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Treatment Patterns, Direct Cost of Biologics, and Direct Medical Costs for Rheumatoid Arthritis Patients: A Real-World Analysis of Nationwide Japanese Claims Data

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ABSTRACT

Purpose: The aims of this article were to characterize the patterns of treating rheumatoid arthritis with biologics and to evaluate costs using claims data from the Japan Medical Data Center Co, Ltd.

Methods: Patients aged 16 to <75 years who were diagnosed with rheumatoid arthritis and prescribed adalimumab (ADA), etanercept (ETN), infliximab (IFX), tocilizumab (TCZ), abatacept, certolizumab, or golimumab between January 2005 and August 2014 were included. For the cross-sectional analysis, the annual costs of ETN, IFX, ADA, and TCZ from 2009 to 2013 were assessed. For the longitudinal analysis, patients prescribed these biologics as the first line of biologics, from January 2005 to August 2014, were included. The cost of biologic treatment over 1, 2, and 3 years (including prescription of subsequent biologics) and direct medical costs (including treatment of comorbidities) were compared between groups. Discontinuation and switching rates in each group were estimated, and multivariate analyses were conducted to estimate an adjusted hazard ratio of discontinuation and switching rates among each group. The dose of each first-line biologic treatment

Findings: The cross-sectional annual biologic costs of ETN, IFX, ADA, and TCZ were ~\$8000 (2009 and 2013), \$13,000 (2009) and \$15,000 (2013), \$10,000 (2009) and \$11,000 (2013), and \$9000 (2009) and \$8000 (2013), respectively. In longitudinal analyses (n = 764), 276 (36%) initiated ETN; 242 (32%), IFX; 147 (19%), ADA; and 99 (13%), TCZ. The 1-year cumulative annual biologic costs per patient from the initial prescription of ETN, IFX, ADA, and TCZ as the first-line biologic treatment were \sim \$11,000, \$19,000, \$16,000, and \$12,000. The corresponding direct medical costs over 1 year from the initial prescription were \sim \$17,000, \$26,000, \$22,000, and \$22,000. Costs remained greatest in the IFX-initiation group at year 3. The discontinuation rates at 36 months with ETN, IFX, ADA, and TCZ were 37.7%, 52.3%, 55.8%, and 39.5%; the switching rates were 12.5%, 27.1%, 31.0%, and 16.7%. The mean (95% CI) relative dose intensities until discontinuation of ETN 25 mg, ETN 50 mg, IFX, ADA, and TCZ were 1.02 (0.95-1.10), 0.82

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until discontinuation was analyzed to calculate relative dose intensity.

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(0.79–0.85), 1.16 (1.12–1.20), 0.95 (0.90–0.99), and 0.96 (0.93–1.00).

Implications: Considered costs and discontinuation and switching event rates were lowest with ETN versus IFX, ADA, or TCZ used as the first-line biologic. Despite limitations, these findings imply clinical cost-reductive benefits of ETN as the first-line biologic treatment option for rheumatoid arthritis in Japan. (*Clin Ther.* 2016;1:111-1111) © 2016 Elsevier HS Journals, Inc. All rights reserved.

Key words: biologics, claims data, cost, Japan, rheumatoid arthritis.

INTRODUCTION

Rheumatoid arthritis (RA) is a chronic inflammatory autoimmune disease characterized by joint pain and stiffness, followed by progressive joint destruction and disability. In addition to physical impairment and a shortened life expectancy, RA can result in substantial socioeconomic costs. ^{1,2} The prevalence of RA in Japan is estimated to be between 0.6% and 1.0%, ³ which is comparable to that in other parts of the world. ⁴ Thus, the socioeconomic impact of RA cannot be overlooked.

Despite the debilitating nature of RA, several biologic immunotherapies have been approved for inhibiting the progression of structural damage and for improving physical function in patients with moderate to severe disease. For over a decade, biologics—including the tumor necrosis factor (TNF)α inhibitors etanercept (ETN; approved by the Pharmaceuticals and Medical Devices Agency [PMDA] in Japan in 2005 and by the US Food and Drug Administration [FDA] in 1998), infliximab (IFX; PMDA, 2003; FDA, 1999), and adalimumab (ADA; PMDA, 2008; FDA, 2002)—have been used for treating RA in global markets including Japan. The interleukin-6 inhibitor tocilizumab (TCZ) was first approved by the PMDA in 2008, followed by the FDA in 2010. The cluster of differentiation 80/86 inhibitor abatacept was approved by the PMDA in 2010 and by the FDA in 2005. The TNF inhibitors certolizumab pegol and golimumab were approved by the PMDA in 2012 and 2011, respectively, and by the FDA in 2009. To date, few head-to-head randomized clinical trials have assessed the comparative effectiveness of these biologics in the treatment of RA, but those few have generally demonstrated comparable efficacy. 6-12

The treatment of RA is required long term, which creates a significant clinical and economic burden for patients and payers. The cost of RA varies widely between countries, ¹³ partly because of the varying use of biologic treatments, which are substantially more costly than are conventional synthetic disease-modifying antirheumatic drugs. 14-16 The market for developing original biologics for the treatment of RA is saturated, and cost considerations by rheumatologists are becoming more important, especially as biosimilar biologics become more available.¹⁷ The impact of drug costs on direct medical expenditures is also a cause for concern owing to the widespread use of biologics for the treatment of RA. However, a recent study from Germany showed that improvements in functional status and reductions in health care resource utilization as a result of biologic use have largely offset the increased drug costs.¹⁸

Accumulating data from global registries^{19–21} and from Japanese cohorts²² suggest that continuance rates differ among biologic treatments for RA, even between members of the same drug class. The main reasons for discontinuations are lack of efficacy and adverse events (AEs). Poor adherence to medications can reduce effectiveness and increase the utilization of health care services, thereby increasing overall costs.^{23,24}

Current RA treatment practices in Japan are poorly documented,³ and the impact of biologic use on costs is unknown. The aim of this study was therefore to characterize the patterns of treating RA with biologics and to evaluate the direct costs of biologics and medical costs using claims data from Japan.

MATERIALS AND METHODS Data Source

This retrospective analysis utilized reimbursement data from the Japan Medical Data Center Co, Ltd (JMDC). Data were received from the JMDC on February 4, 2015. The JMDC, in collaboration with multiple health insurance societies, has accumulated inpatient, outpatient, and pharmacy claims data from approximately 2.8 million insured members cumulatively from 2005 to 2014. Claims data contained within this database are nationwide and are

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