

## **Abstract**

**Introduction.** The aim of the study was to introduce a new BKV PCR protocol in our centre and to verify its accuracy as well as to assess the prevalence, risk factors of BK virus replication, course of BKV infection and therapeutic approaches in simultaneous pancreas and kidney (SPK) recipients in order to design a screening protocol.

**Methods.** The results analysed by both Affigene® and Transplantation Virology, Basel PCR protocols were compared. Thereafter 183 SPK patients were examined to assess the prevalence of BK viremia, viruria and BKVN and to identify the risk factors of BKV replication. The cases of retransplantation after a graft loss due to BKVN were retrospectively described.

**Results.** 100 of results were analysed according to the Affigene ® and Transplantation Virology, Basel PCR protocols with the accordance of 95%,  $Rho = 0,946$ , 95% CI: 0.920 – 0.963,  $P < 0,0001$ , Bland–Altman plot analyses: bias Basel PCR protocol/Affigene® BKV trender: -0,1 (mean)  $\pm 1.96$  SD: -1,6 – 1,3] for both methods. Point-prevalence was assessed in 183 patients; Viruria found in 17,3 %, viremia in 3.8% of patients. High-level viruria  $>107$  copies/mL detected in 3,7% of patients, high-level virémia  $>104$  in 1,6% of patients simultaneously with high-level viruria. BKVN was found in 0,5% of patients. Diabetes duration before SPK (OR 5.24, 95% CI (1.22-22.6),  $p = 0.028$ ) and delayed graft function (OR 3.38, 95% CI (1.38-8.24),  $p = 0.0085$ ) were independent risk factors of BKV replication.

**Conclusion.** The Affigene ® PCR protocol newly introduced in our centre is a high-quality and fully comparable method with the Transplantation Virology, Basel PCR protocol. Prevalence of high-level BK viremia, viruria and BKVN were low in our centre. Diabetes duration before SPK and delayed graft function were independent risk factors of BKV replication. Kidney retransplantation after a graft loss due to BKVN is a relevant therapeutic option.