

## **Protocol Biopsies in Solitary Pancreas Transplants. The Wake Forest University School of Medicine Experience.**

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**Background:** Solitary pancreas transplants (SPT) have higher rates of rejection (AR) and lower graft survival than simultaneous kidney-PTs (SKPT). The aim of this study was to determine the impact of protocol pancreas biopsies (bxs) on outcome in SPT.

**Methods:** From 1/02 to 8/06 we performed 29 SPT in 27 patients (pts) with depleting antibody induction and Tac/MMF/steroid immunosuppression (IS). Bxs were performed 3±2 weeks post-transplant and 1 month later if initial bx showed no AR. Bxs were scored according to the Maryland criteria. AR ≥grade II episodes were treated with steroids ±antibody with follow-up (f/u) bxs every 2-4 weeks until inflammation resolved. Grade I bxs were managed by optimizing maintenance IS and f/u bxs as above. Clinical bxs were prompted by biochemical parameters.

**Results:** 26 PAK and 3 PA transplants were performed, with f/u of 2.2±1.3 years (3-58 months). 20 (69%) grafts underwent at least 1 surveillance bx (2.2±0.8 bxs/graft). 4 grafts were not biopsied due to technical failure (TF, 2pts) or early infection (2 pts); 5 pts eluded bx protocol. Of the 20 biopsied grafts, 10 (50%) had inflammation detected (≥grade I) and 8 (40%) had at least 1 bx with AR ≥grade II. 7/8 (88%) AR ≥grade II episodes were subclinical, occurring in the absence of biochemical abnormalities. Pre-bx biochemical parameters and IS levels/doses were similar between grafts with and without AR ≥grade II. 5 of 27 grafts (18.5%, TF excluded) developed clinical AR; none had positive surveillance bxs. One- and 3-year actuarial pt and graft survival rates were 100%, 100% and 86%, 78%, respectively, which is equivalent to the 1-year death-censored pancreas graft survival (86.6%) of 72 contemporaneous SKPT under the same IS. One- and 3-year graft survival rates were similar between pts with treated AR ≥grade II (1- and 3-year 100%) vs. no AR (1-year 90%, 3-year 75%), p=0.28.

**Conclusions:** There is a significant incidence of early subclinical AR in SPT. Protocol pancreas bxs in SPT with aggressive treatment of subclinical AR results in excellent medium-term pancreas graft survival, comparable to that observed in SKPT. The historically inferior pancreas graft survival in SPT may be related to inadequate detection and treatment of early subclinical AR episodes before they become clinically evident.