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ALIGNING CLINICAL TRIALS IN RHEUMATOID ARTHRITIS WITH REAL-LIFE POPULATIONS

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Background: Despite the huge benefits of biologics in the treatment of rheumatoid arthritis (RA), the level of success reported in Randomised Controlled Trials (RCTs) is not achieved in standard practice (1-5).

Objectives: To establish the level of discrepancy in biologic-naïve cohorts between RCTs and the standard RA population from two local registries (Leeds and Dublin) focusing in particular on patient characteristics.

Methods: A comprehensive literature review was undertaken to identify all published RCTs in biologic-naïve RA patients. The characteristics of patients recruited to the selected RCTs were collated and summarised. Datasets from biologic-naïve patients consented to the biologics registries at the University of Leeds (BMC) and the University College Dublin (UCD) were also collated and summarised. This allowed the identification of the most common patient characteristics representative of RCTs and the general population in RA. The characteristics of patients from the RCTs were compared to BMC/UCD cohorts.

Results: A total of 32 RCTs for biologic-naïve RA patients were identified from the literature review. A total of 1107 datasets from biologic-naïve RA patients were identified from the Leeds (n=684) and Dublin (n=423) registries. The comparison of the patient characteristics from these cohorts showed that patients from RCTs are older than in the registries (mean(SD) age: RCTs=52.6(2.67); registries=50.9(15.06); **p**=0.0001), however more female patients comprise registries (RCTs=66.14%; registries=73.98%). Almost all disease activity components at presentation are higher in RCTs, leading to significantly higher DAS28 score for patients recruited to RCTs (mean(SD) DAS28-CRP=5.59(0.38); DAS28-ESR=6.56(0.37)) than those in the registries (mean(SD) DAS28-CRP=5.38(1.19); DAS28-ESR=5.76(1.26); **p** =0.0001)(refer to Table 1). Data on co-morbidities and concomitant drugs is limited in RCTs mainly due to the exclusion criteria that limit the studies population. The data from the registries, albeit incomplete, shows that these patients present with varied co-morbidity, with hypertension (25.9%) being the most common. Other conditions are present in less than 10% of the total.

Image/graph:

Table 1. Baseline characteristics for bio-naïve RA patients in standard care (local registries in Leeds and Dublin) and recruited to selected RCTs.

Baseline Characteristics (variables)	Source (RCTs / Registries)	Number of Patients with data	Mean (SD)	P value	95% Confidence Interval
Age (years)	RCTs	16779	52.6 (2.67)	0.0001	1.35 – 1.91
	Registries	1069	50.97 (15.06)		
DAS28-CRP	RCTs	966	5.59 (0.38)	0.0001	7.6 – 1.95
	Registries	926	5.38 (1.19)		
DAS28-ESR	RCTs	6299	6.56 (0.37)	0.0001	0.76 - 0.84
	Registries	882	5.76 (1.26)		
CRP (mg/dL)	RCTs	12533	4.08 (5.27)	0.0001	1.18 – 1.6
	Registries	1026	2.69 (3.17)		
ESR (mm/hr)	RCTs	8365	43.19 (11.91)	0.0001	5.25 – 8.65
	Registries	957	36.24 (26.46)		
SJC28	RCTs	1795	10.62 (2.39)	0.0001	2.09 – 2.8
	Registries	1042	8.16 (5.87)		
TJC28	RCTs	1795	13.74 (2.71)	0.0001	1.25 – 2.21
	Registries	1042	12.01 (7.67)		
Patient Global Health VAS (0-100mm)	RCTs	7336	61.63 (14.16)	0.0004	3.89 – 1.13
	Registries	1040	64.14 (22.10)		
Physician Global Health VAS (0-100mm)	RCTs	7537	61.79 (13.38)	0.0001	6.88 – 2.96
	Registries	444	66.71 (20.77)		
EMS (mins)	RCTs	2004	162.92 (105.29)	0.0001	44.57 – 90.5
	Registries	450	95.39 (242.77)		
HAQ-DI	RCTs	9890	1.55 (0.13)	0.0001	0.32 – 0.28
	Registries	634	1.85 (0.64)		

Conclusions: This initial evaluation illustrates that the selected RCT populations are not representative of real-life general biologic-naïve RA population, limiting the applicability of RCTs. The higher disease activity inclusion in RCTs illustrates they are yet to adopt the treat to target strategies in the management of RA. Extending the comparison to a larger, registry-based population would add further insights into the disparity between RCT and real-life populations.

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