Prisoners treated for hepatitis C with protease inhibitor, New York, USA, 2012

Harish Moorjani, Emory University
Carl Koenigsmann, Emory University
Min Jung Kim, Emory University
Anne C Spaulding, Emory University

Journal Title: Emerging Infectious Diseases
Volume: Volume 21, Number 1
Publisher: Centers for Disease Control and Prevention (CDC) | 2015, Pages 186-188
Type of Work: Article | Final Publisher PDF
Publisher DOI: 10.3201/eid2101.141025
Permanent URL: https://pid.emory.edu/ark:/25593/msw7v

Final published version: http://dx.doi.org/10.3201/eid2101.141025

Accessed October 20, 2023 3:10 AM EDT
to phenotypic traits. Because changes in the 5′ untranslated region have the potential to affect the rate of replication (8–10), it is possible that minor genome changes are responsible for the rapid spread and high severity of disease in 2014. Correlation between clinical features of patients in conjunction with additional genomic analysis might provide further insight into the pathogenetic determinants of this strain. Therefore the genome sequence of EV-D68 determined from the 2014 outbreak in St. Louis, Missouri, provides a resource for tracking and genomic comparison of this rapidly spreading virus.

Acknowledgments

We thank Stephanie Bledsoe for her assistance with obtaining samples from the virology laboratory at St. Louis Children’s Hospital and Maria Cannella and Sheila Mason for their assistance with PCR assays. We thank The Genome Institute staff for their assistance with sequencing and data submission, particularly Lucinda Fulton, Debbie Moeller, Joanne Nelson, Sean McGrath, and Amy Ly.

This work was funded by the Alan A. and Edith L. Wolff Distinguished Professorship (to R.K.W.) and R01AI097213 (to G.A.S.).

References

1. Midgley CM, Jackson MA, Selvarangan R, Turabelidze G, Obringer E, Johnson D, et al. Severe respiratory illness associated with enterovirus D68—Missouri and Illinois, 2014. MMWR Morb Mortal Wkly Rep. 2014;63:798–9.
2. Peng Y, Leung, HCM, Yiu SM, Chin YL. IDBA-UD: a de novo assembler for single-cell and metagenomic sequencing data with highly uneven depth. Bioinformatics. 2012;28:1420–8.
3. Wang S, Sundaram JP, Stockwell TB. VIGOR, an annotation program for small viral genomes. Bioinformatics. 2010;11:451.
4. Pickett BE, Sadat EL, Zhang Y, Noronha JM, McLellan MD, Lin L, et al. VarScan 2: somatic mutation and copy number alteration discovery in cancer by exome sequencing. Genome Res., 2012;22:568–76. http://dx.doi.org/10.1101/gr.129684.111
5. Kircher M, Sawyer S, Meyer M. Double indexing overcomes inaccuracy in multiplex sequencing on the Illumina platform. Nucleic Acids Res. 2012;40:e3.
6. Prachayangprecha S, Schapendonk CM, Koopmans MP, Osterhaus AD, Schürch AC, Pas SD, et al. Exploring the potential of next-generation sequencing in detection of respiratory viruses. J Clin Microbiol. 2014;52:3722–30.
7. Yeh MT, Wang SW, Yu CK, Lin KH, Lei HY, Su IJ, et al. A single nucleotide in stem loop II of 5′-untranslated region contributes to virulence of enterovirus 71 in mice. PLoS ONE. 2011;6:27082.
8. Chang SC, Li WC, Chen GW, Tsao KC, Huang CG, Huang YC, et al. Genetic characterization of enterovirus 71 isolated from patients with severe disease by comparative analysis of complete genomes. J Med Virol. 2012;84:931–9.
9. McHugh MB, Kean KM, Gharbi J. Molecular analysis of the role of IRES stem-loop V in replicative capacities and translation efficiencies of coxsackievirus B3 mutants. Mol Biol Rep. 2009;36:255–62.

Prisoners Treated for Hepatitis C with Protease Inhibitor, New York, USA, 2012

Harish Moorjani, Carl Koenigsmann, Min Jung Kim, and Anne C. Spaulding

Author affiliations: New York Medical College, Valhalla, New York, USA (H. Moorjani); New York State Department of Corrections and Community Supervision, Albany, New York, USA (C. Koenigsmann); and Emory University, Atlanta, Georgia, USA (M.J. Kim, A.C. Spaulding)

DOI: http://dx.doi.org/10.3201/eid2101.141025

To the Editor: Globally, epidemics of infection with hepatitis C virus (HCV) tend to be concentrated in correctional facilities, according to a review of worldwide literature during 1990–2012 (1,2). Nearly 1 in 3 persons infected with HCV in the United States spends at least part of each year in either a prison or jail (3). Proficiency by correctional health facilities in hepatitis C treatment by using the most effective agents may mitigate the predicted burden of end-stage liver disease and hepatocellular cancer in the coming years. The first wave of direct-acting agents against HCV had substantial side effects. Nonetheless, the New York Department of Corrections and Community Supervision (NYDOCCS) systematically approached the challenge of using these agents, and their experience serves as a lesson that prison medical services can overcome substantial barriers to care.

In 2011, NYDOCCS piloted a hepatitis C treatment program for HCV genotypes 1a and 1b, comprised of telaprevir, pegylated interferon, and ribavirin. Patients underwent extensive mandatory pretreatment screening for mental health issues, pregnancy, and cirrhosis by using the FibroSURE assay (LabCorp, Burlington, NC, USA) and Doppler sonogram of the portal vein. Eligibility requirements were a negative HIV test result, and liver fibrosis assessed either by liver biopsy or noninvasively, at META VIR stage 2 or 3, or 4 (reference range 0–4) (4) with compensation. A patient in stage 1 was eligible if the patient had poor prognostic factors. An infectious disease consultant saw every patient; each patient received mandatory patient education. Mandatory conditions for patients participating in the program were to sign a consent
form agreeing to the medication, participate in laboratory monitoring, and attend primary or specialty clinic follow-up appointments; 3 refusals of any program component in any combination would result in medication discontinuation. Because referring physicians conducted the initial screening of potential participants, the exact number of patients screened cannot be determined. The most frequent factor for ineligibility was uncontrolled psychiatric disease.

Facilities were encouraged to treat ≤5 patients at any given time. Staff physicians, mid-level providers, nurses, pharmacists, and social workers participated in extensive training. Telaprevir was administered with a fat supplement by directly observed therapy. Patients waited in lines every 7–9 hours to receive the medications. All patients received antihistamine prophylaxis before therapy was initiated. Patients received containers of high potency topical steroid creams at the initiation of treatment with instructions to start applying it 2 times daily at the first sign of a rash. The nurses questioned the patients about rash and pruritus during each weekly interferon injection appointment. The infectious disease consultant conducted follow-up visits by telemedicine, using video and audio equipment for remote monitoring and supervision of treatment.

Among the 50 patients who began therapy, 38 (76%) were naïve to any treatment, 7 (14%) were experiencing relapses, 4 (8%) had responded partially to prior treatment, and 1 (2%) had not responded to prior treatment. Ages of the patients ranged from 21 to 67 years. All 50 treated patients experienced rash, pruritus, or both. All but 1 patient (98%) experienced fatigue. Anemia was detected in 68%, yet none received erythropoietin. Rather, the infectious disease consultant aggressively reduced ribavirin doses. Because of difficult-to-access, paper-based recording of dosing, determining the mean dose of ribavirin used in each patient was not feasible. None required transfusions. Thrombocytopenia developed in 2 patients. In 64%, neuropsychiatric effects were observed. Of 50 patients, 2 (4%) dropped out of the program. As shown in the Table, 44 (88%) experienced a sustained viral response.

By using the most effective agents available to treat hepatitis C, correctional health care systems can make a unique contribution to public health (5). Despite the substantial side effects of the first direct acting agents, the NYDOCCS health care personnel observed and reported a sustained viral response in a select group of patients which exceeded that seen in the drug registration trials (6). Recruiting a multidisciplinary health care team facilitated administration of a cumbersome regimen. Prophylactic treatment for rash and ribavirin dose reductions in 68% may have minimized dermatologic side effects. Mandatory patient education may have enhanced patient motivation to adhere to the protocol. As shown previously, telemedicine was a valuable tool in hepatitis C management of prisoner-patients (7). Treatment administered by the NYDOCCS treatment team cured many HCV-infected patients. Correctional health providers can manage complex therapeutic protocols for treatment of voluntary participants in the controlled environment of these facilities.

Treatment with novel agents has ushered in a new era in hepatitis C management. The cost of newer drugs is daunting (e.g., $84,000 for a 12-week course of sofosbuvir), but prison providers are starting to use this next generation of agents (8). Recent clinical trials with newer direct-acting agents that spare interferon have even higher rates of virologic success and fewer side effects (9,10) which should lead to even more widespread success.

**References**

1. Larney S, Kopinski H, Beckwith CG, Zaller ND, Jarlais DD, Hagan H, et al. Incidence and prevalence of hepatitis C in prisons and other closed settings: results of a systematic review and meta-analysis. Hepatology. 2013;58:1215–24. http://dx.doi.org/10.1002/hep.26387
2. Harzke AJ. Regional and global summary estimates of antibody to hepatitis C virus prevalence in detainee populations: seeing the forest and the trees? Hepatology. 2013;58:1197–9. http://dx.doi.org/10.1002/hep.26474
3. Varan AK, Mercer DW, Stein MS, Spaulding AC. Hepatitis C seroprevalence among prison inmates since 2001: still high, but declining. Public Health Rep. 2014;129:187–95.
4. Bedossa P, Poyrand T. An algorithm for the grading of activity in chronic hepatitis C. The META VIR Cooperative Study Group. Hepatology. 1996;24:289–293. [PubMed]
5. Rich JD, Allen SA, Williams BA. Responding to hepatitis C through the criminal justice system. N Engl J Med. 2014;370:1871–4. http://dx.doi.org/10.1056/NEJMp1311941
6. Jacobson IM, McHutchison JG, Dusheiko G, Di Bisceglie AM, Reddy KR, Bzowej NH, et al. Telaprevir for previously untreated chronic hepatitis C virus infection. N Engl J Med. 2011;364:2405–16. http://dx.doi.org/10.1056/NEJMoa1012912
7. Azora S, Thornton K, Murata G, Deming P, Kalishman S, Dion D, et al. Outcomes of treatment for hepatitis C virus infection by primary care providers. N Engl J Med. 2011;364:2199–207. http://dx.doi.org/10.1056/NEJMoa1009370
8. Federal Bureau of Prisons. Clinical practice guidelines: interim guidance for the management of chronic hepatitis C infection: The Bureau; 2014 [cited 2014 Jul 14]. http://www.bop.gov/resources/ pdfs/hepatitis_c_current.pdf

**Table. Outcomes of 50 prisoners treated for hepatitis C within the New York State Department of Corrections and Community Supervision, New York, USA, 2012–2013**

| Outcome                           | No. (%) prisoners | Metavir staging of fibrosis, no. (%) prisoners |
|-----------------------------------|-------------------|-----------------------------------------------|
| Disenrolled                       | 2 (4)             | Stage 1–3                                      |
| Treatment failed                  | 4 (8)             | Stage 1                                        |
| Sustained viral response          | 44 (88)           | Stage 1–3-2                                    |
| Early rapid viral response        | 34 (68)           | Stage 2                                        |
| Total                             | 50 (100)          | Stage 3-4                                      |

*Treatment consisted of telaprevir, pegylated interferon, and ribavirin.

New York, USA, 2012–2013*
9. Kowdley KV, Gordon SC, Reddy KR, Rossaro L, Bernstein DE, Lawitz E, et al. Ledipasvir and sofosbuvir for 8 or 12 weeks for chronic HCV without cirrhosis. N Engl J Med. 2014;370,1879–88. http://dx.doi.org/10.1056/NEJMoa1402355

10. Feld JJ, Kowdley KV, Coakley E, Sigal S, Nelson DR, Crawford D, et al. Treatment of HCV with ABT-450/r–ombitasvir and dasabuvir with ribavirin. N Engl J Med. 2014;370:1594–603. http://dx.doi.org/10.1056/NEJMoa1315722

Address for correspondence: Anne C. Spaulding, Rollins School of Public Health, Department of Epidemiology, 1518 Clifton Rd, Room 3033, Atlanta, GA 30322, USA; email: ASpauld@emory.edu

**Correction: Vol. 20, No. 3**

The name of author Magnus Rasmussen was misspelled in the article Septic Arthritis Caused by *Streptococcus suis* Serotype 5 in Pig Farmer (C. Gustavsson, M. Ramussen). The article has been corrected online (http://wwwnc.cdc.gov/eid/article/20/3/13-0535_article).