



Clinical science

Effectiveness of a 26-week glucocorticoid taper in giant cell arteritis treated with tocilizumab in real-world clinical practice: a single-centre cohort study

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Abstract

Objective: To assess the feasibility of the Giant Cell Arteritis Actemra (GiACTA)-based 26-week glucocorticoid (GC) taper in patients with newly diagnosed GCA.

Methods: We conducted a retrospective, single-centre study including patients with newly diagnosed active GCA treated with tocilizumab (TCZ) and GCs, GC monotherapy or GCs combined with conventional DMARDs. In all patients treated with TCZ the standard GC taper was the GiACTA-based 26-week GC taper. A subgroup of TCZ-treated patients at high risk for GC-associated adverse events was identified, in which, based on a decision between the patient and physician, a shorter 16-week prednisone taper was used. Data on relapses, steroid doses and therapy-related adverse events were collected from patients' records.

Results: A total of 101 patients with newly diagnosed GCA were included; 47 (46.5%) patients were treated from the beginning with TCZ. Of the 47 patients, 28 (59.6%) treated with TCZ tapered off GCs completely within 26 weeks. Of these patients off GCs within 26 weeks, 25 (89.3%) were in relapse-free remission at week 52. In 15 patients treated with TCZ, GCs were tapered off completely within 16 weeks. Of these patients off GCs within 16 weeks, 14 (93.3%) were still in relapse-free remission at week 52 and no further flares occurred in this group of patients by week 104. No case of GCA-related vision loss or cerebrovascular ischaemia occurred during follow-up.

Conclusion: In this real-world setting, 26- and 16-week GC tapers were effective and safe in patients with newly diagnosed GCA treated with TCZ.

Keywords: giant cell arteritis, tocilizumab, glucocorticoid taper.

Key messages

- A majority of patients (59.6%) with newly diagnosed giant cell arteritis treated with tocilizumab could taper off glucocorticoids completely within 26 weeks.
- In patients at high risk for glucocorticoid-associated adverse events, a faster 16-week glucocorticoid taper was effective and safe.

Introduction

GCA is the most common vasculitis in individuals >50 years of age and is associated with severe morbidity and potential irreversible complications such as visual loss and cerebrovascular events [1–3]. Until recently, prolonged glucocorticoid (GC) courses averaging 24 months were the mainstay of pharmacological treatment of GCA [4, 5]. However, a majority of patients treated with GC monotherapy experience disease flares within 1 year if GCs are tapered off completely, and even if GCs are continued at lower doses the flare rate is 35–75% [6–8]. Due to the high rate of flares, many patients receive long and repeated courses of GCs with cumulative

doses reaching almost 10 g of prednisone-equivalent by the end of follow-up in studies [9–11]. High cumulative GC doses are associated with significant toxicity [12–14].

Two randomized clinical trials have demonstrated the efficiency of interleukin 6 (IL-6) receptor blockade with the humanized monoclonal antibody tocilizumab (TCZ) in reducing the number of flares and cumulative GC dose in patients with newly diagnosed or relapsing GCA [15, 16]. With slight variations, both the 2021 ACR/Vasculitis Foundation (VF) guidelines and the 2018 update of the EULAR recommendations endorse the use of TCZ in GCA [17, 18]. While the ACR/VF guidelines support treatment with TCZ for all patients with

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newly diagnosed GCA, EULAR recommends starting TCZ in those with or at risk of GC-related adverse events or in patients with relapsing disease [17, 18]. Based on the results of the Giant Cell Arteritis Actemra (GiACTA) trial, the EULAR recommends the use of a 26-week GC taper regimen in patients with GCA treated with TCZ [18]. However, the 26-week GC tapering regimen based on the GiACTA trial is somewhat arbitrary and studies comparing the effectiveness and safety of different GC tapering protocols are scarce, resulting in uncertainty about the optimal duration of GC therapy in patients with GCA treated with TCZ.

It is known that GC exposures in patients with GCA in the context of real-world TCZ use far exceed the quantities of GCs used in clinical trials [19, 20]. Despite several observational studies demonstrating a significant GC-sparing effect of TCZ in GCA, there are no studies analysing the applicability of the GiACTA-based 26-week GC taper in a clinical practice scenario.

The objective of the present study was to evaluate the applicability of the GiACTA derived 26-week GC tapering regimen in patients with newly diagnosed GCA treated with TCZ in real-world clinical practice. In all patients treated with TCZ, the standard GC tapering regimen was the 26-week tapering protocol used in the GiACTA trial. In a subgroup of TCZ-treated patients at high risk for or with observed GC-associated adverse events (e.g. patients with insufficiently controlled diabetes or osteoporosis), a shorter 16-week prednisone taper was used based on a decision between patient and physician.

Finally, we compared cumulative GC exposures, remission outcomes and safety in a large series of patients with GCA treated with or without TCZ in a clinical practice scenario.

Material and methods

Study design and participants

We conducted a monocentric retrospective study analysing electronic medical records for all patients who had received a diagnosis of GCA at our tertiary rheumatology centre between August 2008 and May 2023. The local ethics committee of the University Regensburg approved the study (approval number 12-101-0074) and written informed consent was obtained from all participants.

We included patients according to the following inclusion criteria: age ≥ 50 years at the time of diagnosis, newly diagnosed GCA with inflammatory activity, started treatment within 2 weeks after diagnosis with TCZ and GCs or GC monotherapy or GCs combined with conventional DMARDs (cDMARDs) and follow-up for ≥ 1 year after diagnosis of GCA.

The diagnosis of GCA required an age ≥ 50 years, the presence of characteristic cranial symptoms, symptoms of PMR or constitutional symptoms like weight loss, weakness or fever; elevated inflammatory markers (i.e. ESR ≥ 50 mm/h or CRP ≥ 10 mg/l); results of a temporal artery biopsy consistent with GCA or imaging studies demonstrating large vessel vasculitis. Imaging techniques used for the diagnosis of GCA were US, PET, CT or MRA. All patients fulfilled the 2022 ACR/EULAR classification criteria for GCA.

Patients received TCZ at the discretion of the treating rheumatologist because of comorbidities that required a GC-sparing strategy. All patients treated with TCZ received 162 mg as a subcutaneous injection, initially weekly, then,

where applicable, with extended intervals. In all patients treated with TCZ, the standard GC tapering regimen was the 26-week protocol used in the GiACTA trial. In a subgroup of TCZ-treated patients at high risk for or with observed GC-associated adverse events (e.g. patients with insufficiently controlled diabetes or osteoporosis), a shorter 16-week prednisone taper was used based on a decision between the patient and physician. The 16-week GC taper started with a GC dose of 60 mg/day prednisone-equivalent, then GCs were weekly tapered by 10 mg until a dose of 20 mg/day was reached. Thereafter, GCs were tapered by a dose reduction of 2.5 mg/week until a dose of 5 mg/day prednisone-equivalent. After that, GCs were tapered off completely by a reduction of 1 mg/week prednisone-equivalent. Before starting an oral GC therapy with 60 mg/day prednisone-equivalent in patients with visual symptoms, GC therapy was started with intravenous GC doses of 100–250 mg/day prednisone-equivalent for 3 consecutive days.

Study assessments

From disease diagnosis, disease assessment including a clinical evaluation, blood tests and vascular imaging, where appropriate, was performed at variable intervals, but at least every 3 months. The primary retrospective outcome was the applicability, i.e. effectiveness and safety, of the GiACTA derived 26-week GC tapering regimen in patients with newly diagnosed GCA treated with TCZ in real-world clinical practice. Effectiveness was operationalized by the proportion of patients with relapse-free remission at weeks 52 and 104 who stopped GCs within 26 or 16 weeks.

A relapse was defined as the reappearance of signs or symptoms of GCA or elevated ESR (≥ 30 mm/h) or CRP (≥ 10 mg/l) attributed to GCA that required treatment intensification, such as increased doses of GCs, resumption of GCs after weaning or the introduction or intensification of adjuvant immunosuppressive therapy. Remission was defined as the absence of a relapse.

Secondary retrospective outcomes comprised a comparison between patients treated with TCZ and patients treated with GCs based on a decision between patient and physician $\pm$ cDMARDs regarding effectiveness, safety and cumulative GC dose by weeks 52 and 104.

A serious adverse event (SAE) was defined as a life-threatening event requiring hospitalization or leading to persistent or significant disability. The use of intravenous antibiotics or the need for hospitalization defined a serious infection.

Statistical analysis

All analyses were carried out using R 3.6.1 statistical software (R Foundation of Statistical Computing, Vienna, Austria). All continuous variables were expressed as mean (s.d.). Categorical variables were reported in percentages. The Mann–Whitney U test and Fisher's exact test were used to analyse differences between groups of patients with different treatments and different patterns of GC tapering, respectively. Relapse-free survival was summarized by means of Kaplan–Meier curves. *P*-values < 0.05 were considered significant.

Results

Characteristics of patients

A total of 101 patients who had received a new diagnosis of GCA between August 2008 and May 2023 were included in

the study. Of these, 47 (46.5%) patients were treated with TCZ (weekly subcutaneous dose of 162 mg) as GC-sparing therapy within 2 weeks of the GCA diagnosis; 54 (53.5%) patients were treated with GC monotherapy or GCs combined with cDMARDs. Of the 37 patients treated with cDMARDs, 32 were on methotrexate and 5 were treated with azathioprine. The characteristics of the study patients are presented in Table 1.

All patients were followed up until week 52 and 76 (75.2%) patients were followed up for 104 weeks. The mean follow-up time in all patients was 96.2 weeks (s.d. 16.9). In patients treated with TCZ, the mean follow-up was 95.5 weeks (s.d. 17.2). In patients treated with GC±cDMARD the mean follow-up time was 96.7 weeks (s.d. 16.6).

As relapses in GCA are associated with potentially severe and irreversible complications and as convenient and biologic immunosuppressive therapies act with latency, every relapse was treated with increased doses of GCs or a resumption of GCs as fast-acting therapy, irrespective of whether an adjunct immunosuppressive was newly started or intensified.

Due to remission intervals, in 33 (70.3%) patients treated with TCZ the applications were extended from 1 to 2 weeks [mean time of interval extension: week 59.8 (s.d. 18.7)]. The mean duration of treatment with TCZ was 92.7 weeks (s.d. 17.8).

Patients with newly diagnosed GCA treated with TCZ tapering off GCs within 26 weeks

A total of 28 of 47 patients (59.6%) with newly diagnosed GCA treated with TCZ tapered off GCs completely within 26 weeks and 35 patients (74.5%) were able to reduce GCs

to a dose ≤2.5 mg/day prednisone-equivalent up to week 26. Of these patients off GCs within 26 weeks, 25 of 28 (89.3%) were in GC-free remission without any relapse at week 52 (Table 2). From week 52 to week 104 no further flares occurred in this group of patients tapering off GCs completely by week 26.

Patients with a slower GC taper not stopping GCs within 26 weeks had a numerically higher relapse rate (relapse-free remission by week 52: 73.7%; $P = 0.24$; Table 2). From week 52 to week 104 no further flares occurred in this group of patients with a slower GC taper not stopping GCs within 26 weeks.

Comparing the mean cumulative prednisone dose at week 52 and 104 in patients tapering off GCs completely by week 26 and patients with a slower GC taper, cumulative GC doses were significantly lower in the group of patients stopping GCs within 26 weeks [mean at week 52: 2063 mg (s.d. 676) vs 3097 mg (s.d. 807), $P < 0.001$; mean at week 104: 2079 mg (s.d. 566) vs 3392 mg (s.d. 899), $P < 0.001$; Table 2]. A total of 96% of the patients tapering off GCs completely by week 26 remained GC free until week 52 and all patients stopping GCs by week 26 were GC free at week 104. Patients with a slower GC taper had a lower proportion of GC-free patients at week 52 (57.9%, $P = 0.0002$). However, all patients treated with TCZ not stopping GCs within 26 weeks were GC free by week 104 (Table 2).

Patients with newly diagnosed GCA treated with TCZ tapering off GCs within 16 weeks

In 15 patients (31.3%) at higher risk for or with observed GC-associated side effects and based on a shared decision between patient and physician, a 16-week GC taper was used.

Table 1. Characteristics of the study patients.

Characteristics	TCZ ($n = 47$)	GC±cDMARD ($n = 54$)
Age, years, mean (s.d.)	67.3 (8.4)	69.2 (7.1)
Sex, n (%)		
Female	35 (74.5)	32 (59.3)
Male	12 (25.5)	22 (40.7)
BMI, mean (s.d.)	26.0 (4.5)	26.0 (4.1)
CRP at diagnosis, mg/l, mean (s.d.)	59.5 (48.5)	51.9 (50.7)
ESR at diagnosis, mm/h, mean (s.d.)	64.9 (32.5)	58.9 (30.1)
Clinical manifestations at disease onset, n (%)		
Cranial symptoms ^a	14 (29.8)	15 (27.8)
PMR symptoms	7 (14.9)	16 (29.6)
AION	9 (19.1)	3 (5.6)
Other	17 (36.2)	20 (37.0)
New-onset disease	47 (100)	54 (100)
Diagnosis		
Positive temporal artery biopsy	5 (10.6)	4 (7.4)
US	29 (61.7)	32 (59.3)
PET-CT	10 (21.3)	17 (31.5)
MRA	1 (2.1)	0
CT angiography	1 (2.1)	0
Conventional DMARD therapy, n (%)	0	37 (68.5)
Initial prednisone dose, mg/day, mean (s.d.)	137.2 (120.7)	110 (87.8)
Internal diseases/comorbidities, n (%)		
Arterial hypertension	19 (40.4)	37 (68.5)
Cardiovascular disease (coronary heart disease, peripheral arterial disease, heart failure, state after cerebral ischaemia)	7 (14.9)	7 (13)
Osteopenia or osteoporosis	24 (51)	12 (22.2)
Hyperlipidaemia	6 (12.8)	7 (13)
Diabetes mellitus type 2	4 (8.5)	12 (22.2)
Absolute arrhythmia	5 (10.6)	2 (3.7)
Chronic renal insufficiency	4 (8.5)	3 (5.6)

AION: anterior ischaemic optic neuropathy; BMI: body mass index.

^a Cranial symptoms: new-onset headache, scalp tenderness, temporal artery tenderness, decreased pulsation, jaw or mouth claudication.

Table 2. Flares and cumulative GC doses in patients with newly diagnosed GCA ($n = 47$) treated with TCZ tapering off GCs within 26 or 16 weeks.

Characteristics	Tapering off GCs by week 26 [$n = 28$ (59.6%)]	Not tapering off GCs by week 26 [$n = 19$ (40.4%)]	Tapering off GCs by week 16 [$n = 15$ (31.9%)]	Not tapering off GCs by week 16 [$n = 32$ (68.1%)]
Flare-free remission by week 52, n/N (%)	25/28 (89.3)	14/19 (73.7)	14/15 (93.3)	25/32 (78.1)
<i>P</i> -value		0.240		0.406
Total number of flares by week 52, n (%)	3	5	1	7
Total number of flares by week 104, n (%)	3	5	1	7
Time to first flare, weeks, mean (s.d.)	6.3 (2.2)	11.2 (3.3)	3	10.3 (3.3)
Cumulative GC dose by week 52, mg, mean (s.d.) ^a	2062.8 (676.1)	3096.8 (807.0)	1766.6 (445.6)	2816.6 (848.9)
<i>P</i> -value		<0.001		<0.001
Cumulative GC dose by week 104, mg, mean (s.d.) ^a	2078.7 (565.7)	3392.1 (899.3)	1921.9 (280.1)	2903.6 (980.5)
<i>P</i> -value		<0.001		0.003
GC-free week 52, n/N (%)	27/28 (96.4)	11/19 (57.9)	15/15 (100)	23/32 (71.9)
<i>P</i> -value		0.002		0.041
GC-free week 104, n/N (%)	18/18 (100)	14/14 (100)	9/9 (100)	25/25 (100)

^a Prednisone-equivalent dose.

Of these patients off GCs by week 16, 14 (93.3%) were still in GC- and relapse-free remission at week 52. From week 52 to week 104, no further flares occurred in this group of 15 patients (Table 2). Comparing the mean cumulative prednisone dose at week 52 and week 104 in patients tapering off GCs completely by week 16 and patients with a slower GC taper, cumulative GC doses were significantly lower in the group of patients stopping GCs by week 16 [mean week 52: 1767 mg (s.d. 446) *vs* 2817 mg (s.d. 849), $P < 0.001$; mean week 104: 1922 mg (s.d. 280) *vs* 2904 mg (s.d. 981), $P = 0.003$; Table 2].

All patients tapering off GCs completely by week 16 remained GC-free until week 52 and all patients tapering off GCs within 16 weeks were GC-free at week 104. Patients with a slower GC taper had a lower proportion of GC-free patients at week 52 (71.9%, $P = 0.041$). However, all patients tapering off GCs within 16 weeks were GC-free by week 104 (Table 2).

Outcomes of patients treated with TCZ compared with patients treated with GCs $\pm$ cDMARDs

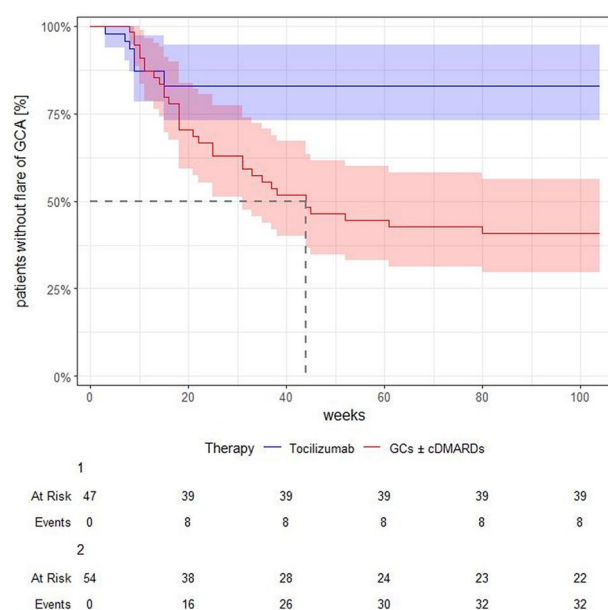
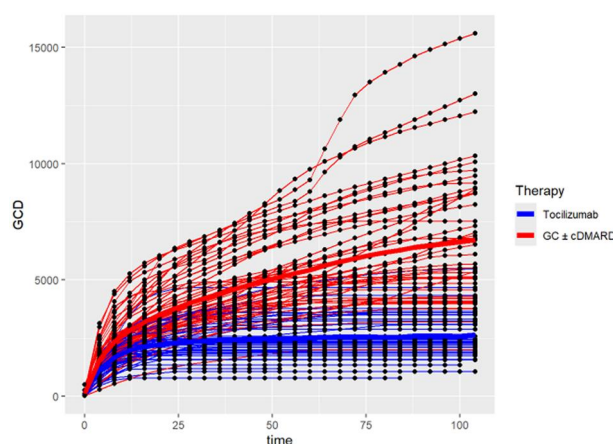
Flares

A total of 83.0% of the patients treated with TCZ were in relapse-free remission at week 52. Until week 52, eight flares occurred in eight patients. The mean time to relapse was 9.4 weeks (s.d. 3.7). Between week 52 and 104, no further flares occurred (Fig. 1). At weeks 52 and 104, a total of 80.9% and 100%, respectively, of all patients treated with TCZ were in GC-free remission.

In the group of patients treated with GCs $\pm$ cDMARDs, 44.1% and 40.1% of the patients were in relapse-free remission at week 52 and 104, respectively (Fig. 1). At week 52 and 104, 3.7% and 47.7%, respectively, of all patients treated with GCs $\pm$ cDMARDs were in GC-free remission.

Cumulative GC dose

The total mean cumulative prednisone dose at week 52 was 2480.8 mg (s.d. 890.6) in patients treated with TCZ compared with 5127.1 mg (s.d. 1555.4) in patients treated with GCs $\pm$ cDMARDs (Fig. 2). At week 104, the mean cumulative prednisone dose in the group of patients treated with TCZ was 2635.9 mg (s.d. 954.8) compared with 6712.9 mg (s.d. 2810.9) in the group of patients treated with

**Figure 1.** Kaplan–Meier curve for the occurrence of flares in patients with newly diagnosed GCA treated with TCZ (1, blue line) or with GCs $\pm$ cDMARDs (2, red line)**Figure 2.** Cumulative GC dose for patients with newly diagnosed GCA treated with TCZ (blue line) or GCs $\pm$ cDMARDs (red line)

GCs $\pm$ cDMARDs (Fig. 2; $P < 0.001$ for all comparisons of tocilizumab with GCs $\pm$ cDMARDs).

Safety

The percentages of patients with adverse events were similar in the group of patients treated with TCZ and in the group of patients treated with GCs $\pm$ cDMARDs (Table 3). In the group of patients treated with TCZ, five (10.6%) patients had an SAE (Table 3). These included two severe bacterial infections with the need for hospitalization and intravenous antibiotic therapy; one case of diverticulitis without bowel perforation; one anaphylactic reaction and one grade 3 neutropenia, which was not related to a severe infection or any infection at all. In four of the five patients with an SAE, therapy with TCZ was stopped.

Among patients treated with GCs $\pm$ cDMARDs, four (7.4%) were affected by a severe adverse event, all of which were severe infections (Table 3): one case of urosepsis with renal failure, one case of septic arthritis, one patient with a bacterial prostatitis with the need for intravenous antibiotics and one patient with a urinary tract infection with multiple renal abscesses.

In both the group of patients treated with TCZ and the group of patients treated with GCs $\pm$ cDMARDs, no patient had a GCA-associated visual or cerebrovascular manifestation during the time of follow-up. No gastrointestinal perforation was observed.

Discussion

With several observational studies confirming the GC-sparing effect of TCZ in patients with GCA in real-world clinical practice [21–24], there is still considerable uncertainty about the optimal duration of GC therapy in patients with GCA treated with TCZ. Based on the results of the randomized controlled GiACTA trial, the EULAR recommends the use of a 26-week GC tapering regimen in patients with GCA treated with TCZ [18]. Even after a thorough literature review, to our knowledge this is the first study analysing the feasibility of the GiACTA 26-week GC taper in patients with exclusively newly diagnosed GCA treated with TCZ in a real-world scenario.

The results of this observational study suggest that TCZ in combination with a 26-week GC taper regimen can induce and maintain disease remission safely in real-world patients with newly diagnosed GCA. The majority of patients (59.6%) could taper off GCs completely within 26 weeks and 74.5% of all patients treated with TCZ could taper off GCs to a dose ≤ 2.5 mg/day prednisone-equivalent up to week 26. The GiACTA-based 26-week taper protocol proved to be

sustainable and effective in real-world clinical practice: a vast majority of all patients who had tapered off GCs completely by week 26 were still GC-free by weeks 52 and 104 (96 and 100%, respectively) and 89% of all patients who had stopped GCs by week 26 were in relapse-free remission by week 52 with no further flares occurring by week 104. Notably, compared with the patients tapering off GCs within 26 weeks, patients with a slower GC taper did not show a higher remission rate by weeks 52 and 104.

In the last few years, one pilot study, two proof-of-concept studies and one prospective observational study have been published evaluating the effectiveness and safety of TCZ monotherapy without GCs and after short or ultra-short pulse GC administration in patients with GCA [25–28]. In a proof-of-concept study by Christ *et al.* [26], 18 patients with newly diagnosed GCA received 500 mg methylprednisone intravenously for 3 consecutive days. Thereafter, GC treatment was discontinued followed by weekly subcutaneous TCZ injections. Thirteen of the patients (72%) showed no relapse by week 52. However, anterior ischaemic optic neuropathy occurred in one patient.

Muratore *et al.* [28] selected a similar study design, enrolling 18 patients with newly diagnosed or relapsing GCA receiving 500 mg/day of methylprednisone intravenously for 3 consecutive days followed by subcutaneous TCZ monotherapy until week 52. The proportion of patients with relapse-free remission at week 52 was 76% and vascular inflammation, as evaluated by PET/CT, was significantly reduced at weeks 24 and 52. A third small prospective pilot study from Japan confirmed the effectiveness of TCZ monotherapy without any GCs in eight patients with newly diagnosed GCA [25]. Of these, 75% were in complete remission, defined as the absence of vasculitis symptoms and normalization of CRP at week 52. Interestingly, none of the newly diagnosed GCA patients experienced a disease flare (i.e. recurrence of clinical symptoms of vasculitis, an increase in CRP attributable to vasculitis or the need for initiation of GCs) during the TCZ monotherapy phase by week 52. In a prospective proof-of-concept study including 30 patients with newly diagnosed or relapsing GCA by Unizony *et al.* patients received 12 months of TCZ 162 mg subcutaneously in combination with 8 weeks of prednisone. At week 52, 77% of patients were in sustained prednisone-free remission [27].

In our real-life cohort of 47 patients with newly diagnosed GCA, 15 patients (32%) at high risk for GC-associated side effects were tapered off GCs completely within 16 weeks, based on a shared decision between the patient and physician. The 16-week GC taper proved to be sustainable and effective. All patients who had tapered off GCs completely at week 16

Table 3. Safety.

Characteristics	Tocilizumab ($n = 47$)	GC $\pm$ cDMARD ($n = 54$)
Observation time (patient-years)	84.3	98.3
Patients with one or more adverse event, n (%)	29 (61.7)	33 (61.1)
Adverse events, n (%)		
Total number	54	80
Rate per 100 patient-years	64.1	81.4
Patients with one or more SAE, n (%)	5 (10.6)	4 (7.4)
Patients with one or more infections, n (%)	10 (21.3)	5 (7.4)
Patients with one or more severe infections, n (%)	2 (4.3)	4 (7.4)

were still GC free at week 52 and 104 and 93% of the patients tapering off GCs completely within 16 weeks were in relapse-free remission at week 52 with no further flares up to week 104. Notably, patients with a slower GC taper were not characterized by lower relapse rates.

Analysing the outcome of the whole group of patients treated with TCZ, the proportion of patients without a flare at week 52 was similar to that of the GiACTA patients treated with weekly TCZ (83% *vs* 73%, respectively). Also, the proportion of patients treated with GCs $\pm$ cDMARDs without a flare at week 52 was similar to the proportion of patients in the GiACTA trial treated with placebo and a 52-week GC taper (44% *vs* 51%).

In terms of safety, the proportion of patients treated with TCZ experiencing SAEs (10.6%) was similar to that of other retrospective and prospective studies, including the GiACTA trial, with 15% of patients treated with weekly TCZ experiencing at least one SAE [15, 21, 15].

Despite the relevant proportion (32%) of patients in the present study with a relatively short 16-week GC taper, no case of GCA-associated visual or cerebrovascular manifestation during the follow-up until week 104 was observed.

Study limitations

The strength of our study lies in the application of a fast GC tapering regimen in clinical practice outside of highly controlled study settings. The main limitations of our study are the retrospective approach, the relatively small sample size, the limited observation time and the inclusion of patients from a single centre, which limits the generalizability of the results. Furthermore, as the present study defined remission of GCA independently from imaging evaluation, it gives no answer to the question if TCZ with a faster GC taper is able not only to achieve clinical remission, but also to resolve vessel inflammation and prevent vascular damage [28].

Conclusions

Our results demonstrate that the GiACTA-based and EULAR-recommended 26-week GC taper in patients with GCA treated with TCZ is effective and safe in a real-world clinical setting. Even a more rapid 16-week GC taper proved to be effective and safe, suggesting a high potential to further spare GCs in patients with newly diagnosed GCA treated with TCZ.

Especially for the 16-week GC tapering protocol, larger cohort studies and randomized controlled trials are required to confirm these findings before this type of prednisone taper can be recommended for routine clinical practice.

Data availability

The datasets used and/or analysed during the current study are available from the corresponding author upon reasonable request.

Authors' contributions

All authors contributed to the study design, delineated suitable patients for the study and obtained informed consent from patients, analysed the data, participated in writing the manuscript and approved the final version of the manuscript.

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