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BENEFITS OF CONTROL RENAL BIOPSIES IN THE ASSESSMENT OF ANTI-REJECTION THERAPY EFFICACY IN PATIENTS WITH HISTOLOGICAL LESIONS DIAGNOSED EITHER BY PROTOCOL OR BY "FOR CAUSE" BIOPSIES

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Background and Aims: Efficacy of acute rejection (AR) therapy has always been evaluated based upon improvement of renal function. On the contrary, the degree of histological lesion (HL) regression has rarely been considered for this purpose.

The main goal of this study was to evaluate the percentage of failures in HLs regression after treatment aimed at both "subclinical" and "clinical" AR. Treatment efficacy was therefore evaluated with control renal biopsies (CBs) performed 30-60 days after anti-rejection therapy. In addition, the correlation between graft function and histological data was assessed. The results of treatment for "subclinical" and "clinical" AR were considered separately.

Method: Real-time ultrasound-guided CBs were performed in an outpatient setting using 16G tru-cut needles. The HLs considered were: interstitial inflammation (i), tubulitis (t), glomerulitis (g), arteritis (v), capillaritis (ptc). Each lesion was graded from 0 to 3 (sec Banff 2013-2017). For this study, only HLs with a score $\geq$2 were considered. Therapy failure was determined both by the percentage of patients (pts) with persistence of HLs and by the change of HLs score after treatment, in the control biopsies. Anti-rejection therapy varied according to AR type and severity. In patients failing AR therapy, serum creatinine was evaluated before and after the treatment.

Results: 111 BCs were performed after treatment either for subclinical (n = 47) or for clinical (n = 64) AR. Before therapy, HLs (with score $\geq$2) present in subclinical and clinical AR were: i: 23% and 52%; t: 30% and 30%; g: 34% and 41%; ptc: 11% and 28%; v: 15% and 19%.

After therapy, in the setting of subclinical AR, HLs were still present with a range between 29% (v) and 81% (g) with stable or improved histological score. In this scenario, renal function resulted stable and satisfactory (Tab 1).

In the case of clinical AR, the persistence of histological lesions ranged from 25% (v) to 92% (g), also with stable or improved histological scores. In this case, therapy was always followed by an improvement in renal function (Tab 2).

Conclusion: After AR therapy, only the morphological data obtained with histological analysis can disclose failures of anti-rejection therapy, both in presence of subclinical and clinical AR.

The high rate of treatment failure may explain the correlation between AR and worse graft survival.

Our results could lead us to consider the need for a more aggressive anti-rejection treatment.

Control renal biopsies after AR therapy should always be considered on clinical grounds.

Histological lesions (HLs) considered in the study	Pts with HLs score ≥ 2 at biopsy	Pts with persistance of HLs at control biopsy	Pts with persistance of HLs at control biopsy					
			Score of HLs (m±sd)			Serum Creatinine (mg/dL; m±sd)		
			pre therapy	post therapy	p	pre therapy	post therapy	p
Interstitial inflammation	11 (23%)	5 (45%)	2,1±0,3	1,4±0,5	0,003	1,6 ± 0,6	1,7 ± 0,6	0,762
Tubulitis	14 (30%)	11 (79%)	2,1±0,3	1,7±0,4	0,009	1,8 ± 0,7	1,8 ± 0,6	1
Glomerulitis	16 (34%)	13 (81%)	2,4±0,5	2,4±0,8	1	1,5±0,4	1,4±0,4	0,509
Capillaritis	5 (11%)	2 (40%)	2,0±0,0	2,0±1,4	1	1,7±0,3	1,3±0,0	0,125
Vasculitis	7 (15%)	2 (29%)	2,4±0,5	2,0±1,4	0,498	1,6±0,3	1,5±0,1	0,668

Table 1. Patients with persistence of HLs after subclinical AR treatment. Grading of histological lesions and renal function before and after therapy.

Histological lesions (HLs) considered in the study	Pts with HLs score ≥ 2 at biopsy	Pts with persistance of HLs at control biopsy	Pts with persistance of HLs at control biopsy					
			Score of HLs (m±sd)			Serum Creatinine (mg/dL; m±sd)		
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Vasculitis	7 (15%)	2 (29%)	2,4±0,5	2,0±1,4	0,498	1,6±0,3	1,5±0,1	0,668

Table 2. Patients with persistence of HLs after clinical AR treatment. Grading of histological lesions and renal function before and after therapy.

Figure: