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## **Assessment of the safety and effectiveness protocol biopsies of transplanted kidney - experiences its own center**

### **Summary**

Renal biopsy remains the primary diagnostic tool for obtaining information on the type, activity, and severity of disease occurring within the kidney. It is considered the gold standard for both the diagnosis of native kidney disease and the determination of renal allograft dysfunction aetiology. Protocol biopsies of the kidney are performed when the kidney function is stable within a specific time frame to detect clinically silent pathological changes. The present investigation was conducted as a retrospective study, without the inclusion of a control group. The investigation evaluated 575 protocol biopsies obtained from renal transplant recipients, predominantly from deceased donors. We analysed protocol biopsies obtained between 2010 and 2020 in patients under the care of the Department of Transplantation, Immunology, Nephrology and Internal Medicine at the Medical University of Warsaw. At our centre, protocol biopsies of the transplanted kidney are usually performed at fixed time points: 0, 3, 12, 36 months after transplantation. For objective reasons, it was not possible to perform so-called early biopsies in all patients undergoing transplantation during this period. Consequently, predominantly late protocol biopsies conducted more than 3 months post-transplantation were analysed. Each patient gave written consent for a protocol biopsy of the transplanted kidney. Immediately before the biopsy, the patient was prepared for this invasive procedure—blood clotting disorders were excluded, antiplatelets and anticoagulants were discontinued, and basic haemodynamic measurements were taken. It is worth noting that 1/3 of the biopsied patients received Acard—this medicine was discontinued 5 days before the protocol biopsy. Renal biopsies were performed by an experienced nephrologist, under ultrasound guidance, using a Magnum BARD equipped with a 16G semi-automatic cutting needle. Usually, 2 specimens were taken and immediately transferred to the Histopathology Laboratory. The specimens were evaluated according to the Banff 97 Classification. After the biopsy, the patient remained in bed for 8–12 hours. On the following day, a follow-up ultrasound was performed to exclude any complications after the biopsy (haematoma, a-v fistula). Follow-up blood tests, urine tests and patient examinations were also performed. Recipients and kidney donors were predominantly male, accounting for >60% of cases. Only 8.5% of recipients received a kidney transplant from a living donor. The

average age of both recipients and donors was 45 years. The mean INR value before biopsy was normal, but in individual patients, the value exceeded the acceptable reference values. The performance of protocol biopsies in such patients should be postponed until the coagulation parameters are stabilised. Paradoxically, a significant increase was observed on the day following the biopsy, both in Hct and Hb concentration, probably due to insufficient fluid intake during the peri-biopsy period. There was no deterioration in the function of the transplanted kidney on the day following the protocol biopsy as assessed by both creatinine concentrations and eGFR. Macroscopic haematuria was not observed in any patient after the protocol biopsy. An increase in microscopic haematuria was observed in one-third of the urinalyses performed, mainly demonstrated as an increase in erythrocyturia from 0–3 per HPF to 4–10 per HPF. An increase in erythrocyturia to 26–100 per HPF was observed in only 6% of the urinalyses performed. These instances did not require any intervention.

In the ultrasound of the transplanted kidney performed on the following day after the protocol biopsy, a trace haematoma was observed in 4.35% of cases, subject only to observation. In only one case was a haematoma observed necessitating surgical intervention and transfusion of 2 units of concentrated red cells. Among the predictive factors examined for all protocol biopsies performed, only elevated INR was identified as a significant risk factor for haematoma formation subsequent to biopsy. Upon detailed analysis, another risk factor for haematoma formation, in addition to the aforementioned INR, in late protocol biopsies was low platelet count. Hct values were observed to be on the threshold of statistical significance. When assessing the efficacy of protocol biopsies, it was found that a representative specimen was obtained in 573 out of 575 protocol biopsies performed. In one-third of cases, subclinical pathologies were detected; these predominantly comprised borderline changes and TCMR.

**Summary:** Patients exhibited a minimal rate of complications following protocol biopsy of the transplanted kidney, with only one case requiring intervention. It is important for the safety of the procedure that every effort is made to ensure that the INR value and platelet counts are within the normal range. Utilising a 16G cutting needle, representative specimens were obtained. It is safe for the patient to perform this procedure. At the same time, the advantages of conducting protocol biopsies are substantial and should not be underestimated. This is attributable to the fact that the application of treatment during the early, subclinical stages of the underlying process may positively impact the function of the transplanted organ and potentially extend its functional lifespan, which, consequently, may also reduce the costs associated with renal replacement therapy.