Use of Generic Tacrolimus in Paediatric Transplantation

Mignon McCulloch
Paediatric Nephrologist/Intensivist
Red Cross War Memorial Children’s Hospital
University of Cape Town

Walsh G, Thornhill W, Jones H, Clothier J, Haq S, Taylor J.
Evelina Children’s Hospital London, Guy’s & St. Thomas’s Trust
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)
De novo renal transplants
November 2012 – September 2014

Mean age of 12.4 yrs (range 6-17)

Gender:
- Boys
- Girls

Donor Type:
- Living related donor (LRD) (71%)
- Deceased donor (DD)
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

Gender

3 Boys

Type of Donor

3 Living Related Donors

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
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.
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