Transition of Intervention of Clinical Trials for Obesity

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ABSTRACT

Objectives: Earlier studies have revealed that modification of lifestyle habits from the aspects of nutrition and exercise is the most effective measure to control metabolic syndrome, and this finding may be reflected in the number of registered clinical trials. This paper aims to test this assumption and conduct exploratory analysis of the recent trends in clinical trials related to obesity.

Design and methods: Of the clinical trial data registered with the International Clinical Trial Registry Platform (ICTRP), we used 1,478 data sets of obese patients for analysis (available as of August 2016). This study is exploratory analysis, aiming to test some hypotheses and identify the overall tendency. The target hypotheses are as follows. Among clinical trials targeting obese patients, the amount of these intended to verify the effect of lifestyle modification has been increasing year by year. Results: the share of clinical trials targeting obesity has been increasing year by year. We clearly found that the amount of clinical trials using lifestyle intervention has been increasing .

In the study conducted by Knowler in 2002, the research team divided obese patients with BMI25 or higher into three groups, i.e., those given a placebo, those treated with metformin, and those instructed to modify their lifestyle, and observed their conditions over four years. The research team found that the cumulative incidence of diabetes was statistically significantly lower among the lifestyle modification group than among the metformin group. Following a number of similar study results, more importance has been given to lifestyle modification than to treatment with mediation as a strategy to control obesity, or metabolic syndrome. Leading the planet during this area, Japan introduced a system of specified medical checkups and specified medical guidance in 2008. Under this technique , people receiving medical checkups undergo measurement of their waist circumference, BMI, then forth. The system is designed to thereby find people who are at risk of lifestylerelated diseases due to high blood sugar, high blood pressure, and lipid abnormality, from among those whose measurement results exceed the standard ranges. These people are given health guidance to switch their lifestyle habits. Other countries followed Japan, starting to implement government-led measures to modify people's lifestyle habits including diet and exercise. Backed up by a number of study results such as those obtained by Sacks and Eyles , the first bill in the United States to levy tax on soda and other sugar-sweetened beverages was passed by the council of the City of Berkeley, California . A similar soda tax is also scheduled to be introduced in the City of Philadelphia . This trend has the potential of spreading across the United States.

Thus, earlier studies have revealed that modification of lifestyle habits from the aspects of nutrition and exercise is the most effective measure to control metabolic syndrome, and this finding may be reflected in the number of registered clinical trials. Presumably, among clinical trials targeting obese patients, while the amount of trials using surgery and drugs has been relatively decreasing year by year, the amount of these intended to verify the effect of lifestyle modification has been relatively increasing year by year. This paper aims to test this assumption and conduct exploratory analysis of the recent trends in clinical trials related to obesity

In the Advanced search of ICTRP [7], when inputting the disease name in the condition column, data of the corresponding clinical trial is output. In this study, we entered "obesity" within the condition field of Advanced search and analyzed the info of all clinical trials output. Of the clinical trial data registered with the International Clinical Trial Registry Platform (ICTRP) [8], we used 1,478 data sets of obese patients for analysis (all from database inception to August 19, 2016)

In order to analyze these hypotheses, we extracted data regarding Date Registration, Study Type, Gender, Minimum Age, Maximum Age, and Phase, from the 1,478 data sets mentioned above. We also read data regarding interventions one by one and classified the data into five categories, i.e. Surgery, Device, Supplement, Lifestyle Habits, and Other. An intervention that may fall within more than one category, such as modification of lifestyle habits after surgery, is classified as "Surgery." Other interventions that may fall within more than one category are classified into the category of more invasive intervention. "Device" covers a good range, including implantable devices, communication devices for remote medical aid , and even video games. "Supplement" mainly includes vitamin tablets and plant extracts. As "Lifestyle Habits,"

we selected nutrition and exercise as well as education on these as the major types of interventions. Other interventions that cannot be assigned to one of these categories, such as acupuncture and moxibustion therapy, music therapy, and survey, are classified into "Other."

The percentage of clinical trials targeting obesity has been increasing year by year. This trend is clear from the residuals adjusted for degrees of freedom. While all residuals in clinical trials targeting obesity conducted years ago take negative values, all residuals in recent clinical trials take positive values. Table 2 shows the yearly trends of interventions used in clinical trials targeting obese patients. Looking at the residuals adjusted for degrees of freedom after conducting a chi-squared test, we clearly found that the number of clinical trials using lifestyle intervention has been increasing

Keywords: Obesity; Metabolic syndrome; Clinical trials