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A rapid scan of the literature

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Intestinal transplants: a rapid literature scan

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The systematic review of the evidence will ultimately be used by The Sector Capability and Innovation Directorate team to inform policy decision making in conjunction with other information. The content of the review alone does not constitute clinical advice or policy recommendations.

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Executive Summary

Introduction

Intestinal transplantation (ITx) involves the transplantation of an intestinal allograft for the purpose of restoring intestinal function in patients with irreversible intestinal failure (IF). The procedure is usually reserved for patients with irreversible IF who have failed total parenteral nutrition (TPN). This report provides a brief scan of the literature available on the role of intestinal transplants in the treatment of intestinal failure. It was commissioned by the New Zealand Ministry of Health.

Methods

A systematic method of literature searching and study selection was employed in the preparation of this report. The literature was searched using the bibliographic databases of EMBASE and Medline. The Cochrane Database of Systematic Reviews, The FDA/EMEA website and numerous health technology assessment websites were also searched to help identify existing reviews or clinical practice guidelines. In addition, the bibliographies of key included papers were examined for relevant studies. It is important to note that as this was a brief scan of the evidence, and not a full systematic review, detailed quality appraisal, data extraction and interpretation of the identified literature was not performed. The review relies heavily upon material reported in each publication's abstract.

Key results

The search strategy identified a total of 542 citations, of which 40 qualified for inclusion in this review. These included two medical position statements, one report from Medicaid, one systematic review, one prospective study, 34 case series reports (including one report that also contained some relevant cost information) and one cost effectiveness analysis. The case series reports include three reports that present results from the Intestinal Transplant Registry, which captures information about all intestinal transplant recipients worldwide.

The results of the literature search show that there are no reliable studies directly comparing TPN and ITx for the treatment of IF. Case series data show that although mortality rates are improving over time, ITx is still associated with more risk than other transplant procedures. Factors associated with improved survival after transplant have been identified e.g. disease aetiology, transplantation of patients waiting at home versus in the hospital, use of induction antibody therapies, conduct at centres that have performed at least 10 transplants, patient body weight, recipient age and type of graft. Most reports also agree that the majority of surviving ITx recipients achieve nutritional autonomy.

There is one prospective study that attempts to quantify the difference between TPN and ITx (Pironi *et al.*, 2008) after three years of follow-up. The study found that the three-year survival rate was higher in ITx candidates who were not transplanted than it was in ITx recipients; however the study results are probably subject to bias because

ITx recipients are likely to have poorer prognosis than those who are candidates but don't receive transplants.

There is a limited amount of cost effectiveness information available, and results are largely inconclusive.

Conclusions

Currently ITx is only recommended in those patients with total irreversible IF who can no longer be maintained on TPN. Because of the risks associated with the treatment, transplants are not recommended for quality of life reasons alone. Given the paucity of data, this approach appears to be appropriate.

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List of Abbreviations and Acronyms

AGA	American Gastroenterological Association
AHRQ	Agency for Healthcare Research and Quality
ANZHSN	Australia and New Zealand Horizon Scanning Network
AST	American Society of Transplantation
CADTH	Canadian Agency for Drugs and Technology in Health
CI	Confidence interval
CL	Confidence limit
CMS	U.S. Centers for Medicare and Medicaid Services
CPG	Clinical Practice Guideline
TPN	Home parenteral nutrition
HTA	Health Technology Assessment
IF	Intestinal failure
INAHTA	International Network of Agencies for Health Technology Assessment
ISB	Isolated short bowel
ITx	Intestinal transplantation
MMF	Mycophenolate Mofetil
MSAC	Medical Services Advisory Committee
MV	Multi-visceral
NEC	Necrotising enterocolitis
NICE	National Institute for Clinical Excellence.
RCT	Randomised controlled trial
SB-L	Short bowel-liver
SBS	Short bowel syndrome
SD	Standard deviation
TPN	Total parenteral nutrition

Introduction

Intestinal failure (IF) occurs when the intestine is unable to meet the nutritional and fluid requirements of the body through the enteral route. IF can be due to intrinsic diseases of the gastrointestinal tract, or result from major loss or resection of the intestine, which leads to a condition known as short bowel syndrome (SBS). Patients with IF usually receive total parenteral nutrition (TPN), whereby nutrients are administered intravenously. Although TPN is generally considered to be a safe and effective treatment, a subset of patients experience treatment-related complications including liver failure and loss of venous access due to recurrent infection. These patients are said to have “failed” TPN therapy.

Intestinal transplantation (ITx) is usually reserved for patients with irreversible small IF who have failed TPN. Until recently, immunological graft intolerance presented a significant barrier to successful transplantation. The large number of white cells in the bowel provides a strong stimulus for rejection, and the large number of bacteria in the gut increases the risk of infection after transplantation.

In recent years, improved anti-rejection drugs, refined surgical procedures, and a greater understanding of immunology have improved the survival rates in transplant recipients. Transplantation offers patients the chance of an improved quality of life, and as a one-off cost it may be more cost effective than TPN in the long-term. It is possible that ITx will become a feasible alternative to TPN, as opposed to a second line treatment. In spite of these advantages, at present ITx remains a dangerous procedure associated with relatively high mortality. Direct comparison of the results of ITx with long term survival rates in patients with TPN are generally invalid, as transplantation is currently only considered for selected patients likely to experience a poor outcome on intravenous feeding. As a result, this review does not nominate a specific comparator. Instead, provides an overview of the current literature describing the efficacy and safety of ITx for the treatment of patients with IF.

An extensive literature search was conducted to identify relevant systematic reviews, randomised controlled trials (RCTs), case-control studies, longitudinal studies and clinical trial registries. Since ITx is usually a last-resort life-saving therapy, it is not surprising that no RCTs were identified. This report therefore presents the results of one systematic review, one prospective study, an international registry, a number of retrospective case-series and other miscellaneous publications. The results of each identified study should be considered with the year of publication in mind, as there have been significant advances in transplantation methodology in recent years.

Methods

Literature search

A search of the EMBASE, Medline and Cochrane database as well as numerous Health Technology Assessment (HTA) and clinical practice guideline (CPG) websites (**Appendix A**) was undertaken to identify any published guidelines, systematic reviews or publications pertaining to the use of ITx in patients with IF. In addition, a general internet search was performed to identify any relevant publications that were not identified by other means. The literature source, search terms, number of citations identified and date of the search is outlined in **Table 1**. Many of the citations identified through the search of the Cochrane library and HTA websites were duplicates already identified through the EMBASE/Medline search, or were irrelevant to the topic of interest, and were therefore excluded before downloading into the Reference Manager database.

Table 1: Summary of the literature search

Source	Search terms	Citations	Date
EMBASE.com (Includes EMBASE and Medline)	(('small bowel transplant') OR ('intestine transplant'/exp OR 'intestine transplant') OR ('intestine transplantation'/exp OR 'intestine transplantation') OR ('intestinal transplant'/exp OR 'intestinal transplant') OR ('intestinal transplantation') OR ('intestinal graft'/exp OR 'intestinal graft') OR ('intestine graft'/exp OR 'intestine graft') AND [english]/lim AND [humans]/lim) AND (('short bowel syndrome'/exp OR 'short bowel syndrome') OR ('intestinal failure' OR 'intestinal failure')) AND [english]/lim AND [humans]/lim)	522	07/05/2009
Cochrane library	"intestinal transplant" or "intestine transplant" or "intestinal graft" or "intestinal transplantation" or "intestine transplantation" (full text search)	12	03/02/2009
CADTH	"Intestinal transplant"	0	03/02/2009
EuroScan	"Intestinal transplant"	0	03/02/2009
National guideline clearinghouse	"Intestinal transplant"	0	03/02/2009
NHS Evidence	"Intestinal transplant"	2	
NICE	"Intestinal transplant"	0	03/02/2009
INAHTA	"Intestinal transplant"	1	03/02/2009
MSAC	"Intestinal transplant"	0	03/02/2009
ANZHSN	"Intestinal transplant"	0	03/02/2009
AHRQ	"Intestinal transplant"	0	03/02/2009
Medicaid	"Intestinal transplant"	1	03/02/2009
Manual searching	N/A	4	
Total		542	03/02/2009
Remove duplicates ^a		537	

^a duplicates were removed by hand

Abbreviations: AHRQ, Agency for Healthcare Research and Quality; ANZHSN, Australia and New Zealand Horizon Scanning Network; CADTH, Canadian Agency for Drugs and Technology in Health; INAHTA, International Network of Agencies for Health Technology Assessment; MSAC, Medical Services Advisory Committee; NICE, National Institute for Clinical Excellence; NHS, National Health Service

There were 542 citations downloaded into the Reference Manager database from the various sources described in **Table 1**. These included 522 citations found through the EMBASE/Medline search, 12 citations identified from the Cochrane Library, four citations identified from online HTA/CPG databases and four through manual searching. Five duplicate citations were removed manually from the Reference Manager database. The titles and abstracts were reviewed using the inclusion and exclusion criteria outlined below in **Table 2**.

Table 2: Criteria for inclusion/exclusion in review

Reason for exclusion	Number of citations excluded
Incorrect study type: case study (<20 patients), opinion piece, letter	250
Incorrect intervention/outcomes: does not examine intestinal transplantation	247
Included	40

After reviewing the citations, there were 40 that qualified for inclusion. These included two medical position statements, one report from Medicaid, one systematic review, one prospective study, 34 case series reports (including one report that also contained some relevant cost information) and one cost report. The case series reports include three reports that present results from the Intestinal Transplant Registry, which captures information about all intestinal transplant recipients worldwide. Included citations are listed in **Appendix B** while excluded citations are provided in **Appendix C**.

Results

Overview of intestinal transplants

Intestinal transplants (also known as small bowel transplants) involve the transplantation of an intestinal allograft for the purpose of restoring intestinal function in patients with irreversible IF. Intestinal failure has many causes, including primary defects of intestinal epithelial absorption, motility disorders, and loss of large portions of the intestine due to surgical resection for congenital defects, necrotizing enterocolitis (NEC), ischemia, trauma, and inflammatory bowel disease.

The standard of care for patients with IF is TPN in the hospital, or at home. Although TPN is generally regarded as safe and effective, some patients develop serious long-term complications including liver failure, central line-related sepsis, central venous thrombosis, pulmonary embolism and severe dehydration. At present, ITx is usually only indicated in patients who fail TPN for one of the aforementioned reasons.

There are three types of ITx procedure:

- isolated small bowel transplantation (ISB)
- combined small bowel-liver transplantation (SB-L)
- multi-visceral transplantation, which can include stomach/pancreaticoduodenal complex in addition to the intestine and liver (MV).

The type of ITx procedure indicated (solitary or composite graft) in a given patient depends on the aetiology of IF and the extent of intestinal and extra-intestinal organ involvement. Cadaveric donors have been used in most ITx cases, although isolated successful procedures have been performed with an intestinal segment from a living related donor (Botha, 2005).

Although IF occurs in patients of all ages, the rates and indications for ITx candidacy differ between adults and children. A large multi-centre survey undertaken by Pironi *et al.* (2006) concluded that the rate of ITx is twice as high in children as it is in adults. In adults, candidacy for ITx was primarily related to failure of TPN, while in paediatric patients, candidacy was most often due to an underlying disease-related risk of death (e.g. desmoids tumours, congenital mucosal disorders or ultra-short bowel syndrome).

Medicaid advice

In 2000, the U.S. Centers for Medicare and Medicaid Services (CMS) provided coverage for intestinal and multi-visceral transplantation under certain conditions. Medicare agreed to cover ITx for the purpose of restoring intestinal function in patients with irreversible IF only when performed for children and adults who have failed TPN for one of the following reasons:

- impending or overt liver failure (increased serum bilirubin and/or liver enzyme levels, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy, stomal bleeding, hepatic fibrosis, or cirrhosis)
- thrombosis of major central venous channels (two thromboses in subclavian, jugular, or femoral veins)
- frequent central line-related sepsis (two episodes of systemic sepsis secondary to line infection per year, one episode of line-related fungemia, septic shock, or acute respiratory distress syndrome)
- frequent severe dehydration.

Transplantation was only covered by Medicare in centres that had an annual volume of ten intestinal transplants per year and a one-year actuarial survival of 65 percent. The 2000 decision was based on an analysis of the relevant clinical literature including 11 distinct studies submitted by the requestor, the Thomas E. Starzl Transplantation Institute. CMS also analysed a July 1999 technology assessment performed by Blue Cross Blue Shield, and an April 2000 technology assessment performed by Agency for Healthcare Research and Quality (AHRQ). Full reports of the two HTAs were not made publically available, and are therefore not included in the scope of this report. Of the 11 distinct studies, one by Grant, *et al.* (1999) reported that programs that have performed at least 10 transplants had significantly higher graft survival rates. The 2000 Decision Memorandum notes two studies that support linking annual volume levels of other types of high risk surgical procedures to successful outcomes (Hosenpud *et al.*, 1994, and Edwards *et al.*, 1999). This was the rationale for Medicare's implementation of an annual volume criterion.

Clinical practice guidelines and position papers

Because of limited publications and a lack of controlled studies, there are no clinical practice guidelines relating to the conduct of ITx procedures. The search of guideline databases identified one guideline from the British Society of Gastroenterology for the management of patients with a short bowel (Nightingale *et al.*, 2006); however it does not provide any specific recommendations regarding the use of ITx.

Instead of formal guidelines, the American Society of Transplantation (AST), and the American Gastroenterological Association (AGA) have both published medical position papers on the use of ITx. These papers were identified through the clinical literature search and are shown below in **Table 3**.

Table 3: Position papers on intestinal transplantation

Citation	Reference
American Society of Transplantation (AST)	Kaufman SS, Atkinson JB, Bianchi A, Goulet OJ, Grant D, Langnas AN, McDiarmid SV, Mittal N, Reyes J, and Tzakis AG. (2001) Indications for pediatric intestinal transplantation: A position paper of the American Society of Transplantation. <i>Pediatric Transplantation</i> 5:80-87.
American Gastroenterological Association (AGA)	American Gastroenterological Association. American Gastroenterological Association Medical Position Statement: Short Bowel Syndrome and Intestinal Transplantation. <i>Gastroenterology</i> 124[4], 1105-1110. 2003.

The AGA paper endorses the position assumed by Medicare and Medicaid, whereby intestinal transplants are reserved for those patients who fail TPN therapy. The AST guideline is intended for paediatric patients only. This guideline identifies a subset of children with IF who are at risk of developing life-threatening complications arising from TPN. Complications warranting consideration of ITx include TPN-associated liver disease, recurrent sepsis, and threatened loss of central venous access. Because a critical shortage of donor organs exists, waiting times for transplantation are prolonged. Therefore, it is essential that children with life-threatening complications of IF and TPN therapy be identified comparatively early, i.e. in time to receive suitable donor organs before they become critically ill.

In summary, the key U.S. medical bodies and associations agree that ITx should be reserved for patients who have failed TPN, or in whom TPN is not an option. Because of the risks, it is not recommended that transplants should be offered for quality of life reasons alone. Pre-emptive assessments for ITx are recommended in patients (usually children) with primary defects of intestinal epithelial absorption e.g. ultra short gut or microvillus inclusion disease.

Systematic review

The literature search identified one systematic review of the effectiveness and cost effectiveness of ITx for the treatment of IF (Ontario Ministry of Health, 2003). The purpose of this report was to review the evidence on the effectiveness and cost effectiveness of small bowel transplant in the treatment of intestinal failure. The review presented evidence from 35 reports from nine case series and one from the Intestinal Transplant Registry, which provides data on all ITx procedures performed in the world since 1985. Although provision of information to the registry is voluntary, it has full participation from all ITx programs worldwide. The Ontario review included survival data from the 1997 report of registry results (Grant *et al.*, 1999) which contained data for transplants occurring from February 1995 up to February 1997. The review also included some limited data from the registry website that was valid up to May 2001, at which time 651 patients from 55 centres had received intestinal transplants worldwide. More current registry data is available in a subsequent report (Grant *et al.*, 2005); however this was not available at the time the Ontario report was published. The systematic review also presented individual results from the seven transplant programs with published reports on 20 transplants or more, and one program in Ontario. While the review provides a comprehensive overview of the literature, its results should be considered with the year of publication in mind, as there have been significant advances in transplantation methodology in recent years. The main findings of the review are presented below.

Patient outcomes

As of May 2001, the one-year actuarial patient survival rate from the Intestinal Transplant Registry was 69% for isolated small bowel transplant, 66% for small bowel-liver transplant, and 63% for multi-visceral transplant, and the graft survival rate was 55% for ISB and 63% for SB-L and MV. One-year patient survival rates ranged from 33-87% and one-year graft survival rates ranged from 46-71%. The largest centre (Pittsburgh) reported an overall one-year patient and graft survival rate of 72% and 64% respectively, and 5-year patient and graft survival of 48% and 40% respectively. The majority (70% or higher) of surviving small bowel transplant recipients were able to wean from TPN and meet all caloric needs enterally. Some needed enteral nutrition or TPN during periods of illness. Growth and weight gain in children after ISB were reported by two studies while two other studies reported a decrease in growth velocity with no catch-up growth. Patient survival was associated with the type of organ transplanted with better survival in isolated small bowel recipients.

The systematic review also reported the results of three quality of life studies in which the quality of life following ITx was at least equivalent to that of patients on TPN and seems better than their quality of life before transplantation.

Adverse events

Despite improvement in patient and graft survival rates, small bowel transplant was found to be associated with significant mortality and morbidity. The Intestinal Transplant Registry identified sepsis as the leading cause of post-intestinal transplant deaths worldwide (51.3%). Bacterial, fungal and viral infections were all reported. The most common viral infections were cytomegalovirus (18-40%) and Epstein-Barr virus. According to the Intestinal Transplant Registry, graft rejection was the second leading cause of death after ITx (10.4%) and was responsible for 57% of graft removal. Acute rejection rates ranged from 51% to 83% in the major programs. Anti-lymphocyte therapy was needed in up to 27% of patients. Isolated small bowel allograft and positive lymphocytotoxic cross-match were found to be risk factors for acute rejection. Post-transplant lymphoproliferative disease occurred in 21% of ITx recipients and accounted for 7% of post-transplant mortality. The frequency was higher in paediatric recipients (31%) and in adults receiving composite visceral allografts (25%). The allograft itself was often involved in post-transplant lymphoproliferative disease. The reported incidence of host versus graft disease varied widely among centres (0-14%).

Cost studies

The review also identified two studies (Langnas *et al.*, 2002 and Abu-Elmagd *et al.*, 1999) that presented some data on the costs of intestinal transplant, although neither of these were formal economic analyses. Based on the results of these studies, the median cost of intestinal transplant in the U.S. was estimated to be approximately US\$275,000 per case. Based on the costs of TPN, it was calculated that small bowel transplant could be cost-effective by the second year after the transplant. Note that these estimates were based on a relatively crude analysis, and should be interpreted accordingly.

Prospective studies

The U.S. Medicare indications for ITx are based on failure of TPN. The American Society of Transplantation also includes patients at high risk of death from their primary disease or with high morbidity IF (Kaufman *et al.*, 2001). A three-year prospective study evaluated the appropriateness of these indications (Pironi *et al.*, 2008). The study compared the survival rates of patients with irreversible IF, who were not candidates for ITx (e.g. had not failed TPN); (i) candidates for ITx who did not undergo transplantation; and (ii) candidates who underwent transplantation. A total of 310 non-candidates and 152 candidates completed the study. Fifteen candidates underwent transplantation, 5 patients in each year. Ten patients received an ISB (one retransplantation), one received MV graft, three received an SB-L, and one received an isolated liver transplant.

The probabilities of survival in non-candidates, candidates who did not receive a transplant and candidates who did receive a transplant are presented in **Table 4** below. The three-year survival rate on TPN was significantly lower in candidates who did not undergo transplantation (87%) than in non-candidates (94%); however in the subgroup of candidates who experienced parenteral failure there was an increased risk of death with a survival rate of 80%. The comparison between candidates who did not receive a transplant and candidates who did receive a transplant significantly favours candidates who were not transplanted. It is important to note that these comparisons are probably subject to bias as a result of inherent differences between the three groups.

Table 4: Survival in patients with intestinal failure

Study group		Survival (95% CI)			
		Year 1	Year 2	Year 3	
Non-candidates	n=310	98% (96%–99%)	96% (94%–98%)	94% (92%–97%)	p<0.001
Candidates not receiving an ITx	n=137	96% (93%–100%)	92% (87%–97%)	87% (81%–93%)	
Candidates receiving an ITx	n=15	73% (51%–96%)	59% (34%–84%)	59% (34%–84%)	p<0.001

Abbreviations: CI, confidence intervals; ITx, intestinal transplantation

The authors stated that the role of TPN as the primary therapeutic option for irreversible IF was supported by three observations. Firstly, the three-year survival rate of the non-candidate group (94%) was greater than that in patients who underwent transplantation. Secondly, only one sixth of deaths were due to parenteral complications, whereas in patients who received a transplant all the deaths were related to the treatment. Finally, one-third of patients who were weaned from TPN during the follow-up period had been on TPN >3 years indicating that even though the duration of parenteral dependency suggests irreversible IF, some patients may still regain intestinal function a long time after initial treatment.

The authors of this study conclude that TPN should remain the primary therapeutic option for IF and support the appropriateness and potential life-saving role of timely ITx for patients with parenteral nutrition failure. It is important to note that by categorising patients as candidates, or non-candidates, patients are effectively being grouped by severity and the extent to which they have already failed TPN.

Therefore, there the study contains inherent biases that limit the interpretation of its results.

Intestinal transplant registry

The most recent published report of the Intestinal Transplant Registry was written by Grant *et al.* (2005). The authors sent report forms to all known transplant programs asking for information on intestine transplants performed between April 1985 and May 31, 2003. Sixty one centres provided data on 989 grafts in 923 patients, in 19 countries. As far as the authors are aware, the registry includes all intestinal transplants performed in the world since its inception in 1985. Four patients were lost to follow-up. The number of cases per year has increased over time, with 11 transplants performed in 1990 compared to 140 per year in 2003. Sixty-one percent of the patients were ≤ 18 years of age; 39% were adults.

The one-year overall graft/patient survival rates were 57.6/64.7% for cadaveric donors compared to 59.3/66.7% for living donor transplants. An additional analysis of cases since 1998 was undertaken to determine the outcome of intestine transplantation in the modern era. The one-year graft/patient survival rates for patients transplanted after 1998 were 65/77% for intestinal grafts, 59/60% for small-bowel and liver grafts, and 61/66% for multi-visceral grafts. **Figure 1** presents the overall graft survival rates after intestinal transplantation across three eras: 1991 and earlier, from 1992 to 1997, and 1998 and after.

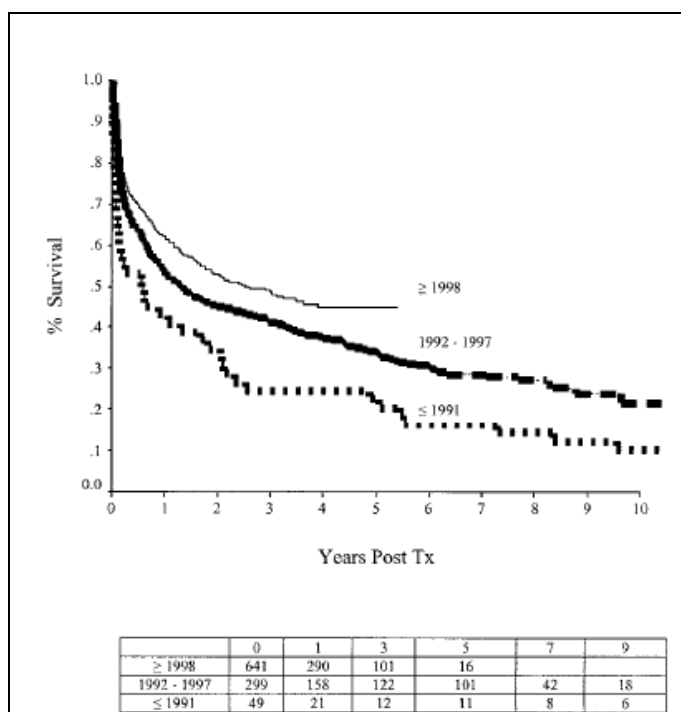


Figure 1: Graft survival rates after intestinal transplantation

Factors associated with improved survival included transplantation of patients waiting at home versus in the hospital, use of induction antibody therapies, use of centres that had performed at least 10 transplants, and recipient age. Factors not associated with differences in patient and graft survival included primary diagnosis, donor type, transplant type, donor graft irradiation, and maintenance immunosuppression.

Although this study captured 100% of intestinal transplants performed since 1985, the distribution of cases between the centres was highly skewed. The majority of cases were performed in only ten centres, and only 28 programs had performed a transplant within the last two years. This suggests that while patient outcomes in ITx are improving, this success might be limited to a number of highly specialised centres (which are also responsible for the majority of publications in the area). This is supported by the observation that centre-experience was associated with improved survival.

Case series

The transplant programs responsible for the most cases are also produce the majority of published reports and case series. The papers presented in this section are therefore categorised by centre, and the discussion will focus on the most current reports from each program. Case reports of fewer than twenty patients were not included. Outcomes discussed from the case series reports include survival (in paediatric and combined adult/paediatric populations), transplantation technique, factors influencing survival and nutritional autonomy.

Table 5: Case series of patients undergoing intestinal transplant

Centre	Reference	Abstract / Summary	Population	Years
Pittsburgh	Matarese <i>et al.</i> , 2009	In ITx, the ability of a graft to maintain normal micronutrient levels including vitamins has yet to be evaluated. After an initial clinical observation of isolated cases of pyridoxal-5'-phosphate (PLP) deficiency, this prospective study was designed to address the incidence of, risk factors for, and management of PLP deficiency in adult intestinal transplant recipients. Over one year, 30 patients were transplanted with ISB (n=19), SB-L (n=3), and MV graft (n=8). PLP deficiency occurred in 10% of candidates and in 96% of recipients. Despite development of severe deficiency in most cases, none of the subjects experienced clinical manifestations of PLP deficiency because of prompt replacement therapy.	Adult n=30	Oct 2005- Oct 2006
	Nucci <i>et al.</i> , 2008	389 paediatric patients were referred to this centre for interdisciplinary assessment of IF since 1996 (median age=1 year; range 1 day–28.8 years), with 338 patients ultimately referred to TPN. Within 2 years of referral to TPN, 109 patients died, and many while waiting for transplantation. Approximately one third of patients referred on TPN (n=119, 35%) received ITx. Survival rates at 1, 5, and 10 years post-transplant were 94%, 73%, and 69%, respectively. 95% of patients who received an intestinal transplant and survived were weaned from TPN.	Paediatric n=389	1996-2006
	Akhavan <i>et al.</i> , 2007	The medical records of 175 consecutive adult intestinal recipients were reviewed. Of the patients 43 experienced a total of 53 urogenital disorders for an overall incidence of 25%, including 24 (56%) who had the disorder before referral and 19 (44%) in whom the morbidity developed as a result of transplantation.	Adult n=175	May 1990- Jul 2005
	Bond <i>et al.</i> , 2005	122 children received 129 intestinal containing allografts (70 SB-L, 42 ISB and 17 MV transplants). Mean age was 5.3 ± 5.2 years, and 55% were boys. Indications for ITx were mostly short gut syndrome. The overall Kaplan-Meier patient/graft survival was 81%/76% at 1 year, 62%/60% at 3 years, and 61%/51% at 5 years.	Paediatric n=122	Jul 1990- Dec 2003
	Nucci <i>et al.</i> , 2002	The aim of this study was to describe the long-term nutritional status of a large population of children after ITx and to identify factors associated with nutritional outcomes. 24 paediatric patients received an ISB or SB-L transplant (median age, 3.2 years). The majority of cases (75%) had been diagnosed with surgical short bowel syndrome and were dependent on TPN at the time of transplant. Of the 23 patients who survived the initial post-operative period, 87% were weaned from TPN to an amino-acid or peptide-based enteral formula or solid food within 3 months. A positive trend in z-scores for weight and height/length was observed in only 30% and 26% of patients, respectively, during the follow-up period. Steroid doses were weaned within 3 to 4 months after transplantation but not discontinued. The cumulative survival rate was 91% at 1 year and 86% at 2 years post-transplant, whereas those weaned from TPN achieved 100% and 94% survival, respectively.	Paediatric n=24	1996-2002

Table 5: Case series of patients undergoing intestinal transplant (*continued*)

Centre	Reference	Abstract / Summary	Population	Years
	Abu-Elmagd <i>et al.</i> , 2001	During an 1one-year period, 155 patients received 165 ITx under immunosuppression based on tacrolimus and prednisone: 65 ISB, 75 SB-L and 25 MV. For ITx after 1994 (n=99) an adjunct immunosuppressant (cyclophosphamide or daclizumab) was used for 74 ITx, adjunct donor bone marrow was given in 39, and the intestine of 11 allografts were irradiated.: The actuarial survival rate for the total population was 75% at 1 year, 54% at 5 years, and 42% at 10 years. Recipients of SB-L had the best long-term prognosis and the lowest risk of graft loss from rejection (P =.001). Since 1994, survival rates have improved due to improved techniques for early detection of infections, bone marrow augmentation, the adjunct use of the interleukin-2 antagonist daclizumab, and allograft irradiation.	Adult and paediatric n=155	1990-2001
	Bueno <i>et al.</i> , 1999	257 children (mean age, 3.4) with IF were evaluated for ITx. All patients were dependent on TPN for a mean of 31 ± 2.7 months. The mean follow-up time from the date of evaluation was 9.2 ± 0.9 months. 82 (32%) children underwent ITx with a mean waiting time of 10.1 months (SB-L in 68% instances). Of the 175 patients who did not undergo transplantation, 120 died, 23 were lost to follow-up, and 32 are alive. Younger patients had poorer survival rates than patients older than 1 year (P<.0001). The patients with the worse prognosis were those with necrotizing enterocolitis, and those with the best prognosis were those with Hirschsprung's disease.	Paediatric n=257	1990-1998
	Abu-Elmagd <i>et al.</i> , 1999	This study reports the overall long-term results with 115 ITx in 109 consecutive patients that were transplanted over 8 years. Of these, 64 (59%) were children and 45 (41%) were adults. The overall cumulative patient survival is 72% at 1 year and 48% at 5 years with a graft survival rate of 64% and 40%, respectively. With a mean follow-up of 40 6 29 months (range, 1 to 94 months), 31 patients were alive with good nutrition beyond the third postoperative year and 18 were well beyond the 5-year mile stone.	Adult and paediatric n=109	1990-1998
	Abu-Elmagd <i>et al.</i> , 1994	43 consecutive patients were given ISB (n=15), SB-L (n=21), or MV allografts that contained four or more organs (n=7). Treatment was with FK 506 based immunosuppression. After six to 39 months, 30 of the 43 patients are alive, 29 bearing grafts. The most rapid convalescence and resumption of diet, as well as the highest three month patient survival (100 percent) and graft survival (88 percent) were with the isolated intestinal procedure. However, this advantage was slowly eroded during the first two postoperative years, in part because the isolated intestine was more prone to rejection. By the end of this time, the best survival rate (86 percent) was with the MV procedure.	Adult and paediatric n=43	May 1990- Apr 1993

Table 5: Case series of patients undergoing intestinal transplant (*continued*)

Centre	Reference	Abstract / Summary	Population	Years
Paris	Goulet <i>et al.</i> , 2005	126 patients with protracted or irreversible IF were assessed. Patients' ages ranged between 6 months to 14 years. Among them, 21 patients with severe liver disease died within 6 months; 32 were on TPN; seven were no longer dependent on TPN; 52 underwent isolated or combined liver-intestine transplantation; and the others were still on the waiting list. 37 patients were alive at the time of writing, with a global 3-year survival rate of 71.5%. Patient survival rate did not differ between ISB and SB-L transplantation being 78.5% and 69%, respectively. 25 (9 SB-L) died within 4 months following grafting. 27 intestinal grafts were lost (patient's death or graft removal), 1- and 3-year graft survival being 58% and 52.5%, respectively. One- and 3-year graft survival for ISB and SB-L were 53.5% and 65.5% and 43% and 62%, respectively.	Paediatric n=126	1994-2004
	Goulet <i>et al.</i> , 1999	20 children (2.5 to 14 years) received a jejunoileal graft alone (ISB; n = 10) or in combination with the liver (SB-L; n = 10 and/or the right colon (5 MV). Current follow-up ranges from 6 to 54 months. 5 patients died within the first 2 months. Acute liver rejection occurred in 5 patients during the first 2 months. Sixteen episodes of intestinal rejection during the first 3 months in 11 patients were successfully treated in all but 3 by increasing tacrolimus dose and/or a 3-day methylprednisolone bolus or required antilymphoglobulins in 3 cases. The SB graft was removed in 5 recipients. Currently, 10 of 11 children achieved digestive autonomy after 5 to 30 weeks.	Paediatric n=20	1994-1998
	Lacaille <i>et al.</i> , 2008	31 children with ITx were followed for 2-18 years (median 7 years). 12 patients had ISB, 19 had SB-L and 17 received an additional colon graft. All children were weaned from TPN after Tx and 26 children remained TPN-free. Enteral nutrition was required for 14/31 (45%) patients at 2 years post-Tx. All children had high dietary energy intakes. The degree of steatorrhoea was fairly constant, with fat and energy absorption rates of 84-89%. Growth parameters revealed at transplantation a mean height Z-score of -1.17. After Tx, two-thirds of children had normal growth, whereas in one-third, Z-scores remained lower than -2, concomitant to a delayed puberty. Adult height was normal in 5/6. Endoscopy and histology analyses were normal in asymptomatic patients. Chronic rejection occurred only in non-compliant patients. Five intestinal grafts were removed 2.5-8 years post-Tx for acute or chronic rejection.	Paediatric n=31	1988-2006
	Sauvat <i>et al.</i> , 2008	74 ITx were performed in 69 children, including 39 ISB and 35 SB-L. Follow-up was 1 to 12 years (median 5 years). At the time of publication, 31 children had a functioning graft (42%). All were at home without TPN, with a good quality of life. One child was TPN-dependent 1.5 years post ITx. 16 children were de-transplanted: 12 early on (1 for mechanical complications, 11 because of resistant rejection. In 2 noncompliant teenagers, TPN was reintroduced (one was de-transplanted later on). Several years post ITx, 2 children underwent bowel de-transplantation due to an acute viral infection complicated with rejection. Twenty-two children died, 18 early on from infectious or surgical complications, 4 more than 1 year post IT, 3 after re-transplantation (1 in another unit). Bad prognostic factors are multiple previous surgeries, an older age (> 7 y), and chronic intestinal pseudo-obstruction.	Paediatric n=69	1994-2007

Table 5: Case series of patients undergoing intestinal transplant (*continued*)

Centre	Reference	Abstract / Summary	Population	Years
	Sauvat <i>et al.</i> , 2006	59 patients aged 2.5 to 15 years received ITx. After 6 months to 10.5 years, the patient and graft survivals were 75% and 54%. Sixteen patients died within 3 months from surgery (n = 3), bacterial (n = 5) or fungal (n = 6) sepsis, or posttransplant lymphoproliferative disorder (n = 2). Rejection occurred in 27 patients and grafts were removed due to uncontrolled rejection in 7 transplant recipients. Surgical complications were observed in 38 recipients within 2 months. 42 children remained alive at the time of publication. Weaning from TPN was achieved after 42 days (median). Factors related to death or graft loss were pre-Tx surgery (P < .01), pseudo-obstruction (P < .01), age over 7 years (P < .03), fungal sepsis (P < .03), steroid resistant rejection (P < .05), hospitalized versus home patient (P < .01), and retransplantation (P < .05). Colon transplant did not affect the outcome. Interleukin-2 blockers improved ISB (P < .05).	Paediatric n=59	1994-2005
	Jan <i>et al.</i> , 1999	A retrospective study was conducted of 26 patients with a mean age of 5 years (range, 0.3 to 14 years). 3 groups were isolated. In group A (1987 to 1990), 7 patients received 9 ISB. Immunosuppression therapy consisted of cyclosporine, aziathioprine, and corticosteroids. In group B (1994-current), 9 patients received 9 ISB; and in group C (1994-current), 10 patients received 10 SB-L transplants. In groups A and B, immunosuppressive treatment consisted of tacrolimus, aziathioprine, and corticosteroids. Overall patient survival and graft survival are 61% and 50%, respectively. Tacrolimus improves graft and patient survival (group A v group B). The lower severity of graft rejection in combined liver-small bowel transplantation improves functional results of ITx in children without additional mortality or morbidity (group B v group C)	Paediatric n=26	1987-1999
Miami	Tzakis <i>et al.</i> , 2006	This study reports 98 patients who received primary multi-visceral transplantations. Three eras can be distinguished based on the evolution of technique, immunosuppression, and monitoring: August 1994 to December 1997 (first era); January 1998 to December 2000 (second era); and January 2001 to present (third era). Fifty-three patients were alive at the time of publication with a median follow-up of 37.5 months (range: 1 to 116 months). The leading cause of mortality was infection (n = 17), followed by rejection (n = 6). 7 patients required re-transplantation and five of them subsequently died. The estimated 3-year survival was 25% ± 11% for period 1; 44% ± 12% for period 2; and 58% ± 7% for period 3. Additionally, 45.3% (29/64) of patients in the third period never developed rejection versus 23.5% (8/34) of patients in the first two periods combined.	Adult and paediatric n=98	1998-2006
	Wada <i>et al.</i> , 2006	This study reviewed ITx in patients with gastroschisis to elucidate those factors affecting the outcome of children with SBS. 32 transplants were performed in 28 children with gastroschisis during the study period. Most of the patients had a complicated course and required multiple abdominal surgeries before transplant. Fifteen (53.6%) patients were alive at a median follow-up of 23.5 months.	Paediatric n=28	1994-2003

Table 5: Case series of patients undergoing intestinal transplant (*continued*)

Centre	Reference	Abstract / Summary	Population	Years
	Kato <i>et al.</i> , 2003	A review of 70 ITx performed at a single centre. Factors affecting patient survival were analysed. Older patient age at the time of transplant was a significant factor favourably affecting patient survival ($P = .031$). Trends toward better survival rates were observed in those transplants performed more recently ($P = .063$), in those patients with greater body weight ($P = .084$), in those not hospitalized at the time of transplant ($P = .14$), and in those without concomitant liver failure ($P = .12$). Three-year survival rate for patients greater than age 2 years and without liver failure was 90%. However, 32% of our recipients underwent transplant at age less than one year, and most in this group (75%) had concomitant liver failure.	Paediatric n=70	1994-2002
	Nishida <i>et al.</i> , 2002	Data were collected from 95 consecutive ITx, 54 of which were children and 41 of which were adults. The procedures performed included 27 isolated intestine transplants, 28 combined liver and intestine transplants, and 40 multi-visceral transplants. The one-year patient survival rates for isolated intestinal, liver and intestinal, and multi-visceral transplantations were 75%, 40%, and 48%, respectively. Since 1998, the one-year patient and graft survival rates for ISB have been 84% and 72%, respectively.	Adult and paediatric n=95	1994-2000
	Pinna <i>et al.</i> , 2000	The impact of different immunosuppressive strategies, patient and graft monitoring, and improvements in surgical techniques was evaluated at the University of Miami in a series of 77 intestine transplants performed in 69 patients during 3 program phases: 1994-95, 1995-97, and 1997-99. Two-year graft survival rates for isolated small intestine transplantation for phases 1, 2, and 3 were 0%, 50%, and 80%, respectively. Graft survival rates in combined liver-intestine and multi-visceral groups at 2 years during the same phases were 40%, 30%, and 48%	Adult and paediatric n=69	1994-1999
	Misakos <i>et al.</i> , 1998	42 ITx were performed in 39 patients, including 23 children and 16 adults. 21 patients were still alive at the time of publication; 19 patients had their primary allografts and none required TPN. Severe rejection and the consequences of its treatment were the cause of death in 11 patients and sepsis was the cause of death in 2 patients; other causes of death were arterial disruption probably due to pseudoaneurysm formation, infectious complications, lung infection, viral encephalitis, and a post-transplant lymphoproliferative disease in a paediatric case. Graft-versus-host disease was encountered in 8 patients and was treated successfully with corticosteroids.	Adult and paediatric n=39	1994-1997

Table 5: Case series of patients undergoing intestinal transplant (*continued*)

Centre	Reference	Abstract / Summary	Population	Years
Nebraska	Langnas <i>et al.</i> , 2002	At the University of Nebraska, 117 ITx were performed in 106 adults and children in the period of 1990 - 2001. The majority (89%) of the transplants were performed in children. Of the 117 allografts, 37% were ISB and 63% SB-L transplants. Two year patient survival was 70% overall; and 82% for ISB and 60% for L-SB. The main cause of death in both groups was sepsis.	Adult and paediatric n=106	1990-2001
	Iyer <i>et al.</i> , 2002	47 ITx were carried out in 46 children. There were 19 ISB and 29 SB-L transplants. Median age at transplantation was 3.7 years (range, 0.4 to 16.6 years), and median graft survival time was 1,084 days (range, 368 to 3308 days). Nine patients died, and there were 11 graft losses, including those of the non-survivors. All survivors with functioning grafts received all of their calories via the enteral route.	Adult and paediatric n=46	1990-2001
Italy	Lauro <i>et al.</i> , 2007a	28 isolated ISB and 9 MV transplants were performed. The mean follow-up was 892 ± 699 days. Twenty-five patients were alive (67.5%) with 3-year patient survivals of 70% for ISB and 41% for the MV transplantations (P = .01). The mortality rate was 32.5% with losses due to sepsis (63%) or rejection. 3-year graft survival rates were 70% for ISB and 41% for MV transplantations (P = .02); graftectomy rate was 16%. At the time of writing, 88% of grafts were working properly with patients on regular diet with no need for TPN.	Adult n=37	2000-2006
	Lauro <i>et al.</i> , 2007b	25 ISB from cadaveric donors were performed. The mean hospital stay was 37 days. The mean follow-up 27 months. 20 patients (80%) were alive at the time of publication, with two- and five-yr patient survival rate of 80% and 66%; mortality rate was 20% due to sepsis in all cases. The 2- and 5-year graft survival rates were 76% and 64%, graftectomy rate was 16%. At the time of writing, 16 grafts were working properly, with no need of TPN.	Adult n=25	2000-2005
	Lauro <i>et al.</i> , 2007c	Twenty ISB recipients and 5 MV patients (2 with liver) were divided into 3 groups: patients started on Sirolimus (because of nephrotoxicity or biopsy-proven rejection), who continued therapy longer than 3 months (n=11); patients started on Sirolimus (because of nephrotoxicity or biopsy-proven rejection), who received therapy <3 months because of side effects (n=4); and a control group, who never received rapamycin (n=10). During prolonged treatment combined with Tacrolimus, both Sirolimus groups showed a decreased number of acute cellular rejections (P=0.01). Cumulative 3-year graft and patient survival rates were 81% in the Sirolimus >3 months group, 100% in the Sirolimus < 3 months group, and 80% and 90% in the control group, respectively (P =0.63 and P=0.62).	Adult n=20	2000-2005
	Lauro <i>et al.</i> , 2005	20 ISB and 7 MV transplants (including three with liver) were performed. One-year patient actuarial survival rate was 94% for ISB and 42% for multi-visceral recipients (P = .003), while one-year graft actuarial survival rate was 88.4% for ISB patients and 42.8% for multi-visceral ones (P = .01). The death rate was 18.5%. Our graftectomy rate was 14.8%.	Adult n=27	2000-2004

Table 5: Case series of patients undergoing intestinal transplant (*continued*)

Centre	Reference	Abstract / Summary	Population	Years
New York	Fishbein <i>et al.</i> , 2002	The Mount Sinai Medical Centre performed 37 grafts in 34 patients, 68% of whom were children. 43% of transplants were ISB, 51.5% were SB-L and 5.5% were MV grafts. Eight patients died of rejection (n=2), adenovirus infection (n=2), fungal sepsis (n=1), PTLs (n=1) and surgical complication (n=2).	Adult and paediatric n=34	Nov 1998- Sep 2001
	Harpaz <i>et al.</i> , 2005	The aim of this study was to examine the recurrence of Crohn's disease in small intestinal allografts. Of 67 patients undergoing 70 transplantations between, 6 adults (mean age 48.1 years) had Crohn's disease complicated by SBS and TPN failure. 4 survivors surveyed endoscopically for a mean 29 (range, 20-40) months and underwent a mean 37 endoscopic examinations with biopsies (range, 31-44) while on maintenance immunosuppression. Despite absence of any endoscopic or clinical manifestations of Crohn's disease throughout this period, two patients had granulomatous enteritis characteristic of Crohn's disease in multiple biopsies. No comparable changes occurred in 57 other patients without Crohn's disease followed endoscopically under the same protocol	Adult n=67	1998-2004
U.K.	Beath <i>et al.</i> , 2002	21 children received 21 transplants, including 5 ISB, 14 SB-L and 2 MV grafts. 4 (19%) of patients died of multi-organ failure and respiratory distress syndrome within 6 weeks of transplant. Three patients were excluded due to <12 months follow up. 1 year survival was 61% (11/18) and 2 year survival was 50% (9/18).	Paediatric n=21	Apr 1993- Dec 2001
U.C.L.A	Farmer <i>et al.</i> , 2001	Twenty-one intestinal grafts were transplanted into the 17 recipients. All donors were cadaveric and were matched by ABO blood group and size. Patient survival at 1 and 3 years was 63% and 55%, respectively. Death-censored graft survival at 1 and 3 years was 73% and 55%, respectively. There were 1.5 acute cellular rejection episodes per graft and 3 grafts were lost to rejection. Incidences of infection with the Epstein-Barr virus and cytomegalovirus were negligible with aggressive prophylaxis and pre-emptive therapy. Nutritional autonomy was achieved in 69% of grafts surviving more than 30 days after intestinal transplantation.	Adult and paediatric n=20	1991-2000

Abbreviations: IF, intestinal failure; ISB, isolated short bowel; ITx, intestinal transplantation; MV, multi-visceral; n, number of participants; PLP, pyridoxal-5'-phosphate; SB-L, short bowel-liver transplantation; SBS, short bowel syndrome; TPN, home parenteral nutrition.

Survival

Based on the most recent reports of survival from each centre, overall patient survival in children undergoing ITx is presented in **Table 6** below.

Table 6: Patient survival in children

Centre	1 year	2 year	3 year	5 year	10 year
Pittsburgh (Nucci <i>et al.</i> , 2008)	93%	NR	NR	73%	69%
Paris (Goulet <i>et al.</i> , 2005)	NR	NR	71.5%	NR	NR
Miami (Kato <i>et al.</i> , 2003) (Period I, II and III)	50%, 50%, 86%	38%, 46%, NR	NR	NR	NR
U.K. (Beath <i>et al.</i> , 2002)	61%	50%	NR	NR	NR

Abbreviations: NR, not reported

In children, the international one-year patient survival rates ranged from 61% to 93%, with a distinct trend towards higher survival rates in the more recent studies. There is less long-term data, with only one study (Nucci *et al.*, 2008) reporting five and ten year survival rates (73% and 69%, respectively). The study by Kato *et al.* (2003) looked at one and two year survival rates in patients who were categorised according to the year in which they received their transplants. Survival rates were found to improve markedly from the first period (1994-1997) to the final period (2001-2002). It was found that those patients with liver disease require transplantation the most urgently.

Table 7 presents survival data in studies that examined adult populations, or mixed adult and paediatric populations.

Table 7: Patient survival in adults or adults and children

Centre	1 year	2 year	3 year	5 year	10 year
Pittsburgh (Abu-Elmagd <i>et al.</i> , 2001)	75%	NR	NR	54%	42%
Miami (Tzakis <i>et al.</i> , 2000)	MV: 44%, 56%, 73% Period I, II and III	NR	MV: 25%, 44%, 58%	NR	NR
Miami (Nishida <i>et al.</i> , 2002 and Pinna <i>et al.</i> , 2002)	ISB: 64%, 84% SB-L: NR, 40% MV: NR, 48% Period I and II	ISB: 50%, 50%, 90% SB-L: 40%, 33%, 58% MV: 30%, 30%, 70% Period I, II and III	NR	NR	NR
Nebraska (Iyer <i>et al.</i> , 2002)	NR	Overall: 70% ISB : 82% SB-L: 60%	NR	NR	NR
Italy (Lauro <i>et al.</i> , 2007a)	NR	NR	Overall: 68% ISB: 70% MV: 41%	NR	NR
New York (Fishbein <i>et al.</i> , 2002)	74%	NR	NR	NR	NR
U.K. (Beath <i>et al.</i> , 2002)	61%	50%	NR	NR	NR
California (Farmer <i>et al.</i> , 2001)	67%	NR	60%	NR	NR

Abbreviations: ISB, isolated short bowel; ITx, intestinal transplantation; MV, multi-visceral; NR, not reported; SB-L, short bowel-liver transplantation

In adult and adult/paediatric populations, the lowest survival rate for all ITx procedures was reported by the Birmingham centre in the U.K. (Beath *et al.*, 2002) as 61%, while the highest survival rate was reported by the Pittsburgh program as 75% (Abu-Elmagd *et al.*, 2001). By five and ten years, the survival rate reported by Abu Elmagd *et al.* (2001) had dropped to 54% and 42%, respectively.

The most recent studies reporting one-year patient survival rates for the adult and adult/paediatric populations were undertaken at roughly the same time, so it is difficult to say if there is a trend towards higher survival rates in more recent studies. However, a brief examination of the older publications (refer to **Table 5**) shows that published survival rates for each site have been improving over time. Many of these more recent case series also include data from older cohorts, meaning that the calculated survival rates probably underestimate the success of ITx at this point in time.

This observation is supported by the results of the Miami studies, in which patients were categorised according to the year in which they received their transplant. The study by Nishida *et al.* (2002) demonstrated that one year patient survival rates for ISB transplants improved from 64% prior to 1998, to 84% after that year. Similarly, Pinna *et al.* (2002) analysed patient survival according to three different time periods: Period 1 (August 1994-June 1995), Period 2 (July 1995 - December 1997) and Period

3 (January 1998 - September 1999). Three different induction agents (cyclophosphamide, OKT3, MMF) were tested in Period 1; mycophenolate mofetil was used as the induction agent Period 2 and daclizumab used in Period 3. The two year survival results were markedly improved in Period 3 compared to Periods 1 and 2. Improvements in survival over time are probably also related to advances in post-transplant immunosuppression and better selection of candidate patients.

Transplantation type

The results of these case series also indicate that the survival rate in patients receiving ISB transplants is much higher than that in patients receiving SB-L and MV grafts. Lauro *et al* (2007a) for example, found that the three year survival rate in patients receiving ISB transplants was 70%, compared to 41% in patients receiving MV grafts. This is confirmed by the most recent analysis of the Intestinal Transplant Registry (Grant *et al.*, 2005), in which the one-year patient survival rates for patients transplanted after 1998 were 77% for ISB, 60% for SB-L and 66% for MV grafts.

Immunosuppression regimen

Bond *et al.* (2005) reported the results of various immunosuppression regimens employed at the Pittsburgh ITx program. One hundred and twenty-two children received 129 intestinal transplants between July 1990 and December 2003. Immunosuppressive protocols were divided into three categories: (i) tacrolimus and steroids ($n = 52$, 1990–1995, 1997–1998), (ii) tacrolimus, steroids and induction therapy with either cyclophosphamide ($n = 16$, 1995–1997) or daclizumab ($n = 24$, 1998–2001) and (iii) induction with rATG and tacrolimus alone ($n = 37$, 2002–2003). One year graft/patient survival by groups was: (i) 62%/71%, (ii) 75%/77% and (iii) 100%/100%. Figure x presents a comparison of survival in paediatric patients in groups (ii) and (iii) (i.e. patients who received induction therapy) compared to those in group (i) (i.e. patients on maintenance therapy alone).

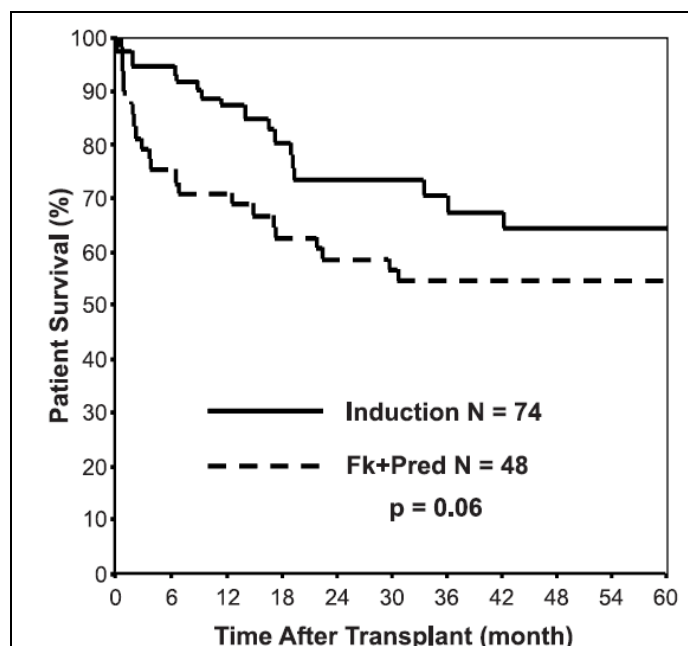


Figure 2: Survival in patients receiving induction vs. non-induction

These results, combined with some of the other outcomes reported in the paper (e.g. graft rejection rates) demonstrate improved survival outcomes with the evolution of improved immunosuppression protocols. The most recent protocol with rATG induction and tacrolimus has the best one-year survival outcomes and also minimises the need for steroid treatment.

Factors influencing survival

Bueno *et al.* (1999) investigated factors impacting survival of children with IF referred for ITx at the Pittsburgh centre. Based on their study of 82 patients, it was found that younger patients (\leq one year) had poorer survival rates than patients older than one year. The patients with the worst prognosis were those with NEC, and those with the best prognosis had Hirschsprung's disease. Patients with surgical causes also had poorer survival rates than patients with non-surgical causes. With multivariate analysis, independent prognosis risk factors of poor outcome were elevated bilirubin levels and severity of histopathologic damage. Sauvat *et al.* (2008) from the Paris program reported the results of a similar analysis, where it was found that bad prognostic factors for survival were multiple previous surgeries, an older age (> 7 years) and chronic intestinal pseudo-obstruction. In their review of 70 paediatric patients, Kato *et al.* (2003) from the University of Miami reported trends towards improved survival in those patients with greater body weight, in those not hospitalised at the time of transplant, and in those without concomitant liver failure.

In a sample of 389 paediatric patients with IF, Nucci *et al.* (2008) investigated some of the factors predictive of weaning from parenteral nutrition without transplantation. These included increased mean bowel length for patients with gastroschisis (44 cm vs. 23 cm), and atresia (35 cm vs. 20 cm) and lower mean total bilirubin for patients with NEC. Patients weaned from TPN by 2.5 years after referral achieved 95% survival at 5 years, vs. 52% for those not weaned.

Nutritional autonomy after transplantation

Where reported, most studies suggest that surviving patients are generally able to receive all their calories via the enteral route, with no need for further TPN (Iyer *et al.*, 2002; Goulet *et al.*, 1999; Farmer *et al.*, 2001; and Lauro *et al.*, 2007a). In spite of the high levels of nutritional autonomy, it has been observed that some transplant recipients experience nutritional deficiencies, including low levels of zinc, vitamin E and folate. Matarese *et al.* (2009) aimed to investigate the occurrence of micronutrient deficiencies, specifically of pyridoxal-5'-phosphate (PLP), in ITx recipients. The results of this study demonstrated PLP deficiency in 10% of candidates and in 96% of recipients within a median onset of 30 days after transplantation. Most of the deficiencies occurred in the early post-operative period, despite continuation of TPN therapy; however none of the subjects experienced clinical manifestations of PLP deficiency because of prompt replacement therapy.

Cost studies

Retrieved citations that mentioned costing or cost effectiveness in ITx were grouped together. These papers were identified through the clinical literature search and are shown in **Table 8**.

Table 8: Summary of cost based studies

Study	Reference
Abu-Elmagd <i>et al.</i> , 1999	Abu-Elmagd KM, Reyes J, Fung JJ, Mazariegos G, Bueno J, Janov C, Colangelo J, Rao A, Demetris A, and Starzl TE. (1999) Evolution of clinical intestinal transplantation: improved outcome and cost effectiveness. <i>Transplantation Proceedings</i> 31:582-584.
Longworth <i>et al.</i> , 2006	Longworth L, Young T, Beath SV, Kelly DA, Mistry H, Protheroe SM, Ratcliffe J, and Buxton MJ. (2006) An economic evaluation of paediatric small bowel transplantation in the United Kingdom. <i>Transplantation</i> 82:508-515.

The paper by Abu-Elmagd *et al.* (1999) reports the results of a costing study (rather than a cost effectiveness study). The authors report that the average per-patient cost of ITx between 1990 and 1994 was \$203,111 for the isolated intestine; \$252,453 for the combined liver-intestine transplantation; and \$284,452 for the multi-visceral procedure. In the following four years, these costs were significantly reduced to an average of \$132,285, \$214,716, and \$219,098, respectively. Based on Medicare data, the average yearly cost of TPN in 1992 was more than \$150,000 per patient not including the cost of frequent hospitalization, medical equipment, and nursing care. Unlike transplantation, the overall cost of TPN is increasing because of the yearly increase in TPN cost, and the cumulative increase of the home and hospital bound TPN population. Based on these data, the authors conclude that ITx becomes cost-effective by the second year after transplantation. It is difficult, however, to see how the authors have reached a conclusion regarding cost effectiveness; the analysis they have performed is partial in that it fails to take into consideration any differences between the two treatments in health, safety and quality of life outcomes. Consequently, on the basis of the information made available in the article, it should be viewed as a cost study rather than a cost-effectiveness study. Even still, it is worth noting that it doesn't consider other related costs e.g. anti-rejection drugs and the costs of adverse events.

Longworth *et al.* (2006) undertook a more formal economic evaluation of paediatric ITx in the United Kingdom. The study cohort consisted of all children assessed for their suitability for ITx at a single centre between April 1997 and April 2001. Fifty-three children were recruited to the study, and followed for 30 months from date of entry to the study or until date of death. The subjects were aged between one month and 14 years; 33 were male and all were residents in the UK or Republic of Ireland. Children assessed for ITx were categorized as:

- requiring ITx following TPN-related complications (n=23)
- stable at home not requiring ITx (n=24)
- terminally ill and unsuitable for ITx (n=6)

Detailed resource use and clinical data were collected prospectively for each patient and entered onto the database using information from patient notes, dietetic records, and physiotherapy records. Data were collected on: length of inpatient stay (including type of ward); frequency of outpatient visits; details of tests and treatments undergone; types of quantities of blood products, parenteral nutrition and enteral nutrition; number of dietician and physiotherapy sessions; details of high cost and/or high volume drugs received; and the length of transplant operation. All estimates of

unit costs were based on 1998/1999 prices, which was the midpoint of the study. Costs were estimated from detailed resource-use data.

Three separate analyses were conducted on the data. The first analysis estimated the costs and survival of all patients considered for a transplant. The second and third analyses estimated the cost effectiveness of ITx compared to the experience without transplantation using (i) a prognostic model and (ii) an intent-to-treat approach.

The prognostic model was applied to the 14 patients who received a small bowel transplant during the 30 months of the study in order to estimate their likely survival if transplant was not performed on these patients. The mean observed survival of transplanted patients over 30 months was observed as 1.86 years, compared with the expected survival without transplantation estimated to be 1.74 years. The transplanted group survival time was 0.12 years greater than the predicted survival in the absence of transplantation, although the confidence limits around the mean gain are wide and have a negative lower bound (95% CL, -0.52 to 0.74 years). Note that expected survival estimates depended on the validity of the prognostic model. This prognostic model was built on a very small sample of patients. The validity of using it to estimate expected survival will depend upon the model capturing all prognostic determinants of survival. The mean cost (95% CI) of treatment for transplanted patients was £275,000 (£222,000 to £337,000) over 30 months, compared with £326,000 (£264,000 to £403,000) in the absence of transplantation. The incremental costs indicate that on average transplantation is cost-saving by £50,000 over the 30-month period although confidence limits are wide (95% CL, £149,000 to £38,000).

In the intent-to-treat analysis, 23 patients fulfilled the criteria for ITx and of these 14 received a transplant during the 30 months of the study. The observed survival of the 14 patients in the transplant group was compared with the waiting-list survival of all 23 patients, including transplanted patients (censored at time of transplant) and non-transplanted patients (n=9). The observed survival for transplanted patients over 30 months from listing was 1.86 years compared with 2.10 years for the comparison group estimated using the waiting list survival data. Thus the mean (95% confidence interval) survival was 0.24 (-0.93 to 0.45) years less for transplanted patients than the comparison group. Mean (SD) lengths of stay were much higher for transplanted patients at 140 (83) days, compared to 26 (34) days for the nine patients who were placed on the waiting list but not transplanted during the study period. The average cost for the 14 transplanted patients over 30 months was £275,000 (95% confidence limit £218K to £338K) per patient compared with £143,000 (95% confidence limit £96K to £202K) for patients on the waiting list for a transplant.

The authors state that firm conclusions on cost effectiveness of ITx are not possible given the two different estimates (i.e. one dominant, and one dominated). The prognostic model approach suggests that paediatric ITx may provide a small survival benefit at a small reduction in costs; however it is important to note that the study is limited by its small sample size, poor sampling, the questionable validity of the prognostic model used to estimate expected survival, and the fact that it only includes 30 months of prospective data. Furthermore, it should also be noted that of the 14 patients who received ITx during the study, ten were combined SB-L grafts, and two were MV grafts. Given the poorer survival rates associated with multi-organ grafts, it is likely that the survival rate seen in this sample is lower than that in real-world ITx

recipients. Finally, with a poor level of detail on how the prognostic economic model was developed, the validity of these results should be questioned.

Summary and Conclusions

The conduct of head-to-head trials in this area is difficult, so evidence for the efficacy and safety of ITx is largely based on case series reports. Most of these reports come from a number of key ITx centres that are responsible for the majority of cases and also produce the greatest volume of publications. Thus the evidence available generally reflects the experience of several large and highly specialised programs. In addition, an important source of valuable information is the Intestinal Transplant Registry, which captures information about all ITx procedures undertaken worldwide.

There is one prospective study that attempts to quantify the difference between TPN and ITx (Pironi *et al.*, 2008) after three years of follow-up. The study found that the three-year survival rate was higher in ITx candidates who were not transplanted than it was in ITx recipients; however as discussed earlier, the study results are probably subject to bias because ITx recipients are likely to have poorer prognosis than those who are candidates but don't receive transplants.

To date, a single systematic review of published case series has been undertaken. This report, by the Ontario Ministry of Health and Long Term Care, concluded that for patients who can no longer continue home enteral nutrition due to life-threatening complications, ITx offers the only viable alternative. The majority of patients who survived the procedure were able to discontinue total parenteral nutrition and receive the required nutrients enterally. In spite of an improvement in outcomes in recent years, the procedure was found to be associated with high mortality and high rates of reoperation after transplant. This review included a number of case series with data from many years ago, when survival rates were poorer. The mean survival data are therefore an underestimate of true survival in current transplant recipients. To address this issue, the most recent report of the Intestinal Transplant Registry (Grant *et al.*, 2005) includes an additional analysis of survival in cases since 1998. The one year patient survival rate in this group was 77%, compared to 65% in the group including patients from 1985. Survival estimates from case series reports are generally consistent with this estimate and describe the same trend towards improved outcomes in recent years. The reason for these improvements is likely to be a combination of factors, including better selection of patients, improved surgical techniques, and advances in immunosuppression. Most reports also agree that the majority of surviving ITx recipients achieve nutritional autonomy. Based on reports from the Intestinal Transplant Registry and reports from individual centres, possible factors impacting survival included disease aetiology, transplantation of patients waiting at home versus in the hospital, use of induction antibody therapies, use of centres that have performed at least 10 transplants, patient body weight and recipient age. Most studies clearly suggest that survival in patients receiving an ISB graft is higher than it is in those receiving SB-L or MV grafts.

At present, it is not possible to determine the cost effectiveness of ITx. The recent study by Longworth *et al.* (2006) provided contradictory findings, dependent on assumptions regarding expected survival.

Based on the range of evidence presented above, the major professional societies and Medicaid endorse ITx only in those patients with total irreversible intestinal failure

who can no longer be maintained on TPN. Because of the risks associated with the treatment, transplants are not recommended for quality-of-life reasons alone.

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Appendix A: HTA websites searched

- HTA and systematic review databases searched for this project are:
- Health Technology Assessment Database (via the Cochrane Library):
<http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME>
- INAHTA website database: <http://www.inahta.org/Search2/?pub=1>
- MSAC: <http://www.msac.gov.au/>
- ANZHSN: <http://www.horizonscanning.gov.au/>
- NZHTA: <http://nzhta.chmeds.ac.nz/>
- NICE: <http://www.nice.org.uk/>
- AHRQ/USPSTF: <http://www.ahrq.gov/>
- CADTH: <http://www.cadth.ca/>

Appendix B: Included citations

Medicaid report

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