

# TAPERING INFLIXIMAB IN ANKYLOSING SPONDYLITIS: CAN WE REDUCE COSTS?



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## Introduction

The approved dose of infliximab (IFX) for the treatment of ankylosing spondylitis (AS) is 5mg/kg body weight every 6 weeks. Several studies have shown the 3mg/kg dose to be effective in a subgroup of AS patients but there is few published evidence regarding other dose-reduction regimens, namely adjusting the interval between doses and individualized dose adjustment. We analyzed AS patients disease activity upon increasing IFX administrations intervals on an individual basis.

## Methods

The Rheumatic Disease Portuguese Register was used to select all patients diagnosed with AS, under IFX therapy for  $\geq 4$  months, followed at Santa Maria Hospital. All patients received IFX 5mg/kg at 0-2-6 weeks and thereafter at variable intervals, between 6 and 11 weeks, on an individual basis, determined by clinical judgement. Response to treatment was assessed using BASDAI (reduction  $>50\%$  and/or  $\geq 2$  points) and ASDAS ( $\Delta > 1.1$ ). Clinical remission was defined as an ASDAS  $< 1.3$  for  $\geq 4$  months and recurrence as ASDAS  $\geq 1.3$  during 2 or more consecutive visits.

## Results

50 patients were included with a mean time of follow-up of  $57 \pm 35$  months. The baseline characteristics of the studied population are showed in Table 1.

Baseline characteristics	
Males, nr. (%)	36 (72%)
Age, mean (SD)	45 ( $\pm 12$ )
Global disease activity assessment (patient), mean (SD)	53.2 ( $\pm 29.2$ )
Tender joints, mean (SD)	3.4 ( $\pm 3.9$ )
Swollen joints, mean (SD)	0.5 ( $\pm 1.3$ )
CRP (mg/L), median (max-min.)	8 (0-170)
BASDAI, mean (SP)	5 ( $\pm 2.5$ )
BASFI, mean (SP)	4.9 ( $\pm 2.3$ )
ASDAS, mean (SP)	3.3 ( $\pm 1.4$ )

Table 1 – Baseline characteristics of studied population.

The time between starting infliximab and the decision to increase dose intervals was of  $18.2 (\pm 11.1)$  months. The mean difference between baseline BASDAI and this time point was of  $-3.7 (\pm 3.4)$ . 65% of patients had achieved BASDAI50 and 76% ASAS response criteria (table 2).

Infliximab dose intervals increase	Nr. patients(%)
Maintained IFX every 6/6 weeks	11 (22%)
Immediately after the 3rd administration of IFX	12 (24%)
Later than the 3rd administration of IFX	27 (54%)

Table 2 – Infliximab dose intervals increase according to physician decision.

21 patients (42%) achieved remission with the physician determined regime,  $21.5 \pm 28.1$  months after starting IFX. Regarding these patients, 16 (76%) showed persistent remission, 5 (24%) had recurrence of activity (ASDAS  $\geq 1.3$ ), on average 12,9 months after remission; at the last visit 19 (90%) had ASDAS  $< 1.3$ .

Disease activity after remission	Nr. (%)
Maintained recurrence	2 (10%)
Transitory recurrence	3 (14%)
Persistent remission	16 (76%)

Table 3 – Evolution of disease activity in patients that achieved remission.

At the last visit almost 50% of patients shows inactive disease.

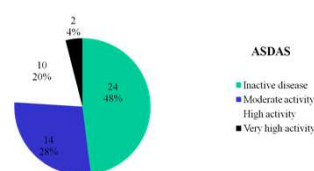


Figure 1- Disease activity at the last patient's visit.

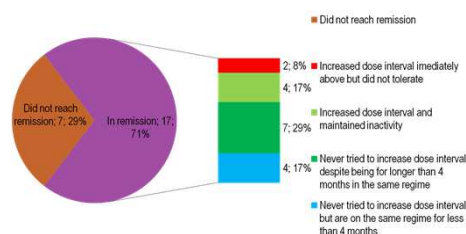


Figure 2- Infliximab regimes and disease activity at the last visit in patients with inactive disease

Interval between doses (weeks)	6	7	8	9	10	11	12
Annual costs(€)	13021,67	11161,43	9766,25	8681,111	7813	7102,727	6510,833
Differences(€)		1860,238	1395,179	1085,139	868,111	710,2727	591,8939

Figure 3- Estimation of cost reduction according the IFX regime.

## Conclusions

78% of patients increased IFX intervals between administrations, 24% of those immediately after the 3rd administration.

The average time to increase IFX intervals based on the physician decision was of 18 months after starting this therapy.

65% of patients showed a BASDAI50 response at the time of physician decision to increase IFX administration intervals.

42% reaches remission with the prescribed regimes and maintains remission through follow-up (32%).

•65% of patients is under increased IFX intervals regimes at the time of the last visit.

Increased IFX intervals regimes are associated with adequate disease activity control in a significant proportion of patients.