Assessment of the total direct medical cost of patients in second-line TNF inhibitor therapy and of the respect of clinical practice recommendations

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Background

Until recently, in the absence of a specific marketing authorisation, patients who failed a TNFα inhibitor (anti-TNFα) therapy switched to another TNF α inhibitor.

No specific study has been conducted on this specific population treated in 2nd and subsequent lines, so that resources consumption of this population was unknown. In order to feed a budget impact model *(EULAR 2007 – Poster SAT0024)* an observational study has been developed.

Objective

To establish the total direct medical cost of patients in second-line anti-TNFα therapy from the French health care system perspective and to assess whether the three treatments marketed in France - infliximab (INF), etanercept (ETA) and adalimumab (ADA) - are administered with respect to the clinical practice recommendations.

Methods

Study design

- Observational study (TC2)
- 4 months period
- Multicenter: 59 centres spread in France
- 3 groups of treatment: INF, ETA and ADA
- Hospital recruitment of patients responding to the following criteria:
  - ✓ adult patient
  - ✓ patient suffering from rheumatoid arthritis as defined by the American College of Rheumatology
  - ✓ treated since at least 4 months with an anti-TNFα therapy, after failure of a previous one
  - ✓ not in 3rd or subsequent lines of anti-TNFα therapy

Retrospective data collection

Treatment administration
- ✓ Hospitalisations
- ✓ Outpatient visits
- ✓ Concomitant treatments
- ✓ Imaging and tests
- ✓ Hospital-home transport

Costs valorisation

- French DRGs to estimate hospitalisation costs
- Drug acquisition costs were accounted for in addition to the top of DRGs
- Public prices to estimate concomitant treatments cost
- Outpatient visits, imaging, tests and transport valued through the tariffs edited by the French national health insurance

Results

The patients

	All patients (N=277)
Duration of disease (Mean ± SD)	13.2 ± 8.5
DAS28 (Mean ± SD)	5.4 ± 1.2
Erosive RA	90.5%

277 patients were included. Globally, the population presents an active and erosive RA. Those patients had an advanced and severe disease which is consistent with the fact that they had already failed to the 1st line of an anti-TNFα treatment.

Respect of clinical practice recommendations

- INF: 4,7% of patients received more administrations than expected, while 18,6% had a higher dosage than recommended
- ETA: 11.4% of patients received more than 32 injections
- ADA: 24.5% of patients received more than 8 injections
- Treatments are sometimes used with higher doses or more frequently than recommended in the SmPC in order to compensate the fact that patients already failed an anti-TNFα therapy.

Direct medical cost

Mean annual cost per patient:
- ✓ Outpatient: 1 300€
- ✓ Inpatient: 14 700€
- ✓ **Total direct medical cost: 16 000€**

Cost structure

	All (n=277)	INF (n=43)	ETA (n=132)	ADA (n=102)
Hospital cost				
Administration cost	**783**	**4 571**	**96**	**68**
Other hospitalisations	**935**	**685**	**969**	**996**
Outpatient visits - tests	**176**	**245**	**153**	**176**
Ambulatory cost				
Consultations	**137**	**150**	**131**	**140**
Others	**1 131**	**1 135**	**1 043**	**1 239**
Treatment cost	**12 797**	**12 738**	**11 420**	**14 592**
TOTAL (1 year)	**15 957**	**19 524**	**13 812**	**17 210**

ETA is 20% cheaper than INF and 11% cheaper than ADA. ADA is more expensive than ETA due to higher treatment cost (+ 28%). INF has a specific profile because of its hospital administration. Compared to the others, INF presents an over consumption of:
- associated treatments
- hospital rheumatologist and GP consultations
- hospitalisations mainly due to treatment administration
- biological and imagery testing at hospital
- transport to the hospital

However, the higher cost of INF is mainly due to its administration cost.

Conclusion

- Total direct medical costs for patients treated with anti-TNFα in second line reach 16 000€ per patient and per year in France.
- Major differences between anti-TNFα have been observed, mainly due to administration ways and treatment costs.
- In the absence of a registered indication for 2nd line treatment, anti-TNFα are prescribed, but the clinical practice recommendations are not always respected.