531. Results of a Hepatitis C Virus Screening Program of the 1945-1965 Birth Cohort in a Large Emergency Department in New Jersey

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Background. Persons born between 1945 and 1965 account for an estimated 81% of those infected with hepatitis C virus (HCV) in the United States. However, up to 60% remain undiagnosed. Targeted screening of high-risk populations is essential for reducing HCV-related morbidity and mortality. Prior studies have reported results of HCV screening in large urban emergency departments (ED) with findings which may not be generalizable to other ED settings.

Methods. This is a retrospective electronic medical record review of patients in the 1945-1965 birth cohort screened for HCV in a large ED in New Jersey from June 1, 2016 through December 31, 2016. Starting on June 1, 2016, opt-out HCV testing occurred for any patient from this birth cohort seen in the ED from 11AM-7PM as a result of a service grant. The purpose of this study was to determine the prevalence of HCV antibody (Ab) seropositivity and chronic HCV infection in this population as well as analyze specific characteristics of this population, such as birth decade, gender, race/ethnicity and insurance status. Descriptive statistics were performed and using a multivariate logistic regression model, adjusted odds ratios and 95% confidence intervals were calculated.

Results. A total number of 3,046 patients were screened. 55.8% were white, 17.9% were black. 52.1% had private insurance, 33.4% Medicare, and 3.9% Medicaid. 192 people were positive for HCV (6.3%). Out of those at risk in the screened population, 47 were black (8.6% prevalence). Ninety-one (5.7%) had private insurance, 73 (7.2%) had Medicare, 14 (1.1%) Medicaid. 167 had a HCV viral load result. Of the total population, 2.4% had a positive viral load (71/3021). Of those who were HCV Ab positive, 43% had a positive viral load. Of multivariate analysis, black race (adjusted OR 3.09, 95% CI 1.82-5.27) and Medicaid (adjusted OR 2.68, 95% CI 1.14-6.28) were independently associated with a positive HCV viral load.

Conclusion. Our population had lower rates of HCV Ab seropositivity and chronic HCV infection than reported in prior publications on ED screening of the 1945-1965 birth cohort. Chronic HCV infection was disproportionately associated with black race and Medicaid status. These findings reflect varying prevalence of HCV Ab and positive viral load within this high-risk birth cohort.

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532. Using a Mobile-Health System to Monitor and Provide Support Along the Hepatitis C Virus Continuum of Care for People with Opioid Use Disorders: Experience from a Randomized Trial

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Background. Opioid use disorders are increasingly driving new hepatitis C virus (HCV) infections. Mobile health applications delivered by smartphones represent a promising innovative strategy to promote HCV prevention and improve engagement and linkage to care for people who use opioids. The aim of this study was to assess the feasibility and acceptability of a mobile phone-based intervention, called A-CHESS, to capture data on risk behaviors and HCV screening and care.

Methods. A-CHESS is a mobile application that incorporates previously validated decision aids and interactive feedback designed to improve knowledge and engagement with care for people enrolled in the intervention group. To assess feasibility, A-CHESS was incorporated into an existing evidence-based smartphone application developed for hepatitis C prevention and care. At baseline, 26 of the 72 individuals (36%) were HCV at-risk/untested, 21 (29%) were HCV-negative, 22 (31%) had active HCV and were not receiving treatment. Based on weekly data collected by A-CHESS, 20 of the 72 participants (28%) were noted to change to a different stage in the HCV care continuum (e.g., from HCV positive/untreated to HCV positive/untreated and treatment initiation).

Results. To date, 170 individuals have been enrolled and completed the baseline survey (87 control, 83 intervention). 976 weekly surveys were taken by 72 participants enrolled in the intervention group. At baseline, 26 of the 72 individuals (36%) were HCV at-risk/untested, 21 (29%) were HCV-negative, 22 (31%) had active HCV and had not received treatment, and 3 (4%) had active HCV infection and were receiving treatment. Based on weekly data collected by A-CHESS, 20 of the 72 participants (28%) reported HCV diagnosis, linkage to care, and treatment initiation.

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533. The Impact of Hepatitis C Virus (HCV) Treatment with Direct-Acting (DAAs) on the Incidence of Hepatocellular Carcinoma (HCC) in Patients with Advanced Liver Disease

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Background. Use DAA has resulted in widespread eradication of Hepatitis C virus (HCV) infection in patients with advanced liver disease (ALD) compared to interferon (IFN)-based treatment era therapy. Recent reports have indicated an increased risk of hepatocellular carcinoma (HCC) associated with HCV treatment with DAA and/or after achieving sustained virologic response (SVR). Decreasing incidence of HCC has been reported for patients treated with IFN-based therapy who achieve SVR. Widespread HCV treatment with IFN-based therapy was started in 2006 at a single center. An interest exist whether there was an increase in HCC incidence after introduction of DAA therapy.

Methods. A single-center retrospective analysis of HCC incidence from 2009 to 2016 was conducted. Patients with HCV due to non-HCV-related diseases were included as unmatched controls. HCC cases were reviewed for HCV diagnosis, liver disease stage and evidence of prior HCV treatment. HCC rate was calculated using number of at risk patients with HCV who received HCV treatment each calendar year. Descriptive statistics were utilized for trend analysis. A total of 143 cases of HCC was identified between 2009 and 2016 with 110 cases of HCC in HCV patients. 72% of patients with HCV treated with antiviral therapy.

Results. There was a progressive decrease in the number of incident HCC in HCV patients. The incidence rate of HCC in HCV patients declined from 23.1 in 2009 to 7.9% in 2016 in these patients receiving antiviral therapy. The HCC incidence rates in 2009, 2010, 2011, 2012, 2013, 2014, 2015, and 2016 was 23.1%, 14.3%, 60.0%, 22.2%, 6.25%, 1.48%, 1.11%, and 1.79% respectively. The number of HCC cases in non-HCV patients remain unchanged during the same period. One year HCC survival ranged from 50% to 70% of HCC patients and 38 to 100% in non-HCV patients with no trends in survival identified.

Conclusion. The incidence of HCC decreased in at risk HCV patients with ALD who received antiviral therapy with the largest decline occurring in patients who received DAA therapy. One year survival did not appear to change during the study period.

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534. The use of Direct-Acting Antivirals in Hepatitis C Virus-Infected Patients with Hepatocellular Carcinoma

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Background. Hepatitis C virus (HCV)-infected patients with hepatocellular carcinoma (HCC) are at high risk for direct-acting antiviral (DAAs) failure and controversy exists on the increased risk of HCC recurrence following DAAs. Herein, we evaluate the efficacy, safety and oncologic outcomes of HCV-infected patients with HCC treated with DAAs.

Methods. This prospective observational study included consecutive patients seen at MD Anderson Cancer Center (January 2014–April 2017). Patients received 1 out of 5 different combinations. Efficacy was assessed by intention-to-treat (ITT) analysis based on sustained virologic response 12 weeks after finishing DAAs (SVR12). Adverse events (AEs) and clinically significant drug-drug interactions (DDIs) were analyzed. AEs were graded according to the Division of AIDS Table (v 2.0). Cancer responses were evaluated at the time of initiation and 6 months after finishing DAAs.

Results. Twenty-seven patients were enrolled. The majority were men (85%), white (55%) with genotype 1 HCV (66%), Child-Pugh score A (85%), tumor stage 4 (41%) and eligible for potentially curative options (74%). The SVR12 (ITT) data are depotined in table. The most common AEs were headache (11%) and anemia (7%). Only one pt had grade 3 AE (renal failure) but grade 4 AEs or DDIs were not observed.
Among patients with potentially curable HCC (n = 20), the disease control rate was 35% (complete remission 10%, partial remission 25%) with recurrence rate of 5% (1 pt). None of the patients had de novo HCC within 6 months of DAAs. All 7 patients with unsectectable HCC had stable disease within 6 months of DAAs.

**Conclusion.** DAAs appear to be safe but of suboptimal efficacy in HCV-infected patients with HCC. More studies are needed to identify the subset of patients who will benefit from DAAs.

| Table. SVR12 rates |
|-------------------|
| Variable | SVR12 (ITT) |
| Overall | 18 (66) |
| Treatment regimen | |
| Sofosbuvir + Ribavirin | 2/3 (66) |
| Sofosbuvir + Simeprevir | 2/0 (66) |
| Ledipasvir/Sofosbuvir | 10/16 (63) |
| Sofosbuvir/Velpatasvir | 3/4 (75) |
| Paritaprevir/Ritonavir/Ombitasvir/Dasabuvir | 1/1 (100) |
| Genotype | |
| 1 | 12/18 (66) |
| 1a | 10/15 (66) |
| 1b | 1/2 (50) |
| 2 | 3/4 (75) |
| Other* | 0/2 (0) |
| Type of HCC | 3/3 (100) |
| Potentially curable | 14/20 (70) |
| Unresectable | 4/7 (57) |

*Other genotypes included genotype 6 (1) and mixed genotypes (2).

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535. Effectiveness of 8 or 12 Week Treatment Duration of Ledipasvir/Sofosbuvir for Hepatitis C: Evidence from a Large Academic Medical Center

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**Background.** U.S. FDA labeling restricts 8-week treatment courses of ledipasvir/sofosbuvir (LDV/SOF) to treatment-naive, HCV-genotype 1, non-cirrhotic patients with baseline viral load (VL) < 6 million IU/mL. A large proportion of patients who meet this criteria continue to undergo longer treatment durations. The primary objective of this analysis was to compare sustained virologic response rates at 12 weeks after treatment (SVR12) among patients receiving 8 vs. 12 weeks of therapy in a real-world clinical setting. Our secondary objective was to quantify uptake of the 8-week regimen in eligible patients.

**Methods.** This was a single-center, retrospective study of HCV-infected patients prescribed LDV/SOF at ambulatory clinics associated with the University of Maryland Medical Center (UMMC) from May 2015 to May 2016. Data were obtained from the UMMC electronic medical record and outpatient pharmacy claims database. Comparison between groups were made using Chi-squared or Fisher’s exact test for categorical variables and Student’s t-test or Wilcoxon rank-sum for continuous variables.

**Results.** A total of 288 patients were included. Median age was 58 years; 62.8% were male; 81.9% were black. Patients who received 12 weeks of therapy were significantly more likely to have a cirrhosis diagnosis, higher mean fibrosis score, and HCV/HBV coinfection rate prior to SVR12. SVR12 was achieved in 67 (95.7%) patients in the 8-week regimen vs. 138 (93.9%) in the 12 week group (P = 0.755). Amongst black patients, 168 (93.9%) achieved SVR12 compared with 96 (97.3%) non-black patients, (P = 0.944). Amongst HCV/HBV-coinfected patients, 89 (93.1%) achieved SVR12 compared with 67 (94.7%) without HCV/HBV-coinfection (P = 0.748). Overall, 40.6% (n = 117) met criteria for an 8-week treatment duration and 44% (n = 52) of those eligible patients received 8 weeks of therapy. The uptake rate of the 8-week treatment duration was 44.4%.

**Conclusion.** Eight-week treatment duration of LDV/SOF was effective for treatment-naive, non-cirrhotic, HCV-genotype 1 patients in the real-world setting. Race and HCV/HBV-coinfection did not significantly impact patients’ ability to achieve SVR12. Increased uptake of the 8-week regimen will decrease costs of therapy for patients and payers without compromising outcomes.

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