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BRIEF REPORT

Management of Systemic Anti-psoriatic Drugs in Psoriasis Patients with Concurrent Paraplegia or Tetraplegia: Insights From a 6-Year Multicenter, Retrospective Observational Study

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ABSTRACT

***Introduction*:** Patients with psoriasis (PsO) and permanent spinal cord injuries (SCI) resulting in paraplegia and tetraplegia may experience a higher rate of infections compared to patients with PsO without SCI. It can result in further challenges for therapeutic management with immunosuppressants (biological and non-biological treatments). Thus, we aimed to evaluate the rate of infections in patients with PsO and SCI treated with systemic immunosuppressants.
***Methods*:** This multicenter, retrospective observational study enrolled patients with PsO and traumatic SCI undergoing systemic immunosuppressive treatments for at least 5 years. All patients were evaluated by experienced, board-certified dermatologists and neurologists. Demographic and clinical data were collected.
***Results*:** We enrolled 23 patients with SCI (16 with paraplegia and 7 with tetraplegia) treated with methotrexate (MTX) and different biologics (tumor necrosis factor (TNF) inhibitors (i) and interleukin (IL)-17i/IL-23i). Globally, patients

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with SCI treated with MTX displayed higher rates of infection compared to those treated with biologics. Patients with paraplegia had lower rates of infection compared to patients with tetraplegia during anti-psoriatic therapies ($p<0.05$). Those treated with TNFi had greater rates of infection than those treated with IL-17i/IL-23i ($p<0.001$). Patients with psoriatic arthritis (PsA) experienced a significant diagnostic delay and clinical monitoring of PsA severity was challenging.

***Conclusion*:** In patients with moderate-to-severe PsO and concurrent traumatic SCI, dermatologists should consider using IL-17i/IL-23i as first-line therapy.

Keywords: Psoriasis; Methotrexate; SCI; IL-17/IL-23 inhibitors; Infection; Paraplegia; Tetraplegia; Psoriatic arthritis

Key Summary Points
Patients with permanent spinal cord injury have higher rate of infections.
Anti-psoriatic systemic drugs increase infections rate and no data are present in patients with spinal cord injury.
In patients with spinal cord injuries, Methotrexate and tumor necrosis factor (TNF) alpha inhibitors (i) display higher rate of infections compared with interleukin-17/23i in patients with spinal cord injury.
Patients with spinal cord injuries (SCI), psoriasis, and concurrent psoriatic arthritis (PsA) experienced a significant delay in PsA diagnosis.

INTRODUCTION

Psoriatic disease (PsO) is a chronic, systemic inflammatory disorder [1, 2] with a significant negative impact on the overall quality of life as a result of musculoskeletal [3], cardiovascular [4, 5], psychological [6], and gastrointestinal comorbidities [7]. Furthermore, acute or chronic trauma (e.g., scratching and decubital ulcers) in patients with PsO could induce PsO flares through koebnerization [8]. Complete disease control (Psoriasis Area Severity Index (PASI) 100) and prevention of koebnerization and itch [9] are critical to improving the quality of life. However, systemic anti-psoriatic treatments (i.e., methotrexate and biologics) result in increased upper respiratory and urinary tract infections [10, 11].

Traumatic events may result in spinal cord injuries (SCI), forcing patients with PsO to face further social fragility and increased risk of infection, specifically in the respiratory tract (i.e., traumatic lung injuries) [12, 13] and urinary tract (i.e., self-catheterizations) [14].

Patients with PsO and permanent SCI (i.e., with paraplegia and tetraplegia) may experience a higher infection rate compared to patients with PsO without SCI, making therapeutic management with immunosuppressants (biological and non-biological treatments) even more challenging. Unfortunately, guidelines do not mention this special population, and there are no prior studies evaluating this issue. Herein, we report data on patients with SCI and PsO treated with methotrexate and/or biologics.

MATERIALS AND METHODS

Ethical Approval

The study protocol was approved by the Saint Rafael Hospital (OSR) local ethical committee on August 28, 2021 with the number 176/int/2020 and was conducted according to the Declaration of Helsinki principles established by the World Medical Association (WMA) in 1964 and its most recent amendments in 2013 during the General Assembly. All patients signed an approved informed consent form before screening for participation in the study.

Study Design

This retrospective observational study involved three Italian primary referral centers for psoriasis, namely IRCCS Istituto Ortopedico Galeazzi-Sant'Ambrogio, San Gallicano Hospital, and Policlinico of Messina. All three clinical databases were queried to retrieve demographic (age, gender, smoking status, alcohol use, type of diet) and clinical information (psoriasis duration, type of psoriasis treatment, joint assessment, duration of use, intraclass switching, recorded urinary tract infections (UTI), pneumonia or upper respiratory tract infections) of patients with SCI and PsO that were treated for PsO and followed up for at least 5 years from 2010 to 2022.

Inclusion and Exclusion Criteria

We enrolled adult (>18 years of age) patients with plaque psoriasis and satisfying the following criteria:

(a) Psoriasis duration longer than 6 months
(b) Moderate to severe disease (PASI>10) [15].
(c) Traumatic SCI resulting in paraplegia or tetraplegia.
(d) Available clinical data (i.e., clinical outcomes, diet [16–18], and smoking or alcohol use [19]).
(e) Neurology follow-up.
(f) At least 5 years of follow-ups.
(g) Candidates for subcutaneous administration of methotrexate (MTX) [20], or biologics (TNFα, IL-17, IL-23 inhibitors) [21] both medication naïve [22] and those switching [23, 24].
(h) Patients who signed a consent form.

Conversely, we excluded the following:

(a) Pediatric patients (<18 years of age).
(b) Patients with psoriasis types other than plaque or those with more than one type of psoriasis (e.g., plaque psoriasis and palmoplantar pustular psoriasis).
(c) Patients with concurrent autoimmune diseases (i.e., rheumatoid arthritis, systemic lupus, inflammatory bowel disease).
(d) Patients with chronic infectious diseases (i.e., HIV).
(e) Patients with incomplete clinical data (both neurological and dermatological).
(f) Patients undergoing combination therapy [25].
(g) Patients who refused to sign a consent form.

Dermatological Assessment

The enrolled patients were assessed by board-certified dermatologists with more than 5 years of experience in a psoriasis-specialized ambulatory clinic. Patients' psoriatic lesions were evaluated in terms of extension, infiltration, thickness, and erythema with a PASI score. The Psoriasis Epidemiology Screening Tool (PEST) [26] was administered to detect potential joint involvement and, if present, was classified using the ClASsification for Psoriatic ARthritis (CASPAR) criteria [27].

Neurological Assessment

All patients were clinically evaluated by board-certified, neurologists with more than 5 years of experience and classified using the American Spinal Injury Association Impairment (ASIA) Scale [28, 29]. The scale has five classification levels, ranging from complete loss of neural function in the affected area to completely normal:

Grade A The impairment is complete and consequently neither motor nor sensory functions remain below the level of injury.

Grade B The impairment is incomplete if there is only sensory function below the level of injury and residual sensation in the sacral segments S4 and S5.

Grade C The impairment is incomplete with motor function maintained below the

level of injury and the main muscles below the neurological level experienced a loss of volume.

Grade D The impairment is incomplete and the motor function is maintained with muscle grade 3 or greater (against gravity).

Grade E The patient has no impairments in sensory and motor function.

Statistical Analysis

Before analysis, the data were visually inspected for potential outliers. The normality of data distribution was assessed by conducting the Shapiro–Wilk test, given the small sample size. Data were computed as means ± standard deviations for continuous variables, whereas they were expressed as percentages for categorical parameters. Student's *t* test was applied to compute the mean differences between paraplegics and tetraplegics. All statistical analyses were carried out with the commercial software MedCalc Statistical Software version 17.9.7 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2017). All *p* values less than 0.05 were considered statistically significant.

RESULTS

Demographic Data

In this retrospective observational study, we enrolled 23 patients with traumatic SCI. They were predominantly male and had a median age of 41.5 [36.0–47.5] years of age (Table 1). The median SCI duration was 8.5 [5.5–12.5] years. From a neurological perspective, 7 patients were categorized as tetraplegics (3 Grade A, 3 Grade B, 1 Grade C) and 16 as paraplegics (11 Grade A, 4 Grade B, 1 Grade C).

Clinical and Therapeutic Data

Interestingly, all cases were treated with MTX before traumatic SCI and had a median PASI of 18 [11.0–26.8] at baseline. Decubital areas were frequently involved in psoriasis koebnerization, especially when drug responsiveness decreased, which is helpful in monitoring disease activity. After traumatic SCI, 12% developed PsA (1 oligoarticular and 2 spondylitic), and the diagnosis was delayed because of the lack of sensory function or perceived morning stiffness. Furthermore, clinical scores such as DAPSA (Disease Activity in PSoriatic Arthritis) tended to underestimate the PsA severity because of lack of sensation (i.e., self-evaluation of disease activity and pain).

We also found that 36% were smokers with a prevalence of traditional smokers (cigars and cigarettes) and 47.8% were hazardous drinkers, indicating a need for further assessment. All addictions reported refer to after SCI time.

Patients with traumatic SCI using only subcutaneously administered MTX had a median dose of 15 mg per week for a median duration of 1.6 years (Table 2). Interestingly, patients with paraplegia used higher MTX doses (16.3 [15.0–17.5] vs 10.0 [10.0–10.0], $p<0.05$), had a longer MTX duration (1.8 [1.5–2.0] vs 1.0 [0.9–1.1], $p<0.001$) and a lower rate of infection ($p<0.05$) compared to patients with tetraplegia. In terms of efficacy, all patients achieved PASI 75, and 16/23 were completely clear (PASI 100). The switching from MTX was always to a TNFi (16 vs 6, biosimilars vs originator) with a preference for adalimumab and etanercept. The main motivations for switching were urinary and upper respiratory tract infections that often occur in these patients even without immunosuppression.

The median TNFi duration was 2.0 [1.0–3.0] without consistent differences between patients with paraplegia and patients with tetraplegia. Patients had a high rate of intraclass switching (overall 60.9%), especially patients with tetraplegia (71.4% vs 56.3%, $p<0.05$), and the switch was predominantly from etanercept to adalimumab. Furthermore, the infection rate per year decreased significantly in patients that switched from MTX to TNFi ($p<0.05$). All patients achieved PASI 75 and 16/23 PASI 90, but the infection rate was the main motivation (15/23) to switch to IL-17i/IL-23i, followed by PsA loss of response.

Table 1 Clinical characteristics of the enrolled patients

	Paraplegics (*N* = 16)	**Tetraplegics (*N* = 7)**	**Overall (*N* = 23)**
Age, median [IQR], years	40.0 [35.8–47.0]	45.0 [40.0–49.5]	41.5 [36.0–47.5]
Male, *N* (%)	10 (62.5)	5 (71.4)	15 (60.0)
SCI duration, median [IQR], years	8.5 [5.0–14.0]	9.0 [7.0–12.0]	8.5 [5.5–12.5]
PsO family history, *N* (%)	2 (12.5)	3 (42.9)	5 (20.0)
PsO duration, median [IQR], years	9.0 [6.8–10-3]	9.0 [7.5–12.5]	9.0 [7.0–11.5]
PsA, *N* (%)	1 (6.3)	2 (28.6)	3 (12.0)
Smokers, *N* (%)	6 (37.5)	3 (42.9)	9 (36.0)
Smoking type, *N* (%)			
Cigarettes and cigars	5 (31.3)	3 (42.9)	8 (32.0)
e-Cigarette	1 (6.3)	2 (28.6)	3 (12.0)
Vaping	2 (12.5)	0 (0.0)	2 (8.0)
AUDIT, median [IQR]	7.0 [6.0–8.0]	8.0 [6.5–9.5]	7.5 [6.0–8.5]
Alcohol use,[a] *N* (%)			
Abstinence (0 points)	0 (0.0)	0 (0.0)	0 (0.0)
Low risk (1–7 points)	9 (56.3)	3 (42.9)	12 (52.2)
Hazardous (8–14 points)	7 (43.8)	4 (57.1)	11 (47.8)
Dependence (> 14 points)	0 (0.0)	0 (0.0)	0 (0.0)

AUDIT alcohol use disorders identification test, *IQR* interquartile range, *SCI* spinal cord injury, *PsA* psoriatic arthritis, *PsO* psoriasis

[a]Alcohol use pattern refers to after SCI status. All patients with dependence were followed up by the local addiction center (SERT) and the patients with a hazardous use pattern were warmly suggested to attend an informative event titled "The impact of alcohol on health" at the hospital

All patients switched from MTX to TNFi and then to IL-17i/IL-23i with a preference for secukinumab, followed by ixekizumab with a median drug survival of 3.0 [2.0–3.0] years. Intraclass switching was minimal (13.0%) and limited to patients with paraplegia and PsA. Remarkably, the infection rate was drastically lower, compared to TNFi ($p < 0.05$), especially for UTI in patients with tetraplegia. All patients achieved a PASI 90 and 20/23 maintained PASI 100.

DISCUSSION

Anti-psoriatic biological therapies, especially IL-17i/IL-23i, were associated with a lower rate of infection in patients with traumatic SCI compared to MTX.

Patients with SCI are at an increased risk of UTI mainly due to self-catheterization, neurogenic bladder, and lack of sensitivity to UTI symptoms (i.e., dysuria, urinary urgency, and frequency). The UTI may be further complicated with pneumonia or nephritis which can present a further challenge for diagnosis and treatment in immunosuppressed patients

Table 2 Therapeutic overview and relative infectious episodes

	Paraplegics (*N* = 16)	**Tetraplegics (*N* = 7)**	**Overall (*N* = 23)**
Methotrexate			
MTX dosage, median [IQR], mg	16.3 [15.0–17.5]	10.0 [10.0–10.0]	15.0 [10.0–17.5]
MTX duration, median [IQR], years	1.8 [1.5–2.0]	1.0 [0.9–1.1]	1.6 [1.0–2.0]
Infections, *N* per year, median [IQR], mean			
UTIs	4.0 [3.0–5.0], 4.1	5.0 [4.0–7.5], 5.6	4.0 [3.0–5.5], 4.6
Pneumonias	1.0 [0.0–1.0], 0.9	1.0 [0.5–1.5], 1.1	1.0 [0.0–1.0], 1.0
RTIs	1.5 [0.0–2.3], 1.4	2.0 [1.0–3.0], 2.1	1.5 [0–2.5], 1.7
TNFα inhibitors			
TNFα inhibitor type, *N* (%)			
Adalimumab and its biosimilars	9 (56.3)	3 (42.9)	12 (52.2)
Etanercept and its biosimilars	6 (37.5)	3 (42.9)	9 (39.1)
Infliximab and its biosimilars	1 (6.3)	0 (0)	1 (4.3)
Golimumab	0 (0)	1 (14.3)	1 (4.3)
TNFα inhibitor duration, median [IQR], years	2.0 [1.8–3.0]	2.0 [1.0–2.0]	2.0 [1.0–3.0]
Intraclass switching, *N* (%)	9 (56.3)	5 (71.4)	14 (60.9)
Infections, *N* per year, *N* per year, median [IQR], mean			
UTIs	2.0 [2.0–3.0], 2.3	3.0 [1.5–3.0], 2.4	2.0 [2.0–3.0], 2.3
Pneumonias	1.0 [0.8–2.0], 1.1	1.0 [0.5–1.5], 1.0	1.0 [0.5–2.0], 1.0
Upper RTIs	1.0 [0.0–1–3], 0.9	2.0 [1.5–2.5], 2.0	1.0 [0.0–2.0], 1.3
IL-17/IL-23 inhibitors			
IL-17/IL-23 inhibitor type, *N* (%)			
Secukinumab	9 (56.3)	3 (42.8)	12 (52.2)
Ixekizumab	4 (25.0)	3 (42.8)	7 (30.4)
Risankizumab	3 (18.7)	1 (14.3)	4 (17.4)
IL-17/IL-23 inhibitor duration, median [IQR], years	3.0 [2.7–4.0]	3.0 [1.5–3.0]	3.0 [2.0–3.0]
Intraclass switching, *N* (%)	3 (18.8)	0 (0.0)	3 (13.0)

Table 2 continued

	Paraplegics ($N=16$)	Tetraplegics ($N=7$)	Overall ($N=23$)
Infections, *N* per year, *N* per year, median [IQR], mean			
UTIs	2.0 [1.0–2.0], 1.6	1.1 [1.0–2.0], 1.6	2.0 [1.0–2.0], 1.6
Pneumonias	0.0 [0.0–1.0], 0.5	1.0 [0.0–1.0], 0.6	0.5 [0.0–1.0], 0.5
RTIs	1.0 [0.0–1.0], 0.6	0.0 [0.0–0.5], 0.3	0.0 [0.0–1.0], 0.5

IL interleukin, *IQR* interquartile range, *MTX* methotrexate, *RTIs* respiratory tract infections, *TNF* tumor necrosis factor, *UTIs* urinary tract infections

[30, 31]. In our cohort of patients with traumatic SCI, IL-17 pathway inhibition decreased the rate of UTI.

Patients with PsO present with airway inflammation at baseline that may be mildly responsive to systemic therapies [32, 33]. Furthermore, the airway fragility of patients with PsO is also demonstrated by the prominent respiratory burden [34], independent of tobacco use. Among this cohort, the rate of upper respiratory tract infection and pneumonia decreased.

However, biologic therapy increased upper RTI but not pneumonia. Overall, despite initial data demonstrating an increased risk of COVID-19 during biological therapies [35–37], real-life studies suggest that biologics (both IL-17i and TNFi) are protective against hospitalization, ICU admission, and death [37–40]. In addition, IL-17i and IL-23i are not contraindicated in patients with tuberculosis and do not need eradication before starting [41, 42]. PsO treatment become even more complex during COVID-19 lockdown when switching between conventional and biologic drugs was higher to improve therapeutic manageability, drug discontinuation, monitoring, and hospital-based controls [43, 44]. Since SARS-CoV-2 variants continue to impact our society [45], it is important to establish evidence-based therapeutic management in patients with traumatic SCI.

Finally, our data show that patients with traumatic SCI and PsO experienced a diagnostic delay in detecting PsA due to their lack of pain, morning stiffness, and arthralgia perception, suggesting a need for more frequent dermatology and rheumatology follow-up.

Diagnosis and monitoring with imaging tools such as ultrasound and magnetic resonance imaging (MRI) and laboratory tests (i.e., CRP or ESR) may be preferred compared to clinical tools that account for the pain and daily functionality, which cannot be assessed in patients with traumatic SCI. Furthermore, patients with SCI will be always underscored in terms of disease severity.

Study limitations are its retrospective nature and the limited number of patients; however, it represents the first real-life data dedicated to this special population.

CONCLUSION

Patients with PsO and traumatic SCI should be treated with IL-17i/IL-23i in order to limit UTI, RTI, and pneumonia. Further studies such as this one are needed to improve precision medicine and optimize treatments in special populations such as patients with paraplegia and tetraplegia. Furthermore, guidelines should address a variety of special populations.

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funding acquisition, project administration. Alessia Pacifico: methodology, resources, writing—original draft, writing—review & editing. Stefano Ricciardi: conceptualization, writing—review & editing, supervision. Valeria Corazza: conceptualization, writing—review & editing, supervision. David Trigos: conceptualization, writing—review & editing, supervision. Marco Fiore: conceptualization, validation, visualization, data curation, software, formal analysis, writing—review & editing. Claudio Guarneri: methodology, software, formal analysis, data curation, writing—review & editing.

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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest. Alessia Pacifico, Stefano Ricciardi, Valeria Corazza, David Trigos, Marco Fiore, Claudio Guarneri reported no conflict of interests relevant for the manuscript. Giovanni Damiani is an Editorial Board Member of *Dermatology and Therapy*. Giovanni Damiani was not involved in the selection of peer reviewers for the manuscript nor any of the subsequent editorial decisions.

Ethical Approval. The study protocol is in line with the principles of Helsinki declaration of 1975 (https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/), revised in 2013. The present study received the approval by the Institutional Review Board of San Raphael Hospital (protocol code 178/INT/2021, date of approval 10 November 2021).

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