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Tacrolimus and single intra-operative high-dose of r-atg induction vs. Tacrolimus monotherapy as immunosuppression in liver transplantation: one-year results of an investigator-driven, prospective, randomized, controlled trial

Iesari S.[1,2], Ackenine K.[1], Foguenne M.[1], Komuta M.[3], Ciccarelli O.[1], Coubeau L.[1], Bonaccorsi Riani E.[1], Lai Q.[4], De Reyck C.[1], Gianello P.[5], Lerut J.[1]

[1]Université Catholique de Louvain, T.E. Starzl Abdominal Transplantation Unit, Brussels, Belgium, [2]University of L'Aquila, DISCAB, L'Aquila, Italy, [3]Université Catholique de Louvain, Department of Pathology, Brussels, Belgium, [4]Sapienza University, Department of General Surgery and Organ Transplantation, Rome, Italy, [5]Université Catholique de Louvain, Laboratory of Experimental Surgery and Transplantation, Brussels, Belgium

Background: In liver transplantation (LT), the role of induction with anti-lymphocytic serum in reducing rejection and prompting tolerance is obscure.

Method: We assessed efficacy and safety of rabbit anti-lymphocytic serum (r-ATG, Grafalon®, Neovii) in combination with tacrolimus (TAC, Prograft®, Astellas) in primary adult LT. Our investigator-driven, single-centre, open-label, prospective, randomized, controlled, trial (RCT) allocated patients to r-ATG (a 9 mg/kg intra-operative dose) followed by TAC monotherapy (TAC-ATG group; n=97) and TAC monotherapy (TAC group, n=109).
The primary endpoint was immunosuppression (IS) minimization to monotherapy within 12 months. The secondary endpoints were patient (PS) and graft survival (GS), and one-year biopsy-proven acute cellular rejection (ACR).
All patients had similar clinical and biochemical follow-up (FU) including protocol biopsies. Concordance of Banff score >5 and biochemical score (including bilirubin, platelet and eosinophilia) >2 resulted in ACR treatment. Mean FU for TAC-ATG and TAC groups was 87 and 95 months.

Results: 78/80 (97.5%) TAC-ATG and 100/101 (99.0%) TAC patients were steroid free (p=0.429). A second immunosuppressant (a steroid, antimetabolite or mTOR inhibitor) was administered in 29/80 (36.3%) TAC-ATG and 35/101 (34.7%) TAC patients (p=0.823). No statistically significant differences in one-year PS (83% TAC-ATG vs. 92% TAC patients, p=0.260) and GS (76% TAC-ATG vs. 90% TAC patients, p=0.054) were observed.
A 6-9 Banff score was seen in 25.2% TAC and 16.9% TAC-ATG patients (p=0.164). There was no difference in the percentage of steroid-sensitive rejection (15% TAC-ATG vs. 18% TAC, p=0.449), steroid-resistant rejection (2% TAC-ATG vs. 3% TAC, p=0.628), and chronic rejection (1% TAC-ATG vs. 4% TAC, p=0.307).

Conclusion: This first ever-done RCT comparing r-ATG induction and TAC vs. TAC monotherapy in adult LT did not prove beneficial for IS minimization, survival and ACR treatment, in the short period. Long-term results are required to analyse its influence on tolerance induction. (*EudraCT* 2006-004830-34).

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Outcome of tailored rituximab-based desensitization protocol without local infusion therapy for ABO incompatible adult living donor liver transplantation

Natsuda K., Lee K.-W., Yoon K.C., Hong S.K., Lee J.-M., Cho J.-H., Yi N.-J., Suh K.-S.

Seoul National University College of Medicine, Surgery, Seoul, Korea, Republic of

Introduction: Rituximab (RTx) desensitization protocol in ABO-incompatible (ABOi) living donor liver transplantation (LDLT) offered new paradigm shift beyond ABO blood barrier to obtain donor pool expanding. The Aim of our study is to evaluate the outcome of ABOi adult LDLT using tailored desensitization protocol and to compare with that of ABO compatible (ABOc) LT in single center experience.

Patients and Methods: Between March 2012 and June 2017, 59 cases (13.8%) of ABOi LDLTs were performed in our center among 426 primary adult LDLTs. In ABOi cases, reduced RTx (300mg/m2) was administered around 3 weeks before LDLT, followed by 3 times of plasmapheresis at one week before LT regardless initial and final isoagglutinin titer. If issoagglutinin titer was higher than x32 after the 3 times of plasmapheresis, simultaneous splenectomy with intra- and post- operative high dose intravenous immunoglobulin (5 day s/0.8g/Kg) was selectively added. The immunosuppression was maintained with triple therapy (Tacrolimus, Steroids and Mycophenolate Mofetil). We performed propensity score matching and 120 cases of ABOc LDLTs were selected. Outcomes were then retrospectively compared between ABOc and ABOi cases.

Results: There were no significant differences in recipients' characteristics including MELD score, with HCC or not, and final graft to recipient weight ratio (GRWR) between two groups. Overall survival rates at 5 years are 82.9% in ABOc cases, and 82.5% in ABOi cases without any significant differences. There were also no significant differences in complication rates such as biliary complication, infection, acute cellular rejection. There were no cases with antibody-mediated rejection. In cases with HCC (87 cases of ABOc group, and 42 cases of ABOi group), recurrence-free survival at 5 years were 78.2% in ABOc, and 74.4% in ABOi. There was also no significant difference.

Conclusion: Our RTx-based tailored desensitization protocol for ABOi LDLT was feasible and the outcome was considered acceptable.

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Dual function of IRF1/IRF4 on dendritic cells during mouse liver transplant model

Gu G., Lu T., Xu N., Xia Q.

Renji Hospital, Affiliated by Shanghai Jiaotong University School of Medicine, Shanghai, China

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