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Normal Intraoperative Indocyanine Green Plasma Disappearance Rate Excludes Primary Non-Function after Liver Transplantation

Lars C Pietersen[1], Marije Reekers[2], Hein Putter[3], Maarten E Tushuizen[4], Willemijn N Nijboer[1], Ian PJ Alwayn[1], Bart van Hoek[4] and Andries E Braat[1]*

[1]Department of Surgery, Leiden University Medical Center, The Netherlands

[2]Department of Anesthesiology, Leiden University Medical Center, The Netherlands

[3]Department of Medical Statistics, Leiden University Medical Center, The Netherlands

[4]Department of Gastroenterology and Hepatology, Leiden University Medical Center, The Netherlands

Abstract

Background: In Liver Transplantation (LT) early detection of postoperative graft failure may facilitate timely listing for retransplantation. Unfortunately, no simple and specific early predictor of graft failure is currently available. The aim of this study was to evaluate intraoperative Indocyanine Green Plasma Disappearance Rate (ICG-PDR) directly following complete reperfusion as a predictor for Primary Non-Function (PNF) and one-month graft survival in LT.

Methods: Between January 2010 and May 2017, ICG-PDR measurement was performed intraoperatively immediately following complete arterial and portal reperfusion in all orthotopic LTs performed in a single center (n=197).

Results: LTs with an intraoperative ICG-PDR <18%/min had significantly lower one-month graft survival (87%), compared to LTs with intraoperative ICG-PDR ≥ 18%/min (94%) (Logrank p=0.04). Furthermore, none of the liver grafts with an intraoperative ICG-PDR ≥ 18%/min developed PNF, versus 10% of the liver grafts with an intraoperative ICG-PDR <18%/min (p<0.001).

Conclusion: low intraoperative ICG-PDR (ICG-PDR <18%/min) is a significant risk-factor for one-month graft failure and primary non-function, while normal intraoperative ICG-PDR excludes PNF.

Keywords: Indocyanine green; Liver transplantation; Graft survival; Primary non-function; Retransplantation

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Correspondence:
Lars C Pietersen, Department of Surgery, Leiden University Medical Center, 22333 ZA Leiden, The Netherlands, Tel: +31-71-5266188; E-mail: L.C.Pietersen@lumc.nl

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Abbreviations

LT: Liver Transplantation; ICG-PDR: Indocyanine Green Plasma Disappearance Rate; PNF: Primary Non-Function; LUMC: Leiden University Medical Center; labMELD: Laboratory Model for End-Stage Liver Disease; ET-DRI: Eurotransplant Donor Risk Index; DRM: Donor-Recipient Model; sRRI: Simplified Recipient Risk Index; BAR: Balance of Risk; TPCS: Temporary Portocaval Shunt; IPR: Initial Portal Reperfusion; IAR: Initial Arterial Reperfusion; INR: International Normalized Ratio; SD: Standard Deviation; IQR: Interquartile Range; CIP: Cold Ischemic Period; DCD: Donation After Cardiac Death

Introduction

Liver Transplantation (LT) is the treatment of choice for end-stage liver disease. In case of irreversible graft failure, retransplantation is the only viable treatment option. Retransplantion rates vary between 5% and 22% worldwide [1-3] and re-LT has repeatedly been associated with lower survival rates compared to first LT [4-9]. To timely list a patient for re-LT early detection of graft failure is crucial. Unfortunately, no simple and specific early predictor of graft failure is currently available [10]. Intraoperative Indocyanine Green Plasma Disappearance Rate (ICG-PDR) has been proposed as a tool to predict short-term graft outcome in LT. It both reflects liver perfusion and hepatic metabolism. Currently ICG-PDR is the most widely used quantitative liver function test in patients undergoing liver surgery [11]. Normal ICG-PDR values range from 18%/min to 30%/min

[12-16] and hepatic failure is generally said to occur with an ICG-PDR <18%/min [14,17].

Several studies have reported early postoperative ICG-PDR measurement to be closely associated with overall mortality and graft function after LT [18-22]. Little is known about the value of early intraoperative ICG-PDR measurement immediately following reperfusion. Only two previous retrospective studies have reported late intraoperative ICG-PDR measurement (60 min after reperfusion and at the end of surgery) could predict absence of early postoperative complications in LT [23,24].

Therefore, the aim of this study was to evaluate whether intraoperative ICG-PDR measurement, directly following complete reperfusion of the liver graft, could Predict Primary Non-Function (PNF) and one-month graft survival in LT.

Materials and Methods

Between January 2010 and May 2017, all LTs at the Leiden University Medical Center (LUMC), Leiden, the Netherlands, underwent intra-operative ICG-PDR immediately after complete (both portal and arterial) reperfusion and were included in this study. Recipients who received a split or auxiliary LT were excluded from analysis. Clinical information was obtained from a prospectively collected database with consecutive patients. Covariates included donor demographics, recipient demographics, pretransplant information, intraoperative data, and postoperative outcome. Laboratory Model for End-Stage Liver Disease (labMELD) scores was included in the recipient analysis. If necessary, the original patient notes were reviewed for missing information.

The Eurotransplant Donor Risk Index (ET-DRI), Donor-Recipient Model (DRM), simplified Recipient Risk Index (sRRI) and Balance of Risk (BAR) score were calculated as described previously [25-27].

Operative techniques recipient surgery

LT was performed as previously described [28]. In brief, caval anastomosis was performed in a side-to-side manner [29]. LT was either performed with or without a Temporary Portocaval Shunt (TPCS). Initial perfusion was either done by Initial Portal Reperfusion (IPR) or by Initial Arterial Reperfusion (IAR). Finally, biliary reconstruction was performed, preferably using duct-to-duct anastomosis.

ICG measurement

Measurements of ICG-PDR were performed immediately after complete (both portal and arterial) reperfusion of the liver graft in all recipients included. Pulse dye densitometry was performed using the DDG-2001 A/K (Nihon Kohden, Tokyo, Japan). Each measurement was initiated by the intravenous administration of 10 mg ICG (Infracyanine®) through a large central venous catheter, followed by a rapid bolus of 20 ml of saline. The transcutaneous measurement of ICG was performed using the finger probe, as described earlier [30]. Since hepatic failure is generally said to occur below an ICG-PDR measurement of 18%/min [14,17] this value was used as cutoff for lowered and normal ICG-PDR.

Graft survival and primary non-function

Graft survival, non-death censored, was defined as the period between the date of transplantation and date of recipient death or date of retransplantation. Primary non-function was defined as liver failure requiring retransplantation or leading to death within fourteen days after transplantation, without any other identifiable cause such as hepatic artery thrombosis.

Statistical analysis

Continuous variables were presented as mean and Standard Deviation (SD), or median and Interquartile Range (IQR), whereas categorical variables were presented as number and percentage. The Kolmogorov-Smirnov test was used to assess the normality of the distribution of numeric variables. Univariate analysis between the groups was performed using Student's t-test, chi-square test, or Kruskal-Wallis test, where applicable. Graft survival and incidence of PNF were calculated using the Kaplan-Meier method and compared using the logrank test. A p-value below 0.05 was considered significant. Statistical analyses were performed using SPSS software version 25.0 for Windows (SPSS Inc., Chicago, IL, USA).

Results

In total, 238 recipients received a LT in the period from January 2010, through May 2017. Twelve recipients were excluded due to either receiving a split or auxiliary LT. In 29 recipients, the ICG-PDR could not be traced, and these patients were excluded from further analysis.

Table 1: Donor, transplant, and recipient characteristics.

	K<18 group *(n=40)*	K ≥ 18 group *(n=157)*	P
Donor age (years)	47 ± 14	47 ± 16	0.76
Donor sex (Female %)	50%	49%	1
Recipient age (years)	52 ± 13	54 ± 11	0.19
Recipient BMI (kg/m^2)	25 ± 4	26 ± 4	0.1
Recipient sex (Female %)	30%	25%	0.55
Etiology of liver disease (%)			
Metabolic disease	0%	3%	
Acute etiology	18%	5%	
Cholestatic liver disease	27%	18%	
Alcoholic liver disease	15%	15%	
Malignancy	20%	42%	
Hepatitis B	0%	2%	
Hepatitis C	3%	1%	
Other cirrhosis	10%	5%	
Other/unknown	7%	9%	
ET-DRI	1.76 ± 0.3	1.82 ± 0.3	0.24
sRRI	**2.48 ± 1.0**	**2.04 ± 0.68**	**0.01**
DRM	1.47 ± 0.18	1.41 ± 0.13	0.06
BAR score	**8.4 ± 5.5**	**6.1 ± 4.3**	**0.02**
LabMELD	**19 ± 10**	**15 ± 8**	**0.003**
Liver grafts (DCD%)	38%	44%	0.12
Cold ischemic period (minutes)	**504 ± 140**	**546 ± 107**	**0.04**
Warm ischemic period (minutes)	39 ± 11	37 ± 11	0.33
Operative time (minutes)	316 ± 94	339 ± 90	0.15

Data are presented as mean ± SD

K<18 group=ICG-PDR <18%/min, K ≥ 18 group=ICG-PDR ≥ 18%/min,

ICG-PDR: Indocyanine Green Plasma Disappearance Rate; SD: Standard Deviation; ET-DRI: Eurotransplant Donor Risk Index; sRRI: Simplified Recipient Risk Index; DRM: Donor Risk Model; BAR score: Balance of Risk Score; LabMELD: Laboratory Model for End-Stage Liver Disease Score; DCD: Donation after Cardiac Death

Of the 197 recipients included in the study, 40 recipients (21%) had an intraoperative ICG-PDR <18%/min, 157 recipients (79%) had an ICG-PDR ≥ 18%/min.

Donor, transplant, and recipient characteristics

Table 1 shows the baseline donor, transplant and recipient characteristics of both groups. The sRRI (2.48 ± 1.0 *vs.* 2.04 ± 0.68; p=0.01), BAR score (8.4 ± 5.5 *vs.* 6.1 ± 4.3; p=0.02) and labMELD (19 ± 10.0 *vs.* 15 ± 8; p=0.003) were significantly higher in the ICG-PDR <18%/min group. The cold ischemic period (504 ± 140 *vs.* 546 ± 107; p=0.04) was significantly longer in the ICG-PDR ≥ 18%/min group. The ET-DRI, which best reflects donor liver quality [31], was not significantly different between both groups. No significant difference in median ICG-PDR level was seen when comparing all different operative techniques (p=0.30).

Graft survival

Table 2 shows all causes for retransplantation, as well as causes of death, within one month after LT. In total, 6 recipients (15%) in the ICG-PDR <18%/min group developed graft failure within a month (PNF, n=4; hepatic artery thrombosis, n=2), versus 9 recipients (6%) in the ICG-PDR ≥ 18%/min group (due to bowel ischemia, n=1; pancreatitis followed by sepsis, n=2; intraoperative blood loss after caval switch procedure, n=1; sepsis by unknown cause, n=1); hepatic artery thrombosis, n=4). One-month graft survival was 34/38 (89%) in the ICG-PDR <18%/min group, versus 148/157 (97%) in the ICG-PDR ≥ 18%/min group (logrank p=0.04) (Figure 1). Interestingly, none of the recipients in the ICG-PDR ≥ 18%/min group developed PNF, whereas 4 (10%) of the recipients in the ICG-PDR <18%/min group developed PNF (p<0.001).

Discussion

This cohort study demonstrates intraoperative ICG-PDR <18%/min in LT to be associated with a significantly increased risk of one-month graft failure and PNF, while ICG-PDR ≥ 18%/min excluded PNF.

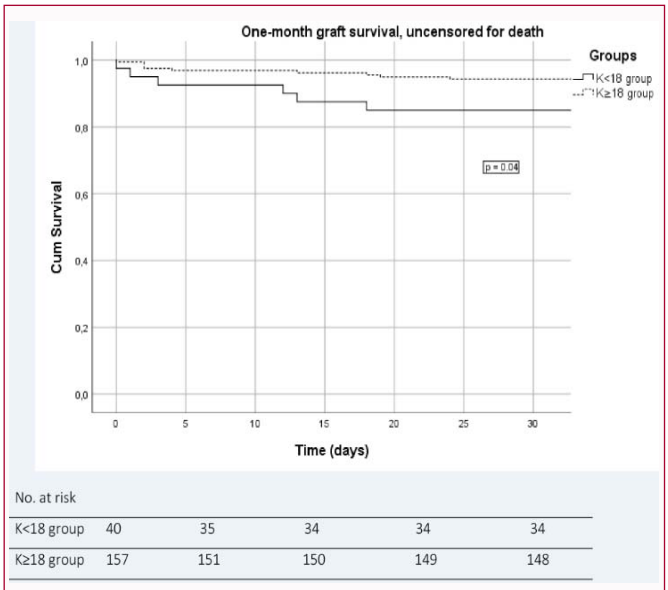
The relationship between lowered ICG-PDR and early graft failure has been described before [23,24]. This study differs from the previous studies in a few ways. First the study by Olmedilla et al. used 1 hour after reperfusion ICG-PDR measurements to assess early graft failure, whereas the present study uses ICG-PDR measurement directly after complete reperfusion of the liver graft. Furthermore, Olmedilla et al. showed a threshold ICG-PDR value of 10.8%/min to accurately predict graft failure, whereas this study showed that immediately following reperfusion an ICG-PDR measurement below 18%/min is a significant risk factor for early graft failure, a cut-off also used in other papers [14,17]. In the study by Vos et al. ICG-PDR measurement was done in the pre-anhepatic phase, anhepatic phase, 30 min after reperfusion and at the end of surgery. In that study only end of surgery ICG-PDR measurement was significantly higher in recipients who did not develop early postoperative complications compared to recipients who did develop early postoperative complications (24.9%/min *vs.* 21.0%/min). Vos et al. did not find a significant difference in ICG-PDR measurement 30 min after reperfusion in patients with or without complications. A possible explanation for this finding could be the relatively small number of inclusions in their study and their wide definition of early postoperative complications, including PNF as well as occurrence of early ischemic biliary lesions and surgical re-interventions. A recent relatively small prospective pilot study by Dousse et al. [32], which included only 76 LTs, showed ICG-PDR to be the only independent predictive factor of graft survival at three months (p=0.01), also demonstrating the clinical importance of ICG-PDR. Whereas Dousse et al. used 3-month graft survival as primary endpoint; the current study used PNF and 1-month graft survival as primary endpoints.

One previous small study, including nine recipients, has described supra-normal ICG-PDR measurements 15 min to 20 min after unclamping of the inferior caval vein in LT [33]. Based on previous literature stating that hepatic failure is associated with an ICG-PDR <18%/min [14,17], this value was used as cutoff for lowered ICG-PDR. An interesting finding in the current study was that none of the recipients with a normal intraoperative ICG-PDR developed PNF, versus 10% of the recipients with a lowered intraoperative ICG-PDR.

Table 2: ICG-PDR and causes of retransplantation or death within one-month after liver transplantation.

ICG-PDR (%/min)	Deceased/retransplantation	No. of days until event	Cause leading to retransplantation or death
6*	Deceased	12	Hepatic artery thrombosis
8	Retransplantation	18	Hepatic artery thrombosis
11	Deceased	6	Primary non-function of transplanted organ.
12	Retransplantation	1	Primary non-function of transplanted organ.
15	Deceased	13	Primary non-function of transplanted organ.
16*	Retransplantation	3	Primary non-function of transplanted organ
19	Deceased	18	Bowel ischemia followed by hemodynamic instability and death
20	Deceased	24	Pancreatitis followed by severe sepsis and death
21	Retransplantation	4	Hepatic artery thrombosis
23	Retransplantation	2	Hepatic artery thrombosis
23	Deceased	1	Occluded portal system, leading to massive intraoperative blood loss.
24	Retransplantation	2	Hepatic artery thrombosis
24	Deceased	19	Postoperative pancreatitis followed by severe sepsis.
25	Retransplantation	13	Hepatic artery thrombosis
28	Deceased	2	Sepsis by unknown cause.

*Both transplantations considered the same recipient
ICG-PDR: Indocyanine Green Plasma Disappearance Rate



No. at risk

K<18 group	40	35	34	34	34
K≥18 group	157	151	150	149	148

Figure 1: One-month graft survival, uncensored for death, (Kaplan-Meier survival analysis) in K<18 group and K ≥ 18 group. K<18 group=ICG-PDR <18%/min, K ≥ 18 group=ICG-PDR ≥ 18%/min
ICG-PDR: Indocyanine Green Plasma Disappearance Rate

Despite this difference being strongly significant (p<0.001), most LTs with lowered intraoperative ICG-PDR recovered (90%). A possible explanation for this finding could be hemodynamic instability right after complete reperfusion of the liver graft, thereby negatively influencing ICG-PDR measurement. In these cases with low post-reperfusion ICG-PDR, additional postoperative re-measurement of ICG-PDR -when the recipient has reached hemodynamic stability- could be considered. When intraoperative measurement of ICG-PDR is above 18%/min, this confirms a functioning liver graft and re-measuring ICG-PDR seems to have no additional value.

Even though there are multiple laboratory and functional tests available to quantify graft function after LT [18,22,34-43], including scoring systems combining ICG-PDR with labMELD or International Normalized Ratio (INR), it is still difficult to accurately predict graft and patient survival after LT. Possibly, a combination of these different scoring systems may predict early graft outcome earlier and better than single indices [24].

A higher sRRI, higher BAR-score and a higher labMELD all were associated with lower ICG-PDR, while ET-DRI was not different between patients with an ICG-PDR above or below 18%/min. This finding requires validation but could indicate that the severity of liver failure and/or the physical condition of the recipient are more strongly associated with a low ICG-PDR than the quality of the donor liver. In addition, it is an interesting finding that neither donor organ quality nor surgical technique influences ICG-PDR. Poor pretransplant recipient factors did negatively correlate with ICG-PDR. In addition, it is well known that ICG-PDR is influenced by cardiac output and blood circulation [44] and a low post-reperfusion ICG-PDR, in those cases, is probably caused by poor hemodynamics of the recipient and not so by liver graft function per se.

This study has some limitations. The retrospective character of the study could bring a potential bias. However, this study included consecutive cases. A clear consensus is lacking for the definition of PNF and different definitions are used within the scientific literature. We chose to use absence of 1-month graft failure instead of using surrogate measures, as has been described previously [45]. Furthermore, even though the incidence of short-term graft failure was relatively low, this study showed a significant correlation between ICG-PDR and graft survival. In addition, it is very unlikely that enlarging the cohort would have altered the extremely low positive predictive value for early graft failure.

Conclusion

Lowered Intraoperative ICG-PDR (ICG-PDR <18%/min) is a significant risk-factor for one-month graft failure and PNF, while normal intraoperative ICG-PDR excludes PNF. This makes normal intraoperative ICG-PDR measurement an easily obtainable indicator for excluding PNF.

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