A comparison of two questionnaires on Informed Consent for extended criteria liver donors

Ann. Ital. Chir., 2015 86: 333-335
pii: S0003469X15023775
www.annitalchir.com

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AIM: *A questionnaire concerning informed recipient's consent for "extended criteria liver donors"(ECD), after approval of the Institutional Review Board(IRB), was sent in different times by e-mail to members of 2 scientific societies, ELPAT (Ethical,Legal and Psychologic Aspects of Organ Transplantation) and ELITA (European Liver and Intestine Transplant Association)-ELTR(European Liver Transplant Registry.*
MATERIALS AND METHODS: *The results were published in different papers in Transplantation Proceedings.*
RESULTS: *By comparing tables in the 2011 ELPAT and 2013 ELITA papers, in the most recent paper less Liver Transplant Centers(LTC) considered age as high as 80 years ($p<.002$)and SGOT>90 IU ($p<.02$), or all criteria together ($p<.0001$), as indicators of ECD.*
DISCUSSION: *This may reflects the fact that more recently LTC have become less selective, due to the rising mortality in the increasing liver transplant waiting list. In all these studies we highlighted both a disparity of practice across centres and the relatively large contribution made by ECD livers to the transplantation effort.*
CONCLUSIONS: *Therefore patients should receive all the required informations concerning the quality of the liver offered to them for transplantation, not only when they are enlisted, but also when the liver becomes available and is proposed to them. It is also possible to create a special waiting list of patients not accepting ECD, although this option could delay liver transplantation and consequently increase mortality.*

KEY WORDS: "Extended Criteria Donors" ECD, Liver, Transplantation

Introduction

The terms "extended"(ECD) [1,2], "expanded" [3,4], "marginal" and "high risk" [5] donors have been proposed worldwide for suboptimal donors whose organs may expose the recipients to some risk of morbidity and mortality, however still there is no widespread agreement in the use of these terms.

Pervenuto in Redazione Gennaio 2015. Accettato per la pubblicazione Marzo 2015
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Materials and Methods

A questionnaire concerning informed recipient's consent for ECD was sent by e-mail to members of 2 scientific societies, first to ELPAT(Ethical,Legal and Psychologic Aspects of Organ Transplantation) members and later on, with few addictions (i.e. D-MELD – Model for End-stage Liver Disease [6] - that is, the product of donor age and preoperative recipient MELD – and Donor Risk Index (DRI) [7] to members of ELITA (European Liver and Intestine Transplant Association)-ELTR(European Liver Transplant Registry) : the results were published in different papers [8-10] in Transplantation Proceedings.
The questionnaires were divided into three sections: section A, defining "extended" criteria, section B, on interaction with recipients, and section C, about the responder.

TABLE I - *Time of informing potential recipients*

	2008 (23 centers)	2013 (31 centers)	P value
When registered for transplantation	10	20	0.12
When an 'extended criteria' liver is available	3	1	0.17
On both occasions	10	10	0.40

TABLE II - *Criteria for "Extended Criteria" liver donors*

	2008 (28 centers)	2013 (35 center)	P value
Steatosis	24	33	0.25
Age up to 80 years	**23**	**15**	**0.002**
Serum sodium > 165 mmo/L	17	25	0.37
SGPT > 105 U/L	10	8	0.26
ICU stay with ventilation > 7 days	16	17	0.67
BMI > 30	10	19	0.14
SGOT > 90 U/L	**12**	**6**	**0.02**
Serum Bilirubin > 3 mg/dL	10	15	0.56
All criteria	13	2	<0.0001

TABLE III - *Criteria for recipients of livers from "Extended Criteria" donors*

	2008 (23 centers)	2013 (35 centre)	P value
Previous history of cancer	21	28	0.24
HBV+	14	16	0.26
HCV+	12	13	0.39
HIV+	10	13	0.69
Critically ill	10	16	0.87
High risk sex practices	7	9	0.77
Drug users	5	12	0.30
Any age		15	
Only age > 65 years	7	6	0.23
Only age < 65 years	1	7	0.09

The main questions to be answered by the survey were:
What are the definitions of ECD liver donations according to European donation organisations and transplant professionals?
Do any discrepancies in definition have implications for potential transplants, which may or may not take place?
Are potential recipients offered the option of receiving an ECD liver?
Is a process of consent carried out with potential recipients to receive ECD livers?
How are the risks of ECD livers explained to potential recipients?
Is a special informed consent form signed by potential recipients?
Pearson chi square test was performed to compare rates relative to each criteria. A P value <0.05 was considered as significant.

Results

By comparing tables in the 2011 ELPAT and 2013 ELITA papers, in the most recent paper less Liver Transplant Centers(LTC) considered age as high as 80 years (p<.002)and SGOT>90 IU (p<.02), or all criteria together (p<.0001), as indicators of ECD (Tables I, II, III).

Discussion

These results may reflect the fact that more recently LTC have become less selective, due to the rising mortality (15%) in the increasing liver transplant waiting list[xi] [xii]. In all these studies we highlighted both a disparity of practice across centres and the relatively large contribution made by ECD livers to the transplantation effort.

Conclusions

Therefore patients should receive all the required informations concerning the quality of the liver offered to them for transplantation, not only when they are enlisted, but also when the liver becomes available and is proposed to them. It is also possible to create a special waiting list of patients not accepting ECD, although this option could delay liver transplantation and consequently increase mortality.

Riassunto

Un questionario riguardante il consenso informato del ricevente per i cosiddetti donatori marginali di fegato ("extended criteria donors"-ECD) è stato inviato, previa approvazione del Comitato Etico, via e-mail ai membri di 2 società scientifiche, ELPAT(Ethical,Legal and Psychologic Aspects of Organ Transplantation) ed ELITA (European Liver and Intestine Transplant Association)-ELTR(European Liver Transplant Registry). I risultati sono stati pubblicati in diversi lavori apparsi su Transplantation Proceedings. Analizzando statisticamente le tabelle negli articoli 2011 ELPAT e 2013 ELITA, nel lavoro più recente meno Centri Trapianto di fegato (LTC) hanno considerato l'età fino a 80 anni ($p<.002$) e SGOT>90 IU ($p<.02$), o tutti i criteri insieme ($p<.0001$), come indicatori di donatore marginale. Ciò potrebbe riflettere il fatto che nel tempo i LTC sono divenuti meno selettivi, a causa della crescente mortalità dei pazienti in lista di attesa. Considerando che in tutti i nostri studi abbiamo riscontrato un notevole ricorso agli ECD, è necessario che i pazienti ricevano tutte le informazioni che vogliano richiedere sia al momento dell'iscrizione in lista di attesa, sia quando il fegato di un donatore venga effettivamente loro proposto. E' anche possibile creare una lista di attesa separata, per pazienti che non accettano ECD: tale scelta però ritarda in modo inevitabile il trapianto e quindi, potenzialmente, aumenta la mortalità in lista di attesa.

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