with HCV cirrhosis. The DAA cohort received DAA treatment between Jan. 2014 and Mar. 2017. The control cohort did not receive HCV therapy between Jan. 2011 and Dec. 2013. The incidence of liver-related hospitalizations, HCC, liver transplant, and all-cause mortality was measured for each cohort. Projected savings was calculated using the 95% CI for reduction in hospitalizations, the total distribution of reasons for hospitalization, and the average cost of an admission for each diagnosis at our institution, to estimate savings per patient treated per year. **Results:** Baseline characteristics between the DAA (n=196) and control (n=182) cohorts did not differ based on sex, race/ethnicity, weight, HIV or HBV coinfection, HCV genotype, HCV viral load, Child Turcotte Pugh (CTP) score distribution, or history of ascites, hepatic encephalopathy, or esophageal varices. Persons in the DAA cohort were older (59 vs. 56 years, p=0.006), had fewer patients listed for liver transplant prior to the study period (4.6% vs. 14.8%, p=0.0008), shorter mean follow-up time (17.7 vs 20.4 months, p=0.004), and a lower baseline MELD (10 vs. 11, p=0.01). The sustained virologic response rate for the treated group was 86.7%, including 89.1% (122/137) for CTP-A and 81.4% (48/59) for CTP-B/C. The DAA cohort had significantly fewer liver-related hospitalizations, and the reasons for hospitalization did not differ between the two groups (Table 1). This difference was mainly observed in patients with baseline CTP- A and CTP-B cirrhosis; however there was no difference in the incidence of hospitalizations in the CTP-C patients. During the short follow-up time, there were no differences in the incidence of HCC, liver transplant, or death between the cohorts. The greatest potential cost savings was derived from treating patients with CTP-B cirrhosis. **Conclusion**: Treatment of HCV with DAA in patients with cirrhosis reduces liver-related hospitalizations resulting in decreased healthcare utilization and reduced costs associated with liver disease. This benefit may not be realized if treating patients with CTP-C cirrhosis.

Event	Untreated group (per 100 person-years of follow up)	DAA-treated group (per 100 person-years of follow up)	Difference (95% CI) per 100 person-years of follow up	P-value	Projected cost savings per patient treated per year
Hospitalizations	29.1 (n=182)	10.4 (n=196)	18.7 (11.5 – 25.9)	<0.0001	$3,634-$8,231
CTP-A	12.0 (n=113)	2.9 (n=137)	9.1 (3.8 – 14.4)	0.0008	$1,208-$1,576
CTP-B	56.6 (n=52)	19.7 (n=52)	36.9 (17.5 – 56.3)	0.0002	$5,561-$17,891
CTP-C	93.7 (n=12)	96.5 (n=7)	-1.7 (-78.2 – 74.8)	0.96	n/a
HCC (n)	5.9 (17)	5.1 (14)	0.8 (-3.1 – 4.7)	0.68	
Liver transplant (n)	4.1 (12)	1.7 (5)	2.4 (-0.45 – 5.1)	0.1	
Death (n)	5.5 (17)	3.8 (11)	1.7 (-1.7 – 5.1)	0.34	
Reasons for hospitalization(%)	24 (26.7)	4 (13.3)		4 (13.3)	
Ascites	48 (53.3)	14 (46.7)		14(46.7)	
HE	10 (11.1)	6 (20.0)		6 (20.0)	
Esophageal Varices	3 (3.3)	2 (6.7)		2 (6.7)	
SBP	5 (5.6)	4 (13.3)		4 (13.3)	
Other					

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Randomized controlled trial of cash incentives or peer mentors to improve HCV linkage and treatment among HIV/HCV coinfected persons who inject drugs: The CHAMPS Study

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Background: Despite access to direct acting antivirals (DAAs), barriers to HCV linkage and treatment of persons who inject drugs (PWIDs) persist. The CHAMPS study aims to evaluate the impact of two innovative strategies, contingent cash incentives and peer-mentors, on HCV treatment uptake and cure in HIV+ PWIDs not engaged in HCV care. **Methods**: HCV treatment-naïve PWIDs with genotype 1 infection were eligible if they received HIV care at Johns Hopkins and had not been evaluated for HCV care within 8 months, had a CD4 count >100 mm3, and no evidence of decompensated liver disease. Eligible participants were randomized (1:2:2) to 1) Usual Care (UC, nurse supervision); 2) UC + Peer-Mentors; 3) UC + Cash Incentives. All participants were provided 12 weeks of ledipasvir/sofosbuvir (LDV/SOF) at no cost. In the Peer-Mentor group, participants engaged in structured interactions with HIV/HCV cured peers. In the Cash Incentives group, participants received escalating cash incentives (up to $220) which were contingent on attendance to clinic visits. The primary endpoint was initiation of LDV/SOF within 8 weeks of enrollment (12 weeks if a change in HIV regimen was required); secondary endpoints were sustained virologic response (SVR), drug/alcohol use, and HCV reinfection. HCV RNA was assessed at treatment weeks 4, 12, and post-treatment week 12. **Results**: 144 participants were randomized to Usual Care (n=36), Peer-Mentors (n=54) or Cash Incentives (n=54). Baseline characteristics were similar in each group. The majority of participants were >55 years old (50%), male (61%), black (93%) and infected with HCV genotype 1a (78%). Despite high levels of depression (61%) and ongoing drug (25%)/alcohol (42%) use, most (97%) were taking antiretroviral therapy with HIV RNA suppression (81%). Initiation of LDV/SOF was observed more frequently in the Peer-Mentor group (83%, 45 of 54) (p=.07) compared to the Usual Care (66%, 24 of 36) and Cash Incentives (76%, 41 of 54) groups. Overall (intention to treat), SVR was more frequently observed in the Peer-Mentor group (76%, 37 of 54) (p=.13) compared to the Usual Care (61%, 22 of 36) and Cash Incentives (68%, 37 of 54) groups. Of those that did not achieve SVR, 1 patient was reinfected, 2 relapsed, and 6 did not complete treatment. Serious adverse events not related to LDV/SOF occurred in 10% of participants. **Conclusion**: Overall, 24% of 144 coinfected PWIDs did not initiate HCV treatment despite access to expert clinicians and LDV/SOF at no cost. Access to DAAs is necessary but may not be sufficient to achieve HCV cure among populations of PWIDs; these data suggest peer-mentors may effectively increase HCV linkage and treatment.

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Sherilyn Brinkley - Consulting: Merck, AbbVie; Speaking and Teaching: Merck, Gilead, AbbVie

David L. Thomas - Advisory Committees or Review Panels: Merck

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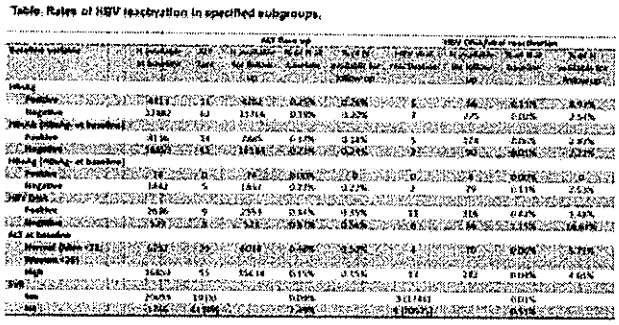
persons. When observed, the risk is higher among those with baseline HBsAg+ and are associated with a higher risk of hepatic decompensation and death.



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123

The Declining Burden of HCV on the Liver Transplant Waitlist associated with the DAA era

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Background: We aim to compare liver transplant (LT) waitlist trends and outcomes prior to and following the availability of direct-acting antiviral (DAA) agents for the treatment of hepatitis C virus (HCV) in the United States (US). **Methods:** Utilizing the United Network for Organ Sharing (UNOS) database, we analyzed LT waitlist outcomes in adult HCV registrants without hepatocellular carcinoma (non-HCC HCV) initially listed during the 36 months before (pre-DAA) and after (DAA) the approval of second-generation DAA agents (November 2013). 90-day rate for waitlist mortality was compared in each era. Cox regression analysis was performed to determine the impact of DAA era on 90-day waitlist mortality and was adjusted for clinical demographics (age, gender, ethnicity), Model for End-Stage Liver Disease score, portal hypertension complications, and UNOS Region. **Results:** From November 2010 to December 2016, the percentage of non-HCC waitlist additions with HCV declined 35% in the DAA era (pre-DAA n=8620, 34.0%. *vs.* DAA n=5579, 21.8%, p <0.001). Moreover, a significant decline in the monthly HCV waitlist addition rate (per 100 non-HCC waitlist additions) was seen in DAA era (p <0.001) (Figure). Among HCV waitlist additions, the DAA era was associated with lower 90-day waitlist mortality (pre-DAA 8.1% vs. DAA 7.3% p <0.001). A similar reduction in mortality was seen among decompensated HCV waitlist additions (pre-DAA 12.3% vs DAA 10.2%, p <0.001). In addition, the DAA era was associated with a 16% reduction in the risk for 90-day waitlist mortality (HR 0.85, p <0.001). **Conclusion:** US national trends in LT waitlist additions and mortality in non-HCC HCV patients suggest DAA agents have reduced the previous HCV burden placed on our LT allocation system.

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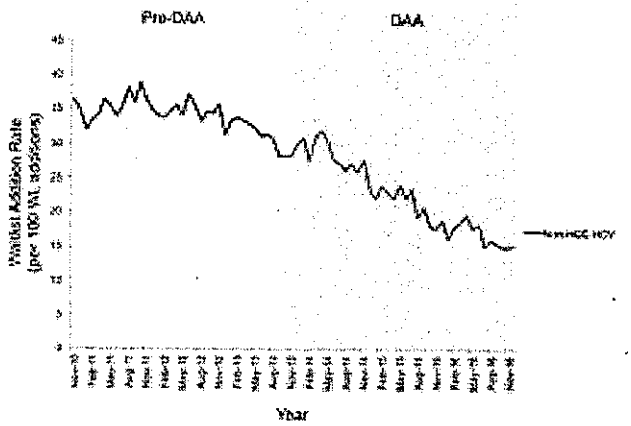

Monthly HCV waitlist addition rate (per 100 non-HCC additions) in the United States from 2010-2016.

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Increasing Primary Incidence of Hepatitis C Among HIV-Infected Men Who Have Sex with Men in San Diego; a Pooled Analysis of Two Large Clinics from 2000-2015

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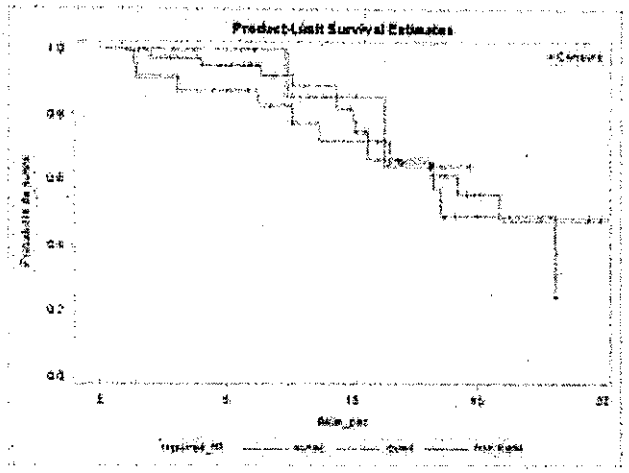
Background: Our recent analyses found increasing hepatitis C virus (HCV) incidence among HIV-infected men who have sex with men (HIV+ MSM) attending the largest HIV clinic in San Diego, but generalizability was unclear. We perform a retrospective pooled analysis of HCV incidence among HIV+ MSM attending two of the largest HIV clinics in San Diego, California. Methods. We performed a retrospective cohort analysis of incident HCV infection among HIV+ MSM attending two of the largest HIV clinics in San Diego (UCSD Owen Clinic and the San Diego Veterans Affairs (VA) Hospital) from 2000-2015. Incident HCV infection was assessed among HIV+ MSM with a baseline negative anti-HCV test between 2000 and 2015, and defined as any new positive anti-HCV or HCV-RNA test after the start of follow-up. Group risks were defined as individ-

patients of the cohort. The graph shows results in the F0-2 subgroup. **Conclusion** : The impact of the treatment on survival decreases with age. Early therapy is important.



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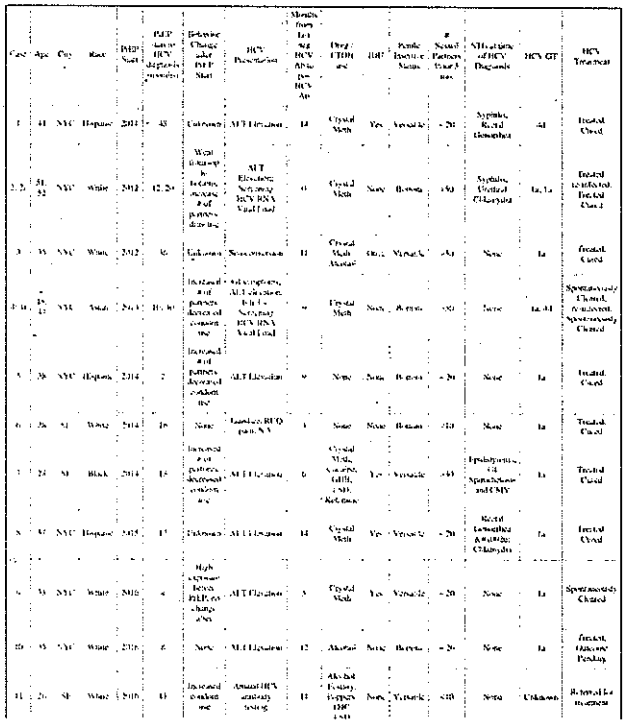
Sexually-acquired HCV Infections Emerging Among HIV-uninfected Men Who Have Sex with Men on Pre-exposure Prophylaxis Against HIV

Jennifer C. Price[1], Jeffrey E. McKinney[1], Pierre-Cedric Crouch[2], Daniel S. Fierer[3]; [1]University of California, San Francisco, San Francisco, CA; [2]San Francisco AIDS Foundation, San Francisco, CA; [3]Mount Sinai Hospital, New York City, NY

Background: An international epidemic of sexually-acquired HCV infections among HIV-infected men who have sex with men (MSM) emerged in the 21st century, but infections among HIV-*un*infected MSM have been rare, likely due to a combination of biological (i.e higher infectivity of HIV than HCV during sex), and behavioral (i.e. HIV avoidance by serosorting) factors. Pre-exposure prophylaxis (PrEP) against HIV infection, however, tips the biological balance toward HCV by preventing HIV infection, and may result in behavioral change by decreasing serosorting. **Methods:** We enrolled HIV-uninfected MSM on PrEP with incident HCV in New York City (NYC) and San Francisco (SF). Incident HCV was defined as finding new HCV Ab and/or HCV RNA. Data on sexual and drug use practices were obtained through self-report. **Results:** We diagnosed 13 incident HCV infections in 11 men taking PrEP between 2013 and 2017, two of whom were re-infected (Table). Seven of the 11 primary infections presented with asymptomatic ALT elevation, 2 with jaundice, and 2 with HCV Ab screening; both re-infections were found by HCV RNA screening. Four men had a concomitant sexually transmitted infection; 8 reported methamphetamine or other drug use, with injection use in 5. All but 2 reported ≥20 sexual partners in the prior 3 mo, and 4 of 8 reported increased sexual or drug risk behaviors since starting PrEP. Ten infections were gt 1a, 2 were gt 4d, and 1 was unknown. Three infections spontaneously cleared and 10 were treated. **Conclusions:** We report multiple cases of sexually transmitted HCV among HIV-uninfected MSM taking PrEP in two large US cities. Many of the men reported that after starting PrEP they increased behaviors associated with acquiring HCV. Further, most HCV infections were asymptomatic, detected first by regular ALT testing. Our findings therefore strongly suggest the need for two additions to the PrEP guidelines for MSM: education about the risks of acquiring HCV during sex; and incorporating ALT and HCV Ab testing into PrEP monitoring.

Characteristics of acute HCV cases



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The following people have nothing to disclose: Jeffrey E. McKinney

1000
Understanding Women's Preferences Regarding Treatment of Hepatitis C During Pregnancy

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Background: Most direct-acting antiviral drugs have been labeled as pregnancy safety category B, but none are approved for use in pregnancy. Treatment during pregnancy may offer a unique opportunity to treat women who otherwise may not have access, and be a means of reducing mother-to-child transmission. The preferences of women with hepatitis C (HCV) regarding the potential use of antiviral therapy during pregnancy are important in guiding future studies. **Methods:** We surveyed women

1240 ★

Technetium-99m-GSA Scintigraphy Obtained Within Three Days of Admission as an Early Predictor of Outcome in Acute Liver Failure and Severe Acute Hepatitis

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Background: Acute liver failure (ALF) is associated with a high mortality, which can be substantially reduced with liver transplantation. Therefore, prediction of ALF prognosis is required for determining the indication for liver transplantation. Technetium-99m-diethylenetriaminepentaacetic acid galactosyl human serum albumin (^{99m}Tc-GSA) scintigraphy is an objective tool for evaluating liver function. The aim of this study was to determine whether ^{99m}Tc-GSA scintigraphy performed within three days of admission could predict the prognosis of ALF or severe acute hepatitis with an INR of >1.5. **Methods:** This was a prospective observational study. From January 2011 to October 2016, 82 patients satisfied the inclusion criteria. Sixteen patients in critical condition did not undergo ^{99m}Tc-GSA scintigraphy. Two patients were excluded due to malignant infiltration of the liver. Therefore, a total of 64 patients were enrolled in the present study. For the procedure, 185 MBq of ^{99m}Tc-GSA was injected into a cephalic vein, then images were obtained in 15-s frames for 20 min with a dual-head gamma camera. Time-activity curves were generated from regions of interest (ROI) for the whole liver and the heart. The hepatic accumulation index was calculated by dividing the radioactivity of the liver ROI by that of the liver-plus-heart ROI at 15 min (i.e., LHL15). The blood clearance index was calculated by dividing the radioactivity of the heart ROI at 15 min by that at 3 min (i.e., HH15). **Results:** Sixteen (25.0%) patients died or underwent liver transplantation (poor outcome), and LHL15 was significantly lower in these patients (0.673±0.057) than in those who survived (0.842±0.061) (p<0.0001). There was a significant negative correlation between LHL15 and HH15 (γ=−0.82, p<0.0001). The optimal cut-off point of LHL15 for distinguishing poor outcome and survival as calculated by Youden's index was 0.737, with a sensitivity of 93.8%, specificity of 93.8%, and AUC of 0.971 (95% confidence interval [CI], 0.908–0.991). At the cut-off point, the positive and negative predictive values were 83.3% and 97.8%, respectively. Gender and age were not significantly different between poor outcome and survival. Bilirubin, INR, HGF, MELD-score, presence of hepatic coma at the time of admission, and LHL15 were adopted as confounders in the logistic regression model for the multivariate analysis. The analysis revealed that only LHL15 was an independent predictor of poor outcome (95% CI, 15.6–78.7, p=0.0112). **Conclusion:** 99mTc-GSA scintigraphy might be clinically useful for predicting the prognosis of patients with ALF or severe acute hepatitis with INR of >1.5.

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1241 ★

Identifying Herpes Simplex Virus (HSV)-Related Acute Liver Failure (ALF)

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Background: Acute liver failure (ALF) is a devastating illness that affects 2000 individuals in the U.S. yearly. Outcomes depend in part on the specific etiology and can be hard to determine; HSV is known to cause ALF rarely, but the extent of its reach is unclear since it is not always sought among the etiologies of ALF. We hypothesized that additional indeterminate cases might be attributed to HSV if this was looked for more carefully. Methods: The ALFSG data base of 3,000+ subjects was queried for any mention of the term "HSV" or "Herpes" to identify all possible HSV instances; 106 cases were manually reviewed to identify HSV cases: definite HSV if there was histology diagnostic of HSV and/or presence of positive serum HSV DNA by PCR, probable HSV if there was no tissue or DNA diagnosis but positive serologies and a clinical picture consistent with HSV, and possible HSV if other ALF causes were ruled out and serologies incomplete but suggestive. Results: Of the 106 cases reviewed, 17 were considered confirmed, 3 were probable, 13 were possible, and 73 were not HSV. Of the definite HSV cases, average age was 40, and 69% were female, similar to non-HSV cases. Eighty-one percent of definite HSV cases endorsed fever at admission, whereas only 58% of non-HSV cases. Median AST for confirmed HSV cases was 4,124 IU/L, significantly higher than non-HSV cases (p=0.04). Only 44% of confirmed HSV cases were alive at 21 days, versus 64% of other ALF combined. Seven of the 20 confirmed/probable HSV cases concurrently had another serious infection (including Candidal pneumonia, Klebsiella pneumonia, Aspergillus and Mucormycosis). Only 4 out of the 20 confirmed/probable HSV cases were immunosuppressed. Only 6 of the 20 confirmed/probable HSV cases had received acyclovir. Of the 20 confirmed/probable HSV cases, we identified 6 new cases, meaning the diagnosis of HSV had not been established at the time of death/discharge. Discussion: Although HSV-ALF is still rare, 6 of 20 HSV cases were initially missed by the care team, so that the diagnosis was first made at autopsy or post-mortem testing. ALF due to HSV carried a poor prognosis and was often found in the presence of another serious infection. In 15 out of 20 confirmed/probable cases, no therapy was given. Providers should consider testing for HSV and treating empirically with acyclovir in caring for ALF patient, particularly when fever and high AST are present.

Etiology	Number of Cases (%)	Median ALT	Median AST	Alive at 21d (%)	Endorsed Fever (%)
Confirmed HSV	17 (15.1%)	2317	4124	43.8	81.3
Probable HSV	3 (2.8%)	1890	4548	66.7	100.0
Possible HSV	13 (12.3%)	1302	1594	76.9	69.2
Not HSV	74 (69.8%)	1558	1371	86.2	58

Disclosures:

William M. Lee - Consulting: Novartis, Sanofi, Syntimune, Repros; Grant/Research Support: Bristol Myers Squibb, Merck, Gilead, Ocera

The following people have nothing to disclose: Lanna Little

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The Frequency of Herbal and Dietary Supplement Mislabeling: Experience of the Drug Induced Liver Injury Network

Victor J. Navarro[1], Ikhlas A. Khan[2], Bharathi Avula[2], Manisha Verma[1]; [1]Department of Transplantation, Einstein Healthcare Network, Philadelphia, PA; [2]National Center for Natural Products Research, University, MS

Background: As Herbal and Dietary Supplements (HDS) are not FDA approved, they could contain unlabeled ingredients, such as chemical and microbial contaminants, pharmaceutical adulterants, or other compounds, some with known hepatotoxic potential. The Drug Induced Liver Injury Network (DILIN) collects and stores HDS consumed by patients enrolled into its prospective study, making them available for chemical verification. **Aim:** To analyze the contents and determine the frequency of HDS mislabeling in samples collected by the DILIN prospective study. **Methods:** Between 2003 and March 2016, DILIN collected 341 HDS from 1268 enrolled patients; to date, 229 products have undergone chemical analysis at the National Center for Natural Products Research (NCNPR) at the University of Mississippi; 203 of the 229 HDS had their contents labeled. Product ingredients as determined through chemical analysis for each HDS product were compared with the ingredients listed on the product labels. HDS were grouped per the composition of the product, such as if principally of botanical, vitamin, or steroidal ingredients; and per their purported use, such as for body building or weight loss. Mislabeling was defined as when the chemical analysis did not confirm the ingredients listed on the label. Analysis of HDS was performed at the NCNPR using standard liquid chromatography-mass spectroscopy with electrospray ionization source protocol. **Results:** We found that only 90 of 203 (44%, 95% CI: 37%-51%) HDS had labels that accurately reflected their contents as determined through chemical analysis. Based on the composition of the product, mislabeling rates (95% CI) were 80% (48%-95%), 54% (35%-73%), 48% (39%-56%) within HDS principally of steroidal (n=10), vitamin (n=26) or botanical ingredients (n=122), respectively. Based on the purported use, products used for bodybuilding (n=34), weight loss (n=36), energy boosters (n=5), and general health/well-being (n=35) had mislabeling rates (95% CI) of 79% (66%-93%), 72% (46%-76%), 60% (23%-88%), and 51% (35%-68%) respectively. Similar rates of mislabeling were also found for the 166 HDS product judged to be responsible for liver injury by DILIN investigators through a structured causality assessment process. **Conclusions:** Using comprehensive chemical analysis, we observed that HDS mislabeling is common, occurring in over half of products collected from DILIN subjects. Products used for bodybuilding, and weight loss have the highest rates of mislabeling. These findings should inform how these agents are evaluated as potential causes for liver injury.

Disclosures:

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Hepatic NK cells play an important role in the development of AIH by contributing to hepatic inflammation

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Background and Aims: Adenovirus-human cytochrome P4502D6 (CYP2D6) induced mouse model is a recently established animal model for mimicing human type 2 autoimmune hepatitis (AIH). As an important innate immune cell inliver inflammation, the role of natural killer (NK) cell in CYP2D6 mouse model has not been investigated so far, and this is the focus of our study. **Methods:** Adenovirus vector containing CYP2D6 (Ad-2D6) or green fluorescence protein (Ad-GFP) were directly delivered into the liver of C57BL/6 mice intravenously and intraperitoneally to establish experimental model and control model respectively. Anti-ASGM1-mediated NK cell depletion was operated on Ad-2D6 mice 24 hours postvirus injection. Serum alanine aminotransferase (ALT) and aspartate aminotransferase (AST) were assessed by The VITROS 350 Chemistry System. Pathological changes of liver were evaluated by hematoxylin-eosin (HE) staining. Anti-CYP2D6 antibody was tested by indirect immunofluorescence. Dynamic proportion of NK cellsin the liver, peripheral blood, and spleen were determined by flow cytometry. **Results:** Compared with Ad-GFP mice, a development of persistent AIH was evident in Ad-2D6 mice from 2-4 weeks post infection, which was characterized by hepatic inflammatory cells infiltration similar to interface hepatitis in human AIH. A gradually increased serum ALT/AST levels and titers of specific autoantibody anti-CYP2D6 were also evidenced. No significant difference was observed in the proportion of NK cells in peripheral blood or spleen between Ad-GFP mice and Ad-2D6 mice. In contrast, Ad-2D6 mice showed a markedly higher proportion of hepatic NK cells than Ad-GFP mice with the exacerbation of hepatic disease. The depletion of NK cells significantly decreased serum AST levels and hepatic inflammatory cells infiltration in Ad-2D6 mice. **Conclusion:** With the successfully established CYP2D6 mouse model, we found that hepatic NK cells contributed to the development of AIH disease via hepatic inflammation.

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The following people have nothing to disclose: Peng Wang, Weiming Yan, Yuli Liu

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Clara cell 10KDa protein alleviated fulminant hepatitis induced by MHV-3 via inhibiting FGL2 expression on macrophages

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Background: Fulminant hepatitis (FH) is a serious life-threatening disease with massive necroinflammation during a short time. Kupffer cells are the major immune cells population for innate immune response which are