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Optimization of surgical evaluation algorithms for living donor liver transplantation

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ABSTRACT

Background: Living donor liver transplantation (LDLT) is an established and endorsed alternative for deceased donor liver transplantation with better recipient outcomes. Nevertheless, while extensive evaluation of potential donors is crucial, evaluation algorithms differ between transplant centres and guidelines.
Methods: We included 317 individuals evaluated for LDLT between 07/2007–07/2022 in a retrospective analysis. The evaluation process was analysed to identify the key reasons for declining 77 potential donors. Additionally, 146 donors that underwent LDLT were analysed regarding risk factors for complications.
Results: The main reasons for donor refusal were liver volumetry (40.3 %) and metabolic factors including obesity or steatotic liver disease (20.8 %). Contrast-enhanced computed tomography (CECT) identified 63.6 % of all declined donors; CECT combined with assessment of medical history, physical examination, blood testing and ultrasonography, identified 87.0 % of declined potential donors. Associated with this selection, complication rates in donors were low (≥II in 17.1 %; none with ≥IVb). Notably, higher age was a risk factor for developing a complication ≥II after hemi-hepatectomy ($p = 0.0373$).
Conclusions: We propose a progressive 4-step evaluation algorithm that begins with a very basic assessment combined with up-front CECT. This early phase of testing is expected to identify nearly 90 % of ineligible donors, thereby conserving critical resources, time and money, as well as minimising burden for potential donors.
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1. Introduction

Organ shortage continues to be a major health issue, globally [1]. In addition to deceased donor liver transplantation (DDLT), living donor liver transplantation (LDLT) has become an established procedure that expands organ supply and gives patients the opportunity to identify a suitable donor, often being a relative, with better outcomes compared to DDLT [2–4]. Nevertheless, the proportion of LDLT compared to DDLT in Western Europa and the United States remains low [4–7].

Knowledge of donor liver volume is crucial, especially when planning the resection of an entire liver lobe. Before LDLT, the evaluation process must ensure that the donor keeps a sufficient remnant liver volume and that the recipient receives an adequate graft size [8]. Several guidelines recommend a remnant liver volume of at least 30 % in the donor and a transplant that accounts for at least 0.8 % of the body weight in the recipient to prevent a small-for-size syndrome [8–14]. These limits can be adjusted in individual cases, but should in general be applied due to otherwise significantly increased complication rates [8].

Since potential living liver donors are relatively healthy individuals, they are considered with great sensitivity by a transplant team because of the “do no harm principle”. For reasons of donor protection, an extensive evaluation is carried out to protect potential donors from avoidable complications [8,15]. In parallel, it must of course be ensured that the liver is suitable for transplantation. The suitability evaluation of potential donors must include assessment of a multitude of parameters to reveal possible

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contraindications [8,15]. The algorithms applied vary between different centres and guidelines [8–10,16]. Most evaluations are performed with increasing invasiveness to protect unsuitable donors from avoidable risks. Thus, orientating interviews with physical examination and abdominal ultrasound as well as blood and urine tests are carried out first. The potential donor is then assessed for cardiovascular, psychiatric and gynaecological or urological comorbidities. Further examinations are performed on potential donors with risk factors. Finally, mostly invasive examinations are carried out, including sectional imaging as contrast-enhanced computed tomography (CECT) to visualise the anatomy of the liver vessels and also to volumetrize the potential liver graft and the remnant liver tissue. To exclude bile duct variants, magnetic resonance imaging (MRI) should also be conducted, which includes contrast-enhanced cholangiopancreatography (MRCP).

Therefore, we asked whether the critical investigations that quickly lead to the refusal of a potential donor are conducted too late in the evaluation process, which then results in an unnecessary medical and economic burden. For that, we retrospectively analysed all individuals that were evaluated for LDLT at the University Hospital Regensburg between July 2007 and July 2022 and identified the factors and diagnostic steps responsible for declining a potential donor. We then analysed the outcomes after successful LDLT to assess the effectiveness of the evaluation process.

2. Methods

2.1. Study population and design

All individuals at the University Hospital Regensburg were identified that underwent evaluation for LDLT between July 2007 and July 2022 using the ICD-10 codes for “living donor” and “assessment of a potential organ or tissue donor” as well as the procedure classification for LDLT. After exclusion of misclassified living kidney donations and bone marrow donors, 317 eligible potential donors were included in this study. All research was conducted in accordance with both the Declarations of Helsinki and Istanbul. The retrospective study was authorized by the Ethics Committee of the University of Regensburg (approval number 13–257_5–101).

2.2. Study analysis

All data collection was performed using the clinic’s patient database. Each potential donor was treated according to local standards. The in-house evaluation checklist was adapted from the national guideline [8].

After identification of individuals evaluated for LDLT, all diagnostic procedures and blood and urine tests were collected. Decision of evaluation, leading causes and the responsible diagnostic procedure for initial detection were either collected from the medical discharge letter, the conclusion of the LDLT commission or the examination reports. The body mass index (BMI) is defined as weight (kg) divided by the square of height (m). Overweight begins at a BMI of 25 kg/m^2. Examination costs were obtained via the clinic’s accounting department.

Details about the surgery were extracted from the surgery reports. Surgery-related complications were extracted from the medical discharge letters and the letters from the outpatient clinic and graded following the Clavien-Dindo classification [17]. Grade I includes any deviation from the normal postoperative course. Several drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes as well as physiotherapy and opening wounds at bedside are allowed within treatment of grade I complications. Grade II includes further pharmacological treatment. Grade III compasses interventions, either with (IIIa) or without (IIIb) general anaesthesia.

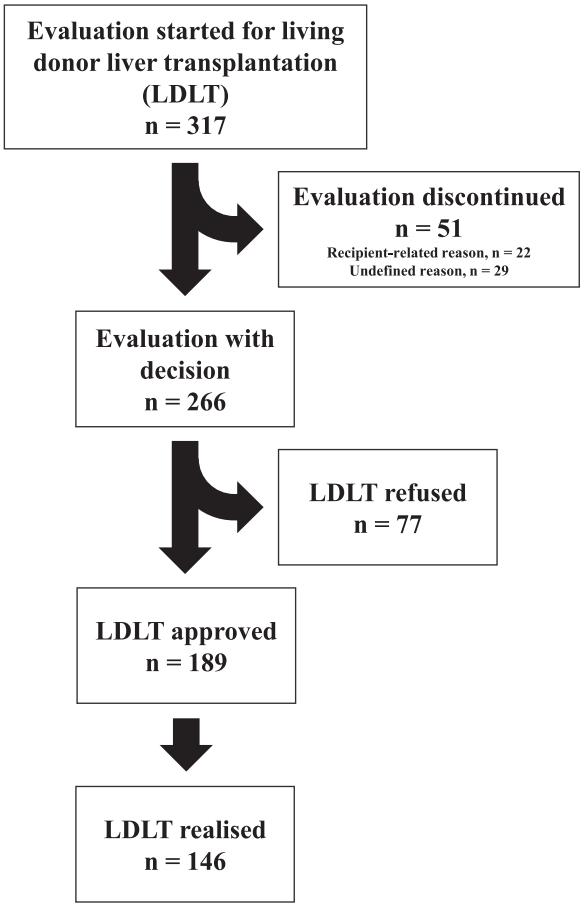

Fig. 1. Flow chart demonstrating the study cohort.

Grade IV compasses life-threatening complications requiring intensive care management. Here, grade IVa includes dysfunction of a single organ and IVb multi-organ dysfunction. Death of a patient is graded as V.

2.3. Statistics

GraphPad Prism v10 (Boston, USA) and IBM SPSS v29 (Armonk, USA) were used for statistical analysis. Tests were performed as indicated in the text or in the respective figure and table legends. A p-value below 0.05 was considered statistically significant.

3. Results

3.1. Outcome of evaluation for LDLT

Of 317 individuals being evaluated for LDLT, 51 (16.1 %) had their evaluation discontinued (see Fig. 1). Of those, 22 were discontinued due to recipient-related reasons and for 29 the reason was not documented. In 266 potential donors (83.9 %), the evaluation process was completed and resulted in a decision pro LDLT in 189 (71.1 %) or contra LDLT in 77 (28.9 %), representing 59.6 % and 24.3 % of all evaluated individuals, respectively. Of 189 approved donors, 146 (77.2 %) finally underwent LDLT, corresponding to 46.1 % of the study population.

3.2. General differences between approved and declined individuals

The gender distribution was similar in both groups, with women accounting for 50.8 % in approved and 55.8 % in declined

Table 1
General characteristics of the evaluated potential donors. Groups were compared using Fisher's Exact Test or Mann-Whitney Test.

	Approved (n = 189)	Declined (n = 77)	p-value
Sex, n ♂/♀	93/96	34/43	0.4997
Age, mean years (95 % CI)	37.18 (35.78 - 38.58)	41.78 (39.29 - 44.27)	**0.0024**
Height, mean cm (95 % CI)	172.6 (171.2 - 174.0)	171.6 (169.6 - 173.5)	0.4391
Weight, mean kg (95 % CI)	74.99 (72.96 - 77.02)	81.52 (76.97 - 86.07)	**0.0165**
BMI, mean kg/m^2 (95 % CI)	25.06 (24.57 - 25.56)	27.67 (26.27 - 29.07)	**0.0027**
Relationship of the donor			
Parent, %	66.7	49.3	**0.0145**
Sibling, %	5.8	14.1	**0.0400**
Child, %	5.8	12.7	0.0723
Grandparent, %	6.4	4.2	0.7660
Distant blood relationship, %	4.2	4.2	> 0.9999
No blood relationship, %	10.6	15.5	0.2876

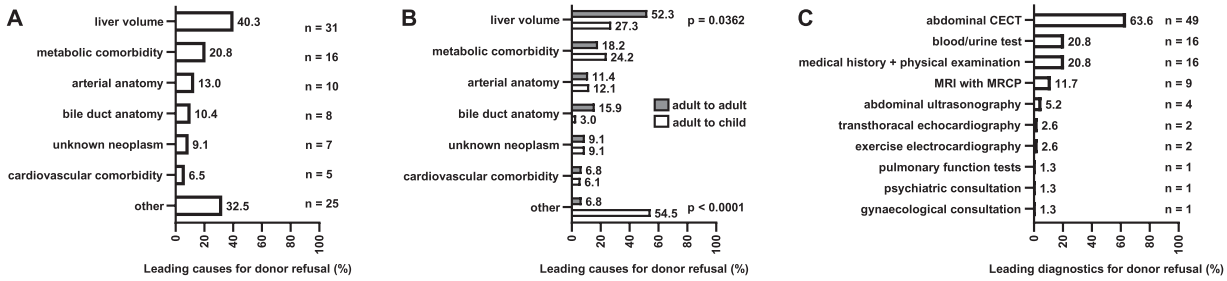

Fig. 2. **(A)** Leading reasons for declining potential donors **(B)** divided into adult and paediatric recipients. Groups were compared using Fisher's Exact Test. **(C)** Leading diagnostics for declining potential donors. Abbreviations: CECT = contrast-enhanced computed tomography, MRI with MRCP = magnetic resonance imaging with cholangiopancreatography.

individuals (see Table 1). Of interest, potential donors being declined were significantly older (37.2 vs. 41.8 years, $p = 0.0024$) and had a higher body weight (75.0 vs. 81.5 kg, $p = 0.0165$) and BMI (25.1 vs. 27.7 kg/m^2, $p = 0.0027$). When taking the relationship of the potential donor to the recipient into account, as expected especially in the paediatric cases, most donors were either mother or father of the recipient; they were approved for donation more frequently (66.7 % vs. 49.4 %, $p = 0.0145$). Siblings were less likely to be suitable donors (5.8 % vs. 14.1 %, $p = 0.0400$); children also tended to be less suitable (5.8 % vs. 12.7 %, $p = 0.0723$). No appreciable difference was observed with grandparents (6.4 % vs. 4.2 %, $p = 0.7660$) or more distant blood relationship (4.2 % vs. 4.2 %, $p > 0.9999$). 10.6 % vs. 15.5 % ($p = 0.2876$) of potential donors were not related to the recipient by blood.

3.3. Reasons for decline of potential donors

Potential donors were evaluated following an in-house algorithm, which was closely adapted to current guidelines. Of the 77 individuals that were refused during the evaluation process, the main reason was the liver volume (31 individuals, 40.3 %), either due to insufficient future remnant liver volume for the donor or a substantial risk for the recipient developing a small-for-size syndrome (see Fig. 2A). In over a fifth of cases (16 individuals, 20.8 %), metabolic comorbidities were the main reason for declining the potential donor, especially obesity, steatosis or arterial hypertension. In 10 (13.0 %) and 8 individuals (10.4 %), unsuitable arterial and bile duct anatomy, respectively, were the reason for declining liver donation. In 7 potential donors (9.1 %), the diagnostic procedures revealed unknown potentially malignant lesions, which led to a discontinuation of the evaluation process. In 5 cases (6.5 %), cardiovascular comorbidity was the main reason to refuse the potential donor. Of note, 20 individuals (26.0 %) were refused for at least two different reasons.

3.4. Different reasons for declining potential donors for adults and for children

Of 77 refused donors, 33 (42.9 %) were evaluated for donation to a child. Notably, as shown in Fig. 2B, insufficient liver volume was less often the decisive reason for refusal than for potential adult donors (27.3 % to 52.3 %, $p = 0.0362$). In more than half of paediatric cases (54.5 % to 6.8 %, $p < 0.0001$), various non-frequent reasons led to declining the potential donor. Especially alcohol and nicotine abuse were crucial reasons in the paediatric subgroup (12.1 % to 0.0 %, $p = 0.0302$)

3.5. Essential diagnostic steps for donor refusal

As shown in Fig. 2C, liver anatomy-related issues were identified as the most important categorical reason for being declined. Next, we analysed the diagnostic steps that in the end determined the denial of the individual for donation. In almost two-thirds of cases (49 individuals, 63.6 %), the reason was a finding in the abdominal CECT. Far less frequently, other crucial diagnostic steps included blood tests (16 individuals, 20.8 %), medical history with physical examination (16 individuals, 20.8 %), MRI with MRCP (9 individuals, 11.7 %) and abdominal ultrasonography (4 individuals, 5.2 %). In 7 cases (9.1 %), evaluation was discontinued due to other diagnostic steps, each of which accounted for less than 5 %. Notably, 21 potential donors (27.3 %) were denied due to findings from at least two different examinations.

3.6. Complications after LDLT following the evaluation process

Next, to assess the impact of the extensive evaluation process, we analysed all 146 individuals that finally underwent living liver donation (see Table 2). In general, the rate of surgery-related complications was low, with a total of 45 events in 25 patients

Table 2
Grade and type of surgery-related complications classified by Clavien-Dindo.

Grade of complications, n (%)	$n = 146$
I	16 (11.0)
II	10 (6.8)
IIIa	7 (4.8)
IIIb	10 (6.8)
IVa	2 (1.4)
IVb	0 (0)
V	0 (0)
Type of complications, n (%)	
Impaired wound healing	8 (5.5)
Bile leakage	6 (4.1)
Cholangitis	5 (3.4)
Hernia	4 (2.7)
Seroma/haematoma	4 (2.7)
Vascular stenosis	4 (2.7)
Cholestasis	3 (2.1)
Burst abdomen	2 (1.4)
Portal vein thrombosis	2 (1.4)
Abscess	1 (0.7)
Adhesive ileus	1 (0.7)
Ascites	1 (0.7)
Atrophy of liver subsegment	1 (0.7)
Biliovenous fistula	1 (0.7)
Intraductal haematoma	1 (0.7)
Pancreatitis	1 (0.7)

(17.1 %). Following the Clavien-Dindo classification, 16 events (11.0 % of all donations) were classified as grade I, 10 (6.8 %) as grade II, 7 (4.8 %) as grade IIIa, 10 (6.8 %) as grade IIIb and 2 (1.4 %) as grade IVa. No grade IVb and V complications were registered.

The most common complications were impaired wound healing (8 events, 5.5 %), bile leakage (6 events, 4.1 %), cholangitis (5 events, 3.4 %), hernia (4 events, 2.7 %), seroma/haematoma (4 events, 2.7 %), vascular stenosis (4 events, 2.7 %), cholestasis (3 events, 2.1 %), burst abdomen (2 events, 1.4 %), and portal vein thrombosis (2 events, 1.4 %). Only 1 event each (0.7 %) was registered for abscess, adhesive ileus, ascites, atrophy of liver subsegment, biliovenous fistula, intraductal haematoma and pancreatitis. Of the 2 patients with a complication grade IVa, 1 patient was treated due to acute liver failure caused by a portal vein thrombosis and 1 patient developed a biliovenous fistula. In this patient, cardiopulmonary resuscitation was necessary, mostly likely due to air or bile embolism.

By classifying the patients by their complication with the highest-grade (see Table 3), we divided them into two groups (130 patients with either no or grade I complications vs. 16 patients with grade ≥II complications). The groups did not differ in terms of gender (proportion of females 53.8 % vs. 56.3 %, $p < 0.9999$) and BMI (24.8 % vs. 25.6 %, $p = 0.3479$). Differences were detected when analysing age (36.4 vs. 43.9 years, $p = 0.0093$), duration of surgery (256.8 vs. 300.7 min, $p = 0.0014$), weight of transplant (391.0 vs. 581.4 g, $p = 0.0134$) and type of liver resection (proportion of hemi-hepatectomies 28.5 % vs. 68.8 %, $p = 0.0032$).

By dividing the donors into two groups [48 patients (32.9 %) that donated either the right or left liver lobe and 98 patients (67.1 %) only donating the left lateral liver lobe] and analysing the ≥II complications depending on the surgery performed, a very low complication rate was observed in donors having only the left lateral liver lobe resected [5 patients (5.1 %)], compared to patients after hemi-hepatectomy [11 (22.9 %)].

As serious complications occurred rarely in the group with minor liver resection, no risk factors could be detected between the groups. In patients with major liver resection, a higher age was a risk factor for developing complications ≥II (39.4 vs. 47.6 years, $p = 0.0373$).

4. Discussion

Preparation for LDLT involves an extensive process in which some potential donors are identified as having issues that may ultimately make them unsuitable for donation. It is therefore particularly important to carry out the tests that identify these issues at an early stage to protect the potential donor from unnecessary procedures and at the same time to save resources. In our study, an analysis of living donor evaluations at our transplant centre revealed that nearly 9 out of 10 ultimately declined liver donors were identified by CECT, assessing metabolic factors and performing very basic examinations, with good surgical outcomes for the donors. From this experience, we designed a specifically-ordered algorithm that prioritizes these specific tests up front to rule out non-suitable donors early in the process.

It was recently shown, that living donors show poorer outcomes than comparable healthy individuals [18]. It is therefore essential to continuously optimize the evaluation process. Simultaneously, a study demonstrated that LDLT provides better outcomes for the recipients and utilizes fewer resources, which makes it an essential component in never-ending times of organ shortage [4].

Due to our comprehensive evaluation, peri– und postoperative complications are rather low. A study analysing adult LDLT showed an overall complication rate of 19.5 %, compared to 17.1 % patients in our study [4]. Another study revealed an overall complication rate of 19.8 % and major complications (≥IIIa) occurring in 4.4 % [16]. In our study, 10 patients (6.8 %) developed a complication ≥IIIa. Although not a true comparison since liver donors are relatively healthy, it is notable that a global liver surgery study revealed a complication rate of 42.2 % for all liver resections [19]. Therefore, LDLT is a comparatively safe procedure for the donor, even if a complete liver lobe is resected. Older donors were associated with a higher rate of complications in our study; interestingly, this was not observed in a large study from the United States, but they did observe worse recipient and graft survival with increasing donor age [20].

Over 15 years, a total of 317 individuals were included in our study for evaluation for LDLT. During the process, 77 potential donors were declined for LDLT. Notably, these individuals were substantially older and had a higher BMI. At the same time, parents were more likely to be accepted for donation versus declined; the outcomes were different for siblings, who were declined more frequently. Some related aspects are worth discussing. On one hand, our study includes two different populations - with individuals who intend to donate only the left lateral part of the liver or alternatively, individuals who are evaluated for donation of an entire liver lobe. This explains why parents were approved more often, as a smaller part of the liver is donated to an infant. Here, the aspect of remnant liver volume plays a subordinate role compared to a hemi-hepatectomy. In contrast, older potential donors and siblings are usually adults who donate for adults. On the other hand, the increased BMI in declined donors confirms the relevance of metabolic factors such as steatotic liver disease (SLD) in the evaluation for LDLT, emphasising the importance of comprehensive SLD diagnostics and the demand for reliable non-invasive markers [21,22].

Notably, our transplant centre performs a high frequency of paediatric liver transplantations. The results of our study must therefore be interpreted with regard to the composition of the recipients at the respective centre. Furthermore, our study involved patients over a long period of 15 years, thus the evaluation procedure and surgical techniques presumably changed during the study period.

It is remarkable that sectional imaging helped to identify the cause in three-out-of-four declined donors. This mostly followed a volumetry assessment that indicated a remnant liver volume or

Table 3
Risk factors for surgery-related complications. Groups were compared using Fisher's Exact Test or Mann-Whitney Test.

All procedures	total (n = 146)	≤ grade I (n = 130)	≥ grade II (n = 16)	p-value
Sex, n ♂/♀	67/79	60/70	7/9	> 0.9999
Age, mean years (95 % CI)	37.22 (35.54–38.90)	36.40 (34.67–38.13)	43.88 (38.16–49.59)	**0.0093**
BMI, mean kg/m^2 (95 % CI)	24.84 (24.28–25.40)	24.75 (24.15–25.34)	25.61 (23.85–27.37)	0.3479
Duration of surgery, mean min (95 % CI)	261.6 (251.7–271.6)	256.8 (246.5–267.2)	300.7 (271.6–329.8)	**0.0014**
Weight of transplant, mean g (95 % CI)	411.3 (368.5–454.0)	391.0 (348.4–433.6)	581.4 (403.0–759.8)	**0.0134**
Procedure, n hemihepatectomy/left lateral resection	48/98	37/93	11/5	**0.0032**
Donation of right or left lobe	total (n = 48)	≤ grade I (n = 37)	≥ grade II (n = 11)	p-value
Sex ♂/♀	28/18	23/12	5/6	0.2963
Age, mean years (95 % CI)	41.27 (37.85–44.70)	39.38 (35.41–43.34)	47.64 (41.38–53.89)	**0.0373**
BMI, mean kg/m^2 (95 % CI)	25.61 (24.66–26.56)	25.56 (24.49–26.62)	25.78 (23.33–28.24)	0.7994
Duration of surgery, mean min (95 % CI)	301.4 (281.2–321.6)	297.3 (272.7–321.9)	315.2 (279.6–350.8)	0.3105
Weight of transplant, mean g (95 % CI)	729.9 (657.5–802.3)	726.3 (645.7–807.0)	742.1 (546.3–937.9)	0.9068
Donation of left lateral lobe	total (n = 98)	≤ grade I (n = 93)	≥ grade II (n = 5)	p-value
Sex ♂/♀	38/60	36/57	2/3	> 0.9999
Age, mean years (95 % CI)	33.88 (32.30–35.45)	33.77 (32.17–35.38)	35.60 (23.80–35.45)	0.7294
BMI, mean kg/m^2 (95 % CI)	24.47 (23.78–25.17)	24.43 (23.71–25.15)	25.23 (21.87–28.60)	0.4577
Duration of surgery, mean min (95 % CI)	242.2 (233.2–251.1)	240.7 (231.6–249.8)	268.8 (209.0–328.6)	0.1820
Weight of transplant, mean g (95 % CI)	266.7 (255.5–277.9)	267.1 (255.3–278.8)	260.0 (222.4–297.6)	0.8962

graft size, which was assessed as too small in 40.3 % of the declined cases. As expected, liver volumetry was less likely to be decisive in paediatric cases. In addition, in more than 10 % of cases each, the arterial and biliary anatomy was found to be too complex and therefore an increased risk for perioperative complications. In additional cases, CECT identified suspect lesions that were later proven to be malignant. Since this part of the evaluation is typically performed in the final stages of the evaluation process, we now question whether this sequence is optimal. Notably, the assessment of the cardiopulmonary, psychiatric and gynaecological or urological status was only decisive for 1–2 donor denials, each. It can be argued that CECT examinations are associated with radiation exposure for the potential donor and that both CECT and MRI examinations are associated with high costs and expenditure, as well as adverse reactions by administration of contrast agents [23,24]. However, long, exhausting and mentally stressful evaluation processes burden potential donors that might have been clearly declined early on in the process. Additionally, in cases where donors can be declined early on, this leaves more time to search for a better donor, especially in situations where the potential recipient is in urgent need of a transplant.

Therefore, we propose a progressive 4-step model in Fig. 3, which represents a recommendation for the evaluation of potential donors for LDLT by taking the examination's invasiveness, cost, complexity and availability into account. Future studies have to be conducted to prospectively assess the utility of the algorithm:

- In step 1, general suitability should be assessed by analysing the potential donor's medical history and performing a physical examination with laboratory tests. In addition, an abdominal sonography with elastography should be performed to identify risk constellations at an early stage. In this phase, it must be determined how the further evaluation will proceed, and if there are indications for performing a colonoscopy or liver biopsy. Twenty-three patients (29.9 %) of our study were refused with step 1, resulting in avoided examination costs of up to €3945 each.
- In step 2, remnant liver volume, size of transplant and vascular anatomy of the liver should be assessed by CECT. With this, vascular variations that are prone to complications must be identified and a residual liver volume of at least 30 % of the total liver volume and a transplant of at least 0.8 % of the recipient's weight must be ensured. Sixty-seven patients (87.0 %) of our study were refused with step 2, resulting in avoided examination costs of up to €3045 each.

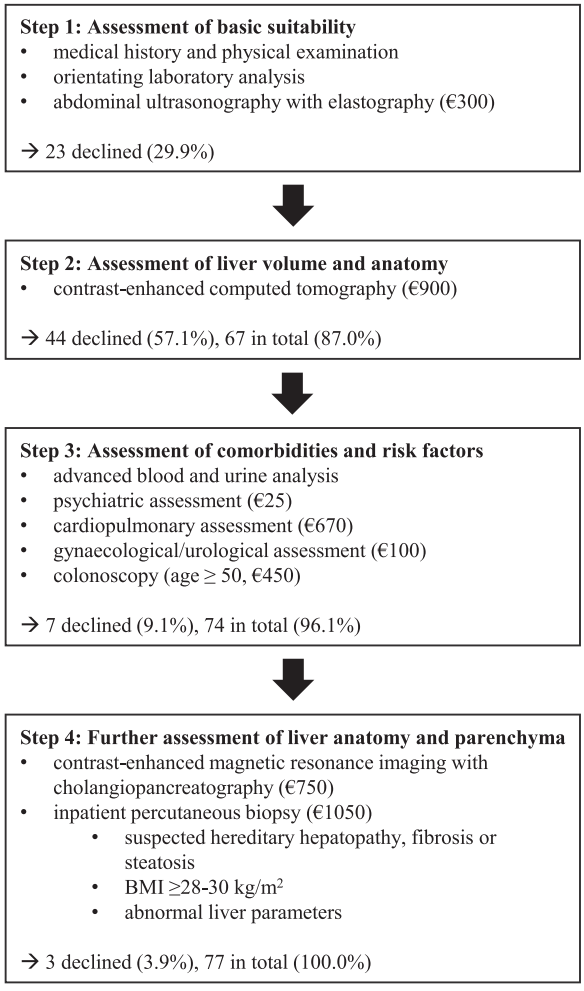

Fig. 3. Proposed 4-step algorithm to optimize the LDLT evaluation for potential donors.

- In step 3, the specific state of health, operability and risk factors are assessed by comprehensive laboratory analysis and the step-by-step evaluation of psychiatric, cardiovascular and gynaecological or urological comorbidities and malignancies, including colonoscopy in risk constellations. Seventy-four patients

(96.1 %) of our study were refused with step 3, resulting in avoided examination costs of up to €1800 each.

- Step 4 involves additional invasive or costly and time-consuming examinations to further determine the liver anatomy and, if necessary, the liver parenchyma. Here, MRI with MRCP should be performed to especially determine bile duct variants. In cases of suspected hereditary liver disease, fibrosis or steatosis of the liver, a BMI from 28 kg/m^2 and a still unclear increase in liver enzymes, liver biopsy should follow.

5. Conclusion

LDLT provides an excellent alternative to alleviate the current organ shortage, owing to the low complication rates affecting the donor. To optimise the assessment of potential donors, we propose a progressive 4-step algorithm, which our study shows identified nearly 9 out of 10 declined donors early in the evaluation process.

Author contributions

P.K. collected and analysed data, drafted figures, and wrote the manuscript; V.S. collected and analysed data; L.A.S., I.D., L.S.K., M.G., E.K.G. and H.J.S. provided clinical feedback; J.M.W. conceived the study, analysed data, and edited the manuscript. All authors agreed to submit the manuscript, read and approved the final draft and take full responsibility for its content, including the accuracy of the data and its statistical analysis.

Data sharing statement

All data presented within the manuscript are available upon request from the corresponding author.

Conflict of interest

The authors have no conflicts of interest to declare.

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