JOURNAL OF
CUTANEOUS IMMUNOLOGY
AND ALLERGY

TYPE Original Research
PUBLISHED 06 May 2026
DOI 10.3389/jcia.2026.16442

OPEN ACCESS

*CORRESPONDENCE
Daisuke Watabe,
dwatabe@iwate-med.ac.jp

RECEIVED 22 February 2026
REVISED 03 April 2026
ACCEPTED 13 April 2026
PUBLISHED 06 May 2026

CITATION
Watabe D, Tsunoda K, Hamabata A, Goto M, Yoshioka W and Amano H (2026) Real-world effectiveness and safety of tildrakizumab in Japanese patients with psoriasis: a single-center 52-week observational study.
J. Cutan. Immunol. Allergy 9:16442.
doi: 10.3389/jcia.2026.16442

Real-world effectiveness and safety of tildrakizumab in Japanese patients with psoriasis: a single-center 52-week observational study

Daisuke Watabe*, Kanako Tsunoda, Akemi Hamabata, Maki Goto, Wakako Yoshioka and Hiroo Amano

Department of Dermatology, Iwate Medical University School of Medicine, Shiwa-Gun, Iwate, Japan

Background: Real-world data on the long-term effectiveness of tildrakizumab in Japanese patients with psoriasis remain limited, particularly in cohorts with relatively low baseline disease severity.
Objectives: To evaluate the 52-week effectiveness and safety of tildrakizumab in a real-world Japanese clinical setting, including exploratory subgroup analyses.
Methods: This retrospective, single-center observational study included 30 consecutive patients with psoriasis treated with tildrakizumab 100 mg in accordance with the approved Japanese dosing regimen. Disease severity was assessed using the Psoriasis Area and Severity Index (PASI) at weeks 0, 4, 16, 28, 40, and 52 (visit window ±1 week). Mean PASI scores were analyzed using observed values. For responder analyses, non-responder imputation (NRI) was applied; patients who discontinued treatment or had missing PASI data were classified as non-responders. Responder endpoints included PASI75 and absolute PASI ≤3. Exploratory subgroup analyses were conducted according to baseline characteristics. Statistical analyses were performed using GraphPad Prism.
Results: The mean PASI score improved from 11.45 at baseline (median 9.2) to 2.90 at week 52. Using NRI, PASI75 and PASI ≤3 achievement rates reached 56.7% and 60.0% at week 52, respectively. Four patients discontinued treatment because of insufficient efficacy, with final PASI scores of 7.5 (week 4), 1.6 (week 16), 3.7 (week 28), and 3.2 (week 40). Twenty-six patients (86.7%) continued treatment through week 52. Seven adverse events were documented during the study period, and no treatment discontinuations related to adverse events occurred.
Conclusion: Tildrakizumab demonstrated sustained real-world effectiveness in Japanese patients with psoriasis, with no treatment discontinuations related to adverse events. Interpretation of the safety and subgroup findings should take into account the retrospective single-center design and exploratory nature of the analyses.

KEYWORDS
interleukin-23, Japanese patients, psoriasis, real-world study, tildrakizumab

Introduction

Psoriasis is a chronic immune-mediated inflammatory skin disease characterized by recurrent skin lesions and systemic inflammation, which substantially impairs patients' quality of life and requires long-term management [1]. Advances in immunological research have identified the interleukin (IL)-23/Th17 axis as a central pathway in psoriasis pathogenesis, leading to the development of biologic therapies targeting specific cytokines involved in this immune cascade [1].

Tildrakizumab is a humanized monoclonal antibody that selectively targets the p19 subunit of IL-23, thereby inhibiting IL-23–dependent Th17 responses while preserving upstream immune pathways [2]. By selectively blocking IL-23 without directly inhibiting IL-17, tildrakizumab allows targeted suppression of pathogenic inflammation while potentially minimizing broader immune perturbation [2, 3]. In phase III clinical trials, including the reSURFACE 1 and reSURFACE 2 studies, tildrakizumab demonstrated robust efficacy and a favorable long-term safety profile in patients with moderate-to-severe plaque psoriasis [3, 4].

However, clinical trial populations are highly selected and may not fully reflect patients encountered in routine practice. In particular, real-world data on tildrakizumab in Japanese patients remain limited, especially regarding long-term effectiveness, treatment persistence, safety, and factors influencing clinical response. Moreover, differences in baseline disease severity, prior treatments, and analytical approaches may substantially influence treatment outcomes in real-world settings.

Therefore, the present study aimed to evaluate the 52-week real-world effectiveness and safety of tildrakizumab in a Japanese clinical cohort, using both relative and absolute PASI outcomes and applying a conservative analytical approach.

Materials and methods

Study design and patients

Thirty patients with moderate to severe psoriasis who received treatment with tildrakizumab from July 2021 to December 2025 at Iwate Medical University were included. During the study period, 49 patients initiated tildrakizumab treatment. Of these, 30 were included in the present analysis after exclusion of 8 patients treated without the approved loading regimen, 10 patients who had not yet reached 28 weeks of treatment at the time of analysis, and 1 patient treated outside the approved dosing interval (Supplementary Figure 1). No patients discontinued treatment before week 28 among those included in the analysis. This retrospective, single-center observational study was approved by the Institutional Review Board of Iwate Medical University (MH2025-092) and conducted in accordance with the principles of the Declaration of Helsinki. As in Japan tildrakizumab is approved only for the treatment of plaque psoriasis, patients with psoriatic arthritis were not included in this study. Written informed consent was waived because of the retrospective nature of the study, and study information was disclosed using an opt-out approach in accordance with institutional requirements. Smoking status was classified from the medical records as current, former, or never smoker at baseline. Exploratory subgroup analyses were performed according to baseline characteristics, including sex, body mass index, age, disease duration, and smoking status.

Treatment

Tildrakizumab was administered at a dose of 100 mg in accordance with the approved Japanese dosing regimen; subcutaneous injections were given at weeks 0 and 4, followed by maintenance dosing every 12 weeks (±1 week).

Safety assessment

Safety was assessed retrospectively based on adverse events documented in the electronic medical records during routine clinical practice. No protocolized adverse event surveillance or active solicitation of adverse events was performed. Therefore, minor events not recorded in the medical records may not have been captured.

Statistical analysis

Continuous variables are presented as mean values, and categorical variables are presented as numbers and percentages. Changes in mean PASI scores over time were evaluated descriptively using observed-case analysis. For responder analyses, non-responder imputation (NRI) was applied, whereby patients who discontinued treatment or had missing PASI data at a given time point were classified as non-responders at subsequent visits. Two-sided 95% confidence intervals for response rates were calculated using the Wilson method. As supplementary analyses, as-observed responder rates were also calculated using evaluable patients at each time point. Comparisons of categorical variables between subgroups were performed using Fisher's exact test. Because subgroup analyses were exploratory, Holm-adjusted p values were additionally calculated to account for multiple comparisons across 20 subgroup tests. All statistical tests were two-sided, and a p value of <0.05 was considered statistically significant. All statistical analyses were performed using GraphPad Prism (GraphPad Software, Boston, MA, USA).

Results

A total of 30 patients were included (22 men and 8 women), with a mean age of 57.3 years (range, 26–81 years), a mean body weight of 69.44 kg, and a mean disease duration of 17.4 years (range, 2–43 years). Twelve patients (40.0%) had a body mass index (BMI) ≥25, and 21 patients (70.0%) were current or former smokers. Thirteen patients (43.3%) had a disease duration of ≥20 years, and nine patients (30.0%) were aged 65 years or older. Five patients (16.7%) had previous exposure to biologic therapy, whereas 25 patients (83.3%) were biologic-naïve; prior biologics included ustekinumab in 4 patients and risankizumab in 1 patient. Other prior treatments included apremilast in 15 patients, topical therapy alone in 7 patients, etretinate in 2 patients, and cyclosporine in 1 patient. Concomitant topical therapy was used in 27 patients (90.0%), and concomitant

TABLE 1 Patient characteristics.

Characteristic	Value
Number of patients	30
Male sex, n (%)	22 (73.3)
Female sex, n (%)	8 (26.7)
Age, years, mean (range)	57.3 (26–81)
Age ≥65 years, n (%)	9 (30.0)
Body weight, kg, mean	69.44
BMI ≥25, n (%)	12 (40.0)
Current or former smoker, n (%)	21 (70.0)
Never smoker, n (%)	9 (30.0)
Disease duration, years, mean (range)	17.4 (2–43)
Disease duration ≥20 years, n (%)	13 (43.3)
Biologic-naïve, n (%)	25 (83.3)
Biologic-experienced, n (%)	5 (16.7)
Prior biologics, n (%)	
Ustekinumab	4 (13.3)
Risankizumab	1 (3.3)
Other prior treatments, n (%)	
Apremilast	15 (50.0)
Topical therapy alone	7 (23.3)
Etretinate	2 (6.7)
Cyclosporine	1 (3.3)
Concomitant topical therapy, n (%)	27 (90.0)
Concomitant systemic therapy, n (%)	1 (3.3)
Cyclosporine co-therapy	1 (3.3)

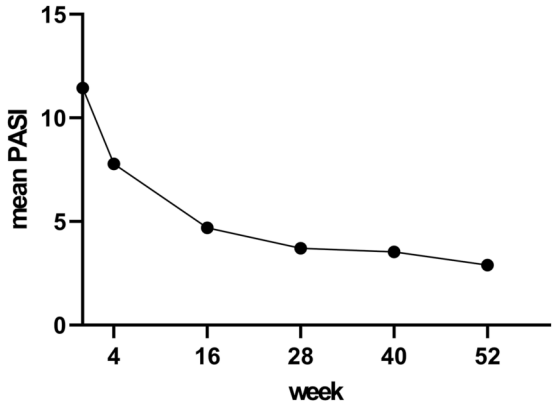

FIGURE 1
Mean Psoriasis Area and Severity Index (PASI) scores over 52 weeks of treatment with tildrakizumab. The numbers of patients evaluated at each time point were n = 30 at baseline, n = 29 at week 4, n = 29 at week 16, n = 28 at week 28, n = 26 at week 40, and n = 25 at week 52.

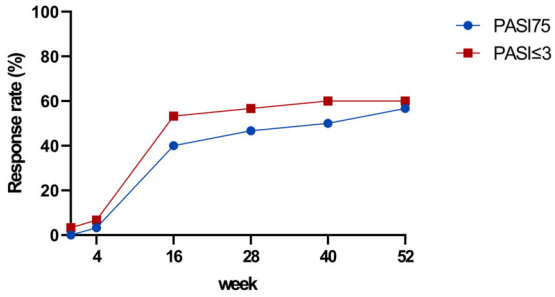

FIGURE 2
Proportions of patients achieving PASI75 and absolute PASI ≤3 during 52 weeks of tildrakizumab treatment. Response rates were calculated using non-responder imputation, with the full analysis set (n = 30) as the denominator at all time points.

systemic therapy was used in 1 patient (3.3%; cyclosporine). Detailed patient characteristics are summarized in Table 1.

Overall effectiveness

The mean PASI score decreased from 11.45 at baseline to 7.79 at week 4, 4.69 at week 16, 3.71 at week 28, 3.53 at week 40, and 2.90 at week 52 (Figure 1).

A marked reduction in disease severity was observed during the early treatment phase, particularly by week 16, followed by sustained improvement through week 52. Notably, mean PASI scores continued to decline or remained stable during the maintenance phase, indicating durable disease control over long-term treatment. These findings suggest that tildrakizumab induces a rapid initial response that is maintained with continued dosing in routine clinical practice.

Responder analyses

Using non-responder imputation, PASI75 achievement rates increased over time (0.0% at week 0; 3.3% at week 4; 36.7% at week 16; 46.7% at week 28; 50.0% at week 40; and 56.7% at week 52). A substantial proportion of patients achieved PASI75 by week 16, with further gradual increases observed during the maintenance phase (Figure 2).

PASI ≤3 achievement rates showed a similar temporal pattern, increasing from 3.3% at baseline to 53.3% at week 16 and reaching 60.0% at weeks 40 and 52. At week 52, PASI75 and PASI ≤3 were achieved by 56.7% (95% CI, 39.2–72.6) and 60.0% (95% CI, 42.3–75.4) of patients, respectively, using NRI. These responder rates remained stable during long-term treatment, despite the application of non-responder imputation. As-observed response rates were higher than NRI-based rates at later time points and are shown in Supplementary Table 1. Additional responder analyses for PASI90 and PASI100 are provided in Supplementary Table 2.

Subgroup analyses

Exploratory subgroup analyses were performed according to baseline patient characteristics. At week 52, non-smokers showed a

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TABLE 2 Exploratory subgroup analysis of PASI75 and PASI ≤3 responses at weeks 16 and 52.

Outcome	Week	Factor	Category	n/N (%)	Unadjusted p	Holm-adjusted p
PASI75	16	Sex	Male	8/22 (36.4%)	0.678	1.000
			Female	4/8 (50.0%)		
PASI75	16	BMI	≥25	4/12 (33.3%)	0.709	1.000
			<25	8/18 (44.4%)		
PASI75	16	Age	≥65	6/9 (66.7%)	0.102	1.000
			<65	6/21 (28.6%)		
PASI75	16	Disease duration	≥20 years	7/13 (53.8%)	0.264	1.000
			<20 years	5/17 (29.4%)		
PASI75	16	Smoking	Current/former	7/21 (33.3%)	0.418	1.000
			Never	5/9 (55.6%)		
PASI75	52	Sex	Male	11/22 (50.0%)	0.407	1.000
			Female	6/8 (75.0%)		
PASI75	52	BMI	≥25	6/12 (50.0%)	0.711	1.000
			<25	11/18 (61.1%)		
PASI75	52	Age	≥65	4/9 (44.4%)	0.443	1.000
			<65	13/21 (61.9%)		
PASI75	52	Disease duration	≥20 years	6/13 (46.2%)	0.460	1.000
			<20 years	11/17 (64.7%)		
PASI75	52	Smoking	Current/former	10/21 (47.6%)	0.229	1.000
			Never	7/9 (77.8%)		
PASI≤3	16	Sex	Male	12/22 (54.5%)	0.199	1.000
			Female	7/8 (87.5%)		
PASI≤3	16	BMI	≥25	6/12 (50.0%)	1.000	1.000
			<25	10/18 (55.6%)		
PASI≤3	16	Age	≥65	6/9 (66.7%)	0.440	1.000
			<65	10/21 (47.6%)		
PASI≤3	16	Disease duration	≥20 years	8/13 (61.5%)	0.484	1.000
			<20 years	8/17 (47.1%)		
PASI≤3	16	Smoking	Current/former	9/21 (42.9%)	0.118	1.000
			Never	7/9 (77.8%)		
PASI≤3	52	Sex	Male	12/22 (54.5%)	0.419	1.000
			Female	6/8 (75.0%)		
PASI≤3	52	BMI	≥25	6/12 (50.0%)	0.458	1.000
			<25	12/18 (66.7%)		
PASI≤3	52	Age	≥65	7/9 (77.8%)	0.249	1.000
			<65	11/21 (52.4%)		
PASI≤3	52	Disease duration	≥20 years	8/13 (61.5%)	1.000	1.000
			<20 years	10/17 (58.8%)		

(*Continued*)

TABLE 2 Continued

Outcome	Week	Factor	Category	n/N (%)	Unadjusted p	Holm-adjusted p
PASI≤3	52	Smoking	Current/former	10/21 (47.6%)	0.049	0.984
			Never	8/9 (88.9%)		

Exploratory subgroup analyses were performed at weeks 16 and 52 using Fisher's exact test. Non-responder imputation was applied. Unadjusted p values and Holm-adjusted p values are shown for 20 subgroup tests.

numerically higher PASI ≤3 achievement rate than current or former smokers (8/9 [88.9%] vs. 10/21 [47.6%]). This association reached nominal significance in unadjusted analysis (p = 0.049) but was no longer significant after Holm adjustment for multiple comparisons (adjusted p = 0.984). No other baseline factors, including sex, body mass index, age, or disease duration, were associated with significant differences in treatment response (Table 2).

Treatment discontinuation and safety

Four patients discontinued tildrakizumab due to insufficient efficacy. Prior treatments in these patients included apremilast, cyclosporine, ustekinumab, and risankizumab (one patient each). The timing of final administration was week 4, 16, 28, and 40, respectively. Two patients were subsequently switched to another biologic agent, and two returned to conventional systemic or topical therapy. Seven adverse events were documented in the electronic medical records during the 52-week observation period, including low back pain associated with spinal canal stenosis, injection-site erythema, facial erythema, pruritus, hyperlipidemia, chest tightness, and vesicular eruptions on the hands and feet (one event each). No treatment discontinuations due to adverse events occurred.

Discussion

In this real-world Japanese cohort, tildrakizumab demonstrated sustained effectiveness over 52 weeks, with reductions in mean PASI scores and lower absolute PASI scores. Although PASI75 achievement rates were lower than those reported in some European real-world studies, PASI ≤3 was achieved in 60% of patients at week 52, indicating stable long-term disease control in routine clinical practice.

Real-world studies have reported heterogeneous effectiveness outcomes for tildrakizumab, likely reflecting differences in study design, patient characteristics, baseline disease severity, and analytical approaches. The findings of the present study are conceptually aligned with those of the TILOT study, a prospective German real-world cohort, in that both studies support sustained clinical benefit of tildrakizumab in routine practice and emphasize absolute disease control [5]. However, direct comparison should be made cautiously because TILOT primarily reported observed-case and LOCF analyses, whereas our study used a conservative NRI approach, and because response rates and baseline disease severity differed between the two cohorts.

By contrast, several other European real-world cohorts have reported markedly higher relative response rates than those observed in our study. The Italian IL-PSO multicenter retrospective study reported PASI75 achievement rates approaching 90% at week 52 [6], and a Spanish multicenter real-world study likewise reported high treatment response rates at 52 weeks [7]. More recently, a large multicenter real-world study from the Basque Country, Spain, including 212 patients, reported PASI75 in 66.4% of patients and PASI ≤3 in 68.8% at week 52 [8], while a German retrospective multicenter analysis over 76 weeks reported PASI75 in 85.5% and absolute PASI <3 in 79.7% at week 52 [9]. These differences should be interpreted in the context of substantial methodological and population-level differences between studies. In particular, cohorts with higher baseline PASI scores, relative response-based endpoints, and predominantly observed-case analyses are more likely to yield higher PASI75 rates. Thus, discrepancies among real-world studies are more plausibly attributable to differences in baseline disease severity, outcome definitions, and analytical strategies rather than true differences in drug efficacy.

In the Japanese subgroup analysis of reSURFACE 1, tildrakizumab demonstrated durable efficacy, and the subsequent 5-year extension study likewise showed sustained long-term efficacy and tolerability in Japanese patients [10, 11]. These trial-based data provide an important point of reference, while also highlighting the need for post-marketing real-world evidence from routine clinical practice. In this context, our cohort may help bridge the gap between Japanese clinical trial data and everyday treatment outcomes.

Several factors may explain why the week-52 PASI75 rate in our cohort was lower than those reported in some previous studies. First, our cohort had a relatively low baseline mean PASI score (11.45), compared with 16.0 in TILOT and 14.45 in IL-PSO, and was closer to that reported in the Basque Country cohort (11.21) and the German multicenter cohort (median 12.6). These differences in baseline disease severity may have influenced the likelihood of achieving relative response thresholds such as PASI75. Second, our primary responder analyses used non-responder imputation (NRI), whereas many real-world studies preferentially reported observed-case outcomes. In our cohort, as-observed response rates at week 52 were higher than NRI-based estimates, reaching 68.0% for PASI75% and 72.0% for PASI ≤3, compared with 56.7% and 60.0%, respectively, using NRI (Supplementary Table 1). Third, differences in treatment history and cohort composition, including prior biologic exposure, may also have contributed to cross-study variability. In patients with relatively low baseline PASI scores, absolute disease activity measures such as PASI ≤3 may provide a more informative assessment of treatment response than relative thresholds alone [12]. In routine Japanese clinical practice, maintaining stable low disease activity may represent a more practical therapeutic goal than achieving large relative improvements. Taken together, these considerations suggest that the relatively lower PASI75 rate observed in our study should be

interpreted in the context of a conservative analytic strategy and a lower-severity real-world Japanese cohort, rather than as evidence of inferior drug performance.

From an immunological perspective, selective inhibition of the interleukin-23 (IL-23) p19 subunit by tildrakizumab allows targeted suppression of the IL-23/Th17 axis while preserving upstream immune pathways involved in host defense [1, 2]. Accumulating immunological evidence suggests that such selective IL-23 inhibition may provide durable control of pathogenic inflammation with limited immune perturbation, which could contribute to long-term disease stability and favorable safety outcomes [13].

Although no statistically significant age-related differences were detected in the present exploratory analyses, the numerically comparable or favorable responses observed in older patients are consistent with previous real-world studies reporting maintained effectiveness and tolerability of tildrakizumab in elderly and frail elderly populations [14, 15]. These findings support the clinical applicability of IL-23p19 inhibition in older patients requiring long-term treatment.

This immunological selectivity may be particularly relevant in real-world populations, including older patients and those requiring prolonged therapy. In the present cohort, seven adverse events were documented in the electronic medical records during the observation period, and no patients discontinued treatment because of safety concerns. However, safety findings should be interpreted cautiously because adverse events were retrospectively ascertained from routine medical records rather than through protocolized surveillance, and minor events not documented in the records may have been missed. Nevertheless, the absence of safety-related discontinuations is consistent with the generally favorable tolerability profile of tildrakizumab observed in clinical trials and long-term extension studies [3, 4]. Furthermore, accumulating evidence indicates that IL-23 inhibitors as a therapeutic class are associated with a favorable long-term safety profile, supporting their suitability for chronic disease management in psoriasis [16].

Exploratory subgroup analyses generally did not identify patient background factors associated with differential treatment response. At week 52, non-smokers showed a numerically higher PASI ≤3 achievement rate than current or former smokers in unadjusted analysis; however, this association was no longer significant after adjustment for multiple comparisons. This finding should therefore be considered exploratory and hypothesis-generating, particularly given the small sample size and the lack of adjustment for potential confounders such as body mass index, disease duration, and prior biologic exposure. Nevertheless, smoking has been reported to adversely affect treatment response in patients with psoriasis receiving biologic therapies [17]. Our observation may warrant further investigation in larger cohorts.

This study has several limitations. First, its retrospective, single-center design and limited sample size restrict statistical power and generalizability. Second, no formal *a priori* sample size calculation was performed because this was an exploratory real-world study. Third, adverse events were retrospectively ascertained from routine electronic medical records rather than through protocolized surveillance, and minor events may therefore have been underdetected. Fourth, subgroup analyses were exploratory and underpowered, and residual confounding could not be excluded. Despite these limitations, the present findings provide valuable real-world evidence supporting the effectiveness and safety of tildrakizumab in Japanese patients with psoriasis. By emphasizing absolute disease control and applying conservative analytical methods, this study offers a clinically relevant perspective on long-term treatment outcomes and may serve as a hypothesis-generating basis for future multicenter investigations.

Conclusion

In this real-world Japanese cohort, tildrakizumab provided sustained long-term effectiveness and low absolute disease activity over 52 weeks. Interpretation of the safety and subgroup findings should take into account the retrospective single-center design and exploratory nature of the analyses.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by Institutional Review Board of Iwate Medical University. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required from the participants or the participants' legal guardians/next of kin in accordance with the national legislation and institutional requirements.

Author contributions

DW was responsible for patient management, data collection, statistical analysis, and drafting of the manuscript. KT, AH, MG, and WY contributed to patient management and data acquisition. HA supervised the study and critically revised the manuscript. All authors contributed to the article and approved the submitted version.

Funding

The author(s) declared that financial support was not received for this work and/or its publication.

Conflict of interest

DW, KT, and HA have received lecture fees from Sun Pharma. The department has received research funding from Sun Pharma for studies unrelated to the present work.

The remaining author(s) declared that this work was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontierspartnerships.org/articles/10.3389/jcia.2026.16442/full#supplementary-material.

SUPPLEMENTARY FIGURE 1
Flow diagram of patient selection. During the study period, 49 patients initiated tildrakizumab treatment. Of these, 8 patients treated without the approved loading regimen, 10 patients who had not yet reached 28 weeks of treatment at the time of analysis, and 1 patient treated outside the approved dosing interval were excluded. The remaining 30 patients were included in the present analysis.

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