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Baricitinib in the Treatment of Adults with Pyoderma Gangrenosum: A Phase II Open Label Trial

Morgan Vague[1], Sharon Choe[2], Shannon Throckmorton[1], Alexandra Shinde[1], Alex Ortega Loayza[1]

[1] Oregon Health and Science University, Portland, United States
[2] Creighton University School of Medicine, Phoenix, United States

Introduction

Pyoderma gangrenosum (PG) is a rare neutrophilic dermatosis marked by chronic, painful skin ulcerations. While biologics have shown efficacy, none are currently approved for PG by the US Food and Drug Administration or European Medicines Agency. Given its role in autoimmune and inflammatory pathways, the JAK-STAT axis is a promising target. Baricitinib, an oral JAK inhibitor, is approved by the European Medicines Agency (4mg and 2mg) and the Food and Drug Administration (2mg) for rheumatoid arthritis (RA), one of the most common PG comorbidities with several shared inflammatory pathways.

Materials and Methods

This open-label phase II trial evaluated the safety and efficacy of baricitinib in five adult female patients with classic PG (median age 50). Patients received 4mg of baricitinib daily for 24 weeks. A brief course of prednisone (starting at 30 mg daily) was administered for 2-4 weeks prior to baricitinib initiation to stabilize inflammation, then tapered to ≤8 mg by week 7 and discontinued by week 13.

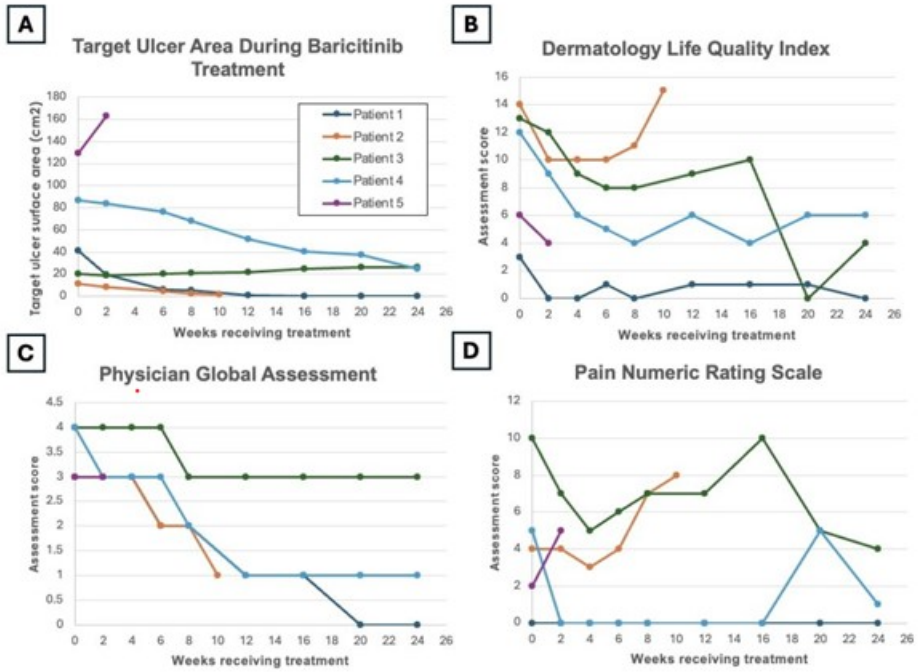
One target ulcer (TU) was followed per patient. The primary outcome was complete TU re-epithelialization. Secondary outcomes included reductions in TU surface area, Physician Global Assessment (PGA) score, Dermatology Life Quality Index (DLQI) score, and Numeric Rating System (NRS) pain score. The DLQI ranges from 0 to 30, the PGA from 0-4, and the NRS from 0 to 10, with higher scores indicating greater impairment, disease activity, and pain respectively. Clinically meaningful thresholds were defined as PGA of 0 or 1 (no to minimal disease activity), ≥4 point reduction in DLQI, and ≥2 point reduction in NRS.

Results

Three of five patients completed the 24-week course. One patient withdrew at week 10 due to lower extremity edema and weight gain. One patient died, likely due a cardiopulmonary event in the setting of multiple risk factors (BMI > 50, hypertension, recent long-haul air travel). This event was deemed possibly related to baricitinib.

Of the five patients, one (20%) achieved complete TU re-epithelialization. Three (60%) reached a PGA of 0 or 1. Three (60%) achieved ≥4-point DLQI reductions. Two (40%) achieved ≥2 point NRS reductions. All four surviving patients successfully discontinued corticosteroids, a common first-line treatment in PG. Adverse events potentially related to baricitinib included peripheral edema, weight gain, and the cardiopulmonary event. No patients developed new ulcers during the study period. Trends in target ulcer area, PGA scores, DLQI and NRS pain scores over 24 weeks are presented in **Figure 1**.

Figure 1. Clinical response over 24 weeks of baricitinib treatment Each line represents an individual patient. Patient 2 withdrew at week 10, and patient 5 died after week 2. A) Target Ulcer Area (cm^2) decreased in 3 of 5 patients, with one patient achieving complete healing. B) DLQI scores decreased for 4 of 5 patients. C) PGA scores decreased for all patients and remained stable in 1 patient. D) NRS scores improved in 3 of 5 patients.



Conclusion

Baricitinib demonstrated signs of clinical benefit in classic PG. Two patients remain healed one year after the trial, and one patient continues to improve after 3 additional months on JAK inhibitor tofacitinib. Only one patient experienced disease recurrence on a location separate from her TU. These findings support further investigation of JAK inhibition in PG, with careful attention to cardiovascular risk stratification.