A clinical decision support tool to aid in the management of hospitalized cirrhotic patients

Osman Ahmed, MD, Mayur Brahmania, MD, FRCPC
Department of Gastroenterology, University of Toronto, Toronto, Canada

Goals and Objectives:

We propose a randomized controlled trial to study the introduction of a clinical decision support tool (Liver Care Bundle), to be used in conjunction with a computerized physician order entry (CPOE) in the management of patients admitted with decompensated cirrhosis. Ultimately, we believe the clinical decision support tool has the potential to improve the confidence of trainees and clinicians in the management of hospitalized patients with cirrhosis, improve adherence with the medical guidelines, and reduce hospital re-admission rates and 90-day mortality rates in this vulnerable population.

Educational Gap:

Managing patients with decompensated liver disease can be quite challenging for the trainee (fellows, residents, medical students) as well as for clinicians due to the complexity of the disease, the difficulty and labor-intensity of treating critically-ill patients, and the lack of awareness of subtle presentations. The care for patients admitted with decompensated liver cirrhosis can be quite heterogeneous despite widely accepted guidelines. \(^1\) Studies have shown that less than half of admitted patients receive the ideal recommended care for decompensated cirrhosis. \(^2\) Additionally, there has been some evidence that lack of adherence to quality care indicators can affect 90-day mortality rates and 30-day re-admission rates, although this data is conflicting. \(^2,3\) With an increasing burden in liver disease and hospitalizations related to liver disease, the ability to adhere to quality indicators will become paramount. \(^4\) Encouragingly, there has been a recent trend towards identifying measures for quality improvement in gastroenterology and hepatology. \(^5\) Many quality improvement measures have been studied but most have had mixed results. Interventions including
mandatory gastroenterology consults, dedicated nursing, and post-discharge calls have not shown any improvement in outcomes in the management of cirrhotic patients, though the use of pre-made paper checklist and comprehensive multidisciplinary outpatient evaluations did show a decrease in re-admission rates.6

The use of a clinical decision support tool has been demonstrated to improve adherence to guidelines. In one study involving patients with variceal bleeds, optimal guideline based care improved from 41% to 65%, and notably, readmission decreased from 41% to 13%.7 Similar tools have been used in other gastrointestinal diseases, including inflammatory bowel disease, with positive impressions.8 Overall, these studies demonstrated the important principle that significant improvements in access and adherence to guidelines is achievable for patients, including cirrhotic complications, but further work is still needed to show that guideline-based management tools can be scaled to treat multiple diseases.

Proposal:

Toronto General Hospital is a quaternary care centre responsible for over 150 liver transplants per year and has over 300 admissions per year for decompensated cirrhosis. Patients with decompensated cirrhosis are typically triaged by emergency physicians and then referred to one of medical services staffed by Internal Medicine, Gastroenterology and Hepatology house staff.

The study will be a randomized controlled trial comparing the impact of CPOE with an integrated clinical decision support tool (Liver Care Bundle) to a system of CPOE alone. The Intervention group (consisting of Internal Medicine and Gastroenterology house staff) will have access to CPOE along with our developed Liver Care Bundle. The group will also receive a lecture on standard of care management of decompensated cirrhosis along with additional training on how to use the standardized orders sets. The team would get weekly feedback from the hepatology attending physician as to the percent of time the tool was being appropriately applied. They will also receive sample cases on how to optimize the use of the Liver Care Bundle. Routine audits of selected cases will be performed to fix any programming issues and to aid with troubleshooting. The control group (similarly composed of Internal Medicine and
Gastroenterology house staff) would have access to the standard CPOE along with a lecture on standard of care management of decompensated cirrhosis.

Upon admission, a patient with complications of decompensated cirrhosis (i.e. ascites, gastrointestinal bleed, hepatic encephalopathy, spontaneous bacterial peritonitis and acute kidney injury) will be randomized to the intervention group or the control group. Informed consent will be obtained for the study. Clinical equipoise during intervention phase will not be violated, as there is no published data that a Liver Care Bundle improves outcomes when decision support is instituted.

The Liver Care Bundle will be integrated into the CPOE and automatically initiated when the standard liver order set is selected. When a patient is randomized to the intervention arm, the physician will be notified via an onscreen prompt within the CPOE system. Prior to letting the physician complete the admission order set, the physician will have to determine (with the assistance of clinical cues and reminders to aid the clinician) if the patient meets any or all of the liver decompensating event described above. If met, decision support will recommend appropriate recommendations on fluid replacement, haemoglobin transfusion, antibiotics, etc. The recommendations will be provided on the CPOE screen and will give the physician an opportunity to accept or reject. The tool will incorporate allergies, evidence of renal disease, and other medications to potentially make alternate medication recommendations or dose adjustments. Additionally, the Liver Care Bundle will have easy-to-access links to document the relevant studies and evidence behind the interventions proposed. The intervention will occur at the time of acceptance by the primary team at admission. Patients in the control arm will receive care as per current standard of care and CPOE.

Evaluation of Liver Care Bundle

The primary outcome is adherence to guidelines. Each guideline will receive a 1 or 0 depending on whether it was followed. Percentage of guidelines followed will be calculated from this. For example, in a patient with a variceal bleed: Endoscopy within 24 hours (1/0), octreotide used (1/0), proton pump inhibitor (1/0), etc. Secondary outcomes of length of stay in hospital will be determined from arrival to discharge measured in hours. 30-day readmissions
will be retrieved from the EMR. Death will be determined by patient follow-up in-hospital or via telephone or clinic visit.

Baseline characteristics between the control and intervention groups will be compared using two-sample t-test for continuous covariates and Pearson’s Chi-Squared test for categorical variables. The primary outcome will evaluate the length of stay from admission to discharge. Secondary outcomes will include 30-day re-admission rates along with 30-day mortality rates. The primary outcome will be analysed using multivariate logistic regression analysis adjusting for age, sex, race, cirrhosis stage, and decompensating event. The secondary outcome of re-admission and mortality will be analyzed using Cox regression analysis adjusting for the same covariates as the primary outcome. For group comparisons a p-value of <0.05 will be considered to be statistically significant. Our sample size is calculated based on the estimates that baseline adherence to guidelines is 41% and that with clinical decision support adherence will increase to 65% (25% increase). At an alpha of 0.05 and a beta (power) of 80% we would need to enroll at least 67 patients per arm.

**Detailed plan of resource utilization:**

We expect to utilize the majority of funding on the development of the clinical decision tool. Access to CPOE is already available and widespread, and therefore we are at the stage of finalizing the Liver Care Bundle and incorporating it to CPOE. The ability to randomize order sets based on the user is already incorporated to the existing CPOE. All potential stakeholders at the Toronto General Hospital have been identified and involved as deemed necessary.

The development of the clinical decision tool will mainly involve the assistance of hepatologists, general internists, and current trainees in Internal Medicine and Gastroenterology. We will send out a pre-intervention questionnaire identifying the ideal approach to delivering the Liver Care Bundle and identify any potential pitfalls that would lead to non-adoption to the tool. Some potential limitations already identified include ease-of-interface and the possibility of increasing workload for clinicians. Once we have finalized the content and algorithm to the Liver Care Bundle, we will then, with the aid of our in-house
information technology group, program the Liver Care Bundle and incorporate it into CPOE. We expect a 6-month timeline before we are ready to introduce the Liver Care Bundle to clinicians.

**Conclusion:**

The burden of chronic liver disease will continue to increase, and along with it so will the mortality due to the complications of cirrhosis. This will ultimately require hospitalizations that are prolonged, expensive, and have a high mortality given that cirrhosis is under-diagnosed and occasionally inappropriately managed. With increasing knowledge about management options, there are opportunities to treat complications according to international guidelines, however, for many individual practitioners this knowledge remains largely unapplied due to inadequate extraction of knowledge from existing sources. The Liver Care Bundle described has the potential to have a dramatic impact on the lives of patients by making existing clinical information available to physicians in a useful, convenient and timely manner with potential benefits of reducing healthcare costs and patient mortality.

**References:**


