

研究成果の刊行に関する一覧表

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
篠崎尚史・青木大	「厚生科研における「移植医療の社会的基盤に関する研究」概要	移植	Vol. 48 (1)	2-5	2013
篠崎尚史	移植医療と再生医療	別冊日本医師会雑誌	142巻4号	746	2013
篠崎尚史・青木大	日本組織移植学会の立場から～組織バンク・コーディネーター認定制度～	移植	Vol. 48 (suppl)	264	2013
日下守, 星長清隆	特集 腎移植における新しい展開 【腎保存と臓器提供推進活動】 献腎採取と腎保存	腎と透析	Vol. 75 (1)	99-102	2013
剣持敬・伊藤泰平, 星長清隆	脳死下腹部臓器摘出法	Organ Biorogy	Vol. 20 (2)	159-164	2013
丸山通弘, 坪尚武, 大月和宣, 青山博道, 松本育子, 長谷川正行, 西郷健一, 浅野武秀, 伊藤泰平, 剣持敬, 日下守	特集 腎移植における新しい展開 【腎保存と臓器提供推進活動】 献腎採取と腎保存	日本臨床腎移植学会雑誌	Vol. 1 (2)	206-208	2013
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Oshiro Y, Nakagawa K, Hoshinaga K, Aikawa A, Shishido S, Yoshida K, Asano T, Murai M, Hasegawa A	A Japanese multicenter study of high-dose mizoribine combined with cyclosporine, basiliximab, and corticosteroid in renal transplantation (the forth report)	Transplantation Proceedings	Vol. 45 (41)	476-1480	2013
Kusaka M	Editorial Comment to Dual kidney transplantation from uncontrolled deceased donors after cardiac arrest: A possible option.	International Journal of Urology	Vol. 21 (2)	207	2014

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Fukushima N, Ono M, Saiki Y, Kubota S, Tanoue T, Minami M, Konaka S, Ashikari J.	Japanese Strategies to Maximize Heart and Lung Availabilities: Experience from 100 Consecutive Brain-Dead Donors.	Transplant Proc	45	2871-2874	2013
Fukushima N, Ono M, Saiki Y, Minami M, Konaka S, Ashikari J.	Donor evaluation and management system (medical consultant system) in Japan: experience from 200 consecutive brain-dead organ donation.	Transplant Proc	45	1327-1330	2013
Konaka S, Shimizu S, Iizawa M, Ohkawara H, Kato O, Ashikari J, Fukushima N.	Current status of in-hospital donation coordinators in Japan: nationwide survey.	Transplant Proc	45	1295-1300	2013
小野 元	特集■腎移植における新しい展開 【腎保存と臓器提供推進活動】 臓器提供と家族へのグリーフ・ケアの大切さ	腎と透析	75	109-112	2013
小野 元	特集■臓器移植の現況と今後の展望 9. 臓器提供推進活動におけるグリーフ・ケアのあり方	医薬ジャーナル	49 No. 9	106-109	2013
中村 晴美	Hop・ステップキャリアアップ 第34回 臓器移植コーディネーター	Smiley Nurse	34	10-13	2013
中村 晴美	Hop・ステップキャリアアップ 第34回 臓器移植コーディネーター	臨床看護 臨時増刊号	39 No. 12	1750-1753	2013

研究成果の刊行に関する一覧表

著書

発表者氏名	論文タイトル名	書籍全体の編集者名	書籍名	出版社名	出版地	出版年	ページ
吉村了勇, 星長清隆	腎移植連絡協議会からの 提言 献腎を増やすため に、今やるべきことは？	吉村了勇, 星長清隆	日本臨床腎 移植学会	医学図書 出版	東京	2013	
N Fukushima	Extended criteria donors (ECD) in heart transplantation.	Asano T, Fukushima N, Kenmochi T, Matsuno N	Marginal Donors	Schpring er Japan	Tokyo	2014	in press
N Fukushima	History of marginal donors in the world.	Asano T, Fukushima N, Kenmochi T, Matsuno N	Marginal Donors	Schpring er Japan	Tokyo	2014	in press
N Fukushima	Management of extended criteria donor.	Asano T, Fukushima N, Kenmochi T, Matsuno N	Marginal Donors	Schpring er Japan	Tokyo	2014	in press
N Fukushima	Donation after cardiac death for heart transplantation.	Asano T, Fukushima N, Kenmochi T, Matsuno N	Marginal Donors	Schpring er Japan	Tokyo	2014	in press
N Fukushima	Chapter: Donor Assessment and Management for Maximiazing Organ Availability.	Saidi R	Organ Donation and Organ Donors: Issues, Challenges and Perspectiv es	Nova Science Publishe rs	New York	2013	13-32
小野 元	第6章 脳死の臨床的問題 臨床的問題 18 妊婦の脳死		BRAIN DEATH		東京	2013	203-206
小野 元	第6章 脳死の臨床的問題 臨床的問題 19 脳死における法律上の課題		BRAIN DEATH		東京	2013	203-206

IV. 研究成果の刊行物・別冊

特集「拡大臓器提供推進委員会 2012 年度」

厚生科研における「移植医療の社会的基盤に関する研究」の概要

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はじめに

わが国の臓器移植は、改正臓器移植法の施行に伴い、脳死下臓器提供数は明らかに増加した。このことは改正法施行後に発生した事例のほとんどが家族承諾により提供に至っていることから、法改正の一つの効果の表れといえる。しかし、改正点は他にもあり、運転免許証・健康保険証に意思表示できるような施策も進んでいる。こちらの効果が表れるにはある程度の時間を要するが、こうした状況を鑑みると、今後わが国での臓器提供数は、徐々に増加することが予想される。同時にこのことは、移植コーディネーター不足という状況になることを示唆するものであり、移植コーディネーター、特に院内コーディネーターの教育機関の設立は急務といえる。

このような現状の中、厚生労働省科学研究費補助金免疫アレルギー疾患等予防・治療研究事業「移植医療の社会的基盤に関する研究」において、わが国における移植医療の適正な発展に必要な社会基盤について検討することを目的として研究がなされている。

研究目的

本研究では、コーディネーター教育機関の設立に向けた基盤整備として、教育プログラムの設計、教育ツールの開発、指導指針の作成、実践的教育プログラムの作成を行う。また、将来的な事業化に向けての運用制度設計を実施する。また、現場に必要な教育、処遇待遇および、システムと、教育体制について研究すると

ともに、提供施設への負担軽減のための直接的、間接的な介入研究を行う。また、関連する分担研究との連携の中で活動を進め、臓器提供者の増加と同時に提供家族への配慮がなされる提供施設構築を図ることを目的としている。

研究概要

現在、当研究班では前項に示す目的に向け、さまざまな角度からの研究を行っている。以下、研究の概要を示す。

1. Donor Action Program (DAP)

DAPとは、臓器提供病院にフォーカスして臓器提供に至るプロセスを分析し、臓器提供に至らなかった原因を明確にし、問題点の改善策を盛り込んだ、アクションプランを作成、実行することにより、臓器提供の増加を図る実践的なプログラムである。日本では2002年度より厚生労働省科学研究「病院開発モデル作成」として取り組んでいる。

具体的には、施設合意が得られ、院内に精通した担当者・委員会が設置された段階で、2つの調査を実施する。1つが、Hospital Attitude Survey (HAS: 医療従事者意識調査)で、もう1つがMedical Record Review (MRR: カルテレビュー)である。HASは、その施設のスタッフ個人の臓器移植に対する考え方、知識、どんなことにストレスを感じているか、提供システム・教育プログラムについての要望などを分析するツールである。MRRは、その症例がどういった理由により臓器提供に至らなかったのかを分析するツールであ

る。以上の調査結果を、国際データベースに入力・分析することで、他施設、他国と比較し特徴を把握することができる。具体的な各プロセスは以下のとおりである。

- ①ターゲットを絞る
- ②DAPを導入することについて施設合意を得る
- ③施設内にDAP委員会を設置する
- ④運用方法をデザインする
- ⑤HASを実施し、職員の移植医療に対する意識を解析する
- ⑥MRRを実施し、過去の死亡症例から臓器提供適応患者の解析と、その結果を職員と共有する
- ⑦これらの情報を基に、臓器提供者の増加に向けたアクションプランを検討、実行する
- ⑧アクションプランを評価する

臓器提供数が伸びるためには、標準的な臓器提供プロセスを前提に、医療機関においてポテンシャルドナーがどのような現象で臓器提供に至らないかを解析し、科学的に、そのボトルネックを解消する必要がある。

HASでは、ニーズを把握し、ニーズに応じたセミナー等を実施した後に再度、HASを実施して改善の検証をすることができる。また、MRRでは、分析から浮かび上がる提供に至らない理由の中に、改善点を見出すことができる。これらから、その施設特有のボトルネックを解消していく作業こそが、臓器提供増加への道となる。DAPをどう活かすかで、終末期における臓器提供の意思確認を推進することが可能となり、ゆえに臓器提供数増加に結び付けることができるシステムである。

現在、DAP導入病院にて実施しているDAP、MRRの調査データに関して、DAP財団の運営するWEBサイトにおいてデータベース管理を行い、その分析を進めるとともに、その結果これまでの実績から有効性の高い施設に限定して実施し、病院全体として取り組むための具体的手法のさらなる確立、各都道府県コーディネーターを通じて把握し、移植医療推進に対する地方行政の行政支援の在り方について検討し整備を進めている。その結果、HAS(33,791人/76施設)のデータから、医師、看護師など医療職種においても、①一般に移植には賛成であり、半数近くが、死後自分の臓器提供を希望していること、②脳死を死の妥当な判定方法であると考ええるものは、医師の約6割に比較して、看護師、事務職では4割程度に過ぎないこと、③

ドナー候補の特定、臓器提供の同意を得ることに必要な能力・知識を有すると考えるものは、医師で約2割、看護師ではごく少数であることが分かった。そのような中で、MRR(6,662人/40施設)の結果から、全参加病院において、家族へのオプション提示の割合が年々着実に増加していることが分かった。一方、12道県(新潟県、福岡県、神奈川県、沖縄県、千葉県、富山県、熊本県、静岡県、兵庫県、福井県、愛知県、北海道)で61施設がDAP導入を図っている。また、2012年4月1日～11月30日の期間において、DAP導入地域の臓器提供は27例、うち脳死下臓器提供14例である。全国の臓器提供数とDAP導入都道府県の提供の割合は、腎提供で全国95例のうち27例(28.4%)、脳死下臓器提供の全国33例のうち14例(42.4%)であり、心停止下、脳死下いずれの場合も全体の3～4割がDAP導入地域で提供されていることとなる。

2. 教育機関の基盤整備

現在日本で活動している臓器提供(ドナー)側の調整を行う移植コーディネーターは、社団法人日本臓器移植ネットワーク(以下、JOT)所属のコーディネーター、JOTからあっせん業の委託を受けた都道府県コーディネーター、そして提供施設に所属する院内コーディネーターに分けることができる。加えて、組織提供にかかわる組織移植コーディネーター、献眼にかかわるアイバンクコーディネーターも存在する。院内コーディネーター以外は、事例発生時に提供施設に派遣され、事例ごとにチームが組まれる。実際の提供事例では、「臓器・組織にかかわらず可能なものをすべて」提供したいというケースも多く、各種のコーディネーターがかかわることとなる。しかし現状では、各種コーディネーターに対する標準化されたドナーコーディネーターの教育体制は存在しない。現場では同じ立場でかかわりながら、標準化された教育体制がないことは望ましいことではない。

そのため、質の担保という意味でも、移植コーディネーターの教育に必要な、教育プログラム、教育ツール、教育機関運用制度等の社会基盤が必要である。

特に救急現場において、臓器提供施設への負担の軽減と、臓器提供の有無にかかわらず医療機関で継続的にご家族との連携や院内連携を行う「院内移植コーディネーター」の存在が重要である。従来のポテンシャルドナーが発生した後に介入し、臓器提供がある場合

のみ家族ケアを行うコーディネーターではなく、医療機関での重症患者への対応を組織的に行い、終末期医療全体の管理を行う体制整備に必要な人材育成に関しての検討を行っている。つまり、医療の中で臓器提供だけに特化することなく、救急医療現場での一連の医療行為の中で終末期に至った場合、選択肢の一つとして臓器提供が位置付けられ、質の高い家族ケアやスタッフサポート、院内教育などが実施できる人材育成が必要である。そのためのクオリティマネージャー養成を目的とした教育プログラムを作成、試行し、その内容について検証している。なお、研究を進めるにあたっては、日本救急医学会、日本臨床救急医学会、日本救急看護学会の協力を得て実施している。

一方、現在、スペインでは人口100万人あたりの臓器提供者数が世界一であるが、その背景には家族への意思確認・家族ケアから、脳死判定・ドナー管理にまで及ぶ知識を有したコーディネーターが臓器提供施設に配置されている体制がある。そして、そのコーディネーター教育を実施しているのが Transplant Procurement Management (TPM) という教育機関であり、現在では多くの国の移植コーディネーターが TPM の教育プログラムに参加している。わが国においても、日本版 TPM のような教育機関の設置が望まれる。

3. 提供施設支援ツールの開発

移植医療の社会的基盤として、提供施設の負担軽減は必要不可欠なものである。提供件数の増加が見込まれる状況では、今後わが国での移植医療が発展するかどうかの鍵は、まさしく提供施設の負担軽減といえる。そのためのツールの開発は重要である。研究では、提供施設内の情報共有システムの構築により、必要なタイミングで受取るべき人だけに情報を配信するシステム、さらに、臓器提供の各段階における作業手順、マニュアル、法令・ガイドラインの解説が自由に参照できるツールを開発し、提供施設スタッフの負担、不安を軽減する。また、これまでのドナー家族が訴えた精神的負担などを症例として蓄積し、今後の精神的ケアに寄与するためのデータベースの構築、そして、脳死下臓器提供が進むことで、これまで以上に1人のドナーから多数のレシピエントに提供される症例が増えることから、双方の安全性確保のためにドナー・レシピエント双方の情報が登録できる統一システムを目指した調整を行っている。これらのツールを整えることにより、提供施設の負担軽減に寄与できれば、終末期

における医療現場での臓器提供の意思確認も進むことが期待できる。

4. ドナー評価・管理および摘出手術の呼吸循環管理の体制整備

脳死臓器提供におけるドナー評価・管理および摘出手術の呼吸循環管理と移植後の成績を検討し、わが国にあったドナー評価・管理法を開発するとともに、そこで得られた結果を基にマニュアルを作成し、メディカルコンサルタント、提供病院のスタッフ、ドナーコーディネーターの研修を行うとともに、そのメンバーを基本にした体制整備を行っている。わが国では、欧米と異なり、2002年以降メディカルコンサルタント制度を導入しており、その結果、2012年11月20日現在(200件の脳死臓器提供)のわが国の臓器提供率は、心臓74.0%、肺62.4%、腎臓95.6%、肝臓80.2%、膵臓70.9%と高い水準を示している。臓器提供率を米国と比較すると、腎臓は同程度で、肝臓は少なかった(脂肪肝、ショック肝が多いため)が、心臓、膵臓、肺は3~4倍の臓器提供率である。それぞれの移植後の成績も欧米の成績と遜色はない。呼吸器外科医を中心とするメディカルコンサルタントがドナーの呼吸管理に参画することで、さらに肺の提供が増加するとともに、肺移植後の成績が向上している。スペイン、韓国、米国の Organ Procurement Organization (OPO) と連携して、ドナー評価・管理システムを検討し、臓器提供にかかわる医療者の教育・研修システムを構築中である。

■ ■ ■ まとめ

DAPの導入病院は増加傾向にあり、データ数は増加しつつある。HAS、MRRはDAPでの主要なツールであるが、全体の集計によりおおよその動向を知ることが可能であるとともに、個別病院における問題把握、介入効果判定のツールとして利用が可能である。また、症例の考察から、救命救急治療とともに家族ケアが充実しており、家族と医療者の信頼関係が十分であることがDAPを推進するうえで最も重要な要素であることが推察される。また、地域独自の取り組み、例えば、官民一体の活動の強化やMRRを多用した詳細な医療機関診断からのアプローチ、さらに家族ケアの観点から“救急における看取り医療の充実”などにより、家族にとっても、医療スタッフにとっても、満

足度の高い医療が展開されていることが DAP の大きな特徴である。加えて、臓器提供者数は、わが国の人口比 0.88 人/pmp (2010 年度) のうち 0.2 人/pmp を DAP 導入地域がカバーしている。DAP 導入地域における活動のさらなる発展と、また非導入地域への DAP の導入・展開によって臓器提供数は飛躍するものと考えられる。また、継続的に運用しているドナー家族精神的ケア窓口であるが、ドナー家族が抱える精神的問題点を詳細に発掘する為にはその運用にさらなる工夫が必要である。一方、提供施設のスタッフの負担や不安を軽減するための、情報を参照できるツールの開発やコーディネーターの教育プログラムの必要性が重要な位置付けと考えられる。

■ ■ おわりに

臓器移植法の改正後、脳死下臓器提供が増加する中、移植医療の社会的基盤としての研究により、提供施設の負担の軽減およびコーディネーター教育が重要な課題であることが明らかにされたが、提供現場への具体的教育、処遇待遇がシステムとして機能するのか、また教育体制の確立が重要である。このことが、提供者家族が一貫した医療行為の延長上にある臓器提供のステップを踏んで行けるための重要な鍵となる。

移植医療に関する院内システムを構築する際の介入

ポイントの設定の見直しが必要である。従来、介入ポイントは、患者の予後不良診断後からの動きにフォーカスされていた。しかし、救急搬入患者家族の多くは突然の発症、すなわち非日常の出来事を受け止めなくてはならない。一方、医療機関側からすれば救命救急治療の限界点で移植医療が突然介入してくるのには違和感があることは否めない。院内システム構築の際には、むしろ患者搬入時からの取り組みこそが重要であり、そのプロセスのなかからポテンシャルドナーを見出し、患者に対する可能な限りの救命救急治療を提供するのと並行して、刻々と変わる病状を受け止めなければならない家族に対するケア、救命できなかった場合の看取りの医療から臓器提供へとつながる連続的な流れを構築してゆくように医療機関啓発活動の内容を見直すことが重要である。DAP の手法はある程度集約されてきた。そのことを十分に行うことのできる人材育成、とりわけ院内コーディネーターについてはその発展系の、すなわち多角的視野で組織展開ができる“クオリティマネージャー”の育成が重要である。各分担研究ともリンクしながら院内システムとそれを遂行するプロフェッショナルの育成が最重要課題であり、同時に、提供施設の負担軽減のためのデータベースシステムの構築を含め本研究を進めていくことが必要である。

移植医療と再生医療

篠崎尚史

iPS細胞研究が2012年ノーベル生理学・医学賞を受賞し、再生医療が再燃している。再生医療は夢の医療のように報道されているが、わが国の再生に関する研究はすでに70年近い歴史をもち、世界に大きくリードしている研究分野である。1992年に、岡田節人、江口吾朗らと日本再生研究会を立ち上げたことが思い出される。特に江口氏の網膜再生の研究は初めて脊椎動物の中樞神経系を再生させたことで世界を驚愕させた。

再生技術を医療に用いるとなると、臨床応用への熟慮されたシステムの確立と革新的な技術が不可欠となる。移植医療は100年以上の歴史のなかで、倫理性、安全性の担保が行えるシステム構築と、それを裏付ける法的整備が行われてきた。臓器・組織の提供者の医学的、社会医学的スクリーニングとトレーサビリティ確保、臨床成績の透明化である。

しかしながら骨髄をはじめとする角膜や多くのヒト由来の細胞・組織・臓器が国際間で SHIPPING され、さらには生活習慣病の増加などに起因する移植待機患者の増大により非倫理的な取り引きの報告が世界各地から寄せられ、2003年、WHO総会¹⁾にて、この件に関する調査(EB112/5, EB113/14)が決定し、2004年のWHAでは、1991年に制定された臓器移植のガイドライン(Guiding Principles on Human Organ Transplantation)の改訂を決定した²⁾。国際的なネットワークによるすべてのヒト由来製剤に関して、倫理性、安全性を担保すべきであるという結論に至り、その過程で国際移植学会や国際腎臓学会等の協力の下、臓器売買、渡航移植を禁止するという「イスタンブール宣言」の制定に漕ぎ着けた。2005年のマニラで開催されたアジア政府間会議には、中国の衛生部より黄副部長が参加し、国際的な倫理的

議論がより現実的な法整備と連動し、中国でも外国人の移植を禁止する法律「人体器官移植条例」(2007年)が制定されるに至った。

骨髄移植では、国際間のドナー・レシピエントマッチングが有効に機能したことで、国際ルールが最も早く完備された領域である。ICCBBAが制定したISBT(International Standard for Blood and Transplant)128という輸血で用いられたコードを使用して、トレーサビリティを確保している。WHOのガイドライン改訂の過程で、この有用性が検討され³⁾、移植医療のなかでのさまざまなincidentにより構築したシステムについて調査、検証がなされた。

再生医療における日本の研究・技術レベルは、世界のトップクラスである。しかし、北米や欧州でも研究は加速化しており、知的財産権の獲得数も驚くべき勢いである。このような環境下でわが国の国策として実現化するためには、安全性、倫理性に十分配慮しながらも、基礎研究からシステム化された前臨床試験、非臨床試験を支援し、治験と承認作業を急ぐ必要がある。知的財産権も世界規模での戦略で獲得する必要がある。

再生医療分野は、根本的に移植医療と同様に進める医行為の部分と、製造や管理といった薬事に係る部分が両立されなければならない新しい医療分野である。特に遺伝子改変を行った細胞の際には、その安全性、有効性試験はさらに厳格に行う必要がある。どのような医療でもリスクを完全に排除することは不可能であるが、治療不可能であった分野に新たな技術が導入され、それらを治癒させることこそが医学のイノベーションである。同時に、そのリスクをいかに最小化させ、また、万が一の副作用の際に、医学的、政策的にどのように対応するかの基本ルールを明確にして、世界的競争のなかで発展させるバランスが重要である。

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Japanese Strategies to Maximize Heart and Lung Availabilities: Experience from 100 Consecutive Brain-Dead Donors

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ABSTRACT

Objective. Because the donor shortage is extremely severe in Japan because of a strict organ transplantation law, special strategies have been established to maximize heart and lung transplantations (HTs and LTs, respectively). We reviewed 100 consecutive brain-dead donors to evaluate our strategies to identify and manage heart and lung donors.

Methods. We retrospectively reviewed all 100 consecutive brain-dead donors procured since the law was issued in 1997. There were 56 mens and the overall mean donor age was 43.5 years. The causes of death were cerebrovascular disease ($n = 62$), head trauma ($n = 20$), and asphyxia ($n = 16$): Since November 2002, special transplant management doctors were sent to donor hospitals to assess cardiac and lung functions, seeking to identify transplant opportunities. They stabilized donor hemodynamics and lung function by administering antidiuretic hormone intravenously and performing bronchofibroscopy for pulmonary toilet.

Results. Seventy-nine HTs, 1 heart-lung transplantations, and 78 LTs (46 single and 32 bilateral) were performed. By applying these strategies organs per donor were increased from 4.5 to 6.8. Among heart donors, 61/80 were marginal: high inotrope requirement ($n = 29$), cardiopulmonary resuscitation ($n = 28$), and/or >55 years old ($n = 20$). None of the 80 HT recipients died of primary graft failure (PGF). Patient survival rate at 10 years after HT was 95.4%. Among lung donors, 48/65 were marginal: pneumonia ($n = 41$), chest trauma ($n = 4$), and >55 years old ($n = 9$). Only 2/78 LT recipients died of PGF. Patient survival rate at 3 years after LT was 72.2%. After inducing frequent pulmonary toilet, lung procurement and patient survival rates increased significantly after LT.

Conclusions. Although the number of cases was still small, the availability of organs has been greater and the outcomes of HT/LT acceptable.

HEART AND lung transplantation (HT and LT, respectively) represent established procedures that show in satisfying long-term results for end-stage heart and respiratory failure patients.¹ However, these therapies are limited by severe donor organ shortages. Therefore, optimal utilization of all suitable donor organs is mandatory to increase graft availability.²

In Japan, the donor shortage has been more severe than in other developed countries because of the strict Japanese organ transplantation law issued in 1997, which requires a living person to grant written consent for organ donation after brain death. Until September 30, 2010, only 100 brain-dead donors have been procured in Japan since the law was issued.³⁻⁶ In 2007, the cardiac donation rate per million population in Japan was only 0.08, compared with 7.3 in

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USA, 5.3 in Spain, and 0.97 in South Korea. The mean waiting times for HT and LT are extraordinary long in Japan, namely, 1,026 and 1,673 days respectively, in 2010. The organ shortage and long waiting times have forced Japanese transplant programs to consider the use of hearts and lungs from donors who would be considered to be marginal.⁶

The most troublesome issue facing transplantation is primary allograft failure (PGF). This complication is the leading cause of death in the first 30 days and in the 1 year after transplantation in the world.¹ The use of marginal donor organs seems to increase the rate of PGF. Therefore, it is necessary to establish special donor evaluation and management systems that maximize cardiac and lung donor utilization. The purpose of the present study was to review our special strategies to identify and manage heart and lung donors among 100 consecutive brain-dead donors since issuance of the Japanese organ transplantation law.

MATERIALS AND METHODS

In this study, we reviewed retrospectively 100 brain-dead donors procured in Japan from October 17, 1997, to September 30, 2010, 56 were male, and the ages of the donors range from 18 to 72 years (mean, 43.3 ys). The cause of brain death was cerebral stroke in 61, including 52 with subarachnoid hemorrhage, 5 cerebral infarctions, and 4 cerebral bleedings, head trauma in 20 including 10 motor vehicle accidents, 16 in staves of asphyxia, and 4 of brain injury after cardiopulmonary resuscitation.

Donor Evaluation and Management System

Organ transplantation from brain-dead donors started in 1999. Since then, each organ procurement team includes staff physicians who evaluate the condition of donor heart and lungs by echocardiography and flexible bronchofibroscopy (BFS) in the intensive care unit before the procurement operation.⁶ Since November 2002, a medical consultant (MC) has been sent to the procurement hospital, to also assess donor organ function and identify suitable organs for transplantation. They also intensively care for the donor, stabilizing hemodynamics by administering a bolus infusion of 0.01 U/kg followed by a drip infusion of 0.01 U/kg/h of antidiuretic hormone (ADH) and reducing intravenous catecholamine doses as much as possible. They seek to prevent or to treat lung infections before the procurement teams arrive.

If the ratio of arterial oxygen tension to inspired oxygen fraction ($\text{PaO}_2\text{-FiO}_2$ ratio) was <300 , one lung was transplanted if the $\text{PaO}_2\text{-FiO}_2$ ratio of the pulmonary venous blood of that side sampled at the procurement operation was >400 .

After the 50th brain dead donor in December 2006, we modified the lung management. While, regular toilet and turning of the donor were performed as previously, repeated BFS was carried out when there were symptoms and/or signs of atelectasis or pneumonia on the chest X-ray or computerized tomography (CT) scan.

We defined a marginal donor heart as one from a donor with a history of cardiopulmonary resuscitation >5 minutes, with left ventricular dysfunction defined via transthoracic echocardiography demonstrating left ventricular ejection fraction $<50\%$, with high inotrope requirement defined as a sustained need for dopamine $>10\mu\text{g}/\text{kg}/\text{min}$, or >55 years of age.

We defined as marginal donor lung was among from a donor with infections sputa or findings of pneumonia by chest-X-ray, who is hemodynamically unstable, who sustained chest trauma, or >55 years age.

Preprocurement Meeting and Management of Procurement Operation

Before starting a procurement operation, all surgeons, anesthesiologists, operating rate and nurses gathered in the meeting room. They negotiated the types of procured organs, how to procure each organ (eg, organ dissection/perfusion technique, incision lines, blood drainage technique), needed samples (eg, blood, lymph nodes, spleen), and donor management during the operation. Because most Japanese anesthesiologists have never experienced a procurement operation from a brain-dead donor. The MC also supported them to stabilize donor hemodynamics during the operation. Skillful staff surgeons, not resident surgeons, harvested the donor organs.

Because an inverse relationship between volume of intraoperative colloid and early lung allograft function has been reported,⁷ packed red blood cells and albumin were transfused to maintain the circulating blood volume and to replace proteins and fluids. To improve organ perfusion with preservation solution, additional catecholamine was not administered (as possible to dilate the vessels of organs). ADH and all catecholamine infusions were discontinued at the time of the heparin sulfate (400 U/kg) bolus.

RESULTS

Among 100 brain-dead donors, we obtained 79 HTs (80.0%), 78 LTs (32 bilateral and 46 single) from 65 donors (58.7%), and 1 heart and lung transplantations (HLT).

Heart Transplantation

Seventy-nine HTs were performed at 7 centers, 58 of them male. The overall age of the HT recipients was 8–60 years (means 36.7 ys). Their underlying diseases were dilated cardiomyopathy (DCM; $n = 60$), dilated hypertrophic cardiomyopathy ($n = 6$), ischemic cardiomyopathy ($n = 6$), secondary DCM ($n = 5$), restrictive cardiomyopathy (RCM; $n = 1$), and in complex cardiac anomaly ($n = 1$). All patients were transplanted under status 1 hemodynamic condition with 69 requiring left ventricular assist support for a mean duration of 821 days (range 21, 1,593). The mean waiting period for HT was 950 days (range 29, 2,595).

Among 79 HTs, 61 donors were marginal including 35 treated with high-dose catecholamines, 4 with $<50\%$ left ventricular ejection fraction, 29 with history of cardiopulmonary resuscitation, and 9 > 55 years old without coronary angiography.

Although 3 patients required mechanical support (2 for extracorporeal membrane oxygenation and 1 for intraaortic balloon pumping) and 2 required high dose inotropic support, none of the 79 HT recipients died from PGF. Two succumbed to infections at 3 months and 4 years after HT. Patient survivals at 1, 5, and 10 years after HT were 98.7%, 96.2%, and 96.2%, respectively (Fig 1).

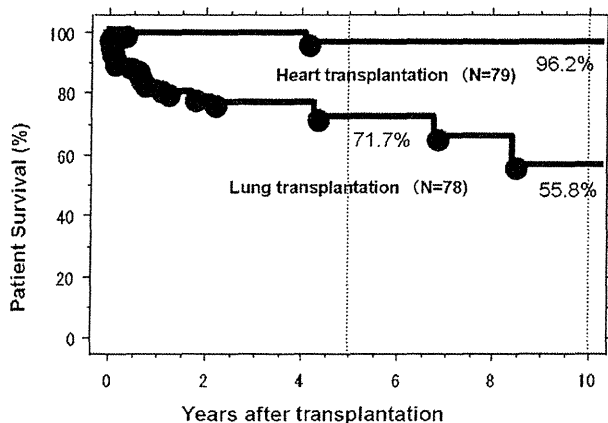


Fig 1. Patient survival after heart and lung transplantation.

Lung Transplantation

The 78 LTs included 32 bilateral (BLT) and 46 single (SLT) LTs at 7 centers, the in of 29 men. The overall age/range of the LT recipients was 19–60 years (mean, 38.3 ys). The underlying disease for LT was lymphangioliomyomatosis (LAM; n = 28) primary pulmonary hypertension (n = 16), idiopathic or other interstitial pneumonia (n = 14), bronchiolitis obliterans (n = 4), Eisenmenger syndrome (n = 3; ventricular septal defect, 1 partial pulmonary venous anomalous drainage, and 1 patent ductus arteriosus), emphysem (n = 6), bronchoectasia (n = 3), or another reasons (n = 3). The waiting period for LT was 22–2,345 days (mean, 1,056 ds).

Among 65 lung donors, 48 were considered to be marginal including 32 due to infectes sputa or pneumonia by chest-X-ray or CT scan. There were 7 hemodynamically unstable donors, and 6 had experienced chest trauma. Nine were >55 years old.

Among the 8 recipients who, died early after LT, 4 succumbed due to PGF, 2 due to technical reasons, and 2 due to sepsis. Patient survivals at 1, 5, and 10 years after LT were 82.5%, 71.7%, and 55.8 %, respectively (Fig 1). The 1 HLT performed for Eisenmenger syndrome associated with double-outlet right ventricle, was alive after 2 years.

After the 50th brain dead donor, lungs management was modified as described above. Before modifying lung management, 29 LTs (13 SLTs and 16 BLTs) were performed from 27 donors. After modifying lung management, 49 LTs (33 SLTs and 16 BLTs) were performed from 38 donors. Lung procurement rate per donor significantly increased to 74.5% from 55.1% after the modification (Pearson, chi-square test: $P = .04$). However, there was no difference in the rate of early death after LT due to PGF and other causes. Patient survival at 1, 2, and 4 years after LT significantly increased after the modifications from 89.1%, 85.8%, and 85.8% before to 72.4%, 65.5%, and 62.1% respectively, after modification, (log rank test: $P = .02$; Fig 2).

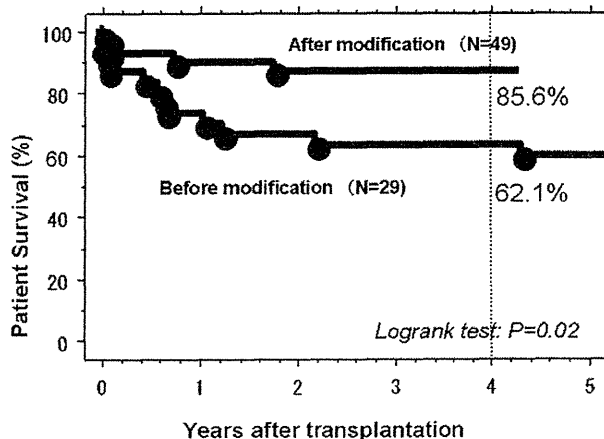


Fig 2. Patient survival after lung transplantation before and after modification of donor management.

DISCUSSION

For many years, HT and LT have represented established procedures for end-stage heart and respiratory failure patients. Over the past 2 decades, there has been a considerable increase in the numbers of patients annually listed for these procedures. Strict adherence to “standard donor criteria” resulted in a undersupply of available organs with the result of significantly extending waiting times and increasing waiting list mortality.^{2,8}

As a consequence of this severe shortage of donor organs, hearts and lungs from marginal donors have been utilized in many countries. However, only 2,407 hearts from 7,944 deceased donors (30.2%) were transplanted in the USA in 2010. Because of the strict Japanese organ transplantation law only 100 brain-dead donors have been procured in Japan in >10 years. Only 30 HTs would have been transplanted, if the cardiac donation rate was the same as in the USA. These great pressures of the organ shortage made transplant programs consider the use of the hearts and lungs that would be considered to be marginal. Therefore, original donor evaluation and management systems have been established, such as the MC and the preprocurement meeting.⁵

High serum adrenaline concentrations have been reported to reduce myocardial β -adrenergic receptor density in brain dead nonhuman animals⁹ and human patients.¹⁰ These concentrations can increase the risk of PGF after HT. Therefore, the dose of intravenous catecholamine should be reduced as much as possible. The American College of Cardiology has recommended it as the initial therapy for hemodynamic support after failure of treatment of diabetes insipidus,^{11–13} which shows catecholamine-sparing effects.^{6,14} Vasopressin replacement treats diabetes insipidus as well as maintains hemodynamic stability and prevents electrolyte imbalance. A substantial number of brain-dead donors show resolution of their focal/regional wall motion abnormalities. Aggressive attempts at hemodynamic stabilization with the use of hormonal resuscitation

have dramatically improve reversed cardiac function and yield.^{12,14}

The ideal lung donor shows a PaO₂-FiO₂ ratio of >300, a positive end-expiratory pressure requirement >5 cm H₂O, a clear chest X-ray, age >55 years, a smoking history of >20 packs/year, and absence of trauma, surgery, aspiration, malignancy, and purulent secretions. Pathologic studies of lungs deemed to be unsuitable for donation have indicated that bronchopneumonia, diffuse alveolar damage, and lung consolidation are the most common reasons to reject a lung. Given these findings, it is recommended that every lung donor undergo bronchoscopy for a therapeutic toilet and to isolate potential pathogens to guide antibiotic therapy in both the donor and the recipient.¹²

In the present study, after modifying lung management, lungs procured per donor significantly increased and, moreover, with significantly increased patient survival.

In conclusion, although the number of transplantations is still small, the availability of hearts and lungs has been greater in Japan than in other developed countries the outcomes of HT and LT were acceptable. These strategies may be useful to maximize HT and LT opportunities in other countries.

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Donor Evaluation and Management System (Medical Consultant System) in Japan: Experience From 200 Consecutive Brain-Dead Organ Donation

N. Fukushima, M. Ono, Y. Saiki, M. Minami, S. Konaka, and J. Ashikari

ABSTRACT

Purpose. As the donor shortage is extremely severe in Japan because of a strict Organ Transplantation Act, special strategies must be established to maximize organ transplant opportunities. The purpose of this study was to evaluate our strategies to identify and manage 200 consecutive brain-dead organ donors.

Methods and materials. We retrospectively reviewed the 200 donors procured since the Organ Transplantation Act was issued in 1997, including 118 males, a mean overall age of 45.1 years and cause of death being cerebrovascular disease ($n = 119$), head trauma ($n = 37$), and asphyxia ($n = 44$).

Donor evaluation and management system. Since November in 2002, special transplant management doctors (“medical consultants”) were sent to donor hospitals to assess organ function and identify transplantable organs. They also provided intensive care to stabilize hemodynamics and improve cardiac and lung functions by administering antidiuretic hormone intravenously and providing bronchofiberscopic pulmonary toilet.

Results. We obtained 146 heart, 1 heart-lung, and 154 lung (87 single and 67 bilateral), 175 liver (28 splitted liver), 142 pancreas (114 pancreas-kidney), 253 kidney and 12 small bowel grafts. Organs procured from 1 donor increased from 4.5 to 6.8 after applying these strategies.

Conclusions. Although the number of cases was still small, the availability of organs and outcomes of transplantation have been acceptable.

ORGAN TRANSPLANTATION (Tx) has achieved satisfying long-term results.¹ However, these surgical therapies are continuously limited by the severe organ donor shortage. Therefore, optimal utilization of all suitable organs is mandatory to increase graft availability.²

The Japanese Organ Transplantation Act for brain death (BD) organ donation (the former Act) was issued in October 1997. It required written consent for BD and organ donation by a living individual and did not allow it from children younger than 15 years. From these reasons, only 81 BD organ donations were performed in Japan for 13 years. The cardiac donation rate per million populations in Japan is only 0.08, while it is 7.3 in the United States, 5.3 in Spain, and 0.97 in South Korea in 2007. The mean waiting time for heart and lung transplants of 1026 and 1673 days respectively in 2010 was extraordinary long in Japan.

Finally the Act was revised on July 17, 2010.^{1–3} New organs can be donated after BD with consent from the family, if the donor did not deny organ donation pre-mortem. Although the Act was revised in 2010 and brain-death organ donation increased from 13 to 44 cases in a year (Fig 1), the number was still extremely smaller than other developed countries. The great pressures of the organ shortage and the long waiting times made Japanese transplant programs consider the use of organs that might be otherwise considered to be marginal.⁴

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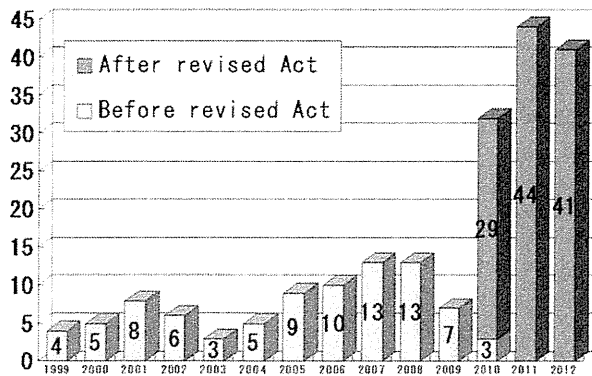


Fig 1. Brain-dead organ donation in Japan.

The most troublesome issue facing transplantation is primary graft dysfunction (PGD). This complication is the leading cause of death in the first 30 days and first year post-transplantation worldwide.¹ The use of marginal donor organs may increase the rate of PGD. From this point of view, it is necessary to establish a special evaluation and management system to maximize cardiac and lung donor utilization. The purpose of this study was to review Japanese special strategies to identify and manage, 200 BD organ donors since issuance of the Japanese Organ Transplantation Law.

MATERIALS AND METHODS

We retrospectively reviewed all 200 brain-dead donors procured in Japan between October 17, 1997, and November 14 2010, including 118 males and 78 females with an overall mean age of 45.1 years. The cause of brain death was cerebral stroke ($n = 119$: subarachnoid hemorrhage, 7 cerebral infarction, and 21 intracerebral bleeding), head trauma ($n = 37$), asphyxia ($n = 27$) and brain injury after cardiopulmonary resuscitation ($n = 17$).

Medical Consultant System to Evaluate and Manage BD Organ Donors

Since BD organ transplantation was started on February 28, 1999, every organ procurement team has obtained a staff physician in each procurement hospital. Before the procurement operation they evaluate the condition of the donor organs by ultrasound examinations of the heart and abdomen and bronchofiberscope (BFS) candidates in the intensive care unit (ICU).⁴

Since November 2002, special transplant management doctors (medical consultants [MC]) who were usually cardiac transplant surgeons, have been sent to the procurement hospital. They assessed donor organ function to identify organs useful for transplantation. They also intensively care for the donor, stabilize the donor hemodynamics by giving antidiuretic hormone (ADH) as a bolus infusion (0.01 U/kg) followed by a drip infusion (0.01 U/kg/h) and reduce the doses of intravenous catecholamines as much as possible, and seek to improve donor cardiac and lung function by preventing and treating infection before the procurement teams arrive at the donor hospital.

Since the 50th BD donor in December 2006, we have modified lung management. Regular toilet and turning of the donor were done as previously. If there were symptoms and/or signs of atelectasis or pneumonia on chest X-ray and chest computed

tomography (CT) scan, repeated we perform BFS and frequent toileting. Since 2011, lung transplant surgeons have played a role in evaluation and management of the lungs. Currently the MCs consist of about 20 cardiac, 30 lung, and 3 liver transplant surgeons.

Current Organ Donor Evaluation System in Japan

First step: donor evaluation. Transplant procurement coordinators (PTC) of Japan Organ Tx Network (JOT) are called to a donor hospital if there is a potential BD donor. They obtain the patient's clinical course from the medical staff and examine clinical records to determine whether the patient is suitable for organ donation. If there are no absolute contraindications, such as an untreated malignancy or severe viral infection, they obtain informed consent for donation from the family. Then a legal examination for BD is performed.

Second step: donor evaluation. After completion of the initial clinical examination, MCs are sent to the hospital. They and the JOT PTC check the clinical records of the course before and after BD, medication review, blood examination, electrocardiogram, chest X-ray, abdominal and chest CT scans, and perform ultrasound examinations of the heart, liver, pancreas, and kidneys as well as a BFS. MCs rule out malignancies from the CT scan and ultrasound examination. JOT PTCs construct donor evaluation sheets which are sent to transplant centers using a mobile system. Then the transplant centers decided whether their recipient is suitable and their procurement team is sent to the hospital.

Third step: donor evaluation. After arriving at the donor hospital, they also evaluate the condition of donor organs by ultrasound examinations for the heart and abdominal organs and BFS by themselves in the ICU before the procurement operation.⁴ They assess organ function to determine whether the organ could be transplanted to their recipient.

Final donor evaluation. After opening the chest and abdomen, the procurement team evaluates organs by watching and touching carefully. Usually a liver biopsy is performed to exclude more than moderate grade fatty liver and malignancies. They also rule out unexpected malignancies in the pleural and abdominal cavities.

Preprocurement Meeting and Management of Procurement Operation

Before starting the procurement operation, surgeons, anesthesiologists and operating room nurses gather in a meeting room. They negotiate the types of procured organs, how to procure each organ (eg, organ dissection/perfusion technique, incision lines, blood drainage technique, etc), the kinds of samples needed (eg, blood, lymphnodes and spleen), and how to manage the donor during the operation.

As most Japanese anesthesiologists have never experienced a procurement operation from a BD donor, MC also support them to stabilize donor hemodynamics during the operation. Skillful staff, not resident surgeons, harvest the donor organ.

As an inverse relationship between volume of intraoperative colloid and early lung allograft function has been reported,⁵ packed red blood cells and albumin was transfused to maintain circulating blood volume and to replace proteins and fluids during the procurement operation. To improve organ perfusion with preservation solution, catecholamines are not additionally administered seeking to dilate the vessels to organs; the ADH and catecholamine infusions are discontinued at the time of the bolus infusion of heparin sulfate (400 U/kg).

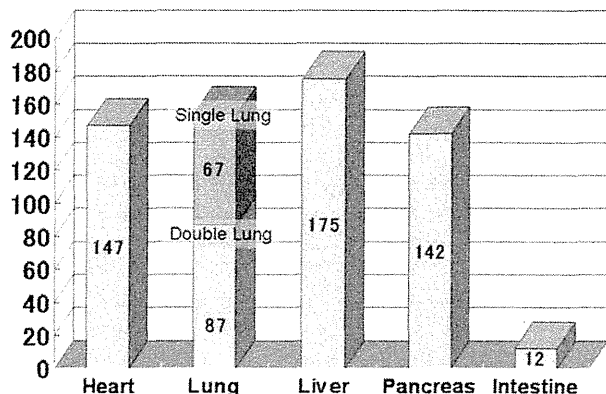


Fig 2. Organs transplanted from 200 brain-dead donors.

RESULTS

We performed 146 heart, 1 heart-lung, and 154 lung (87 single and 67 bilateral), 175 liver (28 split liver), 142 pancreas (114 pancreas-kidney), 253 kidney, and 12 small bowel transplantations (Fig 2). Although donor age has increased after the revision of the Act, the number of organs transplanted per donor and patients transplanted per donor were around 5 and 4 respectively (Fig 3). Patient survivals at 5 and 10 years are shown in Table 1.

DISCUSSION

For many years, “traditional criteria” have been used to identify an appropriate transplant donor. However, over the past 2 decades, there has been a considerable increase in the numbers of patients listed annually for organ transplantation. Strict adherence to standard donor criteria has resulted in a prodigious undersupply of available organs

Table 1. Patient Survival After Organ Transplantation

	Heart	Lung	Liver	Pancreas
5-y survival rate (%)	95.2	72.7	78.6	76.0
10-y survival rate (%)	95.2	54.0	70.8	62.6

with significantly extended waiting times and increased waiting list mortality.^{2,6}

As a consequence of this severe shortage of donor organs, marginal donors have been utilized in many countries. However, only 2407 hearts of 7944 deceased donors (30.2%) were transplanted in the United States in 2010. Because of the strict Japanese Organ Transplantation Law, only 200 BD donors have been procured in Japan for 13 years and 60 heart transplantation (HTx) would have been performed if the cardiac donation rate from the deceased donors was same in Japan as in the United States. These great pressures of the organ shortage had made transplant programs consider the use of organs that would be considered to be marginal. Therefore, an original donor evaluation and management system has been established in Japan, including the MC and the preprocurement meeting.⁴

High serum adrenaline concentrations, as usually observed after its administration, reduce myocardial β -adrenergic receptor density in BD animals⁷ and patients,⁸ which may increase the risk of primary graft dysfunction after HTx. Therefore, the intravenous catecholamine dose should be reduced as much as possible. It has been recommended as initial therapy for hemodynamic support and treatment of diabetes insipidus by the American College of Cardiology,⁹⁻¹¹ due to its catecholamine-sparing effects.^{6,10} Repletion of vasopressin to treat diabetes insipidus to maintain hemodynamic stability and prevent electrolyte imbalance

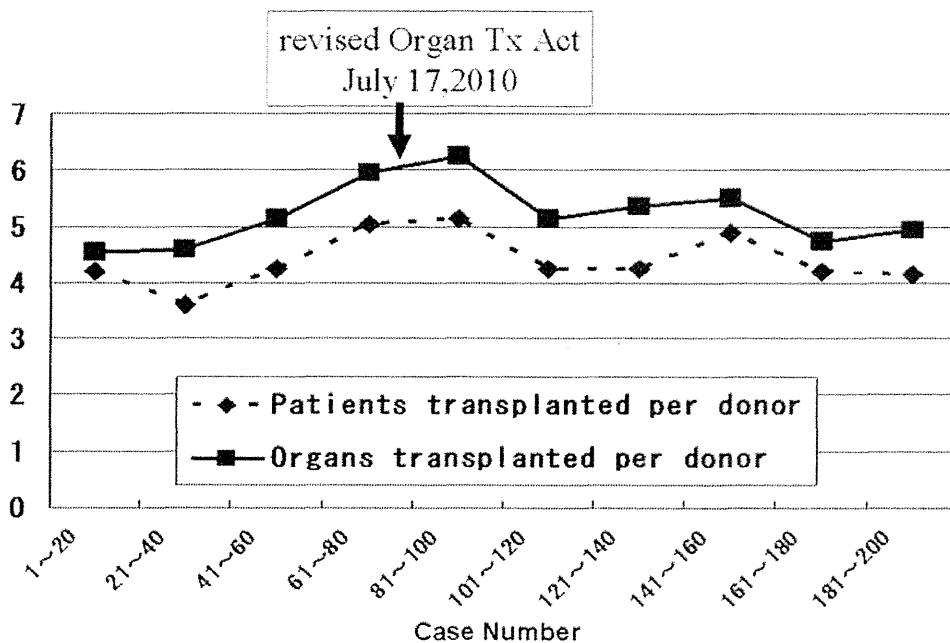


Fig 3. Patients and organs transplanted per donors.

is noncontroversial. A substantial number of BD donors resolve their focal/regional wall motion abnormalities. Aggressive attempts at hemodynamic stabilization using hormonal resuscitation have resulted in dramatic reversibility of cardiac dysfunction.^{10,12}

The ideal lung donor has a PaO₂/FiO₂ ratio more than 300, positive end expiratory pressure requirement greater than 5 cm H₂O, clear chest X ray, age older than 55 years, smoking history of more than 20 packs/y, and absence of trauma, surgery, aspiration, malignancy, and purulent secretions. Pathologic studies of lungs deemed unsuitable for donation have indicated that bronchopneumonia, diffuse alveolar damage, and lung consolidation are the most common reasons to reject a lung. Given these findings, it is recommended that every lung donor undergo BFS for therapeutic bronchial toilet, and to isolate potential pathogens to guide antibiotic therapy in both the donor and the recipient.¹⁰

In conclusion, although the number of transplantations is still small, the availability of organs has been greater in Japan and their outcomes acceptable. The strategies presented herein may be useful to maximize organ transplant opportunities even in other countries.

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We would like to acknowledge and extend our heartfelt gratitude to many heart and lung transplant surgeons who have actually worked as a medical consultant despite of daily hard work and made the completion of this paper possible.

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Current Status of In-Hospital Donation Coordinators in Japan: Nationwide Survey

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ABSTRACT

Objectives. When the Japanese Organ Transplantation Act was issued, the Japanese Organ Transplantation Network (JOT) was established in 1997. JOT lists recipients, assesses and manages organ donors, and educates publics and headquarters for organ donations. JOT procurement transplant coordinators (PTC) play roles in obtaining consent from relatives for organ donation, donor evaluation and management, organ recovery management, organ transport, and care of donor families during and after donation. Every prefecture has at least one PTC who is mainly working in public education and hospital development. They also help the JOT PTC at the time of organ procurement. Most prefectures commission hospital staff in the procurement hospital to be an in-hospital PTC (In-Hp PTC), who make their hospital staff aware of organ donation and support organ procurement. Although the Act was revised in 2010 with brain-dead organ donation increased from 13 to 44 cases yearly, the number was still extremely smaller than other developed countries. In these circumstances, In-Hp PTC may play greater roles to increase donation and smooth procurement procedures. Our primary aim was to describe the current status of In-Hp PTC in Japan.

Materials and methods. Between December 15, 2011, and January 31, 2012, we invited 1889 In-Hp PTC to complete a letter survey using a self-designed questionnaire. In all, 56 In-Hp PTC (40%) completed and returned it.

Results. The occupation of the respondents was nurse (66%), physician (18%), or other (16%). Although 52% of respondents belonged to the hospital, which was designated for brain-death organ donation by the government, only 46% had any experience with a cadaveric donor. Only 2% were full-time In-Hp PTC. They mainly played a role in preparing their own manual for organ procurement (57%), providing in-hospital lectures (44%) or their own simulation exercise (29%), as well as coordinating donation cases. Although 77% had attended seminar about organ donation provided by JOT or the prefecture PTC, 93% wanted more professional education. However, it was difficult for them to attend these activities, to manage a rare and sudden donation case, and to find time to learn about organ donation because they had another post. The topics that they wanted to learn were donor family care (72%), overall organ/tissue donation procedures (65%), the role of In-Hp PTC (67%), simulations of donation (65%), legislation and social system of organ donation (61%), medical indications for donation (61%), current status of donation and transplantation in Japan (57%), donor management (56%), and case studies (49%). There were significant variations in the topics of interest among the occupations.

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As they had another post, they could find only a short period (1 or 2 days) to take professional education, such as lectures. Therefore, it was difficult for them to attend practical on-the-job training.

Conclusions. To establish an organ procurement system and increase organ donation, In-Hp PTC have important roles in Japan. However, none is a full-time In-Hp PTC. Most In-Hp PTC require more professional education. A systematic education program for each occupation must be established soon.

SINCE 1978, the donation of kidneys after cardiac death (DCD) has been legally accepted in Japan after family consent. Small children had been able to donate their kidneys after cardiac death. The Japanese Organ Transplantation Act for brain-death (BD) donation was issued in October 1997. The Act required a living written consent for BD declaration and organ donation; it did not allow BD donation from children younger than 15 years. For these reasons, only 81 BD organ donations were performed in Japan over 13 years since the Act was issued in October 1997.

The Japanese Organ Transplant Act issued in 1997, established the Japanese Organ Transplantation Network (JOT), which lists recipients, assesses and manages organ donors, and educates publics and headquarters of organ donations. JOT procurement transplant coordinators (PTC) play roles in obtaining consent for organ donation from relatives, donor evaluation and management, management of organ recovery, organ transport, and care of donor families during and after donation.

Every prefecture has at least one of their own 1 PTC who is mainly working on public education and hospital development. They also collaborate with the JOT PTC at the time of organ procurement. Most prefectures commission staffs in procurement hospitals to be in-hospital PTC (In-Hp PTC), who make their hospital staffs aware of organ donation and support organ procurement (Fig 1).^{1,2}

Finally the Act was revised on July 17 2010.¹⁻³ Renewal of the Act allowed organs to be donated after BD with family consent if not previously denied before the event. Although the Act was revised in 2010 and BD organ donation increased from 13 to 44 cases in a year, the number was still extremely smaller than that in other developed countries. The revised Act accepts organ donation from BD children younger than 15 years. However, only 158/504 (42.4%) procurement hospitals where BD organ donation is allowed by the Government have established procurement systems from children. In these circumstances, In-Hp PTC may play a great role to increase organ donation and smooth procurement procedures.

The Department of Coordinators and the JOT coordinator committee play the main roles in educating these PTC. JOT has prepared guideline manuals of standard roles and procedures of PTC during organ procurement from BD and DCD donors. Although the JOT has prepared a textbook for In-Hp PTC and held several educational programs for In-Hp PTC, they have been educated mainly by prefectural PTC or their own hospital. Therefore, educational systems for In-Hp PTC should be modified to establish an effective tool once the current status and needs of In-Hp PTC are clarified. Therefore, the primary aim of this study was to describe the current status of In-Hp PTC in Japan based upon a national survey.

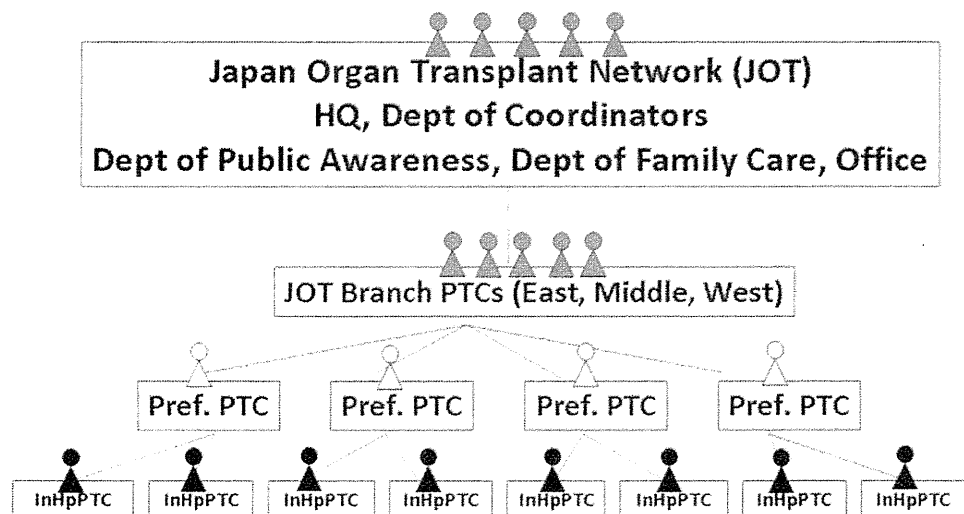


Fig 1. Organ transplant network in Japan. PTC, procurement transplant coordinator; In HpPTC, in-hospital PTC.

MATERIALS AND METHODS

We developed a 28-item self-completed questionnaire that queried: (1) occupation and status; (2) activities and issues (daily and at organ donation); (3) education and experiences of organ donation; (4) needs for learning about organ donation.

Survey letters were sent to 389 donor hospitals and 1889 In-Hp PTC. In 40 prefectures where the In-Hp PTC was delegated by the prefectural government, survey letters were directly or indirectly sent to the delegated In-Hp PTC. In 4 prefectures (Tokyo, Chiba, Saitama, and Osaka) where In-Hp PTC are not delegated, survey letters were sent to the BD donor hospitals. In all, 756 In-Hp PTC (40%) completed and returned the survey. The survey period was December 15, 2011, to March 31, 2012.

RESULTS

Among 1679 letters sent to In-Hp PTC in 40 prefectures where an In-Hp PTC was delegated by the prefectural government, there were 739 (44%) In-Hp PTC responses. But only 17 In-Hp PTC (8%) responded among 210 letters sent to In-Hp PTC in 4 prefectures that had not delegated the In-Hp PTC.

Hospital Where In-Hp PTC Were Working

Overall, 52% of respondents worked in donor hospitals accepted to undergo BD organ donation; 38% in hospitals accepted only to undergo donation after cardiac death (Fig 2a). Only 46% worked in donor hospitals where cadaveric organ donations had been performed in the past (Fig 2b). However, 63% worked in a donor hospital where committees were established for cadaveric organ donation (Fig 2c).

Occupation and Status of In-Hp PTC

The occupations of the respondents were nurse in (66%), physician (18%) or other (16%; Fig 3). Although only 2% of individuals was a full-time In-Hp PTC; 83% had been delegated by the prefectural government and 49% were supported from an advisory committees in their hospital (Fig 4).

Activities and Issued of In-Hp PTC

Their main roles was to prepare a manual for organ procurement (57%), to provide awareness of organ dona-

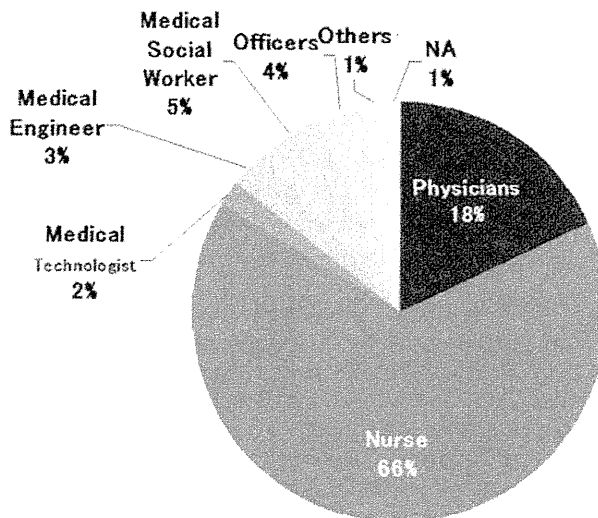


Fig 3. Occupation of in-hospital procurement transplant coordinator.

tion for patients and medical staff (56%), to arrange in-hospital seminars (44%), to consult about organ transplantation and donation (24%), to organize simulations of organ donation (29%), as well as to coordinate donation cases (Fig 5).

Among the 345 respondents who had experienced a cadaveric donor procedure, 77% had coordinated the in-hospital staff and arranged organ procurement; 59% communicated with prefectural and JOT PTC; 58% had cared for the donor family and 35% had obtained informed consent for donation accompanied by a prefectural or JOT PTC (Fig 6).

However, it was difficult for them to do these activities, namely, manage a rare, sudden donation case and to learn organ donation, because they had another post with regard to daily issues, they answered “hard to work as In-Hp PTC due to part time activity” (42%) “no daily time to work as In-Hp PTC” (31%), and “no support by hospital administration and other medical staffs” (29%; Fig 7). With regard to issues at organ donation, they answered no knowledge of their activities at organ donation (77%), “cannot preferentially

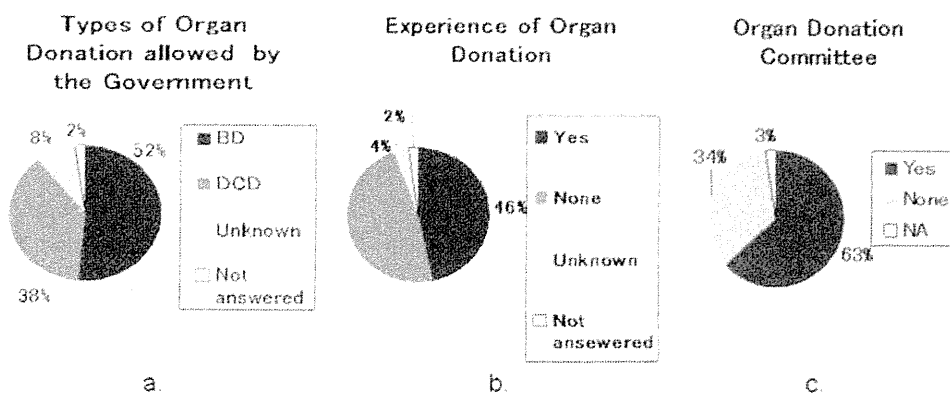


Fig 2. Hospital where in-hospital transplant coordinated works. BD, brain dead; DCD, donation after cardiac death; NA, not applicable.