Use of Generic Tacrolimus in Paediatric Transplantation

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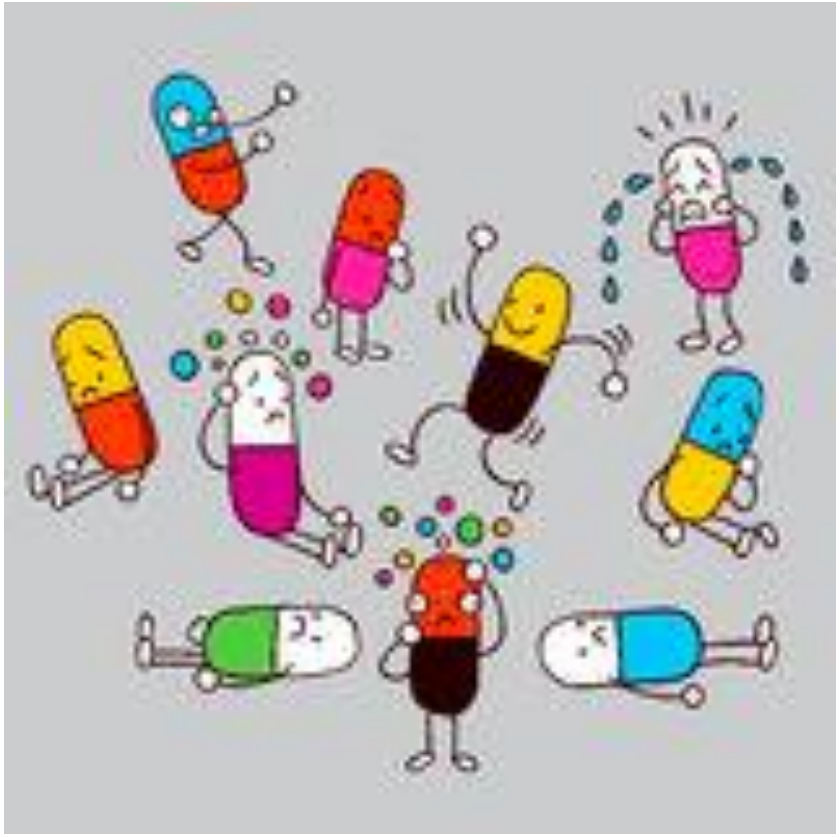
Cost of Drugs problem for everyone!

Generics – saves cost but how good?



Introduction

- Safety and efficacy data of generic immunosuppressive agents has been published for adult patients
- But no similar data for paediatric patients.

- This review is our centre's 21 month experience using Adoport (generic tacrolimus).

Aim

- The introduction of a generic tacrolimus in paediatric transplant recipients

Methods

- Retrospective review of paediatric renal patients who have received generic tacrolimus:
  - De novo for *new* paediatric renal transplants
  - Conversion from branded or liquid to generic tacrolimus in *existing* transplant patients

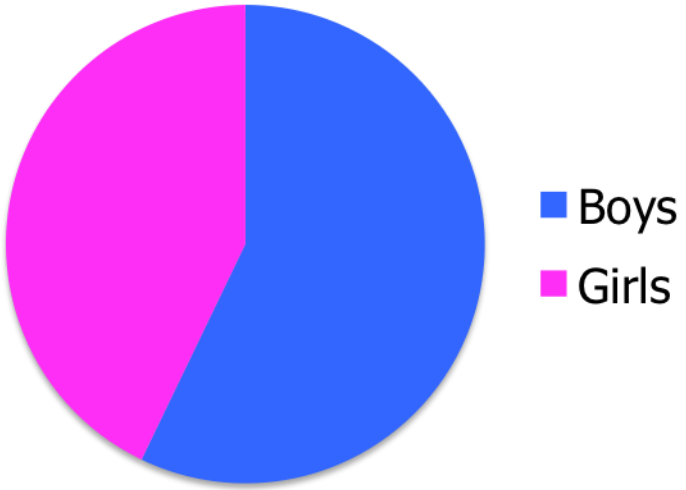
Results
De novo renal transplants
November 2012 – September 2014

- Mean duration on Adoport: 11.7 months (range 2-21 months)
- Mean daily dose/kg per day: 0.17 (range 0.09 – 0.55) with target 12 hr tacrolimus trough levels of 8-12µg/l

- Biopsy proven rejection rate = 28.6% (4/14 patients)

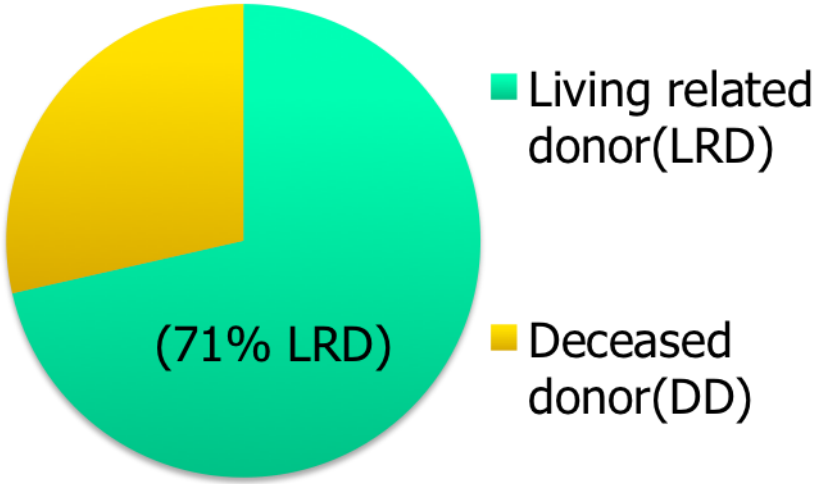
Results
De novo renal transplants
November 2012 – September 2014

Gender



Mean age of 12.4 yrs (range 6-17)

Donor Type



Adult studies

- The use of Adoport in adult
  - Renal (Clin Kidney J (2013) 6: 21–28) and
  - Liver (Clin Transplant. 2014 Aug 21) transplant patients has been reported.
- There is little data in children. Abdulnour (Pediatric Transplantation, 14: 1007–1011) reported

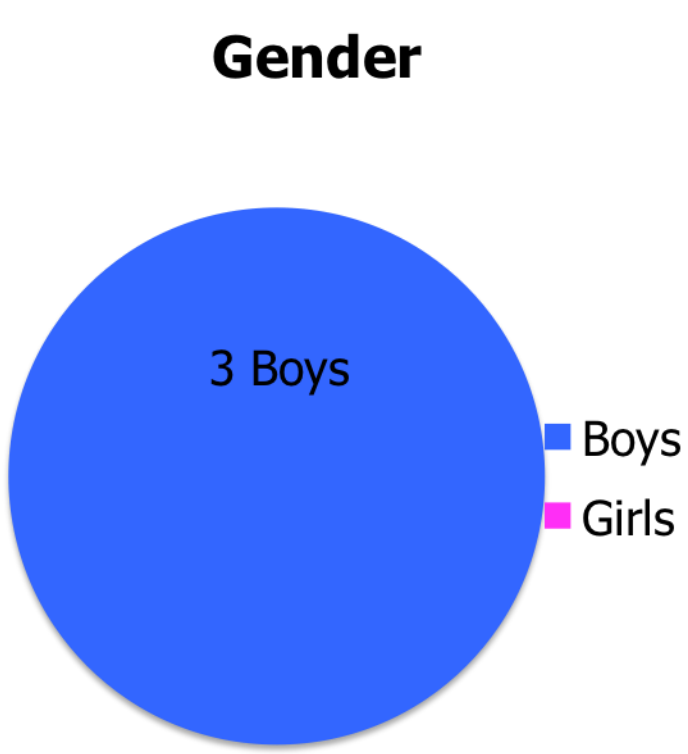
Discussion

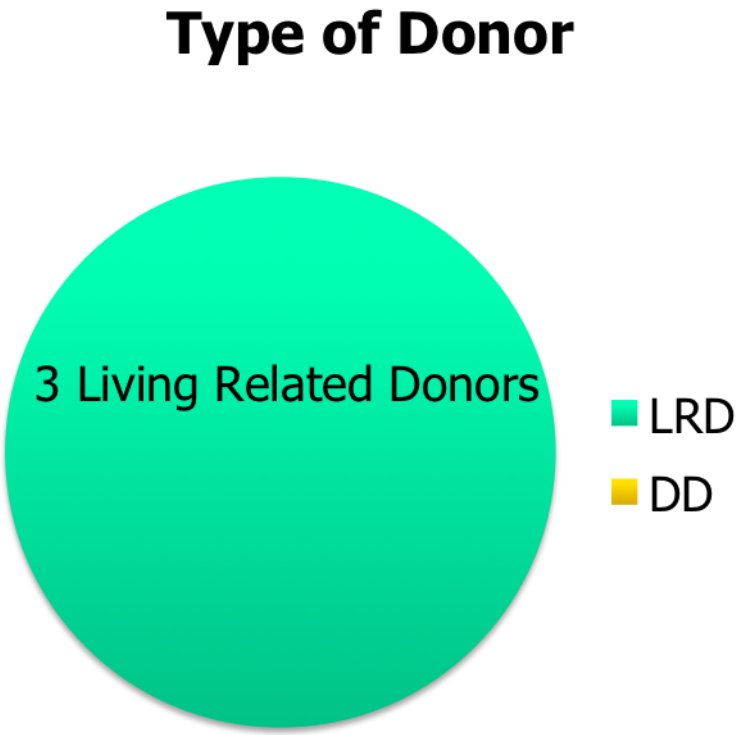
- 4 children who inadvertently switched from Prograf to generic tacrolimus,
  - No difference in measured trough tacrolimus levels in 2 patients
  - Small difference in 1 patient
  - 1 patient who had no change in levels but experienced an acute rejection episode.

Discussion

- First published data on systematic use of Adoport in children.
- No differences in outcome between transplants maintained on Prograf or Adoport,
- No excess of complications in patients converted from Prograf or liquid tacrolimus to Adoport
  - although our numbers are small.

Switch from Prograf to Adoport





Mean age of 15 yrs (range 15-17

Switch from Prograf to Adoport

- Mean time since transplant: 149 months
  - (range 136 -164 months)
- Mean time on Adoport: 5 months (range 1-11 months)
- Mean daily dose/kg/day: 0.17 (range: 0.07-0.32)
- Biopsy proven rejection rate = zero since switch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Switch from Tacrolimus liquid to Adoport Capsules

- 5 patients, 4 boys: 1 girl
- Mean age; 8.6 yrs (range 6-12 yrs)
- LRD: DD = 4:1 (80% LRD)
- Mean time since Transplant: 72 months (range 35-144 months)
- Mean time on Adoport: 10 months (range 1-20 months)
- Mean daily dose/kg/day: 0.11 (range =0.04-0.19)
- Biopsy proven rejection rate: 20 % (1 child with borderline changes)
- Zero graft loss in series of 28 patients.


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Conclusion

- The use of generic tacrolimus
  - manufactured by a reputable pharmaceutical company
  - safe and effective
  - small series of paediatric renal transplant recipients.
- Despite the small numbers,
  - the financial savings have been impressive with a 4.5 x cost reduction
  - compared with the predicted cost of the branded version in our institution.

Conclusion

- This has a significant impact not just on drug budgets
  - Well-resourced countries – cost is becoming more of a concern
  - Provides the possibility of treatment for patients who live in poorly-resourced countries where these drugs were previously unavailable due to cost


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