Clinical parameter of PsA patients receiving bDMARD/tsDMARD monotherapy do not differ from patients receiving bDMARD/tsDMARD in combination with MTX – data from RABBIT-SpA

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Background: While in RA the combination of biologic disease modifying antirheumatic drugs (bDMARDs) and targeted synthetic (ts) DMARDs with methotrexate (MTX) have proven additional benefit, in PSA the additional benefit of MTX in combination with bDMARD/tsDMARD is still a matter of debate.

Objectives: To compare clinical and patient reported parameter of PsA patients starting bDMARD/tsDMARD monotherapy with those starting a combination of MTX plus bDMARD/tsDMARD and to compare drug retention rate.

Methods: RABBIT-SpA is a prospective longitudinal cohort study including axSpA and PsA patients enrolled at start of a new conventional treatment or bDMARD/tsDMARD treatment. In this analysis, PsA patients at start of observation were stratified into the two groups bDMARD/tsDMARD monotherapy and bDMARD/tsDMARD in combination with MTX. Treatment retention was compared by survival analysis.

Results: 69% of the patients started bDMARD/tsDMARD monotherapy. Combination treatment was started in 31% of the patients. In 85% of the patients in the combination group, MTX was given as monotherapy before and treatment was then escalated to the combination with bDMARD/tsDMARD.

Clinical parameter were strikingly similar between the groups (table 1). Interestingly, in the 6 PsA domains skin, joints, dactylitis, enthesitis, nail psoriasis, and axial involvement, there was no difference in the groups. Only the patient question regarding the satisfaction on tolerability of the current treatment (4 point Likert scale) was significantly better in the combination treatment group at the time point of treatment start (combination versus bDMARD/tsDMARD mono).

The drug retention rate did not differ in both groups (p=0.19; figure 1). At 6 months, 62% of patients in combination and 58% in bDMARD/tsDMARD mono group were on their treatment.

Conclusions: Comparing the treatment groups, clinical parameters showed almost no differences. Especially those parameters, which are usually taken into account if considering GRAPPA or EULAR treatment recommendations such as number of swollen or tender joints, enthesitis sites and affected skin did not differ between the treatment groups. Drug retention rate was very similar. It seems that in routine care, the decision to continue MTX at the time point when a treatment escalation is needed may mostly be based on the subjective tolerability of the ongoing MTX treatment.

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Table 1: Patient characteristics separated by the two treatment groups

	b/tsDMARD mono	b/tsDMARD +MTX	Total
n	833	369	1202
Females, n (%)	486 (58)	213 (58)	699 (58)
Age, mean (SD)	51.9 (12.6)	52.2 (12.1)	52 (12.4)
BMI, mean (SD)	29.1 (6)	28.7 (5.9)	29 (6)
CRP mg/l, mean (SD)	7.2 (11.5)	7.6 (13.7)	7.3 (12.2)
TJC (0-68), mean (SD)	7 (8.2)	6.9 (7.6)	7 (8)
SJC (0-66), mean (SD)	3.5 (5.1)	2.8 (3.8)	3.3 (4.8)
Number of sites with enthesitis, mean (SD)	0.6 (1.6)	0.7 (1.8)	0.6 (1.7)
dactylitis, n (%)	161 (20)	60 (16)	221 (19)
axial manifestation, n (%)	180 (22)	76 (21)	256 (22)
body surface area in %, mean (SD)	8.7 (15.8)	7.9 (13.2)	8.5 (15)
nail psoriasis, n (%)	345 (42)	148 (40)	493 (41)
uveitis, n (%)	18 (2)	3 (1)	21 (2)
IBD, n (%)	18 (2)	3 (1)	21 (2)
number of comorbidities, mean (SD)	2.2 (2.3)	2.1 (2.2)	2.2 (2.3)
Physician global disease activity, mean (SD)	5.1 (1.9)	5.3 (1.9)	5.2 (1.9)
Physician skin disease activity, mean (SD)	3.3 (2.5)	3.1 (2.6)	3.2 (2.5)
Physician joint disease activity, mean (SD)	5 (2.2)	5.3 (2.1)	5.1 (2.2)
DAPSA, mean (SD)	22.9 (14)	22.4 (12.9)	22.7 (13.7)
Patient global disease activity, mean (SD)	5.7 (2.4)	5.7 (2.4)	5.7 (2.4)
Patient pain, mean (SD)	5.6 (2.4)	5.6 (2.4)	5.6 (2.4)
DLQI, mean (SD)	6.4 (6.4)	4.8 (5.9)	5.9 (6.3)
HAQ, mean (SD)	1 (0.7)	0.9 (0.7)	1 (0.7)
bDMARDs before, n (%)	380 (46)	122 (33)	502 (42)
csDMARDs before, n (%)	647 (78)	332 (90)	979 (81)
MTX before, n (%)	598 (72)	325 (88)	923 (77)
Glukokortikoids, n (%)	234 (29)	125 (36)	359 (31)
Satisfied with the current treatment, n (%)	260 (43)	149 (52)	409 (46)
Satisfied with the tolerability of the current treatment, n (%)	349 (60)	217 (76)	566 (66)

Figure 1: Drug retention rate separated by the two treatment groups