

## THE COST BURDEN OF PSORIASIS TREATED WITH BIOLOGICS IN AKITA PREFECTURE

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### Abstract

Biologics have been dramatically effective in the treatment of psoriasis and have improved the quality of life of patients. However, to our knowledge, no comprehensive study has been implemented to explore the medical burden created by the administration of biologics. Consequently, we assessed the actual state of the cost burden of patients with psoriasis being treated with biologics in Akita University Hospital. Our results suggested that there were considerable differences in the co-payment of biologics up to the health insurance system. Future studies should carefully consider the cost of biologics from the perspective of the increase in medical expenses.

**Key words :** psoriasis, biologics, cost burden

### Introduction

As of this moment, patients with psoriasis are treated by seven biologics (infliximab, adalimumab, ustekinumab, secukinumab, brodalumab, ixekizumab and guselkumab) in Japan<sup>1,2)</sup>. Although biologics have been dramatically effective and improved the quality of life of patients with psoriasis, the cost burden is a major concern for patients with poor outcomes under conventional treatment. A previous study examined cost-efficacy of biological therapies for patients with psoriasis in Japan. It has been reported that ustekinumab was a more cost-efficient biological therapy than adalimumab or infliximab in a Japanese population based on short-term efficacy evidence and drug costs<sup>3)</sup>. Furthermore, it has been reported that secukinumab was most effective in terms of cost versus

benefit among treatments including cyclosporine, secukinumab, ustekinumab, and adalimumab<sup>4)</sup>. Although these studies provided evidence suggesting certain biologics are superior to other treatments in terms of cost versus benefit, the actual state of the cost burden of patients with psoriasis being treated with biologics remained uncertain.

Accordingly, in this study, we assessed the correlation between the co-payment of biologics and the type of health insurance system of psoriasis patients for the first time in Japan. Our results suggested that there were considerable differences in the co-payment of biologics up to the health insurance system, and that there is a contradiction in which the lower income population benefited from worse services in comparison with the middle to upper income population.

### Cases and Methods

Akita University Hospital is the only medical facility to use biologics for psoriasis cases in Akita prefecture. To assess the cost burden of patients with psoriasis being

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treated with biologics in Akita Prefecture, we conducted a case-series study of psoriatic patients treated with biologics at the Akita University Hospital from January through December 2016.

The consent information and purposes of this study were accurately explained to the participants and they provided informed consent voluntarily. Data about the medical burden were assessed firstly by interviewing each patient about the types of health insurance system in addition to income per year. Secondary, the direct cost was calculated by multiplying the cost of drugs administered in one year by the burden ratio, then subtracted the expenses reimbursed for exceeding upper limit of copayment which be determined by age and income. Error bars on graphs represent standard deviation (SD).

This study was approved by the Institutional Review Board of the Akita University Graduate School of Medicine (permit number : 2071).

## Result

A total of 62 patients, including 50 men and 12 women with an age range of 21 years to 84 years (a mean age of 53.7 years), were recruited in this study. These patients

were treated with biologics : 16 cases with infliximab, 13 cases with adalimumab, 17 cases with ustekinumab, 13 cases with secukinumab, and 3 cases changed biologics (1 case from infliximab to secukinumab, and 2 cases from adalimumab to secukinumab).

With respect to the types of health insurance system and the direct medical costs per year, 10 cases were in receipt of public assistance, 2 cases of the intractable disease medical expenses subsidy program, no case of the welfare and medical care system, 9 cases of fringe benefits and 41 cases of the high-cost medical expense benefit (Fig. 1a). Among the 41 recipients of the high-cost medical expense benefit, 5 were over 70 years old and had an annual income between 1.56 and 3.7 million yen. 36 cases were under 69 years old and, of those, no case had an annual income over 11.6 million yen, 1 case had income between 7.7 and 11.6 million yen, 6 cases had incomes between 3.7 and 7.7 million yen, 24 patients had incomes under 3.7 million yen, and 5 cases were tax-exempt (Fig. 1b).

The annual average co-payment in each types of health insurance system was : 0 yen for patients who were in receipt of the public assistance system, 30,000 yen for patients in the intractable disease medical expenses subsidy program, and 154,577 yen for recipients of fringe

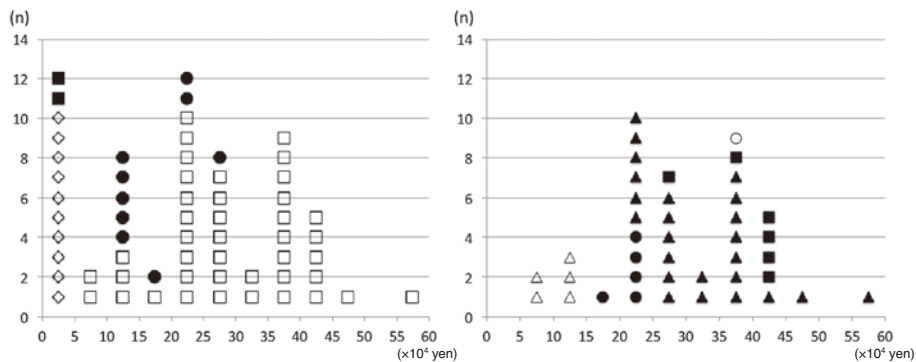


Fig. 1. (a) The direct medical costs per year in 62 patients. The vertical axis shows number of cases and horizontal axis shows the direct medical costs per year (Unit : Yen in thousand). The symbols (◇) shows cases of public assistance, (■) shows cases of the intractable disease medical expenses subsidy program, (●) shows cases of fringe benefits, (□) shows cases of the high-cost medical expense benefit. (b) The high-cost medical expense benefit in 41 patients. The vertical axis shows number of cases and horizontal axis shows the direct medical costs per year (Unit : Yen in thousand). The symbol (○) shows cases with annual income between 7.7 and 11.6 million yen, (■) shows cases with annual income between 3.7 and 7.7 million yen, (▲) shows cases with annual income under 3.7 million yen, (△) shows cases (over 70 years old) with annual income between 1.56 and 3.7 million yen, (●) shows cases (under 69 years) with tax-exempt.

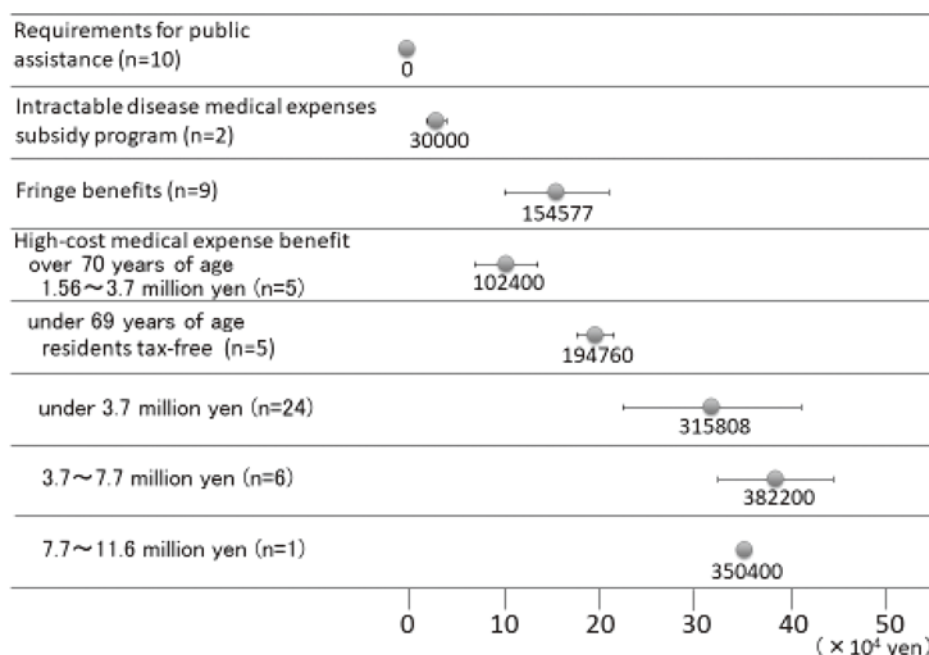


Fig. 2. The results of co-payment by the health insurance system. Horizontal axis shows the direct medical costs per year (Unit : Yen in thousand). Error bars represent standard deviation from the mean (open circles) of the direct medical costs per year.

benefits (Fig. 2). Among recipients of the high-cost medical expense, the annual average co-payment was : 102,400 yen for patients who were over 70 years of age and had an annual income between 1.56 and 3.7 million yen, 194,760 yen for patients who under 69 years of age and were tax-exempt, 315,808 yen for patients who had an annual income under 3.7 million yen, 382,200 yen for patients who had annual income between 3.7 and 7.7 million yen, and 350,400 yen for patients who had annual income between 7.7 and 11.6 million yen (Fig. 2).

## Discussion

Japan's healthcare system is a system of universal health insurance coverage, as all Japanese citizens belong to one of the country's health insurance systems such as the national health insurance, workplace-based health insurance, or government-managed health insurance system. Through these systems, there are various subsidies to relieve the high economic burden of medical treatments. However, health care expenditures have

been rising sharply because of drug costs and is becoming a significant concern for Japan. Accordingly, in this study, we assessed the correlation between the co-payment of biologics and the type of health insurance system of psoriasis patients for the first time in Japan.

Under the Japan's healthcare system, there are no copayments for patients who are in receipt of the public assistance, which guarantees a national minimum standard of living based upon the right to life in the Constitution of Japan<sup>5)</sup>. In the present study, there were 10 patients who were in receipt of the public assistance and their annual copayment was 0 yen. At the present moment, there are no arguments about the unlimited use of biologics for psoriasis patients receiving welfare assistance, while the Ministry of Health, Labour and Welfare of Japan issued a notification indicating that the use of generic pharmaceuticals would be made a principle for persons receiving welfare assistance from October 1, 2018. In future, the use of biosimilar pharmaceuticals may need to be argued carefully in considering the human rights.

Patients with pustular psoriasis are able to participate in the intractable disease medical expenses subsidy program, which provides financial assistance to cover the co-payment of eligible patients in return for providing data for research use<sup>6)</sup>. The upper limit of the copayment is divided into five levels according to annual income: the monthly payment amount is between 2,500 yen and 30,000 yen. In the present study, there were 2 patients with pustular psoriasis who were in the intractable disease medical expenses subsidy program and their mean annual copayment was 30,000 yen. Unfortunately, however, pustular psoriasis is uncommon in Japan, and the prevalence of pustular psoriasis in Japan is only 166 cases, suggesting that few patients benefited from the service. It is to be desired that patients with the other rare types of intractable psoriasis such as psoriatic erythroderma and psoriatic erythroderma could participate in the program.

The fringe benefit system is overseen by a mutual aid association; public servants and health insurance associations such as large corporations that have more than 700 employees must enroll in this program<sup>7)</sup>. This system restricts the monthly copayment for medical expenses and reimburses the individual for expenses that exceed this limit, and the Ministry of Health, Labour, and Welfare recommends a copayment of 25,000 yen per month regardless of income. In the present study, there were 9 patients who were in the fringe benefit system and their mean annual copayment was 154,577 yen. This system relieves a significant economic burden considering the annual income. Namely, since patients participating in this program belong to the middle to upper income patients, their annual copayment is probably only about 2% of the annual income. It is likely that the program is most beneficial for patients with psoriasis, although there is a contradiction in which the middle to upper income population benefited from better services in comparison with the lower income population as described later.

The system used by the most patients is the high-cost medical expense benefit, which avoids catastrophic expenditure for high-cost care and has a cap on monthly co-payment spending<sup>8)</sup>. With this benefit, when medical expenses exceed the copayment limit, the insurer reimburses the individual for those excess expenses depend-

ing on age and income. In the present study, there were 41 patients who were in receipt of the high-cost medical expense benefit and their annual copayment was between 102,400 yen and 382,200 yen. Compared to the fringe benefit system mentioned above, the high-cost medical expense benefit put a significant economic burden for lower income population such as cases exempt from taxes or with an annual income less than 3.70 million yen, whose copayment reached to about 5~10% of the annual income. We regret to say as clinicians that we must accept the reality under the present healthcare system in which the lower income population were resigned to benefit from worse services in comparison with the middle to upper income population.

As described above, we demonstrated the actual state of the cost burden of patients with psoriasis being treated with biologics in Akita University Hospital, suggesting that there were considerable differences in the co-payment of biologics up to the health insurance system. However, in another point of view, more than 90% of medical expenses for biologics used at our hospital for psoriasis treatment were actually covered by public health insurance in 2016, nevertheless subsidy systems to reduce economic burdens are indispensable for patients. Along with the increase in medical expenses, in the future, it will be necessary to carefully discuss the medical burden created by the administration of biologics for psoriasis among a wide range of stakeholders. Meanwhile, steps need to be taken to reduce the medical cost burden by not using biologics without limitation, by using biologics strictly following the psoriasis management guidelines, and by using generic drugs proactively for psoriasis treatment.

In this study, we did not conduct a detailed examination regarding the second year copayment for biologics including the benefit of self-injection of biologics at home, because of an insufficient number of cases. It was speculated that the annual copayment may be much lower, if the number of consultations was reduced by having patients perform self-injections at home. Furthermore, the present study has the limitations of being a single centre, retrospective study and a highly reliable epidemiological analysis could not be performed due to the small sample size. In future, we plan to increase the

sample size and perform a more detailed investigation including not only cost but also benefits and QOL.

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### Funding Disclosure

None reported.

### Conflicts of Interest

None declared.

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