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BASILIXIMAB AND ANTI-THYMOCYTE GLOBULIN AS AN INDUCTION OF IMMUNOSUPPRESSION IN RECIPIENTS OF VASCULARIZED ORGAN TRANSPLANTS

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ABSTRACT

Introduction and Aim: The advancement of immunosuppressive therapy has significantly increased organ transplantations. Among immunosuppressive agents, basiliximab and anti-thymocyte globulin (ATG) are key in induction therapy. However, clear guidelines on when to use basiliximab alone, ATG alone, or their combination are lacking, posing clinical challenges. This study aims to review recent data on basiliximab and ATG use in induction therapy post-transplant.
Materials and Methods: A literature review was conducted using PubMed with keywords “basiliximab”, “ATG” and “immunosupression" including articles published up to September 2024, focusing on studies from the last two years. The review targeted information on their application in induction immunosuppression after vascularized organ transplantation, effects relative to organ type, and drug combinations.
Results: Basiliximab and ATG differ in efficacy and side effects. ATG is more effective in reducing acute rejection, especially in high-risk patients, but carries higher infection and hematologic risks. Basiliximab has a better safety profile, suitable for elderly or low-risk patients. Treatment should be individualized by age, immunological risk, and infection susceptibility. Steroid continuation after basiliximab induction improves outcomes, a benefit not clearly seen with ATG.
Conclusion: Induction therapy is advised for high-risk patients and certain transplants, mainly using ATG, Grafalon, or basiliximab. ATG may be a safe, effective alternative to basiliximab, which is preferred in older or comorbid patients. Limited data support ATG use in other transplants like pediatric heart transplants. Further multicenter trials and personalized therapy are needed.

KEYWORDS

Basiliximab, ATG, Immunosupression, Transplantation

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Introduction.

In 2024, a total of 2,151 organ transplants from deceased donors were performed in Poland. The largest proportion of these procedures involved kidney transplants (1,132), liver transplants (615), and heart transplants (201). [1] Particular attention should be paid to cases of multi-organ transplants, such as kidney+pancreas (32), kidney+liver (10), and heart+lung. (1) Organ transplantation became feasible due to the development of potent immunosuppressive agents that effectively block the rejection process, enabling the survival of the transplanted organ and ensuring at least partial graft tolerance by the immune system. The first treatment regimens that successfully prevented rejection consisted of high doses of corticosteroids combined with an immunosuppressive antimetabolite, such as azathioprine, 6-mercaptopurine, or cyclophosphamide. These combinations allowed initial successes in kidney, liver, lung, and heart transplants in the 1950s and 1960s. [2,3]

Currently used immunosuppressive drugs can be divided into three categories: induction agents, maintenance therapy, and rejection treatment. [4] This review article will focus on two agents used in induction immunosuppression protocols—basiliximab and antithymocyte globulin (ATG).

Basiliximab is a chimeric monoclonal antibody that binds with high affinity to the α-chain of the interleukin-2 receptor (IL-2R), inhibiting the rapid clonal proliferation of activated T lymphocytes without causing their depletion. [5]

Antithymocyte globulin (ATG) is a polyclonal antibody primarily targeting T lymphocyte antigens and class I human leukocyte antigen (HLA) antigens to induce immunosuppressive effects. The main mechanism of ATG action is considered to be complement-dependent T lymphocyte depletion within the intravascular compartment (i.e., in the blood) and phagocytosis of T lymphocytes by macrophages in peripheral and secondary lymph nodes. Pre-activated T lymphocytes present in the blood or peripheral tissues are eliminated through antibody-dependent cellular cytotoxicity and Fas ligand-dependent apoptosis pathways. [6,7]

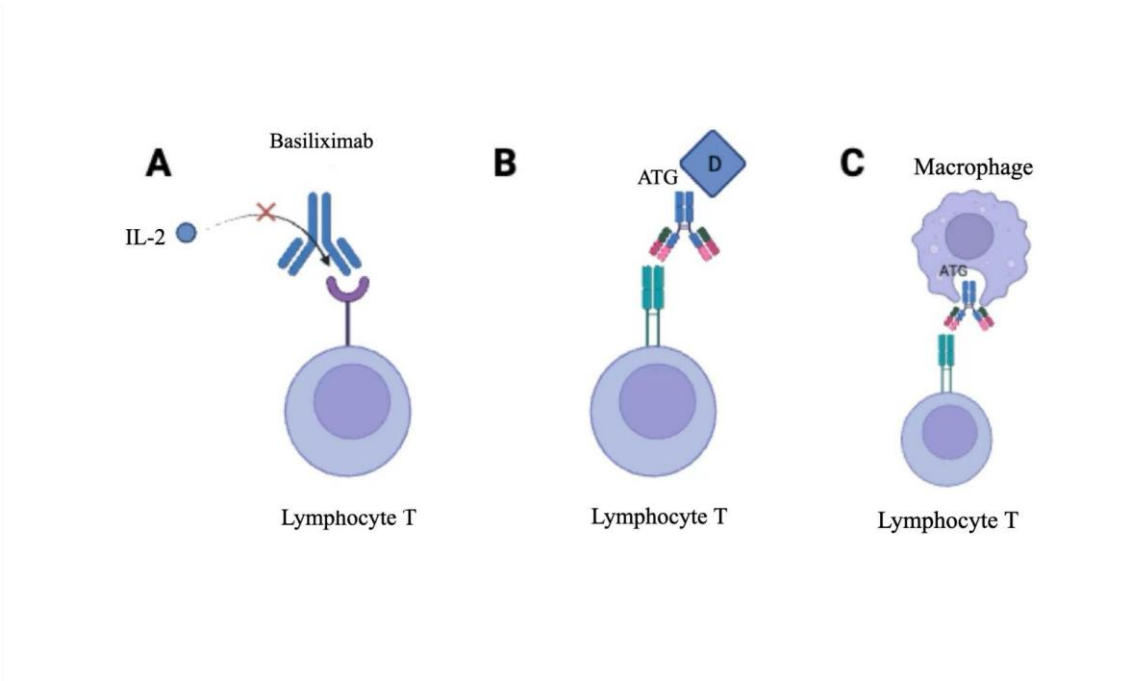

Fig. 1. *A simplified scheme of basiliximab's mechanism of action (A) involves blocking the IL-2 receptor and secondarily inhibiting T lymphocyte proliferation [8], while a simplified scheme of ATG's mechanism includes complement-dependent T lymphocyte depletion (denoted as D in the scheme) within the intravascular compartment (B), as well as phagocytosis of T lymphocytes by macrophages in peripheral and secondary lymph nodes (C). [6] The figure was created using BioRender.com.*

Results

1. Basiliximab and ATG in Immunosuppressive Treatment of Kidney Transplant Patients.

1.1 Induction with basiliximab compared to ATG induction – basiliximab in first-time kidney transplant recipients from living donors, non-immunized, with low mismatch in HLA class antigens.

Hod et al. conducted a retrospective analysis involving 157 first-time kidney transplant recipients (KTR) from living non-immunized donors. Within this cohort, 96 individuals exhibited low HLA antigen mismatch 5–6 mismatches within HLA loci. The low HLA mismatch subgroup was divided into 52 recipients who received basiliximab alone and 44 recipients treated with a combination of a single dose of ATG (1.5 mg/kg) and basiliximab. The primary endpoint was early acute cellular rejection (ACR) within 6 months post-transplant, while secondary endpoints included infection rates, graft function, length of hospital stay (LOS), and hospital readmissions after transplantation.

The analysis results indicated that the incidence of early acute cellular rejection (ACR) was lower in recipients with low HLA mismatch who received induction therapy with ATG-basiliximab compared to recipients who received basiliximab alone (9.1% vs. 23.9%, P = 0.067). Age was a predictor of rejection, while subgroup analysis showed a consistent reduction in rejection across all age groups. However, no significant differences were observed in transplant-related length of hospital stay, perioperative complications, infection rates, graft function, or the number of hospital readmissions up to 6 months post-transplant.

It can therefore be concluded that in first-time, non-immunized kidney transplant recipients from living donors with low HLA mismatch, an induction approach using combined ATG-basiliximab therapy significantly reduced the incidence of early acute cellular rejection (ACR) without compromising the safety of the treatment. [9,10]

1.2 Low-Dose Thymoglobulin Therapy Compared to Basiliximab Induction in Low-Risk Living Donor Kidney Transplant Recipients: A Three-Year Observational Study.

Martinez-Mier et al., in their observational study (3-year follow-up) based on a single-center randomized controlled clinical trial, aimed to assess the impact of low doses of ATG compared to basiliximab induction on outcomes after kidney transplantation. The primary endpoints were patient and graft survival, the incidence of biopsy-proven acute rejection (BPAR), as well as graft function measured by the estimated glomerular filtration rate (eGFR) calculated using the MDRD-4 formula. Other endpoints included infectious complications and adverse events. The study involved a group of 100 kidney transplant recipients divided into two groups: 53 patients receiving basiliximab (BG) and 47 patients receiving ATG (TG).

Patients in the BG group underwent kidney transplant biopsies more frequently than patients in the TG group (50% vs. 31.8%, p = 0.07). Although the 12-month cumulative incidence of biopsy-proven acute rejection (BPAR) was lower in the BG group, by the end of the three-year follow-up period, this incidence was higher (22%) than in the TG group (15%) (p = ns). Steroids were more frequently withdrawn in the TG group, and sirolimus was the most commonly indicated drug. Graft function and graft survival were higher in the TG group than in the BG group after three years of follow-up, but the differences were not statistically significant. Patient survival was similar between both groups (>90%).

Martinez-Mier et al. concluded in the above-mentioned study that the data from the three-year follow-up period confirm the efficacy and favorable safety profile of low-dose ATG (3 mg/kg) in low-risk transplant recipients.[11]

1.3. Comparative Analysis of Kidney Transplant Outcomes with Steroid Use Versus Steroid Withdrawal Following Induction Immunosuppression with Basiliximab and ATG: A Study Based on the UNOS Database.

The relative safety and efficacy of early steroid withdrawal in kidney transplant recipients after induction immunosuppression with basiliximab compared to ATG remain unknown. Nissaisorakarn et al. conducted a retrospective cohort analysis of the United Network for Organ Sharing (UNOS) database, including first-time kidney transplant recipients who received induction therapy with either basiliximab or ATG. Mortality and graft failure rates were compared between patients maintained on steroid therapy and those who discontinued steroids following induction with the aforementioned agents.

Among 106,061 patients who received basiliximab induction, 86.7% remained on steroid therapy (B - Sm), while 13.3% were on a steroid-free regimen (B-Sf). The graft failure rate was significantly higher in the B-Sf group compared to the B-Sm group at 1 year (4.1% vs. 1.8%, p < 0.001), 3 years (6.0 % vs. 4.3 %, p < 0.001), and 5 years (7.7% vs. 6.4%, p = 0.0004). Mortality was higher in the B-Sf group at 1 year (3.3 % vs. 2.4 %, p = 0.0005), 3 years (7.6 % vs. 5.5%, p < 0.001), and 5 years (11.5 % vs. 8.8%, p < 0.001).

A total of 76,837 recipients received ATG induction, of whom 72.4% were maintained on steroid therapy (A-Sm), while 27.6% were on a steroid-free regimen (A-Sf). The graft failure rate was higher in the A-Sf group compared to A-Sm at 1 year (2.6% vs. 2.3%, p = 0.0006), but there were no differences at 3 years (5.0% vs. 5.0 %, p = 0.53) or 5 years (7.2% vs. 8.1%, p = 0.17). No differences in mortality were observed between the A-Sf and A - Sm groups at 1 year (2.5% vs. 2.4%, p = 0.98) or at 3 years (5.5% vs. 5.4%, p = 0.45). (Table 1)

Table 1. Graft Failure Rate and Mortality in Patients with Steroid Maintenance versus Steroid Withdrawal after Induction Immunosuppression with Basiliximab and ATG following Kidney Transplantation.

Group of patients	Steroids	% of all patients	Graft failure rate						Mortality					
			1 year	p	3 years	p	5 years	p	1 year	p	3 years	p	5 years	P
Receiving basiliximab n = 106 061	+	86,7%	1,8%	0.001	4,3%	0.001	6,4%	0.0004	2,4%	0,0005	5,5%	<0,001	8,8%	<0,001
	-	13,3%	4,1%		6,0%		7,7%		3,3%		7,6%		11,5%	
Receiving ATG n = 76 837	+	72,4%	2,3%	0,0006	5,0%	0,53	8,1%	0,17	2,4%	0,98	5,4%	0,45	-	-
	-	32,6%	2,6%		5,0%		7,2%		2,5%		5,5%		-	

Based on the collected data, it was concluded that patients who remained on steroid therapy after basiliximab induction had better graft survival outcomes and lower mortality at 5 years compared to patients who discontinued steroid therapy. However, maintaining steroid therapy after ATG induction did not provide additional benefits and was associated with higher mortality. [12]

1.4. The Necessity of Modifying Induction Immunosuppression in Elderly Kidney Transplant Recipients.

Immunosenescence is the decline in many immunological parameters in elderly individuals compared to young, healthy people. [13] It gradually impairs the functioning of the immune system, making older patients more susceptible to infections while simultaneously less prone to transplant rejection. Therefore, it is necessary to adjust immunosuppressive therapy according to the patient's age. [14]

Kim et al. conducted a retrospective analysis including 704 kidney transplant recipients between June 2011 and April 2019. Patients were divided into two groups based on age: younger than 60 years as the younger group, and older than 60 years as the older group. The older group comprised 74.6% of recipients, while the younger group accounted for 25.4%. The study compared infection rates and biopsy-proven acute rejection (BPAR) depending on the induction agent used, namely basiliximab and ATG.

When ATG was used as the induction agent, fewer cases of biopsy-proven acute rejection (BPAR) occurred within 6 months ($p = 0.03$); however, infections were more frequent in older kidney transplant recipients during this period. Deaths due to infection were more common in the older recipient group ($p = 0.003$). Therefore, less intensive induction therapy may be necessary for older transplant recipients, with dose reduction of ATG being one possible approach. [15]

1.5. The Impact of Immunosuppressive Agents Used in Induction Immunosuppression on T Lymphocyte Subpopulations after Kidney Transplantation.

Kim et al. conducted a prospective observational study aimed at investigating the impact of induction immunosuppression using basiliximab and ATG on T lymphocyte dynamics in the early post-transplant period after kidney transplantation. The study included 157 recipients, who were assigned to two groups: 39.5% received ATG and 60.5% received basiliximab. To analyze the T lymphocyte phenotype, peripheral blood samples were collected from each patient 5 days before transplantation, and at 4 and 12 weeks post-transplant. Flow cytometry was used to analyze T lymphocyte subpopulations, and changes in their levels were evaluated.

In the group receiving ATG, a significant decrease in CD4+ lymphocyte expression was observed compared to the basiliximab group. Conversely, the expression of CD4+CD161+ and CD4+CD25+CD127low lymphocytes significantly increased in the ATG group. Within the CD8+ lymphocyte subpopulation in the ATG group, a decrease in CD8+CD28nullCD57+ and CD8+CCR7+ expression was noted. Furthermore, among patients with biopsy-proven acute rejection, differences in T lymphocyte subpopulation expression were not significant compared to cases without rejection.

Induction therapy with ATG caused more pronounced changes in T lymphocyte subpopulations than basiliximab therapy. In the ATG group, an increase in CD4+CD161+ and CD4+CD25+CD127low lymphocytes was observed, as well as an early decrease in CD8+CD28nullCD57+ and CD8+CCR7+ lymphocytes, some of which may be associated with acute transplant rejection. [16]

1.6. Very low dose antithymocyte globulin (ATG) compared to basiliximab in non-immunized kidney transplant recipients.

Masset et al. conducted a retrospective multicenter cohort study comparing the efficacy and safety of very low-dose ATG with basiliximab in non-immunized kidney transplant recipients. The study included patients who received induction therapy with a very low dose of ATG (total dose ≤3 mg/kg) or basiliximab (20 mg before and after transplantation). Patients with negative panel reactive antibody (PRA) results and without donor-specific antibodies (DSA) were included. The primary endpoints were the incidence of biopsy-proven acute rejection (BPAR) within 12 months, graft and patient survival at 12 months, the frequency of infectious complications, and other adverse events.

The incidence of biopsy-proven acute rejection (BPAR) in the ATG group was 8.2%, compared to 12.1% in the basiliximab group ($p = 0.04$). The ATG group showed a lower rejection rate compared to the basiliximab group. Regarding graft survival, both groups achieved similar rates at 12 months: ATG 96.5%, basiliximab 95.8% ($p = 0.45$). Patient survival was also comparable between groups: ATG 98.2%, basiliximab 97.5% ($p = 0.53$). The ATG group had a slightly higher incidence of CMV viremia (15.4% vs. 11.3%, $p = 0.08$) and BK virus infection (10.5% vs. 8.1%, $p = 0.12$), though these differences were not statistically significant. Additionally, hematologic complications, including leukopenia and thrombocytopenia, were more frequent in the ATG group (21.3% vs. 9.8%, $p = 0.02$), as were hospitalizations within 12 months post-transplant (18.7 % vs. 12.5%, $p = 0.05$).

Therefore, very low-dose ATG constitutes an effective alternative to basiliximab in non-immunized kidney transplant recipients, providing a lower incidence of biopsy-proven acute rejection (BPAR) within the first year after transplantation. [17] However, its use is associated with a slightly higher risk of hematologic complications and hospitalizations. Basiliximab remains a safer option for patients with a higher risk of infections or hematologic complications. [18] To more precisely determine the balance between efficacy and safety of very low-dose ATG and basiliximab in low-risk populations, prospective, randomized studies are needed. [19,20]

1.7. Comparison of the efficacy and safety of basiliximab and ATG in induction immunosuppression after kidney transplantation from a deceased donor.

Hong et al. conducted a study comparing the effectiveness of basiliximab and ATG in induction immunosuppressive therapy in kidney transplant recipients from deceased donors (DDKTR). This multicenter retrospective cohort study analyzed data from DDKTR transplants performed at 10 transplant centers between 2015 and 2020. A total of 1,171 patients were divided into groups based on the induction agent used: basiliximab or ATG. The primary endpoint was biopsy-proven acute rejection (BPAR) within 12 months. Secondary endpoints included graft survival, patient survival, infection rates, and other adverse events within 12 months. Key inclusion criteria were age over 18 years, DDKTR status, and absence of pre-existing donor-specific antibodies (DSA).

The basiliximab group (n = 647, 55.3%) and the ATG group (n = 524, 44.7%) were compared regarding demographics, HLA mismatch levels, and cold ischemia time. The incidence of biopsy-proven acute rejection (BPAR) was 11.4% in the ATG group and 18.7% in the basiliximab group (p = 0.02). ATG induction was associated with significantly lower BPAR rates. Graft survival at 12 months was 92.3% for ATG and 89.6% for basiliximab (p = 0.14). No significant differences were found in 12-month patient survival, which was above 95% in both groups. However, the ATG group had a higher rate of CMV viremia (23.5% vs. 14.9%, p = 0.03) and opportunistic infections, including BK virus viremia (12.8% vs. 8.3%, p = 0.04). Hematologic complications such as leukopenia and thrombocytopenia were more frequent in the ATG group (p < 0.01), and basiliximab was associated with fewer hematologic adverse events. Hospitalizations within 12 months post-transplant were also more common in the ATG group (18.7% vs. 12.5%, p = 0.05).

Induction with ATG demonstrated higher efficacy in reducing biopsy-proven acute rejection (BPAR) compared to basiliximab in kidney transplant recipients from deceased donors. However, it was associated with an increased risk of infections and hematologic complications. Basiliximab remains a safer option for low-risk recipients or those with an elevated risk of infection, while ATG may be preferred for high-risk recipients requiring more aggressive immunosuppression. [21]

Table 2. Comparison of the Efficacy and Safety of Basiliximab and ATG in Induction Immunosuppression Following Deceased Donor Kidney Transplantation.

Endpoints	**Groups of patients receiving:**		**p**
	Basiliximab n = 647, tj. 55,3%	**ATG n = 524, tj. 44,7%**	
BPAR	18,7%	11,4%	0,02
12-month graft survival	89,6%	92,3%	0,14
12-month patient survival	>95%	>95%	-
Viremia CMV	14,9%	23,5%	0,03
Opportunistic infections, including BK viremia	8,3%	12,8%	0,04

2. Basiliximab and ATG in immunosuppressive treatment of patients after heart transplantation.

2.1. The impact of induction therapy on cytomegalovirus (CMV) infection and outcomes after heart transplantation in children receiving routine antiviral prophylaxis.

The study by Zang et al. included 96 children under 18 years old after heart transplantation. Of this group, 46 patients received basiliximab, and 50 patients received ATG induction therapy. The median follow-up period was 3 years (range 1.7 to 4.9 years). All children received routine antiviral prophylaxis to prevent CMV infection. The study aimed to compare the incidence of CMV infection, rejection at 1 year, cardiac allograft vasculopathy (CAV), and mortality between the two induction therapy groups.

The ATG group showed a similar incidence of CMV infection (36% vs. 28.3%, p = 0.418), viremia (22% vs. 19.6%, p = 0.769), and positive tissue biopsies for CMV (30% vs. 22%, p = 0.486) compared to the basiliximab group. However, the ATG group had a significantly lower incidence of rejection at 1 year (16% vs. 36.9%, p = 0.022) and cardiac allograft vasculopathy (CAV) (4% vs. 23.9%, p = 0.006), with no difference in mortality (8% vs. 15.2%, p = 0.343).

Induction with ATG was associated with a lower risk of rejection at 1 year in children after heart transplantation who received routine antiviral prophylaxis. No significant differences were found in the incidence of CMV infection, cardiac allograft vasculopathy (CAV), or mortality between the ATG and basiliximab groups. These results suggest that ATG may provide better outcomes in reducing rejection in pediatric heart transplant recipients without increasing the risk of CMV infection or mortality compared to basiliximab. However, further studies are needed to confirm these findings and assess the long-term effects of such therapy. [22]

Conclusions

Induction immunosuppression is a key component of transplant protocols, especially in patients with increased immunological risk. According to the 2021 guidelines of the Polish Transplantation Society, it is recommended in retransplantation, high panel reactive antibody (PRA) levels, donor-specific antibodies (DSA), HLA mismatch, and in simultaneous pancreas-kidney transplantation, as well as in selected heart and liver transplant recipients.

Induction therapy utilizes either polyclonal antibodies (e.g., ATG, Grafalon) or monoclonal antibodies targeting the interleukin-2 receptor (e.g., basiliximab). In patients with high immunological risk, lymphocyte-depleting agents (ATG, Grafalon) should be used for induction therapy, whereas in cases of moderate or low risk, anti-CD25 agents (basiliximab) are recommended. [23] These drugs are typically combined with glucocorticosteroids. Recent studies, primarily in kidney transplantation, have compared low-dose ATG vs. basiliximab, combination therapies, and the presence or absence of steroids. Results suggest that ATG may be a safe and effective alternative to basiliximab, while the latter may be preferable in older or infection-prone patients. One study on pediatric heart recipients indicated ATG may reduce rejection rates without increasing CMV infection or mortality.

The choice of induction agent should be tailored to the recipient's immunological risk and clinical condition. Prolonged ATG induction can delay the initiation of calcineurin inhibitors in patients with impaired renal function. To refine and personalize induction protocols, further prospective, multicenter studies across various organ types are necessary.

Disclosures

Author's contribution:
Conceptualization: M.S., A.G., D.N., A.Z.
Formal analysis: J.T., M.G., F.Sz., B.Ż., K.K., P.M.
Methodology: M.S., A.G., F.Sz., A.Z., M.G.
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