

Increasing prevalence of nonalcoholic steatohepatitis as an indication for liver transplantation

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Background. In Ohio, the obesity rate has increased from 21.5% in 2000 to 30.1% in 2012. Nonalcoholic steatohepatitis is believed to be increasing as an indication for orthotopic liver transplantation.

Methods. We evaluated the diagnosis of nonalcoholic steatohepatitis as an indication for orthotopic liver transplantation and ensuing outcomes relative to other common hepatic diseases requiring orthotopic liver transplantation in Ohio. We queried 2,356 patients with nonalcoholic steatohepatitis, alcoholic cirrhosis (ETOH), and hepatitis C cirrhosis from the Ohio Solid Organ Transplantation Consortium who were listed for and/or received an orthotopic liver transplant from 2000 to 2012.

Results. The proportion of listed patients with nonalcoholic steatohepatitis increased from 0% to 26% and the proportion of transplanted patients increased from 0% to 23.4%. Compared with patients with hepatitis C and ETOH, patients with nonalcoholic steatohepatitis were older, and more likely to be white, and have private insurance ($P < .05$ for each). There was no difference in median waiting time among patients with nonalcoholic steatohepatitis, hepatitis C, and ETOH ($P = .18$) and Model for End-Stage Liver Disease scores at orthotopic liver transplantation among patients with nonalcoholic steatohepatitis, hepatitis C ($P = .48$), and ETOH ($P = .27$). Patient and graft survival after orthotopic liver transplantation was comparable between patients with nonalcoholic steatohepatitis and ETOH ($P = .79$ and $P = .86$, respectively); however, patients with nonalcoholic steatohepatitis had better patient and graft survival compared with patients with hepatitis C after orthotopic liver transplantation ($P < .01$ and $P = .02$, respectively). Additionally, body mass index had no influence on overall or graft survival for patients with nonalcoholic steatohepatitis undergoing orthotopic liver transplantation.

Conclusion. This study reflects the growing potential for transplantation in patients with fatty liver disease and suggests the outcomes are equivalent or superior to other common indications for orthotopic liver transplantation. (*Surgery* 2014;156:1049-56.)

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IN OHIO, THE OBESITY RATE has increased from 21.5% in 2000 to 30.1% in 2012, paralleling the obesity epidemic seen throughout the United States.¹ Nonalcoholic fatty liver disease (NAFLD) is considered the most common chronic liver disease in the Western world.² A subset of patients with NAFLD progress to nonalcoholic steatohepatitis (NASH), the hepatic manifestation of the

metabolic syndrome constellation of abdominal obesity, hypertension, insulin resistance, and dyslipidemia.³ NASH has a variable histologic and biologic course with some patients developing advanced fibrosis that may require orthotopic liver transplantation (OLT).^{4,5}

NASH was rare as an indication for OLT in 2001, comprising only 1.7% of OLT in that year. But, NASH has increased markedly over the past decade, accounting for 9.7% of all transplants by 2009 and becoming the third most common indication for OLT aside from Laennec's and hepatitis C cirrhosis.⁶⁻⁸ Additionally, a recent report of the Scientific Registry of Transplant Recipients (SRTR) database showed that NASH has become the most common indication for OLT in patients older than 65 years.⁹ More information, however, is

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needed with regard to access and suitability of patients with NASH for referral to OLT, listing, and eventual transplantation. In Ohio's unique registry, data are universally captured once patients are listed, and their outcomes are monitored before and after OLT.

Our aim was to review wait list, access to transplantation, and outcomes thereafter for patients with NASH relative to other common hepatic diseases requiring transplantation in Ohio.

METHODS

A retrospective cohort study was performed using the Ohio Solid Organ Transplantation Consortium (OSOTC) database from 2000 to 2012. The OSOTC is a nonprofit organization, composed of 6 member hospitals in Ohio, that works to improve access to medical care for extrarenal transplantation candidates¹⁰; our study used data from the 4 adult liver transplant programs. The role of the OSOTC is to review and approve all potential patients for listing before being placed on the United Network for Organ Sharing (UNOS) waiting list if the Model for End-Stage Liver Disease (MELD) score is < 22. If the MELD score is > 22, a patient can be listed before approval by the OSOTC Liver Transplant Patient Selection Committee. A majority vote for approval must be obtained before listing is permitted. We queried all patients with NASH, Laennec's cirrhosis (ETOH), and hepatitis C (HCV) cirrhosis from the OSOTC database who were listed for and/or received an OLT from 2000 to 2012. ETOH and HCV were used as controls to compare rates and outcomes to NASH.

Data considered for analysis included patient demographic and medical information and OLT wait list data, as well as perioperative OLT outcomes and graft/patient survival data. All centers were required to submit these data to the OSOTC. Primary outcomes of the study were listing and transplantation rates, as well as patient and graft survival after OLT. The OLT listing rate was defined for each year of the study as the number of new listings for a given liver disease etiology divided by the total number of new listings for that year. The transplantation rate was similarly defined by the number of new liver transplants replacing the number of new listings. Graft failure was defined by either repeat OLT or patient death.

Statistical analysis was performed using the Student *t* test for continuous variables, the Wilcoxon rank-sum test for ordinal categorical variables, and the χ^2 test for nominal categorical variables. Kaplan-Meier survival analysis was performed to examine both patient and graft survival

after transplantation. Multivariable logistic regression analysis was performed to examine factors related to patient and graft survival. All statistical analyses were performed using SAS Version 9.3 (SAS Institute, Cary, NC). Data are expressed as mean \pm SD, median and interquartile range, or as *n* and (%). Significance was defined as a *P* value < .05. The institutional review board of the University of Cincinnati approved this study.

RESULTS

Patient cohort. From 2000 to 2012, 2,356 patients were listed for OLT in Ohio with a diagnosis of HCV, ETOH, or NASH. Of these patients, 1,936 (82.2%) were residents of the state. The patient characteristics are presented in Table I. Nearly half of the patients (1,165, 49.4%) had HCV, whereas 781 (33.2%) had ETOH and 410 (17.4%) had NASH as the primary cause of their liver disease. Compared with both patients with HCV and patients with ETOH, patients with NASH were more likely to be white, female, and have private insurance, and were older at both listing and at OLT and were less likely to be an Ohio resident. Additionally, patients with NASH had higher mean body mass index (BMI) (33.6 ± 5.9) compared with both patients with HCV (28.9 ± 5.4 , $P < .01$) and patients with ETOH (28.1 ± 5.4 , $P < .01$). MELD scores at the time of listing were slightly higher for patients with NASH (17.2 ± 7.2) compared with patients with HCV (16 ± 5.9 , $P < .01$); however, the MELD scores were similar to NASH for patients with ETOH (17.5 ± 8.0 , $P = .6$); these differences were not statistically significant. MELD scores at the time of OLT were similar among the 3 groups. Finally, there were no differences in the proportion of recipients who were on hemodialysis at the time of OLT.

Rate of listing and transplantation. Over the study period, there was a twofold increase in the proportion of patients with NASH listed for OLT as determined by linear regression analysis (Fig 1, A; $r^2 = 0.82$, $P < .01$). Further details of the time spent on the OLT waiting list for our cohort can be seen in Table II. Of the 2,356 patients listed, 1,353 (57.4%) received OLT. The median time from listing to OLT was similar for patients with NASH (71 days), HCV (64 days, $P = .82$), and ETOH (51 days, $P = .18$). The overall rate of transplantation was similar among patients with NASH (56.1%), HCV (61.6%, $P = .06$), and ETOH (51.9%, $P = .18$). The proportion of transplanted patients with a diagnosis of NASH increased by twofold from 2000 to 2012 as determined by linear regression analysis (Fig 1, B, $r^2 = 0.78$, $P < .01$).

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