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Low-dose anti-T lymphocyte globulin (Grafalon) for kidney transplant induction immunosuppression. A pediatric cohort study

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Introduction

Induction immunosuppression (IIS) employs lymphocyte-depleting and non-depleting antibodies, such as rabbit thymoglobulin (rATG) and IL-2 receptor (CD25) targeting basiliximab (BLX)
T-cell suppression may cause CMV reactivation and malignancies
Optimal IS in pediatric solid organ transplantation is debated

Aims of the study

- Evaluate low-dose anti-T lymphocyte globulin (ATLG, “Grafalon”) treatment for IIS in unselected pediatric KT recipients

Outcomes of interest

- Primary outcomes
  - Degree and duration of treatment-induced lymphocyte (ALC) depletion, and
  - Rejection rates after ATLG vs BLX induction
- Secondary out ome
  - Incidence of infusion reactions
  - Effects on neutrophil and platelet counts
  - Infection rates
  - Graft function post KT

Financial disclosure / Conflict of interest
None to declare

Method

Type of study

Retrospective single-center pediatric cohort study

Study population

Included are all pediatric KT recipients since program inception in 10/2018

Observation period 5.4 years

N =44 transplants; 34 (73%) from deceased and 10 from living-related donors (27 %)

Standard immunosuppression protocol

1. ATLG (“Grafalon”) 1.5 mg/kg over 3 days (5 days in case of slow graft recovery), **or** basiliximab (BLX) on POD 0 and 4
2. All recipients received (methyl) prednisolone as IV induction and maintenance, mycophenolate mofetil and tacrolimus

The monitoring protocol was uniform for all recipients

Data analysis is descriptive. Continuous variables are shown as arithmetic means ± SD or median and range. Student’s t and Fisher’s exact tests were used where indicated

Results (1)

N = 44 patients transplanted

ATLG (1.5 mg/kg/dose)
82 % had 3 doses
18 % had 5 doses

ATLG
N = 38 patients
DD = 29, LRD = 9

Basiliximab
N = 6 patients
DD = 5, LRD = 1

Basiliximab
10 mg <20 kg BW
20 mg >20 kg BW

Cytopenia	*ATLG*	*Basiliximab*	
Thrombocytopenia <140/nL	17/38 (35 %)	0/6 (0 %)	p = 0.067
Neutropenia <1.5 x 10^9/L	5/38 (13 %)	2/6 (33 %)	n.s.
Lymphocytopenia (see Figure 1)			

Graft function (eGFR mL/min/1.73 m^2)			
1 mo post KT (median)	78 (range 43-233)	63 (range 41-111)	n.s.
1 year post KT	73 (range 35-118)	64 (range 42-102)	n.s.

Treatment-emergent adverse effects during the study period

No significant difference ATLG versus Basiliximab

Infusion reactions (n=0)

Infections

- Pneumonia (n = 1)
- UTI (n = 8)

Fever of unknown origin (n = 4)

BK virus nephropathy (n = 1)

Symptomatic CMV or EBV (n = 0)

PTLD (n = 0)

Conclusions

- ATLG and basiilximab were tolerated in pediatric KT recipients without serious A/E or opportunistic viral infections
- Lymphocyte depletion after ALTG is immediate, in contrast to basiliximab (Fig 1) and short-lived
- Few instances of transient fever during induction IS may have been ATLG-related
- Rejection rates and graft function were comparable to international standards without apparent differences between induction agents

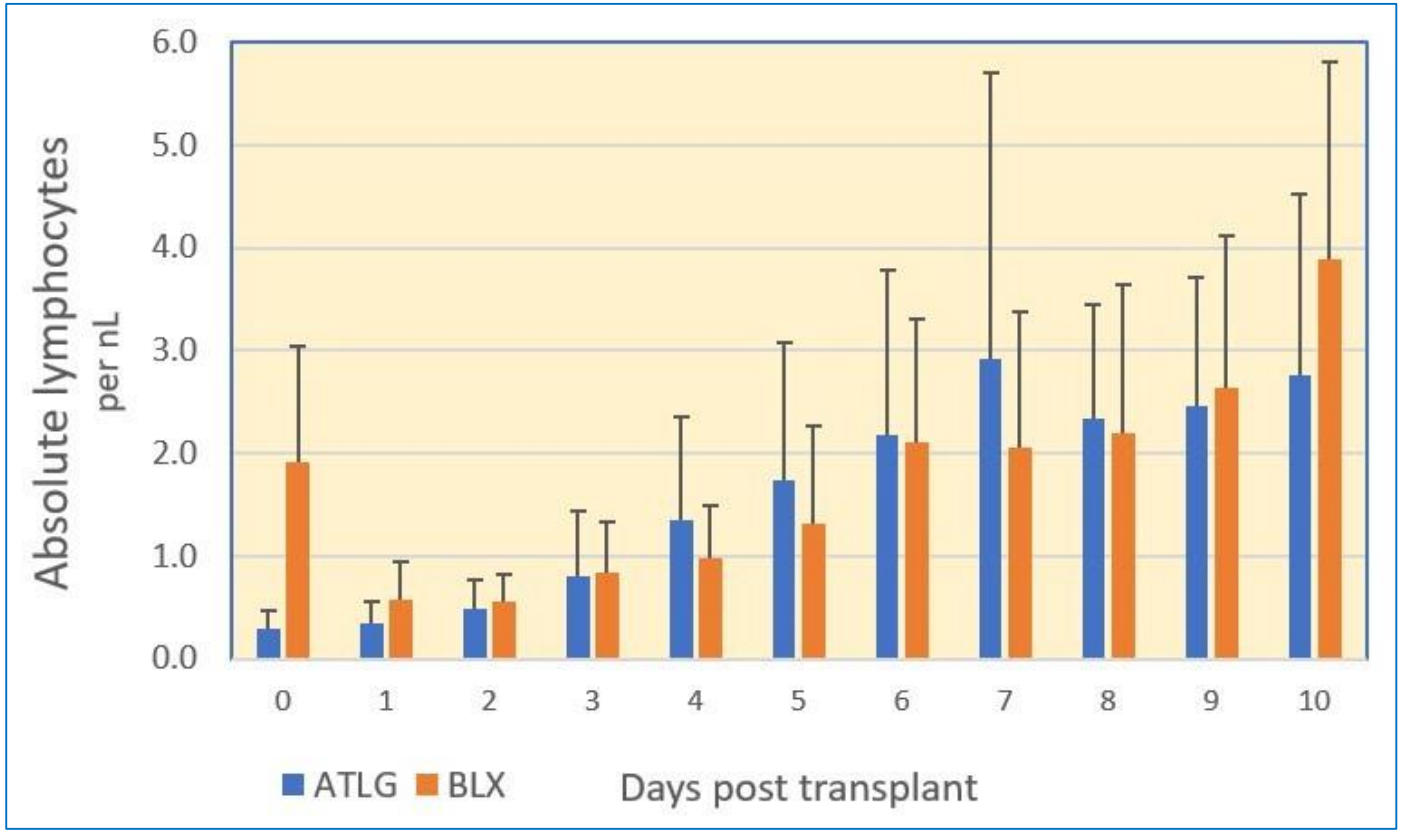

Figure 1 Post KT lymphocyte counts associated with ATLG versus basiliximab induction therapy