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Registo Nacional de Doentes Reumáticos
Rheumatic Diseases Portuguese Register

Sociedade Portuguesa de Reumatologia

Biologic drug efficacy and treatment discontinuation in rheumatoid arthritis patients from Reuma.pt

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Background

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- **Large follow-up registries: essential for long term monitoring of chronic diseases in clinical practice.**

- **Reuma.pt, national register for rheumatic diseases from SPR**
  - **set up in 2008**
  - **to follow up distinct cohorts of rheumatic patients treated with synthetic and/or biological therapies**

Aim

To assess

. treatment efficacy and

. drug discontinuation

in RA patients treated with biologic therapies registered in Reuma.pt

Methods

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INCLUSION CRITERIA

- RA first biological therapy users
- treated with adalimumab, etanercept, golimumab, infliximab or tocilizumab
- starting biological treatment after 1 Jan 2008

EULAR response criteria

post-treatment DAS28	DAS28 improvement >1.2	DAS28 improvement >0.6-1.2	DAS28 improvement ≤0.6
≤3.2	good	moderate	none
>3.2-5.1	moderate	moderate	none
>5.1	moderate	none	none

$$DAS28 = 0.56 * sqrt(tender28) + 0.28 * sqrt(swollen28) + 0.70 * ln(ESR) + 0.014 * GH$$

Disease activity, 4 categories: High, moderate, low and remission

EULAR = European League Against Rheumatism

Van Gestel AM et al. Arthritis Rheum 1996; 39: 34-40

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OUTCOMES

Primary outcome:

- proportion of patients achieving EULAR good response criteria at 6 months.

Secondary outcomes:

- proportion of patients in remission (DAS28, CDAI and SDAI).

Methods

PRIMARY ANALYSIS

- Patients achieving EULAR good response criteria at 6 months for each drug were compared using a multivariate logistic model to adjust for potential confounders.
- Same analyses for remission rates.

Methods

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SECONDARY ANALYSIS

- treatment discontinuation rates across biological therapies

- description of reasons for discontinuation

Analyzed upon 2 time frames:

before and after one year of treatment for the 5 drugs above mentioned.

Results

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520 patients – Baseline characteristics

	ADA	ETA	GOLI	INFLI	TOCI
N	123	204	31	110	52
Age	52.8±12.2	54.2±12.3	57.2±12.1	56.5±12.0	54.1±12.0
Disease duration	11.4±9.6	11.6±9.6	12.5±9.8	11.6±9.7	7.8±9.8
Female (%)	91.0	88.2	80.6	84.5	80.8
ACPA/RF(%)	83.6	87.6	66.7	95.0	84.8

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	ADA	ETA	GOLI	INFLI	TOCI
N	123	204	31	110	52
DAS at baseline **(p=0.12 ANOVA)**	5.3±1.2	5.6±1.2	5.4±1.3	5.6±1.3	5.7±1.2

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Response at 6m

	ADA	ETA	GOLI	INFLI	TOCI
N	123	204	31	110	52
DAS at baseline **(p=0.12 ANOVA)**	5.3±1.2	5.6±1.2	5.4±1.3	5.6±1.3	5.7±1.2
DAS 6m **(p<0.0001 ANOVA)**	3.7±1.3	3.8±1.3	3.5±1.3	3.7±1.4	1.6±0.99
EULAR good response 6m **(chisq p<0.0001)**	25.0%	30.7%	40%	27.7%	88.9%

Results

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Response at 6m

	ADA	ETA	GOLI	INFLI	TOCI
N	123	204	31	110	52
TJC at baseline	9.9±7.4	10.7±7.4	10.3±7.5	11.1±7.5	11.0±7.5
TJC at 6m	4.3±5.4	4.5±5.4	3.4±5.4	4.6±5.5	2.0±5.4

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Response at 6m

	ADA	ETA	GOLI	INFLI	TOCI
N	123	204	31	110	52
TJC at baseline	9.9±7.4	10.7±7.4	10.3±7.5	11.1±7.5	11.0±7.5
TJC at 6m	4.3±5.4	4.5±5.4	3.4±5.4	4.6±5.5	2.0±5.4
SJC at baseline	6.8±5.0	6.9±5.1	7.2±5.0	7.8±5.0	8.9±5.1
SJC at 6m	2.6±3.0	2.0±2.9	3.0±3.0	1.9±3.0	1.8±3.0

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Remission at 6m

	ADA	ETA	GOLI*	INFLI	TOCI
CDAI≤2.8 (Fisher p=0.15)	31.6%	9.7%		21.1%	33.3%
SDAI≤3.3 (Fisher p=0.07)	31.6%	9.7%		26.3%	44.4%
DAS<2.6 (Fisher p=0.005)	36.8%	25.8%		26.3%	88.9%

* Golimumab not assessed for small sample size

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SDAI≤3.3 (Fisher p=0.07)	31.6%	9.7%		26.3%	44.4%
DAS<2.6 (Fisher p=0.005)	36.8%	25.8%		26.3%	88.9%

* Golimumab not assessed for small sample size

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Treatment discontinuation

. Mean duration of treatment: 22.3±13.4 months.

. 144 (27.7%) patients discontinued therapy over the period of follow-up (2008-2011),

88 (61.1%) of them in the first year of therapy.

Results

Reasons for drug suspension

1st year, 88 discontinued:

. inefficacy - 45 (51.1%)

. adverse events - 36 cases (41%)

. other reasons - 13 (14.7%).

2nd year, 56 discontinued:

. inefficacy - 37 (66.0%)

. adverse events - 19 cases (33.9%)

. other reasons - 8 (14.2%).

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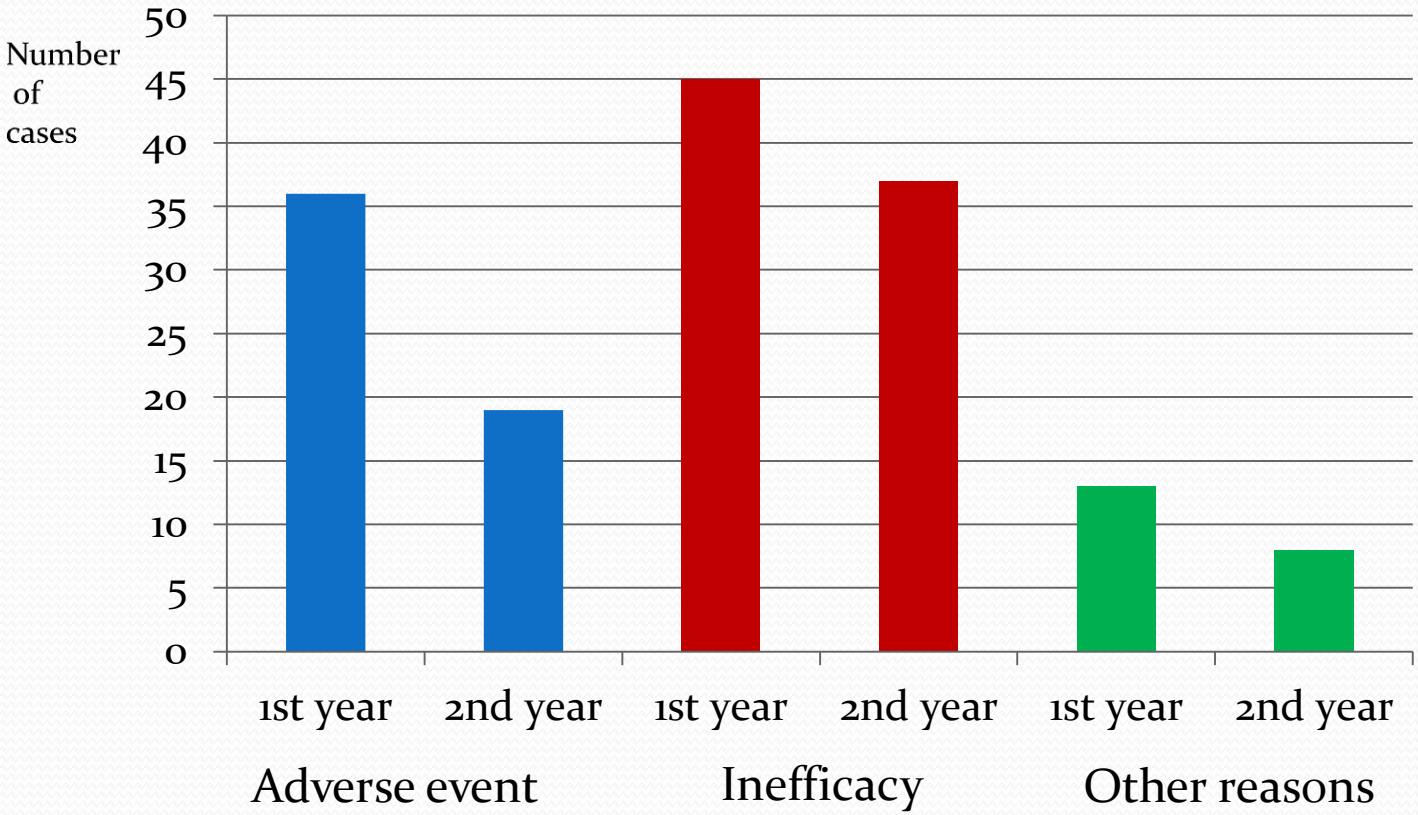

Conclusions

In this group of patients

- delta DAS, proportion of EULAR good response and DAS28 remission criteria at 6m were higher for the tocilizumab group,
- the significant difference was lost when other remission criteria were used.
- Inefficacy was the major determinant of drug discontinuation.

Obrigada!

Proponha o seu projecto de investigação à CC Reuma.pt!

Dados toci

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Comparação na Resposta aos 6m medida por % de EULAR good response

Tocilizumab vs os outros por Logistic regression

- Toci vs Ada p-value 0.0033
- Toci vs Eta pvalue 0.011
- Toci vs Goli p value 0.4793
- Toci vs Infliximab 0.0086

Dados toci em Jan 2012: 69 doentes no reuma.pt; 52 iniciaram toci como 1º biologico (dados nesta apresentação); 43 mantinham toci em Jan 2012.

1º doente iniciou toci a 12 Março de 2009 (destes q fizeram toci como 1º biologico)