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Effectiveness and safety of Basiliximab as induction therapy in liver transplantation: A Retrospective Cohort Study in a Tertiary Hospital in southern Brazil

Chaiane Lemos CASTILHOS[1], Camila Schafer ROJAS[2], Carine Raquel BLATT[1]

[1]Universidade Federal de Ciências da Saúde de Porto Alegre, Rio Grande do Sul, Brasil;
[2]Santa Casa de Porto Alegre, Rio Grande do Sul, Brasil[2].

Corresponding author: Castilhos CL, chaiane.castilhos@ufcspa.edu.br

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Abstract

Objective: to evaluate the effectiveness and safety of basiliximab as induction therapy in adult patients undergoing liver transplantation at a tertiary hospital in southern Brazil. **Methods:** a retrospective cohort study was conducted with adult patients who underwent liver transplantation at a tertiary hospital in southern Brazil from January to December 2023. Patients were divided into two groups: standard immunosuppression regimen (Group 1) and basiliximab induction (Group 2). Sociodemographic variables (sex, age, ethnicity) were evaluated, along with the influence of potential determinants, such as reason for transplantation, pre- and post-transplant comorbidities, presence and type of adverse drug event (ADE), incidence of acute rejection, infections, length of hospital stay, graft loss, and death. **Results:** in 2023, 546 solid organ transplants were performed, of which 109 were liver transplants. Pediatric patients (32), retransplants (4), and patients undergoing multiple organ transplants (3) were excluded, totaling 70 patients. Of these, 51 received a standard immunosuppression regimen (Group 1), and 19 received basiliximab (Group 2). Regarding the sociodemographic profile, most patients were male (Group 1, 78.4%; Group 2, 68.4%) with a mean age of 58.5 and 54.8 years, respectively. Pre-transplant renal dysfunction was slightly more frequent in Group 2 (p=0.05). Regarding post-transplant clinical outcomes, there were no significant differences in survival, infection rate or type, length of hospital stay, graft loss, or death between groups. The acute rejection rate was observed in 17.6% of patients in Group 1, while no cases were recorded in Group 2 (p=0.1). The occurrence of ADEs also did not differ significantly, with 17 cases in Group 1 and 5 cases in Group 2 (p=0.785). **Conclusions:** the use of basiliximab showed no significant differences in survival, acute rejection rate, or other important clinical outcomes, such as infections and mortality, compared to the standard immunosuppression regimen. Additional studies are needed to more precisely assess the role of basiliximab and identify subgroups of patients who may benefit from this intervention.

Keywords: Liver transplant; Induction therapy; Basiliximab.

Efetividade e segurança de Basiliximabe como terapia de indução no transplante hepático: Coorte Retrospectiva em um hospital terciário do sul do Brasil

Resumo

Objetivo: avaliar a efetividade e segurança do uso de basiliximabe como terapia de indução em pacientes adultos submetidos a transplante hepático em um hospital terciário no sul do Brasil. **Métodos:** estudo de coorte retrospectivo realizado com pacientes adultos submetidos a transplante hepático em um hospital terciário do sul do Brasil entre janeiro a dezembro de 2023. Os pacientes foram divididos em dois grupos: regime padrão de imunossupressão (Grupo 1) e indução com basiliximabe (Grupo 2). Foram avaliadas variáveis sociodemográficas (sexo, idade, etnia), além da influência de possíveis determinantes, como: motivo do transplante, comorbidades pré e pós transplante, presença e tipo de evento adverso a medicamento (EAM), incidência de rejeição aguda, infecções, tempo de internação hospitalar, perda do enxerto e óbito. **Resultados:** em 2023 foram realizados 546 transplantes de órgãos sólidos, sendo 109 de fígado. Excluíram-se os pacientes pediátricos (32), retransplantes (4) e que realizaram transplante de múltiplos órgãos (3), totalizando 70 pacientes. Destes, 51 usaram regime padrão de imunossupressão (Grupo 1) e 19 usaram basiliximabe (Grupo 2). Em relação ao perfil sociodemográfico, a maioria dos pacientes era do sexo masculino (Grupo 1, 78,4%; Grupo 2, 68,4%), idade média de 58,5 e 54,8 anos, respectivamente. A disfunção renal pré transplante foi ligeiramente mais frequente no Grupo 2 (p=0,05). Quanto aos desfechos clínicos pós transplante, não houve diferenças significativas na sobrevida, taxa ou tipo de infecção, tempo de internação hospitalar, perda de enxerto e óbito entre os grupos. A taxa de rejeição aguda foi observada em 17,6% dos pacientes do Grupo 1, enquanto nenhum caso foi registrado no Grupo 2 (p=0,1). A ocorrência de EAM também não diferiu significativamente, sendo 17 casos no Grupo 1 e 5 casos no Grupo 2 (p=0,785). **Conclusões:** o uso de basiliximabe não apresentou diferenças significativas na sobrevida, taxa de rejeição aguda ou outros desfechos clínicos importantes, como infecções e mortalidade, comparado ao regime padrão de imunossupressão. Com base nos resultados e nos custos do basiliximabe sugere-se que estudos adicionais para avaliar com mais precisão a efetividade deste medicamento e identificar subgrupos de pacientes que possam se beneficiar dessa intervenção.

Palavras-chave: Transplante hepático; Terapia de indução; Basiliximabe.

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Introduction

Liver transplantation remains a life-saving hope for thousands of patients in Brazil and worldwide, as it is the only definitive treatment for patients with severe liver diseases where drug therapy or other treatments are not effective. According to the Brazilian Association of Organ Transplantation (ABTO), the number of liver transplants in Brazil has been consistently increasing. In 2022, 2,211 liver transplants were performed, with the main source of donations being organs from deceased[1] donors. The improvement in surgical techniques, advances in organ procurement and allocation logistics, and the development of new immunosuppressive drugs have been crucial in increasing the survival of transplant patients, which is currently estimated at 5 years[1].

Immunosuppressive therapy, used to prevent rejection of the transplanted organ, can be divided into induction therapy and maintenance therapy. Induction therapy is usually performed before the surgical procedure, aiming to prevent acute rejection of the graft. Maintenance therapy is administered long-term to ensure continuous acceptance of the organ, requiring the patient to regularly and chronically use immunosuppressive drugs to maintain proper function of the transplant[2].

Calcineurin inhibitors (CNIs), such as tacrolimus and cyclosporine, have played a crucial role in the success of liver transplantation by reducing initial immune damage and acute[3] rejection rates. Despite their significant contribution to improving survival after liver transplantation, the use of these drugs is associated with an increased risk of renal failure and the development of comorbidities such as diabetes, dyslipidemia, and hypertension, which negatively impact the quality of life of patients and increase morbidity[4,5].

In this scenario, basiliximab emerges as a promising therapeutic alternative. It is a chimeric monoclonal antibody that blocks the CD25 subunit of the IL-2 receptor, preventing activation and proliferation of T lymphocytes[6]. This agent is used as an immunosuppressive induction therapy, administered in two intravenous doses: the first 2 hours before surgery and the second 4 days after transplantation[7]. In some protocols, basiliximab is indicated for patients with renal impairment, allowing for a delayed introduction of CNIs, which can help reduce renal impact until renal function stabilizes[8].

The use of basiliximab in the context of liver transplantation is still not consensual, and in some cases, induction immunosuppression is performed exclusively with corticosteroids, such as methylprednisolone, which is widely used in patients without significant comorbidities, with good clinical results[6,9]. Regarding adverse reactions related to basiliximab, there is limited data mentioned in the literature, with studies citing effects related to the patient's immune suppression (susceptibility to infection). Regarding methylprednisolone, analyses demonstrate a wide range of adverse events related to its use, such as metabolic disturbances (diabetes, hypertension, dyslipidemia, among others), infections, and delirium, which raise concerns about its use[10,11].

In light of these considerations, this study aims to evaluate the effectiveness and safety of basiliximab as induction therapy in adult patients undergoing liver transplantation in a hospital in southern Brazil.

Methods

This is a retrospective cohort study, conducted from January to December 2023. The retrospective nature of a cohort study allows for the collection of historical data on exposure factors, enabling longitudinal follow-up of individuals over a defined period, an approach that offers the advantage of evaluating the effectiveness and safety of therapies.

The participants in the study were adult patients (aged 18 years or older) of both sexes who underwent liver transplantation, with or without induction therapy using basiliximab. The study was conducted at the Santa Casa de Porto Alegre at the tertiary hospital Dom Vicente Scherer, a philanthropic institution with a total of 66 beds, including 55 inpatient beds and 11 ICU beds. This hospital is an internationally recognized reference in transplants and has a specialized medical team.

Exclusion criteria included pediatric patients, retransplants, and multi-organ transplants. Data were collected from patients' electronic medical records through the TASY® hospital management system.

The patients were divided into two groups: those who received the standard immunosuppressive induction regimen, characterized by the administration of methylprednisolone during the intraoperative period (Group 1), and those who received basiliximab (Group 2) as immunosuppressive induction therapy. In the basiliximab induction group, a dose of 20 mg intravenous was administered intraoperatively, followed by a second dose on the fourth postoperative day. In Group 1, corticosteroids were administered intraoperatively in doses of 500 mg to 1g of intravenous methylprednisolone, followed by postoperative doses starting at 40 mg from day 1 to day 3, reducing to 20 mg/day until day 6, then transitioning to oral prednisone at 0.3 mg/kg/day, with gradual discontinuation after three months. Tacrolimus (TAC) and mycophenolate mofetil (MMF) were introduced between days 3 and 10, depending on renal function status, with tacrolimus adjusted to maintain levels of 7–10 ng/mL until the third month, then reduced to 5–7 ng/mL, according to the Clinical Protocol for Immunosuppressive Guidelines and Therapies in Liver Transplantation[7].

The variables collected included sociodemographic data (sex, ethnicity, and age), characteristics of liver transplantation (reason for transplantation, induction therapy, maintenance therapy, ICU and hospital length of stay), and pre- and post-transplant comorbidities. Adverse drug events (ADEs) were recorded as any reaction or adverse event that could be related to the immunosuppressive therapy.

The primary outcome was mortality within the first 12 months after liver transplantation. Secondary outcomes included acute rejection, graft loss, renal dysfunction, and other complications such as infections, hepatic artery thrombosis, and biliary disorders. Acute rejection was confirmed by biopsy according to Banff criteria, and renal dysfunction was defined by creatinine levels above 1.5 mg/dL or a 50% increase from baseline, following Rufle criteria[12].

Statistical analysis was performed using SPSS version 28.0. The Student's t-test was applied to compare means. In case of asymmetry, the Mann-Whitney test was used. For comparing proportions, Pearson's chi-squared test or Fisher's exact test were applied. Kaplan-Meier curves were constructed to evaluate the time to death after transplantation and compared using the log-rank test. The significance level adopted was 5% ($p<0.05$).

The study was approved by the Research Ethics Committee (CEP) of the institution under opinion No. 7.066.904.

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Results

During the analyzed period, 546 solid organ transplants were performed at the reference hospital, of which 70 patients met the inclusion criteria for the study, as shown in Figure 1.

Figure 1. Inclusion Diagram of Liver Transplant Patients in 2023 at a Specialized Hospital in Southern Brazil.

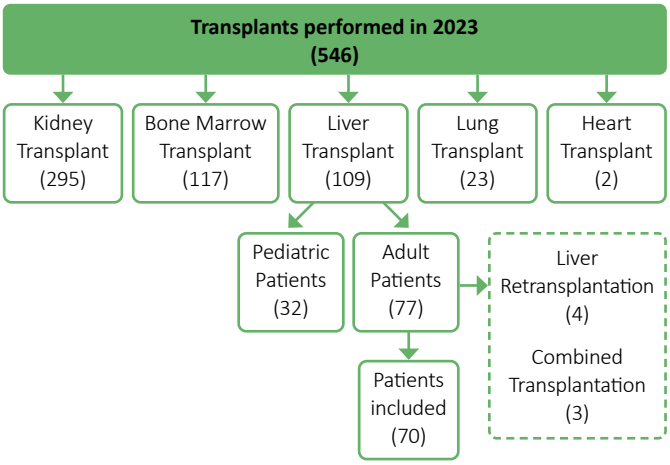


Table 1 presents the characteristics of the sample, including sex, age, ethnicity, reason for transplantation, and pre-existing comorbidities, with the majority of the group being male and white in both groups. It also presents pre-transplant comorbidities, with hypertension (37.3%) being the most frequent in Group 1, while diabetes (52.6%) was more prevalent in Group 2. Pre-transplant renal dysfunction was more common in the basiliximab induction therapy group (15.8%). It was also observed that renal function, measured by serum creatinine levels, remained stable pre- and post-transplant (median 1 mg/dL) in Group 2, while in Group 1, the median increased from 0.8 mg/dL to 1 mg/dL without statistical significance (p = 0.101).

The main reason for transplantation in Group 1 was cirrhosis caused by the Hepatitis C Virus (HCV) (31.4%), followed by cirrhosis due to alcohol (27.5%). In Group 2, the frequency of cirrhosis caused by alcohol was 31.6%, followed by cirrhosis due to non-alcoholic steatohepatitis (NASH) at 26.3%.

Table 2 presents the post-transplant clinical outcomes. It shows that the percentage of adverse drug events (ADEs) was 33.3% in the standard immunosuppressive regimen group (n=17), compared to 26.3% in the basiliximab induction therapy group (n=5; p = 0.785). The most frequent adverse event was hyperglycemia, associated with the use of methylprednisolone and tacrolimus, followed by neurological alterations, also associated with tacrolimus.

Most patients in both groups were discharged from the hospital (Group 1, 88.2%; Group 2, 89.5%). Acute rejection and graft loss were observed in the standard immunosuppression group (17.6% (p=0.101) and 2% (p=1.000), respectively), while no cases of acute rejection or graft loss were recorded in the basiliximab group. The mortality rates were similar between the groups (Group 1, 11.8% and Group 2, 10.5%; p = 1.000).

Figure 2 presents the Kaplan-Meier curves for evaluating 12-month survival after liver transplantation. No statistically significant differences were observed between the groups at 3, 6, 9, and 12 months (p=0.935).

Table 1. Sociodemographic and Clinical Profile of Adult Patients Undergoing Liver Transplantation in 2023. Using Standard Immunosuppressive Regimen (Group 1) or Basiliximab (Group 2).

Variables	Group 1* (n= 51)	Group 2** (n= 19)	P
Age (years) – mean ± SD	58.5 ±12.4	54.8 ±14.0	0.286
Sex – n(%)			0.531
Male	40 (78.4)	13 (68.4)	
Female	11 (21.6)	6 (31.6)	
Ethnicity – n(%)			0.604
White	42 (82.4)	17 (89.5)	
Mixed race	7 (13.7)	1 (5.3)	
Black	2 (3.9)	1 (5.3)	
Comorbidities prior to LT – n(%)			
Hypertension	19 (37.3)	6 (31.6)	0.873
Diabetes	16 (31.4)	10 (52.6)	0.174
Dyslipidemia	6 (11.8)	1 (5.3)	0.665
Renal dysfunction	1 (2.0)	3 (15.8)	0.058
Creatinine (mg/dL) – median (P25-P75)	0.8 (0.7-1.0)	1.0 (0.6-1.6)	0.243
Reason for LT – n(%)			0.677
Cirrhosis due to HCV	16 (31.4)	4 (21.1)	
Cirrhosis due to HBV	3 (5.9)	0 (0.0)	
Cirrhosis due to alcohol	14 (27.5)	6 (31.6)	
Cirrhosis due to NASH	9 (17.6)	5 (26.3)	
Others	9 (17.6)	4 (21.1)	

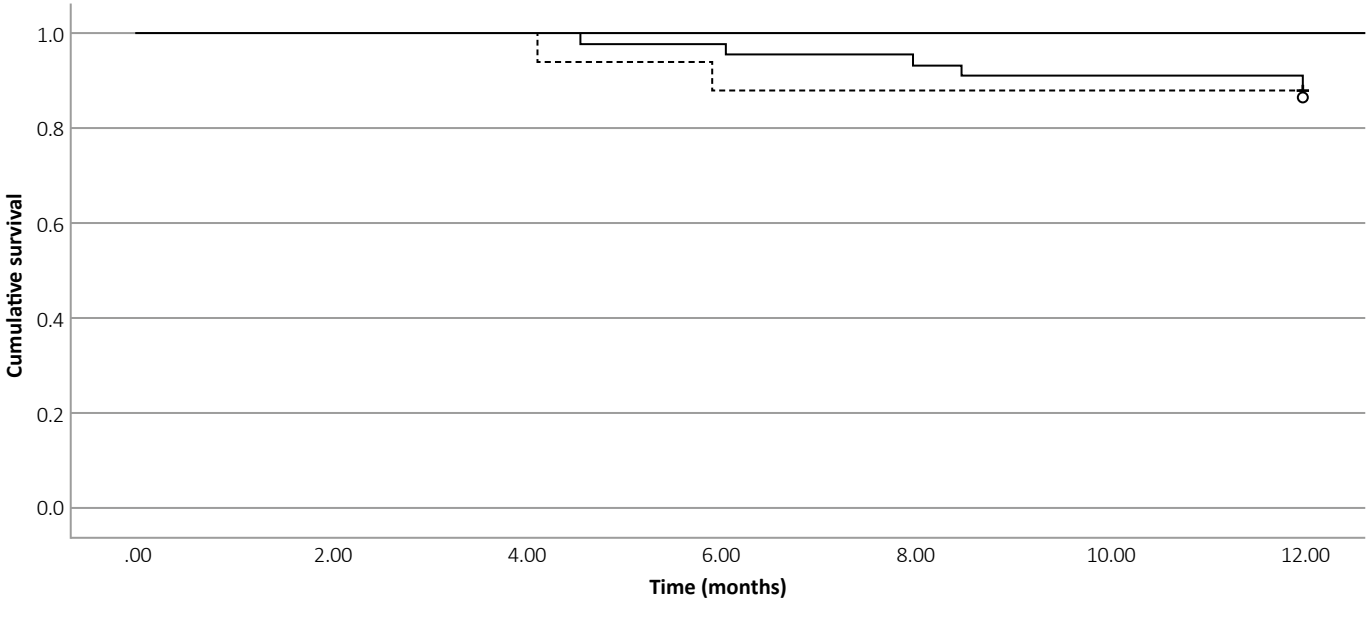
***Group 1:** standard immunosuppression regimen; ****Group 2:** basiliximab group, LT: liver transplantation, HCV: hepatitis C virus, HBV: hepatitis B virus, NASH: non-alcoholic steatohepatitis.

Table 2. Clinical Outcomes in Adult Patients Undergoing Liver Transplantation in 2023. Using Standard Immunosuppressive Regimen (Group 1) or Basiliximab (Group 2).

Variables	Group 1* (n= 51)	Group 2** (n= 19)	P
Post-TxL infections – n(%)			
CMV+	24 (47.1)	11 (57.9)	0.591
Bacteremia	22 (43.1)	12 (63.2)	0.222
Fungemia	2 (3.9)	0 (0.0)	1.000
Post-TxL complications – n(%)			
Hypertension	6 (11.8)	0 (0.0)	0.180
Diabetes	9 (17.6)	0 (0.0)	0.101
Dyslipidemia	2 (3.9)	1 (5.3)	1.000
Kidney dysfunction	17 (33.3)	3 (15.8)	0.251
Creatinine – median (P25 – P75)	1.0 (0.9-1.70)	1.0 (0.8-2.0)	0.931
Hepatic artery thrombosis	8 (15.7)	3 (15.8)	1.000
Biliary disorders	6 (11.8)	3 (15.8)	0.696
Adverse Drug Event (ADE) – n(%)	17 (33.3)	5 (26.3)	0.785
Acute rejection – n(%)	9 (17.6)	0 (0.0)	0.101
Graft loss – n(%)	1 (2.0)	0 (0.0)	1.000
ICU stay (days) – median (P25 – P75)	5 (4-7)	7 (4-12)	0.103
Hospital stay (days) – median (P25 – P75)	25 (20-43)	27 (20-39)	0.953
Outcome – n(%)			1.000
Discharge	45 (88.2)	17 (89.5)	
Death	6 (11.8)	2 (10.5)	

***Group 1:** standard immunosuppression regimen; ****Group 2:** basiliximab group, TxL: liver transplantation, CMV: cytomegalovirus, ADE: adverse drug event, ICU: intensive care unit.

Figure 2. Kaplan-Meier Curve to Evaluate Survival After Liver Transplantation in Adult Patients Undergoing Standard Immunosuppression or Basiliximab Therapy (Log-rank test; p=0.935).



Groups	Survival Probability			
	3 months	6 months	9 months	12 months
1*	100%	98.0%	92.2%	88.2%
2**	100%	89.5%	89.5%	89.5%

***Group 1:** standard immunosuppression regimen group; ****Group 2:** basiliximab group.*

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Discussion

Our results indicated that there were no statistically significant differences in survival, acute rejection, or graft loss between liver transplant patients treated with basiliximab and those who received the standard immunosuppressive regimen.

A large number of published studies have focused on evaluating the use of basiliximab as induction therapy in kidney transplantation, due to its renal-preserving[9,10,13] profile. Previous research suggests that its use may reduce adverse events and preserve renal function, with no significant impact on primary outcomes such as mortality and acute rejection[9,10,15,16]. However, many uncertainties remain regarding the risks and benefits of using this medication in liver transplantation. To the authors' knowledge, this is the first study to evaluate the use of basiliximab in adult patients undergoing liver transplantation in the southern region of Brazil.

For example, in a study by Lin and colleagues, a lower incidence of post-transplant renal failure was observed in the basiliximab-treated group compared to the control group (26% vs. 67%; $p < 0.01$), despite similar rates of acute rejection, CMV infection, and recent-onset diabetes[17]. A recent study published in the *Journal of Hepatology* reported that basiliximab helps preserve renal function postoperatively, especially in patients with chronic renal failure[8]. The present study observed that renal function remained stable pre- and post-transplant for patients receiving basiliximab, while the standard immunosuppression group showed an increase in median creatinine, though without statistical significance. This result may have been influenced by the fact that patients receiving basiliximab had pre-existing renal damage before transplantation (p=0.05), making them more severely ill and in need of therapy with renal protective effects. This statistically significant finding supports the use of basiliximab in patients with renal dysfunction, even though there was no statistical difference in primary outcomes.

Regarding adverse events, Claeys and colleagues highlighted that calcineurin inhibitors (CNIs) are associated with a range of adverse drug events (ADEs), whereas basiliximab can act as a sparing agent for these drugs, with few ADEs reported in association with its use[18]. A delayed start of tacrolimus in post-transplantation immunosuppression is suggested in various studies in the literature, with Kourkoumpetis and colleagues linking this delay to reduced nephrotoxicity[19]. Another recurring adverse effect related to tacrolimus is neurotoxicity, which was noted in this study, where participants presented neurological symptoms such as tremors, delirium, and posterior reversible encephalopathy syndrome (PRESS). The findings from previous studies[18,19] support our results, as no ADEs directly associated with basiliximab were observed, although the sample size in this study was relatively small.

Regarding hospital and ICU stay, both groups showed similar lengths of stay. These findings align with the literature, as evidenced by a single-center study conducted in Egypt in 2020, which also found no statistically significant difference in hospital stay between the basiliximab and standard immunosuppression therapy groups[9]. In the current analysis, the median hospital stay in the standard immunosuppression group was 25 days, while the group that used basiliximab had a median hospital stay of 27 days. The previously mentioned study reported a mean of 29 days for the standard therapy group compared to an average of 47 days for patients receiving basiliximab therapy[9].

There was concern about the increased incidence of infections, including CMV, bacterial, and fungal infections, in patients who received basiliximab. However, we did not identify a significant difference in the incidence of these infections, nor in post-transplant comorbidities such as diabetes, hypertension, dyslipidemia, hepatic artery thrombosis, and biliary disorders, between the groups studied. The meta-analysis by Zhang et al. (2017), which evaluated randomized clinical trials on the use of basiliximab in liver transplantation, found results indicating a significant reduction in the incidence of recent-onset diabetes mellitus (RR=0.56; p=0.02) and a lower rate of acute rejection when combined with steroid-free regimens (RR=0.62; p=0.04). This study supports our findings related to post-transplant comorbidities such as diabetes and hypertension, where the basiliximab group did not show an incidence of diabetes (p=0.101) or hypertension (p=0.180) after transplantation[16]. Other studies have reported similar findings to ours[20,21].

When considering the cost of different immunosuppressive induction therapies in liver transplantation, it is important to note that they have distinct financial implications. While a 125mg vial of injectable methylprednisolone costs $1.36, a 20mg vial of injectable basiliximab has a significantly higher cost of $1,058.98.

Comparative studies on the costs of different immunosuppressive therapies are scarce, but a systematic review by Moini et al. highlights that monoclonal antibodies, such as basiliximab, can increase perioperative care costs, whereas the cost of corticosteroids is lower[11]. These findings align with the cost-effectiveness analysis by Boyd et al.[22] The study also suggests that prescribing personalized immunosuppressive regimens may improve cost-effectiveness, as adapting treatment to patient characteristics can increase graft longevity and reduce long-term costs.

Cost-effectiveness analysis becomes relevant to optimize resource allocation in healthcare systems and propose more affordable interventions for patients. Considering that, in this study, both therapies demonstrated equivalent efficacy in primary outcomes (mortality and acute rejection), the standard induction therapy with methylprednisolone emerges as the more cost-effective alternative, as it provides similar clinical results with a significantly lower financial impact. Nonetheless, the therapeutic decision should consider individual factors, such as the patient's clinical profile and the potential adverse effects associated with each medication. Therefore, the choice of basiliximab would only be economically justified if substantial clinical advantages, such as renal protection, are demonstrated, even though this was not evidenced in the current study, but it is presented in the literature.

The limitations of this study include its single-center design and the relatively small sample size, particularly in the basiliximab group, which limits the generalizability of the results. Additionally, as a retrospective cohort study, there is a potential for selection bias, which is also related to the time period studied. Another limitation is the analysis of renal function based on median creatinine levels, which may have obscured important clinical variations. Larger studies with standardized protocols are needed to validate these findings.

Although current immunosuppressive therapies have significantly improved patient and graft survival, challenges remain, such as long-term toxicity, the risk of infections, and the occurrence of both acute and chronic rejection[6,23]. Therefore, future research addressing immunosuppressive therapies, particularly basiliximab,

is crucial to improve patient outcomes, minimize post-transplant complications[19,23,24], and contribute to the identification of safer and more effective immunosuppressive regimens. Research into new immunosuppressive agents and reevaluating existing drug combinations may also help reduce adverse events and improve patients' quality of life. Moreover, monitoring effectiveness and safety outcomes in real-life settings is important to provide evidence and guide healthcare decision-making.

Conclusion

The use of basiliximab as an immunosuppressive induction therapy in adult liver transplant recipients did not show statistically significant differences in the primary outcomes of mortality and acute rejection compared to the standard immunosuppressive therapy. Although basiliximab therapy presents a potentially more favorable adverse event profile and potential renal function preservation, especially in patients with renal insufficiency, the data found do not support its superiority in terms of efficacy and safety. However, it is important to emphasize that the absence of evidence is not synonymous with evidence of absence, and it is possible that specific therapeutic subgroups may benefit from basiliximab induction therapy.

Additionally, the high costs associated with basiliximab justify its use only in specific situations, such as in patients at risk of renal dysfunction. Furthermore, the lack of statistical significance in outcome variables and the difficulty in standardizing immunosuppressive therapy due to the absence of an established protocol in the studied hospital highlight the need for future studies.

This study, therefore, contributes to the understanding of the impact of basiliximab in the context of liver transplantation but underscores the need for further research to establish specific protocols and evaluate the economic viability of this therapy in different clinical settings.

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Contributors

CLC participated in the conception of the project, data collection, processing and analysis, writing, reviewing, and approving the final version and responsibility for the manuscript for publication. CR participated in the conception of the project, collaborated in data analysis, and reviewed and approved the final version for publication. CRB participated in the conception of the project, collaborated in data analysis, and reviewed and approved the final version for publication.

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Conflict of Interest Statement

The authors declare no conflicts of interest in this study.

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