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ORIGINAL STUDY

A comparison of robotically assisted needle guidance via the PIGA CT system and conventional CT for percutaneous lung biopsies

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Abstract

Objective: The aim was to compare the speed, radiation exposure, needle adjustments, diagnostic efficacy, and complication rate using manual guidance and robotically assisted needle guidance via the Precise Intelligent Guide Arm (PIGA) computed tomography (CT) system for percutaneous lung biopsy.

Methods: A randomized interventional trial was conducted from September 2020 to March 2021 on 30 patients requiring lung biopsies for suspected malignancy. Random allocation of the 30 patients was done in group A (robot-assisted CT scan) and group B (conventional manual CT scan). The outcomes were compared with respect to the total procedural duration, time taken in the navigation of needle insertion, needle manipulations, total radiation, diagnostic efficacy, and complications.

Results: The mean age of the study population was 49 years, and there were 18 males and 12 females. Compared with manual CT, ROBO-assisted CT scan had significantly less duration of the procedure (7.9 ± 1.4 vs. 14.7 ± 5.9 minutes, $P = 0.0002$), less but comparable total radiation exposure (513.5 ± 277.4 vs. 730.8 ± 480.6 mGy, $P = 0.141$), significantly less number of check scans (1.5 ± 0.7 vs. 3 ± 2.3 , $P = 0.022$), significantly less number of needle adjustments (0.5 ± 0.7 vs. 2 ± 2.5 , $P = 0.033$), and significantly more diagnostic efficacy (100 vs. 76.67%, $P = 0.0158$). The complications were comparable between the two groups, with one patient in group A and two patients in group B experiencing small pneumothorax not requiring any therapy or prolonged hospitalization.

Conclusions: Compared with conventional CT with the manual approach, PIGA CT system-guided lung biopsy is a novel technique that reduces procedure duration, needle adjustments, and total radiation exposure and increases diagnostic efficacy without increasing the complications rate.

Keywords: Lung biopsies, Percutaneous, PIGA, Radiation, Robot

1. Introduction

Lung lesions indicative of malignancy are best diagnosed and treated with computed tomography (CT)-guided interventions. CT-guided lung biopsy was first described by Haaga and Alfydi in 1976 [1].

Fluoroscopy and step-and-shoot techniques are used for CT-guided biopsy. Fluoroscopy is useful for smaller lesions and lesions prone to respiratory

motion, whereas step-and-shoot is used for large and immobile lesions [2].

There are some technical limitations with both the procedures, for example, step-and-shoot operates on subjective assessment of positioning and needle path; it may increase the time taken to complete the process and lead to a higher rate of complications. In contrast, CT-fluoroscopy (though considerably quicker) produces higher exposure to radiation for both the patient and the operator [3,4].

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Other technologies like augmented reality [5] and external laser targeting [6] are being considered for better accuracy of diagnosis and decreasing the time taken in CT-guided biopsies. Lately, a plethora of robotic systems have been introduced for assisting in imaging [7]. These include AcuBot (Johns Hopkins Bayview Medical Center, Baltimore, MD 2122), Innomotion: An MR-compatible robotic system (INNOMOTION, Innomedic GmbH, Herxheim, Germany), B-Rob 1 & 2, Developed by Austrian Research Centres (ARC), Seibersdorf, Austria; KUKA-DLR Lightweight Robot, KUKA Laboratories GmbH, Augsburg, Germany; ROBIO EX (M/S Perfint Healthcare Pvt Ltd, Thiruvanniyur, Chennai, Tamil Nadu – 600041, India); iSYS1 (M/S iSYS Medizintechnik GmbH, 6370 Kitzbühel, Austria); PIGA – Precise Intelligent Guide Arm (M/S Perfint Healthcare Pvt Ltd, Thiruvanniyur, Chennai, Tamil Nadu – 600041, India) and Philips brilliance iCT 256 slice CT scanner, Amsterdam, Netherlands [8]. Among all these robotic models, we analyze PIGA in the present study as it is used at our institute.

The Food and Drug Administration (FDA) has approved PIGA (Perfint Healthcare Pvt Ltd) as the robotic positioning system. It aids in percutaneous needle placement during various CT-guided interventional procedures like *radiofrequency ablation*, fine-needle aspiration cytology, biopsy, and drainage procedures. It has a planning station that helps doctors in procedure planning. To start the procedure, one can mark the entry point at the skin and the target point at the lesion center. The robot then calculates the values of the coordinate for the desired needle length. With the system's help, the doctor can now do plan analysis, re-planning, and execution depending on his/her concern. It results in more accuracy as the system enables the physician to measure needle depth and angles robotically [9].

On phantoms, it showed positive results for CT-guided biopsy and ablation [10]. Lesions of the liver were also successfully tested by PIGA for the clinical *radiofrequency ablation* [11]. The objective of the study was to estimate this system's clinical performance and safety for CT-guided intervention of lung lesions.

2. Methods

2.1. Patient population and study details

A randomized interventional trial was done by receiving the approval of the local institutional review board from September 2020 and March 2021. Patients who underwent the chest CT scan for primary lesion suspected of malignancy in the thoracic

surgery department (no lymph nodes were biopsied) of our tertiary care hospital for histopathological characterization were included. Any patient with repeat CT-guided biopsy, clinical diagnosis of secondary malignancies and nonmalignant comorbid lesions like tuberculosis, sarcoidosis, emphysema, and bullae were excluded from the study.

The sample size for the study was based on the observations of Anzidei et al. [9], where the duration of the procedure in robot-assisted procedure was 20.1 ± 11.3 min and in conventional procedure was 31.4 ± 10.2 minutes. Considering these values for reference, the minimum estimated sampling required was 15 patients in each study group (study power 80% and alpha error 5%).

All the participants were explained about the procedure's benefits and the potential risks, and a written consent was taken.

2.2. Study population

A total of 39 patients were found eligible for the study, but five in the treatment arm (Group A) and four in the control arm (Group B) refused to participate in the study. So, finally, 30 patients (15 in each arm) were studied.

2.3. Randomization

Random allocation of the 30 patients was done in group A (robot-assisted CT scan) and group B (conventional manual CT scan). The randomization was done by the sealed envelope system, in which two sealed opaque envelopes were prepared and labeled inside as group A and group B. Once a patient enrolled in the study, he/she was given an envelope to open, and the patient was then placed in the allocated group. The type of investigation modality allocated for each patient was not revealed (allocation concealment) until the patient has irrevocably been entered into the trial regimen, to avoid selection bias.

2.4. Study flow

The demographic details (age and sex) and clinical details (lesion size and location) of the patients were noted.

2.5. Procedure

The same radiologist performed all of the CT-guided biopsies. For the procedure, the radiologist used a Philips brilliance iCT 256 slice CT scanner. An axial scan (detector configuration $\times 1$ mm,

reconstruction interval 1 mm, slice thickness 1 mm) was taken by holding breath before starting the procedure; this was done to confirm the targeted lesion position. To avoid any exposure to critical structures and organs and to decrease any movement of the patient, a vacuum stabilized mattress was used. The path of the needle biopsy was anesthetized locally using lidocaine. A sampling of the tissue was performed using a quick core biopsy end-cutting needle. The low-dose interventional protocol was used to take target CT scans (slice thickness 1 mm, detector configuration \times 1 mm, and reconstruction interval 1 mm). The PIGA CT system is shown in the Figs. 1–3.

The procedural performance was done under local anesthesia by the same experienced interventional radiologist. The primary goal of the intended intervention was to have an adequate instrument position for which baseline plain CT scans were used to identify the lesion, followed by planning of the targeted needle pathway into the robotics system software. After measuring the adequacy of the placement of the needle tip, parameters like depth and size of the lesion from the skin were documented (Figs. 4 and 5).

2.6. Conventional biopsy technique

The step-and-shoot technique was used to gauge angulation and positioning of the needle in all of the conventional biopsies. For the lesions near the chest wall, at least two scans were taken (intralesion and prepleural). However, for the deep lesions, three scans were required (intralesion,



Fig. 2. Overall view of robot-assisted navigation system.

midway to the lesion, and prepleural). Real-time scans and multiplanar reconstructions were performed if required for further needle positioning. After obtaining the desired needle tip position, a biopsy was taken using a combination of push/rotation movements and aspiration with a co-axial needle system.

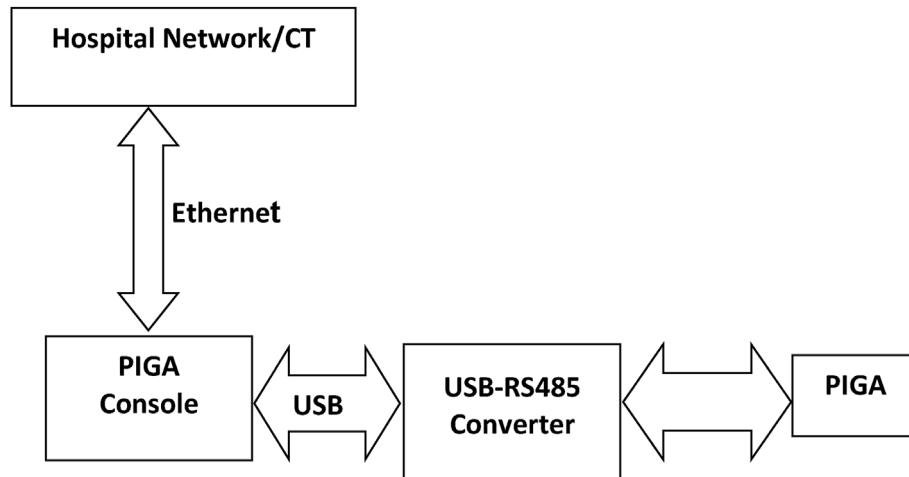


Fig. 1. PIGA computed tomography (CT) working flow. PIGA CT description: the robotic arm is a 5° of freedom system with three linear axes and two angular axes. The device is docked on the left side of the CT into the docking plate installed on the floor. End Effector: end effector holds the sterile bush firmly through which the needle is inserted to reach the target. The clamping operation can be achieved either with the help of foot switch or through the EE clamp/release key on the LCD panel.

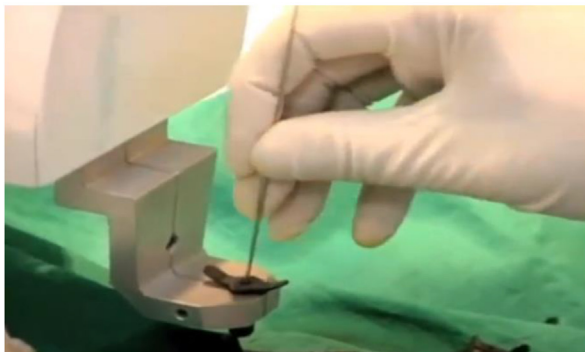
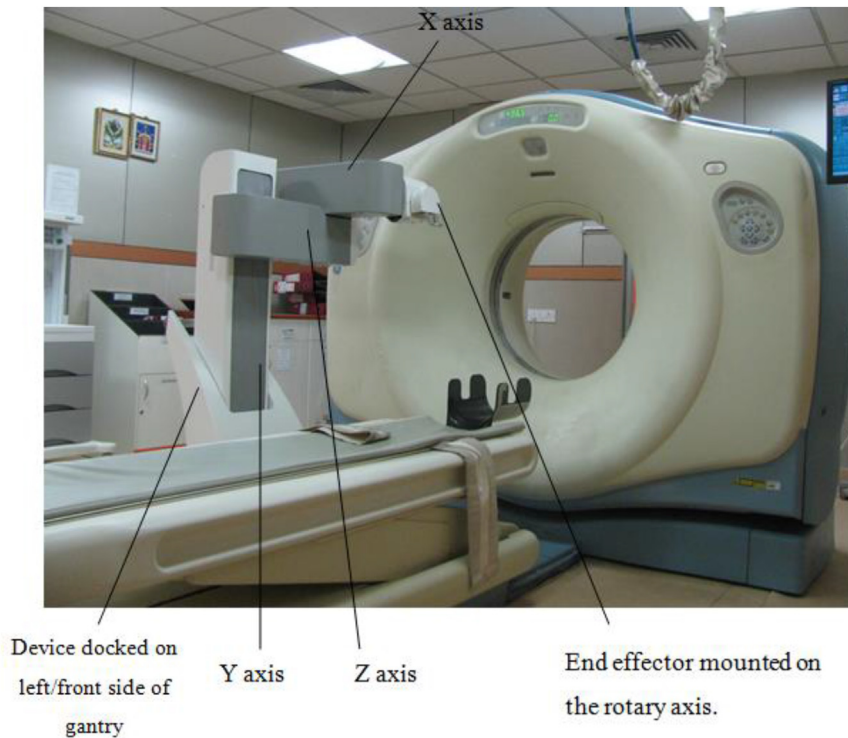


Fig. 3. Robot-assisted navigation system for computed tomography-guided percutaneous lung procedures. Needle placement via the robotic arm at the location of planned pathway.

2.7. Robot-assisted technique

For the robotic system, the arm was located on the CT bedside, as per the requirement of the left or right position. To guarantee the steadiness of the robotic system, the latter was fixed firmly on the ground with metal plates. Transfer of the images was done to the PIGA workstation over a local area network for the planning of the biopsy. Planning software was used for the planning. The operator quickly modified any parameter to avoid any exposure to the critical structures like ribs, vessels, and visceral organs. After confirming the plan, the CT table was adjusted as per the coordinates shown on the workstation, after which activation and positioning of the robotic arm were done for

performing the biopsy. To ensure manual insertion of the needle directly into the lesion through the skin surface in a single pass, the robotic arm's end effector is equipped with a disposable Bush. Once the needle was released from the end effector, the robotic arm was withdrawn, and the position of the needle was confirmed with a CT scan. Adjustments were performed if needed. A biopsy procedure similar to the conventional approach was performed (Fig. 6).

2.8. Outcome measures

The outcomes were compared with respect to the efficacy and safety of the procedure. In terms of efficacy, the total procedural duration, which was

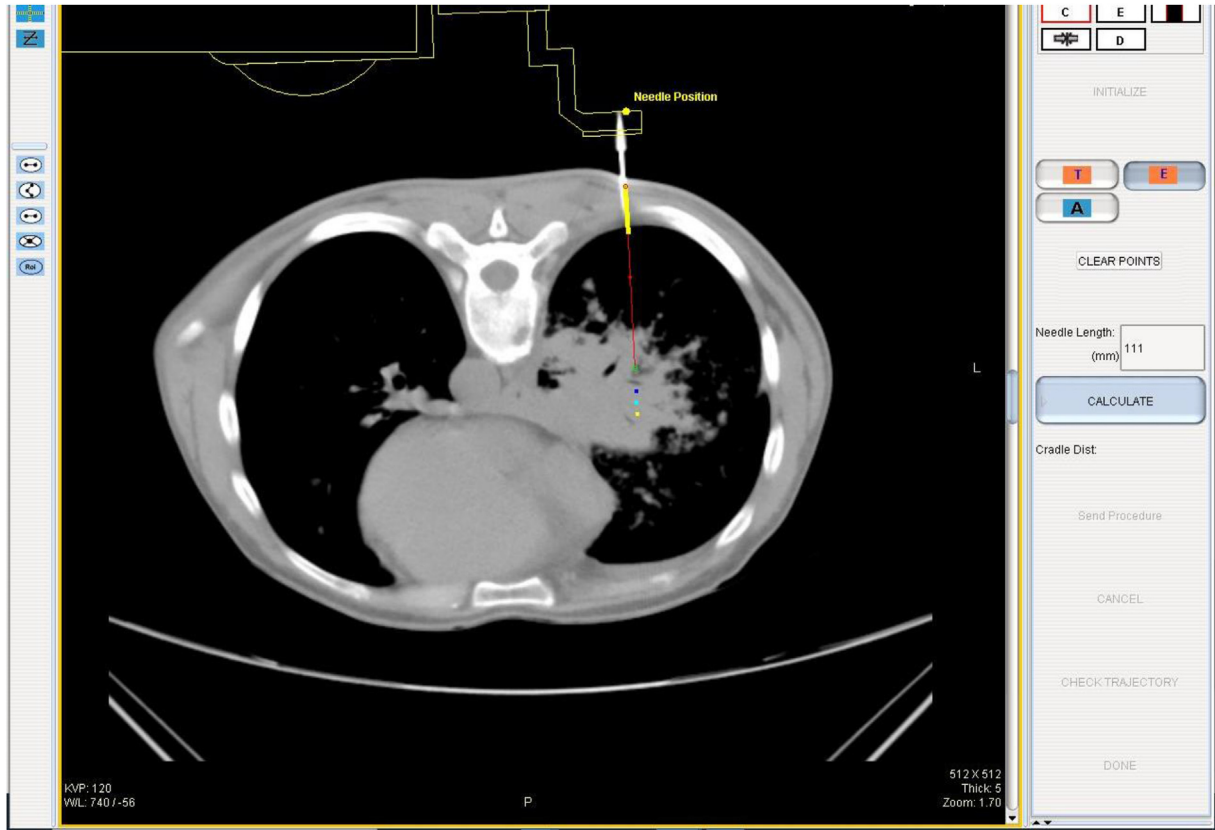


Fig. 4. Planning software projected the needle pathway. The lung lesion was targeted for lung biopsy.



Fig. 5. Verification images after the biopsy needle insertion. The biopsy needle position was almost the same as the original planning pathway.



Fig. 6. Check scan image with needle. Green line indicating the planned trajectory.

the time taken in the navigation from needle insertion for local anesthesia to the needle insertion for the intervention, was noted. In addition, needle manipulations were taken into account. A five-point scale was used to measure the performance of either procedure, wherein 5-1 represents excellent-poor on the scale. The diagnostic efficacy was assessed based on the diagnostic biopsy yield in the first attempt and requirement of further attempts.

In terms of safety, the total radiation exposure and complications were reported and compared among the two groups.

2.9. Statistical analysis

The presentation of the categorical variables was done in the form of number and percentage. On the contrary, the quantitative data were presented as the mean \pm SD. The comparison of the variables that were quantitative in nature like lesion size, distance from the entry point, procedure duration, dose-length product (mGy) – total, dose-length product (mGy) – verification scan, number of check scan, number of needle adjustments, and root mean square error (RMS) were analyzed using the independent *t*-test.

The comparison of the variables which were qualitative in nature like lesion location and complications were analyzed using Fisher's exact test. χ^2 -test was used to compare the diagnostic efficacy.

The data entry was done in the Microsoft EXCEL spreadsheet, Microsoft Corporation, Las Vegas, USA, and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software (ver 21.0; IBM Manufacturer, Chicago, IL). For statistical significance, *P* less than 0.05 was considered significant.

3. Results

The mean age of the study population was 49 years, and there were 18 males and 12 females. The lesion size was greater than 2 mm with all lesions located in the lung at a comparable mean distance from the skin in the two groups (Group A: 72.8 ± 29.6 vs. group B: 71.7 ± 20.5 mm, $P = 0.907$). Compared with manual CT (Group B), ROBO-assisted CT (Group A) scan had comparable lesion size (39.1 ± 23.1 vs. 34.7 ± 24 , $P = 0.613$), comparable distance from entry point (72.8 ± 29.6 vs. 71.7 ± 20.5 , $P = 0.907$), and comparable lesion location in different lung lobes ($P = 1$). The baseline demographic and clinical characteristics were

comparable among the two randomized groups (Table 1).

Compared with manual CT, ROBO-assisted CT scan had significantly less duration of the procedure (7.9 ± 1.4 vs. 14.7 ± 5.9 minutes, $P = 0.0002$), less but comparable total radiation exposure (513.5 ± 277.4 vs. 730.8 ± 480.6 mGy, $P = 0.141$), significantly less number of check scans (1.5 ± 0.7 vs. 3 ± 2.3 , $P = 0.022$), significantly less number of needle adjustments (0.5 ± 0.7 vs. 2 ± 2.5 , $P = 0.033$), and significantly more diagnostic efficacy (100 vs. 76.67%, $P = 0.0158$). During the procedure with ROBO-assisted CT, all 30 cases required only a single biopsy attempt for diagnosis, whereas with the conventional, only 23 cases were diagnosed in the first attempt, three cases required a second CT-guided biopsy, and four cases required a third CT-guided biopsy for the diagnostic yield.

The complications were comparable among the two groups, with one patient in group A and two patients in group B experiencing small pneumothorax not requiring any therapy or prolonged hospitalization (Table 2).

4. Discussion

An amalgamation of medical science and engineering is being observed (both mechanical and computer). In this aspect, the assistance of the robotics to guide percutaneous diagnostic procedures has been a great success, not only for lungs but also for other organs like breast, brain, liver, and prostate [12–15].

Percutaneous biopsies demand high accuracy of needle insertion into the lesions, which are shown to be challenging for the human hand but not so for a

Table 2. Comparison of procedural parameters between two groups

Parameters	ROBO-assisted	Manual	P value
Procedure duration (min)	7.9 ± 1.4	14.7 ± 5.9	0.0002 ^a
DLP (mGy) – total	513.5 ± 277.4	730.8 ± 480.6	0.141 ^a
DLP (mGy) – verification scan	316 ± 187.9	455.2 ± 317.5	0.155 ^a
Number of check scan	1.5 ± 0.7	3 ± 2.3	0.022 ^a
Number of needle adjustments	0.5 ± 0.7	2 ± 2.5	0.033 ^a
RMS	1.2 ± 1.6	1.1 ± 1.3	0.852 ^a
Diagnostic efficacy (%)	100	76.67	0.0158 ^c
Complications [n (%)]	1 (6.67)	2 (13.33)	1 ^b

DLP, dose-length product.

^a Independent *t*-test.

^b Fisher's exact test.

^c χ^2 -test: 5.821.

robotic hand. This is mainly because of the more stiff and precise robotic manipulator [13,14]. The accuracy in the process of biopsy results in an early diagnosis and therapy for cancer, yielding better results for the patients [16].

The present study holds importance in showing that the PIGA accessory used with the conventional CT scan significantly increased the diagnostic accuracy for biopsy and reduced the procedural duration, with resultant reduction in the overall radiation exposure to the patients.

The diagnostic yield with PIGA-assisted CT biopsy was 100% (that is all cases were diagnosed in the first attempt) in comparison with 76.67% efficacy with conventional CT. It was noted that the correct three-dimensional picture and robotic hand decreases the errors incurred while making patient markings in the conventional CT. Moreover, the accurate guidance of the biopsy needle to the center of the malignant lesion through any angulation with minimal damage to the adjoining structures may be the primary cause for increasing the diagnostic efficacy of the procedure. This also stresses on the fact that small and less accessible lesions can be better targeted with the robotic hand as it reaches to the center of the lesion through digitally guided image. However, the PIGA system has an inherent error of 2 mm, and thus, lesions up to 2 mm cannot be biopsied precisely.

With PIGA-assisted CT biopsy, the duration of the procedure significantly reduces as compared with manual CT scans (7.9 ± 1.4 vs. 14.7 ± 5.9 minutes, $P = 0.0002$). This holds importance as the procedure is rapid. The findings were in line with the study by Anzidei et al. [9] (20.1 ± 11.3 vs. 31.4 ± 10.2 minutes, $P = 0.001$), Moeslein et al. [17] ($2 : 06 \pm 1 : 13$ vs. $9 : 11 \pm 3 : 24$ minutes, $P < 0.05$), and Anandakumar et al. [18] [11.7 ± 2.60 (range: 8–20) versus 24.65 ± 10.8 (range: 15–61), $P = 0.001$].

Table 1. Demographic and clinical characteristics of the two groups

Parameter	Group A [n (%)]	Group B [n (%)]	P value
Age (years)	48.93 ± 14.50	49.93 ± 19.99	0.877 ^a
Sex			
Male	8 (53.33)	10 (66.67)	0.456 ^c
Female	7 (46.67)	5 (33.33)	
Lesion size (mm)	39.1 ± 23.1	34.7 ± 24	0.613 ^a
Distance from Entry point (mm)	72.8 ± 29.6	71.7 ± 20.5	0.907 ^a
Lesion location (according to lobar anatomy)			
RUL	2 (13.33)	2 (13.33)	1 ^b
LUL	3 (20)	2 (13.33)	
RML	1 (6.67)	2 (13.33)	
RLL	5 (33.33)	4 (26.67)	
LLL	4 (26.67)	5 (33.33)	

LLL, left lower lobe; LUL, left upper lobe; RLL, right lower lobe; RML, right middle lobe; RUL, right upper lobe.

^a Independent *t*-test.

^b Fisher's exact test.

^c χ^2 -test.

The observed difference in the procedural time among different studies can be accounted by the expertise and a long learning curve for robotic-assisted CT scans. Our institute has been regularly using PIGA for percutaneous biopsies not only for lung lesions but also for liver, and thus the expertise has increased, leading to a lesser mean time of 7.9 min for the procedure, which was lesser than most of the studies.

Furthermore, in corroboration with the reduction in the procedural time, there was reduced exposure to the radiations with PIGA (513.5 ± 277.4 vs. 730.8 ± 480.6 mGy, $P = 0.141$); however, the values failed to cross statistical boundaries. This fact has been statistically more pronounced in studies by Chu et al. [19] (480.4 , range: 196.5 – 959.8 with Maxio vs. 645.4 , range: 285.1 – 1043.5 with conventional CT, $P < 0.05$), Anzidei et al. [9] (324 ± 114.5 vs. 541.2 ± 446.8 mGy, $P = 0.001$), and Anandakumar et al. [18] (536.13 ± 135.7 vs. 647.31 ± 346.18 , $P = 0.001$).

Making the procedure quick always entails a question of accuracy. The primary aim of biopsy is a correct diagnosis, which depends upon the accuracy of the lesion puncture by the needle. In our study, PIGA showed significantly less number of needle adjustments, making the process more accurate (0.5 ± 0.7 vs. 2 ± 2.5 , $P = 0.033$). The findings were in line with Anzidei et al. [9] (2.7 ± 2.6 vs. 6 ± 4 , $P < 0.0001$) and Anandakumar et al. [18] (0.31 ± 0.65 vs. 3.25 ± 2.69 , $P = 0.002$). This further supports the notion of improved precision provided by the robotic arm for percutaneous needle biopsies.

In percutaneous biopsy procedures, the trajectory to be followed is mostly a straight line. Thus, robotic-assisted CT scans can also have utility of integrating images by fusion providing a linear trajectory to the target [8,16].

However, such benefits of robotic applications have not been explored to the full potential in hospital settings, on account of financial constraints and expertise [7]. A gap in the clinical application and technological advancement has always been under scrutiny in the developing country as ours.

However, the present study and other studies in the literature are encouraging enough to surpass these boundaries for the betterment of the patients. Not only they can assist in better diagnosis, robotic-assisted CT can be useful for therapeutic measures also [16]. With advancements, the user interface has eased, with less effort in installation making it approachable for premier institutes. Besides PIGA, there has been an advanced version: MAXIO, which has shown better results in terms of less procedure time [19]. MAXIO is a USFDA 510(k)-approved

device for use in CT procedures. It is an image-guided, physician-controlled stereotactic accessory to a CT system providing assistance in manual advancements of needles and probes during CT-guided percutaneous procedures in many organs such as thorax, abdomen, and pelvis. However, its cost remains a limiting factor for extended use.

As for the adverse effects related to the biopsy, it was minimal in our study with only a single case of pneumothorax with the PIGA system. This further ensures the accuracy of targeting the needle in the space-occupying lesion of the lung. Similar to the present study, even Anandakumar et al. [18] had one complicated case of pneumothorax with PIGA. Anzidei et al. [9] reported 10.4% complication rate with PIGA against 11% of the manual ($P = 0.05$). However statistically, there was no difference in the complications rate between robotic-assisted and manual CT-guided biopsies.

4.1. Limitations

The study was limited by the small sample size. Second, biopsy reports were not retrieved. Third, PIGA CT accessory has a high cost of Rs 55 lacs. Lastly, PIGA CT system does not have additional benefits in terms of breath controlling of the patient. This is present in the advanced version MAXIO as a vacuum stabilized mattress.

4.2. Conclusion

Compared with conventional CT with the manual approach, PIGA CT system-guided lung biopsy is a novel technique that reduces procedure duration, needle adjustments, and total radiation exposure and increases diagnostic efficacy without increasing the complications rate.

Conflict of interest

There are no conflicts of interest.

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