

ERRATUM

The OSAKA Trial: A Randomized, Controlled Trial Comparing Tacrolimus QD and BD in Kidney Transplantation: Erratum

In the November 27, 2013 issue of *Transplantation* in the article by Albano and Banas et al, “OSAKA Trial: A Randomized, Controlled Trial Comparing Tacrolimus QD and BD in Kidney Transplantation”, there was an error in the reporting of the confidence intervals for the composite endpoint (the upper values are reported as negative instead of positive values). The incidence of graft loss (overall) and the incidence of delayed graft function (Arm 4) were also reported incorrectly. The corrected passages appear below with the revised information in bold font. These data adjustments do not affect the clinical conclusions that were presented and discussed in this publication.

Primary endpoint (PPS)

Noninferiority was established for efficacy failure rates between Arms 2 and 1; Kaplan-Meier estimates of efficacy failure rates were 42.2% (111 of 263) versus 40.6% (96 of 237), respectively (difference, -1.6%; 95% confidence interval [CI], -12.2% to 9.0%). Noninferiority of efficacy failure between tacrolimus 0.3 mg/kg per day QD (Arm 3: 44.2% [108 of 246]) and Arm 1 was not achieved (difference, -3.5%; 95% CI, -13.6% to 6.6%). Noninferiority for efficacy failure was also not established for Arm 4 (48.2% [110 of 230]) versus Arm 1 (difference, -7.1%; 95% CI, -16.1% to 1.9%).

Secondary endpoints (FAS)

Kaplan-Meier estimates of efficacy failure rates for the FAS demonstrated the noninferiority of Arm 2 versus Arm 1 (43.7% [132 of 302] versus 43.3% [133 of 309]; difference, -0.4%; 95% CI, -10.0% to 9.3%) and did not show noninferiority for Arm 4 (49.4% [138 of 283]) versus Arm 1 (95% CI, -13.7% to 2.4%) (Fig. 2B). However, Arm 3 (44.6% [135 of 304]) did show noninferiority versus Arm 1 for efficacy failure (difference, -1.3%, 95% CI, -10.3% to 7.7%). In total, 7.5% of patients experienced graft loss; 18, 29, 20, and 23 patients in Arms 1 to 4, respectively.

The incidence of delayed graft function in deceased-donor transplant recipients was similar in all arms (Arm 1: 14.2% [38 of 268], Arm 2: 13.8% [37 of 268], Arm 3: 14.4% [39 of 271], and Arm 4: 15.0% [37 of 247]).

REFERENCE

Albano L, Bernhard B, Klempnauer JL, et al. OSAKA Trial: A Randomized, Controlled Trial Comparing Tacrolimus QD and BD in Kidney Transplantation. *Transplantation*. 2013; 96: 897.