2280

Effects of Repository Corticotropin Injection on Medication Use in Patients with Rheumatologic Conditions: A Claims Data Study

Gihyun Myung, MD[1], Winnie W. Nelson, PharmD, MS, MBA[2], Maureen A. McMahon, MD[1]

[1]*Division of Rheumatology/Department of Internal Medicine, University of California-Los Angeles, Los Angeles, CA,*

[2]*Health Economics & Outcomes Research, Mallinckrodt Pharmaceuticals, Hampton, NJ*

ABSTRACT

► **Background/Purpose**: Repository corticotropin injection (RCI) may produce anti-inflammatory and immune-modulatory effects. This study examined the demographics of patients who used RCI and the trends in medication use, specifically prednisone, after RCI initiation.

► **Methods**: This retrospective analysis of the Symphony Health Solutions Patient Transactional Dataset from 2008 to 2015 included patients with at least 1 claim for RA, SLE, or DM/PM, and any use of RCI. Patients with claims for non-rheumatologic conditions that may also be treated by RCI, namely, multiple sclerosis and proteinuria, were excluded. Demographics, patterns of RCI use, and concomitant medications (corticosteroids [CS], biologics, NSAIDs, and DMARDs) were reported. Patients were followed for concomitant medication use from 2 years prior to and 1 year after RCI initiation. Paired two-tailed t-tests were used to calculate the p values for the use of each drug class before/after RCI initiation.

► **Results**: Out of 2.7 million rheumatologic patients in the database over 6 years, there were 2,749 patients who used RCI – 1,269 RA patients, 874 SLE patients, and 606 with DM/PM (Table 1). SLE patients were younger than RA and DM/PM patients, and most of the patients were female for all 3 conditions. The majority of patients received 80U of RCI twice weekly. The study identified 504 RA, 322 SLE, and 222 DM/PM patients with sufficient follow up time to evaluate concomitant medication use. For all 3 conditions, the proportions of patients who used any CS were significantly lower after RCI initiation: reduced from 67% pre-index to 54% post-index for RA, from 73% to 58% for SLE, and from 76% to 58% for DM/PM ($p < 0.05$ for all comparisons, Figure 1). Proportions of patients on biologics and DMARDs were also significantly lowered after RCI initiation. In Figure 2, among patients who had taken CS consistently 24 weeks before RCI initiation, dose reductions were statistically significant for RA (28%), and trended lower without statistical significance for SLE (25%) and DM/PM (25%). Limitations of the retrospective analysis include uncertainties in diagnosis, medication use, and factors influencing medication changes.

► **Conclusion**: This claims-based study of patients with RA, SLE, and DM/PM indicated that RCI use may be associated with significant reductions in CS requirements.

BACKGROUND/PURPOSE

► RCI works by stimulating the adrenal cortex to secrete cortisol, corticosterone, and aldosterone[1]. Additionally, it has been shown that RCI binds to and activates all five known melanocortin receptors (MCRs)[2]. Thus, RCI may produce anti-inflammatory and immuno-modulatory effects by directly activating MCRs.

► The purpose of this study was to analyze prescription use patterns in patients with rheumatologic conditions and to examine the trends of concomitant medication use, especially prednisone, after RCI administration.

METHODS

Study Design and Data Source

► This study used data from the Symphony Health Solutions claims database, which captures health events in 17 out of every 20 persons in the U.S. with any insurance types, including Medicare and Medicaid.

► Pediatric and adult patients newly initiated on RCI were included in the analysis if they had at least one claim for the following International Classification of Disease, Ninth Revision (ICD-9) diagnosis codes:

- RA (ICD-9 code 714.0, 714.30, 714.31, 714.32, 714.33)
- SLE (ICD-9 code 710.0)
- DM (ICD-9 code 710.3), and PM (ICD-9 code 710.4)

► Patient characteristics were reported for the overall study population

► A subset of patients were followed longitudinally to study medication use patterns. Those with insurance claims two years prior to the first RCI use and one year after the last RCI use were included.

Statistical Analysis

► Paired two-tailed t-tests examined the use of CS, biologics, NSAIDs, and DMARDs during 6 months before and 6 months after RCI initiation. The mean prednisone dose pre-RCI and post-RCI was compared among patients who received prednisone prior to RCI initiation.

RESULTS

Table 1. Patient Characteristics of the Overall Population

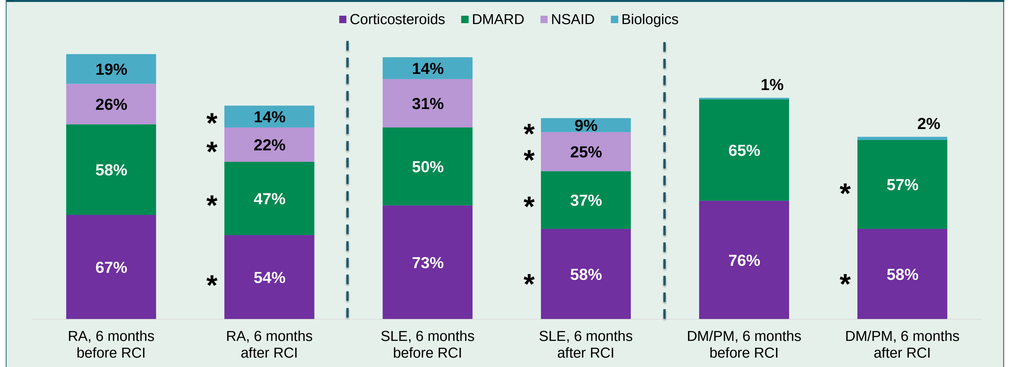
Patient Characteristics	RA	SLE	DM/PM
Number of patients on RCI	1,269	874	606
Age, Mean (Years)	59.1	48.1	55.5
Female	78%	89%	70%
RCI dose of 80U twice weekly	58%	57%	68%
RCI dose of 200U weekly	12%	15%	16%
RCI duration, Mean (Days)	115.7	129.2	157.1

► From the overall population, there was a subset of 504 RA, 322 SLE, and 222 DM/PM patients evaluated for the use of biologics, NSAIDs, DMARDs, and CS before and after RCI use.

► The proportion of patients on prednisone after RCI use decreased from 67% of patients to 54% for RA, 73% to 58% for SLE, and 76% to 58% for DM/PM. The declines were significant for all three disease groups, as indicated by *p* value <0.05 (Figure 1).

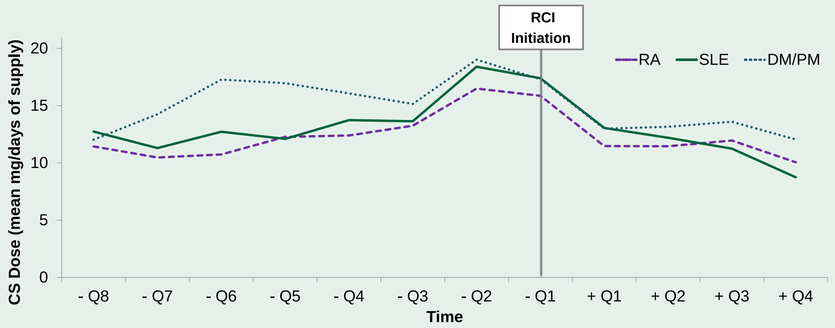
► The use of NSAIDs, DMARDs, and biologics decreased significantly in RA and SLE patients. The use of DMARDs decreased significantly in DM/PM patients (Figure 1).

Figure 1. Medication Use Before and After Repository Corticotropin Injection (RCI) Initiation



* denotes *p*<0.05. Sum of column >100% because patients received multiple medications concomitantly

Figure 2. Corticosteroid (CS) Dose Trends in Patients who had 24 weeks of Consistent Use before Repository Corticotropin Injection (RCI) Initiation



	RA	SLE	DM/PM
Number of patients	**201**	**131**	**121**
CS Dose 1Q Pre-RCI, Mean ± 95% CI	**15.86** ± 1.71	**17.39** ± 2.27	**17.31** ± 2.18
CS Dose 1Q Post-RCI, Mean ± 95% CI	**11.47** ± 1.63	**13.05** ± 2.27	**12.98** ± 2.34

RESULTS

► Among RA patients who had taken prednisone consistently 24 weeks before RCI use, the mean prednisone dose significantly decreased by 28% at 12 weeks (or 1 quarter) after RCI initiation (15.86 ± 1.71 mg per day to 11.47 ± 1.63mg per day) (Figure 2).

► In SLE and DM/PM, the mean prednisone dose trended lower with 25% reductions but without statistical significance (Figure 2).

LIMITATIONS

► Factors such as co-morbidities and disease activities might have influenced medication changes.
► Diagnoses and medication use were derived from information in outpatient, institutional, and pharmacy claims. As a result, no information was available on the diagnostic certainty or disease activity.
► No information was available on clinical consequences of decreases in concomitant medication use after RCI administration.
► Further prospective study will be needed to address disease activities during and after RCI use and to determine clinical impact of reduction in prednisone use.

CONCLUSION

► This claims-based study indicates that RCI use might reduce the use of prednisone, DMARDs, and biologics. Further prospective study is needed to determine the impact of such reductions.

ACKNOWLEDGEMENT

► The authors would like to thank Elaine Böing, HEOR Associate, for assistance with poster preparation.

DISCLOSURE

► Study funding was provided by Mallinckrodt Pharmaceuticals. Data Analysis was performed by Mallinckrodt Pharmaceuticals.

REFERENCES

1. Gettig J, Cummings JP, and Matuszewski K. H.P. Acthar Gel and Cosyntropin Review. *Pharmacy and Therapeutics* 2009;34:250-257
2. Gong R. Leveraging melanocortin pathways to treat glomerular diseases. *Adv Chronic Kidney Dis*. 2014;21(2):134–151