Methods Retrospective study by data gathering form hepatitis clinic, Hatyai hospital during 2014–2017. Statistical analysis: Chi-square test

Inclusion criteria 1. Anti-HCV positive with detectable viral load 2. Measure CAP pre treatment

Exclusion criteria 1. Loss follows up 2. No result of HCV RNA viral load post treatment

Results Seventy-four HCV infected patients participate in the study. 25.42% of the participants were hepatic steatosis (n=15). SVR in hepatic steatosis group were 80% VS SVR in without hepatic steatosis group were 71.19% (P=0.75).

Conclusions No relationship between hepatic steatosis by using CAP and result of HCV treatment

IDDF2019-ABS-0123 PRE-ENDOSCOPY SCREENING FOR HEPATITIS VIRUSES IN UNDER-DEVELOPED AND DEVELOPING COUNTIES: HOW USEFUL IS IT?

Ashish Kumar Jha*, Madhur Chaudhary, Ravish Kumar, Uday Kumar, Vishwa Mohan Dayal, Sharad Jha. *Indira Gandhi Institute of Medical Sciences, Patna, India*

10.1136/gutjnl-2019-IDDFabstracts.265

Background Data regarding the transmission of viral infectious agents via gastrointestinal endoscopes is not available from low-income countries. We aimed to determine the prevalence of HBV and HCV infections in patients underwent upper GI endoscopy (UGIE) in a public sector hospital.

Methods In a cross-sectional study, all consecutive patients undergoing UGIE were screened for hepatitis B and C infection (immunochromatographic assays). Prevalence of HBV and HCV infection in patients underwent UGIE were calculated before and after exclusion of already diagnosed cases of chronic liver disease (CLD).

Results A total of 2,686 patients were screened and 2,499 were enrolled in the study. The mean age of patients was 42.6 (±16.3) years (M: F=1.9:1). Out of 2,499 patients, 221(8.8%) were tested positive for HBsAg. Among them, 123 (55.6%) were previously diagnosed HBV-related CLD cases and 98 (44.3%) were newly diagnosed cases. Past history of blood transfusion, surgery and jaundice were present in 4.5%, 14.4% and 24.4% patients, respectively. Risk factors were unidentified in 57% of patients. Out of 2,499, 36 (1.4%) patients were tested positive for anti-HCV antibody. Among them, 19 (52.7%) were previously diagnosed HCV-related CLD cases and 17 (47.2%) were newly diagnosed cases. Past history of blood transfusion, surgery and jaundice were present in 44.4%, 52.7% and 16.6% patients, respectively. Risk factors were unidentified in 27.7% of patients. In this study, nearly half of the patients were newly diagnosed cases of HBV and HCV infections. Identifiable risk factors were absent in 57% and 27.7% of HBV and HCV infected patients, respectively. Hence, just a negative history was not sufficient to rule out these infections prior to a GIE.

Conclusions Many of the endoscopy units of public sector hospitals of under-developed and developing counties is over-burdened, understaffed, and under-equipped. Proper disinfection/sterilization of endoscopes and accessories is sometimes questionable because of inadequate infrastructures. Therefore, it may be beneficial to include a determination of hepatitis serology of patients prior to endoscopy. However, the cost of pre-screening tests is the major problem for routine screening. Hence, the screening may be recommended for high-risk patients only.

IDDF2019-ABS-0131 ALGORITHMS USING NONINVASIVE TESTS CAN ACCURATELY IDENTIFY PATIENTS WITH ADVANCED FIBROSIS DUE TO NASH: DATA FROM THE STELLAR CLINICAL TRIALS

[1]Vincent Wai-Sun Wong*, [2]Zobair Younossi, [3]Eric Lawitz, [3]Naim Alkhouri, [4]Manuel Romero-Gomez, [5]Takeshi Okanoue, [6]Michael Trauner, [7]Kathryn Kersey, [7]Georgia Li, [7]Mani Subramanian, [7]Robert Myers, [7]Stephen Djedjos, [7]Ling Han, [7]Guang Chen, [7]Tuan Nguyen, [8]Anita Kohli, [9]Natalie Bzowej, [10]Ziad Younes, [11]Shiv Sarin, [12]Mitchell Shiffman, [13]Stephen Harrison, [1]Zachary Goodman, [14]Nezam Afdhal, [15]Maria Stepanova, [16]Quentin Anstee. *[1]Department of Medicine and Therapeutics, The Chinese University of Hong Kong, Hong Kong; [2]Inova Fairfax Hospital, Falls Church, VA, USA; [3]Texas Liver Institute, University of Texas Health San Antonio, San Antonio, TX, USA; [4]Hospital Universitario Virgen del Rocio, Sevilla, Spain; [5]Saiseikai Suita Hospital, Suita City, Osaka, Japan; [6]Division of Gastroenterology and Hepatology, Medical University of Vienna, Vienna, Australia; [7]Gilead Sciences, Inc., Foster City, CA, USA; [8]The Institute for Liver Health, Chandler, AZ, USA; [9]Ochsner Medical Center, New Orleans, LA,, USA; [10]Gastro One, Germantown, TN, USA; [11]Institute of Liver and Biliary Sciences, New Delhi, Delhi, India; [12]Bon Secours Mercy Health, Liver Institute of Virginia, Richmond, Virginia, USA; [13]Pinnacle Clinical Research, San Antonio, TX, USA; [14]Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, MA, USA; [15]Center for Outcomes Research in Liver Diseases, Washington DC, USA; [16]Institute of Cellular Medicine, Newcastle University, Newcastle-upon-Tyne, UK*

10.1136/gutjnl-2019-IDDFabstracts.266

Background There is a major unmet need for accurate, readily available, noninvasive tests (NITs) to identify patients with advanced fibrosis due to NASH. Our goal was to evaluate

Abstract IDDF2019-ABS-0131 Table 1 Diagnostic performance of nits to discriminate advanced fibrosis f3-f4

Test*	Cohort	Sample Size	Sensitivity	Specificity	Indeterminate	Misclassified**
FIB-4 (1.23, 2.1)	Train+Test	2496	85%	85%	32%	15%
	Validation	627	83%	89%	32%	15%
ELF (9.35, 10.24)	Train+Test	2536	85%	85%	29%	15%
	Validation	637	85%	85%	29%	15%
FS (9.6kPa, 14.53kPa)	Train+Test	1408	85%	86%	28%	15%
	Validation	357	82%	88%	25%	17%
FIB-4 (1.23, 2.1) then ELF	Train+Test	2542	79%	81%	13%	20%
(9.35, 10.24)	Validation	638	78%	82%	13%	21%
FIB-4 (1.23, 2.1) then FS	Train+Test	2509	82%	85%	20%	17%
(9.6kPa, 14.53kPa)	Validation	632	78%	87%	20%	19%

*Lower value represents optimal threshold to exclude advanced fibrosis, higher value to diagnose advanced fibrosis, with in-between values classified as indeterminate
**Proportion of misclassified patients relative to total sample size including indeterminate zone

sequential NIT algorithms to minimize the requirement for biopsy and improve accuracy overuse of single tests.

Methods The STELLAR studies (NCT03053050, NCT03053063) enrolled NASH patients with bridging fibrosis (F3) or compensated cirrhosis (F4). Baseline liver biopsies were read using the NASH CRN fibrosis classification and noninvasive fibrosis markers: FIB-4 index, ELF test, and FibroScan® (FS). The performance of these tests to discriminate advanced fibrosis was evaluated using AUROCs with 5-fold cross-validation repeated 100x. Thresholds were obtained by maximizing specificity given ≥85% sensitivity. The cohort was divided (80%/20%) into evaluation/validation sets. The evaluation set was further stratified 250x into training and test sets (66%/33%). Optimal thresholds were derived as the average across training sets, and applied sequentially (FIB-4 followed by ELF and/or FS) to the validation set. Data are from an interim analysis on 26 July 2018.

Results All patients with available liver histology (N=3202, 71% F3-F4) and NIT results were included. While single tests were able to discriminate advanced fibrosis (AUROCs of 0.78, 0.80, and 0.80 for FIB-4, ELF, and FS in validation cohort), up to 32% of patients had an indeterminate result. Using thresholds derived from STELLAR data, FIB-4 followed by FS or ELF in those with indeterminate FIB-4 values (1.23 to 2.1) reduced indeterminate results to as low as 13% (table 1). Published NIT thresholds yielded similar results (data not shown). Adding a third test (FIB-4 then ELF then FS) reduced the rate of indeterminate results to 8%. Misclassification occurred at rates similar to biopsy (15–21%). The majority of misclassifications (63–81%) were false negatives; among false positive cases (19–27% of misclassifications) up to 70% had F2 fibrosis.

Conclusions FIB-4 followed by ELF and/or FS nearly eliminated the need for liver biopsy and accurately identified patients with advanced fibrosis due to NASH with misclassification rates similar to liver biopsy.

IDDF2019-ABS-0133

ROUTINELY AVAILABLE NONINVASIVE TESTS DISCRIMINATE ADVANCED FIBROSIS DUE TO NASH IN THE PHASE 3 STELLAR TRIALS OF THE ASK1 INHIBITOR SELONSERTIB

[1]Vincent Wai-Sun Wong*, [2]Quentin Anstee, [3]Eric Lawitz, [3]Naim Alkhouri, [4]Manuel Romero-Gomez, [5]Takeshi Okanoue, [6]Michael Trauner, [7]Kathryn Kersey, [7]Georgia Li, [7]Mani Subramanian, [7]Robert Myers, [7]Stephen Djedjos, [7]Ling Han, [7]Tuan Nguyen, [8]Anita Kohli, [9]Natalie Bzowej, [10]Ziad Younes, [11]Shiv Sarin, [12]Mitchell Shiffman, [13]Stephen Harrison, [14]Zachary Goodman, [14]Zobair Younossi. *[1]Department of Medicine and Therapeutics, The Chinese Hospital of Hong Kong, Hong Kong; [2]Institute of Cellular Medicine, Newcastle University, Newcastle-upon-Tyne, UK; [3]Texas Liver Institute, University of Texas Health San Antonio, San Antonio, TX, USA; [4]Hospital Universitario Virgen del Rocio, Sevilla, Spain; [5]Saiseikai Suita Hospital, Suita City, Osaka, Japan; [6]Division of Gastroenterology and Hepatology, Medical University of Vienna, Vienna, Austria; [7]Gilead Sciences, Inc., Foster City, CA, USA; [8]The Institute for Liver Health, Chandler, AZ, USA; [9]Ochsner Medical Center, New Orleans, LA, USA; [10]Gastro One, Germantown, TN, USA; [11]Institute of Liver and Biliary Sciences, New Delhi, Delhi, India; [12]Bon Secours Liver Institute of Virginia, Richmond, Virginia, USA; [13]Pinnacle Clinical Research, San Antonio, TX, USA; [14]Inova Fairfax Hospital, Falls Church, VA, USA*

10.1136/gutjnl-2019-IDDFabstracts.267

Background Liver biopsy is currently the reference standard for fibrosis staging, but is an invasive procedure with limitations. There are a major unmet need for accurate, readily available noninvasive tests (NITs) to identify patients with advanced fibrosis due to NASH. Our aim is to describe the performance of NITs using the baseline data from the Phase 3 STELLAR studies of the ASK1 inhibitor selonsertib (SEL).

Methods The STELLAR studies (NCT03053050 and NCT03053063) enrolled patients with bridging fibrosis (F3) or compensated cirrhosis (F4) due to NASH (NAFLD Activity Score [NAS] ≥3). Baseline liver biopsies were centrally read according to the NASH CRN fibrosis classification and noninvasive markers of fibrosis, including the NAFLD fibrosis score (NFS), Fibrosis-4 (FIB-4) index, Enhanced Liver Fibrosis (ELF) test, and liver stiffness (LS) by transient elastography (TE; FibroScan®) were measured. The performance of these tests to

Abstract IDDF2019-ABS-0133 Table 1 Diagnostic performance of nits to discriminate advanced fibrosis F3-F4

Test	Prevalence of F3-F4	AUROC (95% CI)	Cut-off	Sensitivity	Specificity	PPV	NPV
NFS n=2309	78%	0.75 (0.75, 0.75)	≥ -1.455	90%	37%	83%	52%
			≥ 0.676	39%	89%	93%	30%
FIB-4 n=3125	71%	0.78 (0.78, 0.78)	≥ 1.3	82%	57%	83%	56%
			≥ 2.67	36%	93%	93%	37%
ELF n=3183	71%	0.80 (0.80, 0.80)	≥ 9.8	74%	73%	87%	53%
			≥ 11.3	20%	98%	95%	33%
LS by TE	84%	0.80 (0.79, 0.8)	≥ 9.9 kPa	83%	61%	92%	41%
n=1760			≥ 11.4 kPa	75%	71%	93%	36%