

BACKGROUND/PURPOSE

To assess clinical activity, ultrasound synovitis and drug levels in rheumatoid arthritis (RA) patients receiving anti-TNF α therapy in clinical remission with extended interval of administration (EIA)

METHODS

- Type of study: Prospective observational
- Population: Patients diagnosed with RA being in clinical remission and receiving anti-TNF α therapy, adalimumab (ADL) or etanercept (ETN), with extended interval of administration
- Ultrasound equipment: Esaote MyLab 25 Gold (Esaote s.p.a, Firenze, Italy)
- Ultrasound assessment: 12-joint (elbows, wrists, 2nd and 3rd metacarpus-phalangeal, knees and ankles) (Naredo E. Arthritis Rheum 2008;59:515-22) evaluating synovitis through B-mode (BM) and Color Doppler signal (CD), both by semi-quantitative scale from 0 to 3 points. Subsequently, a BM and CD score was calculated, summing the highest score obtained from any one of the synovial sites evaluated at each joint to a maximum of 36 points. The sonographer was blinded to the clinical and laboratory data

RESULTS

A total of 34 patients were included, since February 2011 to January 2016. One patient was excluded due to blindness violation and 2 patients never reduced anti-TNF α due to low drug levels. Baseline characteristics of patients are shown in Table 1. Clinical activity and ultrasound scores are summarized in Table 2. Nine patients (26,5%) returned to standard interval due to worsening of clinical activity and one discontinued treatment due to septic arthritis

Table 1. Basal characteristics of patients

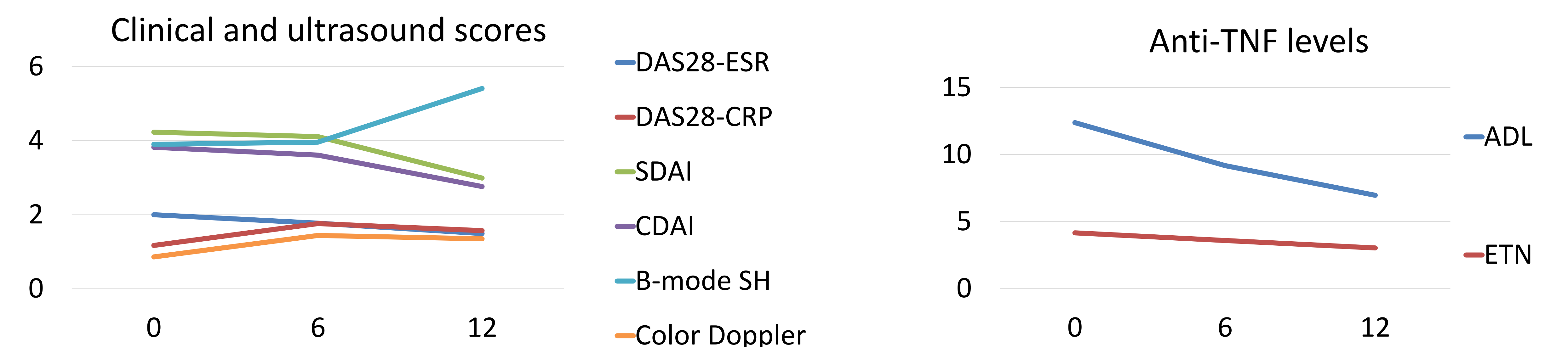
• Nº patients	34
• Women	79,4%
• Age (mean[range])	61 years [39-79]
• RF +	85,3%
• ACPA +	74,2%
• Anti TNF	ADL 18 / ETN 16
• Concomitant DMARD	82,35% (14 MTX, 11 LEF, 2 HCQ, 1 SSZ)
• Low dose corticosteroids	20,59%
• Duration of disease (mean[range])	15,19 years [2,15 – 52,31]
• Time on current anti-TNF (mean[range])	4,11 years [1,39-11,07]

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Table 2. Clinical activity scores, ultrasound scores and drug levels.

	Baseline visit	6 months	12 months
n	30	26	17
DAS28-ESR, mean [SD]	2,0 (0,94)	1,77 (0,81)	1,49 (0,58)*
DAS28-CRP, mean [SD]	1,17 (0,53)	1,76 (0,47)**	1,57 (0,34)**
SDAI, mean [SD]	4,23 (2,63)	4,11 (2,81)	2,99 (1,27)*
CDAI, mean [SD]	3,82 (2,48)	3,61 (2,33)	2,76 (1,3)
B-mode SH score, mean [SD]	3,9 (4,65)	3,96 (3,93)	5,41 (4,29)
Color Doppler score, mean [SD]	0,86 (0,79)	1,44 (1,8)	1,35 (1,46)
B-mode SH score >0 (%)	80,95%	92,00%	100,00%
Color Doppler score >0 (%)	61,90%	52,00%	58,82%
ADL level, mean (SD)	12,38 (7,37)	9,17 (5,51)	6,96 (2,84)*
ETN level, mean (SD)	4,16 (2,74)	3,59 (2,9)	3,03 (0,84)
ADL frequency [days], mean (range)	14 (14)	19,13 (17-21)	21,4 (18-30)
ETN frequency [days], mean (range)	7 (7)	10,82 (10-14)	10,71 (10-14)

ADL: adalimumab; DAS28: Disease Activity Score in 28 joints; ETN: etanercept; SDAI: Simplified Disease Activity Index; CDAI: Clinical Disease Activity Index; SH: synovial hypertrophy. *p<0,05; **p<0,005.



CONCLUSIONS

1. Clinical remission was sustained in most patients receiving ADL or ETN in extended interval of administration
2. Some patients (26,5%) returned to standard interval of administration due to clinical worsening
3. Some patients show subclinical ultrasound synovitis in B-mode or Color Doppler from baseline, although we found no significant worsening over time
4. Drug levels decrease over time as we extend interval of administration
5. It would be advisable to perform periodic ultrasound and monitoring of anti-TNF α levels to maintain clinical remission in patients with extended interval of administration