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Contents

Semimonthly Volume 8 Number 22 November 26, 2020

EDITORIAL

- 5496** Is Dynesys dynamic stabilization system superior to posterior lumbar fusion in the treatment of lumbar degenerative diseases?

Peng BG, Gao CH

MINIREVIEWS

- 5501** COVID-19: A review of what radiologists need to know
Tang L, Wang Y, Zhang Y, Zhang XY, Zeng XC, Song B
- 5513** Holistic care model of time-sharing management for severe and critical COVID-19 patients
Yang B, Gao Y, Kang K, Li J, Wang L, Wang H, Bi Y, Dai QQ, Zhao MY, Yu KJ

ORIGINAL ARTICLE

Case Control Study

- 5518** Bioequivalence of two esomeprazole magnesium enteric-coated formulations in healthy Chinese subjects
Liu ZZ, Ren Q, Zhou YN, Yang HM
- 5529** Osteoprotegerin, interleukin and hepatocyte growth factor for prediction of diabetes and hypertension in the third trimester of pregnancy
Huang SJ, Wang HW, Wu HF, Wei QY, Luo S, Xu L, Guan HQ

Retrospective Study

- 5535** High serum lactate dehydrogenase and dyspnea: Positive predictors of adverse outcome in critical COVID-19 patients in Yichang
Ly XT, Zhu YP, Cheng AG, Jin YX, Ding HB, Wang CY, Zhang SY, Chen GP, Chen QQ, Liu QC
- 5547** Risk factors analysis of prognosis of adult acute severe myocarditis
Zhang Q, Zhao R
- 5555** Sonographic features of umbilical vein recanalization for a Rex shunt on cavernous transformation of portal vein in children
Zhang YQ, Wang Q, Wu M, Li Y, Wei XL, Zhang FX, Li Y, Shao GR, Xiao J

Clinical Trials Study

- 5564** Gemcitabine plus concurrent irreversible electroporation *vs* gemcitabine alone for locally advanced pancreatic cancer
Ma YY, Leng Y, Xing YL, Li HM, Chen JB, Niu LZ

Observational Study

- 5576** No significant association between dipeptidyl peptidase-4 inhibitors and adverse outcomes of COVID-19
Zhou JH, Wu B, Wang WX, Lei F, Cheng X, Qin JJ, Cai JJ, Zhang X, Zhou F, Liu YM, Li HM, Zhu LH, She Z, Zhang X, Yang J, Li HL

META-ANALYSIS

- 5589** Interobserver agreement for contrast-enhanced ultrasound of liver imaging reporting and data system: A systematic review and meta-analysis
Li J, Chen M, Wang ZJ, Li SG, Jiang M, Shi L, Cao CL, Sang T, Cui XW, Dietrich CF

CASE REPORT

- 5603** CLAG-M chemotherapy followed by umbilical cord blood stem cell transplantation for primary refractory acute myeloid leukaemia in a child: A case report
Huang J, Yang XY, Rong LC, Xue Y, Zhu J, Fang YJ
- 5611** Multiple schwannomas with pseudoglandular element synchronously occurring under the tongue: A case report
Chen YL, He DQ, Yang HX, Dou Y
- 5618** Primary myelofibrosis with concurrent *CALR* and *MPL* mutations: A case report
Zhou FP, Wang CC, Du HP, Cao SB, Zhang J
- 5625** Endometrial stromal sarcoma extending to the pulmonary artery: A rare case report
Fan JK, Tang GC, Yang H
- 5632** Malignant acanthosis nigricans with Leser-Trélat sign and tripe palms: A case report
Wang N, Yu PJ, Liu ZL, Zhu SM, Zhang CW
- 5639** Gastric plexiform fibromyxoma: A case report
Pei JY, Tan B, Liu P, Cao GH, Wang ZS, Qu LL
- 5645** Rectoseminal vesicle fistula after radical surgery for rectal cancer: Four case reports and a literature review
Xia ZX, Cong JC, Zhang H
- 5657** Azacitidine decreases reactive oxygen species production in peripheral white blood cells: A case report
Hasunuma H, Shimizu N, Yokota H, Tatsuno I
- 5663** Oral granuloma in a pediatric patient with chronic graft-versus-host disease: A case report
Uesugi A, Tsushima F, Kodama M, Kuroshima T, Sakurai J, Harada H
- 5670** Intrahepatic biliary cystadenoma: A case report
Xu RM, Li XR, Liu LH, Zheng WQ, Zhou H, Wang XC
- 5678** Gene diagnosis of infantile neurofibromatosis type I: A case report
Li MZ, Yuan L, Zhuo ZQ

- 5684** Localized amyloidosis affecting the lacrimal sac managed by endoscopic surgery: A case report
Song X, Yang J, Lai Y, Zhou J, Wang J, Sun X, Wang D
- 5690** Endoscopic resection of benign esophageal schwannoma: Three case reports and review of literature
Li B, Wang X, Zou WL, Yu SX, Chen Y, Xu HW
- 5701** Bouveret syndrome masquerading as a gastric mass-unmasked with endoscopic luminal laser lithotripsy: A case report
Parvataneni S, Khara HS, Diehl DL
- 5707** Nonhypertensive male with multiple paragangliomas of the heart and neck: A case report
Wang Q, Huang ZY, Ge JB, Shu XH
- 5715** Completed atrioventricular block induced by atrial septal defect occluder unfolding: A case report
He C, Zhou Y, Tang SS, Luo LH, Feng K
- 5722** Clinical characteristics of adult-type annular pancreas: A case report
Yi D, Ding XB, Dong SS, Shao C, Zhao LJ
- 5729** Port-site metastasis of unsuspected gallbladder carcinoma with ossification after laparoscopic cholecystectomy: A case report
Gao KJ, Yan ZL, Yu Y, Guo LQ, Hang C, Yang JB, Zhang MC
- 5737** Gonadal dysgenesis in Turner syndrome with Y-chromosome mosaicism: Two case reports
Leng XF, Lei K, Li Y, Tian F, Yao Q, Zheng QM, Chen ZH
- 5744** Gastric mixed adenoma-neuroendocrine tumor: A case report
Kohno S, Aoki H, Kato M, Ogawa M, Yoshida K
- 5751** Sebaceous lymphadenocarcinoma of the parotid gland: A case report
Hao FY, Wang YL, Li SM, Xue LF
- 5758** Misdiagnosis of ligamentoid fibromatosis of the small mesenteric: A case report
Xu K, Zhao Q, Liu J, Zhou D, Chen YL, Zhu X, Su M, Huang K, Du W, Zhao H
- 5765** Intraoperative care of elderly patients with COVID-19 undergoing double lung transplantation: Two case reports
Wu Q, Wang Y, Chen HQ, Pan H
- 5773** Amelioration of cognitive impairment following growth hormone replacement therapy: A case report and review of literature
Liu JT, Su PH
- 5781** Early colon cancer with enteropathy-associated T-cell lymphoma involving the whole gastrointestinal tract: A case report
Zhang MY, Min CC, Fu WW, Liu H, Yin XY, Zhang CP, Tian ZB, Li XY

- 5790** Bleeding of two lumbar arteries caused by one puncture following percutaneous nephrolithotomy: A case report
Liu Q, Yang C, Lin K, Yang D
- 5795** Hemorrhagic fever with renal syndrome complicated with aortic dissection: A case report
Qiu FQ, Li CC, Zhou JY
- 5802** Robot-assisted laparoscopic pyeloureterostomy for ureteropelvic junction rupture sustained in a traffic accident: A case report
Kim SH, Kim WB, Kim JH, Lee SW
- 5809** Large leiomyoma of lower esophagus diagnosed by endoscopic ultrasonography-fine needle aspiration: A case report
Rao M, Meng QQ, Gao PJ
- 5816** Endoscopic reduction of colocolonic intussusception due to metastatic malignant melanoma: A case report
Kasuga K, Sakamoto T, Takamaru H, Sekiguchi M, Yamada M, Yamazaki N, Hashimoto T, Uraoka T, Saito Y
- 5821** Usefulness of ultrasonography to assess the response to steroidal therapy for the rare case of type 2b immunoglobulin G4-related sclerosing cholangitis without pancreatitis: A case report
Tanaka Y, Kamimura K, Nakamura R, Ohkoshi-Yamada M, Koseki Y, Mizusawa T, Ikarashi S, Hayashi K, Sato H, Sakamaki A, Yokoyama J, Terai S

LETTER TO THE EDITOR

- 5831** Is positivity for hepatitis C virus antibody predictive of lower risk of death in COVID-19 patients with cirrhosis?
Mangia A, Cenderello G, Verucchi G, Ciancio A, Fontana A, Piazzolla V, Minerva N, Squillante MM, Copetti M

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Is positivity for hepatitis C virus antibody predictive of lower risk of death in COVID-19 patients with cirrhosis?

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Abstract

Liver injury has been reported in coronavirus disease 2019 (COVID-19) cases but the impact of pre-existing liver damage and related etiology have not been completely elucidated. Our research interests include the potential reciprocal influence of COVID-19 and pre-existing liver damage related to hepatitis C virus (HCV) infection, in particular. To this end, we have evaluated three cohorts of patients admitted at three Italian hospitals during the coronavirus pandemic; these included 332 patients with COVID-19 and 1527 patients with HCV who were from established real-world antiviral treatment study cohorts (sofosbuvir/velpatasvir), with either liver disease (various severities; $n = 1319$) or cirrhosis ($n = 208$). Among the COVID-19 patients, 10 had cirrhosis (3%), including 7 of metabolic origin and 3 of viral origin. Mortality among the COVID-19 patients was 27.1%, with 70% of those with cirrhosis of metabolic etiology having died. Cirrhosis, older age, low white blood cell count and lymphocyte count being identified as risk predictors of death [odds ratio (OR) = 13.7, 95% confidence interval (CI): 2.59-83.01, $P = 0.006$; OR = 1.05, 95%CI: 1.03-1.08, $P = 0.0001$; OR = 1.09, 95%CI: 1.36-1.16, $P = 0.001$; OR = 0.61, 95%CI: 0.39-0.93, $P = 0.023$, respectively]. In the two cohorts of HCV patients, COVID-19 diagnosis was

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made in 0.07% of those with liver disease and 1% of those with cirrhosis. Thus, the prevalence of HCV antibodies among COVID-19-infected patients was comparable to that currently reported for the general population in Italy. Amongst the COVID-19 patients, pre-existing metabolic cirrhosis appears to be associated with higher mortality, while HCV antibodies may be suggestive of "protection" against COVID-19.

Key Words: Hepatitis C virus; Hepatitis B virus; Cirrhosis; COVID-19; Sofosbuvir; Velpatasvir

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Core Tip: This ongoing study aims to investigate the potential reciprocal influence of coronavirus disease 2019 (COVID-19) and pre-existing cirrhosis. To date, it has included 332 patients with COVID-19 admitted to three Italian hospitals during the current pandemic, as well as two large cohorts of hepatitis C virus (HCV) patients from real-world antiviral treatment (pangenotypic sofosbuvir/velpatasvir combination) studies. Despite the limited COVID-19 sample size, cirrhosis was found to be associated with higher mortality, with the majority of deaths related to cirrhosis of metabolic origin. The very low prevalence of COVID-19 in the HCV cohorts supports a possible protective role of HCV antibodies.

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TO THE EDITOR

Coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome-coronavirus type-2 (SARS-CoV-2) presents a spectrum of clinical manifestations; although, it predominantly results in severe respiratory disease that is associated with significant morbidity and mortality. Early reports of COVID-19 cases described hepatic manifestations, but the pathogenesis of liver injury remains unclear. The role of a pre-existing liver disease related to infections with either the hepatitis B virus (HBV) or hepatitis C virus (HCV) [\pm human immunodeficiency virus (HIV) co-infection] or to metabolic liver damage with concomitant obesity and diabetes may be relevant. In a large cohort of SARS-CoV-2 patients in the United States, among which 41.7% of cases had comorbid metabolic disease, HBV and HCV infections were determined to play a marginal role, being reported in only 0.1% and $< 0.1\%$, respectively^[1]. In SARS-CoV-2 patients from China, however, the rate of HBV infection was 2.1%, reflecting the greater local prevalence of HBV^[2]. Otherwise, data on replicative status of these hepatitis patients are lacking. As the global prevalence of HBV and HCV infections is geographically variable^[3,4], data from Europe may help improve our understanding of the reciprocal impact of SARS-CoV-2 and HCV/HBV. We have focused our recent research on determining the liver function markers that show abnormalities in routine laboratory testing, including markers of HBV/HCV \pm HIV co-infections, and rates of pre-existing cirrhosis in patients hospitalized with COVID-19 in Italy. Simultaneously, we have investigated the prevalence of COVID-19 among two real-world cohorts of HCV patients who achieved cure by sofosbuvir/velpatasvir (SOF/VEL) combination antiviral treatment in over 97% of the cases^[5,6].

We prospectively collected demographic, clinical and laboratory data of patients treated at three hospitals in Northern and Southern Italy from March 7 to May 7, 2020. These hospitals represent areas with different COVID-19 prevalence and the patients represent consecutive admissions with SARS-CoV-2 diagnosis.

Simultaneously, we interviewed all the HCV patients enrolled in two original HCV real-world treatment studies on pangenotypic SOF/VEL treatment recently published

by our collaborative group^[3,4]. The interviews were conducted with an “ad hoc” questionnaire, and patients were excluded from analysis if they had died before the COVID-19 outbreak. The first study was unrestricted for HCV genotype (GT) or degree of fibrosis ($n = 1319$ total, 21% with cirrhosis), while the second focused on GT3 infections with compensated cirrhosis and portal hypertension ($n = 208$). Pre-COVID-19 death excluded 29 (2.1%) of the patients in the pangenotypic study and 8 (3.8%) in the GT3 cirrhosis study. Characteristics of these patients were reported^[3,4].

In our subsequent observational prospective study, the prevalence of positivity for HCV antibodies (Abs) and hepatitis B surface antigen (HBsAg) among the COVID-19 patients was compared to the recently reported rates of prevalence of HCVAbs (1.37%) and HBsAg (0.8%-1%) in our country^[7,8]. Baseline demographical and clinical characteristics of patients enrolled in our prospective study were reported as mean \pm standard deviation or median and range for continuous variables, and as frequency and percentages for categorical variables. Group comparisons were carried out using Wilcoxon rank-sum test for continuous variables and Pearson’s chi-square or Fisher’s test, as appropriate, for categorical variables.

We prospectively evaluated 332 patients consecutively admitted with COVID-19. The demographic and laboratory results are summarized in **Table 1**. Mortality rate was 27.1% (**Supplementary Table 1**). Among the total patients, 91 (27.4%) had increased alanine aminotransferase and 81 (24.3%) had increased aspartate aminotransferase at admission, with death rates of 26.1% and 22.2% among those subgroups, respectively. Moreover, only 4.7% of the total patients showed increased liver enzymes during hospitalization, but 36.0% of those died. In total, 10 patients (3.0%) had pre-existing cirrhosis, of metabolic origin in 7 and of viral origin in 3, the latter including 2 HIV co-infections. Considering the subset of COVID-19 patients with cirrhosis, 70% died ($P = 0.005$). Among patients with cirrhosis and leucopenia 50% died. Among patients with cirrhosis only one had antiHBc antibodies.

Among the COVID patients, only 10 (3.0%) showed HCVAbs positivity. Only 1 of those 10, however, showed detectable HCV-RNA; the remaining appeared to have spontaneous resolution or treatment-induced HCV-RNA clearance. None of the patients in the group admitted for COVID were under antiviral treatment. Among the HCV-RNA un-reactive COVID patients, 2 had cirrhosis (1 died due to lung cancer, the other was HIV co-infected). Three of the HCVAbs-positive non-cirrhotic patients also died; the first was 97-years-old, the second was 86-years-old with a history of cardiac rhythm abnormalities, and the third was 80-years-old and the single HCV-RNA-reactive case mentioned above. The age distribution of the COVID-19 patients with HCVAbs positivity is presented in **Supplementary Table 1**. The frequency of HCVAbs among subjects with increased alanine aminotransferase at baseline (6.6%) was significantly higher than in patients with normal liver enzymes (6.6% *vs* 1.8%; $P = 0.038$). HBsAg positivity occurred in 4 patients (1.2%), all of who were under treatment by nucleotide analogs that resulted in HBV-DNA un-reactive status. The 1 death among this subgroup represented an HIV co-infection with cirrhosis. Discounting the patient who died of lung cancer, 7 out of the 10 cirrhotic patients who died had a non-viral etiology.

Cirrhosis, older age, low counts for white blood cells and lymphocytes were predictors of death [odds ratio (OR) = 13.7, 95% confidence interval (CI): 2.59-83.01, $P = 0.006$; OR = 1.05, 95%CI: 1.03-1.08, $P = 0.0001$; OR = 1.09, 95%CI: 1.36-1.16, $P = 0.001$; OR = 0.61, 95%CI: 0.39-0.93, $P = 0.023$, respectively].

Among the HCV infection patients from the real-world antiviral treatment cohorts, 1 (0.07%) with cirrhosis in the pangenotypic study and 2 (1%) in the GT3 cirrhosis study reported COVID-19 ascertained infection; all who were between the ages of 45-65, recovered. All the remaining patients showed no symptoms or, in cases of suspected symptoms, had negative COVID-19 molecular testing results.

These results suggest that pre-existing liver cirrhosis of metabolic origin is associated with higher COVID-19-related mortality. We acknowledge that the number of cirrhotic patients is small, however, our data indicate that patients with cirrhosis and cured HCV/HBV infections may be at a lower risk of fatality than those with metabolic cirrhosis, when infected by SARS-CoV-2.

Whether recently cured HCV patients had a smaller exposure or were less vulnerable to COVID-19 due to possible background cellular immunity deserves further investigation. The results we have discussed here, although limited to the regions involved in our collaborative projects, are representative of geographical areas with both high and low COVID-19 prevalence.

Table 1 Baseline characteristics and laboratory findings of 332 patients hospitalized with coronavirus disease 2019 in three Italian hospitals

Factor	Total 332 patients
Age in yr, median (range)	71.9 (19-100)
Male, <i>n</i> (%)	178 (59.7)
BMI in kg/m ² , mean (range)	26.6 (17-42.7)
Arterial hypertension, <i>n</i> (%)	97 (29.2)
Glucose levels in mg/dL, mean (range)	109.4 (48-505)
Baseline ALT levels in U/L, median (range)	39.1 (4-429)
ALT of > 40 U/L, <i>n</i> (%)	74 (25.8)
Baseline AST levels in U/L, mean (range)	44.7 (7-817)
ALT of > 60 U/L, <i>n</i> (%)	82 (28.7)
Liver cirrhosis, <i>n</i> (%)	10.0 (3.0)
Baseline WBC count as $\times 10^9/L$, mean \pm SD	8.14 \pm 6.28
Neutrophil count as $\times 10^9/L$, mean \pm SD	7.37 \pm 10.84
Lymphocyte count as $\times 10^9/L$, mean \pm SD	1.54 \pm 3.03
Lymphocyte count < 1000 as $\times 10^9/L$, <i>n</i> (%)	160 (50.3)
Platelet count as $\times 10^9/L$, mean \pm SD	227.1 \pm 107.5
Total bilirubin in mg/dL, mean (range)	0.79 (0.5-37.0)

BMI: Body mass index; ALT: Alanine aminotransferase; AST: Aspartate aminotransferase; SD: Standard deviation; WBC: White blood cell.

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