Patient satisfaction and experience after a switch to an adalimumab biosimilar with high concentration and citrate-free: results from a multicentric prospective real-life study

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BACKGROUND

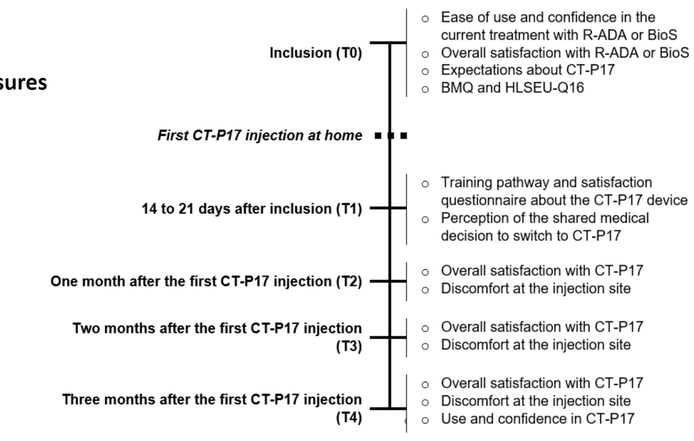
- Switching from a reference product to a biosimilar aims at generating cost savings.
- Patient adherence after the switch is linked to overall experience that can be impacted by patient or treatment characteristics.
- This study aimed to analyse patient experience after a switch from an adalimumab (ADA) to CT-P17[1] (adalimumab biosimilar high concentration and citrate-free).

METHODS

- YU-MATTER (NCT05427942) is a multicenter, prospective observational study conducted in 17 gastroenterology and 13 rheumatology private practices or hospital centers in France.
- To be included, patients had to meet all the following criteria:
  - Adult (aged 18 or older at the time of inclusion) patients presenting a diagnosis of :
    - Chronic inflammatory rheumatic diseases (CIRD): Rheumatoid Arthritis (RA); Ankylosing Spondylarthritis (AS); Non radiographic axial spondyloarthritis (nr-axSpa); Psoriatic Arthritis (PsA)
    - Inflammatory bowel diseases (IBD): Crohn's Disease (CD); Ulcerative Colitis (UC)
  - Stable and treated for at least 3 months prior to the inclusion with an adalimumab (ADA) biosimilar or originator (40 mg or 80 mg)
  - For whom the treating physician has decided to switch to CT-P17 (100mg/mL) on the day of their inclusion (decision independent from the study)
  - Able to initiate treatment within 4 weeks following inclusion
- Patients were switched to CT-P17 and followed-up for 3 months. Clinical characteristics were collected at T0, including patient-experience via 5 self questionnaires. Satisfaction and overall injection tolerance were assessed between T0 (just before switch) and T4 (3 months after switch) (**Figure 1**).

Figure 1: Study design

Electronic patient-reported outcome measures



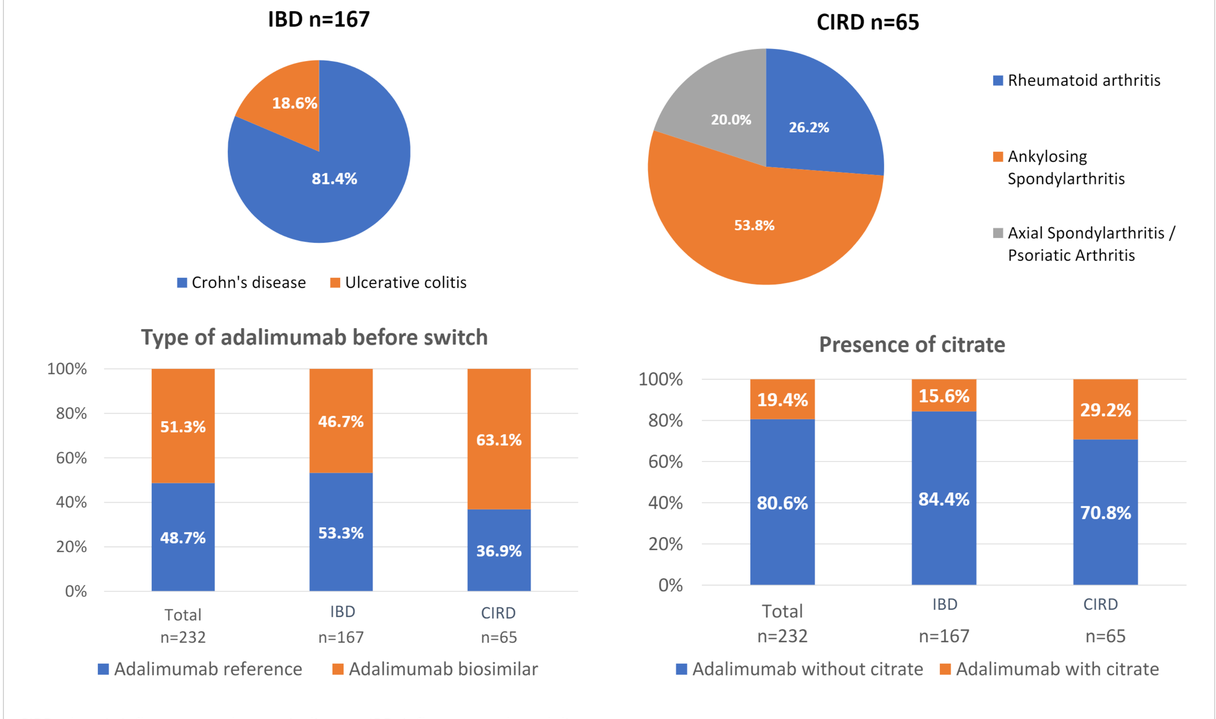
BioS, biosimilar; BMQ, Belief on Medicine Questionnaire; HLSEU-Q16, European Health Literacy Survey Questionnaire; R-ADA, reference adalimumab

RESULTS

Analysis population

232 patients receiving CT-P17 between June 2022 and March 2023 (**Figure 2**) were analysed. 50.9% men, mean age 44±15 years, patients with IBD were younger than patients with CIRD (median age 38.0 versus 57.0 years) while similar disease durations were observed at inclusion (median of 9 years).

Figure 2. Patients' characteristics

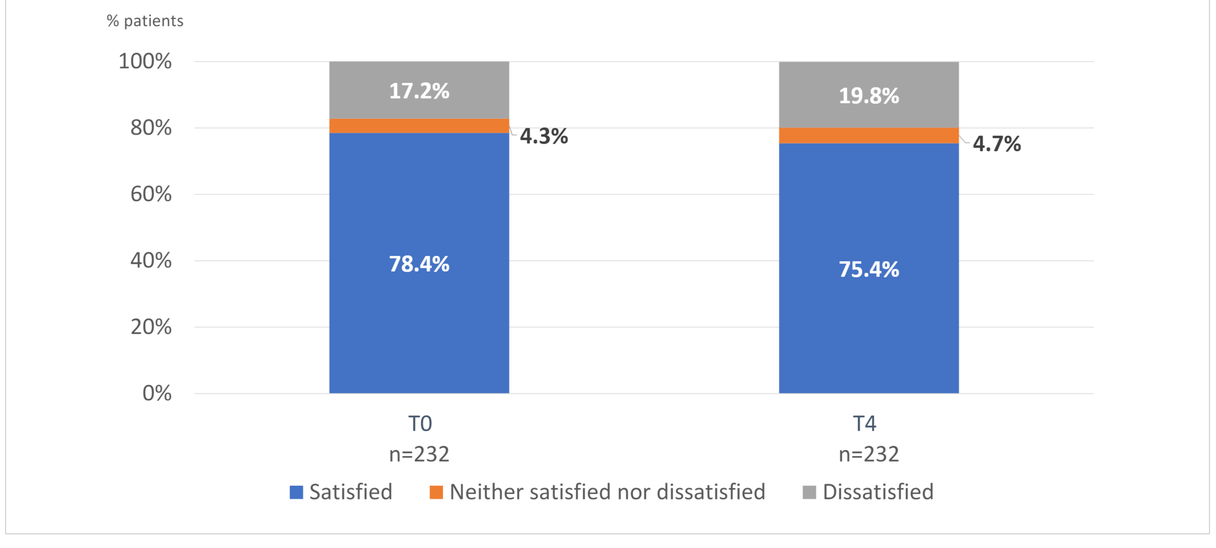


CIRD, chronic inflammatory rheumatic disease; IBD, inflammatory bowel disease.

Global Satisfaction

- Proportion of patients who were extremely, somewhat, or a little satisfied with treatment did not change between T0 (under the previous ADA) and T4 (three months after the first injection of CT-P17): 78.4% (95% CI: [72.7%; 83.3%]) and 75.4% ([69.5%; 80.5%]), respectively. (**Figure 3**).

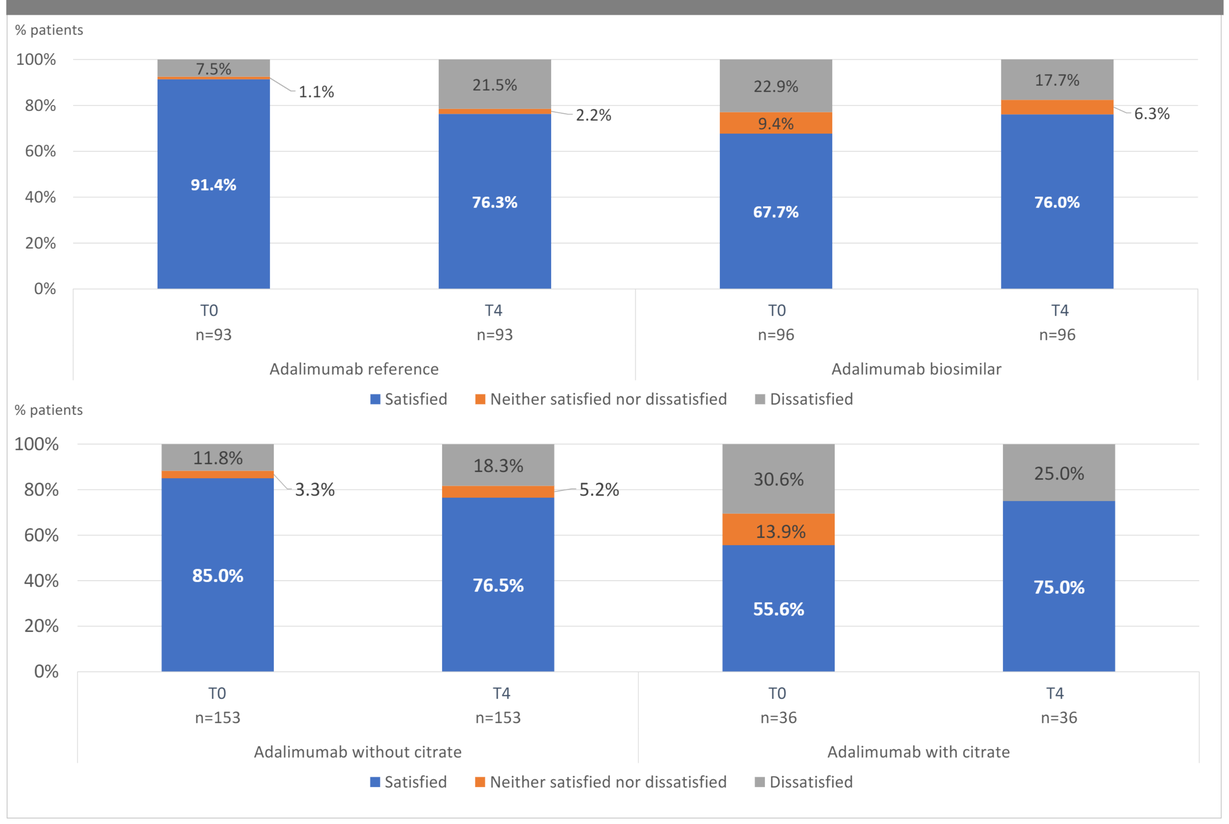
Figure 3. Primary endpoint : Global satisfaction between T0 and T4



Global satisfaction according to previous adalimumab

- Among patients receiving a biosimilar, the presence of citrate was significantly associated with an improvement of satisfaction after switching to CT-P17 (58.3% vs 30.0%, p=0.006) (**Figure 4**).

Figure 4. Global satisfaction between T0 and T4 (type of previous adalimumab)



Generalised linear regression analysis

- In multivariable analysis, the switch from a low concentration adalimumab biosimilar was an independent factor of satisfaction improvement (**Figure 5**).

Figure 5. Factors associated with an improvement in patient satisfaction 3 months after the switch to CT-P17

Factors (p-value <0.05)	**Univariate analysis** OR [95% CI] *(p-value)*	**Multivariate analysis** OR [95% CI] *(p-value)*
Body mass index (≥25 *vs.* <25 kg/m²)	2.37 [1.01; 5.58] *(0.048)*	/
Adalimumab biosimilar LC *vs.* Adalimumab RP HC	3.44 [1.39; 8.54] *(0.008)*	2.88 [1.17; 7.08] *(0.021)*
Pain at injection site (NRS 0-10) at M0 (interval: 1 point)	1.31 [1.11; 1.54] *(0.001)*	1.26 [1.08; 1.47] *(0.004)*

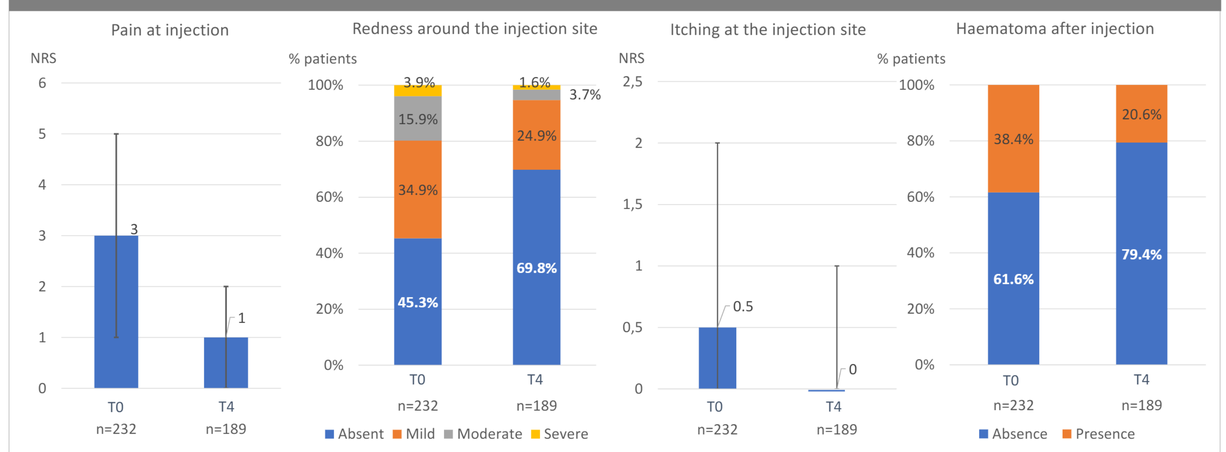
CI, confidence interval; HC, high concentration; LC, low concentration; NRS, numeric rating scale; OR, odds ratio; RP, reference product.

Factors with a p-value <0.10 using univariate analysis were included in the multivariate model

Overall tolerance

- Overall injection tolerance (pain < 4 AND absence of redness AND itching < 4 AND absence of haematoma) significantly improved after switching from 28.9 % at T0 to 57.7 % at T4 (p<0.0001). A significant decrease of injection site pain was observed after the first injection of CT-P17 (median -2 [-4; -1]) for patients switched from an ADA biosimilar and the pain related to injection remained stable for patients switched from the reference product (median 0 [-1;1]) (**Figure 6**).

Figure 6. Overall tolerance between T0 and T4



NRS, numeric rating scale

CONCLUSION

- This real-world study showed that the global experience of patients after the switch to adalimumab biosimilar CT-P17, high concentration and citrate-free, was positive with no decrease in treatment satisfaction, and a significant improvement in overall injection tolerance. The transition from another adalimumab biosimilar low concentration and pain at injection site with the previous adalimumab were shown to be independent factors associated with a successful patient experience.

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Disclosures: **GB** has served as a consultant or advisory board member for Abbvie, Amgen, Biogaran, Biogen, Boehringer Ingelheim, Celltrion Healthcare, Ferring, Fresenius Kabi, Galapagos, Gilead, Hospira, Iterative Scopes, Janssen, Lilly, Mayoli Spindler, Merck, MSD, Norgine, Pfizer, Roche, Sandoz, Sanofi, Shire, Takeda, Tillotts, UCB, Viatris. **LG** has served as a consultant or advisory board member for AbbVie, Amgen, BMS, Celltrion Healthcare, Galapagos, Gilead, GSK, Janssen, Lilly, MSD, Novartis, Pfizer, Sandoz, UCB; has received research funding for Lilly, Pfizer, Sandoz, UCB. **VA** has served as a consultant or advisory board member for Amgen, Celltrion, Takeda, Sandoz, Pfizer, Janssen, Abbvie, Biogen, Arkopharma, UCB, Gilead, Tillots. **ES** has served as a consultant or advisory board member for Nordic, Roche, Chugai, AbbVie, Amgen, Pfizer, Sanofi, MSD, Biogen, Janssen, Fresenius Kabi, and Celltrion Healthcare; has received research funding for Nordic, Roche, Chugai, Fresenius Kabi, Celltrion Healthcare. **GB** has served as a consultant or advisory board member for Abbvie, Amgen, Biogen, Celltrion, Cvasthera, Ferring, Fresenius, Galapagos, Gilead, Mayoli Spindler, MSD, Janssen, Pfizer, Roche, Takeda, Tillots, Sandoz, Viatris. **XR** has served as a consultant or advisory board member for Celltrion, MSD, Pfizer, Abbvie, Amgen, Biogen, Takeda, Janssen, BMS, Ferring, Tillots, Vifor. **YB** has served as a consultant or advisory board member for Abbvie, Amgen, Biogaran, Biogen, Boehringer Ingelheim, Celltrion Healthcare, Ferring, Fresenius Kabi, Galapagos, Gilead, Hospira, Iterative Scopes, Janssen, Lilly, Mayoli Spindler, Merck, MSD, Norgine, Pfizer, Roche, Sandoz, Sanofi, Shire, Takeda, Tillotts, UCB, Viatris. **SN** has served as a consultant or advisory board member for Takeda, Pfizer, MSD, Abbvie, Janssen, Tillots, HAC Pharma, Novartis, Amgen, Sanofi, Hospira, Biogen, Roche, Sandoz, Celltrion, Boerhinger Ingelheim. **NM** has received research funding for Celltrion, Mylan, Sandoz, Abbvie, Amgen, Janssen, Pfizer and Takeda; has served as a consultant or advisory board member for Atawao Healthcare, Celltrion, CTMA, Gilead, Janssen, Abbvie, Amgen, Biogen, Ferring, MSD, Pfizer, Sandoza and Takeda. **JF** has served as a consultant or advisory board member for Abbvie, Amgen, Biogen, Celltrion, Galapagos, HAC pharma, Janssen, MSD, Pfizer, Sandoz, Takeda, Tillotts. **LV** has served as a consultant or advisory board member for Abbvie, Amgen, Viatris, Celltrion Healthcare, MSD, Janssen, Pfizer, Takeda, Lilly, Ferring, Galapagos. **SN** has served as a consultant or advisory board member for AbbVie, Ferring, Hospira, MSD, and ViforPharma. **AD** has served as a consultant or advisory board member for Celltrion Healthcare, Fresenius Kabi and Abbvie. **AD** is an employee of Celltrion Healthcare France. **CH** is an employee of Celltrion Healthcare France. **SB** is an employee of Celltrion Healthcare France. **HM** has served as a consultant or advisory board member for AbbVie, Amgen, Bristol Myers Squibb, Celltrion HealthCare, Galapagos, Lilly France, Merck Sharp & Dohme, Novartis, Nordic Pharma, Pfizer, and Sanofi Aventis; has received research funding for Bristol Myers Squibb, Celltrion HealthCare, Galapagos, Lilly France, Novartis, Nordic Pharma, Pfizer, and Sanofi Aventis.

Reference: **1**- Furst DE, and al. Efficacy and safety of switching from reference adalimumab to CT-P17 (100 mg/ml): 52-week randomized, double-blind study in rheumatoid arthritis. Rheumatology (Oxford). 2022.