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Award Number: W81XWH-18-2-0025

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

PRINCIPAL INVESTIGATOR: Dr. Kathryn Fowler on behalf of Dr. Claude Sirlin

CONTRACTING ORGANIZATION:

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REPORT DATE: Oct 2019

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: (Check one)

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

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1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
Oct 2019	Annual	9/30/18 – 9/29/19

4. TITLE AND SUBTITLE

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

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-18-2-0025

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S) Dr. Kathryn Fowler on behalf of Dr. Claude Sirlin

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
CDMRP
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

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

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRMC
U	U	U	UU		**19b. TELEPHONE NUMBER** *(include area code)*

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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 HRPP 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; prepared MRI and US procedure manuals

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

Key Research Accomplishment

- The Naval Medical Center San Diego IRB reviewed and approved this study on 07 November 2018. HRPP approval was also granted at UCSD.
- Study enrollment began on February 07, 2019.
- A total of 45 patients have been enrolled into the study.
- A total of 40 patients have completed their clinic visit at UCSD.
- Total of 39 patients have completed their imaging visit.
- A total of 38 study patients have completed all study components. Their imaging data has be interpreted.

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.