The 12th Joint Annual Congress of the American Society of Transplant Surgeons and The American Society of Transplantation

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I have financial relationship(s) within the last 12 months relevant to my presentation with:

Xynthisis, LLC: Partner

XynManagement, LLC: CTO & CFO

AND

My presentation does not include discussion of off-label or investigational use

I do not intend to reference unlabeled/unapproved uses of drugs or products in my presentation.

High Pre-transplant
Insulin Requirements
Correlates with
Pancreas Failure Risk
in Simultaneous
Pancreas-Kidney (SPK)
transplantation

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Data

- OPTN data for all recipients of K, SPK or P
- Linked to pharmacy records
 - RxBenchmark Database
 - 50,000 pharmacies
 - 73% of prescriptions in the US
- 2005 2010

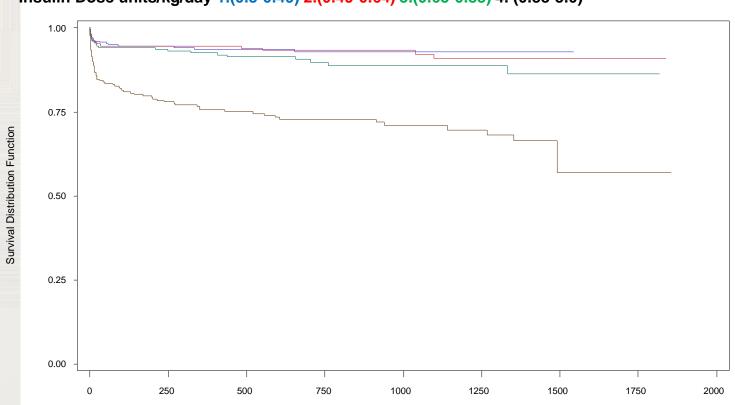
Inclusion criteria

- Adult SPK recipient (age>18)
- One year pre-transplant follow-up pharmacy records
- Estimated average daily insulin dose less than 3.0 units/kg/day
- 957 subjects

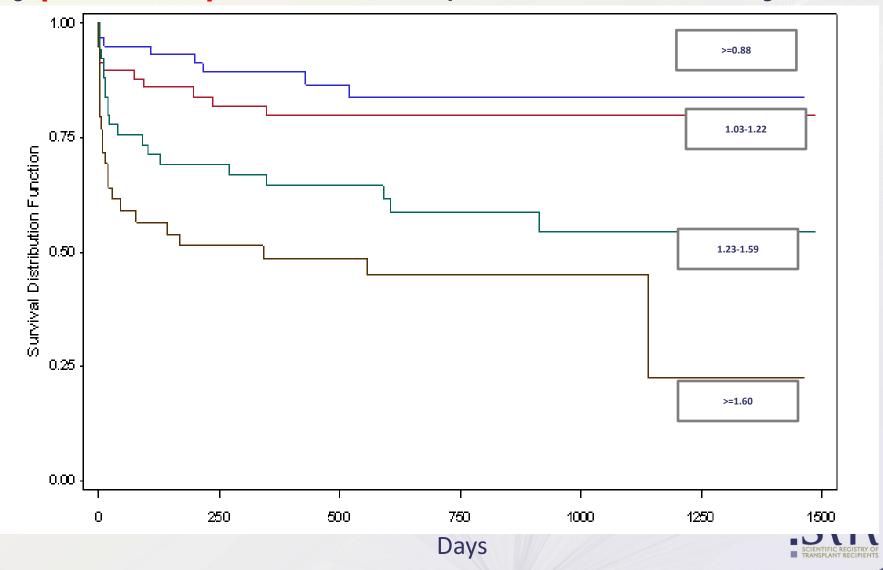


Pancreas survival reported to OPTN by pre-transplant insulin quartiles

Insulin Dose units/kg/day 1.(0.3-0.49) 2.(0.49-0.64) 3.(0.65-0.88) 4. (0.88-3.0)

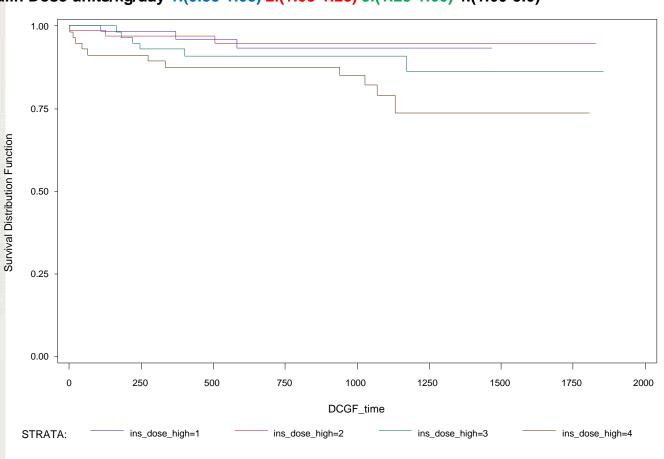


Pancreas survival reported to OPTN by pre-transplant insulin quartiles (sub analysis)



Kidney survival reported to OPTN by pre-transplant insulin quartiles

Insulin Dose units/kg/day 1.(0.88-1.03) 2.(1.03-1.23) 3.(1.23-1.60) 4.(1.60-3.0)



Conclusion #1

- High pre-transplant insulin dose is associated with high risk of pancreas loss after SPK
- Insulin dose itself appears unrelated to direct kidney loss
- However, pancreas failure is risk factor for subsequent kidney loss at all pre-transplant insulin doses
- Thus, pre-transplant insulin dose is an indirect risk factor for kidney loss in SPK



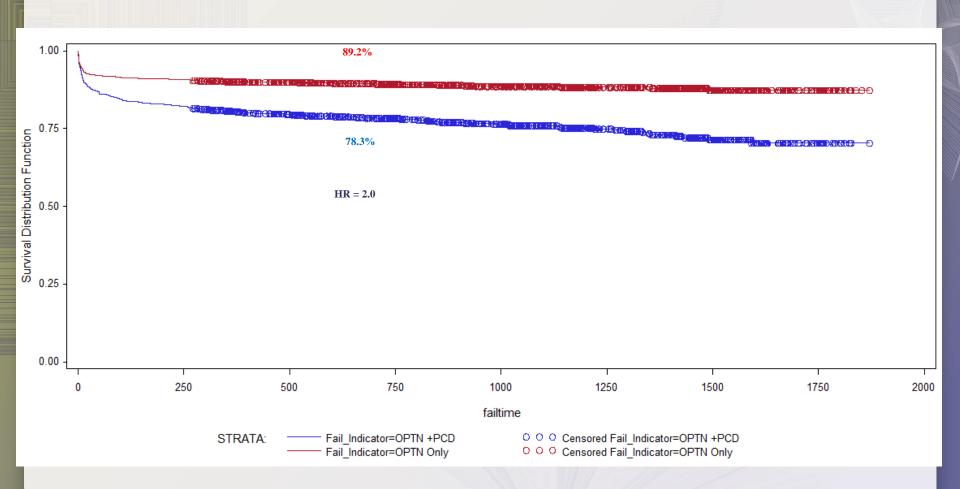
Post Transplant Insulin Data

- Inclusion: All subjects in pre-transplant insulin dose study (957 subjects)
- Exclusion: < 365 days of post-transplant pharmacy claims for any medication (Excludes 118 subjects)
- 839 subjects included

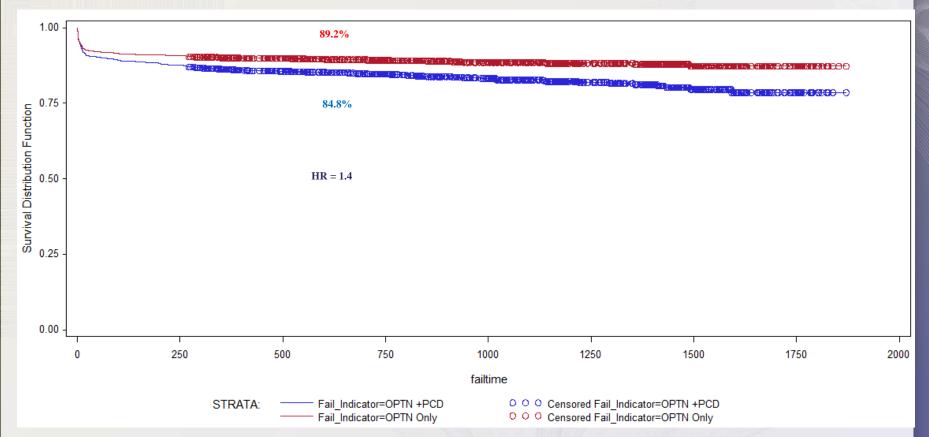


Туре	OPTN PA Failure	Days to 1st Insulin Claim	OPTN Follow- up Days	Span of Insulin Claims Days	Total Vials	Dose u/kg/d	Pre/Post Dose Ratio
Low Dose	No	1291	1853	529	17	0.09	0.02
Missed Failure?	No	824	1590	746	33	0.73	1.13
Failure Lower Dose	Yes	864	1664	862	15	0.27	0.41
Failure Similar Dose	Yes	64	1427	1422	69	0.64	1.44
One Vial	No	125	1343	0	1	?	?
No Insulin	Yes	-	1267	-	0	-	_

Pancreas Survival: OPTN & OPTN +PCD: Any Insulin Fill Post-TX

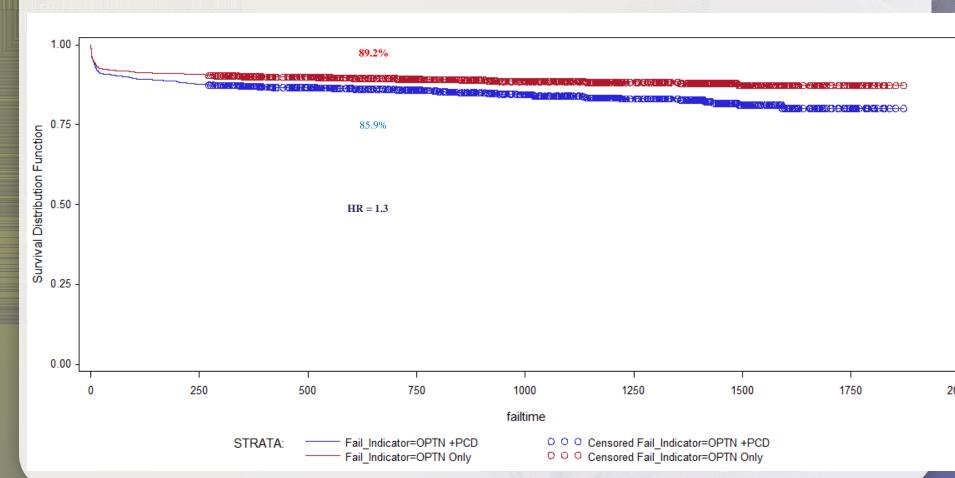


Pancreas Survival: OPTN & OPTN +PCD: > 1 Insulin Fill Post TX



Pancreas Survival: OPTN & OPTN +PCD: 1 Inculin Fill & Doco >-





Conclusion #2

- Is there a consistent definition of pancreas failure in practice?
- Can we validate reported pancreas failure?
 - Other organ failures are validated with:
 - Death: SSDMF
 - Retransplant: OPTN
 - For kidney, resumed maintenance dialysis: CMS 2728
- Can we validate pancreas failure with pharmacy records?
- If we do not have a consistent, validated definition of pancreas failure:
 - Should the SRTR report center specific pancreas failure to the public?

