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ORIGINAL ARTICLE

Dirk L. Stippel
Sebastian Böhm
K. Tobias E. Beckurts
Hans G. Brochhagen
Arnulf H. Hölscher

Experimental evaluation of accuracy of radiofrequency ablation using conventional ultrasound or a third-dimension navigation tool

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D.L. Stippel (✉) · S. Böhm
K.T.E. Beckurts · A.H. Hölscher
Department of Visceral
and Vascular Surgery,
University of Cologne,
Joseph-Stelzmann-Strasse 9,
50931 Cologne, Germany
e-mail: Dirk.Stippel@uni-koeln.de
Tel.: +49-221-4785077
Fax: +49-221-4786258

H.G. Brochhagen
Institute of Radiology,
University of Cologne,
Joseph-Stelzmann-Strasse 9,
50931 Cologne, Germany

Abstract *Background:* Successful radiofrequency-induced ablation is dependent on correct placement of the device. The ultraguide system is a three-dimensional positioning system creating an overlay of the real-time ultrasound image and a virtual image of the device.
Methods: Tumor mimics were produced by injecting an agarose/cellulose/glycerol gel into pig livers on table. The precision of device placement was evaluated either using a freehand ultrasound procedure or using the aid of the ultraguide system either by an experienced or inexperienced surgeon. Tumor mimics were ablated by a protocol yielding an ablation only discretely larger than the mimics to enhance the importance of precise positioning.
Results: The sizes of the 40 tumor mimics were: largest diameter 14.1±2.2 mm, volume 0.89±0.40 cm^3. The largest diameter of ablation was 25.6±3.7 mm, the smallest diameter 21.9±2.9 mm, and the volume 7.20±2.38 cm^3. The experienced surgeon was successful in 7 of 10 cases with and without the ultraguide, the inexperienced surgeon in 4 of 10 without and 7 of 10 with the ultraguide.
Conclusions: The ultraguide system may facilitate precise device placement for the less experienced surgeon. It seems worthwhile to evaluate a possible benefit of the system during placement of devices under operating room conditions.

Keywords Radiofrequency ablation · Three-dimensional navigation · Tumor mimic · Ultrasound

Introduction

Clinical success of radiofrequency ablation may be hampered by incomplete necrosis of the treated lesion. While incomplete, inhomogeneous necrosis of the treated tissue is rather seldom using modern array systems with multiple prongs and generators with sufficient power [1], targeting precisely in all three dimensions is still a challenging task. The accuracy and completeness of ablation is strongly affected by the difference in size of the lesion treated and the necrosis induced. Modern radiofrequency ablation systems facilitate induction of a necrosis with a maximum diameter of 5 cm. However, while the maximum diameter is quite reliable, the minimum diameter in these ellipsoid ablations is often more than 10 mm smaller and decisive on success or failure [2]. The published clinical studies demonstrate a more than 90% local control rate in lesions up to 1 cm diameter and a local recurrence rate of more than 50% in lesions larger than 4 cm in maximum diameter [3, 4, 5].

Intraoperative ultrasound is very sensitive in detection of hepatic metastasis. Intraoperative ultrasound is the gold standard for this purpose, especially with increasing numbers of lesions as seen in patients who are typical candidates for radiofrequency ablation [6]. However, ultrasound does not offer validated criteria to evaluate ablation size. Various extensions to standard ultrasound are under investigation, such as Doppler mode or contrast-enhanced sonography [7]. Therefore the primary correct placement of the device is still of greatest importance.

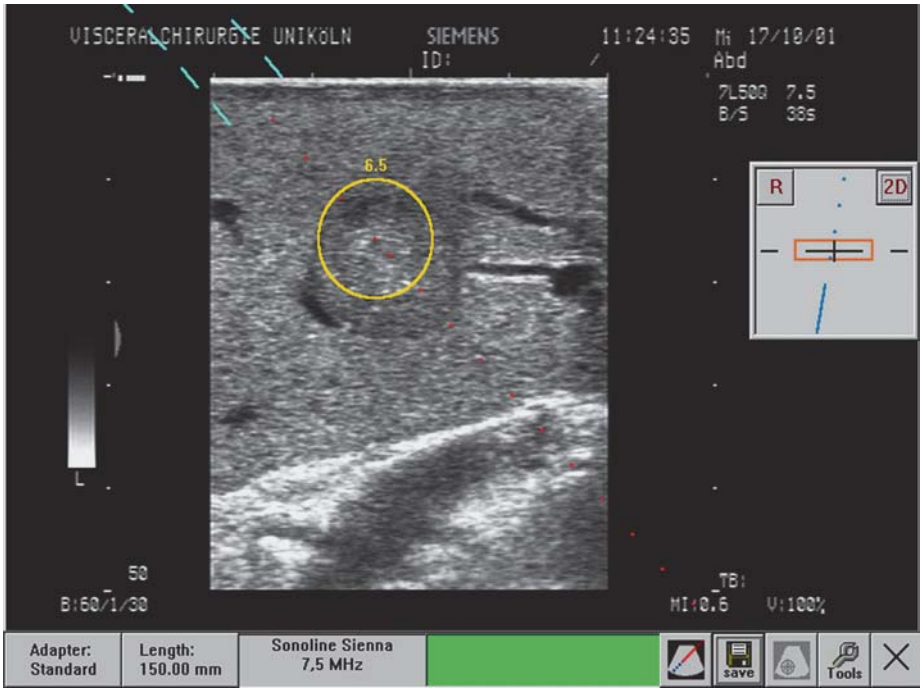

Fig. 1 Out-of-plane mode showing the virtual marker (*yellow circle*), virtual needle track (*red dots*), distance (*yellow number*) to marker and angle (*blue line in small window*) to ultrasound image

The primary purpose of this study was to answer the question of whether the ultraguide system facilitates the exact placement of the radiofrequency ablation device in a model with a small safety margin between size of lesion and size of radiofrequency induced ablation.

Material and methods

Navigation system

Methods to improve targeting offer the possibility of increasing the success rate. Three-dimensional ultrasound has recently been described for this purpose [8]. After satisfactory placement of the ablative device with two-dimensional ultrasound readjustment because of unacceptable device placement according to three-dimensional ultrasound was necessary in 10 of 22 cases. The ultraguide system is an alternative method to create a virtual third-dimension in real time during placement of the ablative device. The system works by determining the position and orientation of the ultrasound probe within a three-dimensional space defined by two high-frequency radiomagnetic transmitter units [9]. This uses a small receiver attached to the ultrasound probe. Within this space a second receiver which is coupled to the device that localizes the position of the ablation device. An overlay is created visualizing the real-time ultrasound image and the virtual image of the device. The angle between the device and the plane of the ultrasound image is constantly being shown as well as the distance of the device tip to a marker that can be placed within the ultrasound image as the proposed target. All these calculations are made in real time, allowing unrestricted free movement of the liver, the ultrasound probe and the surgical instrument.

Figures 1, 2, 3, 4 show examples of the overlay image presented. The third dimension is either visualized by the artificial horizon, as seen at the right edge of Fig. 1, or by a three-dimensional overlay of the device and the image, as shown in Fig. 2. In Fig. 1 the orange box in the middle is the ultrasound probe as seen from straight above. The blue line is the device in the dimension perpendicular to the ultrasound image. Together with the yellow number within the ultrasound image, indicating the distance, this allows an easy and precise placement. In this study the artificial horizon was used for device placement. Figures 3 and 4 demonstrate how the actual accuracy of the system can be controlled in the in-plane mode (in-plane mode: device within the plane of the ultrasound image). Figure 3 shows a precise overlay of the real and virtual needle and Fig. 4 the effect of a defective device that has a slight bend with a resulting image clearly distant from the virtual track.

Tumor mimics

We induced 40 lesions in pig livers by the method described by Scott et al. [10]. Briefly, a gelantine like mixture of 3% agarose, 3% cellulose, 7% glycerol, and 0.05% methylene blue was prepared according to the description. Before use it was reheated by microwave oven. Above 65°C it is a fluid, which was filled into syringes of 5 cm^3 and after cooling to 40°C was injected into the livers. There it formed discrete, hyperechogenic lesions in the ultrasound image. Due to a tendency of invasion into blood vessels, there is a size limit of about 1.5–2 cm in diameter. The tumor mimics do not differ in terms of consistency from normal liver tissue, and therefore they cannot be felt during placement of the needle. The tissue impedance for high frequency current of the lesions is similar to liver tissue as has been shown before [10]. Tumor mimics were created by an independent person.

Study design

We performed 40 ablations in four study groups (10 each). In groups 1 and 2 ablations were performed by an experienced surgeon (more than 100 ablations in humans) with and without the use of the ultraguide system (UltraGuide, Yoqne'am, Israel). In

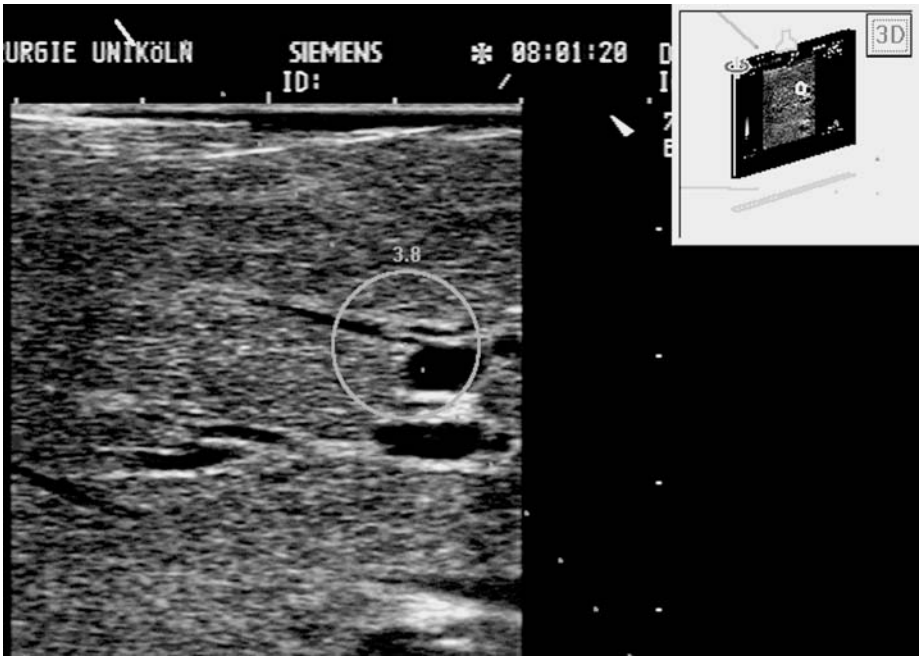

Fig. 2 Three-dimensional overlay of device and ultrasound image

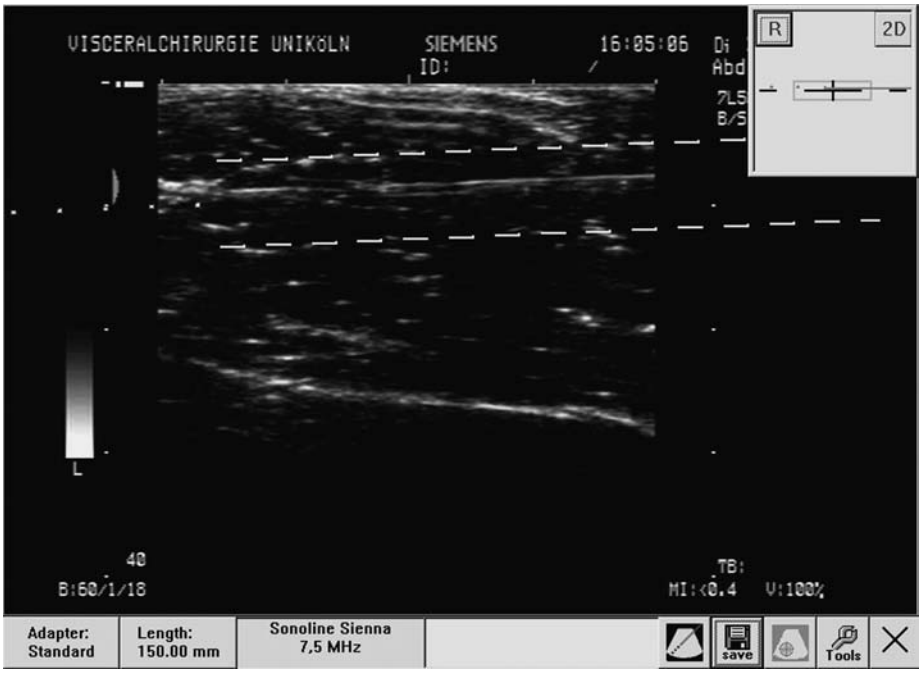

Fig. 3 In-plane mode showing the 14-cc needle within the safety bars (*dashes*) of 3 mm to both sides of the virtual needle track (*dots*)

groups 3 and 4 an inexperienced surgeon placed the device with or without use of the ultraguide system. The livers were placed on an aluminum pan with a grounding pad fixed to the undersurface of the pan. Ultrasonography was performed with a Siemens Sonoline Sienna system using a 7.5 MHz intraoperative probe (Siemens Medical Systems, Issaquah, Wash., USA). Ablation was performed using the Rita Starburst XL device (RITA Medical Systems, Mountain View, Calif., USA) deployed to an ablation diameter of 3 cm. The size of ablation was chosen relatively small in comparison to lesion size to augment differences in targeting.

Without the ultraguide system the device was placed according to the real-mode ultrasound imagining. A single person performed both ultrasound scanning and device placement in a freehand technique. With the ultraguide system the largest diameter of the lesion was determined. Then the needle was positioned in a way that the virtual track matched the largest diameter of the tumor mimic. The needle thereafter was advanced according to the distance calculated by the system until a distance of 2–5 mm to the lesion was reached. At this point the prongs were deployed. This procedure was also carried out by a single person. A standard ablation proto-

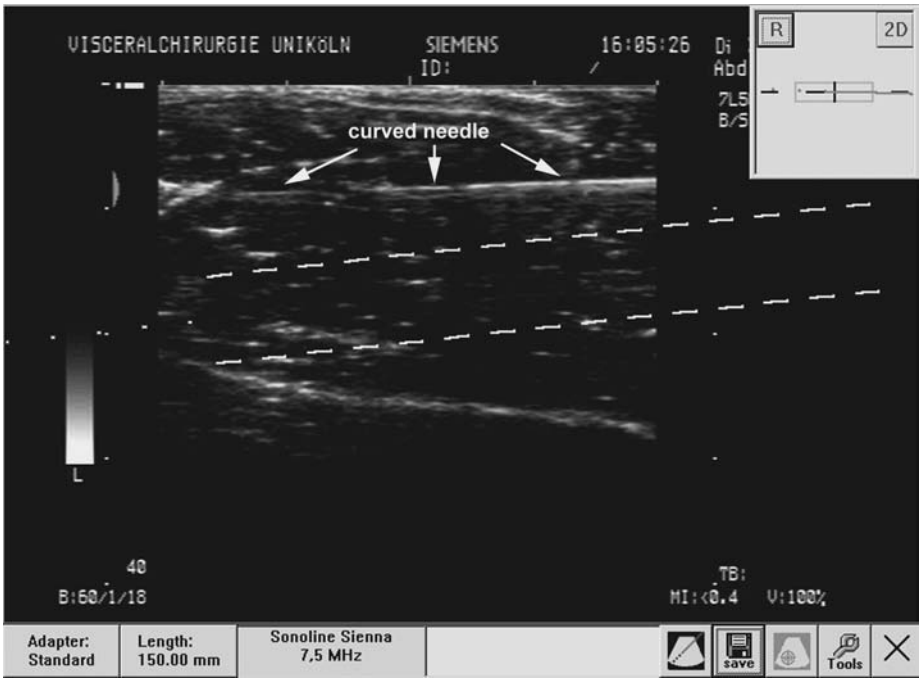

Fig. 4 In-plane mode showing the effect of a bent needle, the virtual straight needle is distant from the real needle which has a slight curvature of 3 mm on 150 mm length

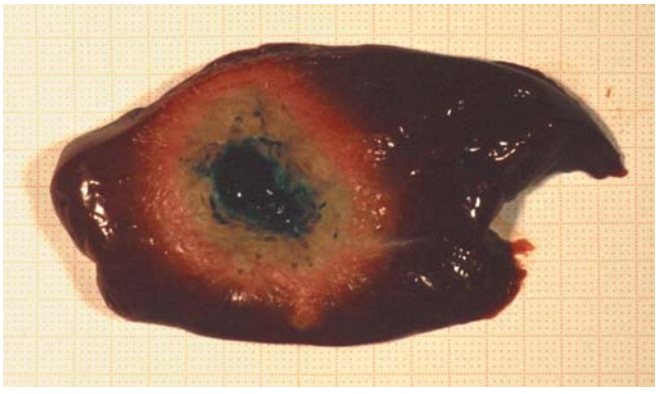

Fig. 5 Sliced lesion demonstrating the *blue* tumor mimic, the *lime-colored area* of secure ablation, the *light red area* of insecure ablation, and the *brown* normal liver tissue

col was employed as used in the clinical setting yielding an ablation size of about 3 cm in diameter (5.5 min, starting with 80°C increasing to 105°C after 30 s, 90 W maximum power, cool down for 30 s, with a temperature above 70°C at the end of cool down). The livers were then sliced with a minimum of six slices of about 4–5 mm thickness covering each lesion. The tumor mimic was a solid blue colored block at this time. Liver slices were placed on millimeter paper, photographed, and digitalized for measurement. Figure 5 shows an example.

Ablation size was determined by the largest ellipsoid that could be fitted into the lime-colored area of the ablation. The two diameters were used to calculate the volume according to the following equation: volume=4/3 ×π ×a/2 ×(a+b)/4 ×b/2. All other volumes were calculated accordingly. These calculated volumes of ablated tissue might be slightly smaller than the largest diameter being determined by measurement of distances, but it avoids any overestimation of volume. Values are given as mean ±standard deviation, if not stated otherwise. All calculations were performed with SPSS for Windows (version 8.0, 1998, SPSS, Chicago, Ill., USA).

Results

All 40 tumor mimics were found by ultrasonography and treated by radiofrequency ablation. All ablations were technically successful with average impedance of less than 80 . Temperature at the end of cool down was always above 70°C. A total of 252 slices (6.3 slices per case) of the ablated areas were analyzed. The largest diameter as measured by ultrasound was 19.6±3.7 mm and the volume 1.54±0.79 cm^3. The largest diameter of the tumor mimics as measured in the digitalized slices was 14.1±2.2 mm and the volume 0.89±0.40 cm^3. The diameter and the volume as determined by ultrasound and slice measurement showed a highly significant correlation with r^2=0.97 and r^2=0.85, respectively. Most mimics showed the morphology of a more or less spherical ellipsoid with the ratio of the largest to smallest diameter being smaller than 2 in 18 cases, the mean ratio being 2.0±0, 59. The largest diameter of ablation was 25.6± 3.7 mm, the smallest diameter 21.9±2.9 mm, and the volume 7.20±2.38 cm^3. The difference between the tumor mimic size and the largest ablation diameter was 11.6±4.5 mm and the difference to the smallest ablation diameter 7.9±3.6 mm. There was only one case in which the smallest ablation diameter was smaller than the largest tumor mimic diameter, this case was ablated successfully.

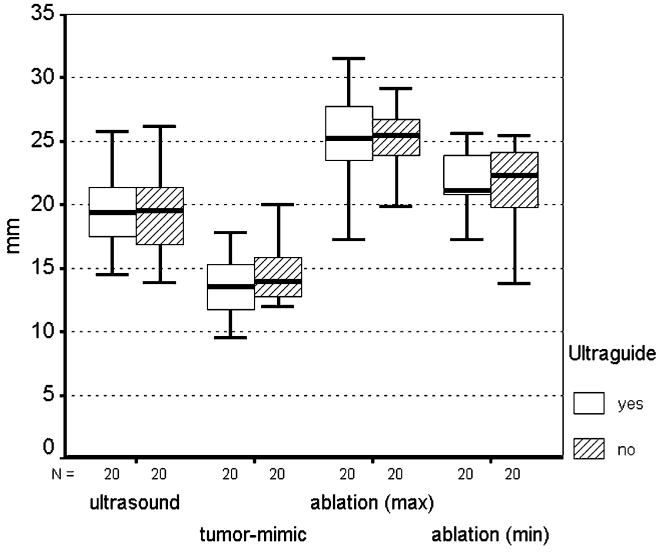

Fig. 6 Boxplot showing the diameters of the tumor mimics as measured by ultrasound and after the ablation and the diameters of the ablation

Figure 6 shows the diameters of the tumor mimics treated with or with out the ultraguide system. There was no difference concerning the diameter in ultrasound, the mimic, or the ablation size. A total of 25 (63%) of ablations were successful, with all of the blue dye within the lime-colored necrosis on all slices, as shown in Fig. 6. In the 15 cases of unsuccessful ablation the lesion was missed by 2.5±1.7 mm. The researcher experienced in radiofrequency ablation was successful in seven of ten cases without ultraguide and also in seven of ten cases with ultraguide. The other researcher was successful in four of ten without ultraguide and seven of ten cases with ultraguide. During two of the unsuccessful ultraguide cases (one each researcher), it was realized that in the in-plane mode the real and virtual image of the device did not match. However, as the reason for this mismatch was not realized at that point of time, the procedure was continued and resulted in an unsuccessful ablation. Later it was found that slightly bent ablation devices had been the reason for failure. According to Fisher's exact test, the difference in proportions of successful ablations without (11/20) and with (14/20) the ultraguide system was not statistically significant.

Discussion

A difference in diameter of 7–11 mm between ablation and treated lesion requires a very precise position of the ablation probe, yielding a safety margin of 3–6 mm. Increasing average ablation by just 8 mm would have meant that all but two ablations would have been successfully ablated without repositioning of the device. This reconfirms the concept of a safety margin of about 10 mm given the uncertainties of current device positioning and ablation size. Ex vivo ablation guaranties optimum conditions for ultrasound control of device positioning using a high-resolution 7.5-MHz probe at a freely chosen angle relative to the lesion and device. During surgery positioning of the ultrasound probe can be limited by insufficient exposure of the liver. Our data show that positioning of the device relying on the real-time measurements of the virtual needle as provided by the ultraguide system is at least as precise as positioning by an experienced surgeon.

The success rate for the ultraguide system would have been even better if bending the needle had been avoided. The technique of changing direction when the needle is already partially inserted into the liver, as used during conventional freehand procedure, must be avoided when using the ultraguide since it leads to a discrete curvature of the needle causing a mismatch with the always straight virtual image of the instrument. The current precision of the system can easily be checked by visualizing the needle in the in-plane mode and is within ±2 mm at the tip of a 150-mm-long device. In contrast to freehand positioning, the ultraguide system has a very short learning curve, as demonstrated in this study by the less experienced surgeon, who had no prior experience with the ultraguide system.

The ultraguide system will be of special value if access to the liver is restricted, as in the case of lesions in the dorsal parts of the liver. The system shows the virtual track of the needle before the needle even touches the liver. This is an advantage of three-dimensional ultrasound, where positioning is evaluated after complete insertion of the device [8]. Further evaluation will therefore include laparoscopic procedures as positioning of the device using freehand technique is difficult in laparoscopic technique due to fixed insertion point at the body wall. Clinical studies must clarify whether the demonstrated workbench precision can be transformed to a clinical benefit.

Conclusion

The ultraguide system offers a reliable mode of device placement. It is simple and intuitive to use resulting in a short learning curve. The current accuracy of the system can easily be checked by the in plane mode. It is safe to conduct studies evaluating the benefit of the system in an intraoperative situation.

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