

# DIAGNOSTIC ADEQUACY AND SAFETY OF IMAGE GUIDED TRU-CUT BIOPSY

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## ABSTRACT

**Objective:** To analyze the safety and adequacy of image guided TRU-CUT biopsy in Kuwait Teaching Hospital, Peshawar

**Materials and Methods:** This retrospective cross-sectional study was conducted in Radiology Department of Kuwait Teaching Hospital from 1<sup>st</sup> January to 31<sup>st</sup> December 2016. A total 354 patients presenting for image guided TRU-CUT biopsies were included in study, specimens were sent to reputable laboratories for evaluation of sample adequacy whereas, safety of the procedure was assessed by rate of major complications. SPSS version 19 was used for statistical analysis.

**Results:** 100% of CT guided biopsies generated adequate samples, whereas 326 out of 336 U/S guided biopsies produced adequate specimen with overall diagnostic adequacy of 97.1%. Scrutiny of results depicts no major complications in any patient. There was statistically insignificant effect of needle parameters or imaging modality, having  $P$  value  $> 0.005$ , on the adequacy of biopsy specimen.

**Conclusion:** Image guided TRU-CUT biopsy is effective and safe procedure. Our study can help counsel patients about safety and effectiveness of procedure and avoiding more invasive open biopsies.

**Key Words:** Diagnostic Adequacy, Safety, Image Guidance, TRU-CUT biopsy

## INTRODUCTION

Performing image guided percutaneous biopsies for tissue diagnosis is a very common procedure. It has a proven diagnostic accuracy for malignancy in adults.<sup>1-5</sup> The diagnostic adequacy is defined as sample sufficient to make definite tissue diagnosis or to identify origin of tumor<sup>6</sup> and safety is defined as rate of major complications.<sup>7</sup> Over the past decade or so, trends have shifted from more invasive open biopsies and less accurate blind biopsies to safer and more effective image guided biopsies.<sup>8-10</sup> Moreover, being an outpatient procedure<sup>11</sup> done with local anesthesia<sup>11</sup> adds to the advantages of image guided biopsy. Computerized Tomography(CT), Ultrasound(U/S) and fluoroscopy all are used for localizing percutaneous biopsy site, however, U/S is most commonly used since it is real-time technique, easily performed and readily available of all the imaging modalities, with added advantage of avoiding ionizing radiation.<sup>12</sup> TRU-CUT/core-needle biopsies are preferred over Fine needle aspiration biopsies (FNAB) for tissue sample not only

provides histological<sup>6</sup> details but ancillary studies like immunohistochemistry and cytogenetic studies can be performed as well. For this purpose, we chose to include only TRU-CUT image guided biopsies in our study. Biopsy is essential diagnostic tool for malignant disease, as tissue diagnosis is mainstay of management. There is high prevalence and incidence of cancer in Pakistan<sup>13</sup>, consequently high demand for centers providing up to date interventional Radiology services with experienced personnel. Since only few centers are so far offering interventional Radiology facilities in Peshawar, upholding high quality of services is of prime importance.

This study was designed to assess adequacy and safety of image guided TRU-CUT biopsies, with the purpose of establishing efficiency of TRU-CUT biopsies performed out in Radiology Department of Kuwait Teaching Hospital Peshawar. We also evaluated effects of needle parameters and type of imaging modality on diagnostic adequacy of TRU-CUT biopsy sample.

## MATERIALS AND METHODS

This retrospective study was conducted in Radiology department of Kuwait teaching hospital from 1<sup>st</sup> January to 31<sup>st</sup> December 2016. A total of 354 patients referred to our department for Image guided TRU-CUT biopsies were included. Pre-procedure evaluation of every patient was done for assessment and localization of target tissue/mass lesion. Imaging modality and needle for biopsy were also selected depending upon the target tissue/lesion location, size and closeness to sensitive anatomical structures. Informed consent was obtained from every patient and patients' demographic profile was recorded. For U/S guided biopsies, *Toshiba iSTYLE Famio XG*® machine with linear and curved probe was used. For CT-guided biopsies, *Toshiba Activion16*®CT-scanner was used. BARD MAGNUM (U.S) fully automatic biopsy gun, was used with disposable cutting needles of various gauges. For most of the biopsies 18G needles were used. 14G needle was used for breast biopsy. For pleural biopsy 16G needle was used whereas deeper retroperitoneal tissues like pancreas were biopsied using small bore 20G needle.

All the biopsies were performed as out-patient procedure. If patient needed prone position, intubation was done. After aseptic measures, Local anesthesia was given to every patient along the tract of biopsy needle. Small incision was made at the skin site to facilitate needle insertion. Needle was directly visualized and maneuvered within tissues under U/S guidance for patient safety and appropriate positioning of needle tip, before firing biopsy gun. For CT guided biopsies, skin markers were applied and coaxial needle position was assessed using low dose non-contrast CT images, until tip of coaxial needle sheath was appropriately position for sampling desired tissue. Patient was asked to hold breath and sample taken. Minimum of 3 cores from each tissue were taken for every patient. Samples were fixed in 10% formalin solution. Sample container was labeled with patient data and tissue sampled for histological examination. Patients were assessed immediately for bleeding from biopsy site or any other major complication. Every patient was kept under observation for 1 hour after biopsy and then discharged. Complications recorded clinically, during or one hour after the procedure, were categorized as Immediate complications in conjunction with Society of Interventional Radiology guidelines<sup>1</sup>. No post-biopsy antibiotics were administered. Tissue samples were sent to reputable institutes for detailed histological examination and immunohistochemistry, if needed. All the samples were assessed by consultant pathologists and reports recorded.

All data was obtained from patients' record files and analyses were performed using statistical software (SPSS 19). Quantitative variables like age were assessed using mean, median and range whereas categorical variables like Diagnostic Adequacy, Safety and gender were evaluated by means of frequencies and percentages. Diagnostic adequacy and safety were calculated. Effect of needle parameters and type of imaging modality on diagnostic adequacy were assessed using tests of significance i.e. one-way ANOVA and chi-square. *P* values were used to evaluate significance of factors effecting diagnostic adequacy. *P* value above 0.005 was considered insignificant.

## RESULTS

Total 354 patients were included in the study. The patient age ranged from 5 to 70 years with median age of  $48 \pm 14.9$  SD years (mean age 46.7). There were 198 (55.9%) females among all 354 (100%) and 156 were males (44.1%).

Our data included 266 (75.1%) biopsies from abdomen, 18 (5.0 %) from pelvis, 46 (12.9%) from thorax, 10 (2.8%) from breast and axilla, 4 (1.1%) biopsies from bone, 4 (1.1%) from anal verge and 6 (1.6%) from neck.

Out of total of 354 trucut biopsy samples, 344 (97.1%) samples were labeled as adequate with overall adequacy rate of 97.1%. 10 (2.9%) samples turned out to be diagnostically inadequate and repeat sampling was required for final tissue diagnosis (Figure 1). No immediate or delayed major complications were observed in all 354 (100%) patients. Safety rate (rate of major complications) of image guided TRU-CUT biopsy turned out to be 100 % ( $n=354$ ). Only Pain at the biopsy site, as minor complication, was encountered. 86 (24.1%) patients out of 354 (100%) experienced immediate post procedure pain at the biopsy site that was relieved within 30 minutes of procedure with analgesics.

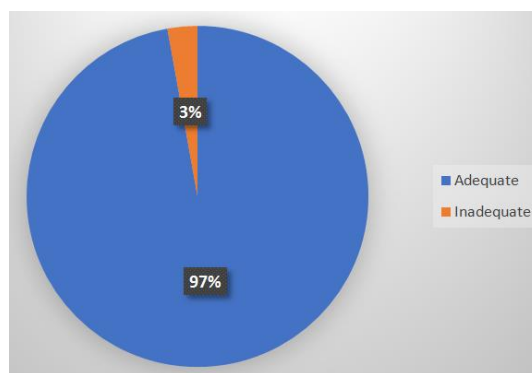
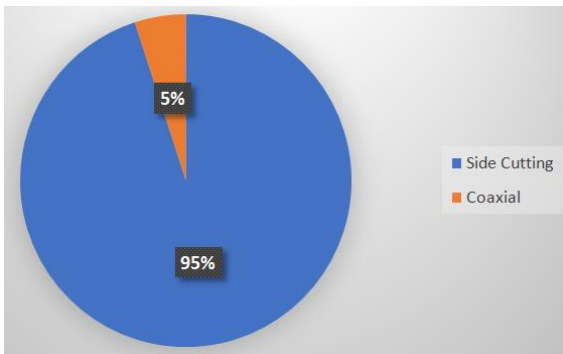
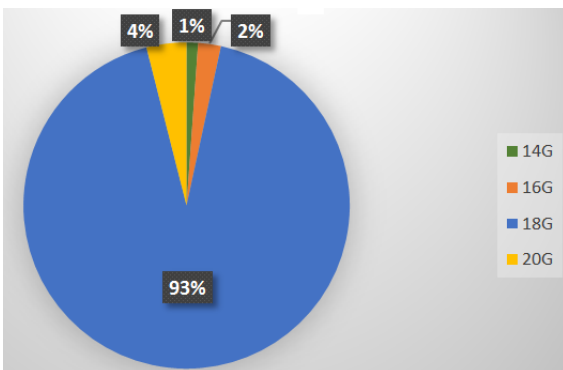


Fig. 1: Diagnostic adequacy



**Fig. 2:** Needle type



**Fig. 3:** Needle gauge

U/S guidance was used for 336(94.9%) and CT was used for 18(5.1%) patients. All CT guided biopsies generated adequate samples, whereas U/S guided TRU-CUT biopsy had diagnostic adequacy rate of 97.1% with total 326 adequate specimens. 10(2.9%) inadequate samples were obtained using U/S guidance. There was no significant effect of imaging modality used on the

adequacy rate of TRU-CUT biopsy ( $p>0.005$ ). Side-cutting needles were used for all 336 (94.9%) U/S guided biopsies whereas coaxial needles were used for all 18(5.1%) CT guided procedures (Figure 2). All 18(5.1%) coaxial needle biopsies generated adequate samples, while 326 out of total 336 side-cutting needles produced 97.1% adequate specimens. Among all 10 (2.9%) inadequate samples, all were taken using side-cutting needle. Effect of type of needle used on adequacy rate was insignificant ( $p>0.005$ ). Frequency distribution of needle gauge used was 4 (1.1%) 14G, 8 (2.2%) 16G, 328 (92.7%) 18G and 14 (4.0%) 20G needles (Figure 3). All 4 (1.1%) 14G needles were used for biopsy samples from abdomen and 8 (2.2%) 16G needles for thoracic biopsies, whereas, 20G needles were used for 10 (2.9%) samples from abdomen and 4 (29%) samples from thorax while 18G needles were used for 252 (71.1%), 34 (9.6%), 18 (5.0%), 10 (2.8%), 6 (1.6%), 4 (1.1%) and 4 (1.1%) TRU-CUT biopsy samples from abdomen, thorax, pelvis, breast, neck, bone and anal verge respectively. 14G and 20G needles produced all adequate samples whereas 16G needle generated 6 (1.6%) and 18G needle resulted in 320 (90.3%) adequate biopsy samples. Insignificant effect of needle gauge was observed in our study on rate of diagnostic adequacy ( $p>0.005$ ). Among all 10 (2.9%) inadequate samples, 2 (0.5%) taken with 16G needle whereas 8 (2.2%) using 18G needle (Table1). Eight (2.2%) out of 10 (2.8%) cases had necrotic tissue resulting in inadequate sample. Two (0.5%) inadequate samples with non-necrotic tissue turned out to be lymphoma in repeat samples.

**Table 1:** Effect of needle parameters and imaging modality on sample adequacy

	Inadequate	Adequate	Total	P value
Needle type				
Coaxial	0	18 (5.1%)	18 (5.1%)	0.057
Side-cutting	10 (2.9%)	326 (92%)	336 (94.9%)	
Needle Gauge				
14 G	0	4 (1.1%)	4 (1.1%)	0.459
16 G	2 (0.5%)	6 (1.6%)	8 (2.3%)	
18 G	8 (2.2%)	320 (90.5%)	328 (92.7%)	
20 G	0	14 (10%)	14 (10%)	
Modality				
CT Guided	0	18 (5.1%)	18 (5.1%)	0.459
U/S Guided	10 (2.9%)	326 (92%)	336 (94.9%)	

## DISCUSSION

From review of recent literature, we verified that there is a shift from blind percutaneous and invasive open biopsies to image guided biopsies<sup>8-10</sup>, both FNAB and

TRU-CUT, in favor of improved safety<sup>9,14</sup> of procedure, as concluded by Huang C, et al. in their study on TRU-CUT liver biopsies, having complications in only 2 among total 200 patients, and high rate of diagnostic

adequacy<sup>6</sup> of sample, supported by National UK audit of 2015, which concluded Diagnostic adequacy of image guided TRU-CUT biopsy as 98%.<sup>11</sup> Another study conducted by Ali, H, et al. portrayed that there was decrease in rate of complication in renal biopsy without U/S guidance vs. U/S, from 5.8% to 1 % respectively<sup>15</sup> with comparable rate of Diagnostic adequacy of 80.5% in image guided Procedures.

In our retrospective study, we gathered data of 354 patients, with diagnostic adequacy of 97.1%. These results are comparable with many recent studies. Joshi et al<sup>6</sup> reported that generated 92% adequacy rate, as compared to 97.1% adequacy rate in our study, while evaluating adequacy and accuracy of image guided percutaneous bone biopsy. A study, conducted by Hao et al<sup>16</sup> concluded that preoperative image guided needle biopsy is a standard diagnostic tool for management of breast lesions instead of open biopsy. It is particularly valuable for lesions that are not easy to resect and tumors for which neoadjuvant chemotherapy can be valuable. Another study by Park et al<sup>14</sup> evaluating U/S guided core biopsy of pelvic masses, resulted in no major complication (100% safety) and only 18% minor complications, had results similar to our study with minor complication rate of 24% in current study and 100% safety rate, thus our study verified that percutaneous biopsy, procedure used to take multiple samples by TRU-CUT needle less invasively than by excision/ open biopsy, is a valuable and safe instrument in diagnostic work up. None of patient in our study experienced bleeding / hematoma formation from biopsy site confirming that image guided percutaneous biopsies performed at Radiology Department of Kuwait Teaching Hospital Peshawar, are following world-wide trends.

Recently national audit done in UK by Howlett<sup>11</sup> including 3490 patients demonstrated U/S is preferred modality for image guidance, used for 2808 (96.3%) of 3490 cases series. Another study by Hari et al<sup>8</sup> also verified ultrasound as favored modality for image guidance, using U/S in 30 (90%) out of total 33 patients. In our study, we also found similar tendency that U/S was preferred modality for image guidance, used for most of the cases 336 (94.9%) out of total 354 and CT was used for only 18 (5.1%) samples. Recent literature also points to similar inclination globally, US being most commonly used modality for image guided interventions, mainly because of easy availability and absence of ionizing radiations<sup>12</sup>, however, we observed in present study that both U/S and CT are equally effective as image guidance modality with adequacy rates of 97.1% and 100% respectively, the choice is influenced by equipment availability, patient anxiety,

and radiologist expertise/preference. Many studies done over the past 5 years confirmed comparable effectiveness of CT and U/S guided biopsies. Sivakumar et al<sup>17</sup> identified diagnostic sensitivity of 71.43% compared to 75% for U/S and CT guided pleural biopsies respectively. Sconfienza et al<sup>18</sup> also validated that U/S and CT biopsies from peripheral lung lesions both have comparable and overall high pathological adequacy of 98% vs 93% respectively.

Other benefit of image guided TRU-CUT biopsy is being an out-patient procedure, besides high diagnostic efficacy and low complication rate. Large case series of UK national audit, with 1852 (55%) biopsies performed as out-patient procedures and 3238 (96%) of 3378 performed under local anesthesia, provided adequate data favoring that day-case biopsy (discharging patient on same day) is a safe procedure and can be performed using only local anesthesia.<sup>11</sup> We also established that fact in our study, where all the patients underwent biopsy as outpatient procedure, under local anesthesia only.

In this study we found that changing needle gauge did not significantly affect the diagnostic adequacy of TRU-CUT biopsy. Choice of the needle gauge depended upon operator choice, considering location and site of the target lesion as well as its closeness to the sensitive anatomical structures. For current study, we used 18 G needles in most (92.7 %) of samples with diagnostic accuracy of 97.1 %, suggesting needle gauge alone doesn't affect the adequacy. Howlett et al<sup>11</sup> in their study, also suggested 18-gauge needle was sufficient in most of cases producing adequate sample with safety. In another recent study, Ocak et al<sup>19</sup> compared use of 16G and 18G needles in liver biopsy, found that rate of diagnostic adequacy was 85% and 80% for 16G and 18G needles respectively, authenticating that needle gauge does not affect the sample adequacy. Ali et al<sup>15</sup> in their study, compared use of 14G and 16G needle in renal biopsy and found no significant effect of changing needle gauge on outcome of biopsy. On the contrary, North American guidelines recommend 16 G needle and a 3cm long specimen being ideal specially for liver biopsies.<sup>11</sup> In current study, we, however, did not look at sample length as a variable and recorded sample to be diagnostically adequate when a histological diagnosis was made.

Our study reflects current practices where side-cutting needles are used in conjunction with spring loaded fully automated biopsy devices.<sup>20,21</sup> Sridharan et al<sup>21</sup> in their study also confirmed that fully automated biopsy device gives better results than semiautomatic biopsy gun. In present study we used cutting needles

with fully automatic biopsy gun in all cases of U/S guided biopsies. Coaxial needle was used in CT- guided biopsies only. In our study, however, no significant correlation was found between type of needle used and diagnostic adequacy of sample.

We did not record presence or absence of necrosis in a lesion/ tissue to be biopsied. This is an important factor effecting adequacy of samples. Inadequate samples in our study were mainly because of the necrotic component in lesion to be sampled, rather than inadequacy of the sampling technique. 8 out of 10 inadequate samples, from our series, had necrotic tissue. Necrotic tissue renders sample inadequate for making histopathological diagnosis and application of immunohistochemistry studies. A large series of TRU-CUT liver biopsies, from UK, also suggested that factors which relate to tissue necrosis, like increased number of passes or large size of lesion, had significant effect on diagnostic adequacy of sample.<sup>11</sup>

## CONCLUSION

In conclusion, current study establishes that image-guided biopsy done at our institute is minimally invasive, effective and safe diagnostic procedure of sampling tissue for histopathological diagnosis. Needle parameters like needle type and gauge do not have significant effect on diagnostic adequacy of sample. Both CT and U/S have comparable diagnostic adequacies and safety for TRU-CUT sampling in present study and both modalities can be used with degree of confidence. Results of our study reflect that interventional Radiology practices at Kuwait teaching hospital, Peshawar are at par with global trends and international standards.

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