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ORIGINAL ARTICLE

Waitlist mortality of young patients with biliary atresia: Impact of allocation policy and living donor liver transplantation

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Abstract

Patients with biliary atresia (BA) below 2 years of age in need of a transplantation largely rely on partial grafts from deceased donors (deceased donor liver transplantation [DDLT]) or living donors (living donor liver transplantation [LDLT]). Because of high waitlist mortality in especially young patients with BA, the Eurotransplant Liver Intestine Advisory Committee (ELIAC) has further prioritized patients with BA listed before their second birthday for allocation of a deceased donor liver since 2014. We evaluated whether this Eurotransplant (ET) allocation prioritization changed the waitlist mortality of young patients with BA. We used a pre–post cohort study design with the implementation of the new allocation rule between the two periods. Participants were patients with BA younger than 2 years who were listed for liver transplantation in the ET database between 2001 and 2018. Competing risk analyses were performed to assess waitlist mortality in the first 2 years after listing. We analyzed a total of 1055 patients with BA, of which 882 had been listed in the preimplementation phase (PRE) and 173 in the postimplementation phase (POST). Waitlist mortality decreased from 6.7% in PRE to 2.3% in POST (p = 0.03). Interestingly, the proportion of young patients with BA undergoing DDLT *decreased* from 32% to 18% after ET allocation prioritization (p = 0.001), whereas LDLT *increased* from 55% to 74% (p = 0.001). The proportional increase in LDLT decreased the median waitlist duration of transplanted patients from 1.5 months in PRE to

Abbreviations: BA, biliary atresia; DDLT, deceased donor liver transplantation; ELIAC, Eurotransplant Liver Intestine Advisory Committee; ET, Eurotransplant; IQR, interquartile range; LDLT, living donor liver transplantation; Lab-MELD, laboratory MELD; MELD, Model for End-Stage Liver Disease; NVGE, Dutch Society for Gastroenterology; NWO, Dutch Research Council; PELD, Pediatric End-Stage Liver Disease; POST, postimplementation phase; PRE, preimplementation phase; STROBE, Strengthening the Reporting of Observational Studies in Epidemiology.

Vincent E. de Meijer and Henkjan J. Verkade shared senior authorship.

0.85 months in POST (p = 0.003). Since 2014, waitlist mortality in young patients with BA has strongly decreased in the ET region. Rather than associated with prioritized allocation of deceased donor organs, the decreased waitlist mortality was related to a higher proportion of patients undergoing LDLT.

INTRODUCTION

Biliary atresia (BA) is the most common indication for pediatric liver transplantation, accounting for 50% of all liver transplantations at pediatric age, and >70% of all liver transplantations in children below 2 years of age.[1,2] Since the end of the last century, developments in pediatric liver transplantation have further improved the prognosis of patients with BA, with the vast majority (87%) now reaching adulthood.[3] Still, waitlist mortality negatively affects the overall prognosis.[4]

We previously analyzed data from the Eurotransplant (ET) registry collected between 2001 and 2014 of young patients with BA listed for liver transplantation.[4] Young age and a high disease severity score (Model for End-Stage Liver Disease [MELD] score) at listing were independent risk factors for waitlist mortality. In patients listed before the age of 6 months and with a MELD score above 20, waitlist mortality was even as high as 21%.[4] ET had prioritized donor organ allocation to young patients with BA on the waiting list for deceased donor liver transplantation (DDLT), by adjustments to the so-called exceptional MELD criteria (December 2014 onward) as a result of a large pediatric liver allocation development meeting in 2014, represented by experts from all ET member countries. The parallel performed analysis[4] in that same year supported the change in priority. This new allocation rule, where exceptional MELD points are awarded to patients whose disease severity cannot adequately be reflected by the laboratory MELD (lab-MELD), was implemented in patients with BA listed below the age of 2 years. In this new allocation rule, these patients are initially rewarded with a pediatric MELD score of 32. At every 90-day period this score is then upgraded by 15%.[5]

Effects of adaptations to allocation rules are not commonly, systematically evaluated in transplantation medicine. Our previous systematic evaluation of the waitlist mortality in young patients with BA offered the unique possibility to evaluate the effects of the adaptation of the allocation rule.[4] The aim of this study was to evaluate whether this ET allocation prioritization changed the waitlist mortality of young patients with BA. We hypothesized that waitlist mortality would be decreased after the introduction of the new allocation rule.

PATIENTS AND METHODS

Study design

We performed a retrospective analysis of anonymized data derived from the prospectively maintained ET database. ET is a nonprofit organization that is responsible for the allocation and cross-border exchange of deceased donor organs in Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands, and Slovenia. The study protocol was approved by the Eurotransplant Liver Intestine Advisory Committee (ELIAC) prior to initiation of the study (March 5, 2020). The study complied with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.[6]

Patients

The cohort consisted of patients with BA listed for liver transplantation before the age of 2 years, between January 2001 and December 2018 in the ET region (Austria, Belgium, Croatia, Germany, Hungary, Luxembourg, the Netherlands, and Slovenia).

Based on a high mortality of young patients with BA listed for liver transplantation,[4] ET further prioritized the allocation of deceased donor organs to patients with BA below 2 years of age at the moment of listing. The actual implementation of the new allocation rule in each participating country required national approval and took place in each country between December 2014 and May 2017. In detail, all ET countries, except for Austria (December 2015) and Germany (May 2017), implemented the new allocation rule in December 2014. All patients were categorized into time "preimplementation phase (PRE)" or "postimplementation phase (POST)," meaning listed before or after the implementation of the new allocation rule according to their country, respectively. Patients who were on the waiting list in both periods were assigned to the group where the event took place. We compared the outcomes "waitlist mortality," "transplanted" (either by DDLT or by living donor liver transplantation [LDLT]), and "still on waiting list" between patients with BA in PRE and POST, respectively.

Allocation system

Liver allocation in ET is based on the leading principle that priority on the waiting list is primarily based on the clinical severity of the patient waiting for a donor organ, estimated by the mortality risk. The MELD score has been developed for adult patients. This scoring system stratifies recipients by their disease severity according to a 3-month probability of death on the waiting list. A high MELD score indicates severe illness. It has been appreciated that the MELD score has drawbacks for assigning priority to pediatric patients. To overcome this, children under the age of 18 years are assigned a pediatric MELD score. Patients listed below 12 years and patients between 12 and 18 years are assigned an initial MELD of 28 or 22, respectively. At every 90-day period this score is then upgraded by 10% for patients listed below 12 years and 15% for patients between 12 and 18 years. In addition, when the country and disease-specific criteria are met, a so-called Standard Exception is granted, and the patient is awarded with exceptional MELD points. The overall ranking is largely determined by the patient's highest total MELD score being either the (national) exceptional MELD points, pediatric MELD score, or lab-MELD score.

Variables

All anonymized registry data were made available by ET. The database included the following characteristics, which were determined at the moment of listing: sex, blood group, age at listing, primary diagnosis, and lab-MELD score at listing. Additional variables provided by ET were whether the patient had been placed on the waiting list prior to, or after the implementation of the new allocation rule, waitlist outcome, and waitlist duration. The latter was related to time to waitlist mortality or time to transplantation. The variables "age at listing" and "lab-MELD score at listing" were categorized into three groups, in agreement with the earlier reported analysis on waitlist mortality. Age at listing was categorized into 0–6 months, 6–12 months, and 12–24 months. Lab-MELD score at listing was categorized into <15 points, 15–20 points, and >20 points. Only cases with complete data (age at listing and lab-MELD score at listing) were used for the time-to-event analysis.

Statistical analysis

Continuous variables were expressed as median and interquartile range. Categorical variables were expressed as number and percentage. The differences between groups were compared using the Mann–Whitney *U* test for continuous variables and Pearson's chi-square test for categorical variables, respectively. Differences were considered statistically significant at $p < 0.05$.

During a maximum follow-up of 2 years for each patient we observed one of the four possible waitlist outcomes: DDLT, LDLT, deceased on waiting list, or still on waiting list. The outcomes "transplanted" and "deceased on waiting list" formed competing risks. Survival analysis with competing risks was therefore performed. We defined the outcome "deceased on waiting list" as the outcome of interest and the outcome "transplanted" as the competing outcome. Patients who were still on the waiting list by the end of the follow-up time were censored. We presented the results of the competing risks analysis by means of cumulative incidence functions according to Fine and Gray.[7] All statistical analyses were performed using SPSS Statistics 23.0 (IBM, New York, NY) and library survival and cmprsk of R, version 4.0.2 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Between 2001 and 2018, a total of 1061 patients with age below 2 years had been listed for liver transplantation in the ET registry. We excluded six patients who were removed from the waiting list because of unknown causes. This resulted in 1055 patients with BA who were eligible for the analysis of waitlist mortality, composed of 882 patients listed before implementation of the new ET allocation rule in the different ET-participating countries (PRE), and 173 patients thereafter (POST).

Table 1 illustrates the characteristics of patients with BA for each period. Sex distribution, median age at listing, and median MELD score at listing were statistically comparable between the two periods. In PRE, lab-MELD score at listing was available in 641 of the 882 patients, whereas in POST, lab-MELD score at listing was available in all 173 patients.

Waitlist outcomes

We compared the patient characteristics between the two periods for each waitlist outcome ("deceased on waiting list," "DDLT," "LDLT," and "still on waiting list") separately. There were no significant differences in sex distribution, median age at listing, and median lab-MELD score at listing (Table S1). Figure 1 shows the cumulative incidence curves of waitlist mortality. Within 2 years after listing, a total of 63 children with BA deceased while waiting for a suitable liver between 2001 and 2018, of which 59 children had been listed in PRE and 4 in POST ($p = 0.03$). The waitlist mortality in young patients with BA at 3, 6, and 24 months

TABLE 1 Characteristics of patients with BA aged <2 years listed for liver transplantation before (2001–2014; PRE) and after (2014–2018; POST) the implementation of the new ET allocation rule

Patient characteristics	PRE (*n* = 882)	POST (*n* = 173)	*p* value
Female sex	483 (55)	98 (57)	0.65
Blood group			
A	357 (41)	69 (40)	
B	147 (17)	30 (17)	
AB	55 (6)	10 (6)	
O	323 (37)	64 (37)	
Age at listing, months	6.2 (4.3–8.6)	6.1 (3.9–10)	0.77
Age at listing in categories, months			
0–6	416 (47)	85 (49)	0.64
6–12	365 (41)	53 (31)	0.008
12–24	101 (12)	35 (20)	0.002
Lab-MELD score at listing	18 (15–21)	17 (14–20)	0.28
Lab-MELD score at listing in categories	Available (*n* = 641)	Available (*n* = 173)	
<15	153 (17)	48 (28)	0.29
15–20	303 (34)	84 (49)	0.76
>20	185 (21)	41 (24)	0.18

Note: Data are presented as median (interquartile range) or *n* (%). Differences were tested by the Mann–Whitney *U* test for continuous variables and Pearson's chi-square test for categorical variables.

Abbreviations: BA, biliary atresia; ET, Eurotransplant; MELD, Model for End-Stage Liver Disease; POST, postimplementation phase; PRE, preimplementation phase.

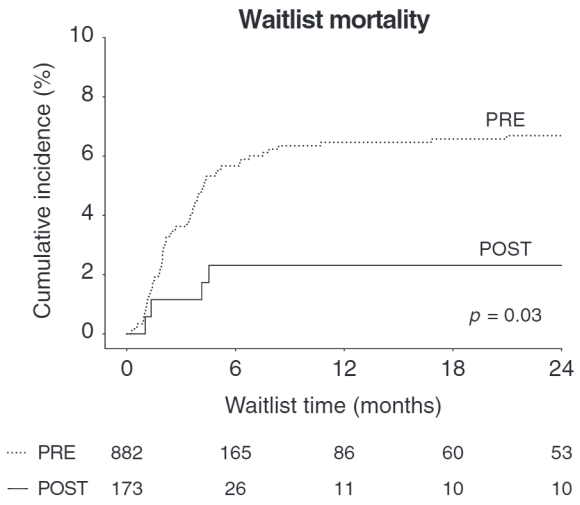

FIGURE 1 Waitlist mortality of patients with BA aged <2 years before and after installing a new donor organ allocation rule. Cumulative incidence curves of the patients with BA aged <2 years who deceased on the waiting list within 2 years after listing before (2001–2014; PRE) and after (2014–2018; POST) the implementation of the new ET allocation rule

after listing decreased significantly from 3.6%, 5.7%, and 6.7% in PRE to 1.2%, 2.3%, and 2.3% in POST, respectively ($p = 0.03$).

Figure 2 shows the cumulative incidence curves of DDLT and LDLT. Overall, 87% of patients with BA listed in PRE received liver transplantation versus 92% of patients with BA listed in POST ($p = 0.09$). The percentage of DDLT at 3, 6, and 24 months after listing decreased from 16%, 23%, and 32% in PRE to 8.1%, 10%, and 18% in POST, respectively ($p = 0.001$). Meanwhile, the percentage of patients transplanted with LDLT at 3, 6, and 24 months after listing increased from 45%, 53%, and 55% in PRE to 59%, 72%, and 74% in POST, respectively ($p = 0.001$). The proportion of LDLT per country in living donor procedures increased in most of the ET countries (Table S1). The proportion of patients who were still on the waiting list after a follow-up time of 2 years were comparable between the two periods (6.0% in PRE vs. 5.8% in POST; $p = 0.96$).

Waitlist time

Median time to transplantation significantly decreased over the two periods: from 1.5 (interquartile range [IQR], 0.23–3.7) to 0.85 (IQR, 0.33–3.2) months ($p = 0.003$). To determine the possible association of the new allocation rule with waitlist outcome, the waiting time of patients who had undergone a DDLT procedure was separately analyzed. Among the patients with BA who had been transplanted via a DDLT procedure, the median time on the waiting list increased from 3.2 (IQR, 1.2–7.0) to 3.8 months (IQR, 1.4–7.1) over the two periods ($p = 0.56$). The waiting time of patients who had undergone an LDLT procedure was lower in POST than in

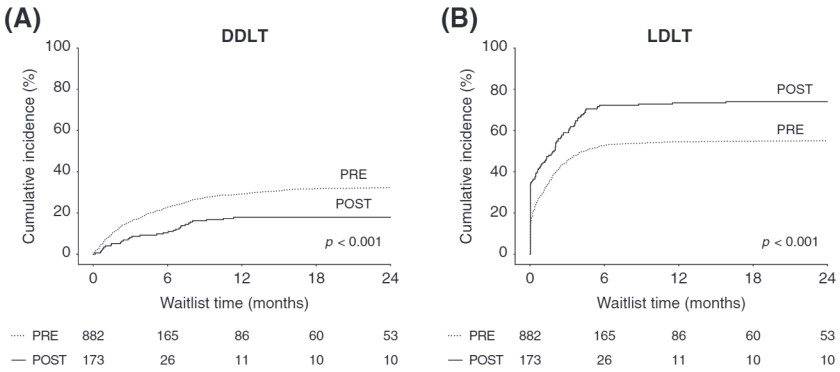

FIGURE 2 Incidence of deceased donor and of LDLT in patients with BA aged <2 years. Cumulative incidence curves of patients with BA aged <2 years transplanted with (A) a deceased donor organ or (B) a living donor organ within 2 years after listing before (2001–2014; PRE) and after (2014–2018; POST) the implementation of the new ET allocation rule

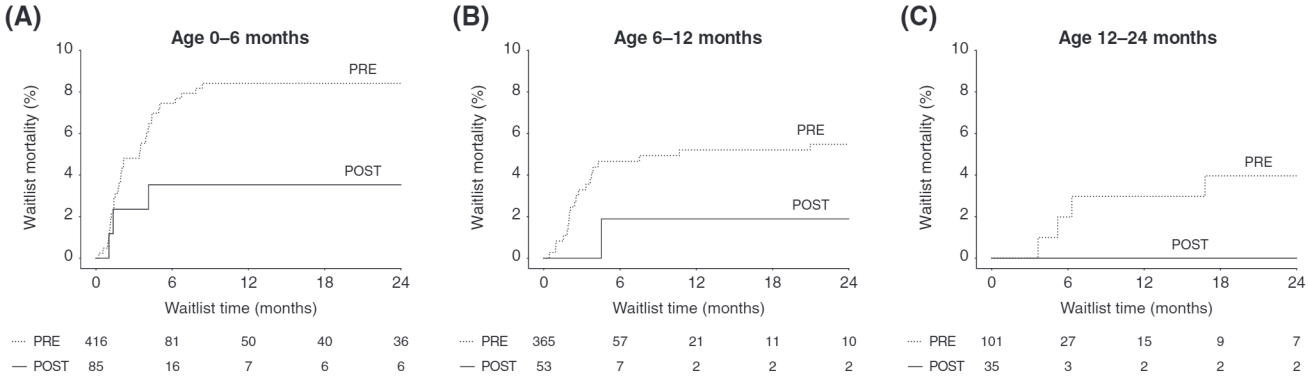

FIGURE 3 Waitlist mortality of patients with BA aged <2 years stratified by age groups. Cumulative incidence curves comparing waitlist mortality of patients with BA per age at listing for age groups of (A) 0–6 months, (B) 6–12 months, and (C) 12–24 months before (2001–2014; PRE) and after (2014–2018; POST) the implementation of the new ET allocation rule

PRE: median, 0.72 (IQR, 0.03–2.3) versus 0.39 months (IQR, 0.03–2.3); $p = 0.05$. Accordingly, Figure 2 depicts a steeper slope of the cumulative incidence curve of LDLT in PRE versus POST.

Waitlist mortality in relation to age at listing and MELD at listing

The mortality risk for children listed at 0–6 months or 6–12 months was profoundly lower in POST than in PRE and had become comparable to each other ($p = 0.001$; Figure 3). Moreover, mortality in patients listed at the age of 12–24 months was not observed in POST. The highest mortality risk was found in the age group 0–6 months for both periods.

Between the two periods, decrease in waitlist mortality was observed in all MELD groups (Figure 4). In POST, for patients listed with a lab-MELD score <15 or >20 waitlist mortality was nil. Among the highest-risk patients (listed below the age of 6 months and with a lab-MELD score >20) waitlist mortality decreased from 14.3% in PRE to 0% in POST ($p = 0.001$).

DISCUSSION

In this study, we evaluated whether the implementation of the new allocation rule changed the waitlist mortality of young patients with BA. We observed a significant decrease in waitlist mortality risk in the POST. However, this finding could not be attributed to an increase in DDLT procedures, nor to a shorter waiting time to DDLT, but was rather associated with an increase in the proportion of LDLT procedures and subsequently decreased duration of time on the waiting list.

The results from our competing risks analysis showed a decrease in waitlist mortality from 6.7% in PRE to 2.3% in POST. Previously, we reported that young age at listing (in particular, age <12 months) and/or high lab-MELD score at listing were associated with increased mortality.[4] We therefore analyzed whether the differences in waitlist mortality could be due to differences between the two periods in age or lab-MELD score at listing. However, the age distribution at listing and the disease severity (lab-MELD score) were similar between the two periods. Moreover, the decreased mortality risk was apparent in the youngest patients at

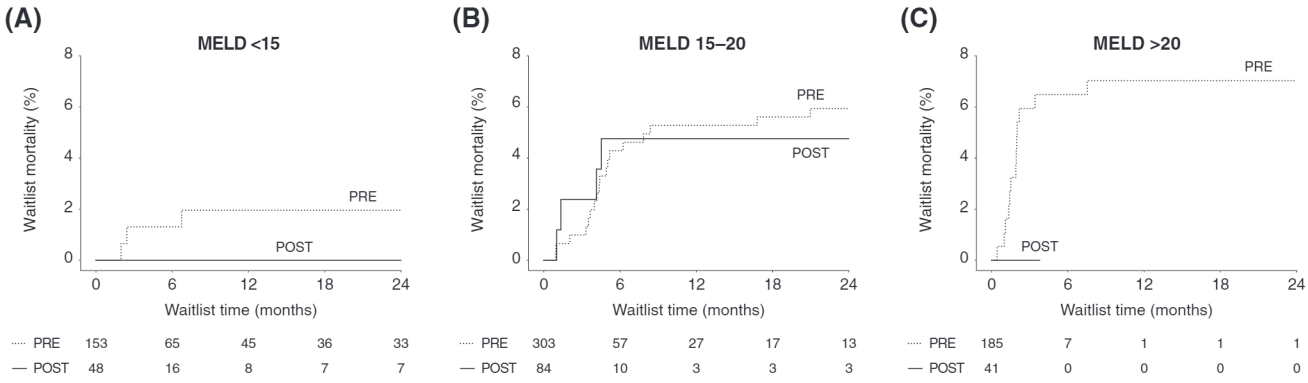

FIGURE 4 Waitlist mortality patients with BA aged <2 years stratified by MELD scores at the time of listing. Cumulative incidence curves comparing waitlist mortality of patients with BA per MELD score at listing for groups of (A) MELD score <15, (B) MELD score 15–20, and (C) MELD score >20 before (2001–2014; PRE) and after (2014–2018; POST) the implementation of the new ET allocation rule

listing (age <6 months) and patients with the highest lab-MELD scores (MELD >20).

As the decrease in waitlist mortality could neither be attributed to differences in age of the patients at listing, nor to their disease severity, we analyzed whether the decreased mortality correlated with a higher availability of deceased donor organs for these patients. From 2014 onward, ET prioritized the allocation of deceased donor organs to patients with BA listed below 2 years of age. Until now, no data had been available regarding the impact of allocation prioritization on waitlist mortality of young patients with BA. In contrast to our expectations, however, the proportion of DDLT procedures *decreased* in the period of the adapted allocation. Further, patients who were transplanted with a deceased donor graft had on average not been shorter on the waiting list in POST than in PRE (3.8 vs. 3.2 months; $p = 0.56$). These observations indicate that the decreased mortality did not associate with favorable consequences of the new allocation prioritization.

Rather than the new allocation rule, the present data point at an important influence of increased LDLT in the most recent period. The percentage of LDLT procedures in all transplanted young patients with BA increased from 55% in PRE to 74% in POST ($p = 0.001$). The time on the waiting list of patients who underwent LDLT was considerably shorter than those that underwent DDLT, which is consistent with our previous report (Table S1).[4] Accordingly, the overall median time on the waiting list in POST was profoundly lower than in PRE (−40%; $p = 0.001$). As a major risk factor for waitlist mortality is time on the waiting list, we conclude that the decrease in waitlist mortality in POST is mainly attributable to the increase in LDLT procedures rather than to the new allocation rule. Our findings of the higher contribution of LDLTs are not limited to the ET region, but seems also apparent for other regions of Europe. de Ville de Goyet et al.[8] recently showed that between 2010 and 2017, LDLT accounted for 31% of all pediatric liver transplantations from the European Liver Transplant Registry, and this percentage was even >50% for those transplanted before the age of 1 year.

We are aware that our present study has certain limitations. First, any residual confounding cannot be ruled out due to the retrospective nature of this study. Second, sample size was unequal between PRE and POST due to a shorter inclusion time in POST. Lastly, we could not reliably investigate lab-MELD scores in PRE because in the period 2001–2006, it was not yet mandatory to register lab-MELD scores at listing.

This study shows a robust increase in LDLT and subsequent decrease in waitlist time for young patients with BA listed for liver transplantation. The proportional increase in LDLT was rather uniformly ditributed among the various ET countries, rather than just a steep increase in only a few countries (Table S1). We speculate that the improved utilization was related to increased awareness of waitlist mortality among patients with BA, possibly related to our prior analysis.[4] The substantial increase in LDLTs has reduced pediatric waitlist time, and, as our data indicate, also waitlist mortality. LDLT allows for optimal donor selection, minimization of preservation time and injury, and optimization of timing and planning of the transplantation procedure. Besides, long-term patient and graft survival outcomes after pediatric LDLT may be superior when compared with DDLT.[9]

In Italy a national mandatory split-liver policy for standard risk deceased donors aged 18–50 years was implemented in 2015. Increased access to left lateral segments for pediatric recipients led to a marked reduction in waitlist time, from 229 to 80 days ($p = 0.045$), and a reduction in waitlist mortality, from 4.5% to 2.5%, albeit not significantly ($p = 0.40$).[10] A substantial reduction in LDLT rate for all pediatric patients younger than 18 years of age was observed, when compared with the control period (4.4% vs. 16.7%; $p = 0.002$). In the United States Organ Procurement and Transplantation Network a change to the allocation system in 2020 led to prioritization of liver offers from deceased donors younger than 18 years of age to pediatric recipients.[11] The aim of this

allocation prioritization was to provide increased access to DDLT for pediatric patients and thereby decreasing mortality on the waiting list; however, especially young patients below 2 years of age may not benefit from this model because of size mismatch and a need for a partial liver graft. Our present data support the concept that for minimizing waitlist time and mortality of especially young patients with BA, further implementation and dissemination of LDLT in pediatric liver transplantation should be advocated when a sufficient and timely supply of deceased donor organs is not available.

In the present study, we addressed to what extent changes in ET allocation prioritization are associated with a different waitlist mortality risk in only patients with BA. We feel that the methodology used should not be limited to this specific category of young patients with BA. Rather, the same evaluation of waitlist mortality and effects of evaluation of allocation adaptations are expected to be applicable for other pediatric or adult recipients of liver or other solid organ grafts. Thus, it may become a means of permanent quality control measure to optimize donor organ allocation rules in times of donor organ shortage.

Since 2014, waitlist mortality in young patients with BA has strongly decreased in the ET region. Rather than associated with prioritized allocation of deceased donor organs, the decreased waitlist mortality appeared related to a higher proportion of patients undergoing LDLT, possibly related to our first analysis that was widely shared within the ET community.[4] Our data indicate that the current shortage of deceased donor organs in the ET region necessitates LDLT programs to minimize the waitlist mortality in young patients with BA.

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CONFLICT OF INTEREST

Nothing to report.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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