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SAT0171

RITUXIMAB IN SYSTEMIC AUTOIMMUNE RHEUMATIC DISEASES: ONE CENTER EXPERIENCE OF TREATMENT 515 PATIENTS

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Background: B cells have important functions in the pathogenesis of systemic autoimmune rheumatic diseases (SARDs).

Objectives: The purpose of the research was to study the therapeutic option of Rituximab (RTM), a chimeric anti-CD20 antibody, in SARDs such as ANCA-associated systemic vasculitis (AAV), cryoglobulinemic vasculitis (CV), systemic lupus erythematosus (SLE), systemic sclerosis (SS), primary Sjögren syndrome (pSS) and IgG4-related disease (IgG4-RD).

Methods: We present data on efficacy and safety of RTM in 515 patients (pts) with SARDs. 103 pts had AAV (58- granulomatosis with polyangiitis, GPA; 35- microscopic polyangiitis, MPA and 10- eosinophilic granulomatosis with polyangiitis, EGPA), 21 pts had CV, 167- SLE, 90- SS, 100- pSS, 34- IgG4-RD. Characteristics of pts and results of RTM treatment are present in Table. Mean follow-up duration after initiation of RTM was 25- 58 months.

Results: The average cumulative RTM dose in all groups exceeded 2.4g, 71% of pts received repeated RTM courses (0.5-1.0g) every 4 – 12 months. Complete (good) clinical response was achieved in 70-93% pts, except for the SLE (49%-complete response, 32- incomplete and 19%- no response). Usage of repeated RTM courses increased the clinical efficacy and reduced the risk of recurrence. Despite the fact that the study population included a high percentage of pts with severe or refractory SARDs, total mortality rate was about 6% during the follow-up period, highest in CV and AAV (14-11%). In AAV and SLE infections constitute a significant proportion of serious adverse reactions (10-11%). Late-onset neutropenia was only in pts with AAV (12%) and SLE (3%).

Conclusion: Treatment with RTM was highly effective in SARDs. In certain SARDs RTM safety profile of should be considered during treatment planning. Further studies of the targeted anti-B-cell therapy, including RTM efficacy and safety in SARDs, clarification of the indications and optimal RTM regimens are needed.

Table.

Parameters	AAV		CV	SLE	SS	pSS	IgG4-RD
	GPA, MPA	EGPA					
N pts	93	10	21	167	90	100	34
Age, years	41 (16-67)	50 (24-71)	53.6±29	41 (18-52)	47 (17-71)	42±12,24,74±15,9	
Percentage of females	56%	90%	52%	92%	75%	97%	60%
Duration of disease, months*	14 (1-288)	11 (1-180)	72 (3-96)	18 (2-47)	70 (7-264)	90 (36-168)	24 (6-60)
Cumulative RTM dose, g*	3 (0.5-8)	3 (1.5-5.5)	4.7±3.8	2.4 (1.8±0.8)	2.9 (0.5-6)	5.5±1.5	4±1.5
Follow-up duration after the first RTM course, month*	37 (1-96)	36 (14-94)	52 (6-108)	38 (12-67)	27 (12-42)	58 (24-96)	25 (3-60)
Clinical response, %							
Complete (good)	93%	90%	71%	49%	70%	92.5%	77%
Incomplete response	6%	10%	29%	32%	24%	6.5%	23%
No response	1%	0%	-	19%	6%	1%	-
Relapse	8%	30%	-	-	nd	-	-
Glucocorticoids dose, mg/day*							
Before RTM	30(5-60)	20(7.5-50)	4,4(0-24)	28(15-40)	12(0-7.5)	7.5(0-40)	10(2.5-40)
After RTM	5(0-10)	7.5(5-10)	1.5(0-4)	7.5(5-15)	25 (9(0-15)	1.25	0.5
Immunosuppressants							
% pts before RTM	72%	90%	38%	65%	43%	44%	40%
% pts after RTM	43%	70%	5%	46%	50%	8%	10%
Infusion-related reactions, including severe	9%	20%	24%	4%	2%	10%	3%
	-	10%	-	0.6%	1%	1%	-

Table.

Parameters	AAV		CV	SLE	SS	pSS	IgG4-RD
	GPA, MPA	EGPA					
N pts	93	10	21	167	90	100	34
Pts with serious adverse reactions,	26%	40%	5%	14%	2%	5%	3%
including: infections,	11%	10%	-	10%	2%	5%	3%
neutropenia	10%	20%	-	3%	-	-	-
Deceased pts during the follow-up	11%	-	14%	5%	6%	2%	-

*Data are provided in the following format: median & min-max range in the brackets

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SAT0172

UTILIZATION OF HYDROXYCHLOROQUINE AND CORTICOSTEROIDS AMONG LUPUS PATIENTS WITH INCIDENT END-STAGE RENAL DISEASE (ESRD) ONSET: A LONGITUDINAL STUDY USING USRDS REGISTRY

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Background: The development of ESRD due to lupus nephritis is one of the most common and serious complications of SLE. Mortality among SLE ESRD patients is 4-fold higher compared to lupus nephritis patients with preserved renal function¹. Mortality in SLE ESRD is also twice as high compared with non-SLE ESRD, even though SLE patients develop ESRD at a significantly younger age. In the absence of ESRD specific guidelines, medication utilization in SLE ESRD is unknown.

Objectives: The objective of this study was to investigate the real-world current US-wide patterns of medication prescribing among lupus nephritis patients with new onset ESRD enrolled in the United States Renal Disease Systems (USRDS) registry. We specifically focused on HCQ and corticosteroids (CS) as the most used medications to treat SLE.

Methods: Inclusion: USRDS patients 18 years and above with SLE as a primary cause of ESRD (International Classification of Diseases, 9th Revision (ICD9) diagnostic code 710.0, previously validated²), who developed ESRD between January 1st, 2006 and July 31, 2011 (to ensure at least 6 months of follow-up in the USRDS). Patients had to be enrolled in Medicare Part D (to capture pharmacy claims). The last follow-up date was defined as either the last date of continuous part D coverage or the end of the study period, Dec 31, 2013.

Results: Of the 2579 patients included, 1708 (66%) were HCQ- at baseline, and 871 (34%) were HCQ+ at baseline. HCQ+ patients at baseline had a slightly lower duration of follow-up compared to HCQ- patients at baseline, median (IQR) of 2.32 (1.33, 3.97) years and 2.55 (1.44, 4.25) years, respectively, p= 0.02. During follow-up period, only 778 (30%) continued HCQ either intermittently or continuously to the last follow-up date, 1306 (51%) were never prescribed HCQ after baseline, and 495 (19%) discontinued HCQ before the last follow-up date. Of the 1801 patients who were either never prescribed or discontinued HCQ early after ESRD onset, 713 (40%) were prescribed CS to the end of the follow-up period: 55% were receiving a low dose <10mg/daily, and 43 were receiving moderate dose (10-20mg daily)

Conclusion: HCQ may be underprescribed and CS may be overprescribed in SLE ESRD. Changing the current prescribing practices may improve outcomes in SLE ESRD

References:

[1] Yap DY et al., NDT 2012.

[2] Broder A et al., AC&R 2016.

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