNoon assistance.

procedure time for both the groups. Needle placement accuracy was calculated in terms of error, defined as the distance between the tips of the needle actually seen on the images and the planned target point. Timestamps for various procedural steps were noted and the time between a CT scan with a local needle to placement and confirmation of the outer coaxial needle tip in the lesion was considered as the needle insertion time.

Data Analysis

Data were entered and analyzed using SPSS ver. 20 software. All parameters were expressed in terms of mean values with standard deviations. An independent sample "*t*" test was performed to evaluate the efficacy of the experiment in comparison with the control group. A p-value < 0.05 was considered statistically significant.

Results

This randomized control trial was performed among 30 participants in the experimental group and 30 participants in the control group. The mean ages of the participants in the experiment and control groups were 53.2 and 47.8 years, respectively. The average lesion sizes in experiment and control groups were 3.6×3.4 cm and 4.4×4 cm, respectively. All participants in the control group had lesions of size more than 1.5 cm; however, 5/30 participants in the experiment group were of lesion size less than 1.5 cm [►**Table 1**].

The comparison of procedure outcomes in terms of plan time, needle insertion time, and the total procedure time between the experiment and control group is given

Table 1 Background parameters of study patients

Procedure parameters	Experiment	Control
Number of procedures	30	30
Average lesion size (cm)	3.6×3.4	4.4×4
# with lesion size (<1.5 cm)	5	1
# with lesion size (≥ 1.5 cm and <3 cm)	4	3
# with Lesion size (≥ 3 cm and <5 cm)	13	14
# with Lesion size ≥ 5 cm	8	12
Average patient age (y)	53.2	47.8

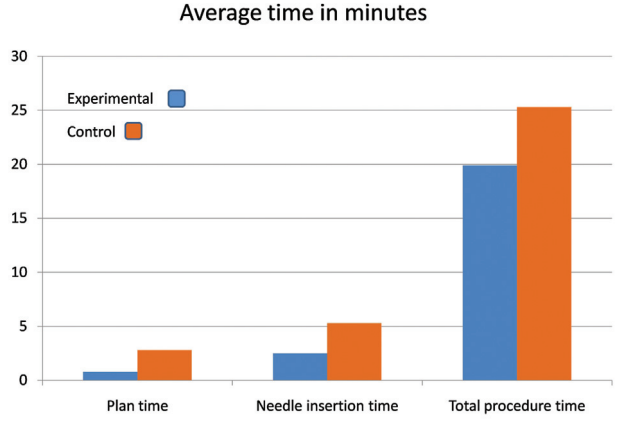

Fig. 5 Comparison of outcomes in terms of procedure duration.

Table 2 Efficacy parameters between experiment and control groups

Procedure parameters	Experiment	Control
Procedure time		
Average plan time (min)	0.8	2.8
Average needle insertion time (min)	2.5	5.3
Total procedure time (min)	19.9	25.8
Needle placement error		
Orbital angle error (degrees)	2.4	6.8
CC angle error (degrees)	2.3	5.7
Average error at target (mm)	2.1	7.2
Average error at entry (mm)	0.8	5.9
Others		
Average Skin punctures	1	1.2
Average check scans	1.3	1.9
Successful yield	100%	96%

Table 3 Comparison between experiment and control group in terms of the test of statistical significance

Parameter	Mean difference	S.E of mean	*t*	*p*-Value
Total procedure time	−5.6	2.05	−2.76	0.008*
Needle insertion time	−2.8	1.02	−2.73	0.008*
Number of check scans	−0.6	0.3	−2.008	0.049*
Entry error	−5.02	0.8	−6.008	0.0001*
Target error	−5.3	1.2	−4.5	0.0001*

*Statistically significant.

in ►**Fig. 5**. The time for needle insertion was 2.5 minutes in the experimental group when compared with 5.3 minutes in the control group. Considerable reduction in plan and overall procedure time was seen in the experiment group [►**Table 2**).

The experimental group showed much lower needle placement errors (2.1 mm) at the target when compared with the control group (7.2 mm). Needle placement error at the entry point and needle angulation error also showed significant differences and superiority when compared with the control group [►**Table 2**].

There was no significant difference in the average patient skin puncture required for a procedure. The average skin puncture for the experiment group was one while the same was 1.2 in the control group.

The average number of check scans taken was 1.3 in the experimental group when compared with 1.9 in the control group [►**Table 2**].

In terms of yield, sufficient yield was obtained in 100% of cases in the experiment group and 96% of cases in the control group. [►**Table 2**]. The histopathology results showed 42 cases of neoplasm (22 in the control group and 20 in the experimental group), 16 infections (seven in the control group and nine in the experimental group).

In the overall efficacy parameters recorded in terms of mean values, the experimental group showed lower mean values for various parameters including total procedure time, needle placement error, the number of skin puncture, and the number of check scan when compared with the control group with a statistical significance value of $p < 0.05$, indicating superiority over the control group [►**Table 3**].

Complications

During the study, 8 out of 60 participants (5 in the experiment group and 3 in the control group) developed pneumothorax, of which two required chest tube placements. One participant in the experimental group had developed mild hemoptysis following the last biopsy, which was conservatively managed and the participant was hemodynamically stable. There was no mortality.

Discussion

According to the World Health Organization (WHO), cancers are the leading cause of death globally. In spite of several technological advancements, 9.6 million cancer deaths were encountered in 2018 and 1.7 million of which were due to lung cancers.[3] Moreover, the WHO predicts a 30% increase in cancer cases by 2030, and has included in its action plan to innovate and acquire best buys to help early detection of cancer to achieve cure and reduce mortality.[4]

Although CT-guided interventions are widely used for various diseases, the most common application is for cancer diagnosis and management. Recent advances in cancer diagnosis and management revolve around various interventions, of which percutaneous CT-guided interventions are highly successful. Interventional radiology is a challenging field that requires adept skills, precision, and accuracy in each of its procedures. As a dynamic sphere of health care, it provides adequate scope for innovations and application-based strategies. For a major proportion of the interventions, the navigation into the targeted area has been subjective, based upon the expertise and skill of the care provider. However, this method is conventional and is liable for errors and adverse outcomes. Therefore, the need for standardized and technology-based assistance for navigation is imminent.

The equipment used in the current study, HigHNoon, is a light- and shadow-based assistance device for CT-guided percutaneous interventions. The device has a central camera, four light sources mounted at right angles to each other, and a laser source that projects a crosshair on the patients. The device can make left-to-right and head-to-foot swinging motions to guide radiologists to make needle insertion in orbital, craniocaudal, or a combination angle. The light

source generates a shadow of the needle, which, along with projected laser crosshair, is used to visually assist the radiologist for instrument insertion into the patient body. HigHNoon also comes with a planning station that helps radiologists to make an optimal plan.

This study demonstrated statistically significant efficacy of the HigHNoon device in terms of accuracy (2.1 mm), needle insertion time (2.5 minutes), check scan (1.3), and the number of skin punctures (1) in comparison with the conventional freehand procedure. The present study has limited the evaluation to the accuracy and ease of reaching the target; the histopathological and culture yield have not been analyzed in this study. We presume a mild difference in the average size of the lesion in the experimental and control groups was by chance factor following randomization. Several assistive devices have been in use for navigation in CT-guided interventions. In a study done by Brabrand et al, a laser-guided system was evaluated in terms of its accuracy. It was observed that the average number of needle manipulations/skin punctures was 1.1 compared with an average of one in the present study.[5] However, the total procedure time in the study was 15.6 minutes, lower than the current study of 19.9 minutes. In another study done by Koethe et al, a robotic assistance platform was evaluated in achieving accuracy in percutaneous CT-guided interventions.[6] The present study demonstrated a shorter mean needle-to-tip target distance and a lower percentage of the residual target using interventional robots for navigation. In another study done by Bhattacharji et al to evaluate the accuracy of a real-time 3D navigation system for percutaneous CT-guided interventions, the average needle placement time for thoracic procedures was 8.8 minutes, while in the current study, it was far lower, with 2.5 minutes.[7] The average check scan in the current study is 1.3 compared with a higher median value of 2 (2–4) in other device studies.[8]

There were potential advantages documented in this study regarding the experimental device. The reduced requirement for repeated check scans with HighNoon device makes the entire procedure advantageous in terms of reduced radiation exposure to the patient. In addition, the shorter time for the procedure and needle placement makes the entire intervention efficient in terms of feasibility and this enables the device to be flexible in application across different vulnerabilities of the patient. The study device is permanently mounted in the CT room and can be easily switched on and used. Unlike other assistance devices available in the market, the study device does not require any registrations or per procedure calibration like other robotic and EM tracking devices available in the market, making the same very simple to use. The overall setup time is less than a minute when compared with 20 minutes in other devices. The device does not require any consumables thereby reducing the per procedure recurrent cost born by the hospitals or patients. The use of such an assistant device is also greatly helpful in procedures needing a combination angle, such as lesions near the diaphragm.

Pneumothorax is one of the common complications of lung biopsy procedures. Though there was slightly a more number of patients developing pneumothorax in the experimental group (5/60) as compared with the control group (3/60), this was not statistically significant.

The three-level confirmations of needle insertion accuracy namely shadow, camera, and laser make the device effective and simple to use.

It is well established that the accuracy of a CT-guided needle intervention is highly affected by the type and size of the lesion, its position, distance from the skin, and operator. The current prototype of HigHNoon can be angled up to 50 degrees in the axial (XY) plane and 50 degrees in the craniocaudal (Z) plane. We did not find this as a major limitation in this study while planning the procedure. The current study indicates the superiority of the experimental group; however, larger studies with other variables such as smaller lesions, lesions close to the diaphragm, and other lesions in organs are required for further evaluation.

Conclusion

The present study has highlighted the efficacy, safety, and effectiveness of using shadow-based navigation tools for percutaneous CT-guided interventions. The present study has demonstrated the ease of application, minimal adverse effects, and high feasibility rates of the technique for larger application in the hospital setting. The device will also be useful especially for the lesions requiring Z-axis angulation, perhaps in the background of emphysematous changes, where one would like to limit the number of passes.

The device under study may be considered as an adjunct tool for CT-guided interventions, to enhance the outcome of the procedure.

Ethical Approval and Informed Consent

The investigation was performed following the rules of the Declaration of Helsinki of 1975. Approval was obtained from the institutional ethics committee prior to the commencement of the study (Reference number: 11370 (DIAGNO) Dated: 27.06.18). Each participant was explained in detail about the study and informed consent was obtained prior to the data collection.

Funding

None.

Conflicts of Interest

None declared.

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