Advances in Abdominal Organ Transplantation in the last Quarter Century

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Enterprise Director of Transplantation
Director, Transplant Center
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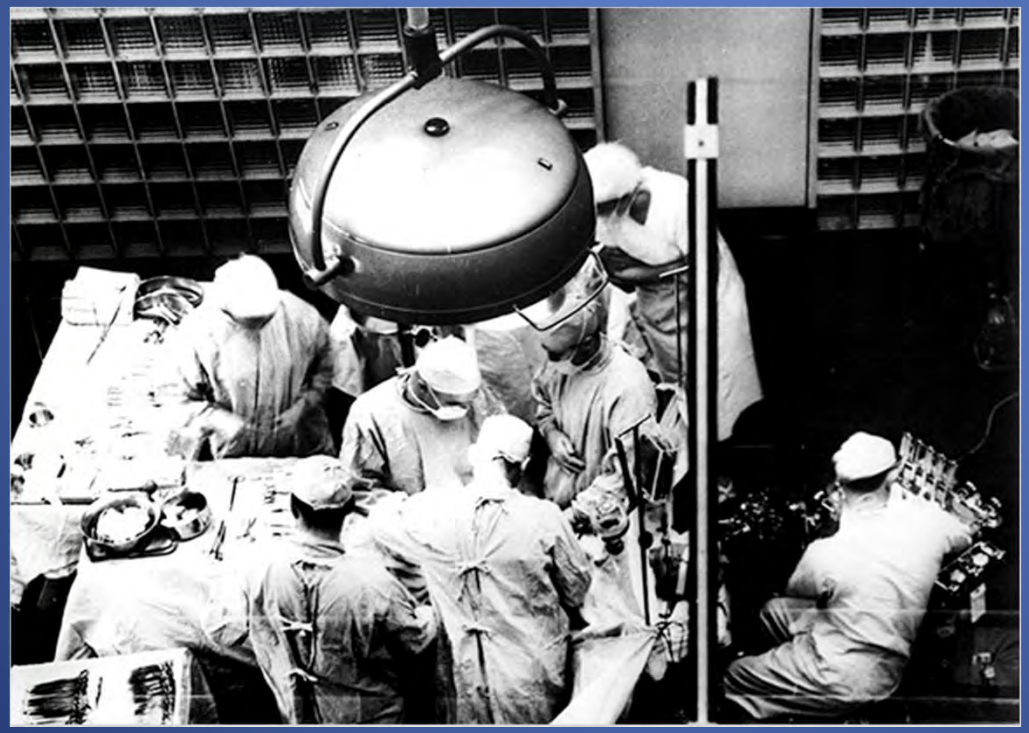
History of Transplantation: First Quarter Century

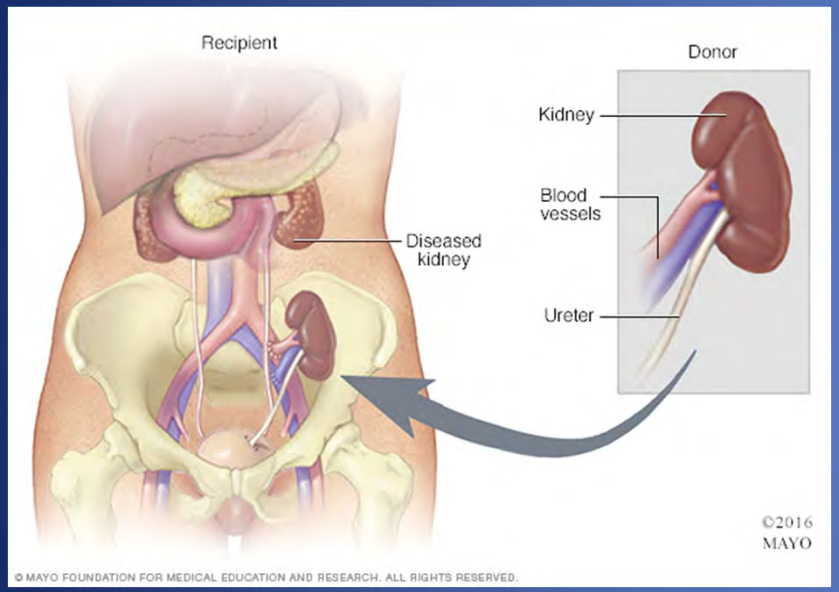
- Technical
- Organ Preservation
- Immunosuppression
- Early acceptance – kidney and liver
- Expansion of indications

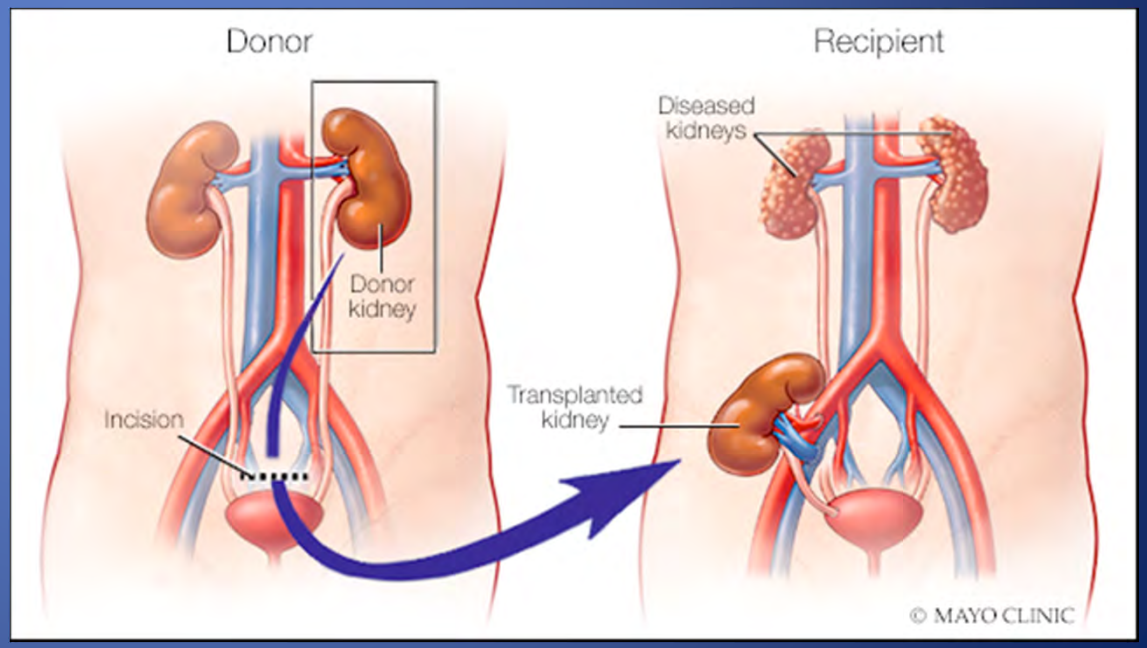
History of Transplantation

On Dec. 23, 1954, a team led by Dr. Joseph E. Murray at the Peter Bent Brigham Hospital in Boston transplanted a kidney from a 23-year-old man named Ronald Herrick to his identical twin, Richard, whose kidneys were failing.



History of Transplantation





History of Transplantation

1963

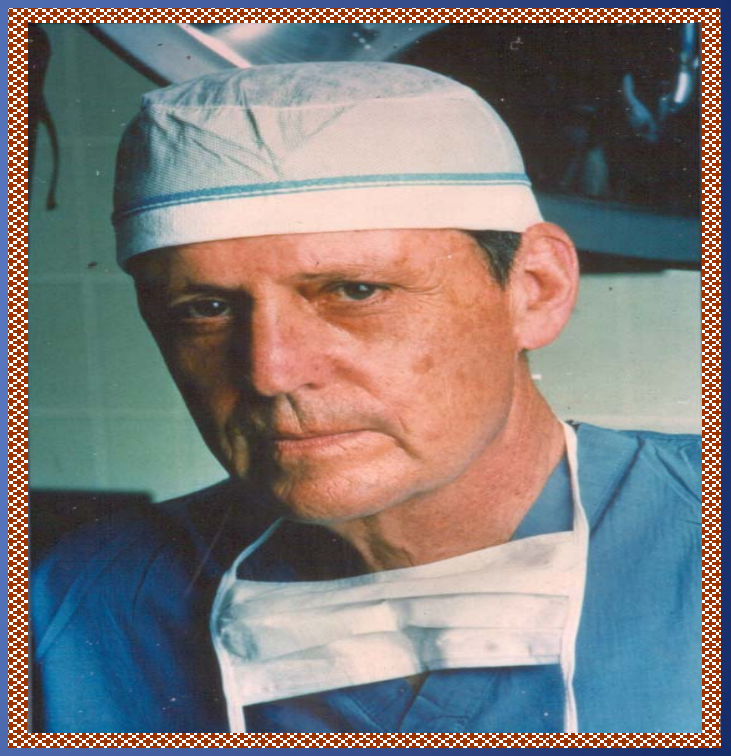
First human liver transplant - Dr. Thomas Starzl

(University of Colorado)

Homotransplantation of the liver in humans

Surgery, Gynecology & Obstetrics, 117: 659-76, 1963

T. E. Starzl, T. L. Marchioro, K. N. von Kaulla, G. Hermann, R. S. Brittain and W. R. Waddell



History of Transplantation

- Collins in 1969: Describes his high potassium flush solution
- Relatively long-term preservation (first of kidneys, then of livers) becomes possible

G.M. Collins et al, Lancet,2: 1219-221969

History of Transplantation

- 1978 is a crucial year:

  Cyclosporine A, discovered by accident by Borel in 1976,

  is used clinically for the first time (in Kidneys) by Calne

R.Y.Calne et al, Lancet, 2: 1033-36, 1979

History of Transplantation

- In 1980, Starzl begins a trial of Cyclosporine A and steroids in liver transplantation:
  - the results are so much better that some do not believe they are true

T.E.Starzl et al, Transplantation Proceeding, 13: 281-5, 1981

History of Transplantation

1983

Liver transplantation is approved as a therapeutic modality by NIH Consensus Conference

National Institutes of Health Consensus Development Conference Statement: Liver Transplantation—June 20–23, 1983

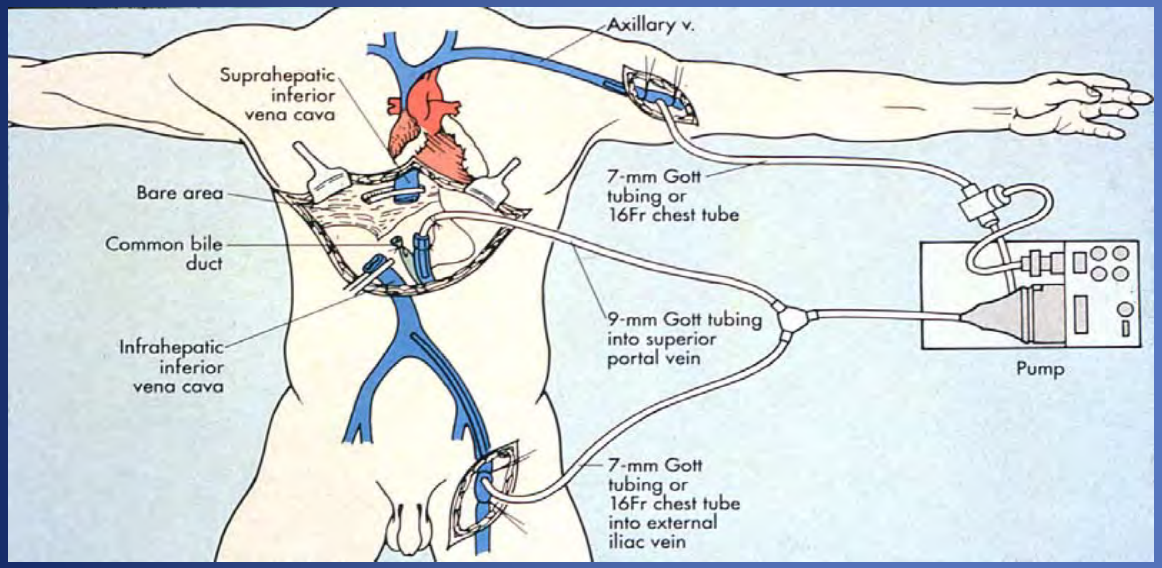
(1) ARE THERE GROUPS OF PATIENTS FOR WHOM TRANSPLANTATION OF THE LIVER SHOULD BE CONSIDERED APPROPRIATE THERAPY?

LIVER TRANSPLANTATION

OPERATION

- **HEPATECTOMY**
- **ANHEPATIC PHASE**
- **IMPLANTATION**
- **BILIARY RECONSTRUCTION**

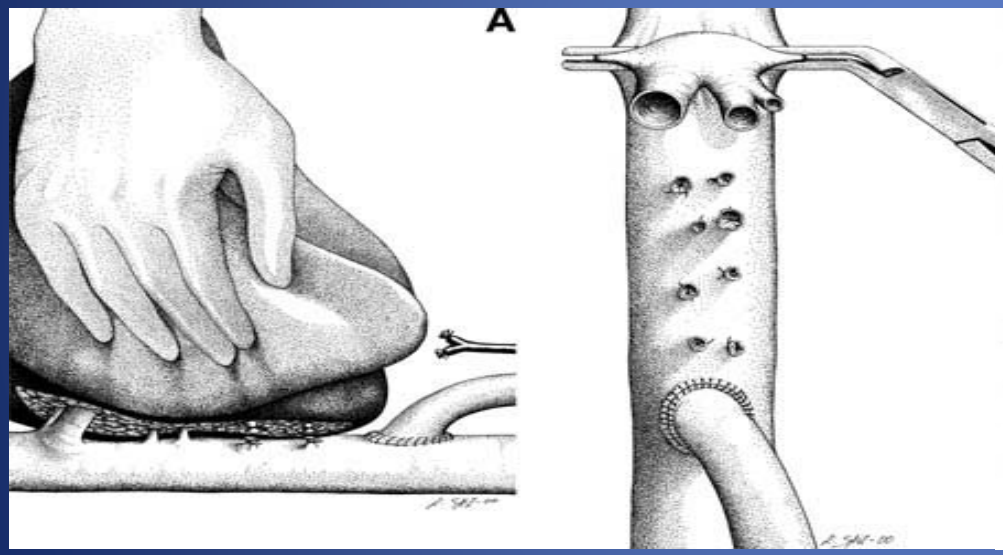
Veno-Venous Bypass

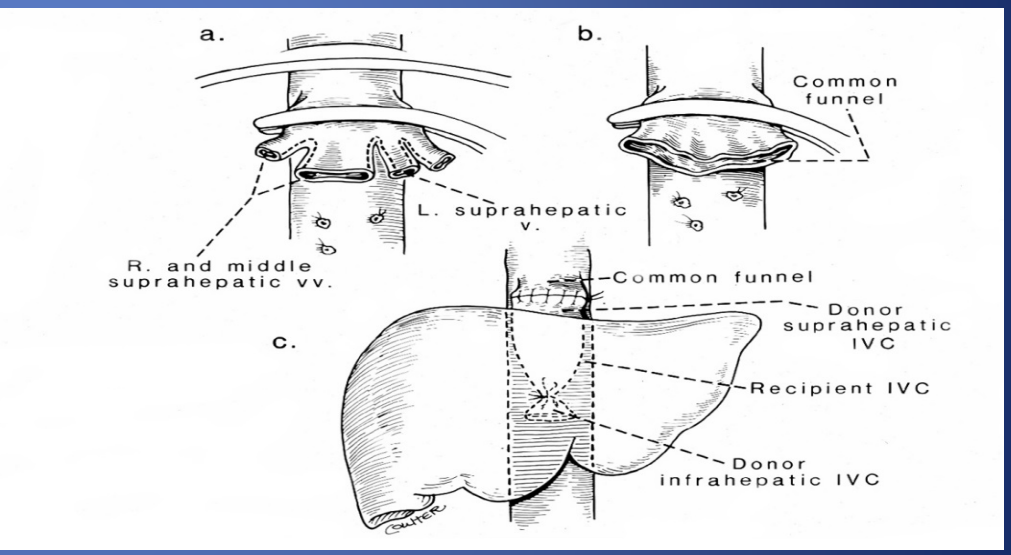


Inferior vena cava flow of up to 60% of cardiac output

Hepatic blood flow up to 2 liters per minute

Piggyback Technique

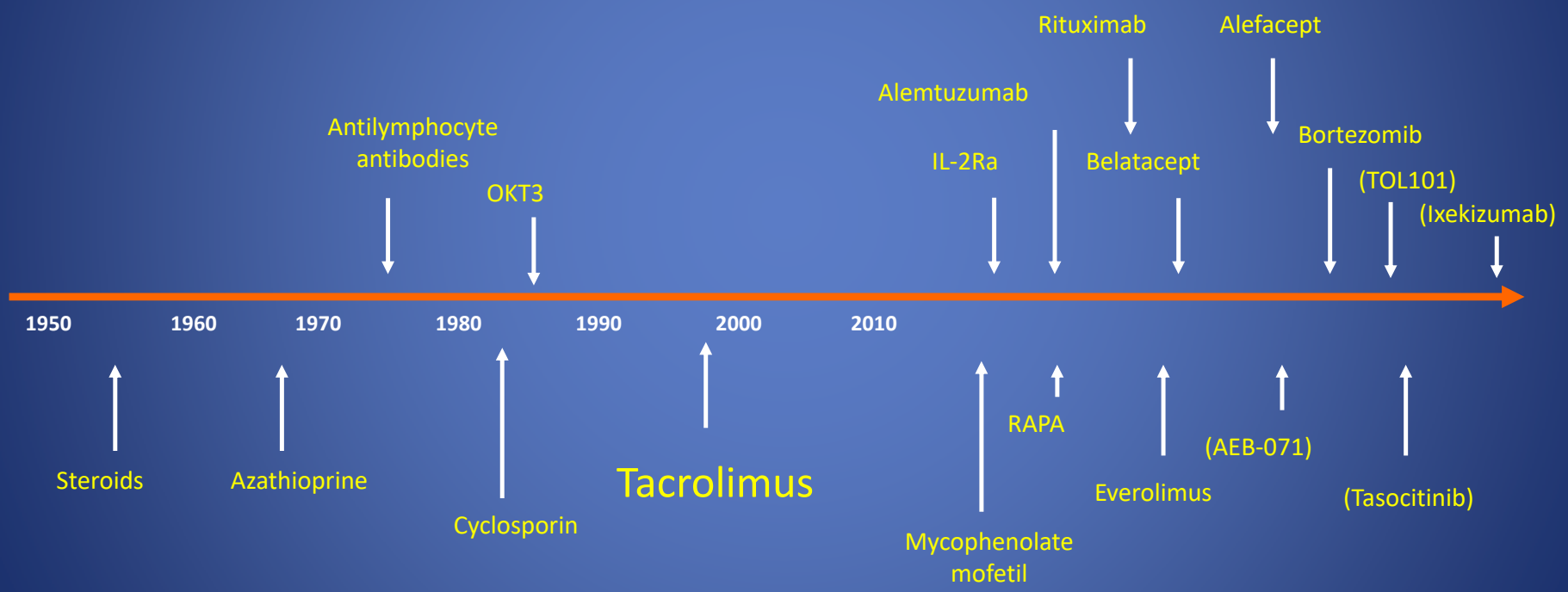




History of Transplantation: Second Quarter Century

- Expansion of scope with improved immunosuppression
  - Multivisceral, Kidney/Pancreas, LDLT, Uterus, Abdominal Wall
- Expansion of indications
  - Growing patient waiting lists, Organ shortage
  - Allocation debates
    - The Liver Wars
- More Media focus
- More regulatory focus
- More focus on finance and value propositions

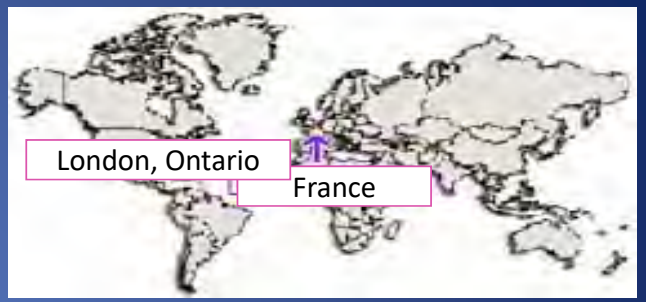
Immunosuppressive Drug Timeline

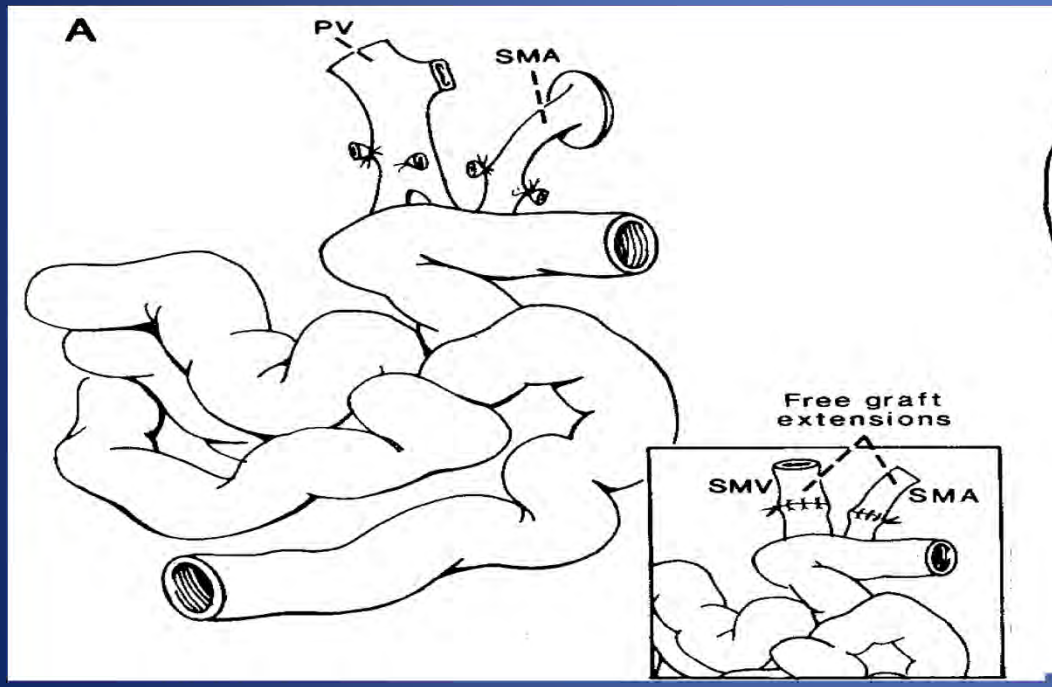


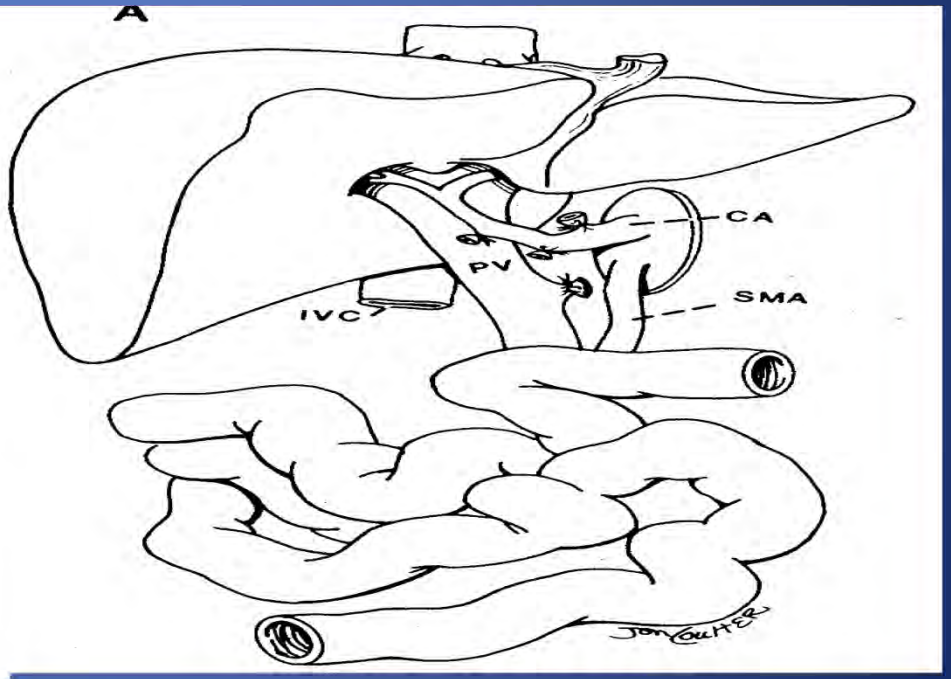
Preservation

- Better preservation solutions
  - UW solution - 1987
  - HTK - 2002
- Machine Preservation of Liver - still in development
  - Hypothermic
  - Normothermic blood

1988
First successful liver-small bowel
1989
First successful isolated small bowel







Gut Failure and Intestinal Transplantation

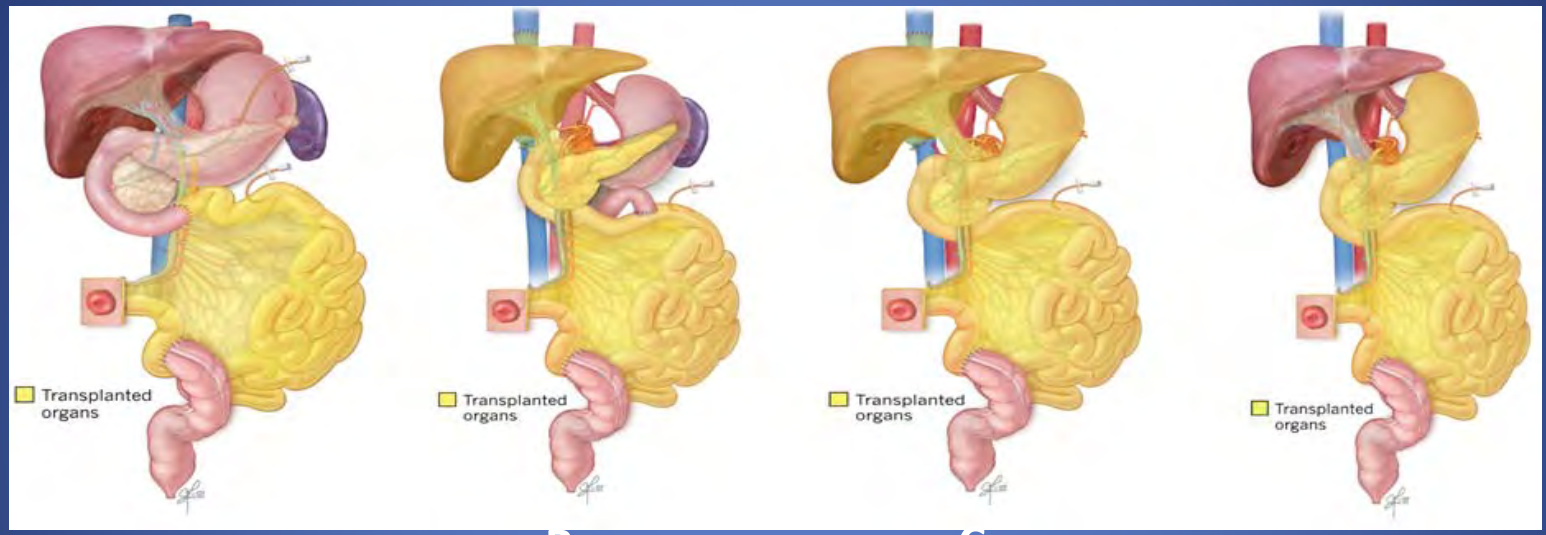
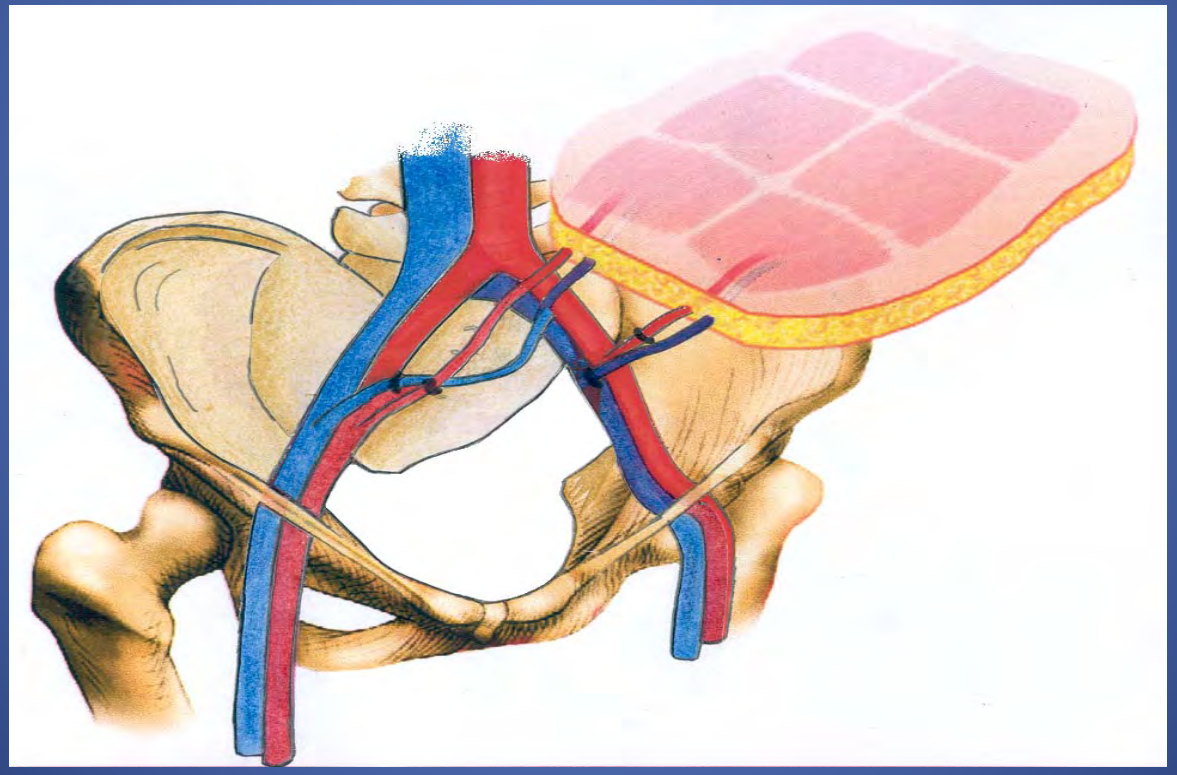


Figure 5:The different types of visceral transplantation; A) Isolated intestine, B) Combined liver-intestne, and multivisceral that includes the stomach, duodenum, pancreas, and intestine with (C) and without the (D) liver (Modified from Abu-Elmagd et al, Annals of Surgery 2015, 262 (4): 586-601, used with permission)

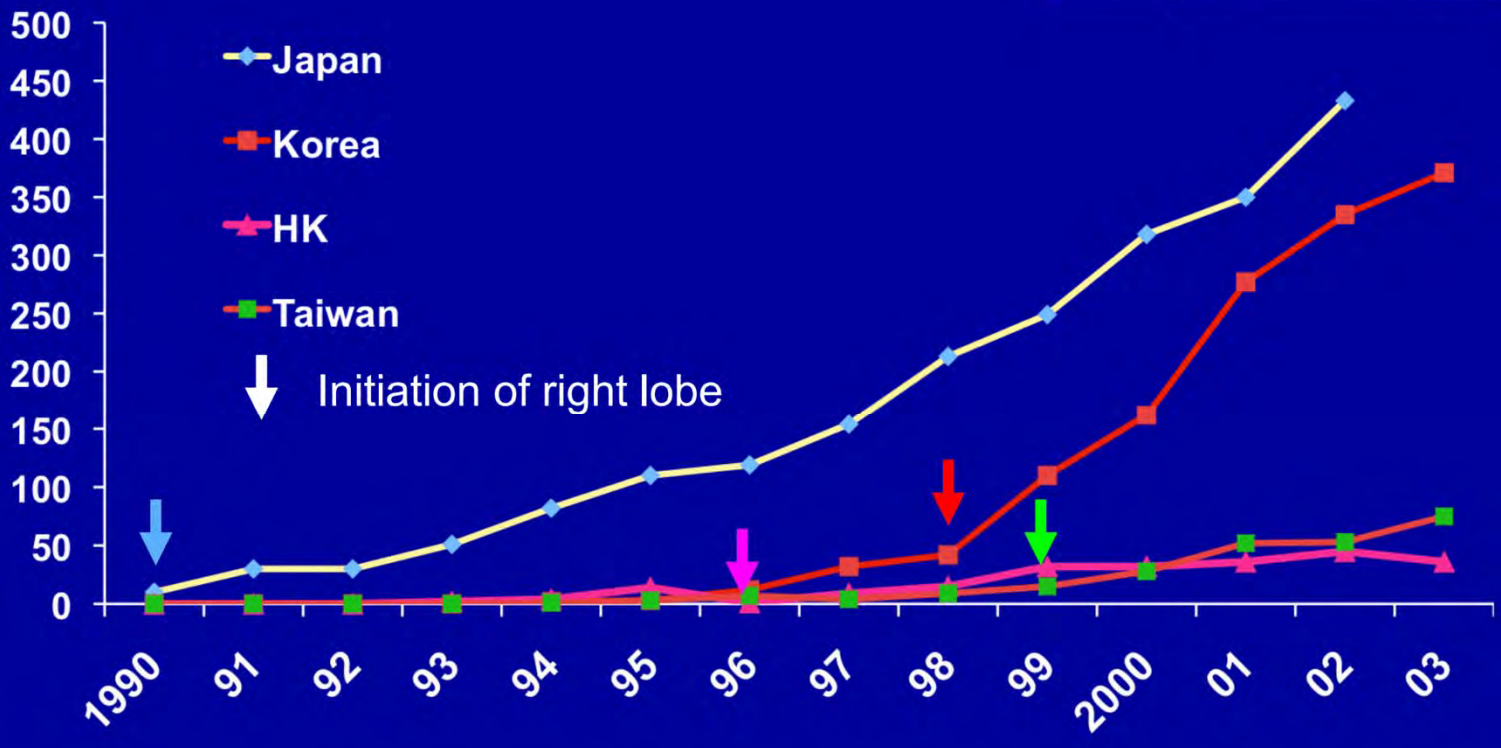
2002

First Successful Abdominal Wall Transplant by Tzakis



1990

Makucchi in Japan is first to perform adult-to-adult living donor liver transplant using left lobe



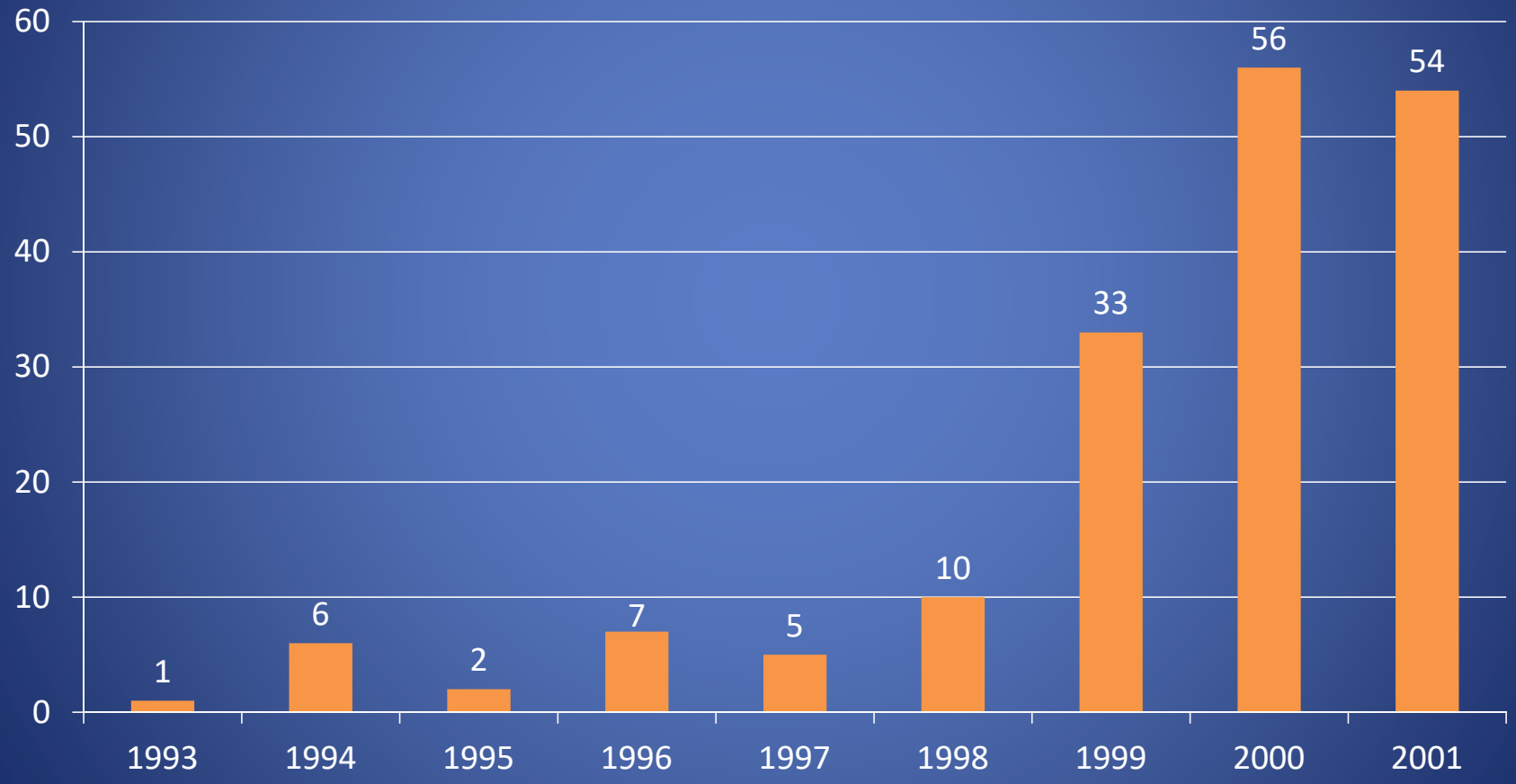
Conundrum of LDLT

- Living donor liver transplantation is a very valuable tool that can help mitigate the organ shortage
- But, there is a low but *finite* risk of donor morbidity and mortality

Context

- LDLT has an especially important role for many patients who have little or no chance of receiving an organ from a deceased donor.
- The last 2.5 decades have produced significant advancements – medically, surgically and technically.
- Originally, an adult donated a left lateral segment for a pediatric recipient; this evolved to full left lobes and then rapidly to full right lobe donation from adult to adult. This is an example of rapidly escalating risk.
- Despite that, the demand caused a rapid growth in the volume of procedures and centers

Living Donor Liver Transplant Volumes at Mount Sinai, NY: 1993-2001



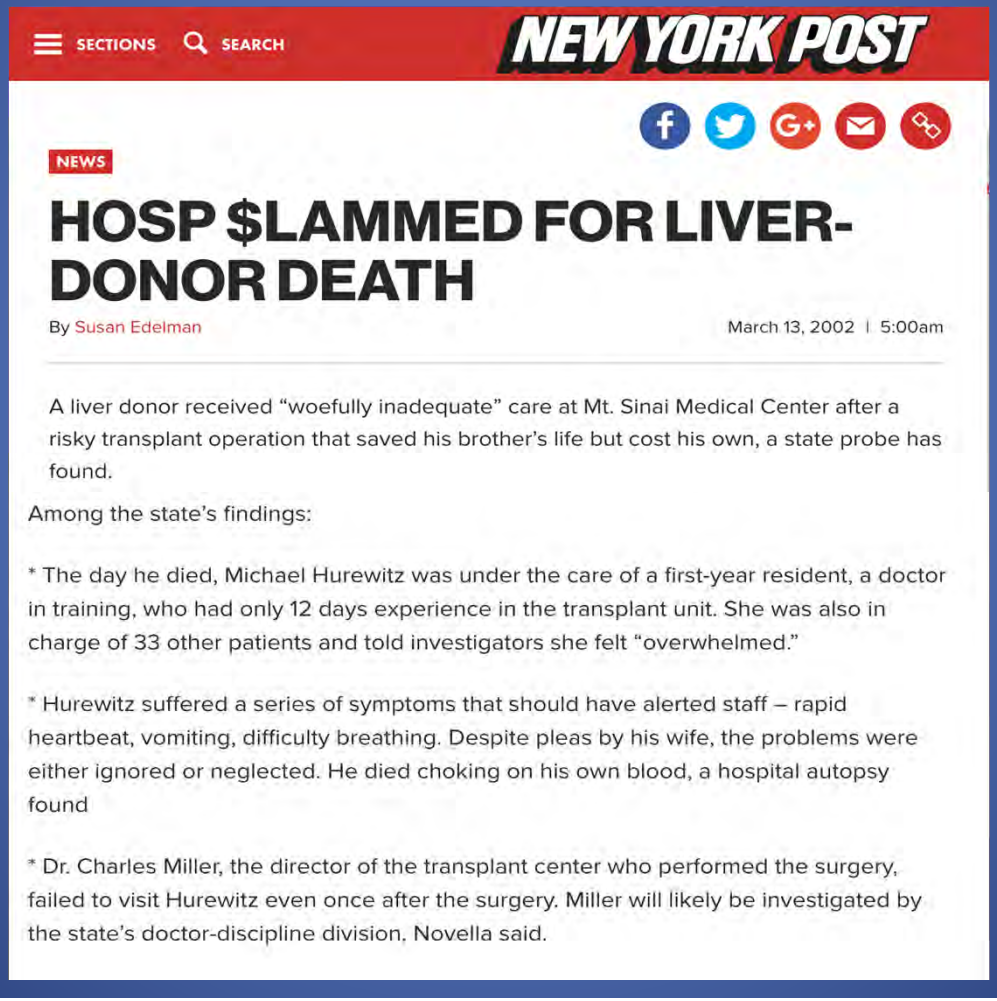
But Remember!

"Success is a lousy teacher. It seduces smart people into thinking they can't lose."

Bill Gates

And the Media is always watching and waiting!

The World as I Knew it Changed…



SECTIONS SEARCH NEW YORK POST

NEWS

HOSP $LAMMED FOR LIVER-DONOR DEATH

By Susan Edelman March 13, 2002 | 5:00am

A liver donor received "woefully inadequate" care at Mt. Sinai Medical Center after a risky transplant operation that saved his brother's life but cost his own, a state probe has found.

Among the state's findings:

* The day he died, Michael Hurewitz was under the care of a first-year resident, a doctor in training, who had only 12 days experience in the transplant unit. She was also in charge of 33 other patients and told investigators she felt "overwhelmed."

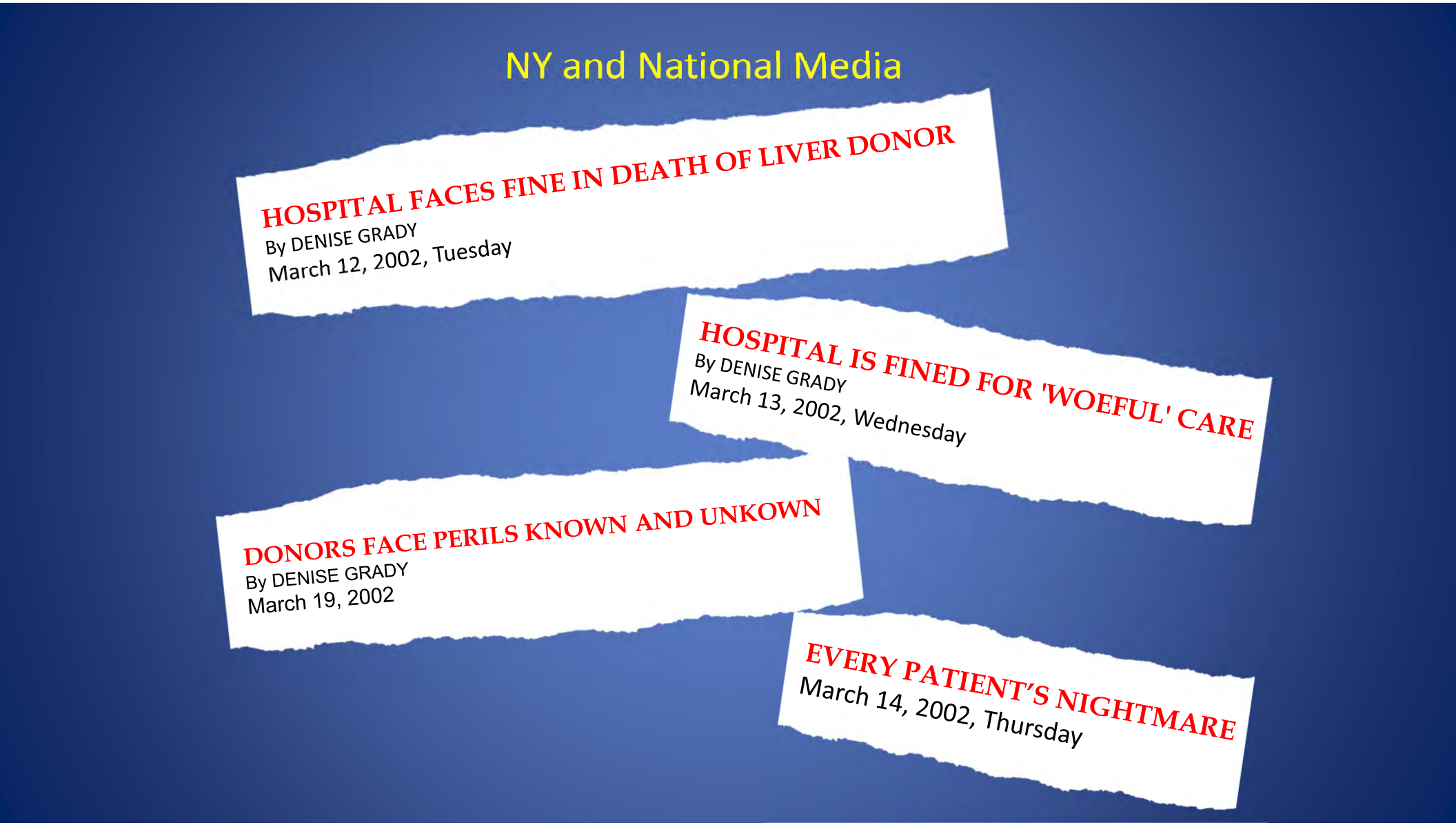
* Hurewitz suffered a series of symptoms that should have alerted staff – rapid heartbeat, vomiting, difficulty breathing. Despite pleas by his wife, the problems were either ignored or neglected. He died choking on his own blood, a hospital autopsy found

* Dr. Charles Miller, the director of the transplant center who performed the surgery, failed to visit Hurewitz even once after the surgery. Miller will likely be investigated by the state's doctor-discipline division, Novella said.

Example of Lack of Preparedness, Recognition and Response

- Michael Hurewitz dies suddenly on a Sunday, Jan. 13, 2002 at Mount Sinai Hospital 3 days after donating the right lobe to his liver to his brother who was a reporter for the Albany Times Union and formerly the NY Post
- The institution was suffering from a crisis of leadership, financial turmoil and loss of confidence at the State DOH
- There was little immediate institutional recognition of the threat the event posed and no plan to deal with the upcoming chain of events and ensuing crisis.
- Cause of death was uncertain and wide-spread media speculation preceded careful review and port-mortem

NY and National Media



The Stressful Investigations

- NY State Department of Health
  - The sentinel event
  - The entire program
  - My culpability
- UNOS
- ABS – my credentialing
- And of course, the media investigations!

And 5 months later…..

State Fines Mount Sinai $66,000 and Bans Live Liver Transplants Indefinitely

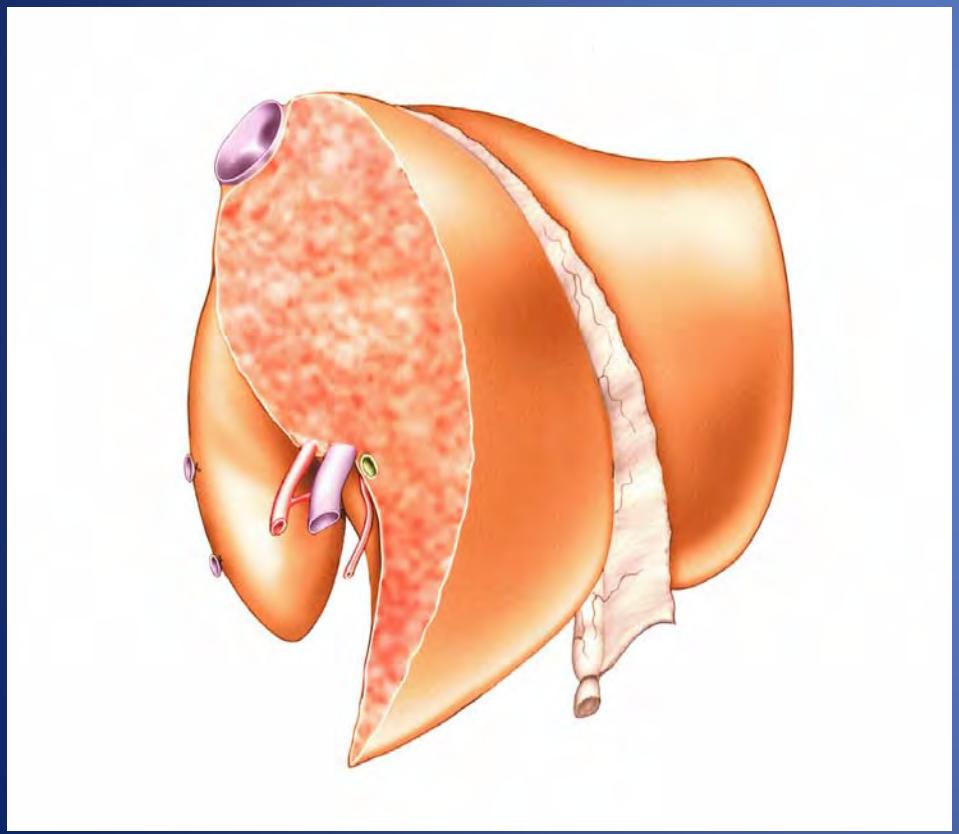
By LYDIA POLGREEN: August 31, 2002

Transplant Chief at Mt. Sinai Quits Post in Wake of Inquiry

By LYDIA POLGREEN: September 7, 2002

Tony Pinna – Modena, Italy

In Search of the Left Lobe

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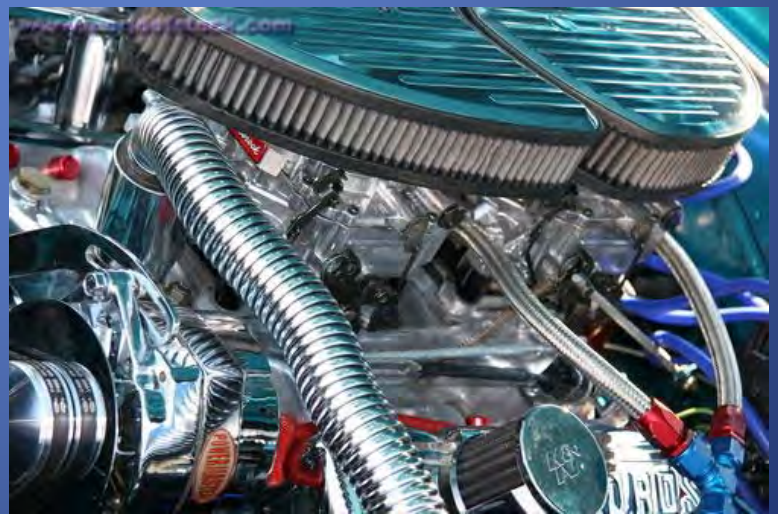
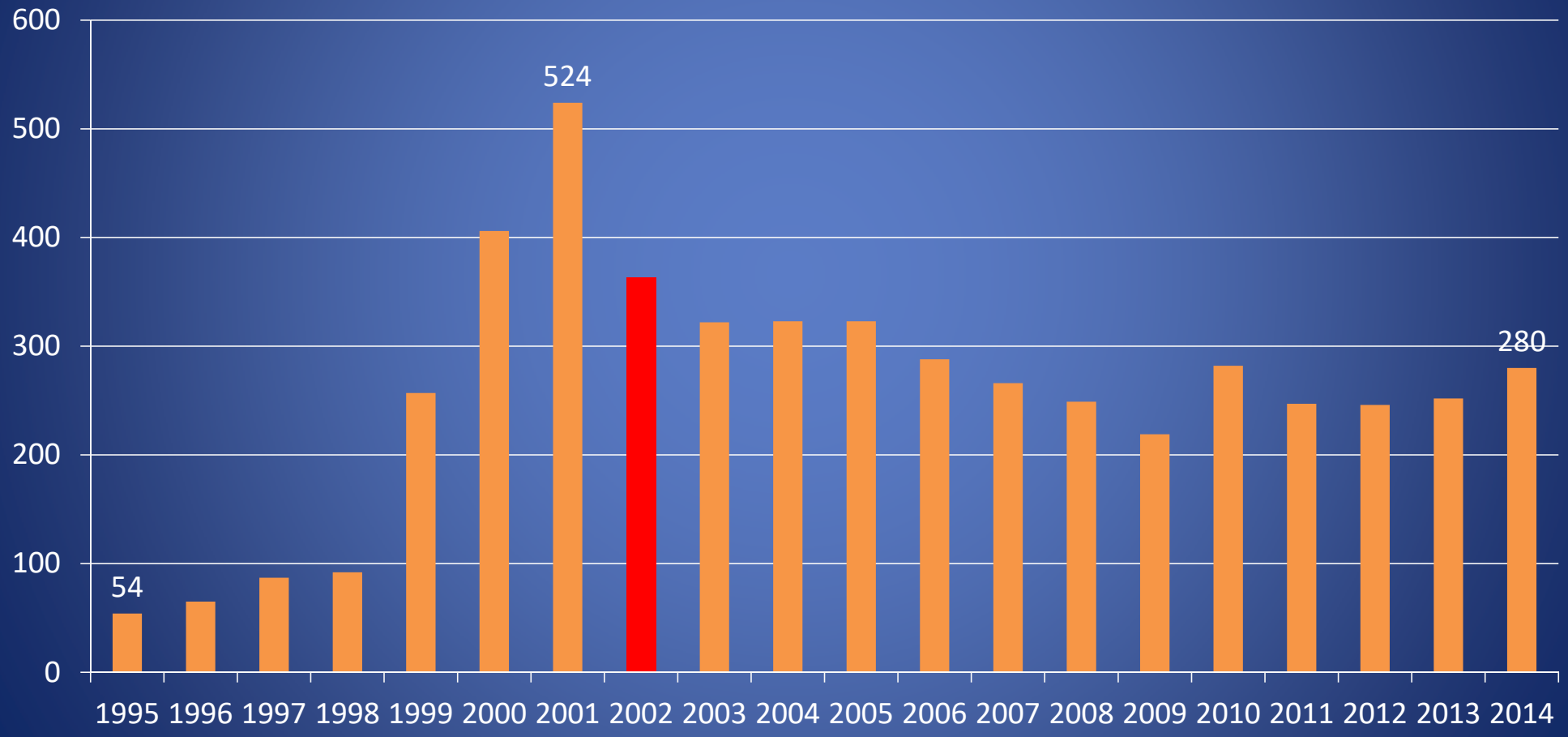



NetCarShow.com

Number of Living Donor Liver Transplants Nationally: 1995-2014



Re-starting: The “Muzzle” was taken off!

THE NEW YORK TIMES **NATIONAL** THURSDAY, MARCH 18, 2004 YT A25

After Unusual Fatality, Transplant Expert Revives Career

By DENISE GRADY

A surgeon involved in a liver transplant that ended in the donor's death two years ago says the death was because of a severe and unusual stomach infection and could probably not have been prevented.

The surgeon, Dr. Charles Miller, had not commented on the publicized death, which occurred after the operation at Mount Sinai Hospital in Manhattan. Dr. Miller spoke to a reporter last week about the case and his leaving Mount Sinai to become head of the liver transplant program at the Cleveland Clinic next month.

The patient, Michael Hurewitz, died on Jan. 13, 2002, a few days after donating part of his liver for a transplant for his brother. The cause of death was found to be an unusual bacterial infection that caused gas gangrene in his stomach. Dr. Miller said no patient in the transplant unit had ever had such an infection. He added that the early symptoms were mild and that by the time it became clear that Mr. Hurewitz was gravely ill, it was too late to save him.

"No one I know in medicine could have had the prescience to diagnose or treat that infection," Dr. Miller said in an interview.

Dr. Miller said that he and his colleagues had submitted a detailed report on Mr. Hurewitz's autopsy to a medical journal, but that it had not yet been accepted for publication.

The report identifies the bacteria as Clostridium perfringens, and says genetic tests found a particularly deadly bacterial toxin, epsilon toxin, that most likely came from shellfish. That would suggest, Dr. Miller says in the report, that the source of the infection was a lobster dinner that Mr. Hurewitz's family brought in from a restaurant.

Roger Mastroianni for The New York Times

Dr. Charles Miller in Cleveland, where he will direct liver transplants.

Dr. Miller acknowledged that others might argue with that. Indeed, Dr. Michael Baden, the former New York City medical examiner hired by Mr. Hurewitz's wife, Victoria, to investigate the case, disagreed.

Dr. Baden said his examination of Mr. Hurewitz's tissue samples indicated that the infection started about the time of the surgery, not days later, when Mr. Hurewitz ate the lobster. Dr. Baden concurred that regardless of where the bacteria came from, the stomach infection killed Mr. Hurewitz.

The circumstances provoked a state inquiry that led to a scathing report, accusing Mount Sinai of providing "woeful" postoperative care by poorly supervised medical residents who were in charge of too many patients. The state fined the hospital, found other deficiencies in its transplant unit and halted its program for living donor transplants to adults for two years.

The death also led New York to become the first state to develop guidelines for treating live organ donors. Ms. Hurewitz became an activist, urging stricter controls on live donor programs. She also sued Mount Sinai and settled recently for an undisclosed sum.

In September 2002, Dr. Miller stepped down as head of the Mount Sinai liver transplant program. Almost instantly, it seemed, he went from the top of his profession to being "almost nothing," he said, as if his entire career had been erased.

He went on sabbatical, traveling in Japan and spending nine months performing research and surgery at a hospital in Modena, Italy, at the invitation of a friend and colleague who knew that a fellow surgeon needed to be in the operating room. Dr. Miller said he spent much of his time working on techniques to make live donor operations safer.

"Italy was a lifeline," Dr. Miller said.

Back in New York, he felt increasingly marginalized at Mount Sinai and looked at other positions, he said. The search was "a torture." He began to wonder whether he would work again in the United States. Friends suggested retiring, but that appalled him, he said, because he is only 51. "I have a skill," he said. "I have something to contribute."

The Cleveland Clinic heard he was available. Dr. Kenneth Ouriel, chairman of its surgery division, said the hospital was eager to hire Dr. Miller because it hoped to expand its live donor program for livers.

"I knew he was really a leader in living related transplants," Dr. Ouriel said.

Before making an offer, Dr. Ouriel checked Dr. Miller's former colleagues and residents who had worked for him.

"It was almost the same thing from every individual," Dr. Ouriel said. "He is an excellent surgeon whose whole life is transplants, especially living related donors, and an unfortunate situation occurred that was essentially on the verge of costing him his career."

When the offer arrived, Dr. Miller said, "I broke down and cried."

Liver transplant expert sees Clinic as fresh start

SARAH TREFFINGER
Plain Dealer Reporter

There's a new beginning in Cleveland for a pioneering liver transplant surgeon who left his professional home of nearly 30 years after the death of a liver donor in 2002.

Dr. Charles Miller will head the Cleveland Clinic's liver transplant program.

Miller, 51, formerly of The Recanati/Miller Transplantation Institute at Mount Sinai Hospital in New York, performed that state's first liver transplant in 1988. Later, he performed the state's first living-donor liver transplants.

Miller

Now, he said, his goal is to build "the leading liver transplant program in the world" here.

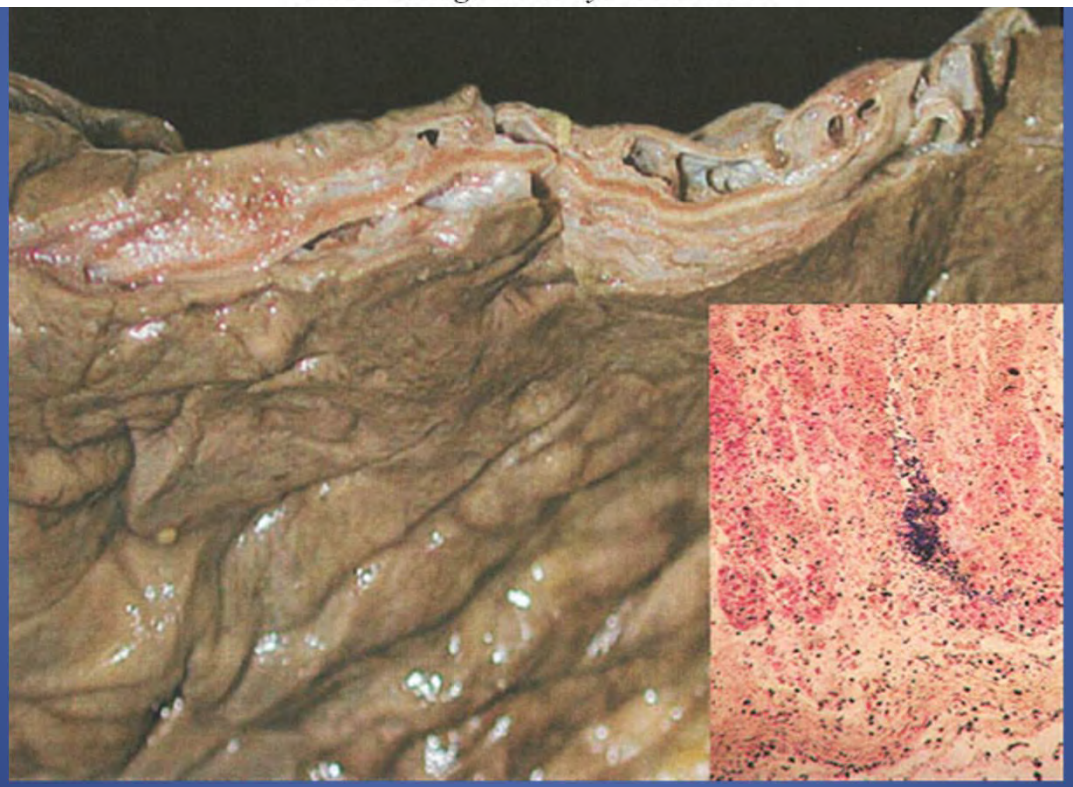
Dr. Kenneth Ouriel, chairman of the Division of Surgery, said the Clinic recruited Miller because "he's the best."

SEE CLINIC | A15

SHORT REPORTS

Fulminant and Fatal Gas Gangrene of the Stomach in a Healthy Live Liver Donor

Charles Miller,[1] Sander Florman,[1] Leona Kim-Schluger,[1] Patrick Lento,[2] Julia De La Garza,[2] Josephine Wu,[3] Boxun Xie,[3] Wandi Zhang,[3] Edward Bottone,[4] David Zhang,[3] and Myron Schwartz[1]



Liver Transplantation, Vol 10, No 10 (October), 2004: pp 1315–1319

More Regulatory Scrutiny
SRTR Graft and Patient Survival

Figure C4L. Adult (18+) 1-year living donor graft failure HR program comparison

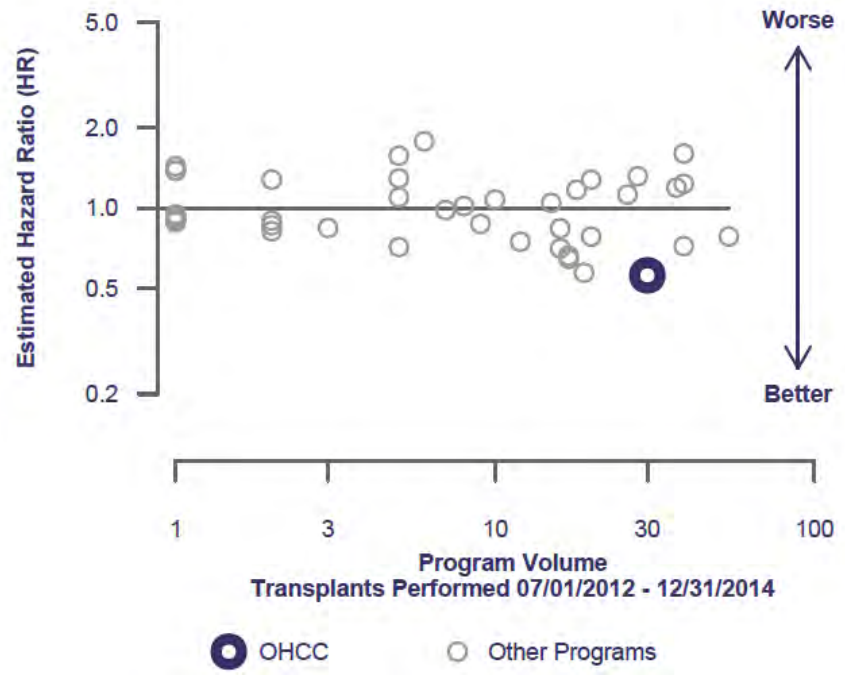
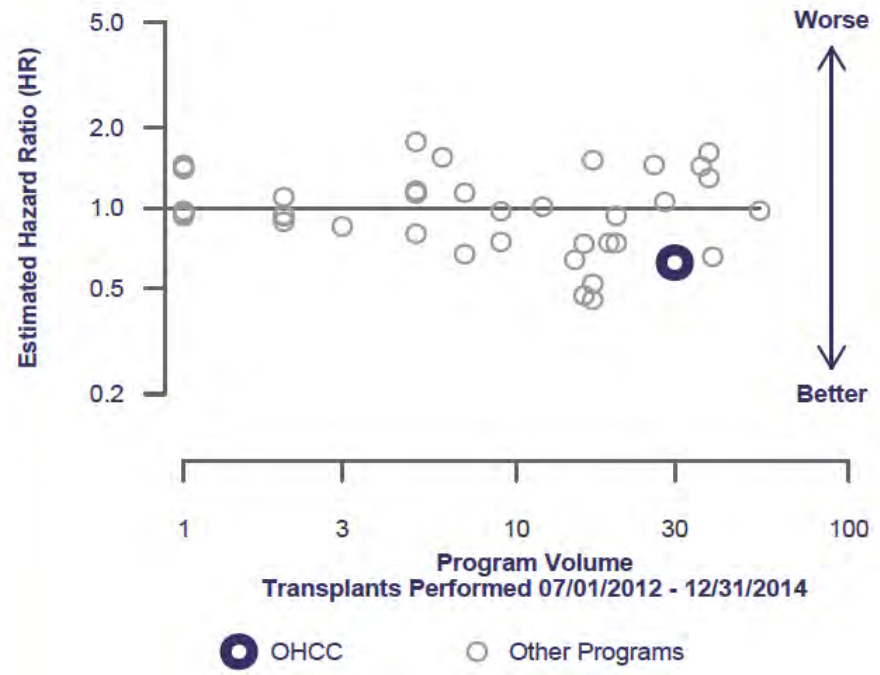
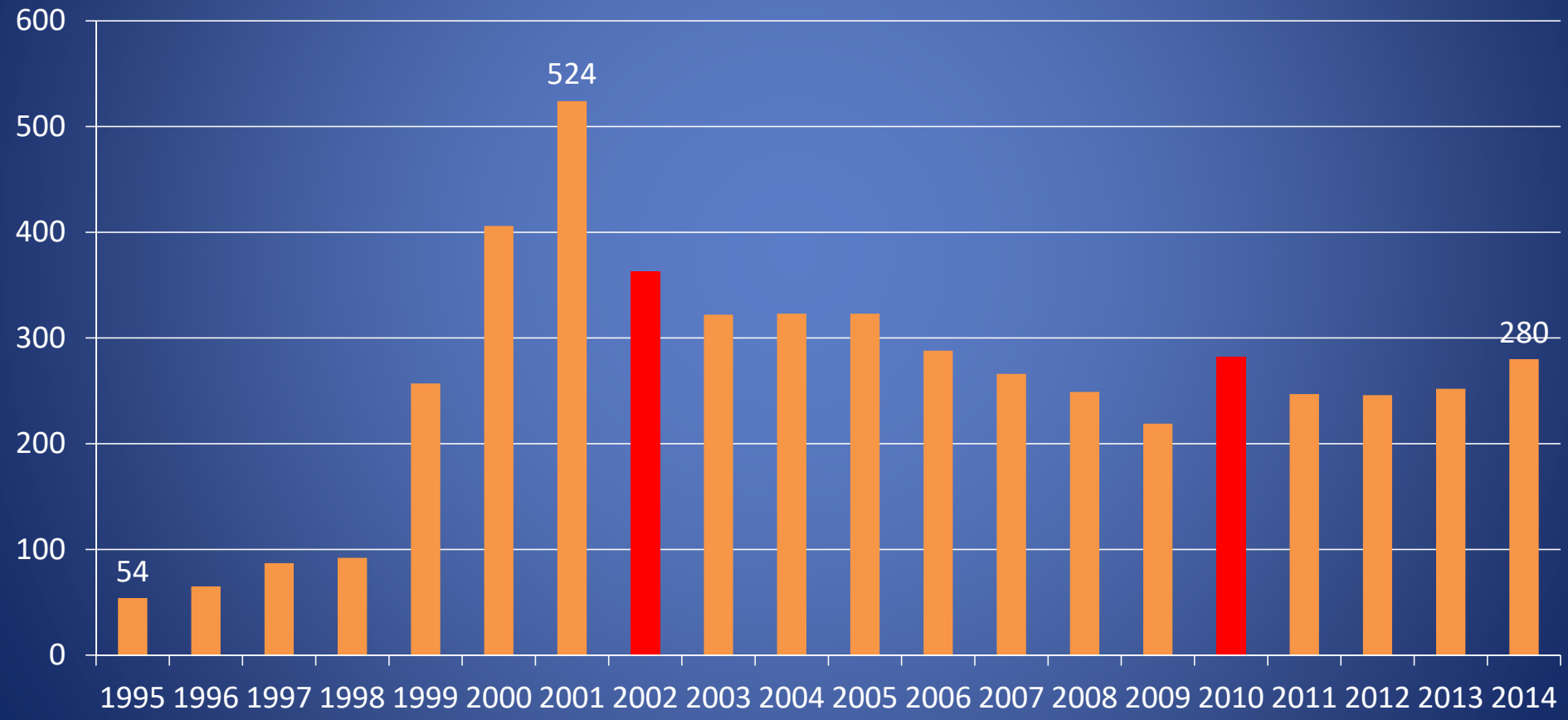


Figure C16L. Adult (18+) 1-year patient death HR program comparison (living donor grafts)



Living Donor Liver Transplants Nationally: 1995-2014



ILTS presentation in Valencia: 2011

Preparing for the Inevitable: The Death of a Living Liver Donor

Charles Miller,[1] **Martin L. Smith,**[2] **Masato Fujiki,**[1] **Teresa Diago Uso,**[1] **and Cristiano Quintini**[1]
[1]*Liver Transplant Program, Department of General Surgery, and* [2]*Department of Bioethics, Cleveland Clinic, Cleveland, OH*

Living donor liver transplantation (LDLT) is associated with a low but finite and well-documented risk of donor morbidity and mortality, so organizations and individuals involved in this activity must accept the fact that a donor death is a question of when and not if. Studies in the field of crisis management show that preparing for the inevitable not only is critical in preparing institutions to better respond to catastrophic events but more importantly plays a crucial role in preventing them. This article describes the background of crisis management with specific reference to the death of a living liver donor and proposes a general framework that can be adopted by LDLT programs around the world. ***Liver Transpl 19:656–660, 2013.*** **© 2013 AASLD.**

Received December 11, 2012; accepted February 25, 2013.

Living donor liver transplantation (LDLT) has evolved into a valuable tool for alleviating the organ shortage. It represents an important option for many patients who have little or no chance of receiving an organ from a deceased donor. However, LDLT is associated with a low but finite and well-documented risk of donor morbidity and mortality. We assert that a donor death is an inevitable event for LDLT programs. Deeming it inevitable implies that a donor death must be considered a question of when and not if. LDLT programs must have specific strategies in place to ensure that such a catastrophic event is carefully anticipated and managed properly in an ethically supportable way. The interests of multiple stakeholders, at times competing, must be given focused consideration and balanced appropriately.

It is important to note that the deaths of living liver

ALL-HAZARDS APPROACH TO DISASTER PLANNING

Best practices for disaster planning dictate that an all-hazards approach provides the strongest basis for a successful response to critical events.[1] All-hazards planning is based on the concept that most disaster response functions are common to all disaster types, and unified planning provides the strongest foundation for an effective response.[2]

Disaster recovery and crisis management are 2 critical organizational functions. An airline company, a nuclear power plant, and a hospital with an active LDLT program are all organizations engaged in risky, high-profile activities. For these organizations, a failure to engage in comprehensive crisis planning can result in a loss of human life and serious harm to society and

Definition

inevitable

– *adj* **1.** unavoidable

2. sure to happen; certain

– *n (often preceded by the)* something that is unavoidable

"If we truly believe that living donor death should be a zero event, we should not be doing living donor transplants, because it will never be a zero event,"

– Mike Abecassis, 2010 AASLD

OK then…

- If it is inevitable and we still believe the service is essential, how do we best prepare for the day when a donor dies?
- Can thoughtful preparation help mitigate against the potential negative impacts (reputational , operational, emotional) to the field, the institution, the program, other patients and the surgeon?

- The answer is *YES*.
- *The goal is to emerge from a challenging situation stronger than before.*

Crisis Preparation

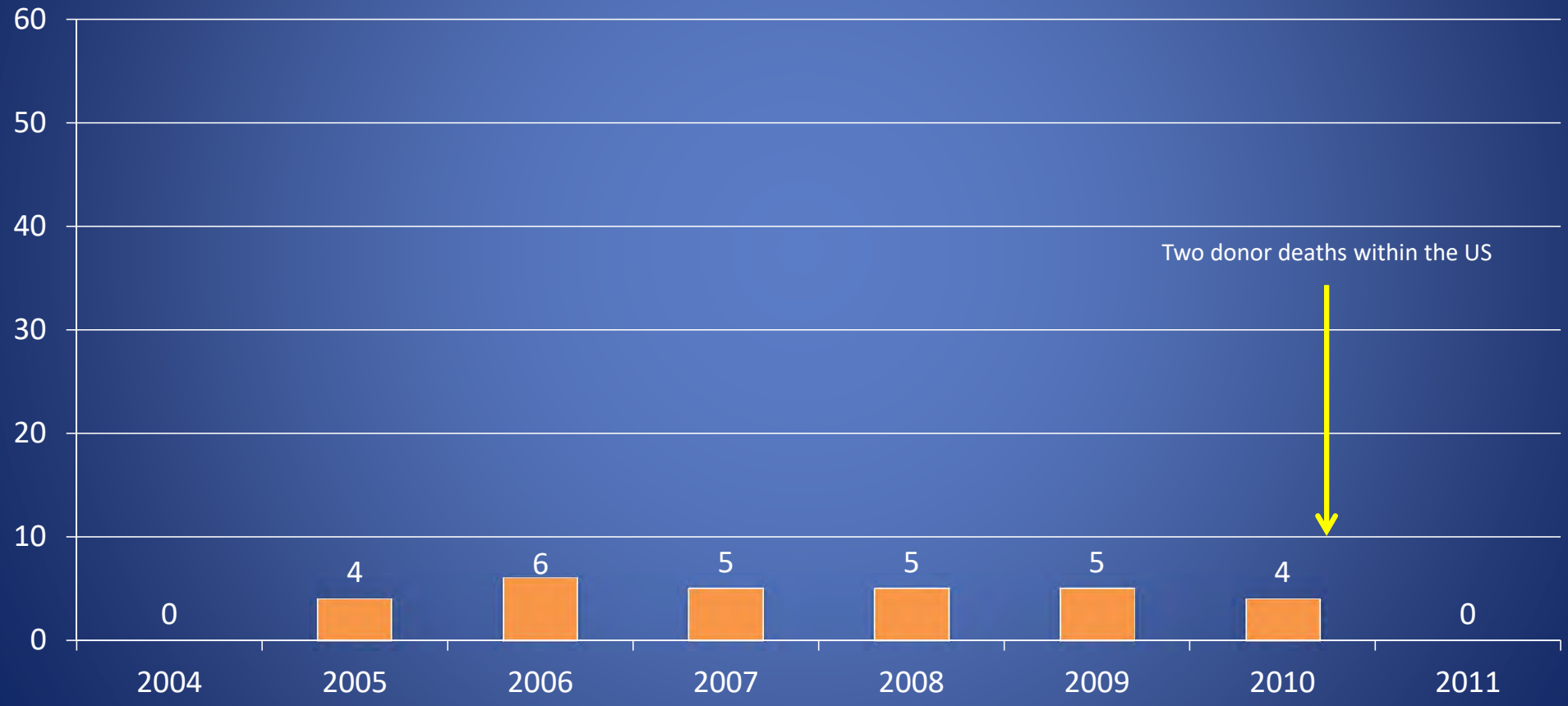
- How and why do other professions and institutions prepare?
  - Disasters can occur anywhere and at any time.
  - The saying in the crisis field is: *"when, not if."*
  - Minimizes the potential for a disaster occurring in the first place
    - Better sense of security
  - Minimizing impromptu decision-making during a crisis
  - Best ensures organizational stability and an orderly recovery
  - Ensuring the safety of customers and personnel
  - Minimizing potential economic loss, legal liabilities and disruption
  - Best ensures organizational stability and an orderly recovery
  - But is labor-intensive and tedious process.

Communication

1. Single communication plan in event of a crisis:
   a. Internal
      Institution wide
   b. External
      Regulatory
      Media relations team – maintain control of the message; communicate only one
      Professional Societies
2. Designate an internal event and analysis core team
      Root cause analysis
      Corrective action plan (depending on RCA)
      Offer grief counseling to team and family

- 3. For some reason deaths of living liver donors generate much more media attention than deaths of living kidney donors
  - Livers area lightening rod: Be prepared!

Annual Volume of Living Donors Liver Transplants: Cleveland Clinic



From Theory to Reality:

Restarting and re-invigorating our sleepy little LDLT program

- Team Retreat
  - Survey of stakeholders – should we do this?
  - Discussion of need for our own crisis plan and team
- Two working groups
  - Clinical Protocol Task Force
    - Focus on left lobe priority
  - Crisis Management Team
    - Global Institutional acceptance and buy-in

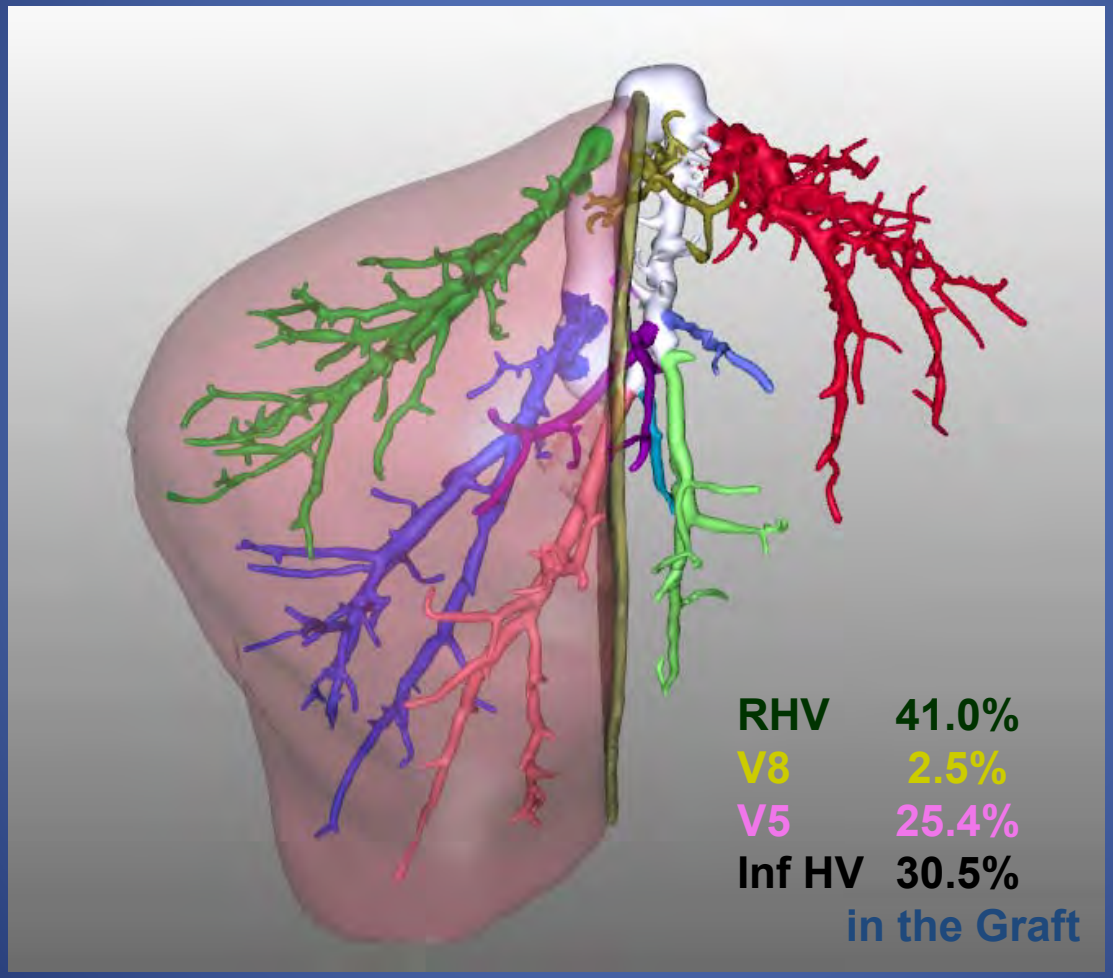
Crisis Management Team

- Assemble Your Core Team
  - Executive leadership, media, legal, ombudsman, risk mangement, Ethics
- Prepare Written Crisis Plan
- Establish Internal Notification Procedures
- Establish external contacts (regulators, media, societies)
- Train for Media Interviews
- Test and practice the Plan

Results – Process Improvement

- Better team work and environment
- Better case planning
- Pre and post-transplant notification to crisis team
- Great enthusiasm for program inside and outside of main campus
- COE approval from Optum - 2013

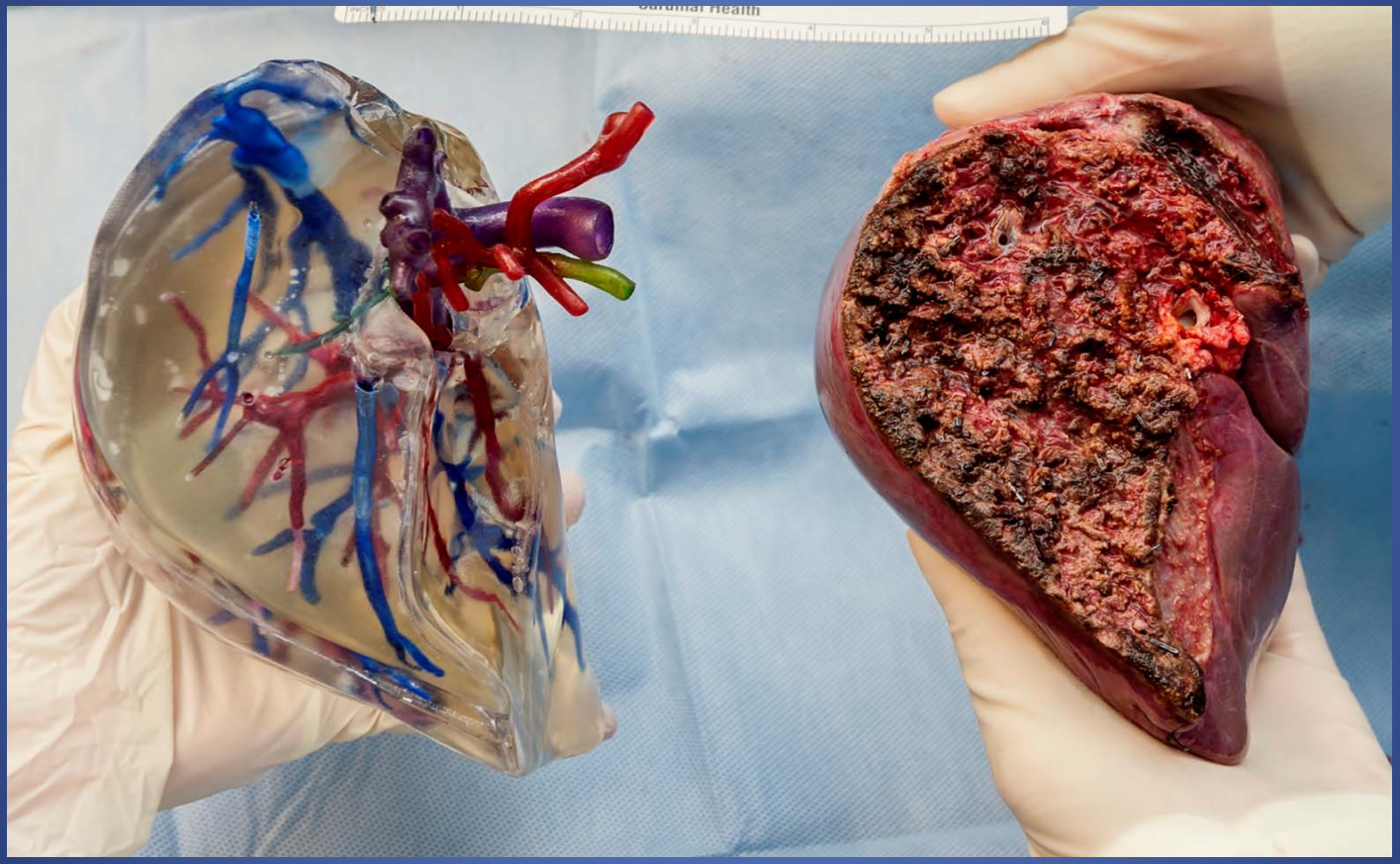
Better case planning



Need V5 reconstruction

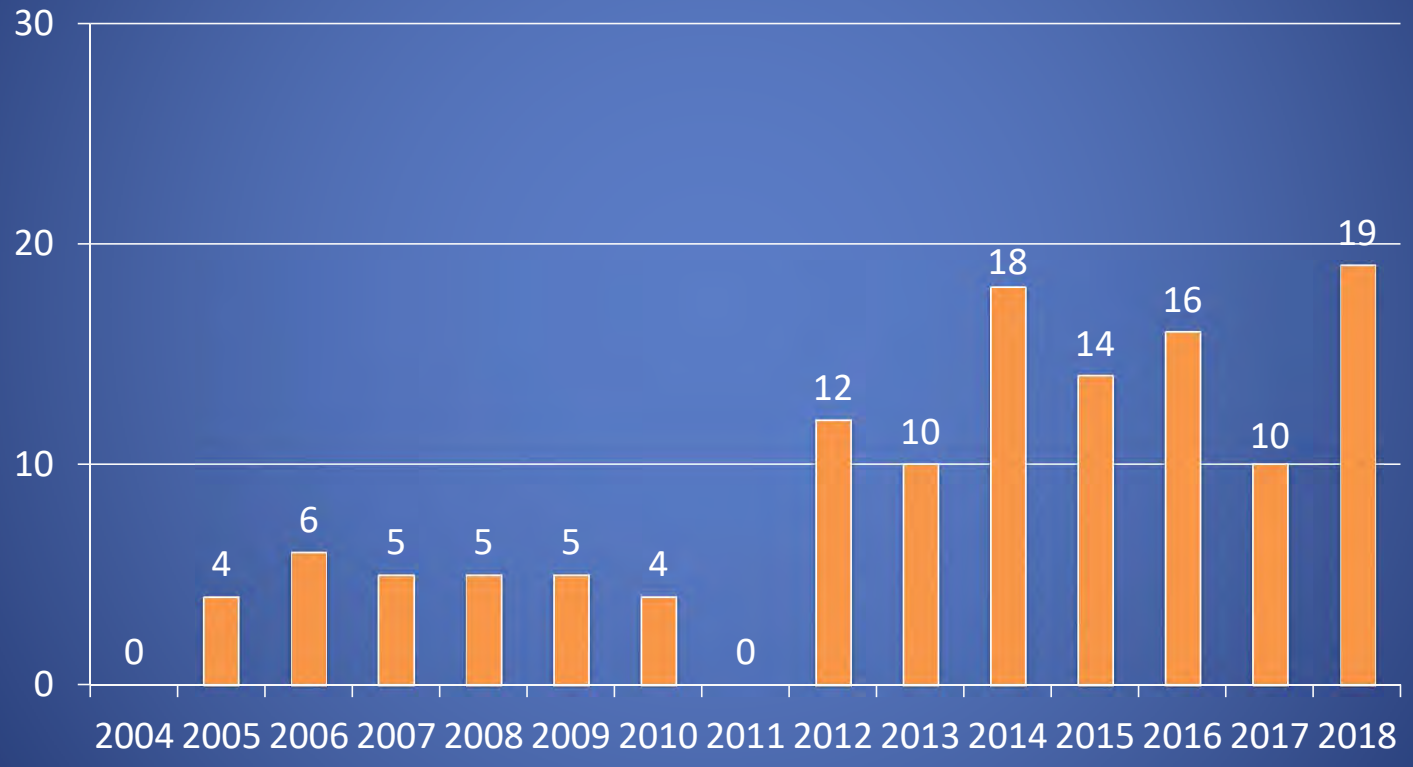
3D Print of Right Liver Lobe of Live Donor

Native Right Liver Lobe of Live Donor



The donor is a 42-year-old brother who underwent right lobe hepatectomy
The recipient is 53-year-old man with HCV cirrhosis

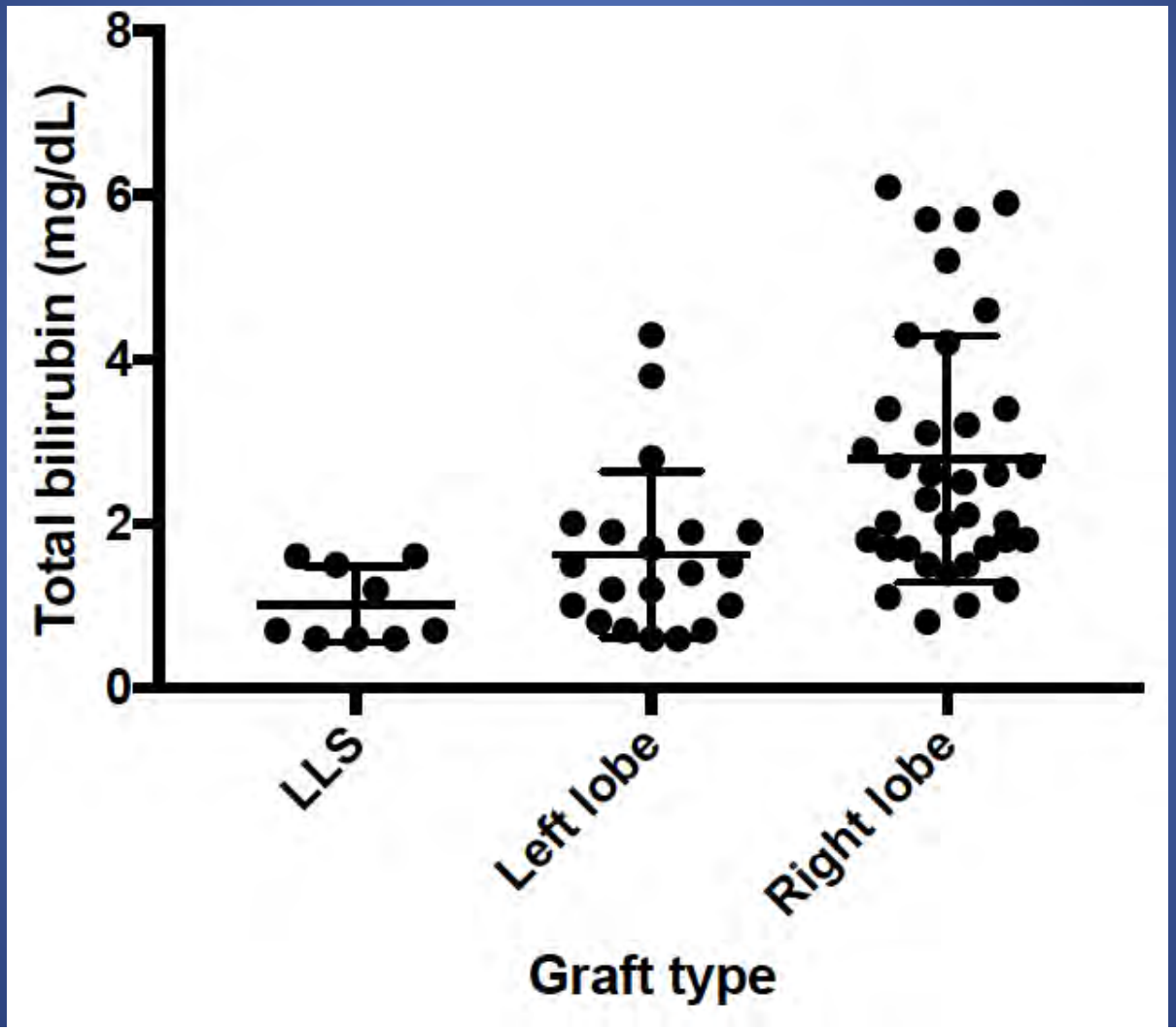
Annual Volume of Living Donors Liver Transplants: Cleveland Clinic

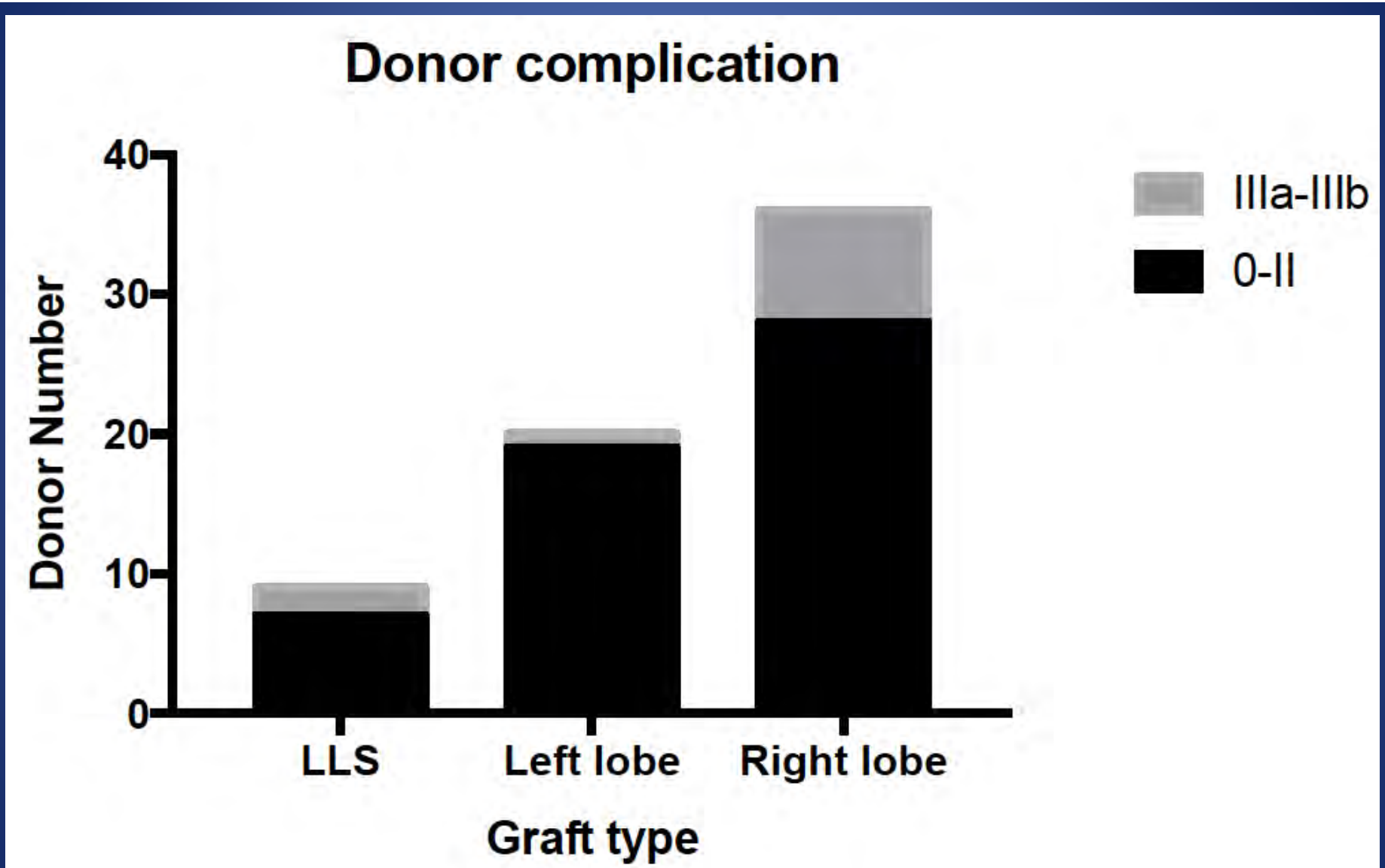


Addition 4 cases at CCAD

Revisiting the Left Lobe
Does Size Really Matter?

Peak donor bilirubin

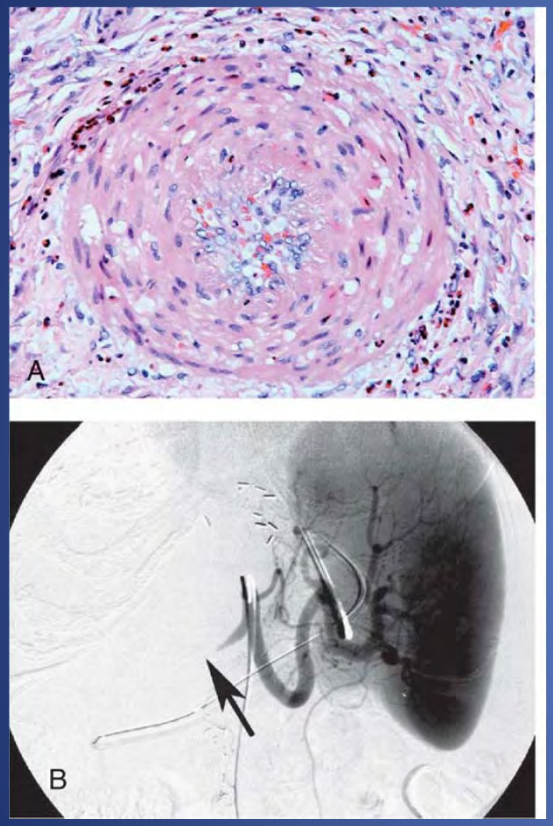



Donor complication
Donor Number
40
30
20
10
0
IIIa-IIIb
0-II
LLS
Left lobe
Right lobe
Graft type

What about the recipient?
Clinical Presentation of Small-for-Size Syndrome

- Jaundice and coagulopathy
- Intractable ascites
- Encephalopathy
- Renal failure
- Sepsis
- No obvious surgical complication

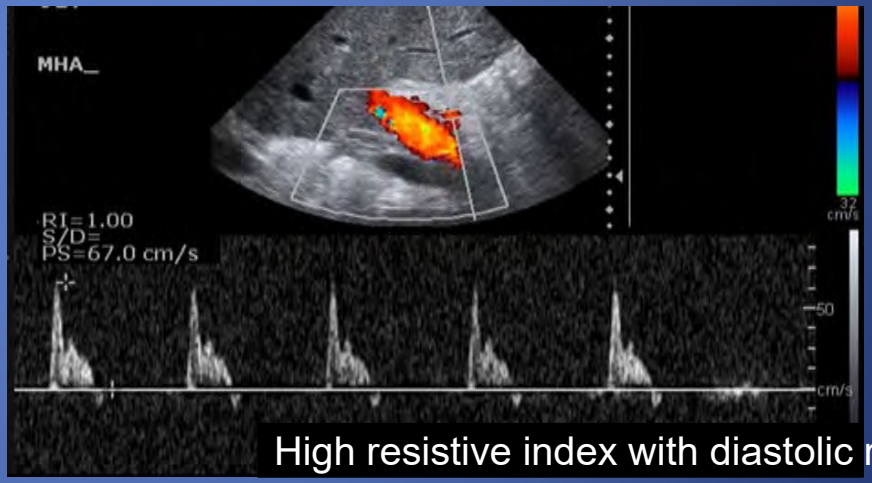
Pathophysiology of Small-for-Size Syndrome



Excessive portal flow to small graft

↓

Hepatic arterial spasm via hepatic arterial buffer response



High resistive index with diastolic reversal

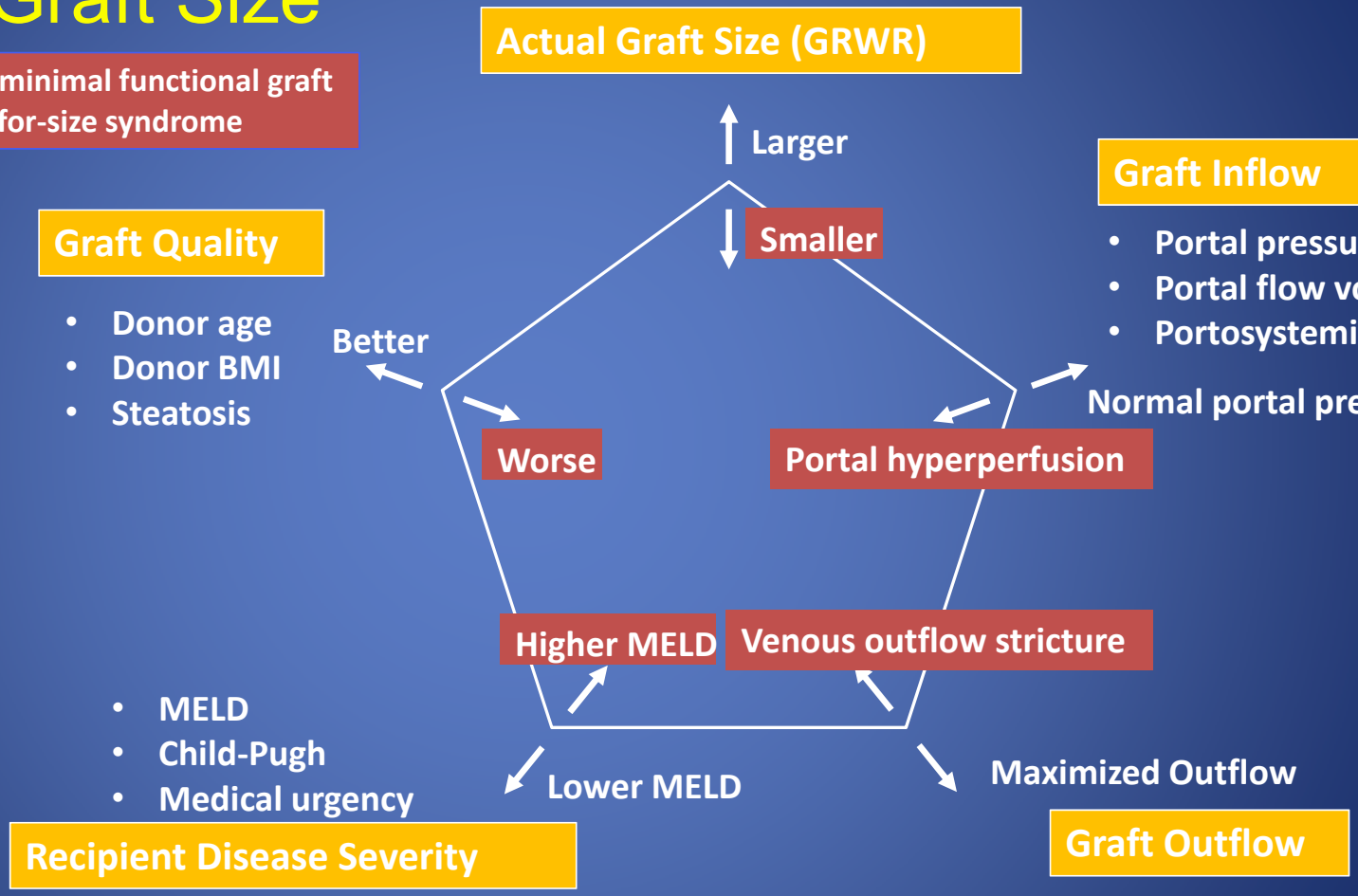
Demetris et al, Am J Surg Pathol 2006

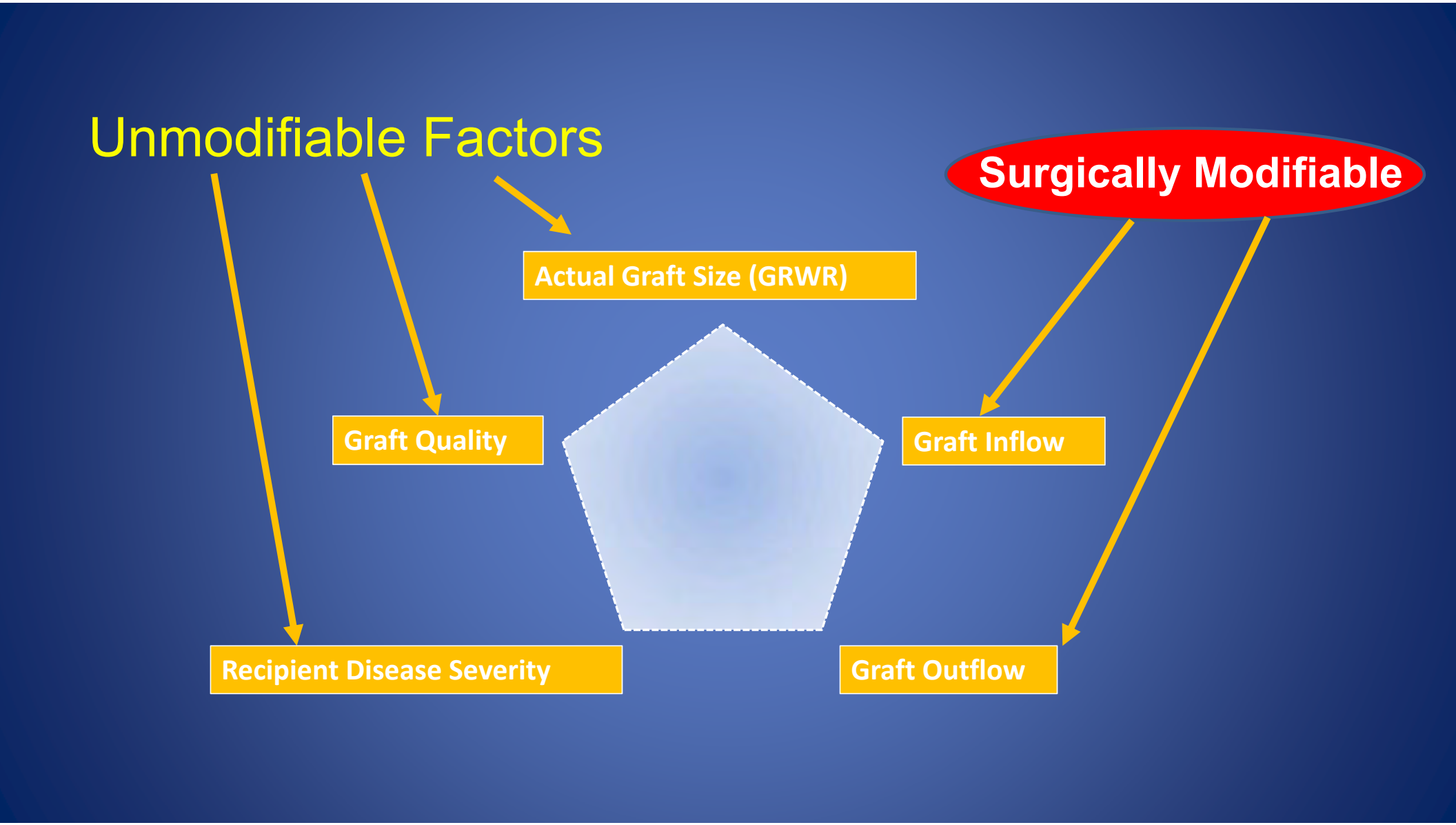
Known Risk Factors for Small-for-Size Syndrome

- Small actual graft size (GRWR < 0.8%, %SLV < 40%)
- Suboptimal graft quality (Donor age > 40 years, donor BMI > 30, steatosis)
- Recipient disease severity (MELD > 20, ICU stay, dialysis, ventilator)
- Excessive portal flow (PVP > 15 mmHg, TIPS, large spleen)
- Suboptimal venous outflow of the new graft

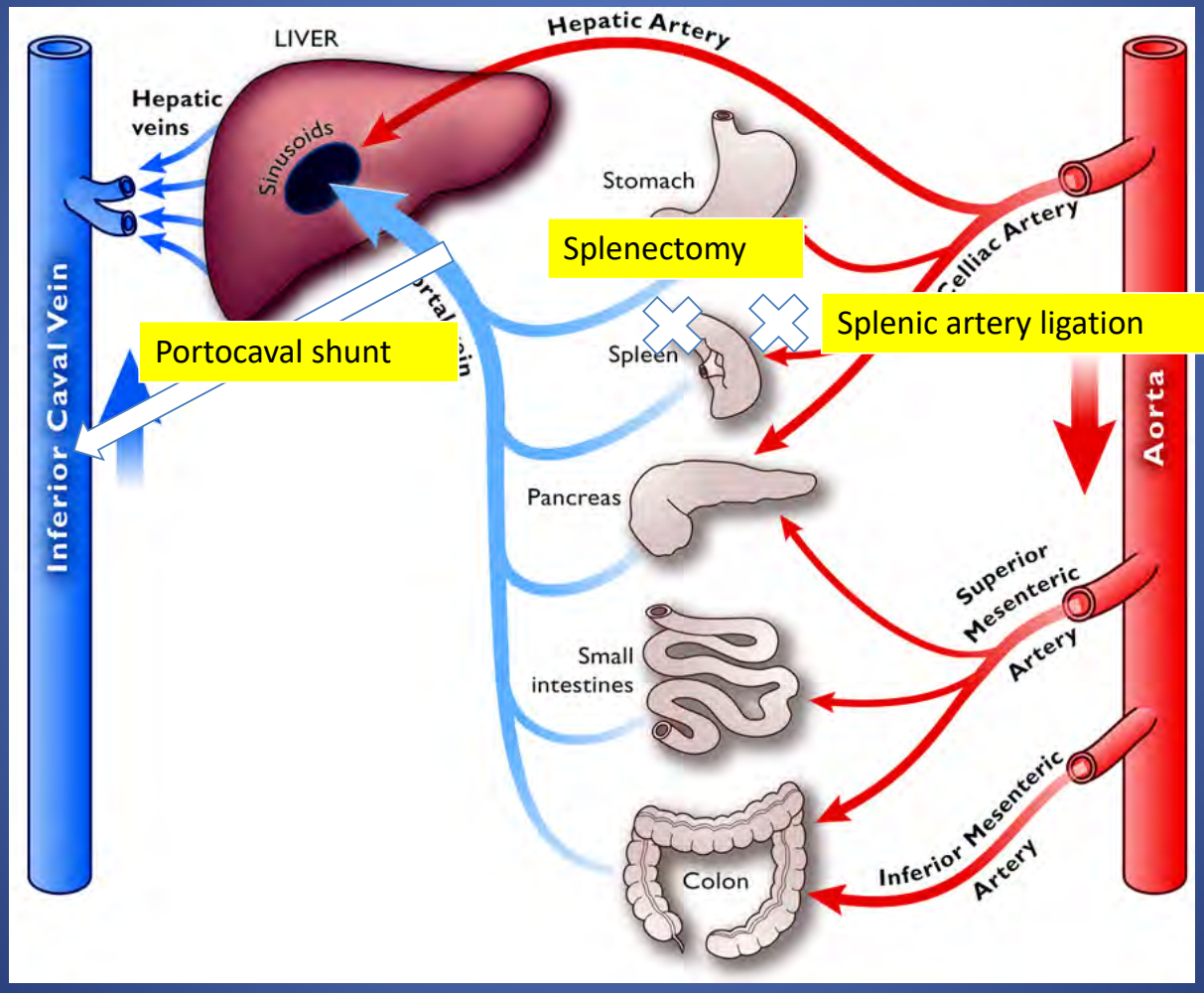
Functional Graft Size

The area of the pentagon is minimal functional graft size to prevent small-for-size syndrome



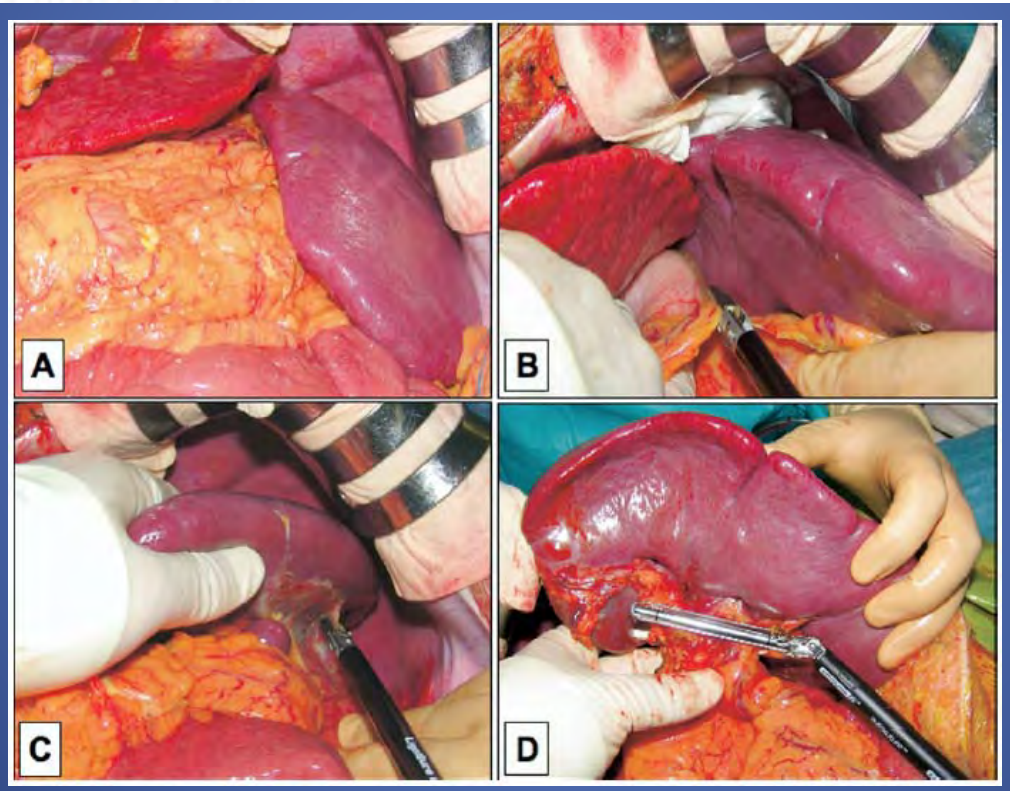

Unmodifiable Factors
Surgically Modifiable
Actual Graft Size (GRWR)
Graft Quality
Graft Inflow
Recipient Disease Severity
Graft Outflow

Surgical Modification of Portal Inflow



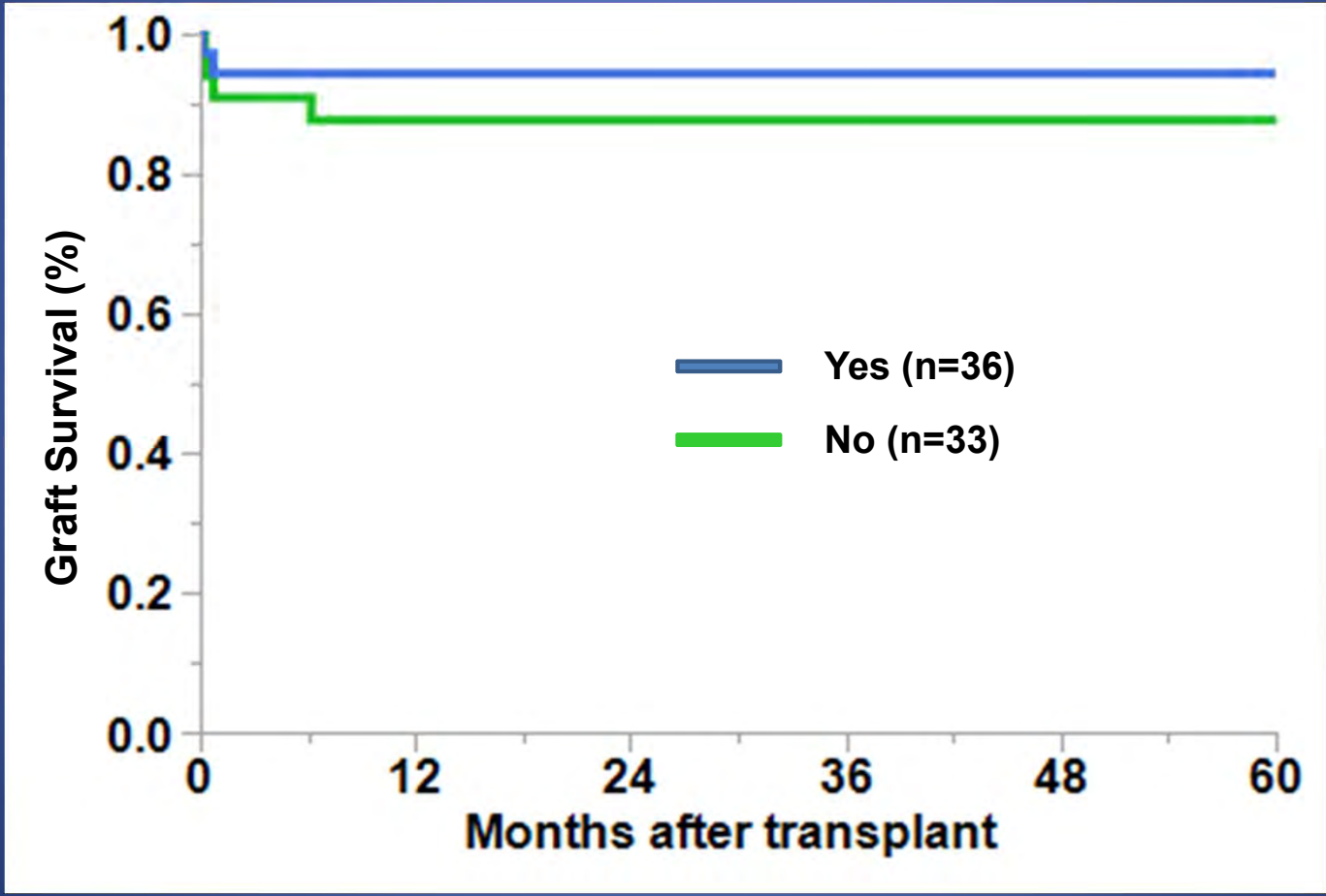
Bloodless Splenectomy During Liver Transplantation for Terminal Liver Diseases with Portal Hypertension

Toru Ikegami, MD, Takeo Toshima, MD, Kazuki Takeishi, MD, Yuji Soejima, MD, Hirofumi Kawanaka, MD, Tomoharu Yoshizumi, MD, Akinobu Taketomi, MD, Yoshihiko Maehara, MD, FACS



Ikegami T, et al. J Am Coll Surg, 2009

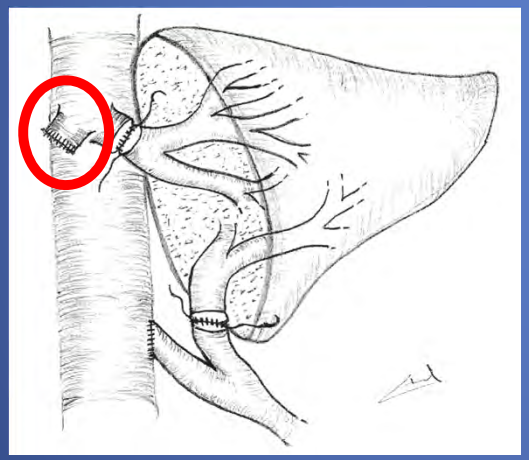
Graft Survival with or without Splenectomy



Outflow Considerations: Don’ts and Do’s

Left Lobe Adult-to-Adult Living Donor Liver Transplantation: Small Grafts and Hemiportocaval Shunts in the Prevention of Small-for-Size Syndrome

Jean F. Botha,[1] Alan N. Langnas,[1] B. Daniel Campos,[1] Wendy J. Grant,[1] Christopher E. Freise,[2] Nancy L. Ascher,[2] David F. Mercer,[1] and John P. Roberts[1]
[1]Division of Transplantation, Department of Surgery, University of Nebraska Medical Center, Omaha, NE; and [2]Division of Transplantation, Department of Surgery, University of California at San Francisco, San Francisco, CA

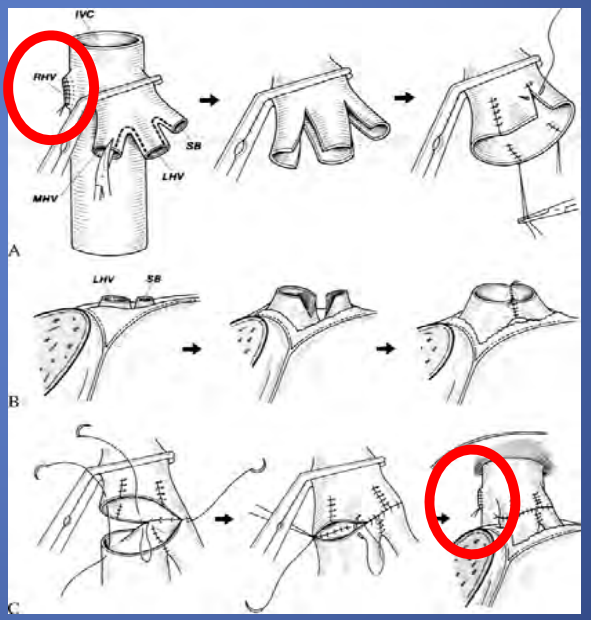


Botha, et al. Liver Transpl, 2010

HPB 2004 Volume 6, Number 2 99–105
DOI 10.1080/13651820310020792

Living donor liver transplantation: issues regarding left liver grafts

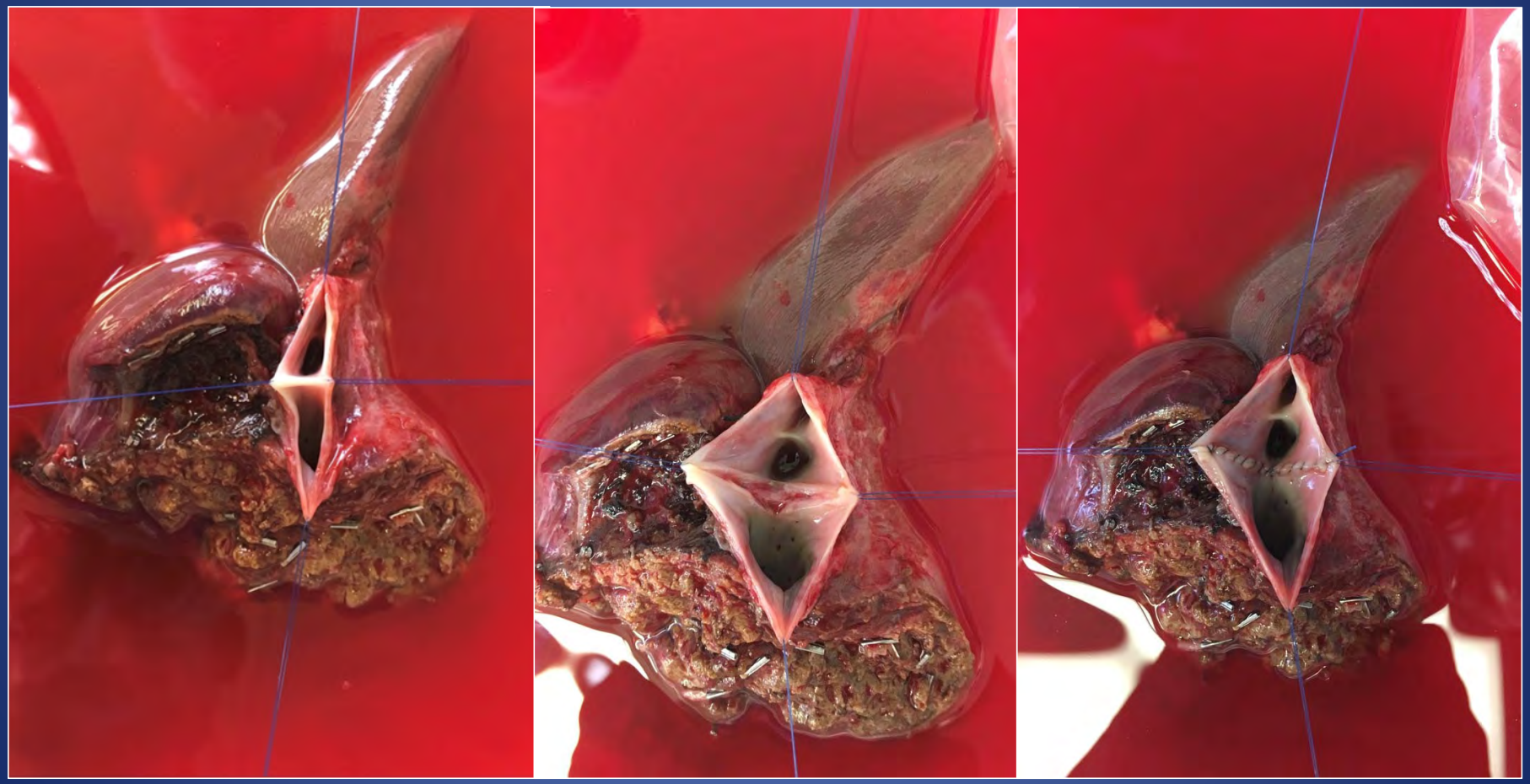
Y Hashikura[1] and S Kawasaki[2]
[1]First Department of Surgery, Shinshu University School of Medicine, Asahi 3-1-1, Matsumoto 390-8621, Japan; and [2]Second Department of Surgery, Juntendo University, School of Medicine, Hongo 2-1-1, Bunkyo-ku 113-8421, Japan



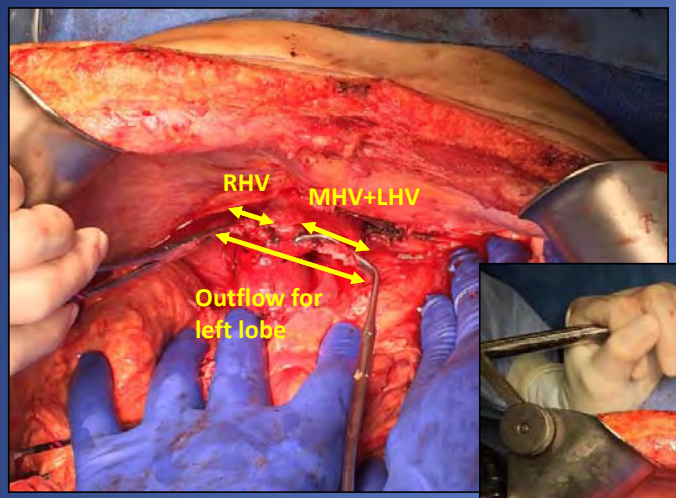
Hashikura, et al. HPB, 2004

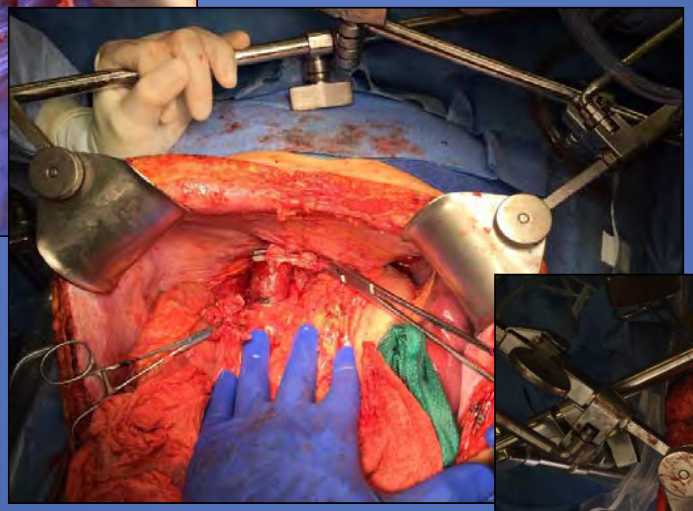
Outflow Maximization

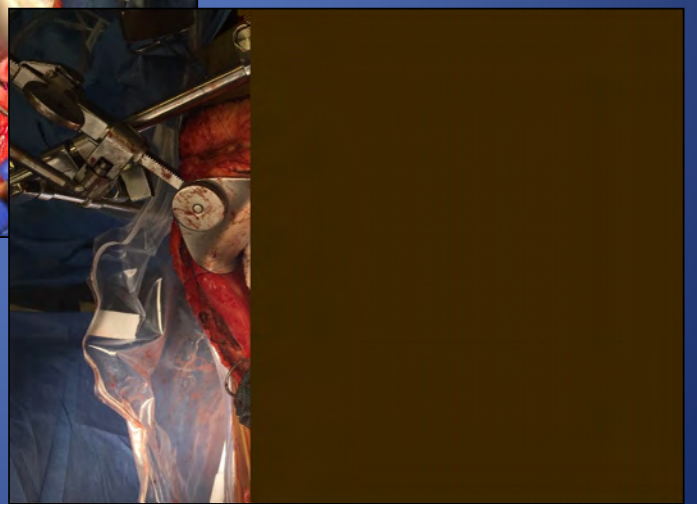
Venoplasty: Left Lobe Graft



Outflow Modulation in Left Lobe Graft

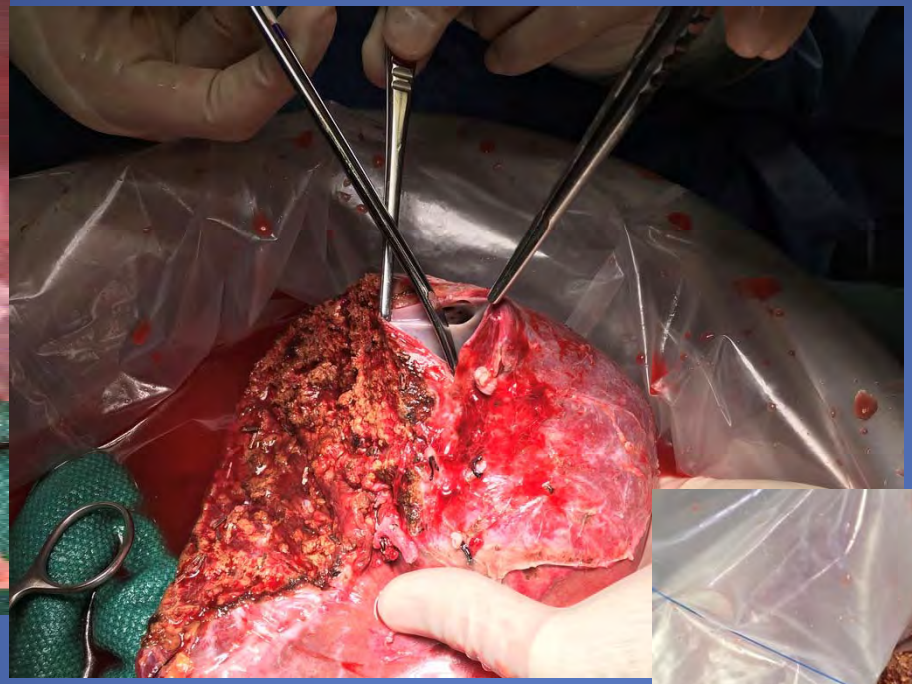






- ✓ Take down the left phrenic vein
- ✓ Use all 3 hepatic veins as outflow
- ✓ May close the left hepatic vein rather than right hepatic vein to adjust discrepancy

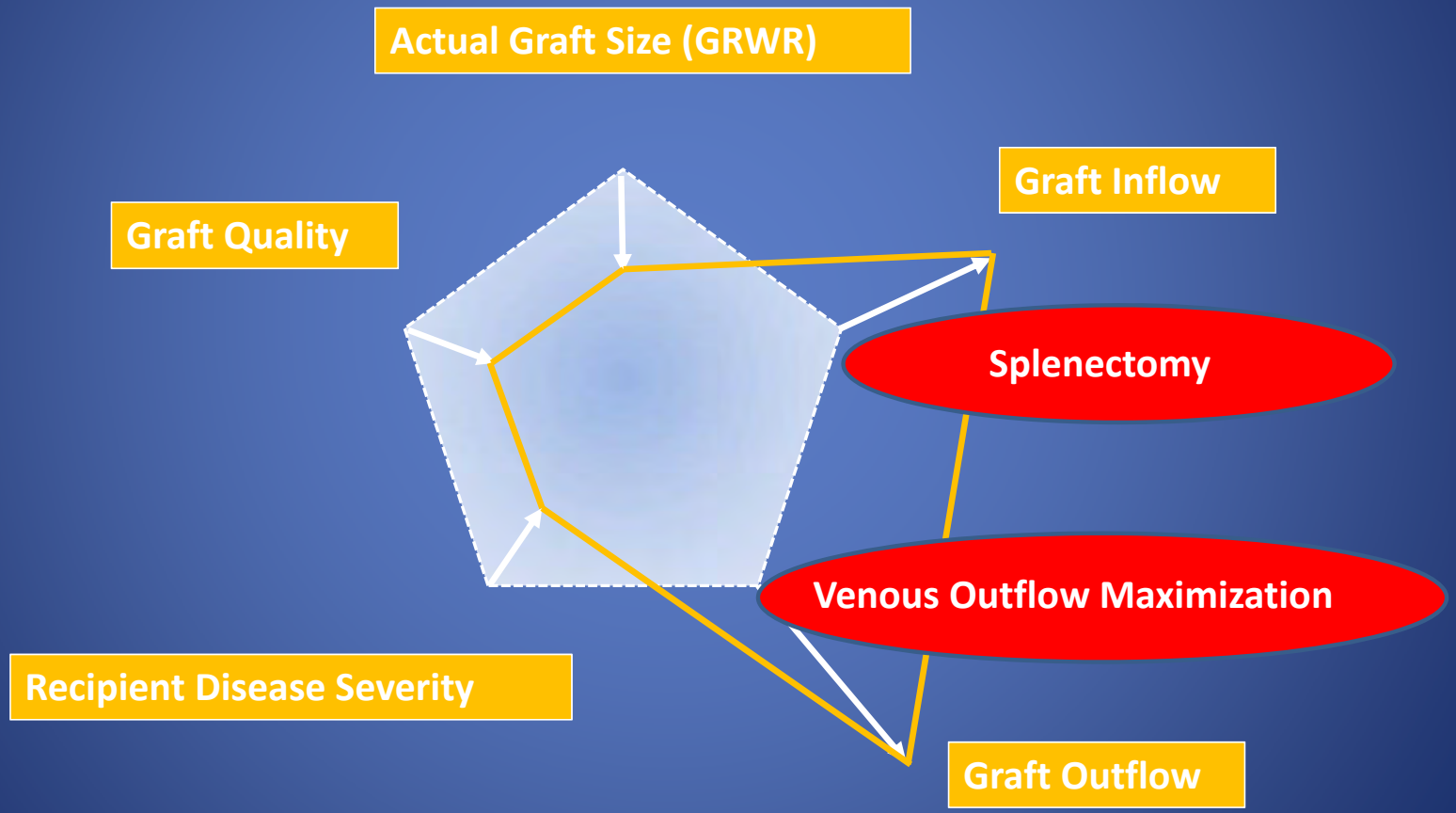
Outflow modification -- Right lobe



Need perfect tri-phasic waveform in OR

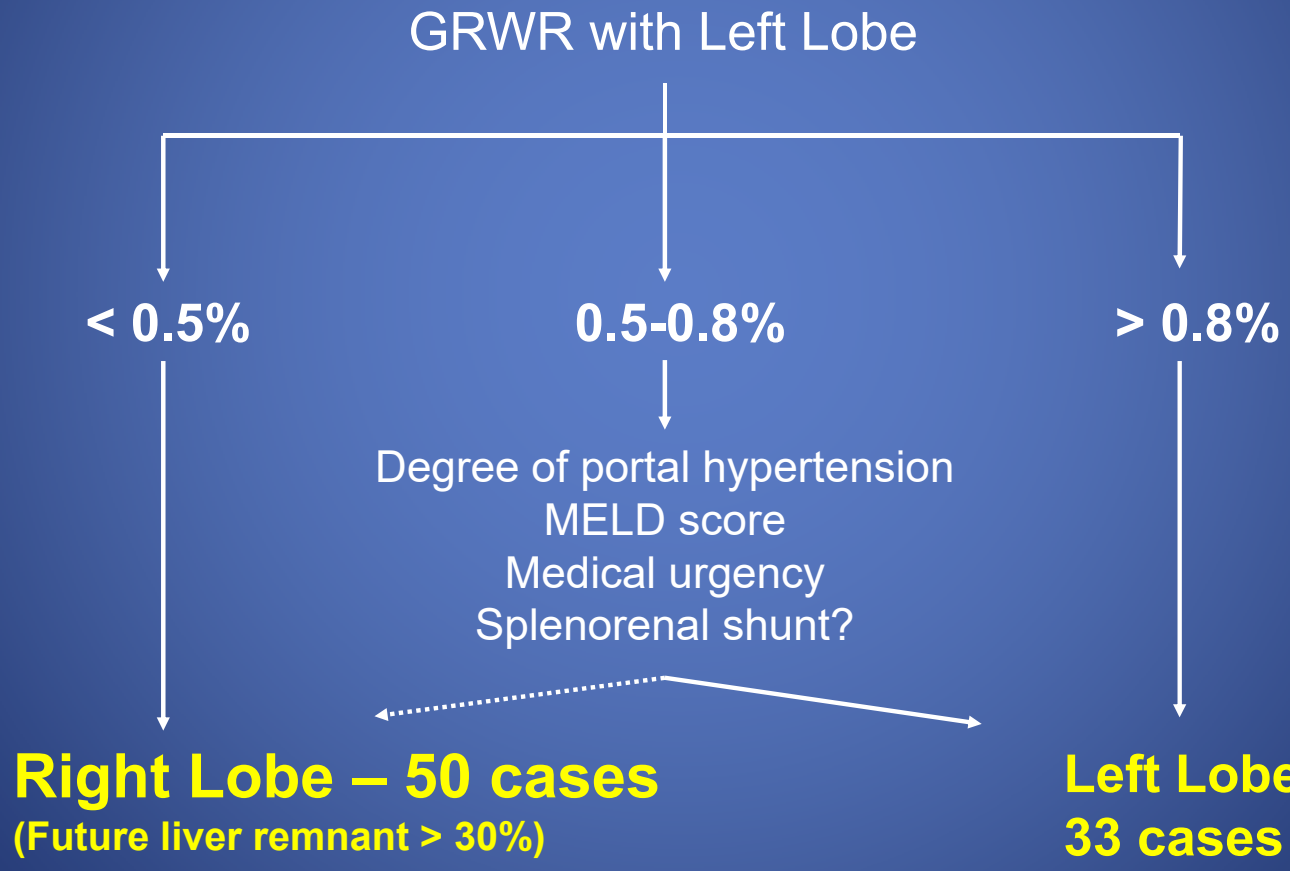
It is almost as if the right atrium is actively siphoning blood out of the liver

Systematic Maximization of Functional Graft Size



Adult Living Donor Graft Selection at Cleveland Clinic

2012-Present



Innovations in Dashboard Metrics
SRTR Graft and Patient Survival

Figure C4L. Adult (18+) 1-year living donor graft failure HR program comparison

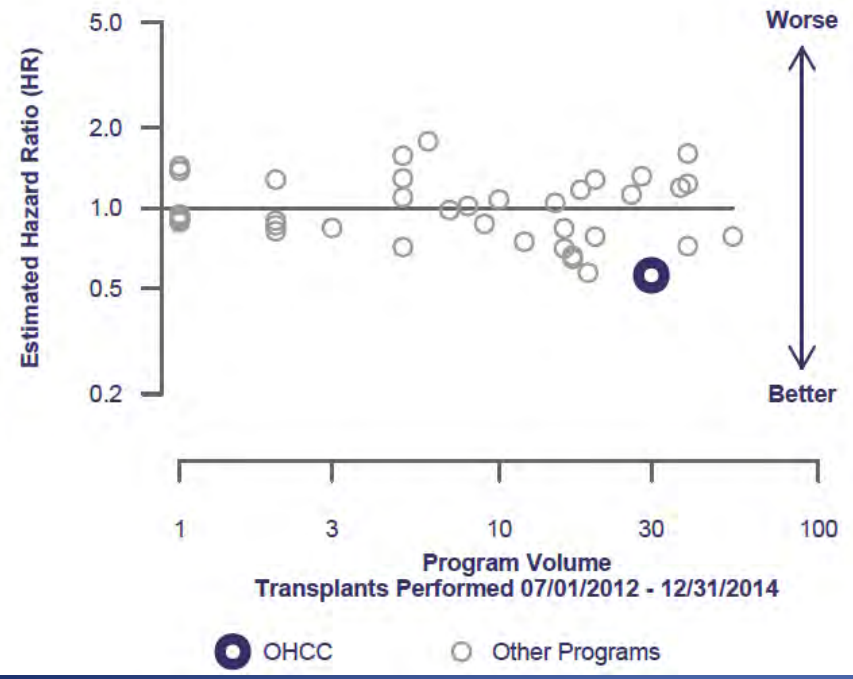
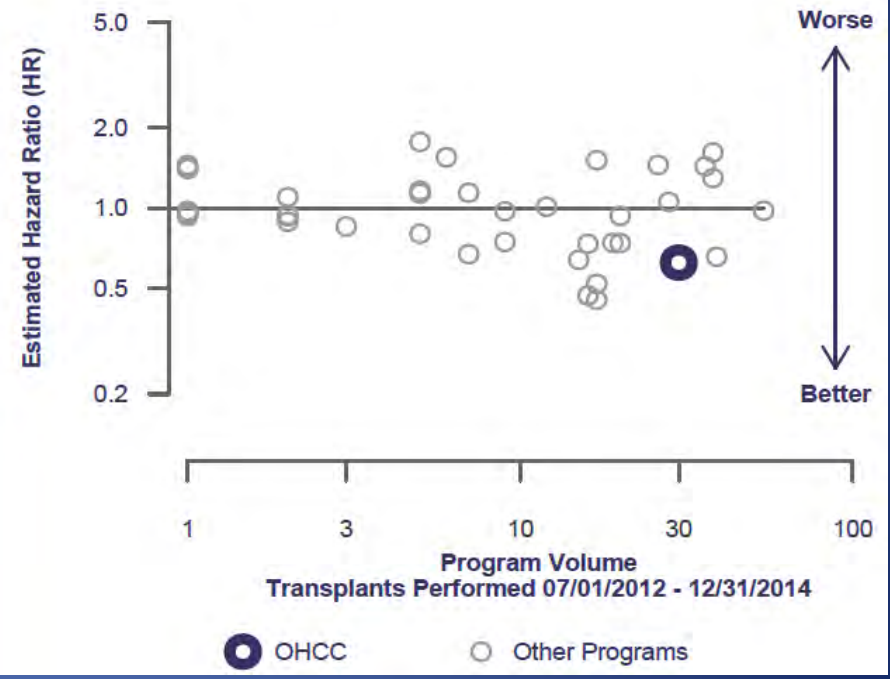


Figure C16L. Adult (18+) 1-year patient death HR program comparison (living donor grafts)

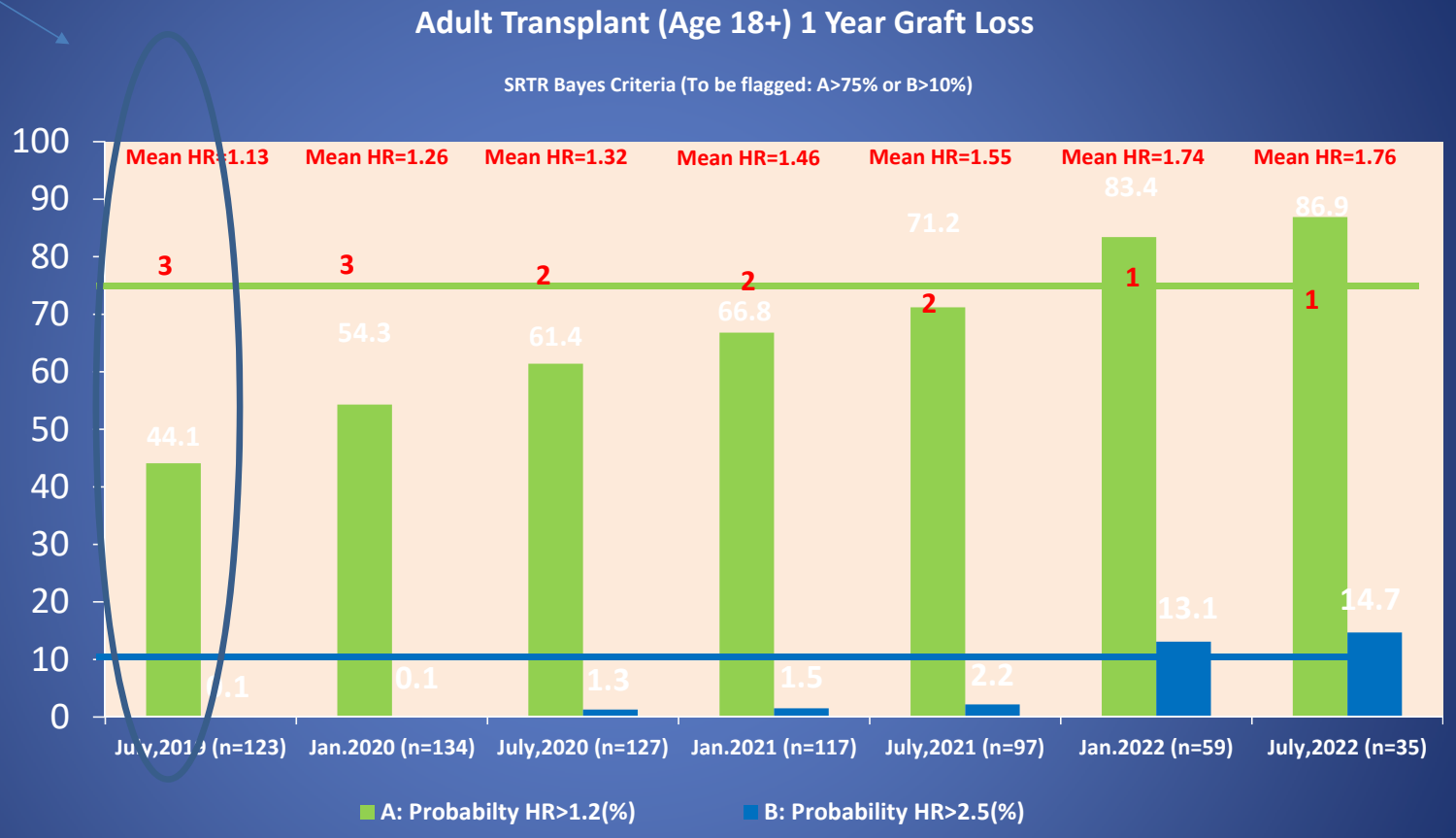


On paper, program is as expected ('3-tier') and no issues apparent

However, examining future cohorts representing transplants and outcomes that have already occurred, there is a noticeable poor trend that would reach thresholds for poor performance

Given opportunity to alter these projections, careful identification of root causes and correction – and NOT just avoiding adjusted risk is critical

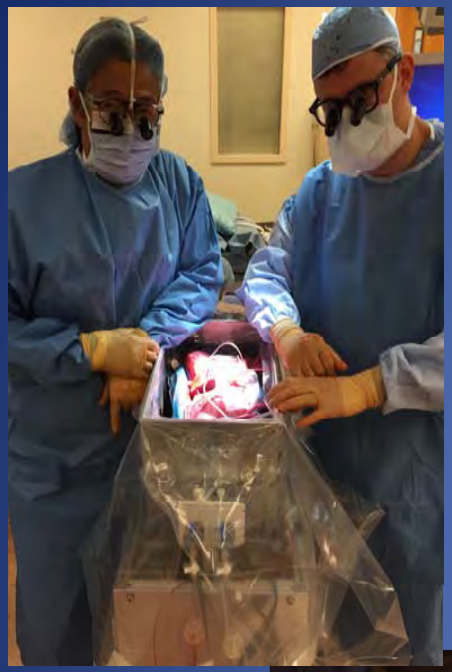
Innovation – Early warning system

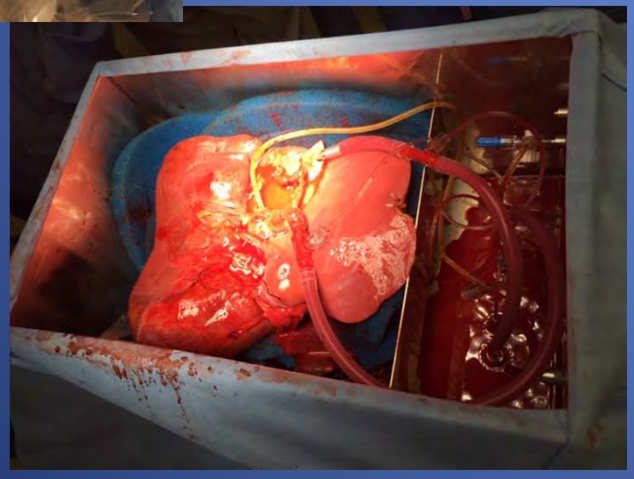


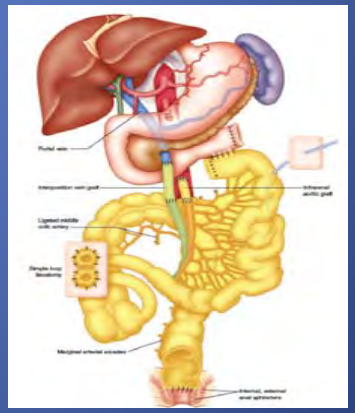
(SRTR Outcome Assessment: 5:better than expected,4:somewhat better than expected,3:as expected,2:somewhat worse than expected,1:worse than expected)

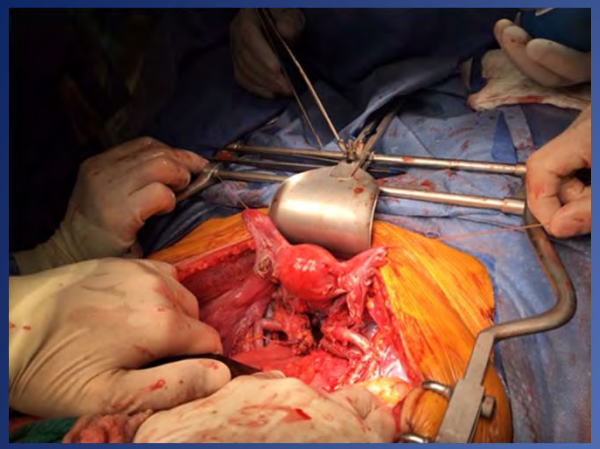
[07/19:TX1/1/16-6/30/18][01/20:TX7/1/16-12/31/18] [07/20: TX1/1/17-6/30/19][01/21: TX 7/1/17-12/31/19][07/21:TX1/1/18-6/30/20][01/22: TX7/1/18-12/31/20]][07/22:TX1/1/19-06/30/21]

Innovations





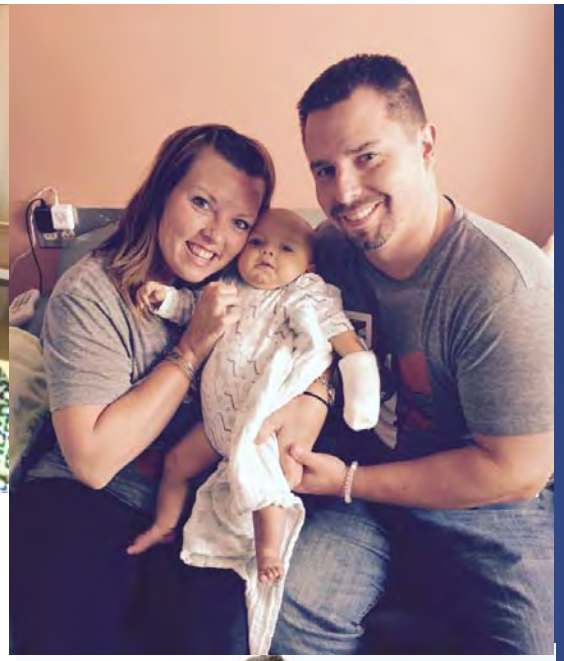


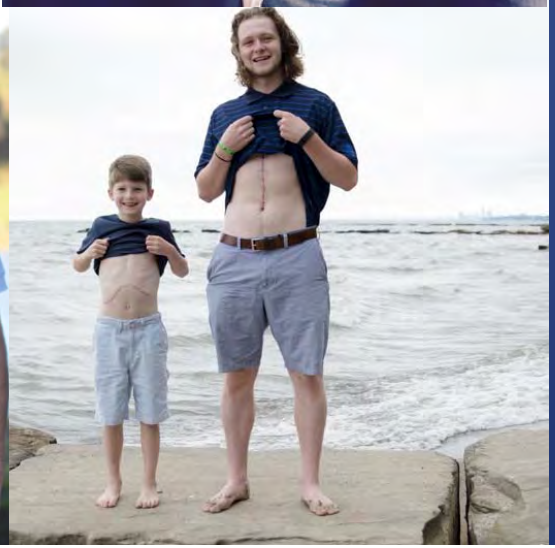


New Innovation – Uterus Transplant for Uterine Infertility

Conclusions

- The model history of Transplantation in over a half a century
  - The first quarter century was informed by proofs of concept that it could be done technically and rejection/infection could be controlled
- The second quarter century was marked by more and more success, expansion to other organs and organ combinations and many many new important innovations
- The regulatory focus on outcomes and the media's focus on anything spectacular made crisis planning a necessary part of any program to protect patients, caregivers and the field
- I think many of us have found "The Left Lobe"; and it is much safer!





Cleveland Clinic Core Values

Thank you

- Cleveland Clinic Main Campus

- Cleveland Clinic Florida (Weston)

- Cleveland Clinic Abu Dhabi (CCAD)

Thank You