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Kidney Medicine Original Research

A Patient Decision Support Tool for Hepatitis C Virus and CKD Treatment

Nerissa George, AnnMarie Liapakis, Kevin M. Korenblat, Tingting Li, David Roth, Jerry Yee, Kevin J. Fowler, Lehman Howard, Jingxia Liu, and Mary C. Politi

Rationale & Objective: Patient education and decision support tools could facilitate decisions around the timing of antiviral therapy in patients living with both hepatitis C virus (HCV) infection and chronic kidney disease (CKD). We previously developed a tool through the HELP (Helping Empower Liver and Kidney Patients) study. This article evaluates the preliminary efficacy and usability of the tool among participants with both HCV infection and CKD.

Study Design: Pre-post study pilot evaluation.

Setting & Participants: Participants were at least 18 years old, were English speaking, and had a diagnosis of chronic HCV infection and CKD; they were seen in CKD clinics, dialysis units, and/or hepatology and liver transplantation clinics.

Intervention: Electronic patient decision support tool.

Outcomes: Participants' change in knowledge, certainty about choice, decision self-efficacy, patients' treatment preferences, and tool usability.

Results: 70 participants were recruited; 56 of 70 (80.0%) completed study procedures. Nearly all (51/56; 91.1%) requested paper-based study procedures despite the electronic design of the tool. Participants reported that they were most worried about the following treatment factors: (1) cost of drugs to treat HCV infection, (2) how their HCV infection affected their CKD, and (3) wait times for a kidney transplant. After using the decision tool, participants had significantly higher HCV infection and CKD knowledge (mean posttest percent of questions answered correctly = 65.74% vs pretest percent of questions answered correctly = 53.44%; $P < 0.001$) and more certainty about choice (mean posttest = 3.13 vs pretest = 2.65; $P = 0.05$). There were no significant changes in decision self-efficacy (mean posttest = 86.62 vs pretest = 84.68; $P = 0.48$).

Limitations: Single-site pilot study to explore preliminary tool efficacy and usability.

Conclusions: This study suggests that a decision tool may support informed patient-centered choices among patients with HCV infection and CKD. Future studies should evaluate ways to improve care decisions in a larger sample using both paper-based and electronic materials.

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Complete author and article information provided before references.

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Approximately 3.5 million US individuals are infected with the hepatitis C virus (HCV).[1] This prevalence is increasing in part due to increased intravenous drug use in the United States associated with the continuing opioid epidemic.[2] HCV infection can lead to serious complications, such as hepatocellular carcinoma, cirrhosis, and/or liver failure.[3] Patients with HCV infection are also 27% more likely to have or develop chronic kidney disease (CKD) than patients without HCV infection.[4] The combination of HCV infection and CKD can lead to kidney failure, kidney transplant failure, poor quality of life, and adverse mental health.[3,5-11]

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Fortunately, current HCV oral direct-acting antiviral (DAA) treatment regimens are highly effective. Patients with HCV infection who take DAAs demonstrate a sustained virologic response of >95%, meaning that HCV is undetectable beyond 24 weeks posttreatment.[12,13] DAA regimens are more effective with fewer side effects than previously available therapies such as interferon and ribavirin.[13] In addition, there are US Food and Drug Administration–approved DAAs that are safe for individuals with both HCV infection and CKD. Patients treated with DAA regimens demonstrated significantly fewer side effects with newer[14,15] compared with older therapies, which were prescribed to as few as 1% of patients with comorbid HCV infection and CKD due to concerns about severe side effects.[16]

Despite the effectiveness of DAAs, patients who have both HCV infection and CKD, especially advanced CKD, face challenging decisions about when to start HCV treatment. Typically, patients spend 3 to 5 years on the waitlist for an HCV-negative deceased donor kidney transplant, and this wait time can be longer in certain United Network for Organ Sharing regions.[17] With improvements in HCV treatments, patients with advanced CKD can consider a kidney from an HCV-viremic donor, leading to shorter wait times for a kidney transplant. The median wait time for a kidney from an HCV-viremic donor is 58 days.[18]

A shorter wait time for a kidney transplant can shorten the time that patients spend on dialysis therapy, decreasing mortality and improving quality of life.[19] Dialysis is a

time-consuming kidney replacement therapy with often burdensome side effects that can affect patients' ability to maintain their social engagement and employment status.[20] Patients on dialysis more frequently report depressive symptoms and reduced quality of life compared with patients who receive a kidney transplant.[20] HCV-positive dialysis patients experience higher rates of mortality when compared with noninfected patients with advanced CKD.[19,21] In some cases, because of shortened wait times associated with accepting a kidney from an HCV-"positive" (antibody positive and/or viremic) donor, patients may be able to receive a pre-emptive kidney transplant before it is necessary to initiate dialysis.

However, in some regions such as the northwestern United States, HCV-positive kidneys are not readily available.[22] Patients' health status and preferences may affect whether patients with decreased kidney function choose to initiate HCV treatment before receiving a kidney transplant. The development of liver fibrosis due to HCV may necessitate treating HCV infection first; for patients with severe hepatic fibrosis, treating HCV infection to slow the progression of disease may be a higher priority than receiving a kidney transplant.[12] Patients with early CKD might not qualify for kidney transplantation and could benefit from HCV treatment, which can slow the progression of both their liver and kidney disease. In some cases, insurance coverage, other medication use, and comorbid conditions[23] can affect patients' HCV infection and CKD treatment decisions.

Given the complexity of the decisions about when and how to treat HCV infection and CKD, consistent communication between patients and their clinicians can facilitate evidence-informed preference-consistent treatment choices.[18,24,25] Patient education and decision support tools could help patients learn about CKD and HCV and navigate through discussions about CKD and HCV treatment with their clinicians, including primary care physicians, nephrologists, hepatologists, and transplant surgeons. Increasing the understanding of patients with HCV infection and CKD of the treatment risks and benefits and considerations about treatment timing could increase their confidence in their treatment choices.

We developed a patient education and decision support tool with an advisory board, which consists of patients, nephrologists, and hepatologists through the HELP (Helping Empower Liver and Kidney Patients) study.[26] This tool provides: (1) plain language information about treatment options for HCV infection and CKD; (2) education that is tailored to a user's self-reported prior treatments, current stages of CKD and liver fibrosis, and additional medical conditions; (3) an assessment to elicit users' values that may influence their choice of treatment; and (4) a printable summary page that can facilitate patient-clinician discussions about treatment needs, values, and questions.

The tool was not designed to replace patients' discussions with their clinicians, but to help patients prepare for these discussions. This report describes the findings of pilot testing the decision support tool.

METHODS

Participants and Study Procedures

Eligible participants were at least 18 years old, could read and understand English, and had a diagnosis of chronic HCV infection (any genotype) and CKD (estimated glomerular filtration rate < 60 mL/min/1.73 m^2 for ≥3 months) in their medical record. Recruitment occurred between September 2017 and August 2018. A research staff member assessed participants' preliminary eligibility for the study by screening medical records in CKD clinics, dialysis units, and hepatology and liver transplantation clinics. In the clinics in which the study team was approved to recruit, clinicians were also able to refer patients to the study directly. The research coordinator then approached eligible patients in person during an on-site medical appointment or by telephone.

After completing informed consent, participants had the option to complete the study procedures using an online version of the decision tool and study measures, a paper-based version of both, or a combination of online and paper-based versions of the study materials based on their preference. The paper-based version of the tool entailed printing each section of the electronic version that participants would have viewed based on their CKD stage (Item S1). Participants had the choice to complete the study materials in person with the research coordinator present or at home. Participants completed the pretest survey before going through the decision tool and a posttest survey after using the decision tool. Participants received a $20 gift card for their time spent completing the study.

This study was approved by the Human Research Protection Office at Washington University (HRPO number 201707154) and was registered on clinicaltrials.gov (NCT03426787). All authors had access to the study data, and reviewed and approved the final manuscript.

Measures

Knowledge

The research team developed 8 questions based on information essential for deciding on treatment choices, understanding HCV infection and CKD, the health effects of both diseases, and understanding risks and benefits of treatment options. Response options included true, false, or unsure. The total number of correct responses were calculated; each correct response counted as 1 and each incorrect or unsure response counted as zero. Item S2 shows the knowledge questions.

Decisional Conflict and Certainty About Choice

The 4-item validated SURE (Sure of myself, Understand information, Risk-benefit ratio, and Encouragement) Decisional Conflict Scale[27] was used to assess whether

participants have enough information to make a choice, are clear about their values for risks and benefits of their choice, and believe that they have enough support to make a choice. Items were scored 1 (yes) or zero (no). Higher values indicate more certainty about choice.

Decision Self-efficacy

The low literacy version of the validated Decision Self-efficacy Scale[28] was used to measure participants' perceived self-confidence in making a treatment decision and how confident they feel taking actions involved in making an informed choice. Responses include not confident, a little confident, or very confident. Higher values indicate more confidence in one's decision-making ability.

Usability

The 10-item validated System Usability Scale (SUS)[29] examined the usability of the tool; minor modifications were made to make the wording relevant to this context. The measure has 1 of 5 responses that range from strongly agree to strongly disagree. Higher values indicate greater usability. A SUS score higher than 68 indicates adequate usability of the tool.

Demographics

Demographic variables including age, sex, education level, race, ethnicity, household income, and insurance status were collected from each participant through self-report or the electronic medical record, when available.

Clinical Characteristics

From the medical record, we collected participants' CKD staging, stage of liver fibrosis, HCV status/length of diagnosis and genotype, dialysis treatment status, and the presence of comorbid conditions, such as diabetes, hypertension, human immunodeficiency virus (HIV) infection, and/or cardiovascular disease.

Health Literacy

The validated Single Item Literacy Screener[30] measured participants' health literacy levels. A score greater than 2 on the 5-point scale indicates limited health literacy; a score of 2 or less on the 5-point scale indicates adequate health literacy.

Preferred Decision Role

The validated Control Preference Scale[31] assessed the degree of involvement that patients prefer in their treatment decisions. Participants were asked to select 1 of 5 statements that best describes their preference level for decision control ranging from active to collaborative to passive roles in treatment decision making.

Financial Toxicity

We used 2 items from the validated Comprehensive Score for Financial Toxicity (COST)[32] measure to assess the financial impact of patients' medical conditions. Items are rated on a 4-point Likert scale. In the full 11-item measure, scores may range from 0 to 44, with lower scores indicating higher financial toxicity. Using the 2 items that we selected from the measure to reduce participant burden completing the study procedures, total scores in our sample could range from 0 to 8.

Data Analysis Plan

We calculated descriptive statistics for all variables. To examine our primary hypotheses, we performed a paired t test to examine the differences between before and after using the decision tool in our primary outcomes (knowledge, decisional conflict, and decision self-efficacy). Separate mixed models using both fixed and random effects explored the relationship between age, race, education, decision role preference, and clinical characteristics on changes in our primary outcomes (knowledge, decisional conflict, and decision self-efficacy) before and after using the tool. Separate analyses were built with decisional conflict and decision self-efficacy as outcomes, controlling for age, sex, self-reported HCV treatment status, presence of fibrosis, dialysis treatment status, and decision role preference. In addition, separate analyses were built with knowledge as an outcome, controlling for health literacy along with age, sex, self-reported HCV treatment status, presence of fibrosis, dialysis treatment status, and decision role preference.

RESULTS

Eighty-eight participants were approached: 70 of 88 (79.5% response rate) enrolled, and 56 of 70 (80.0% completion rate) completed the study procedures, including pre- and posttool surveys. There were no demographic differences between study completers and noncompleters, but noncompleters were more likely to have additional health conditions (Table S1). The final sample of completed data included 56 participants with an average age of 61.0 years, ranging from 40 to 74 years (Table 1). Most (82.1%) participants identified as African American or black and had relatively low reported household incomes (60.7% were <$15,000; Table 1). Nearly all (51/56; 91.1%) participants chose to complete the study procedures using a paper-based modality. More than half (32/56; 57.1%) of the participants opted to complete the study procedures at home rather than in the clinic. The mean COST score was 4.80 (median, 5; range, 0-8), indicating moderate financial toxicity. About 64.8% of patients preferred taking an active or shared role in their health decisions and 35.2% of patients preferred taking a passive role. When reporting what matters most to their decision and treatment plan (scale ranges from 0%-100%), participants reported that they were most concerned with: (1) their ability to pay for the cost of drugs used to treat HCV infection (mean importance, 55%; median, 50%), (2) how their HCV infection affects their CKD (mean

Table 1. Participant Characteristics

Age, y	60.95 ± 6.58 (40-74)
≤50	3 (5.36%)
51-64	36 (64.29%)
≥65	17 (30.36%)
Sex	
Male	35 (62.50%)
Female	21 (37.50%)
Education level	
Less than or some high school	22 (39.29%)
High school diploma or GED	13 (23.21%)
Tech training or certification	5 (8.93%)
Some college	11 (19.64%)
≥College degree	5 (8.93%)
Income level	
<$15,000	34 (60.71%)
≥$15,000 but <$45,000	10 (17.86%)
≥$45,000	4 (7.14%)
Prefer not to answer	8 (14.29%)
Race	
African American or black	46 (82.14%)
Caucasian or white	7 (12.50%)
Native American or Alaskan Native	1 (1.79%)
Mixed	2 (3.57%)
Type of insurance coverage	
Private	2 (3.57%)
Governmental (Medicaid, Medicare, & VA/TriCare)	52 (92.86%)
Uninsured	2 (3.57%)
Financial toxicity[a]	
Mean (median)	4.80 (5.00)
Range	0-8
Health literacy	
Adequate	32 (57.14%)
Limited	24 (42.86%)
HCV treatment status	
Naive	21 (37.50%)
Received	35 (62.50%)
CKD staging and treatment status	
1-3	19 (33.93%)
4-5	5 (8.93%)
Hemodialysis	32 (57.14%)
Fibrosis staging	
0-1	22 (39.29%)
2-3	7 (12.50%)
4	19 (33.93%)
Not in medical record	8 (14.29%)
Additional health conditions	
None	6 (10.71%)
1[b]	14 (25.00%)
2[c]	25 (44.64%)
3[d]	11 (19.64%)
Study completion modality	
Paper	51 (91.07%)
Online	4 (7.14%)
Hybrid	1 (1.79%)

Note: N = 56. Values expressed as number (percent) or mean ± standard deviation (range) unless otherwise noted.
Abbreviations: CKD, chronic kidney disease; GED, General Education Development; HCV, hepatitis C virus; HIV, human immunodeficiency virus; VA, Veterans Affairs.
[a]Lower score indicates worse financial burden.
[b]Patients had only high blood pressure or HIV infection.
[c]Patients had a combination of 2 of the following health conditions: diabetes, high blood pressure, heart disease, or HIV infection.
[d]Patients had a combination of 3 of the following health conditions: diabetes, high blood pressure, heart disease, or HIV infection.

importance, 52%; median, 50%), and (3) the wait time for a kidney transplant in their region (mean importance, 46%; median, 50%).

Changes in Primary Outcomes

After using the patient education and decision support tool, participants had significantly higher HCV infection and CKD knowledge (mean posttest percent of questions answered correctly, 65.74% vs pretest percent of questions answered correctly, 53.44%; $P < 0.001$) and more certainty about their choice as measured using the SURE scale for decisional conflict (mean posttest, 3.13 vs pretest, 2.65; $P = 0.05$; Table 2). There were no significant changes in decision self-efficacy (mean posttest, 86.62 vs pretest, 84.68; $P = 0.48$; Table 2). Mixed-effect models showed that the improvement in knowledge scores remained significant after adjusting for self-reported HCV treatment status ($P = 0.05$) and health literacy ($P = 0.03$). The improvement in decisional conflict scores did not remain significant after controlling for covariates in the mixed-effect models (Table S2). No other potential covariates were statistically significantly related to our primary outcomes.

Usability

The decision tool scored an average of 69.86 ± 20.43 (standard deviation; range, 27.50-100), indicating adequate usability. Almost all (42/54; 77.8%) participants found the tool to be easy to use and 40 of 53 (75.5%) felt very confident using it. More than half (34/53; 64.2%) found the pages of the tool well integrated and 31 of 54 (57.4%) reported they would like to use the tool again. About a third (20/53; 37.7%) of participants thought that they needed to learn many things before they could use the tool, and 19 of 54 (35.8%) thought that they might need technical support to be able to use the tool.

DISCUSSION

Overall, this study suggests that the decision support tool may improve decision quality among patients with HCV infection and CKD. Among participants in this pilot study, after using the decision tool, patients had higher

Table 2. Paired *t* Test Bivariate Analysis of Primary Outcomes

	Pretest	Posttest	Mean Difference (95% CI)	*P*
Knowledge[a]	53.44 ± 21.66 (12.50-100)	65.74 ± 22.80 (12.50-100)	12.30 (18.95 to 5.65)	<0.001
Decisional conflict[b]	2.65 ± 1.39 (0-4)	3.13 ± 1.40 (0-4)	0.47 (0.94 to 0.01)	0.05
Decision self-efficacy[c]	84.68 ± 17.24 (22.73-100)	86.62 ± 18.88 (13.64-100)	1.94 (7.41 to −3.54)	0.48

Note: N = 54. Values expressed as mean ± standard deviation (range) unless otherwise noted.
Abbreviation: CI, confidence interval.
[a]Percent correct of answered questions; possible range 0% to 100%.
[b]Higher values indicate more certainty in their choice.
[c]Higher values indicate more confidence in one's ability to make a choice; possible range 0% to 100%.

knowledge about HCV and CKD and more certainty about HCV infection and CKD treatment choices. Increasing patients' knowledge and certainty about their choices could help them become more engaged in discussions with their clinicians regarding their HCV infection and CKD treatment. Some patients in the study who had not yet received HCV treatment described feeling more prepared to talk to their physician about HCV infection and CKD treatment options. Well-informed patients who participate in their health care decisions may show increased self-care behaviors and decreased stress associated with their diagnosis.[20,33]

However, there were no significant changes in participants' decision self-efficacy. Many participants had high baseline levels of confidence making HCV infection and CKD treatment decisions before viewing the decision tool. Most participants also reported taking an active or shared responsibility decision-making role. These results should be examined in a larger study among participants with varying baseline levels of confidence in the decision-making process.

In addition, some persistent knowledge gaps could be clarified in future versions of the tool. For example, although knowledge improved after using the tool, on average, individuals only answered ∼65% of the questions correctly. The most common incorrect responses were to questions about whether DAAs have fewer side effects than past medications used to treat HCV infection and the possible benefits of treating HCV infection before receiving a kidney transplant. HCV treatment status and health literacy were related to lower knowledge scores. It is possible that the paper-based version with static content, which was unable to provide interactive learning modules, contributed to this lower score than is often seen in decision support tool evaluations. Future iterations of the decision support tool should focus on ways to improve participants' understanding of key details about treatment. Clinicians should also be prepared to reinforce key messages about treatment options in person.

Importantly, the usability score indicates adequate usability per measure guidelines, but the observed scores were lower than some usability scores in our past work.[34] This somewhat lower SUS score might be due to participants' preferences for receiving information on paper. The decision support tool was intended for electronic use to facilitate dissemination and incorporate patients' clinical characteristics information. We anticipate that members of the care team (eg, nurses, medical assistants, or others) can provide patients with this information upon check in, before seeing a clinician for a health care visit to discuss treatment options. It could also be used after a health care visit to supplement the conversation that clinicians have with patients so they can review what was discussed and share it with family members or caregivers. Future studies might consider multiple modalities of information delivery (eg, online vs on paper, at home vs in the clinic) given the preferences of this population.

Some participants who preferred to participate in the study from their homes were hard to reach to complete the study procedures after enrollment. Given the demographics of this sample, who were mostly men with lower incomes than those in the average population, access to and comfort with the internet and/or research overall may have presented a challenge to study completion.[35-37] Although we were available to meet participants in person, additional barriers to meeting in person (eg, transportation and time) might have influenced patients' ability to complete the study procedures.

When asked about values influencing choices, participants expressed that they were most concerned about their ability to pay for the cost of drugs used to treat HCV infection. Health insurance may or may not fully cover HCV treatment costs and might be associated with high copayments or out-of-pocket costs before deductibles. Participants were also concerned with how to balance treatment for both HCV infection and CKD; decision tools addressing both conditions may be particularly useful for this population. Finally, uncertainty regarding the wait times for patients considering kidney transplantation added additional stress as they considered their treatment options. Helping patients communicate these concerns to their clinicians may facilitate patient-centered conversations about HCV infection and CKD treatment.

Strengths of this study include a personalized plain-language decision tool that when delivered electronically is tailored to patients' clinical characteristics. The tool development process included the input of stakeholders, including patients and multiple clinicians from various specialties relevant to HCV infection and CKD treatment.

However, the results of this study should be interpreted within the context of some limitations. Given the small sample and pilot study design, the reported observations can be interpreted as preliminary results supporting future larger studies of the decision tool. This project was also a

single-site study. Although participants may represent the demographics of individuals affected by HCV infection and CKD in the region, they might not be generalizable across other regions. Future larger studies could consider evaluating the decision tool using a multisite randomized trial with a more racially and socioeconomically diverse population.

Overall, the patient education and decision support tool may improve decision quality and patient engagement in their CKD and HCV infection care decisions. In past studies, patients with CKD and HCV infection have reported lack of sufficient patient-provider communication about their condition and treatment options.[38] Uncertainty about the diseases and the quality of treatment can affect patients' care decisions.[39] Patients may choose therapies that positively improve their health outcomes and those that align with their values when they better understand the risks and benefits of options.[40] Future studies should continue to evaluate ways to improve care decisions among this population.

SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

Item S1: Paper-based version of Project H.E.L.P decision guide for hepatitis C and kidney disease.

Item S2: Knowledge questions from the Project HELP Decision Aid Tool

Table S1: Clinical Characteristics Comparison of Completers vs Noncompleters

Table S2: Separate Analyses Examining Mean Difference in Primary Outcomes Controlling for Demographics and Clinical Characteristics

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