Efficacy of a Chronic Disease Management Model for Patients With Chronic Liver Failure

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BACKGROUND & AIMS: **Despite the economic impacts of chronic liver failure (CLF) and the success of chronic disease management (CDM) programs in routine clinical practice, there have been no randomized controlled trials of CDM for CLF. We investigated the efficacy of CDM programs for CLF patients in a prospective, controlled trial.**

METHODS: **Sixty consecutive patients with cirrhosis and complications from CLF were assigned randomly to groups given intervention (n = 40) or usual care (n = 20), from 2009 to 2010. The 12-month intervention comprised 4 CDM components: delivery system redesign, self-management support, decision support, and clinical information systems. The primary outcome was the number of days spent in a hospital bed for liver-related reasons. Secondary outcomes were rates of other hospital use measures, rate of attendance at planned outpatient care, disease severity, quality of life, and quality of care.**

RESULTS: **The intervention did not reduce the number of days patients spent in hospital beds for liver-related reasons, compared with usual care (17.8 vs 11.0 bed days/person/y, respectively; incidence rate ratio, 1.6; 95% confidence interval, 0.5–4.8; $P = .39$), or affect other measures of hospitalization. Patients given the intervention had a 30% higher rate of attendance at outpatient care (incidence rate ratio, 1.3; 95% confidence interval, 1.1–1.5; $P = .004$) and significant increases in quality of care, based on adherence to hepatoma screening, osteoporosis and vaccination guidelines, and referral to transplant centers ($P < .05$ for all).**

CONCLUSIONS: **In a pilot study to determine the efficacy of CDM for patients with CLF, patients receiving CDM had significant increases in attendance at outpatient centers and quality of care, compared with patients who did not receive CDM. However, CDM did not appear to reduce hospital admission rates or disease severity or improve patient quality of life. Larger trials with longer follow-up periods are required to confirm these findings and assess cost effectiveness. Anzctr.org.au, number ACTRN 12609000403235.**

Keywords: Liver Disease; Treatment; Hepatitis; Comparison.

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Chronic liver failure (CLF) is characterized by decompensation events in cirrhotic patients. These include ascites, variceal bleeding, encephalopathy, spontaneous bacterial peritonitis, and hepatorenal syndrome together with other important complications of cirrhosis such as protein calorie malnutrition and hepatocellular carcinoma (HCC). CLF is associated with a poor prognosis with early decompensation (Child–Pugh class B) and advanced decompensation (Child–Pugh class C) associated with a 2-year survival of 60% and 35%, respectively.[1] CLF is also a common condition with significant economic impacts on the health care system. In the United States it accounts for 40,000 deaths annually (equivalent to diabetes and more than kidney diseases) and more than 150,000 hospitalizations, costing $4 billion annually (all amounts are shown in US dollars).[2,3]

Rapidly increasing cirrhosis mortality rates already have been reported in Britain,[4] and in many developed countries the prevalence and costs of CLF are anticipated to increase because of the poor uptake of antiviral therapy for hepatitis C[5] and increasing rates of alcohol abuse[6] and obesity.[7]

Substantial high-quality evidence describes effective disease- and symptom-specific interventions for cirrhosis and CLF, but

Abbreviations used in this paper: CDM, chronic disease management; CI, confidence interval; CLF, chronic liver failure; HCC, hepatocellular carcinoma; IQR, interquartile range; IRR, incidence rate ratio; MELD, model for end-stage liver disease; OBD, occupied bed day.

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despite this evidence base most reports suggest poor implementation in routine clinical practice. Low adherence rates to published guidelines for ascites management,[8] variceal screening and prophylaxis of high-risk varices,[9,10] hepatocellular carcinoma surveillance,[11,12] and hepatitis A and B vaccination[13] have been reported by multiple investigators.

CLF is also a challenging disease to manage and is characterized by frequent, prolonged, and costly re-admissions. A recent study of patients with decompensated cirrhosis showed a 37% re-admission rate within 1 month of discharge at a cost of more than $20,000 per admission and with 22% of admissions considered preventable.[14]

Limitations associated with CLF care suggest significant changes are needed to current models of care to improve implementation of the current evidence base and to reduce the high re-admission rates and health care costs associated with these patients. A potentially promising approach in this setting is chronic disease management (CDM), first articulated by Wagner et al[15] in 1996 and subsequently developed by other groups.[16–18] Several key components of CDM have been described including self-management support, delivery system design, decision support and clinical information systems, community linkages, and support from health care organizations.

CDM principles have been applied in many nonliver chronic disease settings including heart failure, ischemic heart disease, chronic obstructive lung disease, and diabetes, with positive outcomes.[19] Three meta-analyses of more than 30 randomized trials in heart failure have shown a 30% to 42% reduction of heart failure–related admissions and a 12% to 27% reduction in all-cause admissions, together with a mortality reduction of 18% to 25%.[20–22] Cost savings also were shown in the majority of trials in which these were evaluated.[20] CDM style approaches have become the standard of care in heart failure with a class 1 recommendation in practice guidelines.[23]

Despite the promise of CDM style interventions in other chronic diseases, to date there have been no randomized trials of CDM style interventions in CLF. The lack of such trials, and the urgent need for them, has been highlighted recently by key opinion leaders in gastroenterology.[24,25]

The objectives of this study therefore were to test the effects of a CDM intervention in CLF patients in a randomized pilot trial setting. The primary hypothesis was that positive findings from other disease trials would be translated into CLF, despite the unique challenges of this condition. The primary outcome of the study was liver-related occupied bed days (OBD). The secondary outcomes of the trial were as follows: other measures of hospital use (total liver-related admission rate, unplanned liver-related admission rate, planned liver-related admission rate, all-cause admission rate, median length of stay), attendance rates at planned outpatient care, disease severity, quality of life, and quality of care.

Methods

The study was performed using a randomized, controlled, parallel-group study design at a single Australian center. Patients were assigned randomly to intervention vs usual care with a ratio of 2:1.

Selection Criteria and Patients

The study took place within the Hepatology Unit of Flinders Medical Centre in Adelaide, Australia, during 2009 and 2010. The Unit provides both inpatient beds and outpatient clinics for hepatology patients. The hospital is a tertiary care facility, which services the southern suburbs of Adelaide (300,000 people) and also provides liver transplantation services to South Australia (1.6 million people). The health care providers primarily involved in the study included 1.6 full-time nurses and 4 visiting gastroenterologists, both groups with specialized interests in liver disease.

Eligible participants were adults aged 18 years or older with cirrhosis who were admitted with a CLF-related complication(s) including ascites, variceal bleeding, hepatocellular jaundice related to alcohol, spontaneous bacterial peritonitis, sepsis, encephalopathy, HCC, or liver-related renal dysfunction. Exclusion criteria included intensive management by other health care teams (ie, liver transplant team, heart failure program), palliative care management, living outside the metropolitan area of Adelaide, a significant language barrier, and inability to provide informed consent. Recruitment by a study coordinator occurred after a hospital admission.

Ethics and Trial Registration

The study protocol conformed to ethical guidelines of the 1975 Declaration of Helsinki and was approved by the local hospital ethics committee. Written informed consent was obtained from each participant. The trial was registered prospectively with the Australian and New Zealand Clinical Trials Registry (ACTRN 12609000403235). All authors had access to the study data and reviewed and approved the final manuscript.

Randomization

Randomization, without restriction, was performed via telephone call to a third party (hospital pharmacy department), with subsequent selection of opaque, sealed envelopes containing the treatment arm allocation number. The randomization ratio was 2 intervention patients to 1 usual care participant and was designed to gain more experience with CDM-type care.

Intervention Details

The optimal intervention component in CDM remains uncertain, despite multiple studies. We therefore chose a multifaceted intervention, which is supported by the limited available evidence.[16,26] Case management–type interventions (involving intensive monitoring after hospital discharge using telephone calls and home visits) may be the most effective components in heart failure trials[27] and therefore were included in our intervention. It was anticipated that a broader intervention would be more successful in addressing both primary and secondary end points. Key CDM components used in the CDM intervention were as follows.

Delivery system design. Delivery was through coordinated case management by hepatology nurses involving multidisciplinary team care (gastroenterologist, nurse, general practitioner, dietician, alcohol counselors), home visit by nurse within a week after discharge, initial weekly nurse telephone reviews of patients, rapid access to care pathway using a mobile telephone service for patients concerned about deterioration, and written and telephone patient reminders before appointments.

Decision support. Decisions regarding the type of support were made using evidence-based protocols for all major CLF complications and formulation of a protocol-driven care plan by multidisciplinary team.