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ORIGINAL ARTICLE

Living donor liver transplantation in adults in the MELD era in Germany – a multi-center retrospective analysis

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Summary

The aim of this analysis was to provide an update on the current trend in living donor liver transplantation (LDLT) for adult recipients in the model of end stage liver disease (MELD) era in Germany and to encourage a wider implementation of LDLT. We descriptively analysed the data of LDLTs in Germany from 15 December 2006 to 31 December 2009 using a multi-center retrospective analysis via a questionnaire and data provided by Eurotransplant. Ten German centers performed LDLTs in adults. Eighty four transplantations in 50 male recipients and 34 female recipients were performed during the review period, ranging from 1 to 16 LDLTs per center. Hepatocellular carcinoma in cirrhosis (15/84) was the most common transplantation indication. The recipient mean lab-MELD score was 15 (±8). Six re-transplantations were necessary after initial LDLTs. The 1-year patient survival was 81%. We obtained data of 79/84 donors. The incidence of complications was 30.4% (n = 24). There were no grade 5 complications according to the Clavien classification. LDLT is an established treatment option that may reduce the waiting time, provides high quality split liver grafts and should be advocated in the MELD era to reduce organ shortage and 'death on the waiting list'.

Introduction

The number of patients on the waiting lists for liver transplantation is growing worldwide, and there is still a marked shortage of donor organs. In 2009, 2083 patients in Germany have been waiting for a liver. In the same year, only 1035 liver transplantations have been performed [1]. The organ allocation for livers according to the model of end stage liver disease (MELD) score within the Eurotransplant (ET) area, including Germany, was implemented on 15 December 2006. It was the aim to introduce a 'fair' and transparent allocation according to the 'sickest first' principle for this region. Initially, this has led to a reduction of mortality on the waiting list. Currently, however, more than two patients are newly placed on the waiting list for every post mortally donated

and transplanted organ in Germany. In the situation of a persisting organ shortage, there is still a need for alternatives to deceased donor organ donation. With a steady increase of elderly donors within the ET area and an overall increase of marginal donor organs (63% of donor organs have a donor risk index >1.5 [2]), an enlargement of the donor organ pool via 'splitting' is a very limited option [3]. Alterations in the current transplantation legislation with the introduction of an extended refusal regulation as well as the use of 'donation after cardiac death' are currently discussed in Germany to increase organ availability. Another option to enlarge the donor organ pool is liver transplantation from living donors (LDLT). This procedure is now also clinically established for adult recipients. As a result of the complexity of the logistics and the surgical technique as well as the higher donor morbidity, this procedure is performed with reservation in countries having an allocation system for deceased donor organs, in particular, when compared with donation for pediatric recipients for which only segments II/III are being used as donor grafts.

It was the aim of our investigation to provide a current status report of LDLT for adult patients since the introduction of organ allocation according to the MELD score in Germany. With this status report of all German centers performing living donor donation, we would like to discuss possible perspectives of the method for this region.

Patients and methods

Eleven of the 24 currently active centers in Germany maintain an LDLT program. Ten of these centers have been performing LDLT in adult recipients, and nine of these perform living donations for pediatric recipients. Assuming that by the implementation of organ allocation according to MELD, the proportion of patients dying during the waiting time on the waiting list would be reduced and, thus, the need for alternative methods of deceased donor organ transplantations would decrease, it was the aim to assess the role of living donations in adults in Germany overall and in the individual centers. We have obtained the data of donors and recipients from Eurotransplant via a questionnaire for the period from 15 December 2006 (implementation of the MELD allocation system) to 31 December 2009. These data were retrospectively analysed. Survival was calculated using the Kaplan–Meier method and converted into graphic illustrations.

From 15 December 2006 to 31 December 2009, a total of 84 LDLTs have been performed in the 10 participating centers in Germany. The range was between 1 and 16 transplantations per center. During this time period, a total of 3023 transplantations have been performed in adult recipients in Germany. Thus, the proportion of LDLTs amounts to 2.8%. According to the rules of organ allocation within the ET area, patients from the age of 16 years are considered to be adult recipients. Of these 84 patients, 50 were male and 34 were female recipients. The mean patient age was 48.8 (±4.5) years. The indications for transplantations are shown in Table 1. The proportion of patients with cryptogenic cirrhosis and primary sclerosing cholangitis (PSC) was higher among the living donations. Other indications for living donor liver donation include patients with other malignancies Klatskin tumors ($n = 2$) or metastatic livers from neuroendocrine tumors ($n = 2$), Budd–Chiari syndrome ($n = 3$), Caroli syndrome ($n = 1$), polycystic liver degeneration ($n = 1$), M. Wilson ($n = 1$) and familial amyloidosis ($n = 1$).

Table 1. Indications for liver transplantation – adult liver transplant recipients in Germany 15 December 2006 to 31 December 2009.

	Deceased donor donation ($n = 3023$)	Living donor donation ($n = 84$)
Alcoholic cirrhosis	1088 (36)	9 (11)
HCC in cirrhosis	605 (20)	15 (17)
HCV cirrhosis	423 (14)	9 (11)
Cryptogenic cirrhosis	363 (12)	14 (16)
PSC	181 (6)	10 (12)
Acute liver failure	121 (4)	3 (4)
HBV cirrhosis	91 (3)	8 (10)
Auto immune cirrhosis	91 (3)	3 (4)
other	60 (2)	13 (15)

Values within parenthesis are expressed in percentage. PSC, primary sclerosing cholangitis; HCV, hepatitis C virus; HBV, hepatitis B virus.

The mean lab-MELD score of all patients at the time of LDLT was 15 (±8). Seven patients had a lab-MELD ≥25. The time on the waiting list for patients without hepatocellular carcinoma (HCC) was 104 days (median) for living donation recipients. For comparison, the waiting time on the European waiting list was 81 days (mean) for recipients of deceased donor organs.

When comparing the waiting times of HCC patients, those who received a deceased donor organ waited 139 days (mean), whereas LDLT patients waited for 18 days (mean) for surgery. Liver transplantation from living donors was performed in 15 HCC patients. Of those, five (33%) were within the Milan criteria, and seven (47%) were beyond. No data could be retrieved for Milan criteria retrospectively from three (20%) patients.

LDLT was performed with identical blood types in 66 patients, with compatible blood types in 14 and with incompatible blood types in four patients. The right liver lobe was used most frequently [$n = 55$ (65%) without $n = 22$ and with the middle hepatic vein $n = 33$]. Seven (9%) recipients received a left liver lobe. The median graft-body-weight-ratio was 1.02 (0.9–1.24) (Fig. 1). The bile duct reconstruction was performed as a duct-to-duct

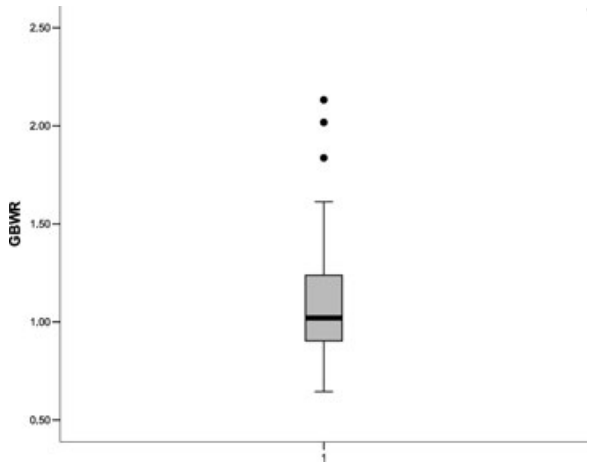


Figure 1 Graft-to-body-weight-ratio of donor organs.

anastomosis in 56 (67%) patients and as bilio-digestive anastomosis in 28 (33%). Statistical analyses were performed with SPSS 17, PASW Statistics 17.0, Version 17.0.2 (IBM, Armonk, NY, USA).

Results

Donor complications

We had obtained data from 79 of the 84 living donors for assessment. The donor age was 40.8 (±11.4) years. The hospital stay was 14 (±7.9) days. Hospital readmissions were not captured by the questionnaire, except for the occurrence of incisional hernias or re-operations for other reasons.

There was no mortality. Impaired liver function with development of transient or persistent liver failure was not observed.

There were 24 complications (30.4%) in 20/79 (25.3%) donors (Table 2). In five donors (6.3%), a reoperation was necessary (one arterial hemorrhage, one portal vein thrombosis, one bile leak, two other indications). Seven donors (8.9%) suffered from bile duct complications. These were treated conservatively in two patients, endoscopically in four patients and open surgically once. Impaired wound healing was observed in five (6.3%) patients, and was treated conservatively. Four (5.1%) donors developed an incisional hernia that was treated surgically.

Recipient complications

There were 98 postoperative complications in 45/84 patients (54%) (Table 3). Grade 1 complications were not captured by the questionnaire. The majority were Clavien 3b complications ($n = 53$) and they included 23 (44%) bile duct complications, four (7%) hemorrhages, six (11%) arterial complications, three (6%) venous complications, two (4%) portal-venous complications, as well as 15 (28%) reoperations for other indications.

The bile duct complications ($n = 41$) have been treated interventionally (CT-guided puncture and drainage or ERC) ($n = 18$, 44%) and by surgical revision ($n = 23$, 56%).

Sixteen of the 84 patients died (19%). The causes were septic multiple organ failure ($n = 6$), hemorrhage ($n = 4$),

Table 2. Postoperative complications in donors ($n = 24$ in 20/79; 25.3%).

Grade according to Clavien	Number	Special type	Number of specific complications
Grade 1	5 (21)	Impaired wound healing	5
Grade 2	4 (17)	Pneumonia	1
		Infection	1
		Bile leak	2
Grade 3a	4 (17)	Bile duct	4
Grade 3b	9 (37)	Arterial	1
		Portal-venous	1
		Bile leak	1
		Others	2
		Incisional hernia	4
Grade 4a	2 (8)	Pulmonary embolism	2
Grade 4b	0		
Grade 5	0		

Values within parenthesis are expressed in percentage.

Table 3. Postoperative complications in recipients ($n = 98$ in 45/84, 54%).

Grade according to Clavien	Number (%)	Specific type	Number of specific complications
Grade 1	Not specifically documented		
Grade 2	5 (5)	Bile leak	5
Grade 3a	18 (18.5)	Bile leak, endoscopic	18
Grade 3b	53 (54)	Bile duct	23
		Hemorrhage	4
		Arterial	6
		Venous	3
		Portal-venous	2
		other	15
Grade 4a	6 (8)	Re-transplantation	6
Grade 4b	Not specifically documented		
Grade 5 death	16 (16.5)	Multiple organ failure	6
		Hemorrhage	4
		Graft failure	2
		Pulmonary embolism	1
		No autopsy	3

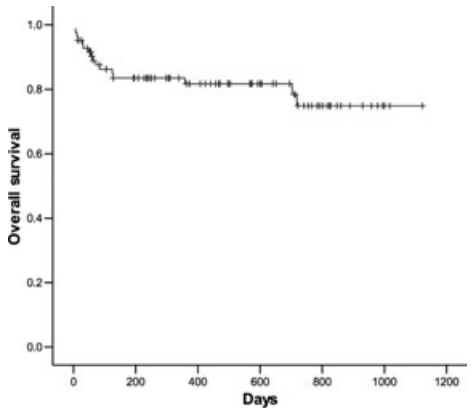


Figure 2 Patient survival after living donation in adults in Germany (transplantation 15 December 2006 to 31 December 2009).

graft failure ($n = 2$), and pulmonary embolism ($n = 1$). In three ($n = 3$) patients, no autopsy was performed.

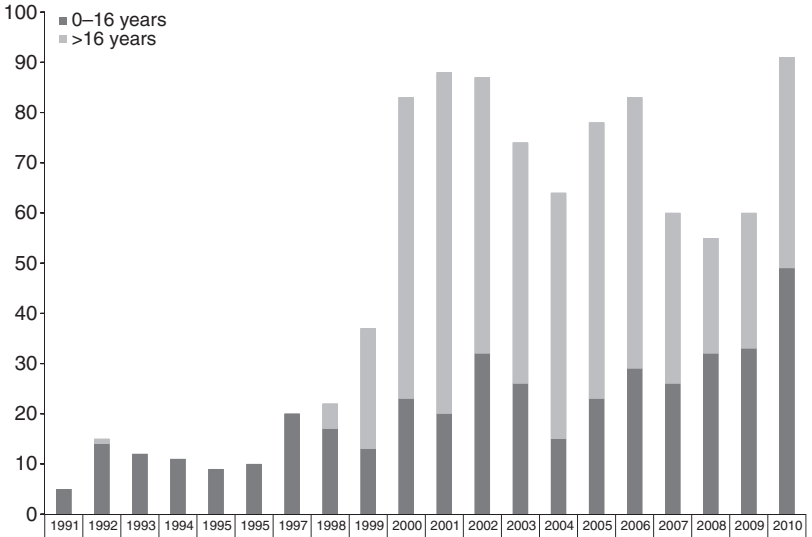
The 1-year patient survival according to the Kaplan–Meier method was 81% (Fig. 2). When separating patients with MELD ≥25 ($n = 7$) from those with MELD <25 ($n = 77$), the latter had a 1-year survival of 81% according to the Kaplan–Meier method. For patients with a MELD score ≥25, the 1-year survival rate was 71.4%.

Discussion

We now know from different international data collections that with living donation the best long-term outcomes are being achieved in pediatric patients (similar as with renal transplantation). This also becomes evident in adult recipients in regions where deceased donor transplantations and living donations are being performed (please refer to e.g. the ELTR report, references 5 and 8 of this paper). On the other hand, there is a risk for the donor. We in Germany had hoped that with the introduction of organ allocation according to MELD, the waiting times could be reduced, and the mortality on the waiting list could be decreased. This is reflected by the decreased numbers of living donations in the years 2007–2009. These hopes did not come true. Patients with low MELD are currently disadvantaged, and have to wait for the first deceased donor organ offer until they have reached a score that is associated with high short-term mortality. If LDLT can be offered with internationally comparable outcomes (as demonstrated in this article) living donation is an alternative option in particular for patients who are 'disadvantaged' by the MELD system and may be offered to these individuals. It was the intention to emphasize this political point with the German data presented in the article.

We have retrospectively analysed the outcomes of adult LDLTs in Germany from 15 December 2006 to 31 December 2009, i.e. since the implementation of organ allocation according to the MELD score. Through a questionnaire, we retrieved the most important data of the donors and recipients of the centers via ET. A comparison with outcomes from the current literature was intended. The outcomes of the transplantations and of the donor operations of the series during the observed period are similar to internationally reported data for adult recipients.

Since the introduction of LDLT by Raia *et al.* [4] 1988 until now, the method is worldwide clinically established



	1991	1992	1993	1994	1995	1995	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
>16 years	0	1	0	0	0	0	0	5	24	60	68	55	48	49	55	54	34	23	27	42
0–16 years	5	14	12	11	9	10	20	17	13	23	20	32	26	15	23	29	26	32	33	49

Figure 3 Number of LDLTs in children and adults in Germany from 1991 to 2010.

for children as well as for adult organ recipients. Living donations are performed in Germany since 1991. The numbers of annual transplantations in children and adults are shown in Fig. 3. LDLT is most frequently performed in Asian countries. Their role in North America and Europe is much smaller to date [5]. Furthermore, the number is currently decreasing in the western world. Although 10% of all transplantations from 2000 to 2002 were LDLTs, this number is currently approximately 3% [5,6]. What is the reason for this development? There are still considerable ethical and technical challenges of this procedure to be overcome. The method is appreciated differently in different countries and in regions with the possibility of organ donation from deceased donors, there is low inclination for living donation.

As reflected by the numbers from Germany (Fig. 3), many centers have obviously assumed that with the introduction of organ allocation according to MELD in December 2006, the need for living donations for the reduction of the organ shortage would no longer be that extensive. During the study period, the indication was essentially the same as that for recipients of organs from deceased donors. It has to be mentioned that German centers decide individually whether they transplant patients with e.g. HCC and a tumor burden beyond the Milan criteria for example with center offer or whether they generally reject these patients. This is also the case for patients with un-resectable hilar cholangiocarcinoma.

Several studies have found a comparable outcome of deceased donor liver transplantation and LDLT in adult recipients [7–9]. With careful evaluation and selection, the organ quality of recovered liver grafts is ideal. Furthermore, the procedure can be appropriately planned, and this is ideal for the implementation of multi-modal treatment concepts that may be part of the treatment.

The donor mortality of the more than 12 000 donor operations that have been performed worldwide so far is 0.2% for donations of the right liver lobe, and 0.1% for the donation of the left liver lobe [10,11]. The causes range from postoperative liver failure [10,11] to embolic complications. The complication rates vary according to centers, scope of recording, and postoperative surveillance period between 10% and 60% [12,13]. In Asia, where the majority of LDLTs worldwide is performed, the complication rates range from 9% to 28% [13]. Considering all reports, the average donor morbidity is currently approximately 35% [14].

The incidence of complications is higher for donations of the right liver lobe (Table 4) than for donations of the left liver lobe [10]. When comparing the reports in the literature, the complication rate decreases clearly with increasing experience [10]. Apart from early postoperative complications (up to 4 weeks after the donation), medium-term complications (up to 3 months after the donation) are sometimes differentiated from late complications [10]. The most frequent complications are bile duct complications. The bile leak originating from the parenchyma or the transection area of the bile duct is the leading early complication. Age, duration of surgery, and extended right split graft are risk factors for its occurrence

Table 4. Comparison of postoperative complications in donors for adult living donation recipients (in particular donation of the right liver lobe).

	Brown, USA, 2003 [21]* 1997–2000 (*n* = 449)	Lo, Asia, 2003 [23]* 1990–2001 (*n* = 554)	Hashikura, Japan, 2009 [11]* 1993–2006 (*n* = 1378)	Adcock, Toronto, 2010 [24] 2000–2008 (*n* = 202)	Ida, Kyoto, 2010 [10] 1990–2007 (*n* = 500)	Azoulay, Paris, 2010 [25] 2000–2009 (*n* = 91)	Germany, 2011* 2006–2009 (*n* = 79/84)
Hernia	n. i.	n. i.	n. i.	7 (3.5%)	1 (0.2%)	n. i.	4
Impaired wound healing	n. i.	26 (4.7%)	n. i.	5 (2.5%)	26 (5.2%)	2	1
Bile leak/stenosis	27 (6%)	34 (6.1%)	50 (3.6%)	7 (3.5%)	61 (12.2%)	13 (14.3%)	7 (8.9%)
Conservative				2	2		2
Interventional				4	55		4
Surgical				1	4		1
Other reoperation	20 (4.5%)	n. i.	n. i.	8 (3.6%)	3 (0.6%)	n. i.	4 (6.2%)
Pulmonary embolism	n. i.	3	n. i.	2 (1%)	6 (1.2%)	0	2
Liver failure	2 (0.44%)	0	n. i.	0	1 (0.2%) Indication for LT	2	0
Mortality	1 (0.2%)	0	1 (0.1%)	0	1 (0.2%)	0	0
Total morbidity	14%	155 (28%)	9.4%†	39.6%†	37%†	53 (47%)†	24 (30.4%)

LT, liver transplantation; n. i., no information.

*Multi-center assessment.

†Includes all grades according to Clavien.

[10]. In cases of extended donations and a complex bile duct anatomy, those authors recommend the placement of an external drainage that is being drained via the cystic duct. In most cases, bile leaks are treated interventionally (CT-guided drainage or decompression via ERCP). A reoperation is necessary only in rare cases (ultimately with construction of a bilio-digestive anastomosis). In our donor series, the incidence of complications that afforded interventional treatment was comparable to single-center or multi-center reports of other authors (Table 4).

The incidence of impaired wound healing and incisional hernias is in agreement with that after liver resection for other indications. Our questionnaire captured only early relevant somatic complications. Information about these possible complications should also be integrated into the discussion with potential donors and is, thus, of direct relevance for clinical practice.

The risk factor waiting time for a donor organ has be to individually weighed for deceased donation and living donation depending on the underlying disease. Depending on the specific situation of individual countries, the waiting time may be reduced to the time required for the evaluation of the donor and the recipient. This is an advantage compared with the allocation of deceased donor organs to elective recipients. A minimum waiting time for selection is occasionally recommended for patients with HCC to perform a transplantation only in patients with a good prognosis [15]. Half of our patients, who underwent transplantation for HCC in cirrhosis, were classified as beyond the Milan criteria. Our questionnaire did not obtain information as to whether this was known prior to the transplantations.

As our data show, many centers prefer the donation of the right liver lobe to obtain a sufficient amount of functional parenchyma. After careful evaluation, partial organs with excellent quality and very short ischemia time are always recovered from living donation. The question whether living donation is also an option for patients with impaired general condition is still under discussion. Initial reports recommended caution [16]. However, more recent data have demonstrated a good outcome for these patients too [17]. We confirm this observation in our series with relatively few patients ($n = 7$) having a MELD score ≥25. The average lab-MELD score of our LDLT recipients was markedly lower when compared with that of deceased donor organ recipients in Germany during the study period. During the waiting time for transplantation, on one hand a maturation process took place in the families and on the other hand, 'more suitable' recipients have been selected.

In our patients, the 1-year patient survival was 81% with a re-transplantation rate of 8%. This is in agreement with the reports from the literature (Table 5). The incidence of re-transplantations also depends on the local possibilities to recruit donor organs [18]. This means that in places where only living donation is being used, re-transplantation is less frequent for reasons of limited donor organ availability.

Septic multiple organ failure was the leading cause of death in our retrospective analysis. This has been reported in other series as well [18]. A super-infection of local biliary complications is the most frequent cause. This accounts also for the majority of postoperative complications. The rate ranges from 15% to 67% in duct-to-duct reconstructions [19]. Their incidence is higher than in transplantations of full-size organs. The reasons for this observation are compromised perfusion of the donor bile duct and the more complex anastomotic technique [19].

Table 5. Comparison of outcomes after living donation in adult recipients.

	Freise, USA, 2008 [20]* 1998–2003 ($n = 384$)	Lo, Hong Kong, 2004 [26] 1996–2002 ($n = 100$)	Kaido, Kyoto, 2009 [18] 1994–2007 ($n = 576$)	Maluf, Richmond, 2005 [27] 1998–2003 ($n = 69$)	Selzner, Toronto, 2010 [17] 2002–2008 ($n = 271$)	Germany, 2011* 2006–2009 ($n = 84$)
Mortality	34 (8%)	8 (8%)	18.9%	16%	n. i.	
Hospital				n. i.	10%	8 (9%)
1-year				21%		16 (18%)
Re-transplantation	35 (9.1%)	4 (4%)	n. i.†	4 (5.3%)	n. i.	6 (8%)
Bile duct complications	207 (54%)	27 (27%)	n. i.†	18 (26.1%)	21%‡	41
Vascular complications	34 (9.4%)	5 (5%)	n. i.†	n. i.	n. i.	9
Lab MELD	15	23	20	13.2	<25, ($n = 227$)	15
					>25, ($n = 44$)	

MELD, model of end stage liver disease; n. i., no information.

*Multi-center.

†No information with respect to the total population as only hospital mortality was assessed.

‡Intervention required.

Vascular complications, in particular, impaired venous drainage and arterial thromboses, respectively, are more frequent than with transplantations of full-size organs. Our data are in agreement with internationally reported data for the incidence of these complications. It is expected that peri-operative morbidity in Germany decreases with growing experience. This was also documented in other single-center and multi-center reports [20,21]. Each center develops its own expertise. Considering the current status of liver transplantation for adult recipients in Germany, the following statements can be made.

Since 15 December 2006, organs are being allocated according to the MELD score. The core underlying problem of scarce donor organs was not resolved with this measure. The organ allocation is only prioritized according to urgency. The initially anticipated reduction of mortality on the waiting list was also not accomplished. Other criteria, such as prospects of success (long-term survival, quality of life, long-term graft function) and equal opportunities, as spelled out in the German transplantation law (§ 13 chapter 3 TPG), are rendered secondary with this organ allocation principle.

The matched MELD values of the recipients who are currently transplanted have increased. Although at the start of the system, donor livers were allocated for a mean match MELD score of 25, the current score (September 2010) is 34. In patients with a lab MELD >30, survival is markedly reduced [22]. Thus, the 1-year graft/patient survival with a MELD score of 30–40 is 55%. Patient survival including re-transplantation is 63% and mortality is 37% (ET data for transplantations 2007 and 2008 in Germany) [2]. This observation may in part be explained by the quality of the deceased donor organs. Over the past 20 years, the average donor age of deceased donor liver donations within the ET area has increased from 26 years in 1990 to 53 years in 2009. The moderate increase of total numbers of liver transplantations over this period is thus to be assigned to an increased use of older donor organs. When compared with the USA United Network for Organ Sharing (UNOS), the quality of the donor organs used for liver transplantation within the ET area is markedly different measured as 'donor risk index' (DRI) [22]. Although only 32% of donor organs have a DRI >1.5, and only 6% >2 within the UNOS area, there are 63% of donor organs with a DRI >1.5 and 23% >2 [2]. Maintaining the organ allocation according to MELD for currently available donor organs and analyzing LDLT in adults, which is generally in agreement with the internationally reported data, it is recommended to further develop the method in Germany. As a result of the complex surgical procedure including the risk for the donor and the logistic provisions, it should perhaps not be performed in all centers.

In particular, patients with a low MELD who currently do not receive a deceased donor organ offer should be motivated to consider this option. A living donation may shorten the waiting time for a suitable organ and, thus, the risk of death on the waiting list following a rapid deterioration of the recipient or complications that are not MELD relevant may be reduced. Furthermore, optimal planning of the surgical procedure is possible.

Authorship

SU: designed study, analysed data, wrote paper. GM: designed questionnaire, collected data, analysed data. RA: collected data. BE: analysed data. SH: collected data. PG: collected data. BD: collected data. LF: collected data. FL: collected data. PA: collected data. SJ: collected data. NS: collected data. OA: collected data. HM: collected data.

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