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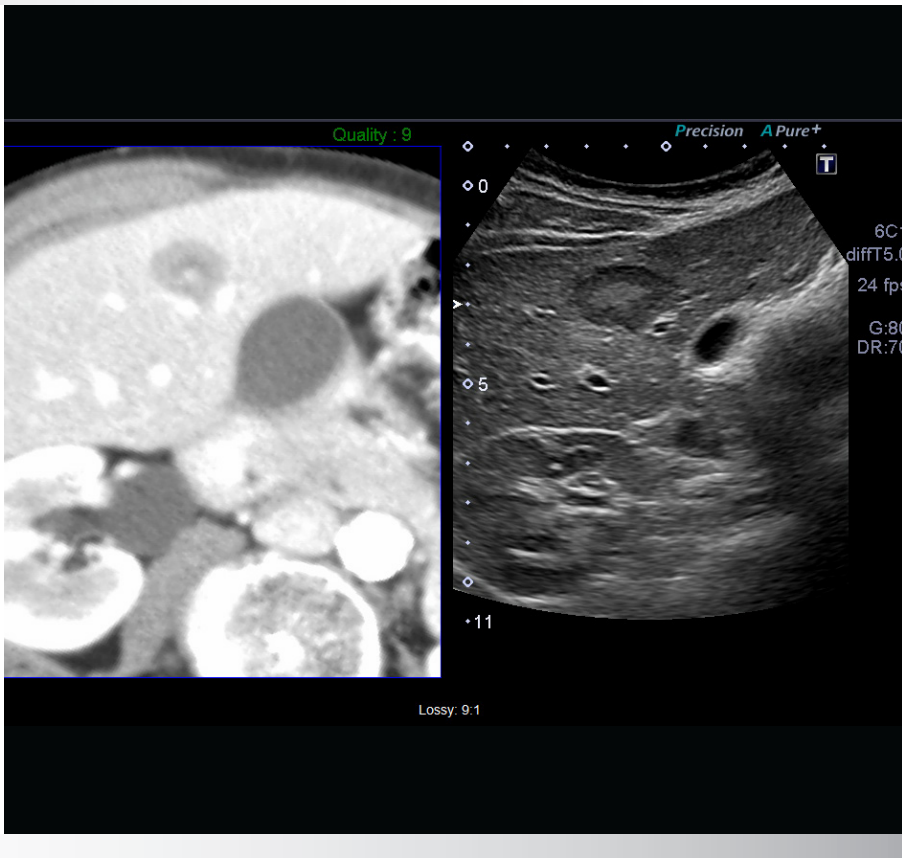
Improved Biopsy Confidence Using Toshiba's Smart Fusion



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Toshiba's Aplio™ 500 with Smart Fusion enables physicians to fuse live ultrasound with previously acquired CT or MR images. Smart Fusion technology helps locate hard-to-find lesions and improves confidence during ultrasound-guided biopsies. The technology reads 3D DICOM data sets from CT or MR systems and displays the corresponding images side by side with the live ultrasound image. Easy to use, Smart Fusion image registration is achieved in a simple two-step process.

Smart Fusion Guidance of Percutaneous Biopsies

A prospective clinical evaluation was undertaken at St. Elizabeth Healthcare to assess the clinical efficacy of ultrasound-guided liver and kidney biopsies using Smart Fusion. A total of 35 patients underwent ultrasound-guided biopsies using Smart Fusion between February 2013 and May 2014, including 33 liver lesion biopsies, one renal core biopsy and one renal lesion biopsy. Live ultrasound images were synchronized with previously acquired CT (N = 32) and MR (N = 3) images. For comparison, a total of 31 CT-guided liver and kidney biopsies were evaluated. Table 1 summarizes the study populations. There were no significant differences between the Smart Fusion and CT biopsies groups in terms of age, gender or BMI.

Diagnostic Accuracy

Abdominal lesion biopsies guided by Smart Fusion technology achieved an impressive diagnostic accuracy. Diagnostic-quality biopsy samples were acquired from the lesion of interest in 34 out of 35 cases (97.1 percent). Three patients had previously undergone CT- or MR-guided biopsies, which were deemed non-diagnostic. In these three cases, Smart Fusion technology was used to attempt repeat biopsies, which were successful in two out of three instances. Even in these most challenging cases, including small lesions located in hard-to-reach locations, Smart Fusion delivered the accuracy needed to confidently biopsy the lesion of interest.

Some abdominal lesions are not well visualized by standard CT imaging alone but recognized only with contrast-enhanced CT. In these instances, CT-guided biopsies are not feasible, since the timing requirements for contrast CT are prohibitive for biopsy guidance. However, Smart Fusion allows physicians to load previously acquired contrast CT images that can be fused with real-time ultrasound, providing a suitable alternative and avoiding the possibility of a more invasive and costly open surgical procedure.

Improved Patient Safety

Compared to ultrasound guidance alone, Smart Fusion biopsies provide greater confidence to ensure patient safety. For example, there are many critical structures to be avoided near many liver masses including the aorta, inferior vena cava, portal vein and hepatic veins. The addition of CT or MR images synchronized with live ultrasound helps to plan an appropriate access point and needle pathway for safe biopsies and reduced complications. There were no adverse events or complications experienced by the patients that underwent Smart Fusion biopsy in this study.

	Smart Fusion biopsies	CT biopsies
N	35 (19M, 16F)	31 (17M, 14F)
Age (years)	35 – 84 (62.5 ± 12.7)	22 – 84 (56.4 ± 16.1)
BMI	16.6 – 44.3 (27.4 ± 5.7)	20.4 – 40.3 (29.6 ± 5.4)
Liver lesion biopsy procedure time (min.)	10 – 32 (17.0 ± 5.4)*	17 – 30 (24.3 ± 5.4)*
Radiation dose:		
CT dose index (mGy)	0*	8.1 – 185.5 (60.9 ± 37.1)*
Dose length product (mGy-cm)	0*	56.8 – 1983.0 (668.2 ± 407.4)*
Effective dose (mSv)	0*	0.9 – 29.7 (10.0 ± 6.1)*

Table 1. Summary of results from patients that underwent percutaneous biopsy using Smart Fusion or CT guidance. Values in parentheses are expressed as mean ± standard deviation. ** p-value < 0.05 using two-tailed Student's t-test.*

Radiation Dose Savings

Patients and physicians alike benefit from the radiation dose savings enabled by Smart Fusion technology. By moving biopsies from CT to ultrasound guidance, Smart Fusion allows diagnostic decision making without needing additional radiation exposure. In this study, the average CT dose index (CTDIvol) and dose length product (DLP) used in the CT-guided biopsy cases were 60.9 mGy and 668.2 mGy-cm, respectively. The average effective dose, assuming a DLP conversion factor for the abdomen of 0.015 mSv mGy-1 cm-1 [1], was 10.0 mSv, which represents the potential dose savings with Smart Fusion-guided biopsies. Patients with lesions detected by ultrasound or MR imaging can complete their screening and diagnostic work-up using Smart Fusion, without any exposure to ionizing radiation. Also note that radiation dose savings from Smart Fusion technology reduce the cumulative exposure experienced by interventional radiologists and other medical personnel involved with CT-guided biopsies so that they can focus more attention on what matters most: caring for their patients.

Shorter Procedure Times

The ease of use and increased confidence afforded by Smart Fusion technology helps to reduce procedure times. Smart Fusion biopsies were completed in less time on average compared to CT biopsies (17 minutes versus 24 minutes, P <0.05). This time savings allows physicians to be more efficient in performing biopsies, giving them more time during the day to perform other clinical activities and work.

Cost Effective

Toshiba's Aplio 500 with Smart Fusion is a cost-effective solution for percutaneous biopsies of abdominal lesions. At St. Elizabeth Healthcare in 2012, the average cost for ultrasound-guided biopsies (CPT 76942) was $99, while the average cost for CT-guided biopsies (CPT 77012) was $228 [2]. So, a cost savings of $129 is achieved for every biopsy procedure that is moved from CT to ultrasound Smart Fusion guidance. In addition, there is an opportunity for increased revenue by freeing up time on the CT scanner that was previously spent on biopsy guidance. In most cases, two CT imaging studies can be completed in the time required for one CT-guided biopsy. Additionally, the overall investment for an Aplio 500 with Smart Fusion is much smaller than the cost of a CT scanner. In a separate cost benefit analysis [3], the annual financial benefit of utilizing Smart Fusion technology, including cost savings per procedure and increased CT revenue, for a hospital system like St. Elizabeth Healthcare was estimated as $84,943.

Patient Satisfaction

Patient satisfaction is increasingly important to hospitals now that patient satisfaction surveys impact Medicare payments under the Affordable Care Act. Smart Fusion delivers the accuracy needed to confidently biopsy the lesion of interest, even in difficult to reach locations, so that patients can avoid more invasive, open-surgical biopsies and unnecessary complications. Biopsies guided by Smart Fusion offer shorter procedure times to provide a more comfortable and less stressful patient experience. Smart Fusion biopsies can be performed in a more calming environment than CT-guided biopsies, and patients appreciate that no additional radiation is needed using ultrasound guidance. Together, these factors can help to improve patient satisfaction during a procedure that is often associated with significant stress and anxiety.

Case 1: A 56-year-old female with a history of lung cancer presents with a new liver mass deep in the caudate lobe, identified by CT exam (Figure 1). The liver lesion measured approximately 3.0 x 6.0 cm, and its deep location in the caudate lobe contributed to a previous, non-diagnostic CT-guided biopsy. The decision was made to attempt the biopsy under ultrasound guidance using the Aplio 500 with Smart Fusion to prevent further CT exposure to the patient and physician. To avoid the major vessels in proximity to the mass, including the aorta, inferior vena cava, portal vein and hepatic veins, the decision was made to advance the needle using an intercostal coronal approach through the right lobe of the liver. The patient's CT data set was uploaded onto the Aplio 500 and synchronized with real-time ultrasound. The location of the mass on the CT image was used to select the appropriate rib space for the pathway of the needle. At this time, the lateral margin of the liver was non-visible sonographically due to rib shadow, and the fused CT image guided the biopsy needle safely. With accurate synchronization and fusion of the ultrasound and CT images, the needle was clearly visualized on real-time ultrasound approaching the mass at a 90-degree angle of insonation to the ultrasound beam (Figure 2). Smart Fusion enabled a successful biopsy of the deep caudate liver mass and saved the patient from undergoing a more invasive and costly opensurgical procedure.

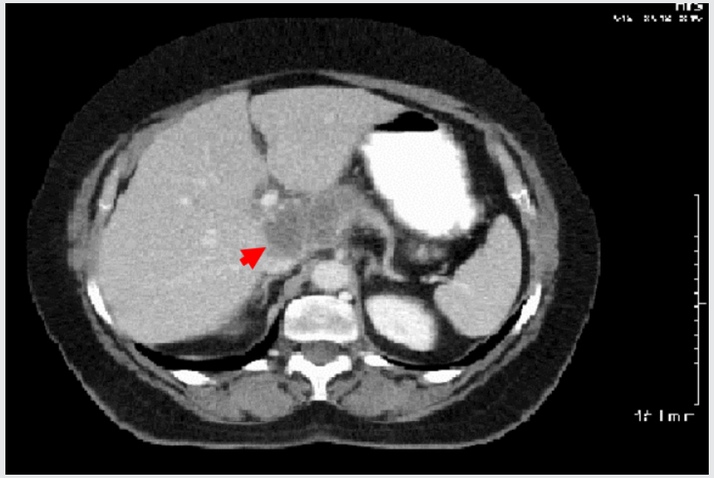

Figure 1. CT visualization of a liver lesion (red arrow) located deep within the caudate lobe.

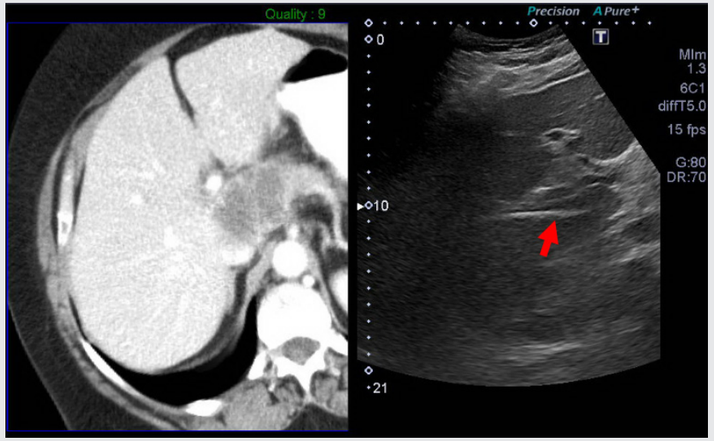

Figure 2. Synchronized CT image (left) and live ultrasound image (right) using Smart Fusion. The biopsy needle (red arrow) is clearly visualized in the live ultrasound image.

Case 2: A 68-year-old female with a history of lung cancer presented with abdominal pain. An abdominal CT was performed and a new liver mass was found (Figure 3). The liver mass was hypermetabolic on a subsequent PET scan, and the decision was made to perform a biopsy using the Aplio 500 with Smart Fusion for guidance. Using the fused, real-time imaging and a right subcostal approach, the lesion was easily biopsied with an 18-gauge core biopsy needle (Figure 4 and 5). Biopsy results were positive for metastatic lung cancer.

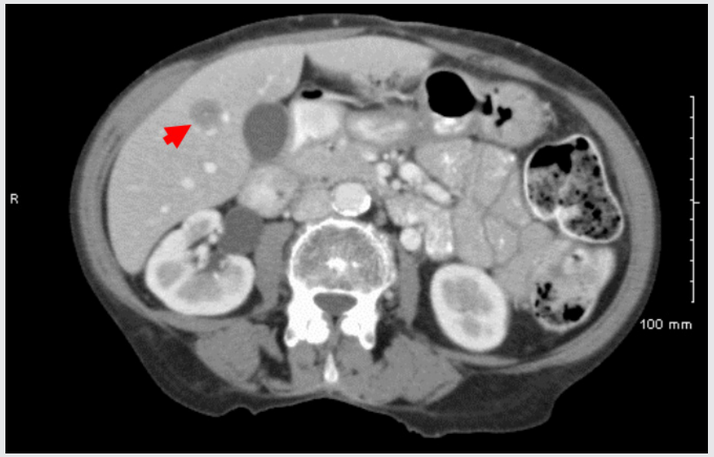

Figure 3. CT visualization of a liver mass (red arrow) in a female patient with a history of lung cancer.

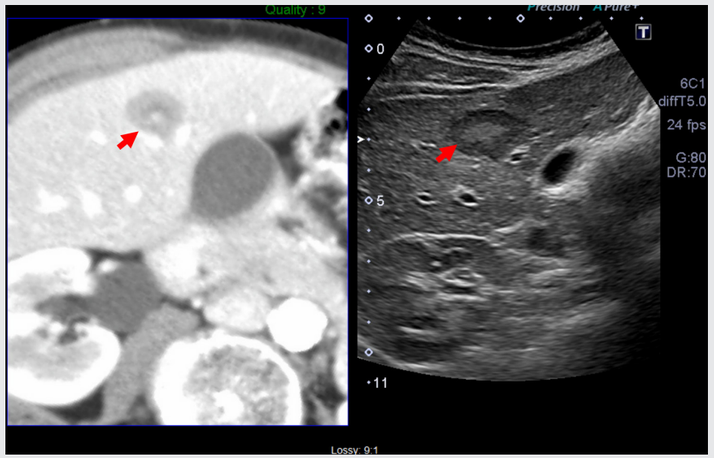

Figure 4. Synchronized CT image (left) and live ultrasound image (right) using Smart Fusion, demonstrating accurate co-localization of the liver mass.

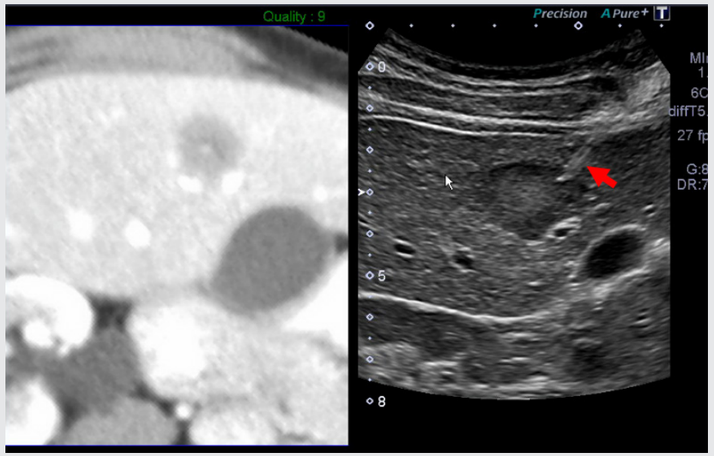

Figure 5. The biopsy needle (red arrow) is clearly visualized entering the liver mass in the live ultrasound image using a right subcostal approach.

Case 3: A 72-year-old male with a history of both prostate and bladder cancer presented with new jaundice. The patient also had renal insufficiency with a creatinine level of 2.3 mg/dL. Therefore, a non-contrast CT was performed demonstrating a new 2.8 cm low attenuation mass in segment 7 of the liver (Figure 6). Due to the challenging location of the mass and difficulty visualizing mass on non-contrast CT, we felt this patient was ideal for Aplio 500 Smart Fusion-guided biopsy. The mass was visible on ultrasound, and real-time ultrasound was synchronized with the non-contrast CT images. Using a right subcostal approach, the lesion was successfully biopsied with an 18-gauge core biopsy needle (Figure 7). Biopsy results were positive for metastatic bladder cancer.

Figure 6. A new 2.8 cm low attenuation liver mass in segment 7 is visualized on non-contrast CT in a male patient with a history of prostate and bladder cancer.

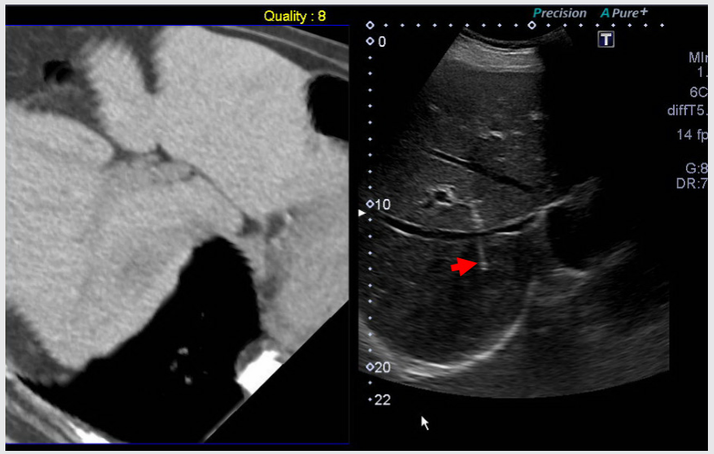

Figure 7. Synchronized CT image (left) and live ultrasound image (right) using Smart Fusion. The 18-gauge biopsy needle (red arrow) is clearly visualized in the live ultrasound image using a right subcostal approach to reach the mass.

Case 4: A 73-year-old female with a history of alcoholic cirrhosis had a liver mass found during a routine hepatoma screening ultrasound. Subsequent MRI demonstrated an enhancing 3.2 cm mass in segment 7 of the liver (Figure 8). The patient's AFP level was normal. Due to the patient's multiple comorbidities, clinical service felt the need for definitive diagnosis before pursuing any potential treatment options. Therefore, the decision was made to biopsy the lesion. Real-time ultrasound was fused with the MR images (Figure 9), allowing for a complete work-up and biopsy without any radiation exposure to the patient. The lesion was successfully biopsied and results were positive for hepatocellular carcinoma.

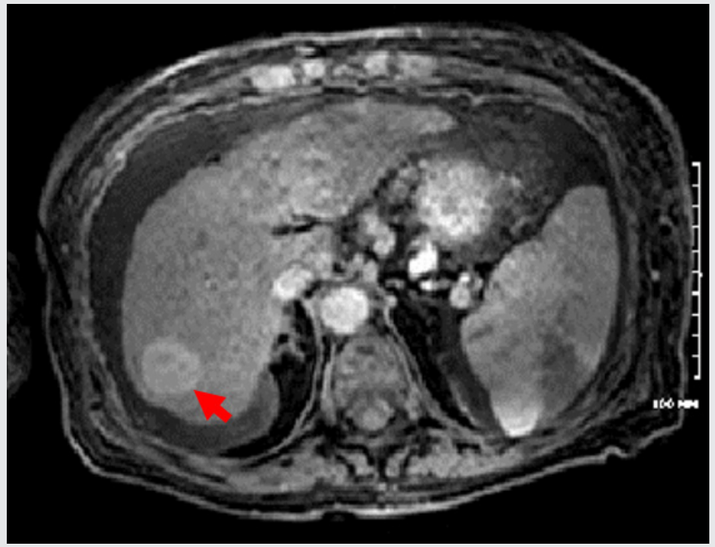

Figure 8. MR visualization of a liver lesion (red arrow) in a female patient with a history of alcoholic cirrhosis.

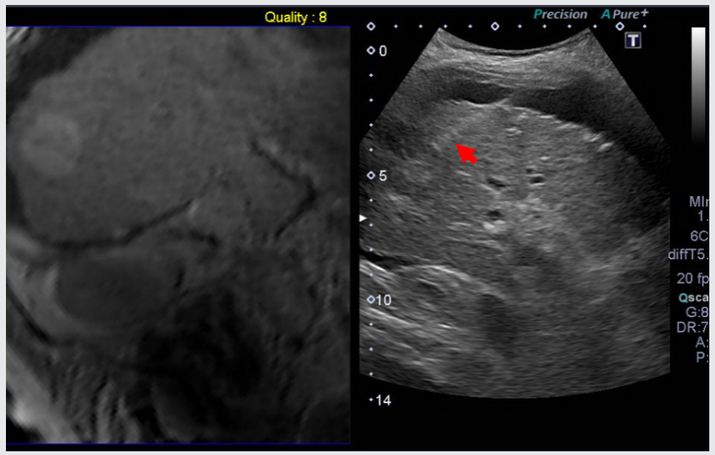

Figure 9. Synchronized MR image (left) and live ultrasound image (right) using Smart Fusion. The biopsy needle (red arrow) is clearly visualized in the live ultrasound image.

Case 5: A 62-year-old female with newly diagnosed lung cancer. During staging work-up, she found to have a 1.8 cm low attenuation right renal mass on CT exam (Figure 10). Clinical management of the patient was dependent on knowing whether the renal mass was a lung metastasis or a primary renal cell carcinoma. Given the small size of the mass, biopsy would be difficult with either CT guidance or ultrasound guidance alone. The decision was made to use Aplio 500 Smart Fusion guidance. With the patient in the prone position, the CT images were fused with real-time ultrasound (Figure 11). The lesion was successfully biopsied using Smart Fusion guidance with an 18-gauge core biopsy needle. Biopsy results were positive for metastatic lung cancer.

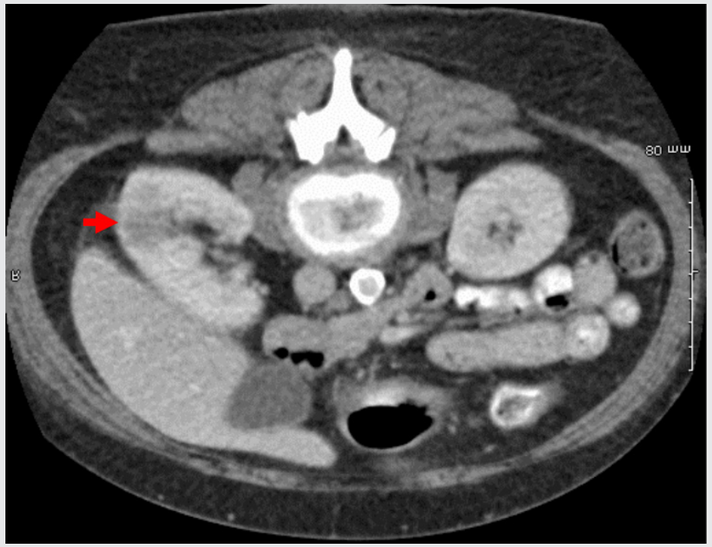

Figure 10. CT visualization of a 1.8 cm right renal mass (red arrow) in a newly diagnosed lung cancer patient.

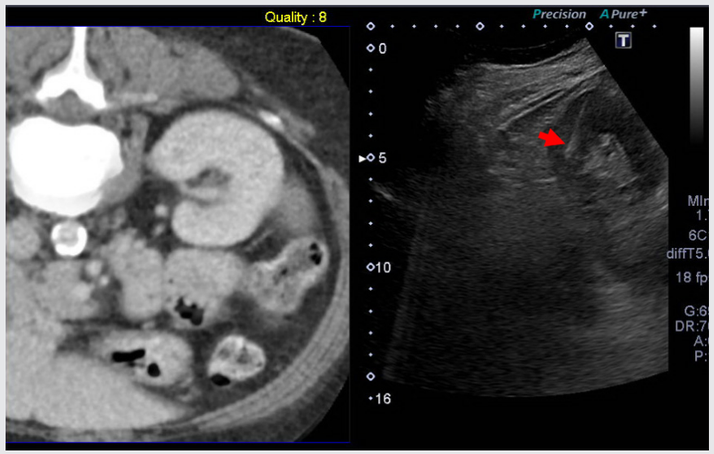

Figure 11. Synchronized CT image (left) and live ultrasound image (right) using Smart Fusion. The lesion was successfully biopsied using an 18-gauge needle (red arrow).

Conclusions

Toshiba's Aplio 500 with Smart Fusion is a valuable tool for percutaneous biopsy guidance. Smart Fusion increases physician confidence in their ability to biopsy small lesions accurately and safely. It is easy to use and offers shorter procedure times, while significantly reducing the radiation dose to patients and physicians compared to CT-guided biopsies. In today's value-based healthcare environment it is critical to provide better quality care at lower costs. Smart Fusion is a cost-effective solution for biopsy guidance that improves the quality of care and patient experience.

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