Comparison of Manual and Computer Assisted Ultrasonic Guidance for Transparenchymal Percutaneous Renal Needle Placement

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Purpose: We evaluated a novel computer based guidance system for deploying needles into the renal parenchyma. We compared it to current standards, including a fixed needle guide and a freehand technique.

Materials and Methods: We performed an in vitro comparison followed by a porcine trial. The in vitro model consisted of a bath of ultrasound medium with suspended metallic targets. We compared the number of attempts and the time needed by the novel guide design with and without its software and a support arm vs the freehand approach. In the porcine model we tested the software guide with and without a support arm for targeting a 5 mm lesion embedded in the renal parenchyma. Impressions of difficulty, time, the number of attempts, needle tip visualization and needle tip divergence were documented.

Results: Compared to freehand targeting the software guide and support arm decreased the number of targeting attempts in the in vitro model from 4.8 to 1.6 ($p < 0.001$) and decreased the time required from 31.8 to 11.4 seconds ($p < 0.001$). In the porcine study needle tip visualization with the software and support arm received an average score of 1.3 vs 1.8 with the software guide alone ($p = 0.04$). Tip divergence received a score of 1.4 with the arm and 1.8 without it ($p = 0.07$). Overall contribution received a score of 1.4 with and without the support arm ($p = 0.35$).

Conclusions: Computer assisted needle deployment decreased the time and number of attempts required to successfully target simulated parenchymal lesions and also decreased the subjective difficulty inherent in the standard freehand approach.

Key Words: kidney, needles, ultrasonography, equipment, swine

Abbreviations and Acronyms

CT = computerized tomography

CUGS = computer based ultrasound guidance system

MRI = magnetic resonance imaging

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IMAGE guided percutaneous procedures are being increasingly performed to diagnose and manage various conditions. Recent advances in image guided technology, including the latest generations of CT, MRI and ultrasound devices, as well as improvements in biopsy needles, and radio frequency and cryoablation techniques have enhanced the safety and efficacy of percutaneous image guided procedures.[1] Lesions previously considered relatively inaccessible can now be safely biopsied and treated.[2] With regard to hepatic and renal percutaneous intervention sonography is widely used in Europe and Asia as the imaging modality of choice. However, radiologists and surgeons in the United States have not readily adopted this technique.[3]

Until recently the use of sonographic guidance was restricted to percutaneous biopsy for large or superficial lesions. Small lesions that were deep or

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precariously positioned were considered inaccessible to sonographically guided intervention.[4] Additionally, the inability of ultrasound to see through air and bone as well as large quantities of soft tissue limits the application of needle core biopsy in the chest, upper abdomen and thick peritoneal regions. Due to these problems with ultrasound CT and MRI scanners continue to dominate the training and practice of many interventional radiologists in the United States.[5] Despite these drawbacks sonography has many benefits, including portability, no ionizing radiation and decreased procedure time when viewing lesions and their adjacent structures or percutaneously introducing instruments.[6] Compared with other modalities ultrasound does not deliver ionizing radiation to the patient or the health care team. Ultrasound also allows real-time imaging since there is no delay due to image processing, as there is with CT.[7,8]

A benefit to parenchymal targeting with ultrasound is that surgical specialists do not always have access to axial imaging technologies such as CT and MRI but they commonly have access to ultrasound, and are proficient with this type of imaging and its application. The recent emphasis on cost containment and patient throughput, especially with high end CT and MRI scanners, favors sonography, particularly for percutaneous applications.[9] Furthermore, the application of sonography has expanded from its use for superficial and large lesions to its use for deep and small lesions.[10]

Despite advances in ultrasound technology, including the use of narrowly collimated ultrasound beams and attached needle guides, limitations continue to exist. One such limitation observed by the novice and the experienced interventionist is the indistinct acoustic interface between the needle tip and the surrounding soft tissue. This limitation results in difficulty finding and following the needle tip, particularly with the small caliber needles (ie 20 and 22 gauge) used for tissue diagnostic aspiration and for new tumor ablation techniques. The smaller caliber needles result in intrinsic needle flexibility, which makes needle tracking difficult. Additionally, most attached needle guides require the needle to be passed at a specific or fixed angle relative to the transducer as well as in the imaging plane. This characteristic limits the procedures to a unique in-plane approach. The freehand technique, that is manual passage of needles through the skin without a guide, exacerbates the issue of the in-plane approach. However, the freehand technique requires considerable practice and experience to master the 2-handed coordination necessary for needle visualization and targeting. Surgical specialists are even more challenged by the lack of daily exposure to ultrasound targeting methods.

We compared the placement of narrow caliber needles using a novel ultrasound coupled guidance system with other commonly used techniques for ultrasound guided percutaneous interventional procedures. This system is unique because it has several df, which to our knowledge makes it unlike any existing system that is currently available. The needle can be pivoted by the user in any dimension, which greatly facilitates the targeting process. The study entailed 2 components, including in vitro comparison followed by a porcine model.

MATERIALS AND METHODS

The Ultrasound Guidance System

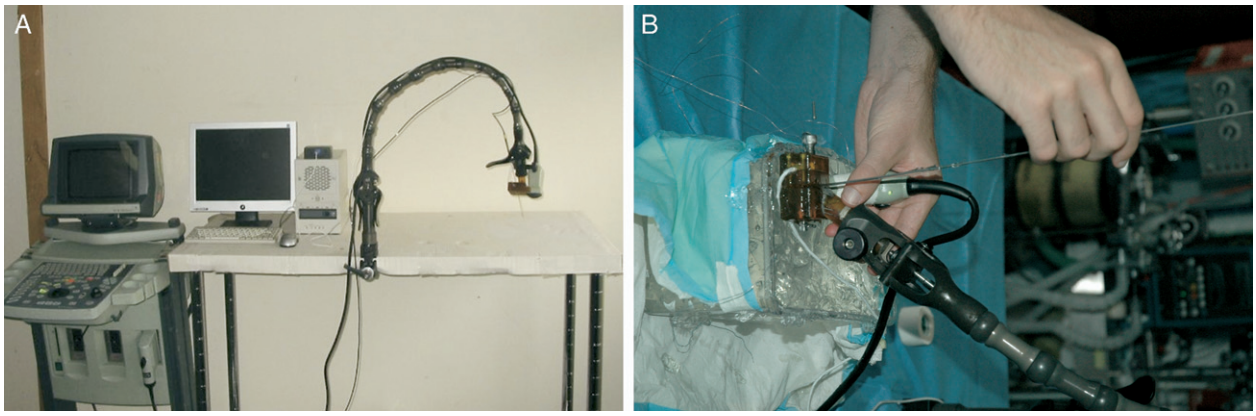
A novel prototype CUGS for parenchymal targeting was tested. CUGS is a freestanding accessory unit that is placed adjacent to the ultrasound unit. CUGS is attached to the ultrasound transducer using a small signal wire (part *A* of figure). The wire is attached along the cable of the transducer to become transparent to the user. The device incorporates a dynamic needle guide attached to an ultrasound transducer. The needle guide contains an encoder that sends a positional signal back to the computer. The computer captures the live ultrasound image and overlays a virtual needle path on a remote monitor. A calibration routine of approximately 30 seconds is completed to ensure accuracy. With this input information the device calculates the angle of the needle relative to the transducer and displays the predicted path as a graphic overlay on the real-time ultrasound image. The needle can then be advanced and observed on the ultrasound and remote monitors. The needle is observed to follow the track projected by the computer, as verified by the ultrasound image.

In Vitro Experiment

An in vitro phantom study was done to evaluate available needle placement techniques (part *B* of figure). The in vitro model consisted of a bath of ultrasound medium with spherical stainless steel targets suspended in set positions.[11] There were a total of 5 targets, including 3, 5 mm targets, a 12 target and an 18 mm target. The 5 mm targets were placed at a depth of 5, 10 and 14 cm, respectively, within the phantom model, while the 12 and 18 mm balls were placed 14 cm deep.

The sides of the bath were constructed of transparent plastic, which was covered on the side of the subject to ensure that the participant relied only on the ultrasound image, while allowing the experimenter to observe the targeting attempts. Targeting was considered successful when the needle tip made contact with the target.

A total of 12 medical students, 4 urology residents, 4 urology fellows and 2 attending physicians completed the in vitro study arm. The level of training and experience related to targeting and use of ultrasound was documented in each participant. Each participant performed image guided needle deployment on the same phantom using a 17 gauge needle. Participants were asked to target each steel ball in turn with the tip of the needle. After each attempt, if it was not successful, the participant was re-



A, novel prototype computer based ultrasound guidance system is freestanding accessory unit that is placed adjacent to ultrasound device. System is attached to ultrasound transducer using small signal wire. *B,* dynamic needle guide is also attached to transducer. Needle guide sends positional signal to computer, which captures live ultrasound image and overlays virtual needle path on remote monitor.

quired to withdraw the needle out of the ultrasound field, reposition the needle and try again. Each participant targeted the series of 5 balls 4 times using 4 methods of ultrasound guided needle placement. The 4 methods tested were in a randomized sequence, including method 1—the freehand technique, method 2—a needle guide attached to the side of the transducer, method 3—a needle guide, including a projected path line superimposed by the targeting software and method 4—a needle guide with the projected path line and a support arm. Each participant received an explanation of ultrasound use and successful location of the lesion with the ultrasound transducer.

In the phantom study the in-plane approach was used. For each targeting attempt the depth and diameter of the implanted lesion, and the time and number of passes required to successfully target the lesion were recorded. The number of passes ceased to be recorded beyond the tenth attempt and the time to target the lesion ceased to be recorded after 3 minutes had elapsed without successful targeting. When either of these end points was reached, participant attempts were stopped, and the time and number of attempts were recorded. Upon completion the participants were asked to subjectively rank the 4 techniques based on their personal preference on a 4-point scale from 1—the most favored to 4—the least favored technique. No criteria were provided to participants since this ranking was intended to be based entirely on personal preference.

Porcine Experiment

The porcine arm of the study included 8 medical students, 5 urology residents and 4 attending physicians, who performed ultrasound guided percutaneous targeting procedures in a deceased domestic pig weighing 25 kg. In the porcine experiment we evaluated the 2 techniques in the in vitro arm of the study that provided the most objective improvement in targeting time and required attempts. The 2 techniques were the needle guide with its software projecting the needle path line 1) with and 2) without the support arm. These 2 targeting techniques were evaluated for the aid that participants subjectively experienced when targeting lesions in the porcine model.

To deploy the targets the pig was placed in the lateral decubitus position. Pneumoperitoneum was established through a Veress needle placed at the umbilicus. After intra-abdominal pressure had attained 15 mm Hg the Veress needle was removed and access was gained using a 3-port laparoscopic technique. A 5 mm target ball was positioned in the renal parenchyma to simulate a lesion. A small wire was attached to the ball and a simple electrical circuit was used to identify successful probe targeting. One electrode was attached to the target and the other was attached to the needle. When the needle contacted the target, the circuit was completed and an alarm sounded to confirm contact. After deploying the target in the kidney the insufflant was vented and the incisions were closed.

Unlike the in vitro model, participants were only given 5 attempts to percutaneously contact the target. For each targeting attempt the recorded parameters were the time and number of passes required to successfully strike the target. Participants were then asked to subjectively rank the 2 techniques. Subjective data included the operator assessment of needle tip visualization and divergence, overall contribution of the guide and the degree of difficulty. Needle tip visualization was scored on a scale of 1 to 4 as 1—visualization throughout the procedure, 2—visualization with minimal adjustment or manipulation, 3—visualization with major adjustment or manipulation and 4—no visualization. The degree of needle tip divergence, defined as deviation from the path predicted by the device, was scored on a scale of 1 to 3 as 1—no divergence, 2—slight divergence and 3—substantial divergence.

A subjective impression of the overall contribution of the device to the procedure was recorded on a scale of 1 to 4 as 1—the device worked with a decrease in time and/or effort, 2—the device worked but there was no decrease in time and/or effort, 3—the device worked with an increase in time and/or effort and 4—the device did not work. The reference for this subjective impression was based on user

Table 1. *In vitro trial targeting results across all experience levels*

	No. Participants	Targeting Method				p Value
		1	2	3	4	
Students:	12					
Time		36.4	21.2	12.3	15.6	0.0001
No. attempts		5.1	2.9	1.9	1.8	0.0001
Residents:	4					
Time		11.5	6.4	5.3	5.4	0.11
No. attempts		3.7	2.1	1.6	1.5	0.0004
Fellows:	4					
Time		37.1	24.2	21.9	7.2	0.2538
No. attempts		4.8	3.5	2.6	1.3	0.02
Attending physicians:	2					
Time		54.5	29.2	4.9	4.7	0.0016
No. attempts		5.3	3.2	1	1.1	0.0017
Overall:						
Time		31.8	19.5	13	11.4	0.0001
No. attempts		4.8	2.9	1.9	1.6	0.0001
Total No.	22					

experience with performing ultrasound guided intervention with an attached needle guide.

The degree of difficulty was also recorded for each procedure, including 1—straightforward, 2—difficult due to the lesion nature (ie difficult for the operator to visualize due to the echo features) or location (ie deep, behind a rib or surrounded by blood vessels) and 3—difficult due to technical factors not related to the lesion. Data were analyzed using Stata™ with Student's t test for continuous variables and the Mann-Whitney U test for categorical variables.

RESULTS

In Vitro

A total of 22 participants participated in in vitro testing, including 2 attending physicians, 4 fellows, 4 residents and 12 students. For ultrasound targeting methods 1 to 4 when not discriminating among participant experience levels, the average number of targeting attempts and average time required for correct probe placement decreased, such that method 1 was the slowest (31.8 seconds) and required the most attempts (4.8), while method 4 was the most rapid (11.4 seconds) and required the fewest attempts (1.6). Methods 2 and 3 were in the middle.

When broken down according to participant experience level, it was found that for medical students and medical residents method 3 was most rapid at 12.3 and 5.3 seconds, respectively. All groups followed the overall trend in regard to the number of targeting attempts required.

When analyzed by targeting method, for methods 1 and 2 medical residents required the least amount of time (11.5 and 6.4 seconds) and the fewest targeting attempts (3.7 and 2.1, respectively) of any experience group. Attending physicians required the least amount of time (4.9 and 4.7 seconds) and the fewest number of targeting attempts (1 and 1.1, respectively) of any experience group using methods 3 and 4 (table 1).

Porcine Experiment

A total of 17 participants, including 4 attending physicians, 5 residents and 8 students, participated in porcine testing. For method 3 (needle guide with targeting software) all experience groups required a similar number of targeting attempts. Attending physicians were quickest and medical students were slowest to achieve successful targeting (4.7 vs 6.7 seconds). Attending physicians were better able to visualize the needle and noted more needle tip divergence (1.5 and 2, respectively). Medical students found that targeting software was the most helpful, while attending physicians found it to be the least helpful (1 vs 1.8).

For method 4 (guide, software and support arm) attending physicians required fewer targeting attempts than residents or medical students (1.25 vs 1.4, $p = 0.93$). Residents required the least time for successful targeting (3.4 seconds). Medical students noted the most divergence in the needle tip and found the software to be most helpful (1.6 and 1, respectively, table 2).

When comparing targeting methods 3 and 4 across experience groups, method 4 was found to have significantly better visualization of the needle tip (1.3 vs 1.8, $p = 0.04$) and lower perceived divergence (1.4 vs 1.8, $p = 0.07$, table 3).

DISCUSSION

Results of the in vitro experiment demonstrate the superiority for all experience levels of the new software enhanced targeting system over a needle guide alone and the current freehand technique. Regard-

Table 2. *Porcine model targeting results for methods 3 and 4 across experience levels*

	Attending Physicians	Residents	Students	p Value
Method 3:				
No. subjects/group	4	5	8	
Av No. attempts	1	1	1.25	0.32
Av time (secs)	4.7	5.6	6.7	0.79
Needle tip visualization score	1.5	1.6	2.14	0.26
Needle tip divergence score	2	1.8	1.5	0.53
Overall software guide contribution	1.8	1.2	1	0.24
Method 4:				
Av No. attempts	1.25	1.4	1.4	0.93
Av time (secs)	13.3	3.4	8.8	0.11
Needle tip visualization score	1.3	1.4	1.4	0.87
Needle tip divergence score	1.3	1.2	1.6	0.37
Overall software guide contribution	1.8	1.2	1	0.41

Table 3. *Porcine targeting results for methods 3 and 4 across groups*

	Guide + Software	Guide, Software + Support Arm	p Value
Av No. attempts	1.1	1.4	0.17
Av time (secs)	5.9	8.2	0.28
Needle tip visualization score	1.8	1.3	0.04
Needle tip divergence score	1.8	1.4	0.07
Overall software guide contribution	1.4	1.4	0.35

less of experience level all groups showed a decrease in the number of attempts and a decrease in the amount of time needed for successful targeting with the software guide. More benefit was realized when striking smaller targets with the software than when striking larger targets, as manifested by a decrease in the number of attempts and in time. While using the software guide, attending physicians did best when they were not using a support arm but less experienced participants found the support arm beneficial. Participants in the porcine study reported increased needle tip visualization and decreased needle tip deflection with CUGS.

In all groups CUGS was believed to result in successful targeting with a decrease in time and/or effort. Residents subjectively experienced the greatest benefit in the porcine trial, while attending physicians least appreciated the assistance of the software. These findings in conjunction with the relatively poor performance of attending physicians in the freehand portion of the in vitro study suggest that attending physicians who have extensive training in and experience with the freehand approach would benefit the least in a clinical setting from the software guide. They were actually hampered by this prior experience in the in vitro model due to its dissimilarity to actual renal parenchyma and, therefore, the inability to guide themselves through the recognition of normal renal architecture.

The current study has some limitations. Because the animal was not alive during the porcine portion of the experiment, there was no respiratory motion of the kidney. Certainly striking a moving target is substantially more challenging than striking a stationary target. However, we believe that CUGS would also be useful in the true in vivo setting. Additionally, a larger subject pool would have allowed more powerful distinctions among experience groups, in addition to the significant efficacy findings overall. This preclinical trial will be used to move forward with clinical efforts.

CONCLUSIONS

In these models CUGS improved the speed and precision of probe targeting. Inexperienced users subjectively benefited most from application of the software targeting system. The support arm provided a significant improvement in needle tip visualization when combined with the software guide. By increasing speed and accuracy, and decreasing the standard difficulties associated with needle visualization the software guide and support arm have the potential to facilitate renal targeting by clinicians of all levels of experience.

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