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Pediatric Intestinal Transplantation: Analysis of the Intestinal Transplant Registry

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Abstract

The Intestinal Transplant Registry (ITR) serves as an international database for centers around the world to contribute to current knowledge about intestinal transplant outcomes. Led by the Intestinal Rehabilitation and Transplant Association and managed by the Terasaki Research Institute, the ITR collects data annually and uses this data to generate reports that guide management strategies and policy statements. The aim of this manuscript was to analyze outcomes specific to pediatric intestinal transplantation.

Outcome data for children transplanted from 1985-2017 were analyzed and predictive factors assessed. A total of 2010 children received 2080 intestine containing allografts during this period. Overall one-year and five-year patient and graft survival were 72.7%/66.1% and 57.2/48.8%, respectively. One-year conditional survival was most strongly associated with being a first-time transplant recipient and liver inclusive grafts. Patient survival was most strongly associated with elective status of transplantation as compared with hospitalized status.

Enteral autonomy following transplantation has continued to improve by era with colonic inclusion demonstrating additional incremental improvement in enteral autonomy and freedom from intravenous fluid. While PTLD and technical complications contribute less to graft loss than in earlier eras, rejection remains the largest contributor to long term graft loss.

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Authorship Statements

Vikram Raghu and George Mazariegos authored the manuscript. Jennifer Beaumont, Matthew Everly, Florence Lacaille, and Robert Venick edited the manuscript. Jennifer Beaumont and Matthew Everly managed the data and conducted the statistical analysis.

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Re-transplantation is linked with significantly worse conditional graft survival and sepsis remains the largest contributor to patient death. Newer data elements are focusing on impact of donor variables, donor and recipient tissue typing, and impact of development of de-novo antibodies.

Keywords

Intestinal transplantation; Pediatric Transplantation; Short Bowel Syndrome; Pediatrics; Registries; Graft rejection

Introduction

Intestinal transplantation serves as a primary treatment option for patients with intestinal failure[1]. Many reports have described the overall trends in intestinal transplantation in the general population[2–6]. Single center experience in intestine transplantation[7–9] has complemented the multi-center comprehensive reports formed from large registries, such as the Scientific Registry of Transplant Recipients (SRTR) and the Intestinal Transplant Registry (ITR)[10].

The ITR began collecting data in 1985 with the mission of providing aggregate analysis to assist centers in improving outcomes and to develop policies in the field. The ITR collects data using a web-based interface that includes information about the donor, the recipient, and the outcomes post-transplant. Between 1985 and 2016, the database was maintained by the University of Toronto. In 2017, it was transitioned to the Terasaki Research Institute (Los Angeles, CA, www.terasaki.org/itr). The current report provides an update from the ITR specifically focusing on global trends in pediatric intestinal transplantation encompassing the data through 2017.

Materials and Methods

Patient data collection for the ITR began in April 1985. All centers performing intestinal transplants worldwide are invited to contribute data. Participating centers obtain individual approval from their respective Institutional Review Boards. The Scientific Committee of the Intestinal Rehabilitation and Transplant Association (IRTA) reviewed pediatric data elements, which were submitted in a web-based form every 2 years up until 2017. After 2017, patient follow-up was collected real time with follow-up data points requested at least annually per patient. The data elements were intentionally selected to be extremely limited to promote complete and accurate reports while minimizing the actual input burden. Prior to 2017, centers were permitted to submit reports via paper submission, Oracle, or Excel spreadsheets. After the Terasaki Research Institute took over management in 2017, all data was migrated to REDCap (Nashville, TN) for secure, web-based electronic data capture[11].

Aggregate reports are generated from this data while maintaining confidentiality of individual center reports. Data collection includes recipient demographics, pre-transplant diagnosis and status, type of transplant, and post-transplant status including anti-rejection medication regimen and complications.

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The current analysis includes only pediatric patients from the ITR, which were defined as those under the age of 18 years at the time of transplant. Analysis includes data collected between April 1985 and December 2017. Data from transplant centers in the United States were cross-checked against the SRTR Standard Analysis File and missing data were updated as needed. Descriptive statistics were used to summarize the number, type, and location of transplants conducted each year and the organs involved. Graft survival was defined as the time from transplant until graft failure or recipient death. Time was censored at the date of the last completed follow-up form in the registry for surviving recipients with functioning grafts. One-year and five-year graft and patient survival rates were estimated overall and stratified by transplant year. Conditional five-year graft survival, given graft survival beyond the first post-transplant year, was also estimated.

Multivariable Cox regression models were fit to the graft and patient survival data for transplants conducted in 2001-2015 to explore the influence of predictor variables. Hazard ratios (HR) and 95% confidence intervals (CI) were estimated from these models. Predictors examined included age at transplant, center volume, recipient gender, indication for transplant (short gut, motility disorder, mucosal defect, regraft), pre-transplant location (home versus hospital/ICU), donor type (living versus deceased), deceased donor pretreatment (yes versus no), native organ removal, liver inclusive graft (yes versus no), and rapamycin maintenance therapy (yes versus no). Transplant center was included in the models as a cluster variable to account for the non-independence of observations within centers. Analyses were performed in R 3.4.1 (R Foundation for Statistical Computing, Vienna, Austria) using survminer and ggplot2. Each predictor variable was examined individually and those with $p<0.20$ were entered into a multivariable model. Then, variables were removed one at a time until only those with $p<0.20$ remained in the final model. The following abbreviations are used in the present report: small bowel transplant (SBT) for isolated intestine without liver or stomach; Liver plus SBT for intestine and liver without stomach; MVT for multivisceral transplant; Modified MVT for intestine and stomach without liver; and Full MVT for intestine, stomach, and liver.

Results

Registry trends in patient demographics and transplant geographic location.

Between 1985 and December 31, 2017, 72 centers submitted data to the ITR on 2080 pediatric intestinal transplants performed in 2010 patients. The number of transplants performed peaked in 2008, declined over the subsequent several years, and has now seemed to stabilize. (Figure 1). Thirty-five intestinal transplant centers worldwide have contributed at least one case since 2015 to the ITR. Over half of these centers are in North America, with the remaining centers distributed across South America (Argentina and Columbia), Asia (Japan and Turkey), and Europe (France, UK, Spain, Belgium, Finland). The majority (75%) of intestinal transplants have occurred in North America, although the numbers in Europe continue to increase. Most transplants were SBT (35%) or Liver plus SBT (46%). The percentage of MVT transplants has increased over time. Over the past decade there has been a trend toward intestinal transplants without a liver component but a relative increase in colon inclusive grafts. Table 1 describes patient and transplant characteristics.

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The leading indications for pediatric intestinal transplants were various forms of short bowel syndrome (65%), motility disorders (20%), re-transplantation (5%), mucosal defects (9%), and tumors (1%). The most common diagnoses for those children transplanted for short bowel syndrome included gastroschisis, volvulus, and necrotizing enterocolitis (Table 1). An increasing majority (71% in 2006-2017) of transplanted patients were called in from home, compared to 59% in 1996-2005 and only 39% in 1986-1995 ($p<0.001$). A small percentage of patients came from the intensive care unit (<3%) and the remaining had been hospitalized immediately prior to transplant.

Intestinal transplant outcomes

Overall one-year and five-year *graft* survival rates were 66.1% and 47.8%, respectively, and overall one-year and five-year *patient* survival rates were 72.7% and 57.2%. Survival rates have improved over time (Figures 2a and 2b). Five-year graft survival has been around 50% or higher every year since 2003. Five-year graft survival, conditional on graft survival beyond the first post-transplant year, has had a less dramatic improvement trend but was above 70% for transplants conducted in 2003-2008. Figures 3a and 3b show the graft and patient survival curves separated by transplant era, demonstrating these improvements over time.

Table 2 shows the results of the multivariate regression analyses of graft and patient survival. Univariate models are in Supplemental Table 1. In the final model, overall graft survival was most strongly associated with being a first-time (rather than re-graft) transplant recipient (HR=0.48, 95% CI: 0.33-0.68), living at home (rather than hospitalized) at the time of transplant (HR=0.70, 95% CI 0.58-0.85), presence of a liver inclusive graft (HR=0.66, 95% CI: 0.56-0.79), and mucosal defect or motility disorder as the indication for transplant. One-year conditional graft survival was also most strongly associated with being a first-time transplant recipient (HR=0.41, 95% CI: 0.21-0.81) and receiving a liver inclusive graft (HR=0.50, 95% CI: 0.39-0.65). In models examining patient survival, living at home pre-transplant (rather than being hospitalized) remained associated with both overall patient survival (HR=0.64, 95% CI: 0.51-0.81) and conditional patient survival given survival to one-year (HR=0.62, 95% CI: 0.50-0.76). The association with re-transplant is further demonstrated in Figures 3c and 3d.

Cause of death for transplanted patients is summarized in Table 3. Sepsis remains the most common cause of death, accounting for nearly half of patient deaths in the current era. After sepsis, graft failure and post-transplant lymphoproliferative disorder (PTLD)/lymphoma are the next highest causes of death following transplantation. Over the last three decades the relative proportions of sepsis, PTLD/lymphoma, and graft failure as causes of death has remained unchanged. Similarly, rejection remains the primary cause of graft loss (Table 4).

Nutritional Status

Freedom from parenteral nutrition has been achieved in over 60% of patients with data on their nutritional status recorded since 2006 (Figure 4) with an additional 9% requiring supplemental IV fluids. This percentage has continued to trend up in each era. Recipients of

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a colon have shown a trend towards weaning off TPN more successfully at a rate of 75% in those with recorded data since 2006.

Discussion

Intestinal transplantation remains the primary treatment for patients with irreversible intestinal failure who develop life-threatening complications associated with long-term parenteral nutrition. The Intestinal Transplant Registry serves as the most comprehensive long term source of data on intestinal transplantation worldwide. This report is the first to focus on the pediatric component of the ITR, is the largest pediatric intestinal transplant analysis reported and complements the overall analyses reported previously that included both adults and children[2–4]. Pediatric outcomes may present particular opportunities or challenges that may benefit from separate analysis.

Although the majority of intestinal transplants historically have involved liver inclusive grafts, there has been a growing trend towards isolated intestinal transplants given the successful strategies of intestinal rehabilitation programs at preventing intestinal failure associated liver disease. A proportion of the decrease in intestine transplant volume correlates with the rise in multidisciplinary intestinal rehabilitation programs and successful efforts to reduce complications of chronic parenteral nutrition use, such as lipid minimization strategies, alternative lipid emulsions, and quality improvement efforts to decrease central line associated bloodstream infections.

The most common diagnosis leading to intestinal failure and subsequent transplant in children remains short bowel syndrome. Despite necrotizing enterocolitis being the most common cause of short bowel syndrome in the pediatric population, gastroschisis is the most common cause for transplant[12]. A growing trend in the identification of motility disorders has led to this diagnosis as the etiology for 20% of transplants, nearly doubling over the last decade. These findings both highlight the importance of bowel motility, which is known to be affected in patients with gastroschisis, while also supporting the notion that intestinal rehabilitation programs have been able to overcome significant deficiencies in bowel length if bowel function is preserved.

With continued improvements in home parenteral nutrition, home antithrombotic therapy, and central line care, a larger number of patients receiving transplants are coming from home. This cohort of patients coming from home has shown significant survival benefits, likely as a surrogate for their stability pre-transplant.

Today, there are over 1,000 survivors of pediatric intestinal transplantation followed in the registry. Overall, graft survival has improved to 70% at five years in the pediatric population, the highest it has been at any point since 1985. Survival was correlated with coming from home for transplant and a liver-inclusive graft. The use of rapamycin in the immunosuppressive regimen trended towards beneficial, which mirrors the data reported by the United Network of Organ Sharing[13]. Data suggests that rapamycin has the potential to ameliorate many of the adverse effects of calcineurin inhibitors and further investigation

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may help to lead to the creation of mTOR inhibitor-based regimens for maintenance immunosuppression[14–16].

In comparison with the overall registry analysis published earlier[10], the primary similarities are in the overall trend of improving actuarial graft survival corresponding with patients being called in from home to receive their transplants and inclusion of a liver component, despite the decreasing need for combined liver grafts. Pediatric survival remains slightly better than adult survival post-transplant. While cardiovascular death represents the third leading cause in adult recipients, children instead are at a higher risk of PTLD.

Despite the improvement in graft and patient survival over time, several areas still require further investigation. Five-year conditional survival after one year post-transplantation has not shown the same improvement as overall survival. Late graft loss from chronic rejection remains a significant problem. There may be a survival benefit from the addition of the liver component attributable to a reduction in donor specific antibodies (DSA) and antibody mediated rejection as previously suggested in the literature[17]. Grafts that contained a liver have been shown to have a higher rate of clearance of preformed DSA, which would correspond to the increased benefit in conditional survival produced by reducing the incidence of chronic rejection and thereby late graft loss. Although post-transplant DSA data were not collected in the registry until 2010, this is a current area of focus that will be analyzed in future iterations.

Re-transplantation is linked with significantly worse conditional graft survival. While we hypothesize this is due to risk of chronic rejection in this sensitized population, further analysis will be required to understand this challenging patient population. Sepsis continues to be the predominant reason for patient death after transplantation and highlights a critical challenge in intestinal transplantation where there exists such a narrow therapeutic window between excessive and inadequate immunosuppression. Similarly, there was a trend towards increasing incidence of graft versus host disease (GVHD). We may hypothesize that as the community has become better with using immunosuppression to prevent and treat rejection that sepsis and GVHD deaths remain concerns for serious morbidity. Focused analyses would be necessary to better describe these trends.

As with any registry report, many limitations are present in this type of retrospective analysis. The associations described above do not prove any causality between the reported factors and outcomes. The dataset is limited by the amount of information reported and may have some missing or incomplete data though efforts were made to maximize the case-capture rate by comparing North American data to SRTR Standard Analysis File. While no similar data exists to verify the case-capture rate outside of North America, the consistent submission of data from the European centers suggests that there has been no change in data submission from years past when an audit was performed.

In conclusion, intestinal transplantation remains a lifesaving solution for many children with intestinal failure. However, the ultimate goal of providing these patients with predictable excellent long-term graft function has not yet been achieved. Advances in the pre-transplant management of intestinal failure patients has significantly improved, allowing more stable

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patients to be called in from home and resulting in better transplant outcomes with improved survival. Newer data elements can focus on impact of donor variables, recipient and donor serologic matching, and impact of de novo donor specific antibody formation on long term outcomes in children.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations:

CI	confidence interval
DSA	donor-specific antibodies
HR	hazard ratio
IRTA	Intestinal Rehabilitation and Transplant Association
ITR	Intestinal Transplant Registry
MVT	multivisceral transplant
PTLD	post-transplant lymphoproliferative disorder
SBT	small bowel transplant
SRTR	Scientific Registry of Transplant Recipients
GVHD	Graft versus host disease

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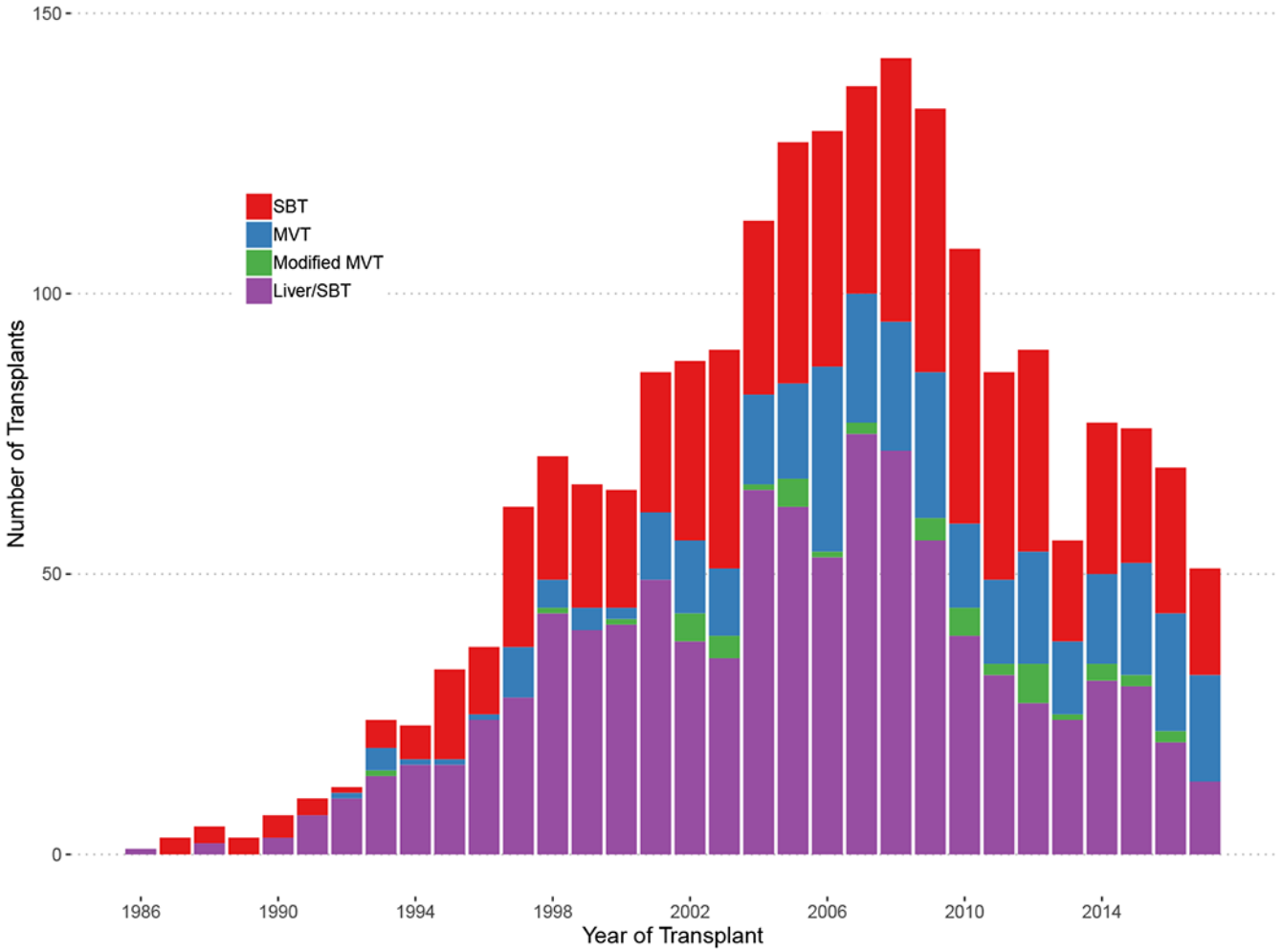

Figure 1.
Number and type of pediatric intestinal transplants performed each year since 1985

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Figure 2.

a. One-year graft survival, five-year graft survival, and five-year graft survival conditional on graft survival beyond the first post-transplant year

b. One-year patient survival, five-year patient survival, and five-year patient survival conditional on survival beyond the first post-transplant year

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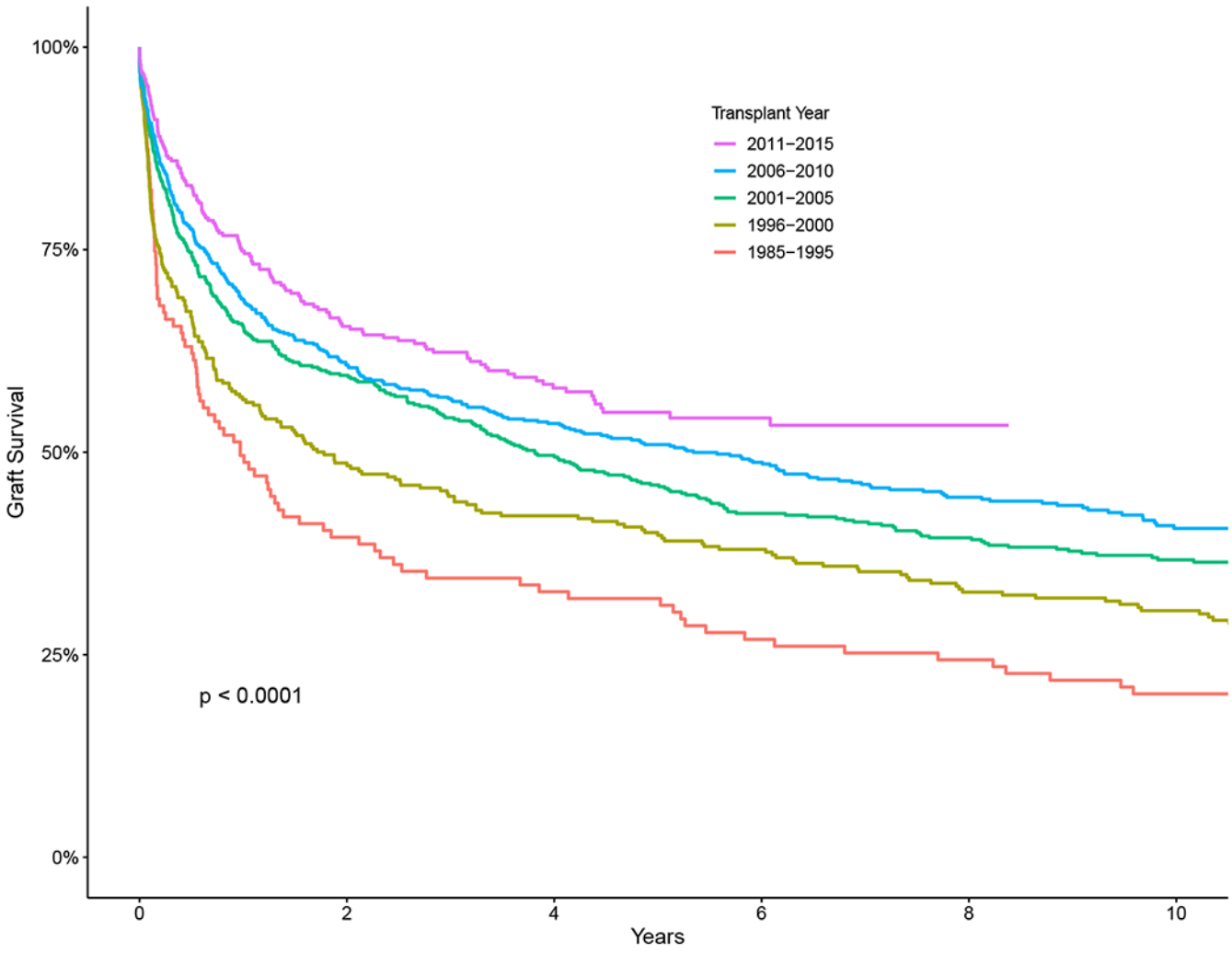

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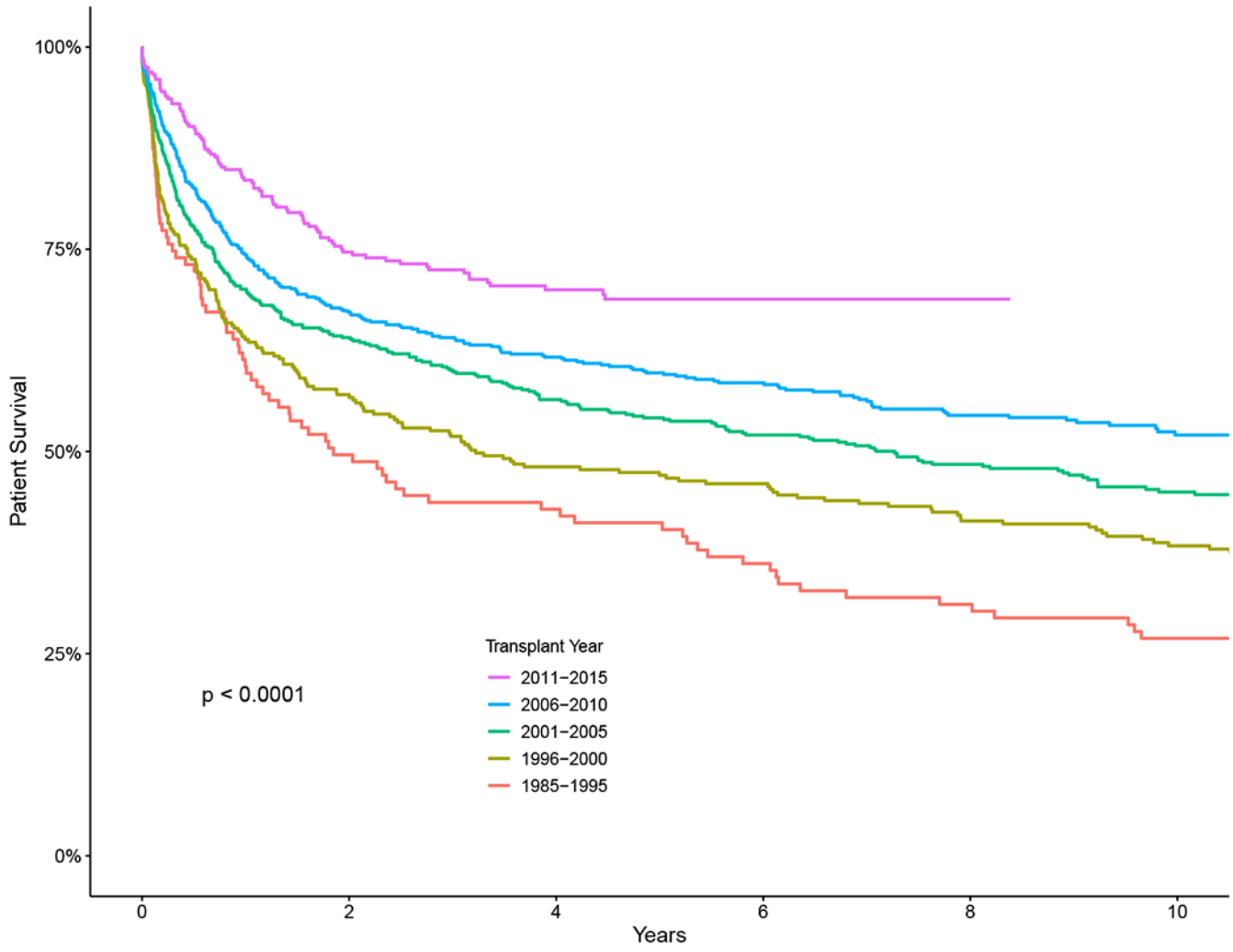

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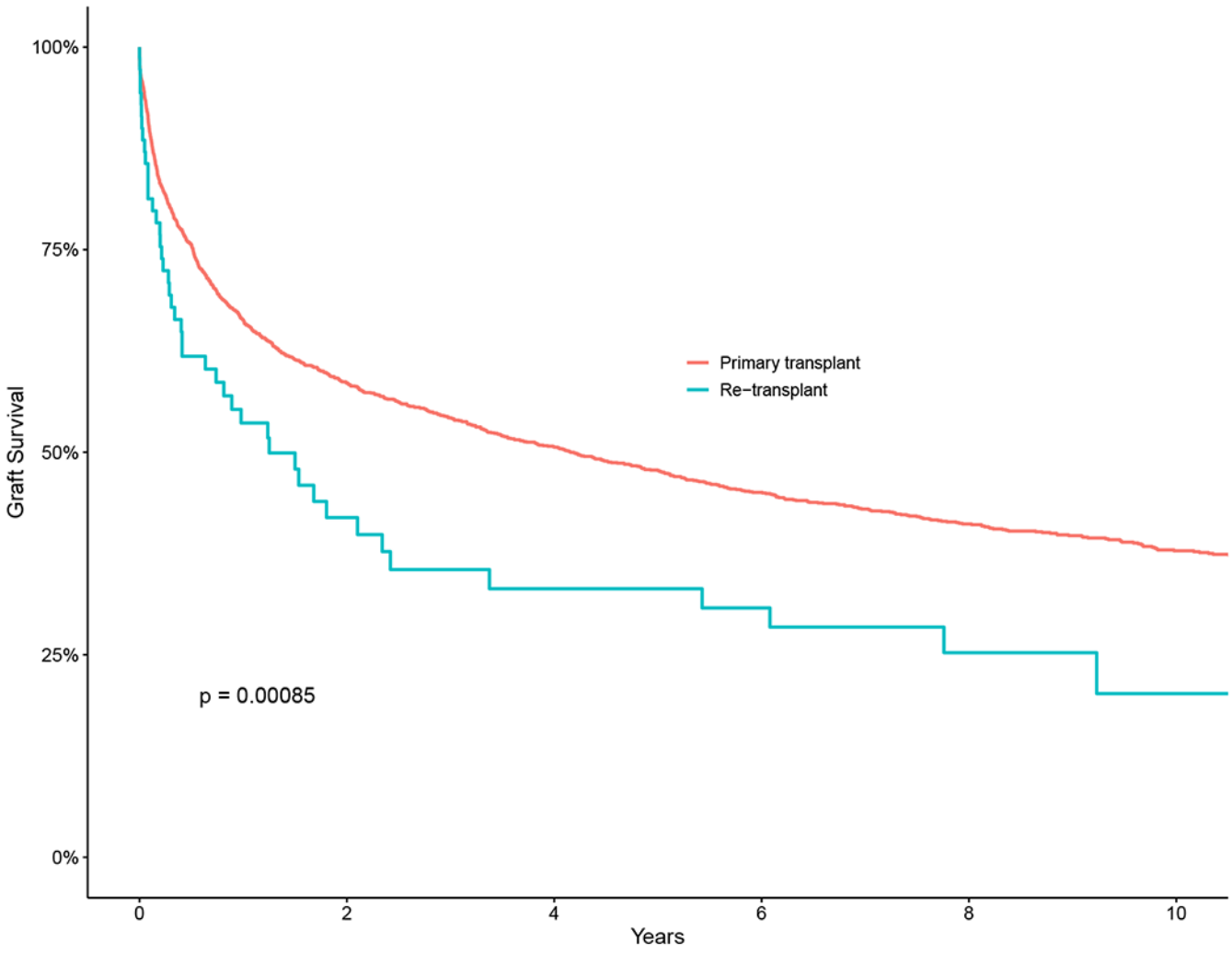

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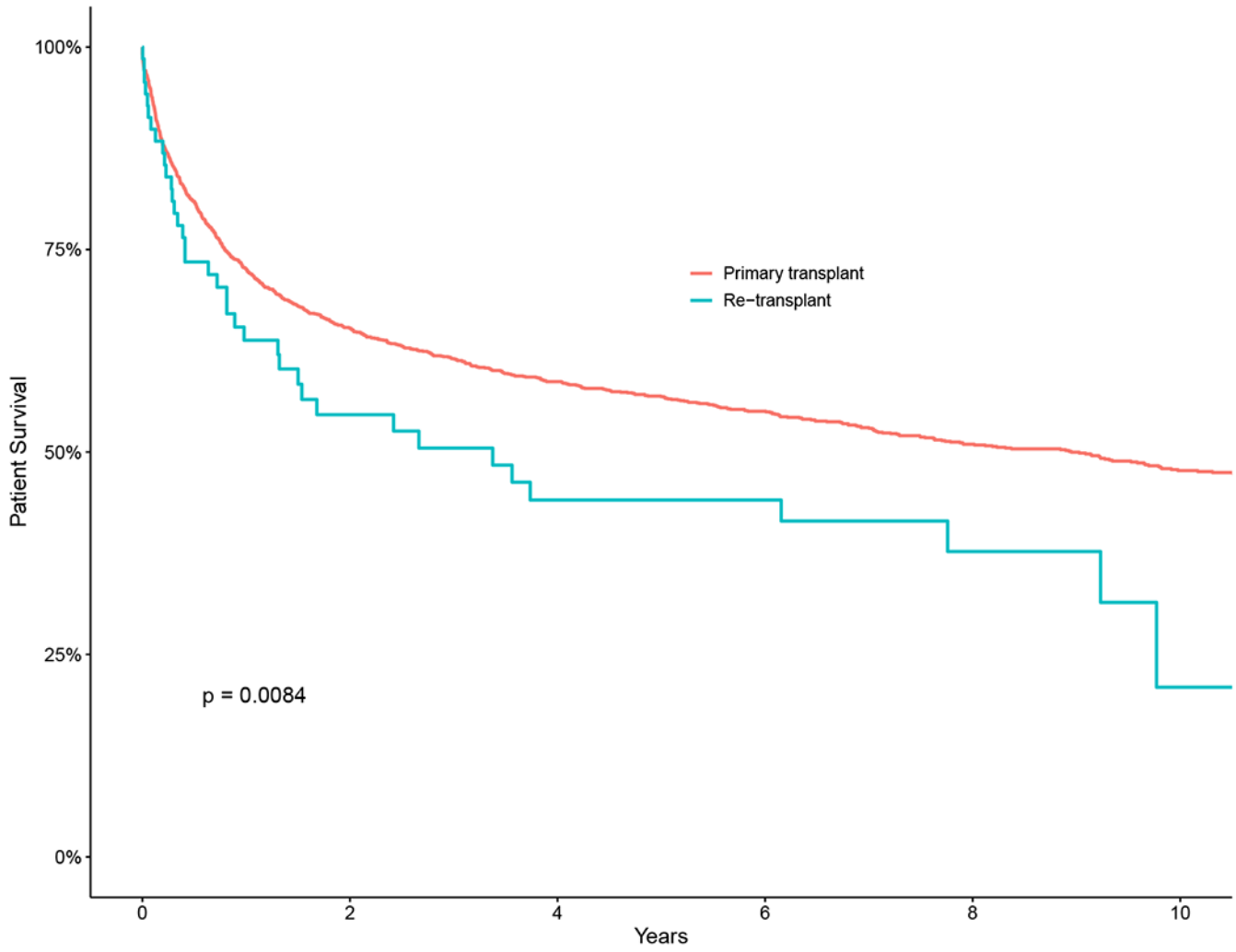

Figure 3.

a. Graft survival by transplant era

b. Patient survival by transplant era

c. Graft survival by re-transplant status

d. Patient survival by re-transplant status

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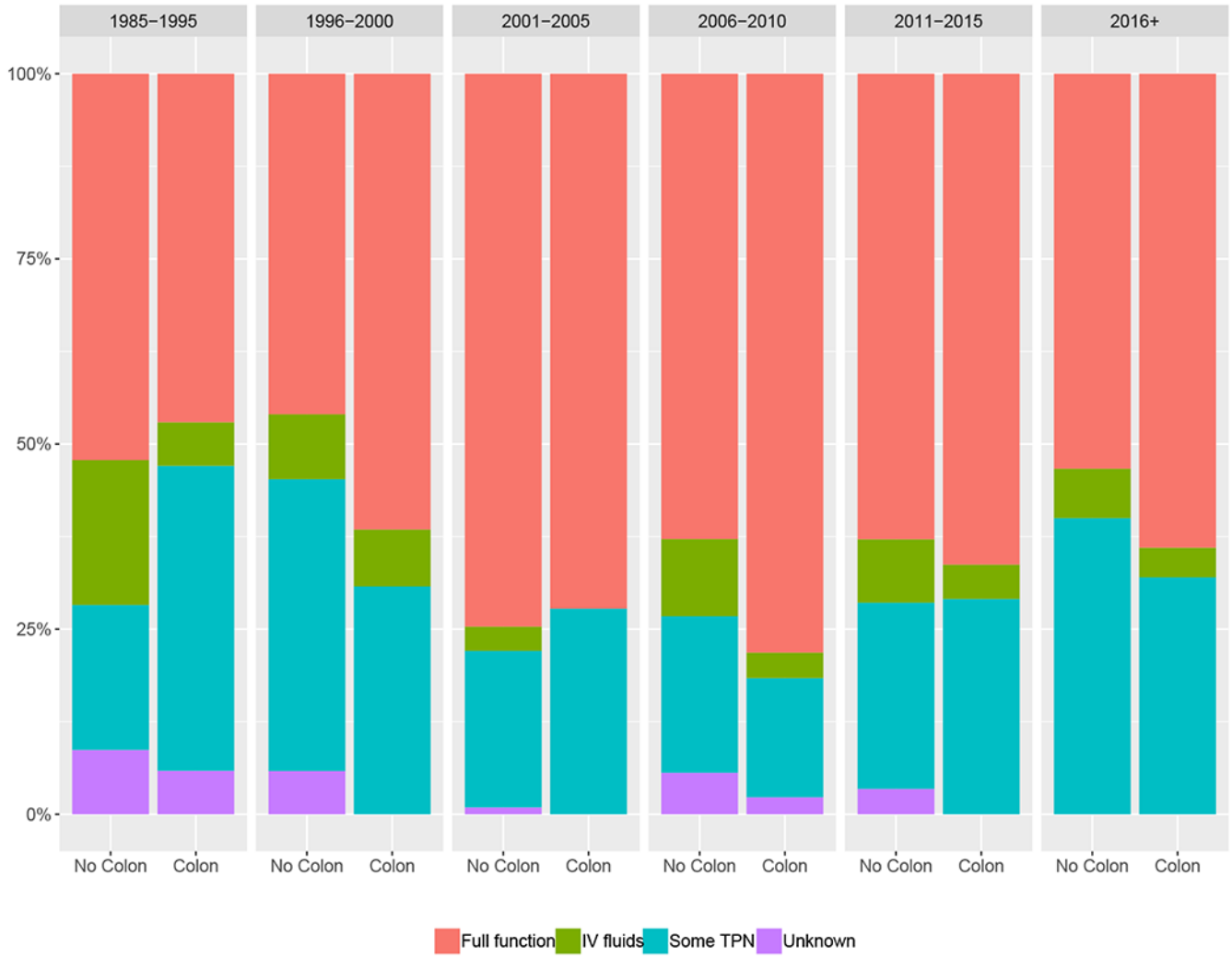

Figure 4.
Functional status of transplant recipients by era

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Table 1.

Characteristics of all pediatric intestinal transplants in the ITR (1985-2017)

	n=2080 transplants
Median Age (in years) at transplant, (Q1, Q3)	2.5 (1.1, 6.3)
Male, n (%)	1177 (57)
Type of transplant, n (%)	
SBT	725 (35)
Liver plus SBT	966 (46)
Modified MVT	47 (2)
Full MVT	342 (16)
Indication for transplant[†], n (%)	
Short gut	1245 (65)
Motility disorder	381 (20)
Mucosal defect	174 (9)
Re-transplant	91 (5)
Tumor	22 (1)
Cause of short gut[‡], n (%)	
Gastroschisis	473 (38)
Volvulus	315 (25)
Necrotizing enterocolitis	290 (23)
Intestinal atresia	49 (4)
Ischemia	24 (2)
Trauma	24 (2)
Other	150 (12)
Rapamycin maintenance, n (%)	160 (8)

[†]Values do not sum to total number of transplants due to missing data

[‡]Patients may have more than one cause listed; denominator for percentage = 1245 with short gut

Abbreviations: Q1 = quartile 1, Q3 = quartile 3

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Table 2.

Cox Proportional Hazards Regression Models for Graft and Patient Survival (2001-2015 cases)

	Overall		One Year Conditional	
	HR (95% CI)	**p-value**	**HR (95% CI)**	**p-value**
Graft Survival				
Female	1.08 (0.96, 1.22)	0.186	--	--
Indication: Motility disorder	1.20 (1.00, 1.44)	0.050	1.36 (1.08, 1.72)	0.009
Indication: Re-transplant	2.10 (1.47, 2.99)	<0.001	2.44 (1.24, 4.81)	0.010
Indication: Mucosal defect	1.39 (1.03, 1.87)	0.032	1.51 (0.92, 2.49)	0.104
Called in from home for transplantation procedure	0.70 (0.58, 0.85)	<0.001	--	--
Included liver component	0.66 (0.56, 0.79)	<0.001	0.50 (0.39, 0.65)	<0.001
Rapamycin maintenance	0.79 (0.62, 1.09)	0.058	--	--
Patient Survival				
Age at transplant, per year	--	--	1.03 (0.99, 1.06)	0.101
Indication: Motility disorder	--	--	1.43 (1.08, 1.89)	0.014
Indication: Re-transplant	1.79 (1.06, 3.03)	0.031	2.11 (1.08, 4.14)	0.030
Indication: Mucosal defect	1.33 (1.01, 1.76)	0.042	1.43 (0.94, 2.17)	0.097
Called in from home	0.64 (0.51, 0.81)	<0.001	0.62 (0.50, 0.76)	<0.001
Living donor	1.55 (0.83, 2.89)	0.166	--	--
Included liver component	--	--	0.84 (0.67, 1.05)	0.126
Rapamycin maintenance	0.81 (0.63, 1.06)	0.132	--	--

HR < 1 = improved survival

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Table 3.

Causes of death in each transplant era[†]

Year of transplant	**1986-1995**	**1996-2000**	**2001-2005**	**2006-2010**	**2011-2015**
Total number of deaths	***97***	***202***	***280***	***276***	***94***
Unknown cause	7 (7%)	12 (6%)	26 (9%)	37 (13%)	19 (20%)
Sepsis/Multi-organ failure	58 (64%)	118 (62%)	154 (61%)	144 (60%)	43 (57%)
PTLD/Lymphoma	13 (14%)	10 (5%)	13 (5%)	18 (8%)	6 (8%)
Graft failure/rejection	10 (11%)	45 (24%)	40 (16%)	39 (16%)	14 (19%)
Kidney failure	1 (1%)	6 (3%)	9 (4%)	10 (4%)	3 (4%)
Liver failure	4 (4%)	6 (3%)	9 (4%)	4 (2%)	3 (4%)
Cardiovascular/stroke	7 (8%)	14 (7%)	28 (11%)	24 (10%)	8 (11%)
Technical complication	12 (13%)	6 (3%)	10 (4%)	11 (5%)	2 (3%)
Graft versus host disease	1 (1%)	3 (2%)	5 (2%)	11 (5%)	6 (8%)
Respiratory failure	1 (1%)	4 (2%)	8 (3%)	2 (1%)	3 (4%)
Other causes of death	22 (24%)	52 (27%)	87 (34%)	87 (36%)	31 (41%)

[†]More than one cause of death may have been listed for each patient; unknown causes excluded from denominator for remaining percentages

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Table 4.

Reasons for graft loss

Year of transplant	**1986-1995**	**1996-2000**	**2001-2005**	**2006-2010**	**2011-2015**
Total number of failures	***100***	***223***	***322***	***345***	***140***
Rejection	25	37	74	74	28
PTLD	1	0	3	2	5
Infection (non-PTLD)	0	1	0	2	0
Surgical (Thrombosis, volvulus, etc.)	3	1	2	5	4
Poor graft function	0	0	2	4	4
Other	1	3	3	2	1
Death	0	6	10	10	8