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ORIGINAL ARTICLE

Allocation procedure has no impact on patient and graft outcome after liver transplantation

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Summary

The aim of our study was to compare the postoperative outcome after liver transplantation (LT) in patients who received a donor liver via standard or rescue allocation (RA). Special emphasize was laid on the effect extended donor criteria might have on the outcome. One hundred and ten LTs have been performed at the University Hospital Aachen, Germany. A total of 49 patients were included in the standard allocation (SA) group and 53 patients in the RA group. The outcome of LT in both groups was evaluated by the length of stay on the intensive care unit (ICU), duration of hospitalization, 1-year patient survival, 1-year graft survival, incidence of primary nonfunction and major complications. Patients in group RA had a significant shorter ICU and overall hospital stay. The 1-year graft survival was 87.8% in group SA and 88.7% in group RA. The 1-year patient survival was 87.9% in group SA and 96.2% in group RA. The number of re-LT was 2% in group SA and 7.5% in group RA. Organs that were rejected for transplantation several times can successfully be transplanted through the RA procedure, thereby enlarging the donor pool without negative effects on the quality of LT.

Introduction

In recent years, there has been a remarkable mismatch within the Eurotransplant (ET) area between patients on the waiting list and the number of liver transplantations (LTs). From 2001 to 2011, the number of patients on the ET waiting list for LT has increased from 1093 to 2614 (239%), while the number of deceased LTs only rose from 1112 to 1770 (159%) [1], thereby resulting in a tremendous organ shortage. Therefore, the criteria for the acceptance of donor organs have been extended more and more. The German Medical Association, for example, has identified seven extended donor criteria (EDC). These include the donor's age, body mass index (BMI), the length of intensive care unit (ICU) treatment, histologically confirmed steatosis, and laboratory results such as serum sodium, bilirubin, and transaminases [2].

Eurotransplant provides two different procedures for organ allocation. First, organs are matched to an individual patient by ET according to ABO-blood group compatibility and Model for End-stage Liver Disease (MELD) score. This is the so-called standard allocation (SA) procedure. If – for various medical and nonmedical reasons – organs are rejected at least three times by different transplantation centers, a regional rescue allocation (RA) procedure takes place. The rejected organ is offered to regional transplantation centers which are authorized to allocate this organ according to their internal waiting lists [5]. The main aim of the RA procedure was to reduce cold ischemic time (CIT) and to expand the possible donor pool.

Even though all German transplantation centers receive the same number of RA organ offers, there is a remarkable difference in the rate of accepted RA livers.

The main concern about RA organs is the fact that those organs have been entitled untransplantable by at least three centers. Objections against RA organ transplantation include endangering the patients who receive a RA organ because of statistical reasons, i.e., to achieve higher numbers of transplantations per year. In addition, it is suggested that the organ allocation may be unfair as transplantation centers are not bound to the normal allocation criteria any more.

However, in 2011, 29% of the deceased donor livers in the ET area were allocated and actually transplanted according to the RA procedure [1].

The aim of our study was to compare the postoperative outcome after LT in patients who received a donor liver via standard or RA with particular regard to the effect EDC might have on the outcome.

Patients and methods

Between May 2010 and August 2012, 110 deceased donor LTs have been performed at the Department of General, Visceral and Transplantation Surgery at the University Hospital Aachen, Germany.

The patient collective was divided into two groups depending on the type of organ allocation. A total of 49 patients who received a donor liver via SA were included in group SA, whereas group RA consisted of 53 patients who obtained donor livers by RA. The remaining eight patients either received combined liver and kidney transplantation, living donor LT or split LT and have therefore been excluded from the analysis. ET carried out the initial organ allocation.

Surgical techniques as well as intraoperative and postoperative care have been standardized. All LTs were performed with an extracorporal venovenous bypass. Immune suppression consisted of a prophylaxis with basiliximab, tacrolimus, and corticosteroids. Acute biopsy proofed rejection was treated with 500 mg/day methylprednisolone for 3 days.

Recipient data were collected for sex, age, etiology of disease, BMI, and lab-MELD score.

The following donor data were examined: sex, age, BMI, CIT, fatty liver degeneration (%), bilirubin (mg/dl), gamma glutamyl transpeptidase (γGT) (U/l), aspartate aminotransferase (AST) (U/l), alanine aminotransferase (ALT) (U/l), sodium (mmol/l), length of ICU stay, history of positive hepatitis serology, and cause of death. EDC were defined according to the German Medical Association as bilirubin >3 mg/dl, AST or ALT >150 U/l, age >65 years, ICU stay >7 days, BMI >30, sodium >165 mmol/l and steatosis hepatis >40%

The outcome of LT in both groups was evaluated by the length of stay on the ICU, duration of hospitalization, 1-year patient survival, 1-year graft survival, incidence of primary nonfunction (PNF) and major complications. Following the specifications of ET, PNF was defined as re-transplantation or death within 14 days after LT.

According to the Clavien classification of negative outcomes in solid organ transplantation, major complications were defined as grade 3 or 4 [3].

Patients' follow-up ended in February 2013. At that time, 58 patients had been followed up for at least 1 year. The median follow-up was 363 days in group SA (range 117–980 days) and 514 days in group RA (range 127–827 days).

Statistics

Statistical analysis was performed with SPSS statistical software (version 20.0; IBM Corp., Armonk, NY, USA) using the chi-squared test or the Fisher exact test for qualitative variables and the Mann–Whitney test or *t*-test for continuous variables. The Kaplan–Meier method was used to estimate observed 1-year graft and patient survival. A two-sided *P*-value of <0.05 was considered to be significant. For continuous variables, results are given as median and range (minimum and maximum). The Eurotransplant Donor Risk Index (ET-DRI) was calculated using the following formula:

$$\begin{aligned}\text{ET-DRI} = \exp[0.960(&(0.154 \text{ if } 40 \leq \text{age} < 50)\\ &+ (0.274 \text{ if } 50 \leq \text{age} < 60)\\ &+ (0.424 \text{ if } 60 \leq \text{age} < 70)\\ &+ (0.501 \text{ if } 70 \leq \text{age})\\ &+ (0.079 \text{ if COD } = \text{ anoxia})\\ &+ (0.145 \times \text{ if COD} = \text{ cerebrovascular accident})\\ &+ (0.184 \text{ if COD } = \text{ other}) + (0.411 \text{ if DCD})\\ &+ (0.422 \text{ if partial/split})\\ &+ (0.105 \text{ if regional share})\\ &+ (0.244 \text{ if national share}))\\ &+ (0.010 \times (\text{cold ischemia time} - 8\text{ h}))\\ &+ 0.06((\text{ latest lab } \gamma\text{ GT(U/l)} - 50)/100)\\ &+ (0.180 \text{ if rescue offer})].\end{aligned}$$

Results

Recipient characteristics

Recipient age and sex did not differ significantly between both groups. The median age was 55 years (range 19–71 years in group SA and range 37–69 years in group RA). The male-to-female ratio was 32:17 in group SA and 37:16 in group RA.

The lab-MELD-score showed a statistically significant difference between both groups. In group SA, the median lab-MELD-score was 26 (6–40) while in group RA, it was 15 (7–28) ($P < 0.001$).

The main reasons for LT in group SA were hepatocellular carcinoma (HCC) (32.7% vs. 28.3% in group RA, $P = 0.671$) and acute liver failure (28.6% vs. 0% in group RA, $P = 0.001$). In group RA, the main indication for LT was alcohol-induced liver cirrhosis (41.5% vs. 12.2% in group SA, $P = 0.001$). Recipient characteristics are shown in Table 1.

In general, the indication for LT is recommended for patients with a MELD-score of 15 or higher [4]. In this study, 43 patients received LT with a MELD-score lower than 15 (13 in group SA and 30 in group RA). Thirty of these patients suffered from HCC or primary sclerosing cholangitis (18 in group RA and 12 in group SA). In the remaining 13 cases, liver cell adenomatosis with malignant transformation (one patient in group SA), recurrent encephalopathy (six patients in group RA) or bleeding complications (five patients in group RA) and hydropic decompensation (two patients in group RA) have been indications for LT. All these indications are not properly represented by the lab-MELD-score.

Table 1. Recipient characteristics.

Recipient	Group SA	Group RA	*P*-value
n	49 (43.8%)	53 (47.2%)	
Age (mean)	55 (19–71)	55 (37–69)	0.46
Gender			0.675
Male	32 (65.3%)	37 (69.8%)	
Female	17 (34.7%)	16 (30.2%)	
Lab-MELD	26 (6–40)	15 (7–28)	**0.001**
BMI	27 (18–39)	26 (15–35)	0.197
Inpatient treatment immediately prior to LT	47 (66.7%)	16 (11.3%)	**0.001**
Indication for LT			
Acute liver failure	14 (28.6%)	0	**0.001**
Alcoholic cirrhosis	6 (12.2%)	22 (41.5%)	**0.002**
HCC	16 (32.7%)	15 (28.3%)	0.671
PSC	3 (6.1%)	6 (11.3%)	0.491
Graft failure	5 (10.2%)	0	**0.023**
HBV/HCV cirrhosis	3 (6.1%)	5 (9.4%)	0.717
Other	2 (4.1%)	5 (9.4%)	0.439

SA, standard allocation; RA, rescue allocation; LT, liver transplantation; PSC, primary sclerosing cholangitis; BMI, body mass index; HCC, hepatocellular carcinoma; HBV, hepatitis B virus; HCV, hepatitis C virus.
Bold values indicate significance.

Table 2. Donor characteristics.

Donor	Group SA	Group RA	*P*-value
Gender			0.232
Male	24 (49%)	33 (62.3%)	
Female	25 (51%)	20 (37.7%)	
Age	53 (24–83)	59 (19–84)	0.46
BMI	26 (19–52)	26 (17–41)	0.91
CIT (min)	456 (265–857)	450 (300–883)	0.20
ET-DRI	1.81 (1.06–2.3)	1.77 (1.22–2.71)	0.992

SA, standard allocation; RA, rescue allocation; BMI, body mass index; CIT, cold ischemic time; ET-DRI, Eurotransplant Donor Risk Index.

Donor characteristics

Between both groups, there were no statistically significant differences with regard to donor age, sex, BMI, and CIT. Table 2 demonstrates the donor characteristics.

The median ET-DRI was 1.81 in group SA and 1.77 in group RA.

Table 3. Extended donor criteria.

EDC	Group SA	Group RA	*P*-value
n = 0	27 (55.1%)	17 (32.1%)	0.090
n = 1	16 (32.7%)	28 (52.8)	
n = 2	5 (10.2%)	7 (13.2%)	
n = 3	1 (2%)	1 (1.9%)	
Age >65	6 (12.2%)	19 (35.8%)	**0.006**
BMI >30	13 (26.5%)	9 (17%)	0.336
ICU >7 days	6 (12.2%)	9 (17%)	0.582
Sodium >165 mmol/l	0	1 (1.9%)	1.00
Transaminase >150 U/l	4 (8.2%)	7 (13.2%)	0.529
Bilirubin >3 mg/dl	0	3 (5.7%)	0.244

EDC, extended donor criteria; SA, standard allocation; RA, rescue allocation; BMI, body mass index; ICU, intensive care unit.
Bold value indicates significance.

Table 4. Differences in donor characteristics: Aachen versus ET.

Donor	Aachen (2010–2012)	ET (2003–2007)*
Gender		
Male	58 (51.8%)	3194 (53.8%)
Female	45 (40.2%)	2745 (46.2%)
Age	55 ± 15	47.6 ± 16.5
BMI	27.97 ± 6.7	25.1 ± 3.7
CIT (min)	477.23 ± 135	582 ± 174
Cause of death		
Anoxia (%)	27.6	6.9
Cerebrovascular accident (%)	70.5	63
Other (%)	1.9	3.4
Allocation		
Local (%)	0	10.3
Regional (%)	54.3	35.2
Extra-regional (%)	45.7	54.5
Rescue allocation (%)	52	22.5
ET-DRI	1.78 ± 0.32	1.70 ± 0.42

ET, Eurotransplant; BMI, body mass index; CIT, cold ischemic time; ET-DRI, Eurotransplant Donor Risk Index.
*Based on Blok *et al.* [20].

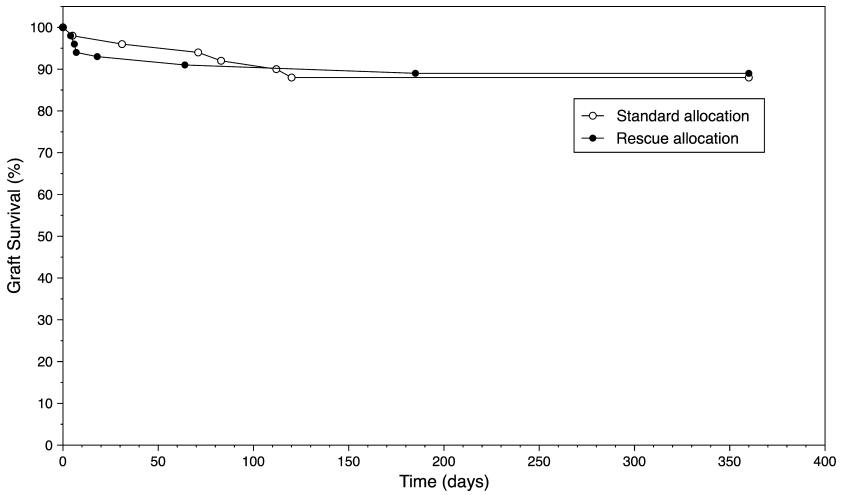

Figure 1 The 1-year graft survival.

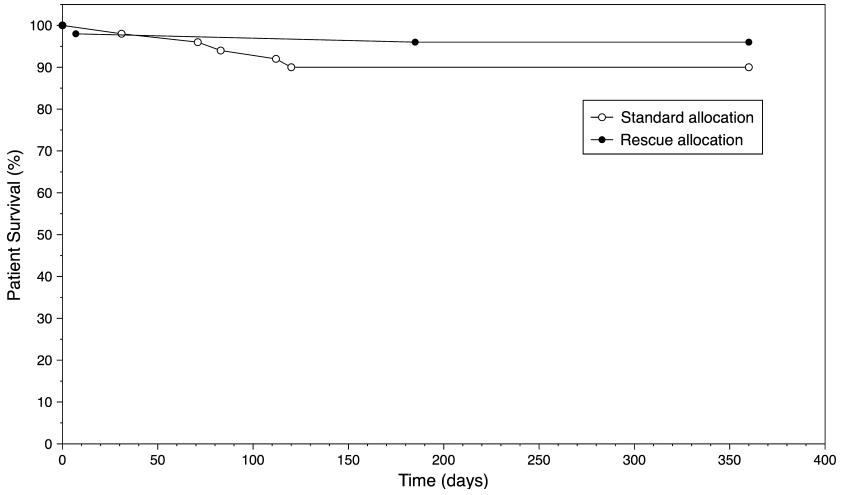

Figure 2 The 1-year patient survival.

Only according to the EDC, there were significant deviations. In group SA, 32.7% of donors fulfilled one EDC whereas in group RA 52.8% of the donor livers satisfied one EDC.

Furthermore, in group SA, there were significantly more donor livers which did not fulfill the EDC at all (55.1% versus 32.1%, $P = 0.043$). The EDC are shown in Table 3.

There were significantly more donor livers within the age-group above 65 years in group RA (35.8% vs. 12.2% in group SA, $P = 0.006$). Other EDC did not have any statistically relevant impact in either group. A total of 26.5% in group SA and 17% in group RA had a BMI above 30. In group SA, 12.2% of the patients had an ICU stay longer than 7 days compared with 17% in group RA. Bilirubin >3 mg/dl and sodium >165 mmol/l did not occur in group SA. In group RA, there was only one donor organ with hyperbilirubinemia and three with hypernatremia. Table 4 shows a comparison between ET's and the University Hospital Aachen's donor characteristics.

Postoperative data

Patients in group RA had a significant shorter ICU (4 days vs. 8 days in group SA, $P = 0.03$) and overall hospital stay (25 days vs. 40 days in group SA, $P = 0.04$). The 1-year graft survival was very similar with 87.8% in group SA and 88.7% in group RA (Fig. 1). The 1-year patient survival was 87.9% in group SA and 96.2% in group RA (Fig. 2).

The number of re-LTs was 1 (2%) in group SA and 4 (7.5%) in group RA ($P = 0.364$). In group RA, two re-LT became necessary because of ischemic type biliary lesion 64 and 185 days after initial transplantation, respectively.

One patient in group RA developed a hepatic artery and portal vein thrombosis with a consecutive re-LT. In each group, a PNF has been the reason for two of the re-LT on postoperative day 3 and 4, respectively.

Postoperatively, there were significantly more major complications according to the Clavien classification grade 3 in group SA (26.5% vs. 9.4% in group RA, $P = 0.044$).

Table 5. Postoperative data.

	Group SA	Group RA	*P*-value
Rejection (biopsy proven)			0.168
Mild	9 (18.8%)	5 (9.4%)	
Moderate	3 (6.2%)	2 (3.8%)	
Severe	4 (8.3%)	1 (1.9%)	
Clavien classification			**0.044**
Grade 3	13 (26.5%)	5 (9.4%)	
Grade 4	6 (12.2%)	6 (11.3%)	
Re-LT	1 (2%)	4 (7.5%)	0.364
ICU stay (days)	8 (1–179)	4 (1–113)	**0.03**
Hospital stay (days)	40 (16–299)	25 (8–113)	**0.04**
One-year mortality (%)	5 (10.2%)	2 (3.8%)	0.256

SA, standard allocation; RA, rescue allocation; LT, liver transplantation; ICU, intensive care unit.
Bold values indicate significance.

Grade 4 complications were similar in both groups (group SA 12.2% and group RA 11.3%).

In group SA, the 1-year mortality rate was 10.2% compared to 3.8% in group RA ($P = 0.256$). Table 5 shows the postoperative data

Discussion

The purpose of our study was to investigate the postoperative difference between organs that were allocated via the RA procedure as opposed to the standard procedure.

Previous studies already indicated that not all EDC have the same relevance as their influence on the postoperative outcome varies significantly. Donor age, the degree of steatosis hepatis, and the cold ischemia time play a more important role than other EDC [6].

Raising the acceptable donor age is the most effective way to expand the organ pool [7]. However, until today, there is no conclusive data on the effect this increase might have on the postoperative outcome after LT. Some studies report on more rejection episodes, as well as biliary and vascular complications, while others could not show any differences compared to younger donors [8–12].

In our study, donor age was the most common EDC. A total of 25% of the donors were older than 65 years. However, we could not find any significant impact on the outcome after LT.

The histologically confirmed steatosis hepatis and its importance are also being discussed controversially. By analyzing 860 LTs, Salizzoni *et al.* have shown that even a macrovesicular steatosis of 15% results in an approximately 20% shorter graft and patient survival. This effect was aggravated if the CIT was longer than 10 h, the recipient was hepatitis C virus positive, or the donor age was >65 years [13].

A matched pair analyses from McCormack *et al.* on the other hand indicated that organs with 90% steatosis hepatis have a similar 60 days and 3-year mortality rate [14].

El-Badry *et al.* contend that the quantification of hepatic steatosis in histological sections is strongly observer-dependent and not reproducible [15]. This may explain the divergence among the published reports and should lead to the reconsideration of the reliability of microscopic confirmed steatosis hepatis.

We did not analyze the impact of steatosis hepatis as only in 40% of the grafts postreperfusion biopsies have been taken and no detailed evaluation of the grade and type (micro- and macrovesicular) of steatosis was available.

Cold ischemic time is not one of the EDC according to the German Medical Association as it is levied only retrospectively. However, the value for the outcome after transplantation is critical and often documented. In their analysis of 34 664 European Liver Transplant Registry LT patients, Burroughs *et al.* have shown that after a CIT of 13 h, the 3- and 12-months mortality rate rose significantly [16]. Pokorny *et al.* were able to show that a CIT >10 h and serum sodium >155 mmol/l came along with an increased risk of PNF [17].

Especially in the context of RA, a long CIT because of a complex organization is a common problem. The University Hospital Essen analyzed the data of 85 RA LT. Here, the average CIT was 14:46 hours [18]. Schrem *et al.* investigated 291 LT with an average CIT of 9:45 hours [2]. Schemmer *et al.* described a mean CIT of 10:18 hours in the RA procedure and 9:38 hours in the SA procedure [19].

In our study, the CIT in both groups was significantly lower than the published CITs. Although the organs allocated via RA often had been already explanted at the time of allocation, it was possible to significantly reduce the CIT because of regional allocation and a high degree of internal organization. On average, the CIT in group RA was under 7:30 hours and therefore even lower than in group SA.

Interestingly, it is of little impact on the current allocation practice whether organs fulfill EDC or not. ET organs are awarded either patient or center based. Reasons why organs cannot be allocated via the standard procedure are various and – unfortunately – often not documented. Retrospectively, it is not possible to evaluate whether an organ seemed to be untransplantable or the organ–patient combination was not favorable. In other cases, there are organizational reasons why organs cannot be allocated by the standard procedure.

Our study included 102 patients, 60 of whom received an extended criteria donor organ, fulfilling at least one EDC. This suggests that 45% of organs transplanted via SA were extended criteria donor grafts. A total of 52% of the

organs we have accepted and transplanted have been offered to us via RA.

The evaluation of the 1-year graft- and 1-year patient survival as well as the rate of re-LT showed no significant detriment of organs transplanted via the RA procedure. If the number of grade 3 complications, ICU, and total hospital stay are taken into consideration, there even was a significant benefit for the RA organs. When interpreting these results, it is important to consider the bias generated by the high urgency allocation and MELD score >38 which only occur in the SA group.

The findings of Schemmer *et al.* support our results. In comparison of 85 RA organs and 168 SA organs in the RA group, ICU and total hospital stay were significantly shorter than in the SA group. Based on the patient and graft survival, no significant difference was observed [2].

Our study implies that the center-based organ allocation according to institutional criteria, leads to equivalently good results and is therefore justified. The main difference between the two groups was that the patients in group RA have been healthier according to MELD criteria, whereas the donor organ quality has been nearly the same. It remains unclear, why for some organs, the allocation procedure has been changed from standard to RA. Therefore, a complete and detailed documentation of the discarding criteria should be mandatory. Furthermore, it would be of great importance if the EDC that have a direct impact on the postoperative outcome would also directly influence the organ allocation procedure.

Conclusion

The acceptance and subsequent allocation of RA organs according to institutional procedures is justified if donor and recipient are individually matched and the CIT is kept reasonably short by means of a considerably higher organizational effort.

Through the RA procedure, organs that have been rejected for transplantation several times can successfully be transplanted, thus enlarging the donor pool without causing negative effects on the quality of LT.

Authorship

AM: designed study, collected and analyzed data, wrote. SK, TFU and IT: collected data. LL: collected and analyzed data. UN: performed liver transplantation. CH: designed study and performed liver transplantation.

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