Diagnostic accuracy and workflow of 240 experimental MR biopsies with a clinical navigation solution outside the bore

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Introduction/Purpose

Minimally invasive diagnostic and therapeutic procedures are often performed under image guidance. Despite some limitations, MRI is increasingly used as guiding modality [1], in particular with magnet designs that allow instrument manipulation with direct imaging control inside the bore [2]. With closed-bore scanners, the instrument typically needs to be operated outside the magnet, which requires more technical efforts and renders the guidance technique more prone to errors caused by patient and organ motion. On the other hand, access to the patient is very flexible outside, scanners are more common, and their performance is superior, which would explain the continued use of these scanners for interventional purposes. Recently, an add-on solution for real-time navigation outside the bore has been presented and clinically deployed (Fig. 1). Given the technical challenges and potential workflow issues of such an approach, the purpose of this work was to thoroughly evaluate the diagnostic accuracy, usability, and workflow on a total of 240 experimental MR-guided biopsies.

Materials and Methods

The navigation technique has been described elsewhere [3]. In short, it allows virtually any device to be tracked optically from arbitrary camera and MR table positions. Automatic registration is established by a one-time, fast 3D localization of table-mounted MR reference markers (Fig. 1). In this experimental study, we have used a large plastic cylinder filled with opaque glaze as phantom tissue. Twenty-four operators were assigned to three groups with different radiological experience (attending radiologists AR, radiology residents RR, and medical students MS). A 6-minute video instruction was presented to each operator immediately before the biopsies. Each operator performed 10 successive biopsy cycles in the same order. A biopsy was counted as a diagnostic success if the biopsy sample clearly contained green material from the pea. For each simulated biopsy, we recorded access planning, arm adjustment, navigation, puncture, and control times. Each operator was also asked to rate 13 items related to the usability and workflow of the system on a Likert scale from strong (5) to basic (4) agreement via indifference (3) to basic (2) and strong (1) disagreement. Between-group differences in the success rates, times, and ratings were analyzed with a Cochran Q test and one-way ANOVAs.

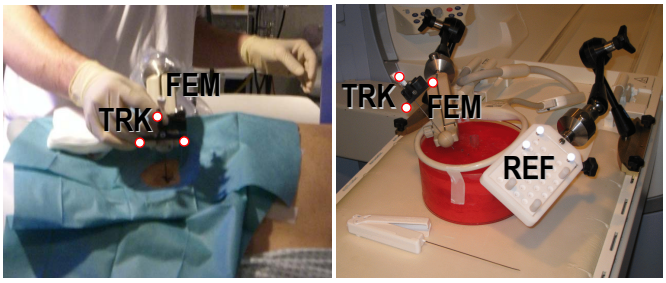

Fig. 1. left: Clinical example of a navigated kidney biopsy performed outside the bore of a standard 1.5T scanner (Magnetom Symphony, Siemens). **right:** Experimental setup with 10 peas (mean Ø: 8.5 mm) at reproducible 3D positions around a vessel model in a plastic cylinder filled with opaque glaze. The add-on components (FEM: front-end module, TRK: instrument tracker, REF: reference marker board) are the same as those used in the clinical setting After MRI-guided placement of a 16G coax needle, samples were directly taken with a fully automatic biopsy gun (Invivo).

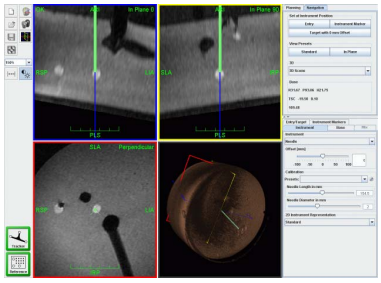

Fig. 2: Screenshot of navigation scene. Targets appear hyperintense, model vessels as signal voids. Virtual instrument is overlaid on three orthogonal views. Position was controlled with T1w VIBE scan (TR/TE=3.8/1.7 ms, matrix 256×167, 0.4×0.4×2 mm^3, TA=22 s).

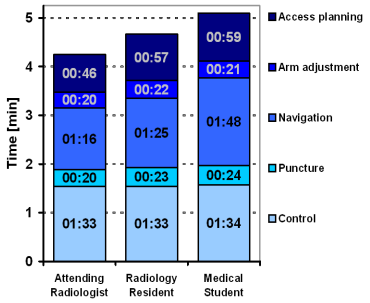

Fig. 3: Average times for one biopsy cycle for different operators and contributions from individual steps. ANOVA showed highly significant ($p<0.001$) differences between groups, mainly due to the navigation step.

Results and Discussion

The average diagnostic success rates were 93% (AR: 9-10 hits), 88% (RR: 7-10 hits), 81% (MS: 6-10 hits) and overall not significantly different (Cochran $p=0.104$). In contrast, the mean times for a complete biopsy cycle in minutes (AR: 4:13, RR: 4:42, MS: 5:06) were significantly ($p<0.001$) different (Fig. 3). The largest individual time difference was observed for the navigation step (AR: 1:16, RR: 1:25, MS: 1:48, $p<0.001$), the time difference of the puncture step was significant ($p<0.05$) but negligible (<3.5 s), all other time differences were insignificant. None of the item ratings were significantly influenced by the factor group (experience). The rounded Likert scores over all items were 4.4 (AR), 4.2 (RR), 4.2 (MS), and 4.2 (all).The majority (9/13) of average item scores showed normal to strong agreement (4.1-4.8), in particular, whether the operators would use the system again (4.8), felt that the outcome justifies the extra effort (4.4), and trusted the system (4.2). While average scores were slightly lower with respect to whether the system was self-explanatory (3.9) and regarding the handling of the guiding device (3.7, lowest score of 3.1 by RR), operators were indifferent about the system's stability against external perturbations (2.8, lowest score of 2.3 by MS).

Given that clinical cases will be performed by attending physicians, the observed success rate (74 of 80) and time for a complete biopsy cycle (median: 3:58 min) suggest that an "in-and-out" approach does not necessarily compromise diagnostic accuracy or clinical workflow. The reported success rates relate to a one-step biopsy without any verification of the needle position. This does not correspond to the clinical scenario, where at least one control scan should be performed before taking the biopsy sample. This will also allow detection of potential errors introduced by shifts of the anatomy, the whole patient, or the reference board. While these shifts are limitations of any stereotactic system, our approach permits to directly correct for them. It should also be stressed, that the reported biopsy times already include the time for table movements and one control scan.

Conclusion

For an in-vitro setting, this study demonstrated good diagnostic accuracy, usability, and workflow of an "in-and-out" navigation solution for closed-bore scanners. Taking some precautions, we believe that this approach is a feasible option for dedicated procedures. While the clinical performance can only be assessed on real patients, this work provides valuable results for a large number of biopsies and different operators.

References

[1] S. Tatli et al., Tech Vasc Interv Radiol 2007; 10:159. [2] M. Moche et al., JMRI 2008; 27:276. [3] H. Busse et al., MRM 2010; 64:922.