

BACKGROUND

**Context:** Ulcerative colitis (UC) is a chronic inflammatory disorder of the colonic mucosa, characterized by alternating periods of remission and relapse.<sup>1</sup> Corticosteroids (CS) remain a key therapeutic option to induce remission and symptom control. However, regardless of whether the disease is mildly or severely active, it is strongly recommended to not use CS to maintain remission, and to transition to CS-sparing therapy once remission is achieved.<sup>1</sup> Avoiding repeated courses of CS and high doses at any time is also recommended mainly because of the risk of adverse events, comorbidities. (Figure 1).<sup>2,3</sup>

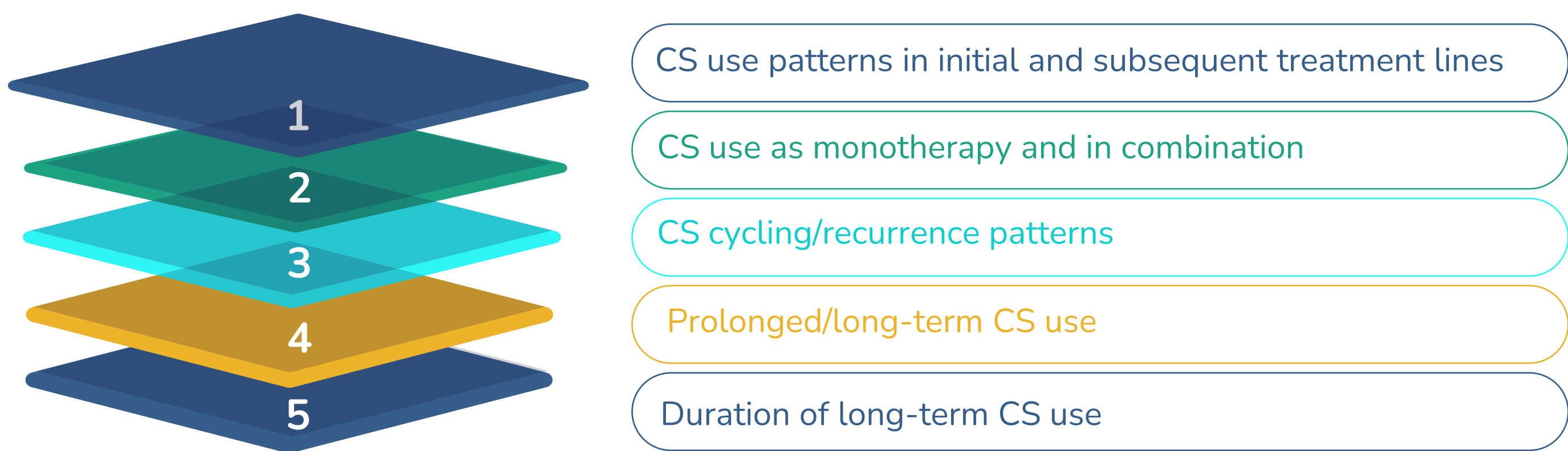
**Objective:** The study aimed to assess CS use prior to the initiation of advanced therapies (ATs) in patients with UC, with a particular focus on identifying patterns of excessive CS exposure in real-world clinical practice.

Figure 1: Disadvantages of excessive CS exposure



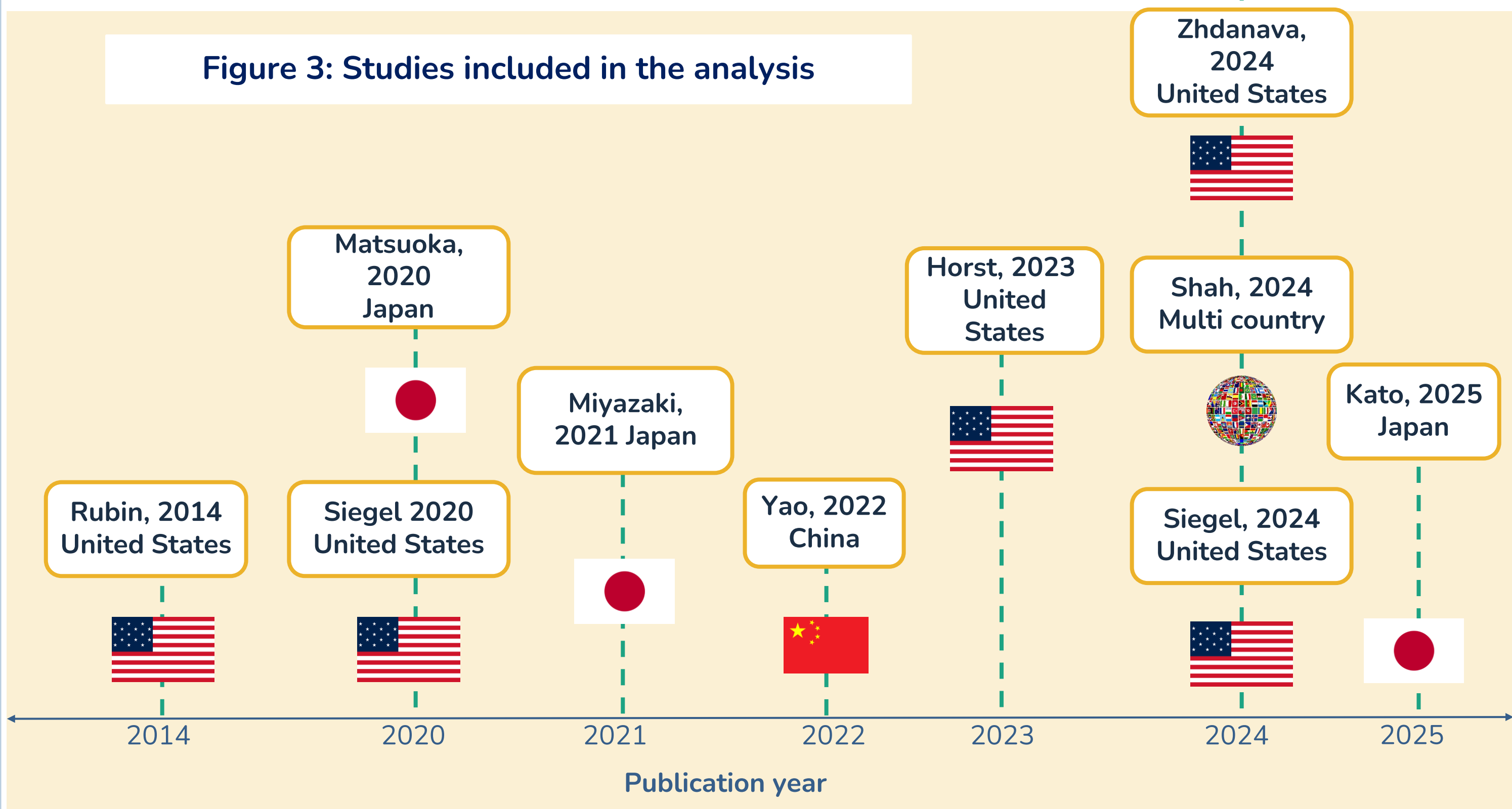
- A targeted literature review was conducted using the PubMed database (January 2014 - January 2025) and was supplemented by grey literature search.
- Only the studies describing real-world excessive CS utilization among adult patients of UC in routine clinical practice, prior to ATs initiation, were included.
- Key outcomes/themes that were extracted from the studies are as given in Figure 2.

Figure 2: Key outcomes extracted from the studies



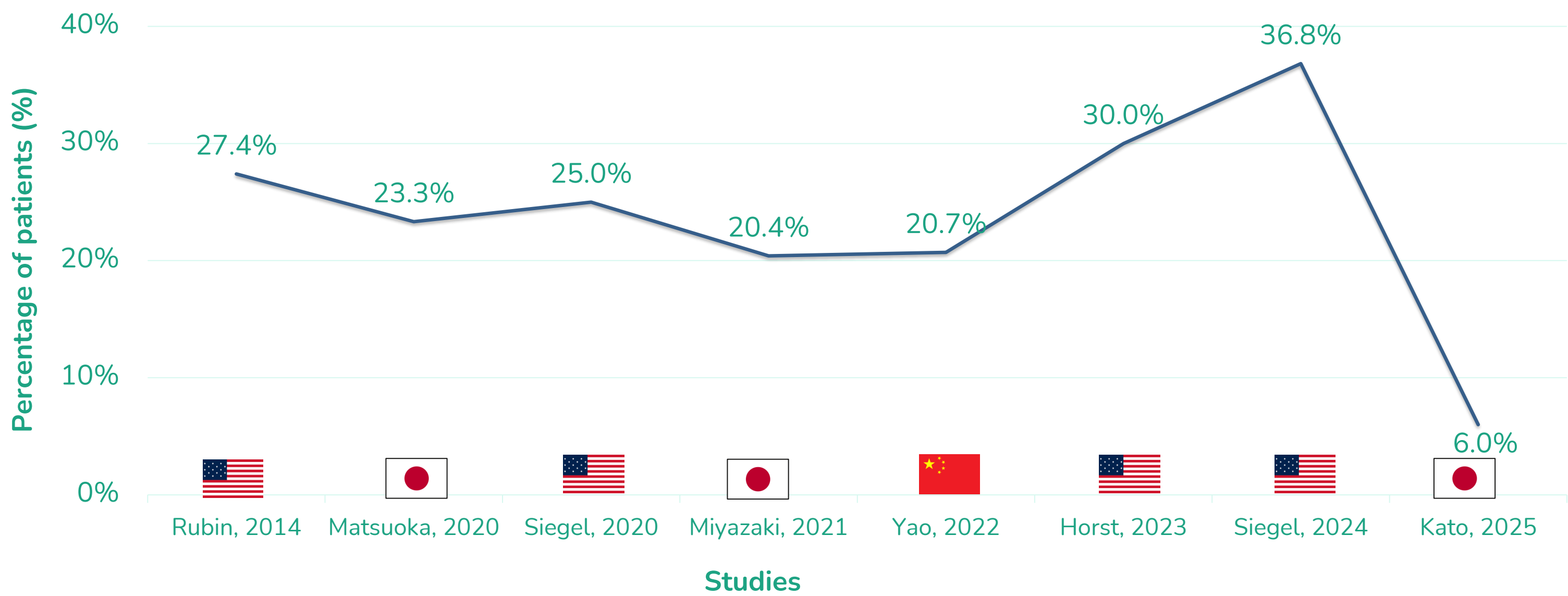
- A total of 222 studies were screened. Ten studies that met the inclusion criteria were included. These studies specifically examined excessive CS exposure alongside real world patterns of CS use. The remaining studies were excluded as they did not address both aspects simultaneously.
- The studies included were from US (n=5), Japan (n=3), China (n=1) and multi-country (n=1) perspective (Figure 3).
- Seven studies reported CS monotherapy as the second most used initial treatment following diagnosis of UC, with 5-aminosalicylates (5-ASAs) being the most frequently initiated therapy. The proportion of patients receiving CS monotherapy ranged from 10% to 37% across these studies. Figure 4 presents the study-wise distribution of CS monotherapy usage.
- One study reported CS use in combination with 5-ASA as the second most used initial regimen.<sup>4</sup>
- Eight studies showed that in subsequent lines of treatment, patients were treated with CS either as monotherapy or in combination therapies with 5-ASA or immunomodulators or both.

Figure 3: Studies included in the analysis



This global review on real-world evidence reveals **persistent overuse of CS in UC, despite guideline recommendations**. This highlights a critical gap in care and the need for earlier adoption of steroid-sparing strategies (with advanced therapies)!

Figure 4: Study-wise distribution of CS monotherapy usage (as first line therapy)



- In a US based study, among patients who initiated treatment with 5-ASAs and subsequently switched therapies, 76% transitioned to CS. Among immunomodulator initiators who switched treatment, 57% transitioned to CS, indicating a high reliance on CS following inadequate response to initial conventional therapies.<sup>5</sup>
- Two studies also reported on specific agents within the CS class, identifying prednisone and systemic prednisolone as the most frequently prescribed CS among patients with UC.<sup>2,3</sup>
- In a Japan-based study, 39.8% of patients receiving  $\geq 1$  CS course exhibited CS cycling, defined as  $\geq 3$  CS courses within one year.<sup>4</sup>
- The prolonged/chronic use of CS (varying definitions across studies) was reported in 11% to 49% of patients (n=10). Table 1 presents distribution of prolonged CS use in studies.
- The reported duration of long-term CS exposure ranged from 209–453 days across studies (209 days in a US based study<sup>6</sup>; 266–366 days in a Japan based study<sup>1</sup>; and up to 453 days in a multi country study<sup>7</sup>).
- Evidence showed that most patients (80-92%) received more than CS course (n=5). One study reported that most patients (91.5%) had  $\geq 1$  CS episode prior to AT initiation, with 65.9% (n = 1465) having  $\geq 4$  steroid episodes.<sup>6</sup>

Table 1: Study-wise distribution of prolonged CS monotherapy use

Studies	Definition of prolonged CS use	Proportion of prolonged CS use
Rubin, 2014	Use of CS for more than 3 months	10–24%
Miyazaki, 2021		11%
Horst, 2023	>90 days or $\geq 2$ episodes in $\leq 1$ year	45.50%
Zhdanava, 2024	More than 90 days of CS use at greater than 5 mg/day	13.5%
Shah, 2024	Use of CS for more than 3 months or had undergone dose escalation within the current course	36.05%
Kato, 2025	consecutive use for > 90 days	38.17%
The remaining studies reported prolonged/long-term CS use descriptively but did not provide exact prevalence estimates.		

DISCUSSION

- Multi country clinical guidelines<sup>11-13</sup> for the management of UC emphasize the importance of early and sustained disease control, recommending a treat-to-target approach and prompt escalation to steroid-sparing strategies (specifically ATs). Despite these recommendations, real-world evidence continues to reveal high rates of prolonged CS use, indicating persistent treatment inertia.
- Delays in therapy optimization may contribute to excessive CS exposure, placing patients at increased risk of serious adverse events such as infection, osteoporosis, metabolic complications, and other associated comorbidities.
- These findings highlight a critical gap between guideline recommendations and real-world clinical practice, underscoring the need for improved implementation of evidence-based treatment pathways to minimize inappropriate CS use.

FINANCIAL DISCLOSURE

All authors are employees of ConnectHEOR Limited and no external funding was received to conduct this research. The authors have no conflict of interest to declare.

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