Advances in the Management of Intestinal Failure

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Acknowledgements

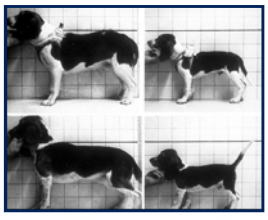
- Jeffrey Rudolph, Intestinal Care and Rehabilitation Team, Children's Hospital of Pittsburgh
- Rob Venick, UCLA Medical Center
- David Grant, Intestinal Transplant Association and International Intestinal Transplant Registry
- SRTR and OPTN 2012 Data Report

Objectives

- Review the main causes of intestinal failure in children and adults
- Understand the top trends and changes in intestinal failure management today
- Understand current indications for intestine transplant today
- Understand the outcomes and main management issues following intestinal transplantation

Historical Perspectives

- The field of intestinal rehabilitation began in 1967, Philadelphia, with TPN
- Initiated in surgical loss of intestine
  - Increased post-operative mortality due to inability to nourish patients
- First administered to a newborn infant girl in July, 1967
  - Born with intestinal atresia
  - Duodenocolonic anastamosis
  - Survived 22 months
    - Adequate weight gain
    - Multiple catheters/infections



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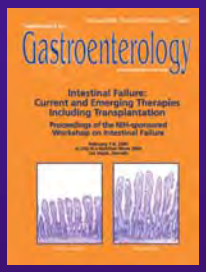
What is Intestinal Failure?

"A critical reduction of *functional* gut mass below the minimal amount necessary for adequate digestion and absorption to satisfy body nutrient and fluid requirements in adults or growth in children."

– *Thompson JS. Overview of etiology and management of intestinal failure. Gastroenterology (2006) 130 (2 Suppl 1): S3-S4.*



Intestinal failure is not a diagnosis: it is a description of a physiological state of organ system dysfunction

Implication of TPN requirement as supportive therapy

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Pathophysiology of Short Bowel Syndrome: Considerations of Resected and Residual Anatomy. Tappenden KA. JPEN 2014 May;38(1):16S

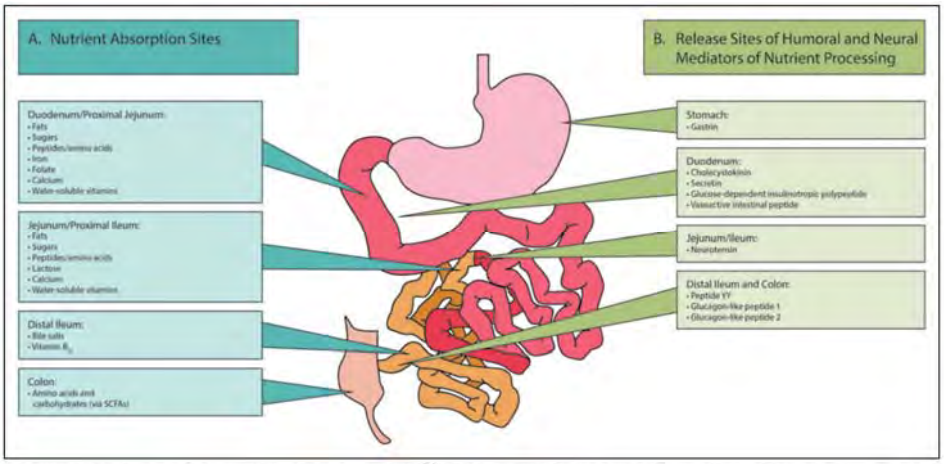
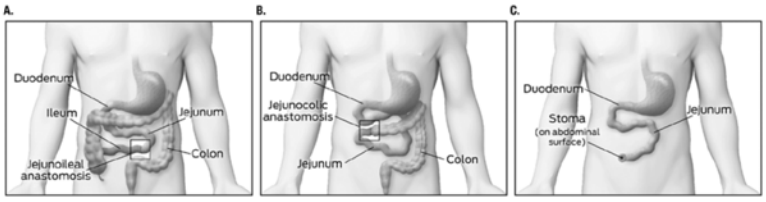


Figure 1. (A) Site-specific absorption of dietary nutrients.[2,38] (B) Location of release and primary effects of the major humoral and neural mediators of nutrient processing. SCFA, short-chain fatty acid.

Pathophysiology of Short Bowel Syndrome: Considerations of Resected and Residual Anatomy. Tappenden KA. JPEN 2014 May;38(1):18S

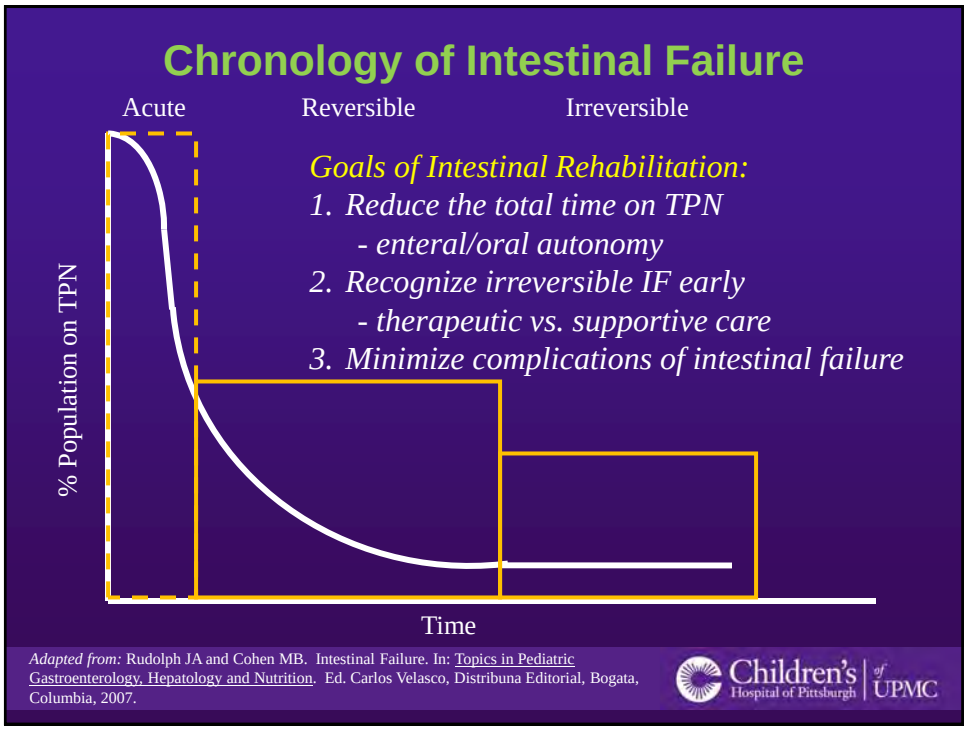


D.

	Jejunoileal Anastomosis	Jejunocolic Anastomosis	Jejunostomy
Probability of PN dependence	Low but increased in patients with <35 cm jejunum remaining	Variable* but generally higher in patients with <60–65 cm jejunum remaining	Variable* but higher in patients with <115 cm jejunum remaining
Possible symptomatic manifestations	Transient gastric acid hypersecretion and impaired digestion	Increased diarrhea; vitamin B_{12} deficiency; impaired bile salt resorption; deficiency in fat-soluble vitamins; fat malabsorption and steatorrhea; choleretic diarrhea	Increased stomal output; significant nutrient and fluid malabsorption; magnesium deficiency; vitamin B_{12} deficiency; impaired bile salt resorption
Prognosis	Good	Fair	Fair

* Depending on length of remnant jejunum.

Figure 2. Types of intestinal resections: (A) jejunoileal anastomosis, (B) jejunocolic anastomosis, (C) jejunostomy, and (D) outcomes associated with each type of resection.[17,60,61] PN, parenteral nutrition.




ARTICLE IN PRESS

THE JOURNAL OF PEDIATRICS • www.jpeds.com ORIGINAL ARTICLES

Natural History of Pediatric Intestinal Failure: Initial Report from the Pediatric Intestinal Failure Consortium

Robert H. Squires, MD[1], Christopher Duggan, MD[2], Daniel H. Teitelbaum, MD[3], Paul W. Wales, MD[4], Jane Balint, MD[5], Robert Venick, MD[6], Susan Rhee, MD[7], Debra Sudan, MD[8], David Mercer, MD[9], J. Andres Martinez, MD[10], Beth A. Carter, MD[11], Jason Soden, MD[12], Simon Horslen, MD[13], Jeffrey A. Rudolph, MD[1], Samuel Kocoshis, MD[14], Riccardo Superina, MD[15], Sharon Lawlor, MBA[16], Tamara Haller, BS[16], Marcia Kurs-Lasky, MS[16], and Steven H. Belle, PhD, MScHyg[16], for the Pediatric Intestinal Failure Consortium*

2008: R21 Proposal (funded)
Intestinal failure in children: A contemporary retrospective review by the Pediatric Intestinal Failure Consortium

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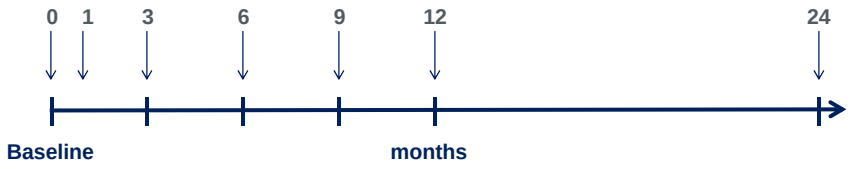
Criteria for Enrollment

- No more than 12 months old at enrollment
- TPN for 60 out of 74 consecutive days
  - Allow for temporary loss of access or surgery
- Data collection:



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Study Demographics

typical patient (2000-2004)

Premature: 30-36 weeks EGA
Sick immediately after birth
Fairly short length of bowel

Fair/good synthetic function
At least mild cholestasis

Table I. Characteristics at birth and at study entry of 272 infants with IF

Feature (N = data available)	Number (%)	Median (25th-75th)
At birth		
Male	156 (57.4)	
Caucasian (250)	204 (81.6)	
Hispanic	42 (15.4)	
Gestation (wk) (264)		34 (30-36)
<37 wk (premature)	202 (76.5)	
Birth weight (kg) (221)		2.1 (1.2-2.7)
≤1.5 kg (very low birth weight)	66 (29.9)	
At study entry		
Age when entry criteria met (d)		63 (61, 74)
Small bowel length (cm) (144)		41 (25-65.5)
Weight age z-score <−2 (174)	37 (21.3)	
Height age z-score <−2 (111)	38 (34.2)	
Weight-for-height z-score <−2 (89)	10 (11.2)	
ALT ≥80 IU/mL (163)	77 (47.2)	
AST ≥ 80 IU/mL (138)	92 (66.7)	
Cholestasis present* (168)	125 (74.4)	
Albumin <2.8 g/dL (167)	82 (49.1)	
INR >1.5 (65)	6 (9.2)	

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Diagnostic Classification

Table II. Diagnoses associated with IF and SBS in infants (N = 272)

Diagnosis	N (%)
Necrotizing enterocolitis	71 (26)
Gastroschisis	44 (16)
Intestinal atresia (large/small)	27 (10)
Volvulus	24 (9)
Long segment Hirschsprung disease	11 (4)
Tufting or microvillus inclusion	3 (1)
Other single diagnoses	14 (5)
Unknown	1
Multiple single diagnoses	77 (28)

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Outcomes:

In patients (2000-2004):

Overall Mortality: 68/272 (25%)

Those without transplant:

Alive without Tx: 154/272 (57%)
Enteral Autonomy: 118/272 (43%)

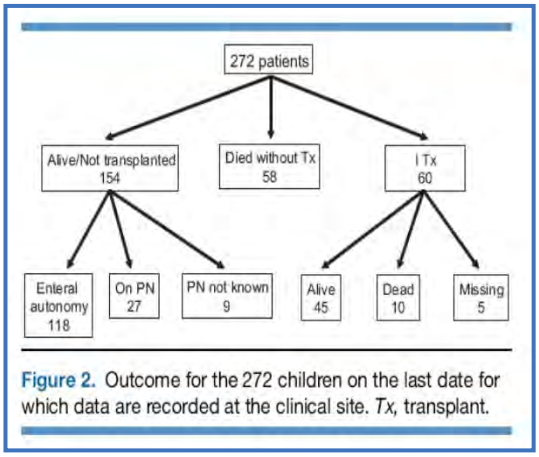


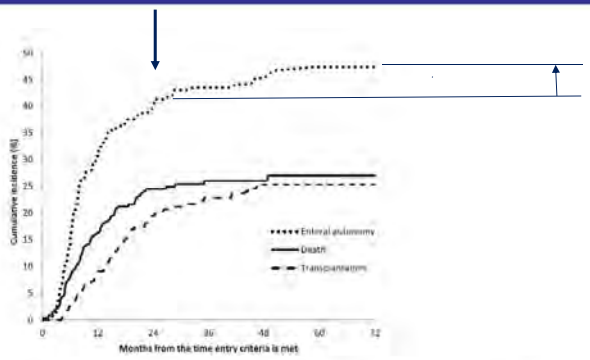
Figure 2. Outcome for the 272 children on the last date for which data are recorded at the clinical site. *Tx*, transplant.

Cause of Death

Table V. Cause of death in infants with IF/SBS before and after ITx

Cause of death	N (%)
Prior to ITx	58
Multiorgan system failure	28 (62)
Sepsis	9 (20)
Hemorrhage	4 (9)
Central nervous system	2 (4)
Meningitis-palliation	1 (2)
Nephroblastoma-palliation	1 (2)
Unknown	13
Following ITx	10
Respiratory failure	4 (40)
Multiorgan system failure	3 (30)
Sepsis	2 (20)
Hemorrhage	1 (10)

Primary Outcomes



Cumulative incidence (Number at risk)	0 mos	12 mos	24 mos	36 mos	48 mos	60 mos	72 mos
Death	0% (272)	16% (220)	23% (182)	26% (126)	26% (126)	27% (75)	27% (75)
Transplantation	0% (272)	9% (199)	19% (142)	23% (89)	26% (52)	26% (52)	26% (52)
Enteral autonomy	0% (272)	21% (120)	40% (42)	44% (18)	45% (14)	47% (9)	47% (9)

Figure 3. Primary outcomes: enteral autonomy, death, and intestinal transplantation. The data below the graph show the cumulative incidence of and the number of children who remain at risk for developing the outcome.

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Infectious Complications

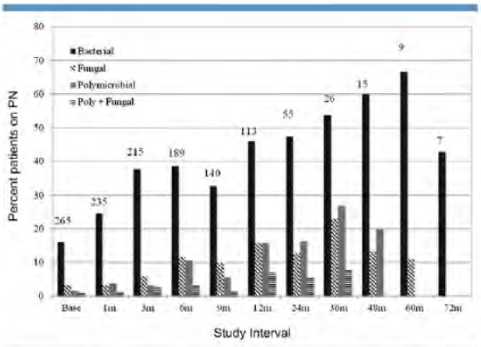

Figure 1. Percent of patients on PN with septic events by study interval. Time intervals were contiguous, with the designated time coinciding with the mid-point of the interval. The numbers on top of the *bars* represent the number of children on PN for that study interval.

As PN progresses, the proportion of Children on PN with infection increases

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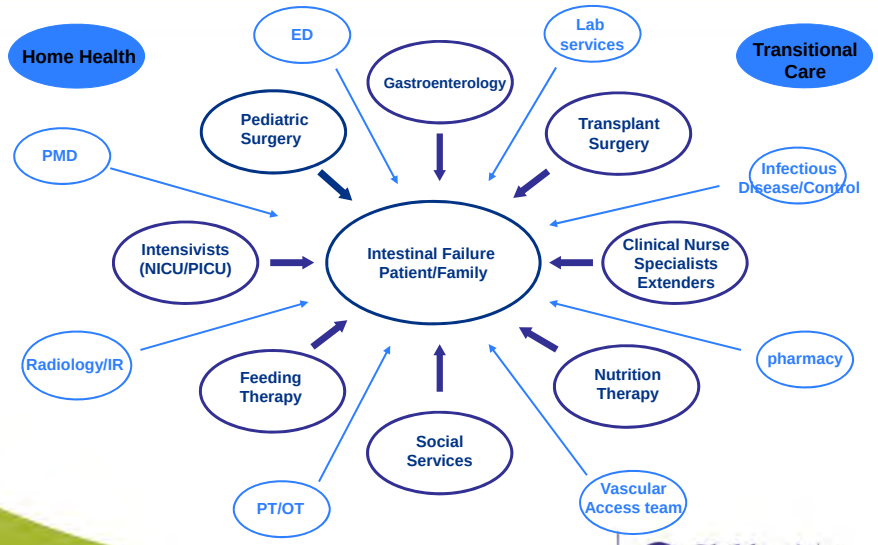
The Genesis of the Intestinal Rehabilitation Team

- After Dudrick's initial report, the use of TPN spread
  - In pediatrics: clearly in the arena of pediatric surgery
    - Ideal for the management of short bowel syndrome
  - Advancements: introduction of lipids and amino acid solutions
  - Long term survival: reality
  - Use of TPN was used for non-surgical patients with intestinal failure
- The management of intestinal failure developed into a chronic care model
  - Home TPN protocols devised
  - Complexity and diversity of the management issues led to the development of multi-disciplinary teams

Impact of Intestinal Rehabilitation on Medical Systems



Short Bowel Syndrome in Adults: The Need for an Interdisciplinary Approach and Coordinated Care. Matarese LE, Jeppesen PB, O'Keefe SJD. JPEN 2014 May;38(1):63S

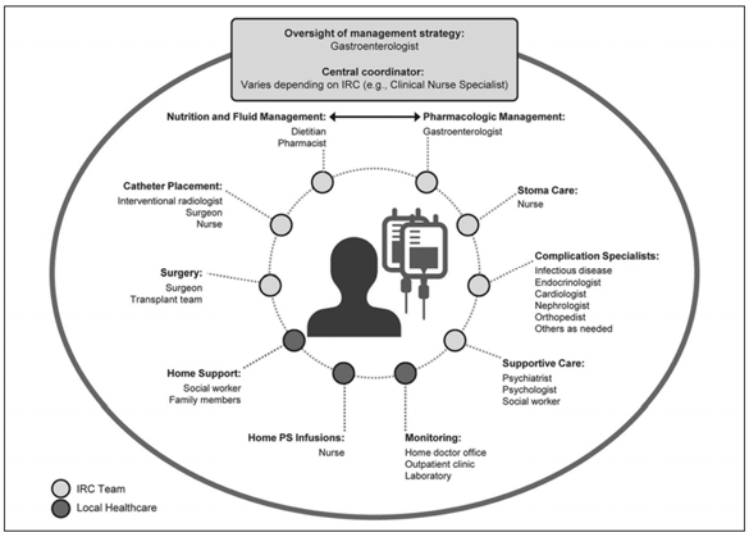


Figure 2. Coordination of care via an IRC interdisciplinary team. IRC, intestinal rehabilitation center; PS, parenteral support of nutrition and intravenous fluids.

Major Complications of TPN Therapy

- Major Morbidities in Intestinal Failure are due to the complications of TPN therapy
- Often the Indications for Small Bowel Transplant
  - Chronic Central Venous Access
    - Vascular Morbidities
    - Catheter Associated Blood Stream Infections
  - Complications due to the Components of TPN
    - Intestinal Failure Associated Liver Disease
    - Role of constituent shortages
      - Copper
      - Thiamine

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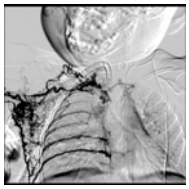
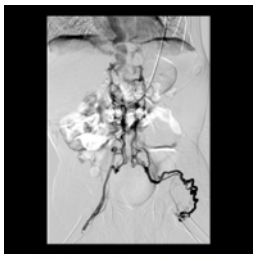
Treatment Strategies

- Nutritional Strategies
- Pharmacologic Therapies
- Sepsis Prevention
- Hormonal Therapy (GH, GLP-2, EGF)
- Keeping Liver Healthy: Novel Lipid Based Approaches
- Autologous Bowel Reconstruction (STEP)
- Transplantation

Central Venous Catheter Complications

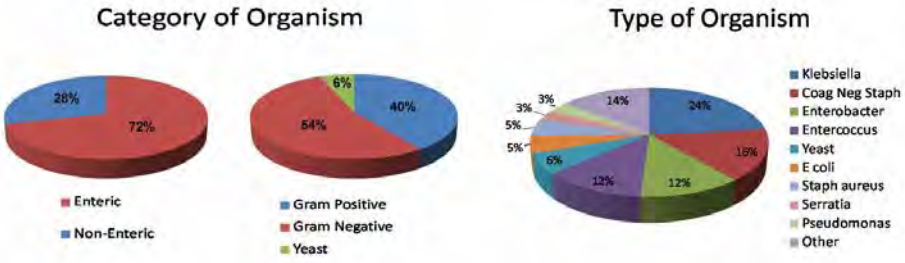
- Central Venous Catheters are a part of everyday life in a child with intestinal failure
- Broken Caths
  - Often from tugging/pulling
  - Trained vascular access team
  - Spiraled lines/holsters/looping
  - Unique Tunneling
- Malocclusions:
  - TPA
- Thrombi
  - Constant manipulation of lines
  - Multiple thrombi: thrombophilia evaluation





Catheter Associated Bloodstream Infections: CLABSIs

- **Unique pathogens in the Intestinal Failure Population**



CCHMC Data: From 6/1/07-6/1/08: N=86 organisms from 75 CA-BSIs

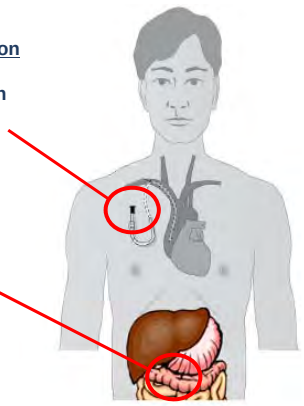
From: Kevan et al. Annual meeting of the North American Society for Pediatric Gastroenterology and Nutrition, San Diego, CA. November 13-15, 2008.

Management of CLABSIs

- Source of Infection
  - External vs. Internal seeding
- Recognition
  - Soft signs of sepsis
  - Potential for decompensation
- Line Salvage therapy
  - Line locks
    - Antibiotic
    - Ambisome
    - ETOH
- Infection Prevention

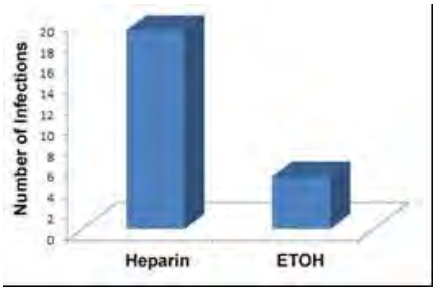
External Contamination
Skin Flora
Stool Contamination

Internal Seeding
GI Translocation
Other infections (UTI, cellulitis, osteomyelitis)



CLABSIs: ETOH Lock Prophylaxis

- Presented at IDSA by Judy Martin, MD
- Enrollment IF with >3 CLABSIs
- Prospective, randomized, double blind-crossover
- 25% ETOH lock solution versus placebo (Heparin)
- 12 weeks therapy with 4 week washout followed by 12 weeks of other therapy
- 11 patients completed
- Average lock time 6 hours (4-8)



Current available therapies for SBS patients

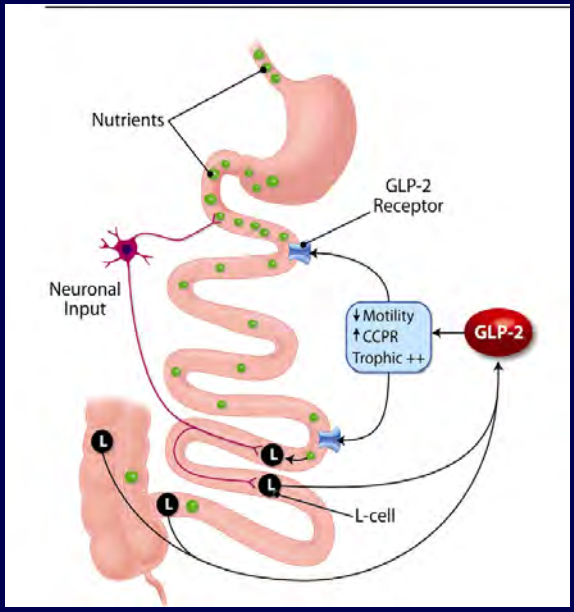
TABLE 8. Medications Used in Short Bowel Syndrome (SBS)[34,41,63,68–70,72–78]

Category	Medication	Action
Antidiarrheals	Diphenoxylate Loperamide Codeine Opium tincture	Increase intestinal transit time
H_2 blockers	Famotidine Ranitidine Nizatidine	Decrease gastric acid secretion
Proton pump inhibitors	Omeprazole Lansoprazole	Decrease gastric acid secretion
Pancreatic enzymes	Pancrelipase	Improve digestion
Somatostatin analogs	Octreotide	Decrease secretory diarrhea
Antimicrobials	Metronidazole Tetracycline Cephalexin	Decrease bacterial overgrowth
Synthetic conjugated bile acid	Cholylsarcosine	Increase fat absorption
Trophic factors	Recombinant human growth hormone Glucagon-like peptide-2	Increase nutrient absorption

Matarese and Steiger. Dietary and medical management of short bowel syndrome in adult patients. 2006 J Clin Gastroenterol

- Medical management
- Bowel lengthening procedures
- Intestinal transplant

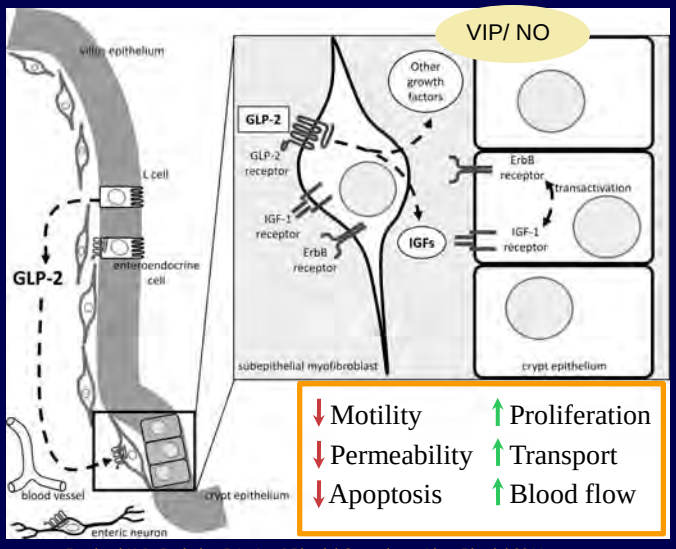
GLP-2 secreted mainly from L cells



Effect exerted mainly in proximal gut

Sigalet et al. Seminars in Ped Surgery. 2009

Model for the proposed mechanism of action of glucagon-like peptide-2 (GLP-2) on intestinal crypt cells.



Rowland K J , Brubaker P L. Am J Physiol Gastrointest Liver Physiol 2011

Single hormone therapy: Teduglutide (GLP-2)

Teduglutide Reduces Need for Parenteral Support Among Patients With Short Bowel Syndrome With Intestinal Failure

PALLE B. JEPPESEN,* MAREK PERTKIEWICZ,‡ BERNARD MESSING,§ KISHORE IYER,‖ DOUGLAS L. SEIDNER,¶ STEPHEN J. D. O'KEEFE,# ALASTAIR FORBES,** HARTMUT HEINZE,‡‡ and BO JOELSSON§§

GASTROENTEROLOGY 2012;143:1473–1481

- Teduglutide (GLP-2 analog)
- 24 week study of adults with SGS
- 0.05 mg/kg/d vs. placebo (n=43)
  - Significant (20%) reduction in PN use
  - Teduglutide: 27/43 (63%)
  - Placebo: 13/43 (30%)
- All patients on parenteral support >1yr
- No data thus far in children

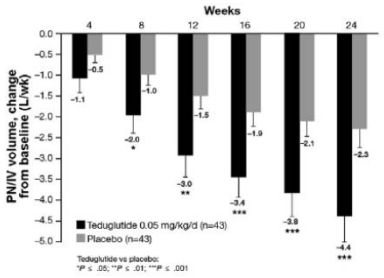


Figure 2. Mean (SE) absolute reduction in parenteral support.

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Intestinal Rehabilitation: Key Questions

- **Length of residual bowel and colon**
- **Underlying disease state**
- **Status of the liver**

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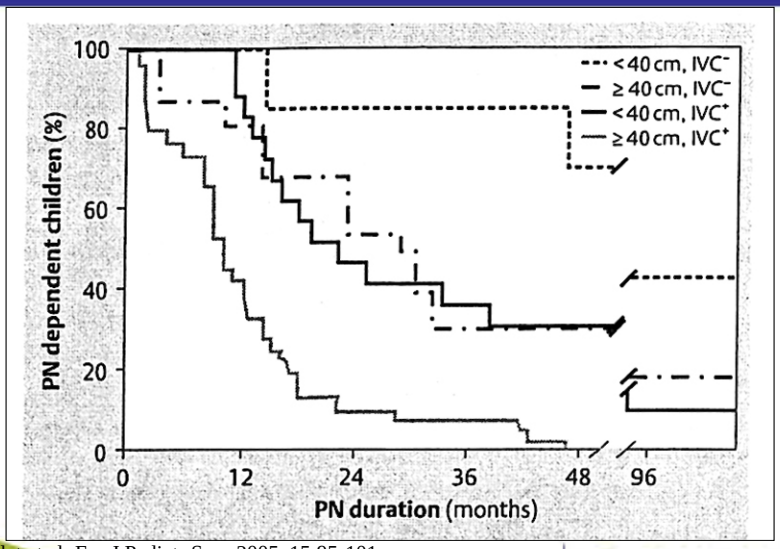
Importance of Residual Bowel Length and Colon



Goulet et al: Eur J Pediatr Surg 2005, 15:95-101

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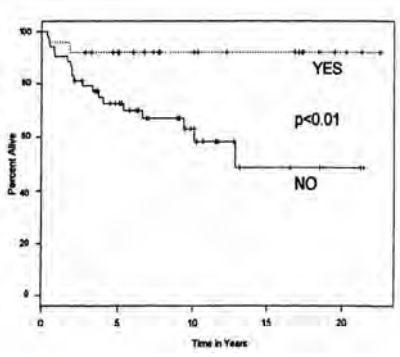
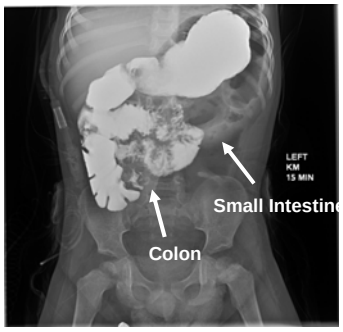
Surgical Therapies: Establishment of Continuity

Restoration of Continuity: Survival





Quiros-Tijeira RE, et al J Pediatr 2005;145:157-163

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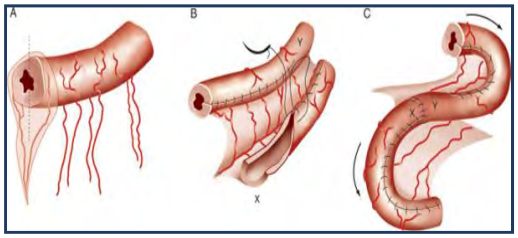
Surgical Adaptation: Bowel Lengthening

Bianchi Procedure



Serial Transverse Enteroplasty (STEP)

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Serial Transverse Enteroplasty (STEP)

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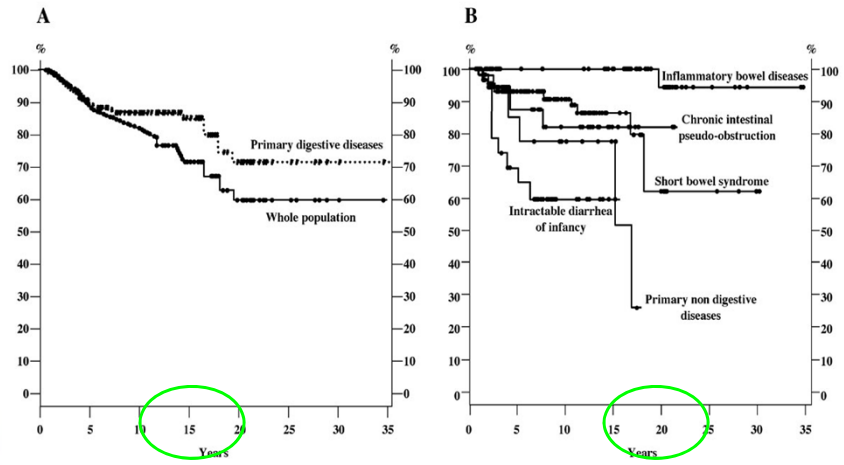
Survival according to PN indication



Colomb V et al, JPGN 44:347-353, 2007 302 patients, Necker-EM, 1980-99

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Keeping the Liver Healthy

- Prevention of CR-BSIs
  - Sterile technique/line handling
  - ETOH lock therapy
- Advancement of feeds/weaning TPN
- Understanding hepatotoxic effects of TPN
  - Trace elements
  - Glucose
  - Protein
  - Lipids

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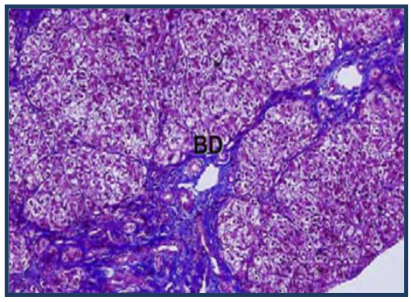
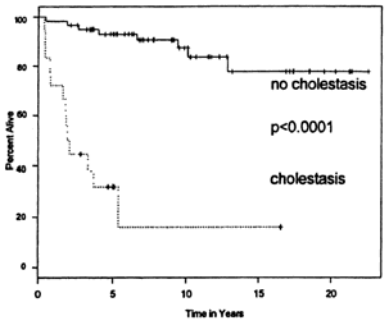
Intestinal Failure Associated Liver Disease

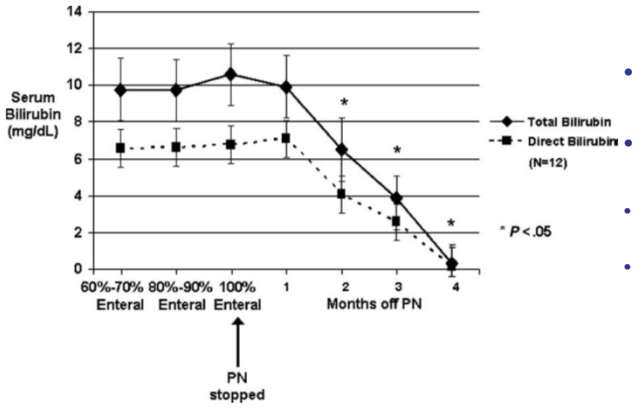




Early and persistent cholestasis: The UCLA Experience (n=78)

Quiros-Tejeira RE, Ament ME, Reyen L, et al. Long-term parenteral nutritional support and intestinal adaptation in children with short bowel syndrome: a 25-year experience. *J Pediatr.* Aug 2004;145(2):157-163.

Role of Parenteral Nutrition in IFALD

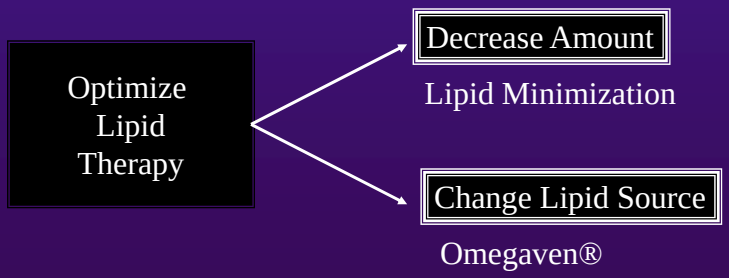


- Retrospective Review (Boston)
- 12 patients
  - Dbili >3.0
- 2/12 improved prior to full enteral nutrition
- 10/12 complete resolution 4 months after completion

Javid PJ, Collier S, Richardson D, et al. The role of enteral nutrition in the reversal of parenteral nutrition-associated liver dysfunction in infants. *J Pediatr Surg.* Jun 2005;40(6):1015-1018

Lipid Emulsions in Parenteral Nutrition Use

- **Lipid is an essential nutrient in newborns**
  - Requirements (type and amount) not well known
- **Soy-based emulsions are only approved form of parenteral lipids in the U.S.**



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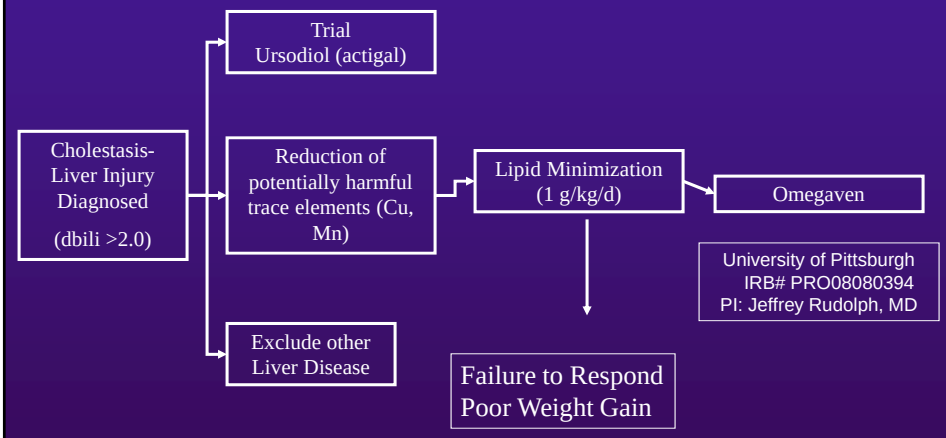
Algorithm: Hepatic Sparing TPN



Personal communication, J Rudolph, Intestinal Care and Rehabilitation Service

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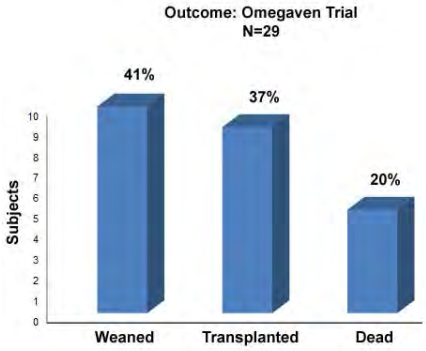
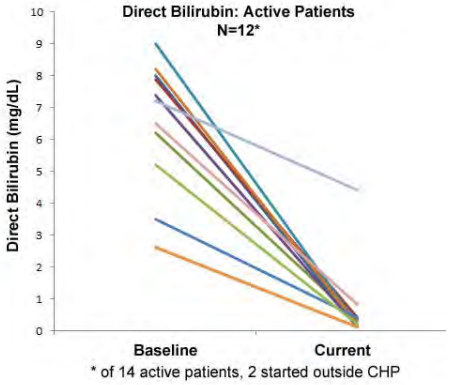
Outcomes on Omega-3 Lipid emulsions





Personal communication, J Rudolph Children's Hospital of Pittsburgh of UPMC

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Does the multidisciplinary approach work?

aspen
American Society for Parenteral and Enteral Nutrition

A.S.P.E.N. Clinical Guidelines: Support of Pediatric Patients With Intestinal Failure at Risk of Parenteral Nutrition–Associated Liver Disease

Paul W. Wales, Nancy Allen, Patricia Worthington, Donald George, Charlene Compher, the American Society for Parenteral and Enteral Nutrition and Daniel Teitelbaum
JPEN J Parenter Enteral Nutr published online 2 April 2014
DOI: 10.1177/0148607114527772

3 Retrospective Medical Record Reviews:

	Survival	
	Pre-IR Team	Post-IR Team
Sigalet et al, 2009	73% (33)	100% (22)
Modi et al, 2008	73% (30)	89% (54)
Diamond et al, 2007	70% (40)	78% (54)

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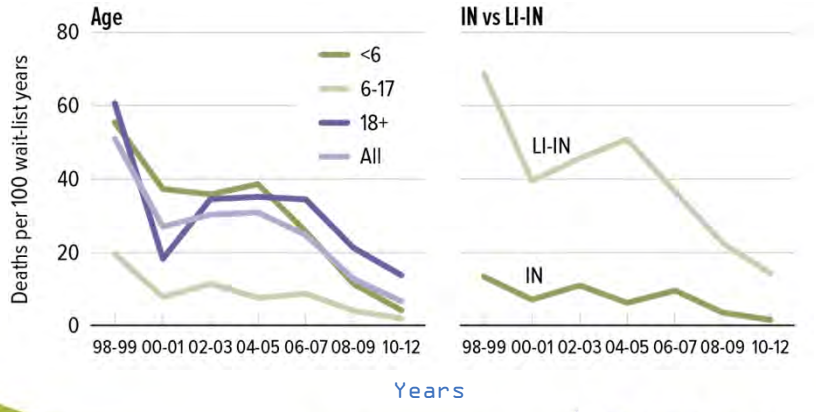
Decreasing pre-transplant mortality rates among patients wait-listed for an intestinal transplant (SRTR)



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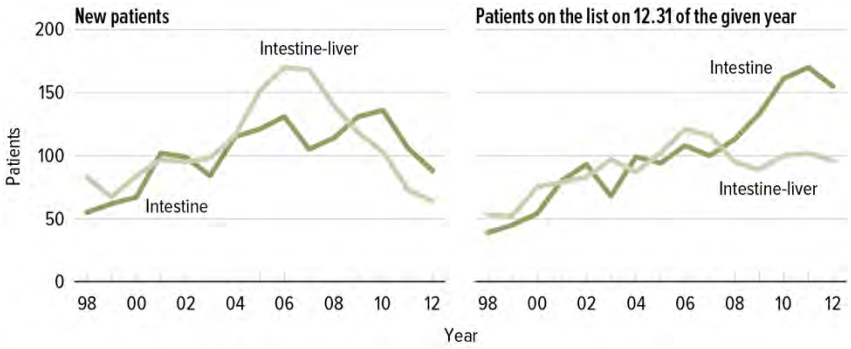
Fewer patients waiting for an intestinal transplant



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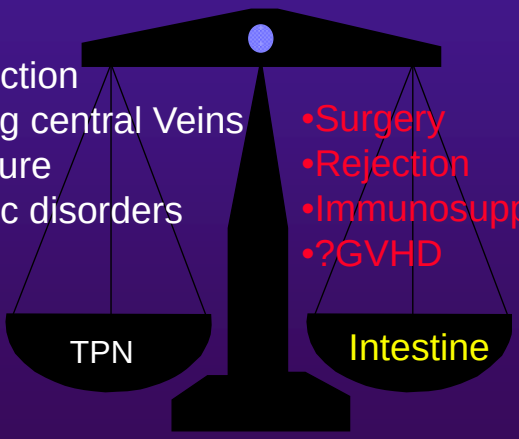
When is the right time for transplant?

TPN VS INTESTINE TRANSPLANT



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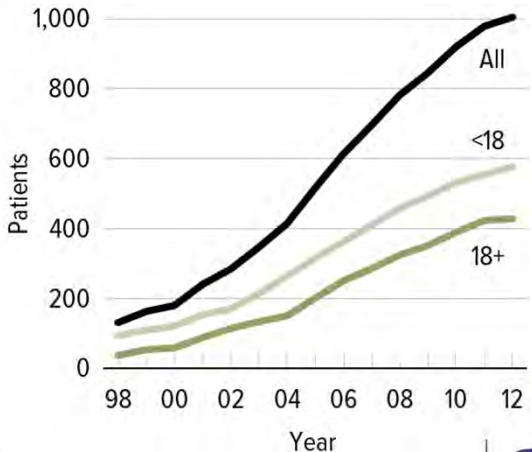
Recipients alive & with a functioning intestinal transplant on June 30 of the year



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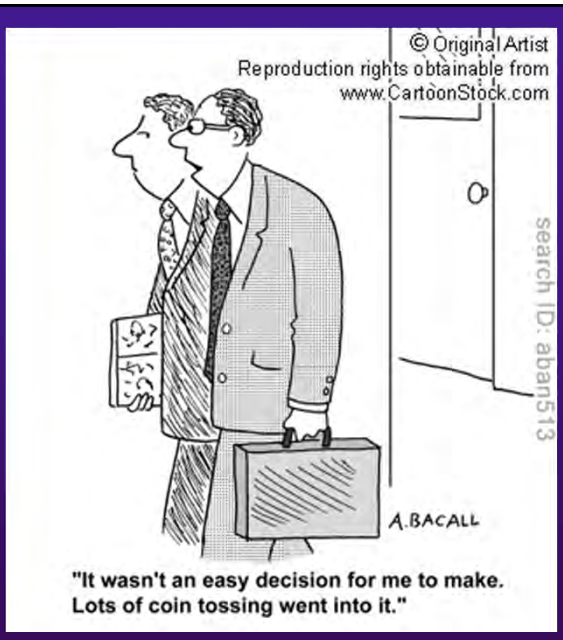

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ESPEN

Indications for Intestinal Transplantation

U.S.A. Medicare & Medicaid

HPN-Failure
- Impending (total bilirubin 3 to 6 mg/dL, progr. thrombocytopenia and splenomegaly) or overt liver failure (portalhypert., hepatosplenomegaly, hepatic fibrosis or cirrhosis)
- Thrombosis ≥ 2 central veins
- Frequent and severe CVC sepsis (≥ 2 yr or single episode of fungemia)
- Frequent episodes of severe dehydration

Am Society of Transplantation

Disease-related risk of death
- Desmoid tumors in FAP
- Congenital mucosal diseases
- Ultra short bowel

High morbidity IF / HPN refusal
- Poor pain control, frequent hospitalization
- Pt. unwillingness to continue HPN

AGA,Gastroenterology, 2003
Kaufman SS,Pediatr Transplant 2001

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When should referral be made for intestine transplantation in children with chronic intestinal failure??

- Infant age
- Evidence of liver disease (jaundice, thrombocytopenia, ascites, splenomegaly, bridging fibrosis
- Primary mucosal disorders
- Massive small bowel resection
- Prognostic or diagnostic uncertainty
- Thrombosis of >/= 2 central veins

Beath et al: Collaborative Strategies to Reduce Mortality and Morbidity in Patients with Chronic Intestinal Failure… TRANSPLANTATION 85:1378-1384 May 2008

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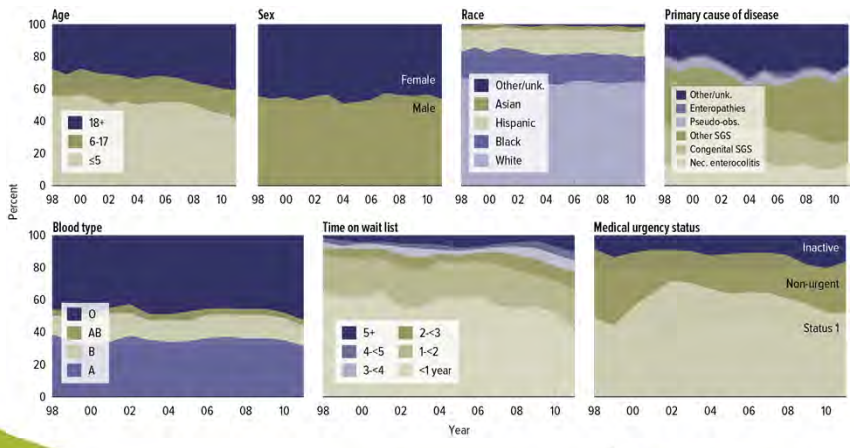
Current distribution of patients waiting for an intestinal transplant



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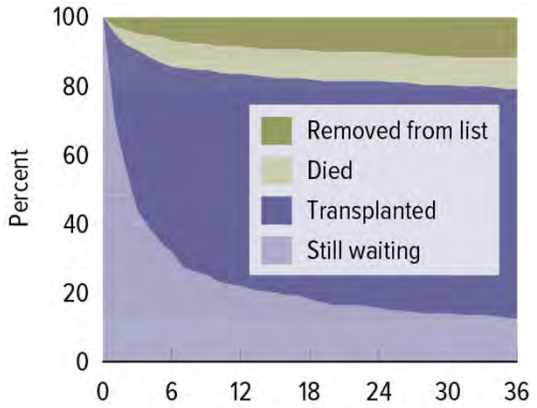
Three-year outcomes for patients waiting for an intestinal transplant among new listings in 2009



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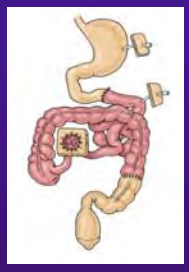
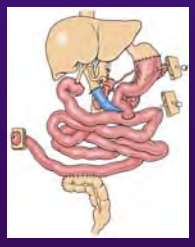
Intestine Transplant Surgical Techniques: Choosing the right operation for the right patient at the right time





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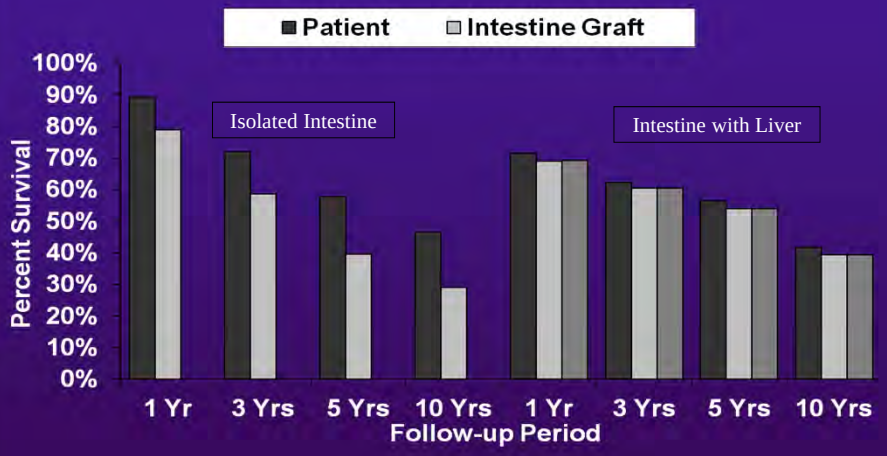
Unadjusted Patient and Graft Survival for Isolated Intestine and Intestine with Liver Recipients



Source: SRTR Analysis, Data as of May 2009. Isolated Intestine: intestine transplant with no other organs. Intestine with Liver: includes all transplants with intestine and liver, with or without pancreas or kidney.

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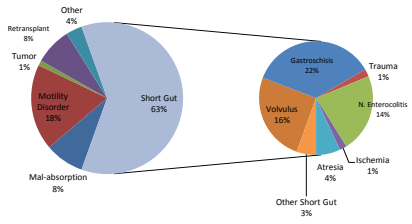
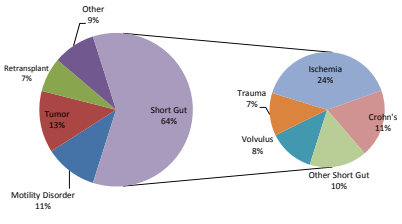
Disease indications for transplant

Children

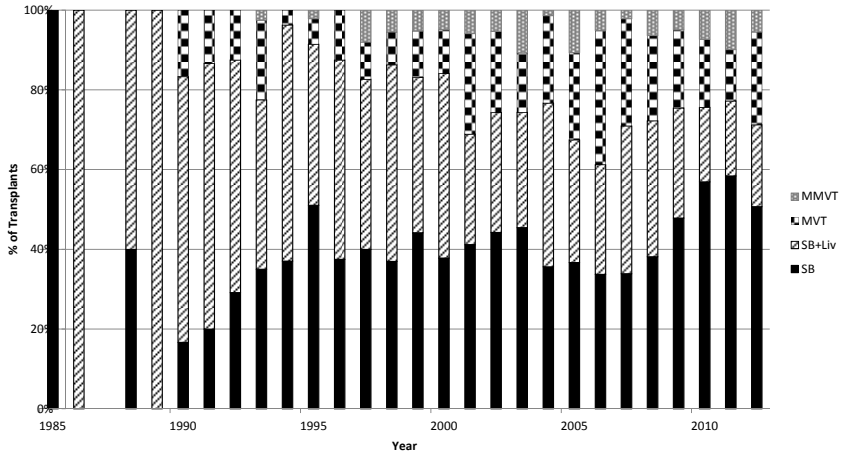


Adults



Intestinal Transplant Registry Report: Global activity and trends.[1, 2]
D. Grant[3], K. Abu-Elmagd[4], G. Mazariegos[5], R. Vianna [6], A. Langnas[7], R. Mangus[8], D.G. Farmer[9], F. Lacaille[10], K. Iyer[11], T. Fishbein[12], and on behalf of the Intestinal Transplant Association AJT Accepted for publication

Changes in transplant type over time



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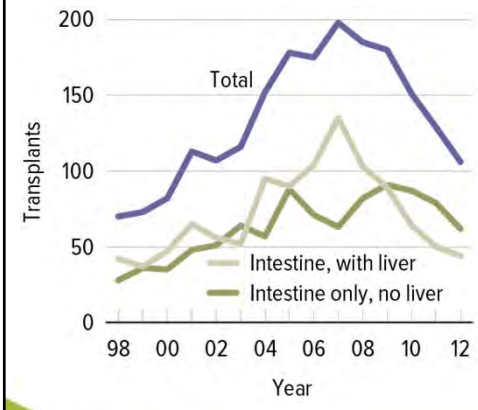
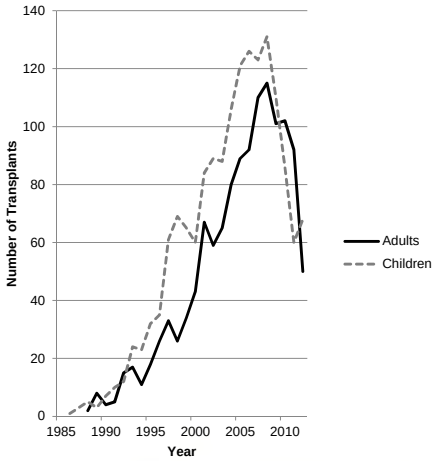
Trends in intestinal transplants (SRTR vs ITR)





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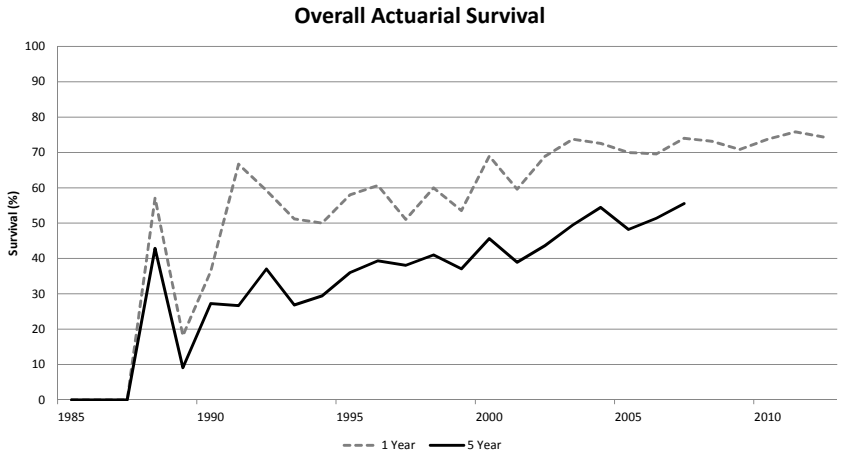
Improvements in actuarial survival



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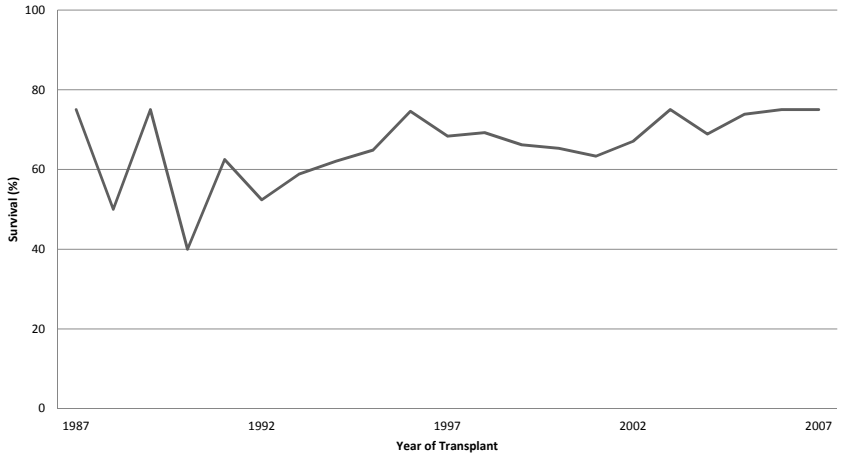
Conditional survival is not changing



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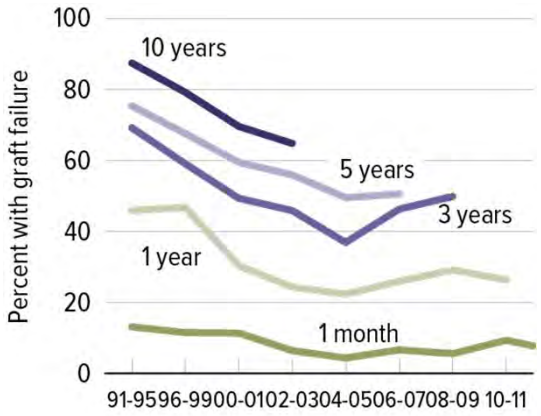
Graft failure among intestinal transplant recipients: deceased donor



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What are the challenges to long term survival of the intestine recipient?

- Infection and PTLD
- Chronic Rejection
- Immunosuppressant Related Morbidities

(Renal Failure, Htn, etc)

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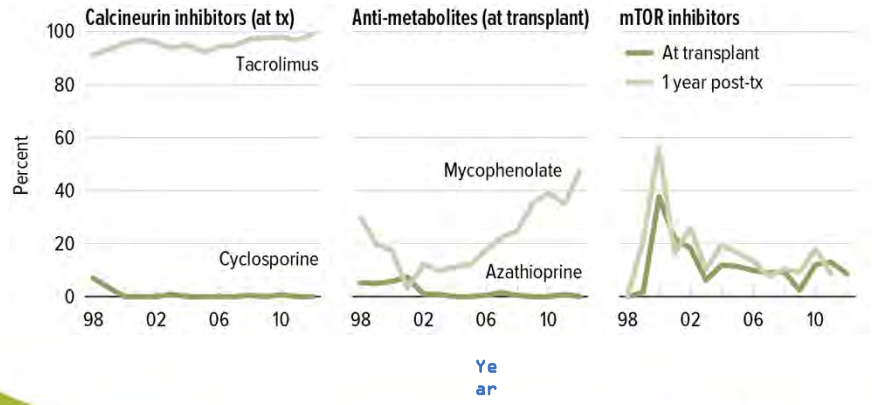
Immunosuppression use in intestinal transplant recipients



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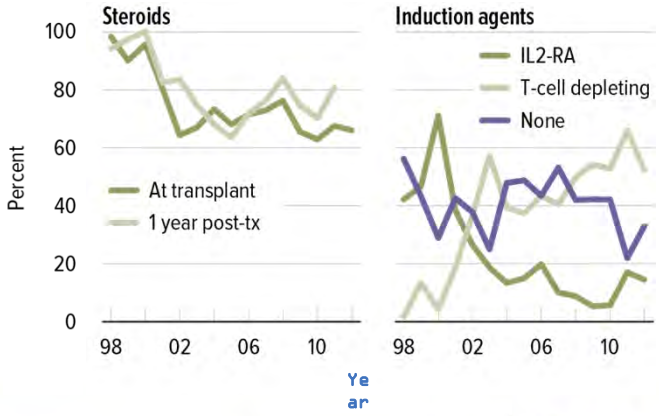
Immunosuppression use in intestinal transplant recipients (continued)



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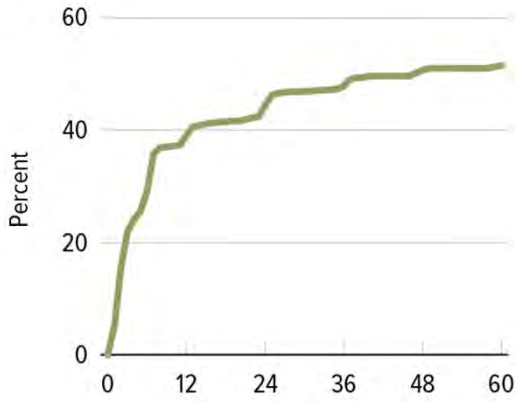
Incidence of first acute rejection among patients receiving an intestinal transplant in 2006–2010



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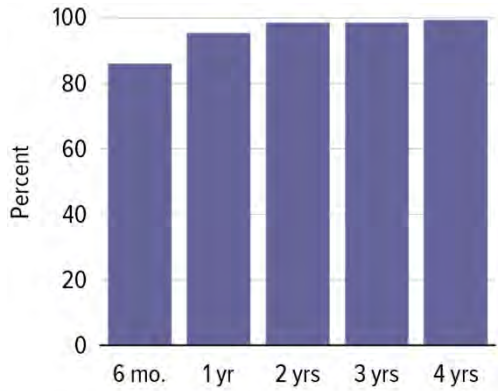
Reported cumulative rehospitalizations among pts receiving an intestinal transplant in 2007–2012



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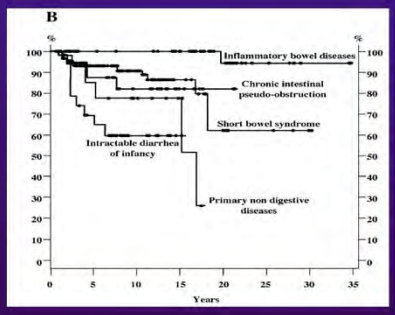
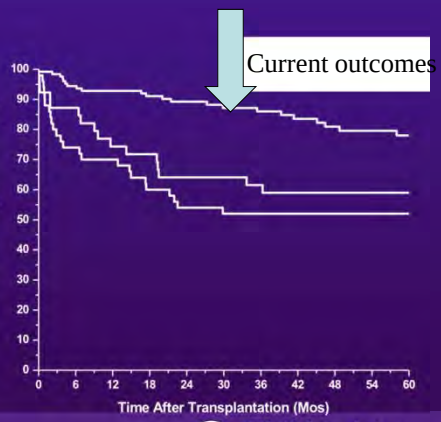
Decision making?

TPN



Intestine Transplant



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Final Considerations

- Current decision making in intestinal failure requires expert multidisciplinary assessment and care
- Understand risk factors, underlying diagnosis, morbidities, and probability of adaptation along with assessment of quality of life
- Improved liver sparing therapy, hormonal therapy and increased non-transplant surgical options are changing the need for intestine transplantation

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