

THE CLINICAL BENEFIT OF PROTOCOL BIOPSIES FOLLOWING KIDNEY TRANSPLANTATION: A SYSTEMATIC REVIEW

Background:

Protocol (or surveillance) biopsies are defined as those taken without specific clinical indication with the intention of detecting subclinical changes within the graft. There has been longstanding debate regarding the role of protocol biopsies in renal transplant recipients as biopsy is an invasive procedure with definable risks to both graft and recipient, and therefore must be justified by yielding useful information that will modify patient management and improve clinical outcomes.

Methods:

A literature search was performed using Medline, Embase, the Transplant Library and the Cochrane library to identify randomised controlled trials (RCTs) that compare the use of protocol biopsies (with appropriate clinical response) to biopsies for clinical indication only. Studies were assessed for methodological quality using the Jadad scoring system, presence of adequate allocation concealment and an intention-to-treat analysis.

Results:

11 publications from 6 RCTs met the inclusion criteria. All of these studies were of low methodological quality with Jadad scores of 2/5. Heterogeneity in baseline immunosuppression, timing of biopsies and length of follow-up precluded meta-analysis and made interpretation difficult. There were however some important observations. The benefit of early biopsies to detect subclinical rejection in an era of modern immunosuppression (tacrolimus and mycophenolate mofetil) is limited and most benefit is likely to be seen with later biopsies to detect early chronic changes such as interstitial fibrosis and tubular atrophy (IF/TA) or CNI toxicity. Existing studies also suggest that to assess the benefit of a protocol biopsy program, long-term follow-up of longer than 2 years is needed. All studies reported low complication rates from the protocol biopsies with no graft losses, suggesting that the practice is safe in experienced hands.

Conclusions:

Existing studies are of poor quality and provide conflicting results. However, the lessons from these studies can be used to inform the design of future RCTs to answer this important and longstanding question.