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TITLE: Abbreviated Magnetic Resonance Imaging and Biomarker-Based Detection of Early Liver Cancer

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CONTRACTING ORGANIZATION:

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14. ABSTRACT
Hepatocellular carcinoma (HCC) is the second leading cause of cancer-related death worldwide and is the fastest growing cause of cancer death in the United States. Current national guidelines recommend surveillance of all patients at risk for HCC with a lab draw and an Ultrasound (US) examination every 6 months. However, many studies have shown that Ultrasound's ability to detect cancer reliably, especially small tumors, is poor. Many centers in the United States perform contrast-enhanced magnetic resonance imaging (MRI) for HCC surveillance as it has been shown to be more accurate in the detection of HCC than US. However, complete contrast-enhanced MRI is too expensive to be considered a first line surveillance examination. We previously simulated and studied a novel abbreviated MRI (AMRI) protocol, using a unique intravenous contrast agent used for liver MRIs that takes approximately 10 minutes to complete. We found that the accuracy of the AMRI protocol was 20% better than that of US. We have shown that in moderate to high-risk groups, AMRI is more cost effective than US. We now seek to fill remaining gaps by rigorously comparing the performance of AMRI vs. US for HCC screening in a large prospectively assembled cohort of subjects at risk for HCC; assessing the added diagnostic value of clinical biomarkers (AFP, AFP-L3, DCP) and other clinical variables; examine the cost effectiveness of AMRI, US, and of each imaging method in combination with clinical biomarkers; and bank biospecimens for future biomarker discovery studies.

15. SUBJECT TERMS
AMRI hepatocellular carcinoma liver cancer

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Introduction

Hepatocellular carcinoma (HCC) is the second leading cause of cancer-related death worldwide and is the fastest growing cause of cancer death in the United States. Current national guidelines recommend surveillance of all patients at risk for HCC with a lab draw and an Ultrasound (US) examination every 6 months. However, many studies have shown that Ultrasound's ability to detect cancer reliably, especially small tumors, is poor. Many centers in the United States perform contrast-enhanced magnetic resonance imaging (MRI) for HCC surveillance as it has been shown to be more accurate in the detection of HCC than US. However, complete contrast-enhanced MRI is too expensive to be considered a first line surveillance examination. We previously simulated and studied a novel abbreviated MRI (AMRI) protocol, using a unique intravenous contrast agent used for liver MRIs that takes approximately 10 minutes to complete. We found that the accuracy of the AMRI protocol was 20% better than that of US. We have shown that in moderate to high-risk groups, AMRI is more cost effective than US. We now seek to fill remaining gaps by rigorously comparing the performance of AMRI vs. US for HCC screening in a large prospectively assembled cohort of subjects at risk for HCC; assessing the added diagnostic value of clinical biomarkers (AFP, AFP-L3, DCP) and other clinical variables; examine the cost effectiveness of AMRI, US, and of each imaging method in combination with clinical biomarkers; and bank biospecimens for future biomarker discovery studies.

Body

Finalized study protocol, obtained IRB approval, obtained HRPO approval, executed CRADA between NMCSD and UCSD, developed study database, prepared case report forms (CRFs), held investigator startup meetings

Held training sessions for radiology readers, MRI technologists, and US sonographers; prepare MRI and US procedure manuals

Recruited 21 patients with cirrhosis or cHBV. Performed safety monitoring, and submitted for IRB and HRPO continuing approval/review.

Key Research Accomplishment

- The Naval Medical Center San Diego IRB reviewed and approved this study on 07 November 2018. HRPO approval was also granted.
- Study enrollment began on April 10, 2019.
- A total of 21 patients have been enrolled into the study.
- A total of 13 patients have completed their clinic visit at UCSD.
- Total of 9 patients have completed their imaging visit.
- A total of 7 study patients have completed all study components. Their imaging data has be interpreted.
- A flyer for recruitment was also submitted to the IRB for approval.
- A protocol amendment has been submitted to increase enrollment from 75 to 100 for potential screen failures and study withdrawals.

Reportable Outcomes - Provide a list of reportable outcomes that have resulted from this research to include manuscripts, abstracts, presentations, etc.

No reportable outcomes to report.

Conclusion

Study enrollment has been steady with a total of 21 patients enrolled since April 10, 2019. The research team is actively screening patients for study participation. A study flyer has been submitted to the IRB to increase enrollment and reach quarterly enrollment goals. A total of 7 patients have completed all study visits and their images have been interpreted.

References - List any references using standard journal format.

No references to report.

Appendices - Can include copies of journal articles, manuscripts and abstracts, patent applications, study questionnaires and surveys, etc.

No appendices to report.