Comparison of Hyakudoku-Kudashi® with Laxative A or Laxative B in drug-taking satisfactory
- Characteristic effect of "Hyakudoku-Kudashi®" as a herbal laxative-

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Introduction

Constipation is one of the frequently-developed physical symptoms, while it is one of the symptoms for which doctor visit is quite rare. Constipation is hardly recognized, not only by the patients but also by doctors, as a disease requiring treatment. Patients self-handle it in their everyday life and they are said to seldom visit gastroenterological medicine specialists.[1)]

Medicinally, constipation would be diagnosed if it is acute or chronic, functional or organic, or unidentified or accessory symptom of other diseases.[2)] Symptoms of constipations are classified into following cases: 1. transient and simple 2. flaccid 3. spastic and 4. rectal constipation. Since transient and simple constipation is caused by stress and relieved by lowering stress, approach of mental health care is required as well. Chronic constipation that becomes an issue in daily life is 2, 3 and 4.[3)4)] Regarding to innervations of enteric canal, study in brain gut axis that mediates automatic nerve between central nervous system and enteric nervous system, has made advance these day in relation to hypersensitive colitis, which has promoted the study for approach from brain science as well as for organic viscerosensory reflex.[5)6)]

Healthy person has once or twice bowel movements a day. Some people think themselves constipating even though they have more than three times of defecation a week, while others don't think they suffers from constipation if they experience no distress despite they have few bowel movements. It is very difficult to define costiveness by number of bowel movement, shape of stool or feeling after defecation. There are many people who feel difficulty, frustrated in defecation, and think themselves become constipation if they do not have the movement everyday, or they are distressed by discomfort defecation even if they have a motion every day. As long as constipation causes decline in quality of life (QOL), some countermeasures seem to be needed. On the other hand, patients normally care themselves by taking commercially available "over the counter" medicine (OTC laxative) or supplements.

Recently we had an opportunity to perform a study to determine characteristics effect of Hyakudoku-Kudashi, a Japanese-Chinese herbal OTC laxative.

I. Purpose of Study

Characteristics effects of a Japanese-Chinese herbal laxative Hyakudoku-Kudashi was evaluated in comparison with synthetic laxative Laxative A and dietary fiber laxative Laxative B (registered mark will be dispensed hereinafter) as control drugs.

Clinical effects and impressions such as sense of dosage when these drugs were taken were assessed as “satisfaction” using questionnaire (It is called “dosing comparison test”)

Profiles of there three OTC medicines, which is released in their web sites, are shown in Table 1.

As lipid metabolism-improving effect of Hyakudoku-Kudashi is suggested in nonclinical test[7)], its influence on lipid metabolism of human was also evaluated in parallel (“Lipid Measurement” test).

This study was performed using OTC laxatives, complying with their dosage regimen allowed by Ministry of Health, Labour and Welfare (“accustomed dose” hereinafter).

Table1　Test Sample　(Source: Web site of each company, 7th March, 2008)

	Hyakudoku-Kudashi (SuiShoDo Pharmaceutical Corporation)	Laxative A	Laxative B
Nomal Applied Dose	Dosage: 12 - 32 pills a day Tale 12 -16 pills on an empty stomach morning and evening (or before meal)	Take 2 tablets once a day without chewing before going to bed or several hours before defecation is expected.	Take 1/2 -1 package 3 times a day after each meal
effect -efficacy	Constipation Relief of following symptoms with constipation: heaviness of the head , feeling dizzy , rough skin, spots , inappetence (decreased appetite), abdominal distension ,abnormal fermentation in the intestine, hemorrhoid	Chronic constipation Habitual constipation	Constipation Relief of following symptoms with constipation: heaviness of the head , hot flushes , rough skin, spots , inappetence, abdominal distension , abnormal fermentation in the intestine,hemorrhoid
Component	In a day's dosage (32pills) ・Powdered rhubarb 0.880g ・Powdered aloe 0.100g ・Powdered pharbitidis semen 0.170g ・Eijitsu (rosa multiflora) extract ※0.043g from Eijitu0.344g ・Sankirai (smilax china) extract ※0.040g from Sankirai 0.5g ・powdered licorice 0.150g including　precipitated calcium carbonate, powdered early plum , bleached beeswax , carnauba wax , talc , medicinal charcoal as additives.	In a day's dosage(2 tablets) ・bisacodyl 10mg [2 (4,4'-diacetoxy diphenylmethyl) pyridine] aditive: white sugar , talc , arabiagum , ricinus methacrylic acid copolymer S, methacrylic acid copolymer L, cornstarch, stearic acid Mg , glycerin , titanium oxide, milk sugar , red No.3 , carnauba wax , bleached beeswax , macrogol	In a day's dosage 6g (3 packages) ・Ispaghul 2,550mg ・Sennoside 83.53mg (sennoside A・B 48g) Aditive: aroma chemical , red No.102 , blue No.1 and yellow No.5 <caution about component and dosage> Although this medicine may make urine brownish yellow or red, it is because of　sennoside as a major component, so there is nothing to worry about.
Product Feature	Although Hyakudoku-Kudashi is a Japanese and Chinese herbal medicine includes six crude vegetable drugs, It improves not just for constipation. This medicine relieves collateral symptoms like rough skin , spots etc except constipation. ・working not only for the large intestine but also for whole intestine to promote bowel movement. ・promoting spontaneous defecation with releaving sharp stomachache and tolerance ・Relieving symptoms with constipation like rough skin, spots etc ・Iit is easy to control dosage suited dejection because of small size of pills is easy to control dosage, and easy to swallor for both adult and children.	・Small pink tablet for contipation, coated with five layers so that active ingredient can work steadily in the intestine without melting in the stomach. As bisacodyl stimulates the large intestine to promote fuel peristaltic movement, it takes overnight reaction. (about 6 - 11 hours as a measure). ・works for chronic constipation, provides a　refleshing feeling without a sensation of incomplete defecation.	・Vegetable constipation medicine from vegetable fiber and crude drug component (senna). Physical and chemical effects of ispaghul (swelling property) and sennoside (stimulus property) help spontaneous defecation and recover a rhythm of bowel movement. ・Agreeable chocolate-flavored glanule in stick package are handly to carry on a outing or a trip.

II. Object and Method

1. Object

The test was conducted by a non-profit organization Japan Clinical Research Supporting System (JCRSS). Women who suffered from constipation were recruited via volunteer panel of JCRR as participant of “dosing comparison” test, and those for “lipid measurement” test was recruited at the same time. The participants were required 1, to suffer from chronicle constipation 2. not to received treatment of constipation by doctor and 3, to have examined self-care.

JCRSS calls the volunteers “Monitor” when they participate in tests, and do clinical research coordinator who have medical knowledge and experience in joining clinical trials “clinical research promoter (CRP).

The study underwent the assessment by Ethical Review Board of Goto internal disease clinic, Itami city, Hyogo prefecture. After the approval was received, volunteers were recruited as Monitors mainly from Hyogo pref, Osaka pref and Tokushima-city. Besides being constipated, monitors were recruited under the criterions : 1) not being an “obstinate” constipation, 2) dosing OTC laxatives in daily life within the limit of dosage regimen allowed by the Ministry of Health, Welfare and Labour, 3) not having a lot of food that help relieve constipation, e.g. senna, in addition to OTC laxatives. 4) understanding the study contents and giving first-person’s informed consent. 5) making sure to contact CRP on a daily basis. 6) being expected to complete the four-week test. CRP explained the study contents to all volunteers, and people who submit written confirmation were registered for the study as monitors.

2. Method

1) Design (Table 2)

105 monitors, who were registered after being ascertained their suitability, were divided into two groups: 82 for “dosing comparison” test and 23 for “lipid measurement” test, and the tests were conducted in parallel. After providing the informed consent for registration, the monitors received written information concerning the study, questionnaire, and minimum package of pertinent OTC laxative, and were instructed by CRP to adhere rigidly to the dosage and dose method of sample drugs.

Then they intermitted the self care such as dose of OTC laxative that they had taken previously and started the test at the time they felt themselves constipated. During the test period, the subjects took sample drugs within the amount of recommended dose, wrote in the questionnaire for each sample after dosing. The questionnaire was collected by CRP in two weeks and in four weeks.

Table 2 Design of the Study

A. "Dosing Comparison" Test Group		No. of Monitors	4-week dosing period	
			2 weeks	2 weeks
1. Hyakudoku-Kudashi/ Laxative A	A1. Hyakudoku-Kudashi-Prior Group	20	Hyakudoku-Kudashi	Laxative A
	A2. Laxative A-Prior Group	20	Laxative A	Hyakudoku-Kudashi
2. Hyakudoku-Kudashi/ Laxative B	A3. Hyakudoku-Kudashi-Prior Group	21	Hyakudoku-Kudashi	Laxative B
	A4. Laxative B-Prior Group	21	Laxative B	Hyakudoku-Kudashi
		No. of Monitors	4-week dosing period	
B. Group for “Lipid Measurement” Test Group	B1. Continuous Dosing	16	Continuous dosing of Hyakudoku-Kudashi	
	B2. Control	7	Dosing no laxatives	
Total Monitors		105		

(A) “Dosing Comparison” test

Crossover test was conducted concerning order effect of dosing, and eighty-two subjects participating to “dosing comparison” were allocated to two groups by envelop method: 1) was to compare between Hyakudoku-Kudashi and Laxative A, 2) was to compare between Hyakudoku-Kudashi and Laxative B. Of these groups, twenty subjects of 1) who took Hyakudoku-Kudashi first was named A1, another twenty who started from Laxative A was A2. Comparison group 2) taking Hyakudoku-Kudashi and Laxative B was divided into A3 that took Hyakudoku-Kudashi first (twenty-one participants) and A4, twenty-one who started from Laxative B. Prior test drug was taken for two weeks, and afterwards, followed the two-week’s dose of the control drug. Monitors were required to have switching period for temporary halting after first two weeks, and then start another two-week dosing at the point when they felt themselves constipated.

(B) “Lipid Measurement” test

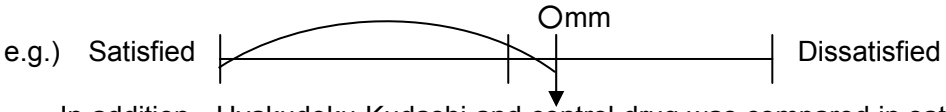
To assess lipid metabolism-improving effect of Hyakudoku-Kudashi, the test was performed by “continuous dosing” group and control group. Blood samples were collected before starting (Week 0) and after finishing (week 4) the study. Monitors were divided into two groups of B1 (sixteen) who took Hyakudoku-Kudashi as continuous as possible within the recommended dosage amount during the test period, and control group of B1 who kept self-care without taking any OTC laxatives. The grouping was made to adjust its initial level of total cholesterol fallen into 220 – 230 mg/dL. Answer to questionnaires was required in the “Lipid measurement” test, as well as “Dosing Comparison” test. Inspection items of blood samples were total cholesterol (TC), triglyceride (TG), HDL, white blood cell count, red blood cell count, hemoglobin, hematocrit, platelet count, AST, ALT, γ-GTP, ALP, LDH, total bilirubin, total protein, ZTT, A/G ratio, BUN, and albumin. LDL was calculated using Friedewald formula.

2) VAS as index of satisfaction

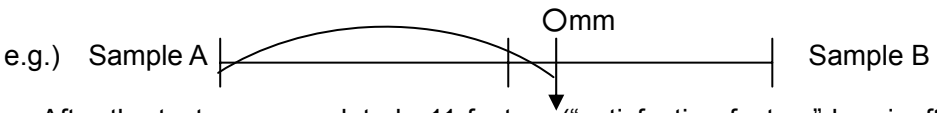
Satisfaction for dosed drugs was evaluated with VAS (Visual Analogue Scale)[8]. VAS is often used to describe relative impression degree on questioned issues.

In this study, total impression of clinical effect and feeling of usage was evaluated as degree of “Satisfaction” using VAS. (VAS evaluation hereinafter)

To the question “how was the total satisfaction?”, “Satisfy” and “dissatisfy” was expressed on axis.



In addition, Hyakudoku-Kudashi and control drug was compared in satisfaction after the test and VAS was used to response to the question “Which drug were you more satisfied?” (“compared satisfaction” hereinafter). The prior drug was placed on the left side of VAS axis.



After the test was completed, 11 factors (“satisfaction factors” hereinafter) on the satisfaction of each drug was assessed.

To the question “Which do you thin have the higher curative properties by comparison?” VAS was introduced to evaluate the responses to 11 issues: 1) having quicker effect 2) having sure effect 3) being less likely to produce abdominal pain. 4) being not long before bowel movement 5) feeling good with no sensation of incomplete defecation 6) decreasing flatulence 7) recovering the regular bowel movement 8) improving symptoms that accompanies constipation 9) being easy to control dosage 10) providing a sense of reassurance and safety 11) having something good for the body.

3. Evaluation Notation and Statistical Analysis

Percentage of actual measurement value to the length of VAS axis (VAS axis value) was used as VAS value. Monitors were required to mark a down-pointing arrow on the VAS axis, and the length from the left to the cross point of the arrow and the axis were measured in mm (actual measurement value), then the actual measurement value was divided by the VAS axis value to obtain the percentage.

For evaluation notation of each question, the lower was the actual measurement value of a question, the higher was the VAS value. Thus, VAS value (%) = (VAS axis value – actual measurement value)/VAS axis value x 100. Statistic value obtained from the statistical analysis is expressed in Mean±SD. Unpaired t-test was applied for background of monitors divided into groups, and Mann-Whitney U-test was introduced for comparison of VAS value. Comparison of lipid measurement value was performed with paired t-test in before-and-after, unpaired t-test for comparison of “control” groups. $p \leqq 0.05$ was considered as significant difference for each comparison test.

III. Results

1. Background of monitors (Table 3)

No significant differences were observed between A1 and A2, A3 and A4, and B1 and B2 in monitors regarding to the age, BMI, satisfaction to bowel movements (VAS value), physical condition at the start of the study (VAS value).

Table 3 Background of monitors who participated in the study

	A) Dosing Comparison Group				B) Lipid Measurement Group	
	1. Group comparing Hyakudoku-Kudashi and Laxative A		2. Group comparing Hyakudoku-Kudashi and Laxative B		Total Cholesterol at week O (mg/dL)	
					227±13.7	228.4±15.5
	Hyakudoku-Kudashi -Prior Group (A1)	Laxative A -Prior group (A2)	Hyakudoku-Kudashi -Prior Group (A3)	Laxative B -Prior Group (A4)	Continuous Dosing Group(B1)	Control Group (B2)
Monitors (n)	20	20	21	21	16	7
AGE (Old)	41.6±13.6	44.1±14.2	39.9±14.1	42.0±14.9	44.6±8.3	42.6±12.1
BMI (Kg/m^2)	21.1±1.8	21.7±2.5	21.4±2.3	21.0±1.8	20.9±2.0	20.5±2.7
Satisfaction with bowel movement (VAS) (%)	56.0±12.9	57.4±15.4	58.1±16.3	55.3±16.9	58.5±11.8	55.1±13.1
Physical Condition (VAS) (%)	47.8±9.3	50.1±8.2	47.2±6.2	51.3±9.4	51.0±16.2	56.8±14.9

NS: not significant with each in-group

2. Comparison of satisfaction in "dosing comparison" groups

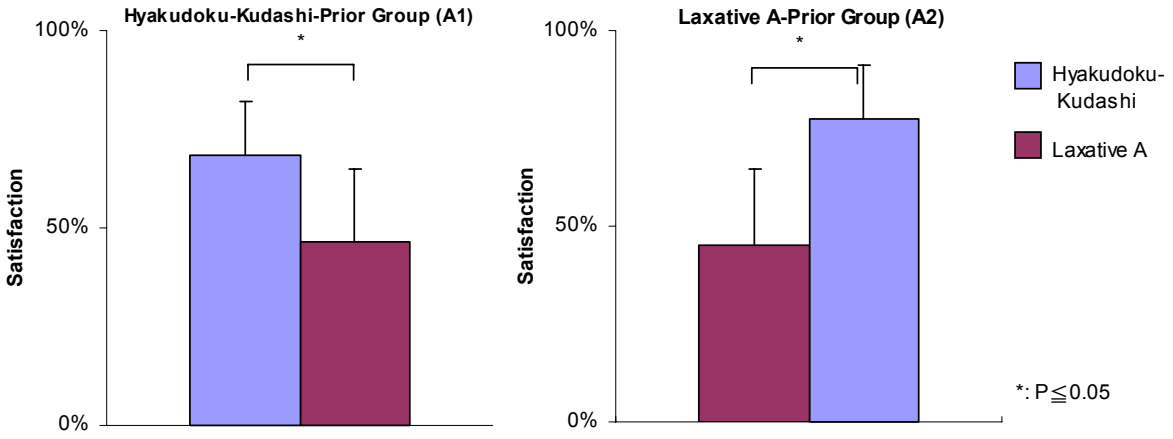
1) The group comparing satisfaction with Hyakudoku-Kudashi and Laxative A (A1, A2) (Fig.1)

Satisfaction "after taking" Hyakudoku-Kudashi was 68.4±13.6% in the group that took Hyakudoku-Kudashi first (A1), compared to 46±18.4% in the group that started from Laxative A (A2). Satisfaction with Hyakudoku-Kudashi was significantly higher ($p<0.001$) than Laxative A. On the other hand, satisfaction of the group who taking Laxative A first was 45.0±19.6%, in comparison with 77.5±13.7% of Hyakudoku-Kudashi. Hyakudoku-Kudashi got significantly higher assets ($p = 0.002$) than Laxative A (Fig.1-1). Regarding to the "compared satisfaction", Hyakudoku-Kudashi scored higher both in A1 and A2 (A1: Hyakudoku-Kudashi 74.0±22.5%, A2: Hyakudoku-Kudashi 79.0±18.7%).(Fig.1-2)

2) The group comparing satisfaction with Hyakudoku-Kudashi and Laxative B (A3, A4) (Fig.2)

Satisfaction "after taking" Hyakudoku-Kudashi was evaluated higher with 68.0±17.9% in the group that took Hyakudoku-Kudashi first (A3) when compared to 49.6±28.5% of the group taking Laxative B first, while satisfaction "after taking" Laxative B was 54.0±19.6% in the group taking Laxative B as a prior drug (A4) compared to 64.3±21.2% of Hyakudoku-Kudashi, significant difference were not observed between these samples ($p=0.161$) (Fig.2-1). Hyakudoku-Kudashi was evaluated higher in the "compared satisfaction for both A3 and A4 (A3: Hyakudoku-Kudashi 59.0±31.8%, A4: Hyakudoku-Kudashi 62.6±24.5%) (Fig.2-2).

1. Satisfaction "After Dosing"



2. Satisfaction "Dosing Comparison"

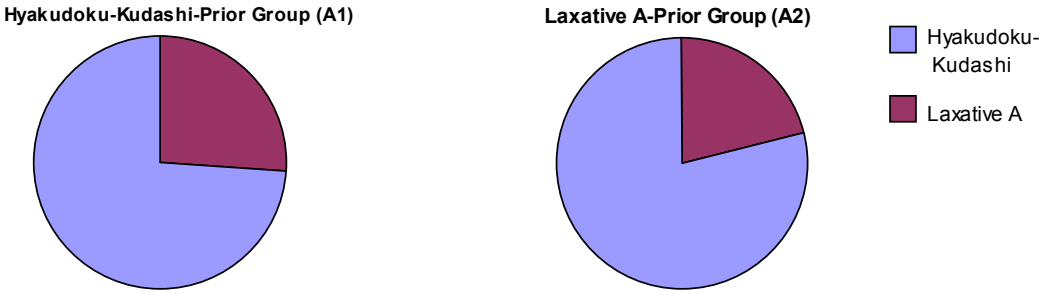
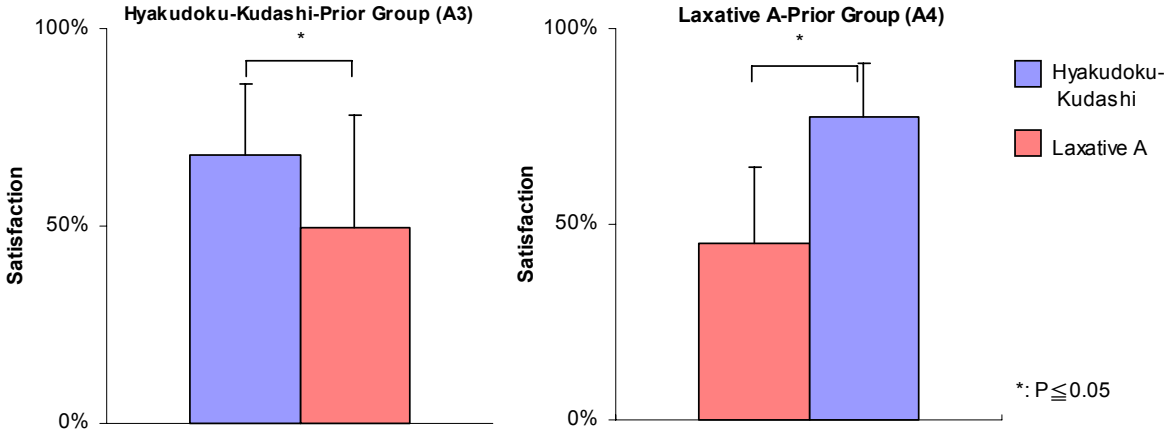


Figure 1 VAS Evaluation of Hyakudoku-Kudashi / Laxative A "Dosing Comparison" Test Group

1. Satisfaction "After Dosing"



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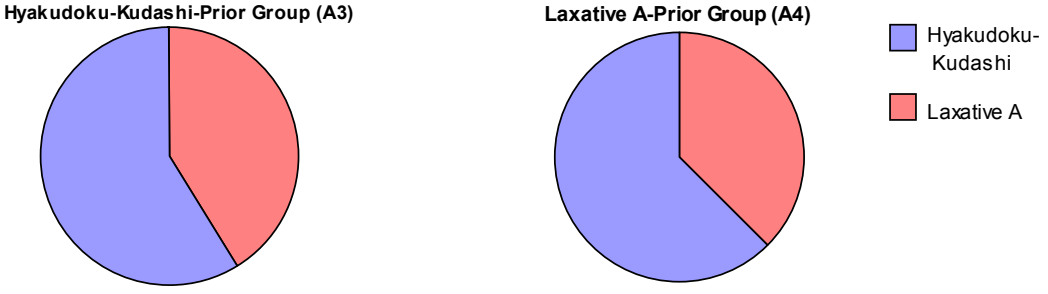

Figure 2 VAS Evaluation of Hyakudoku-Kudashi / Laxative B "Dosing Comparison" Test Group

3. Comparison of satisfactory factors (Fig. 3)

Regarding to the mean values of VAS evaluation (VAS mean value) on 11 issues of satisfactory factors, Hyakudoku-Kudashi was 62.5±19.6% in the group comparing with Laxative A (A1 and A2), and 54.0±20.8% in that of Laxative B (A3 and A4). The issues marked higher figures than VAS mean value by both comparison groups were 3) being less likely to produce abdominal pain 9) being easy to control dosage 10) providing a sense of reassurance and safety, and 11) having something good for the body.

1) The group comparing Hyakudoku-Kudashi and Laxative A (A1 and A2)

The issues that figures of Hyakudoku-Kudashi was higher than VAS mean value were 3) being less likely to produce abdominal pain (78.6±18.9%), 7) recovering the regular bowel movement (65.5±16.1%), 8) improving symptoms that accompanies constipation (66.0±16.4%), 9) being easy to control dosage (71.3±27.6%), 10) providing a sense of reassurance and safety (83.5±16.9%), and 11) having something good for the body (74.9±20.2%). The higher issues Laxative A obtained were 1) having quicker effects and 2) having sure effect, both with over 50%.

2) The group comparing Hyakudoku-Kudashi and Laxative B (A3 and A4)

The issues that Hyakudoku-Kudashi obtained higher evaluation than VAS mean value were 3) being less likely to produce abdominal pain (61.6±24.5%), 9) being easy to control dosage (69.3±25.8%), 10) providing a sense of reassurance and safety (65.9±23.8%), and 11) having something good for the body (64.3±17.3%), while Laxative B was highly verified of more than 50 % with 1) having quicker effect, 2) having sure effect, 5) feeling good with no sensation of incomplete defecation, and 6) decreasing flatulence.

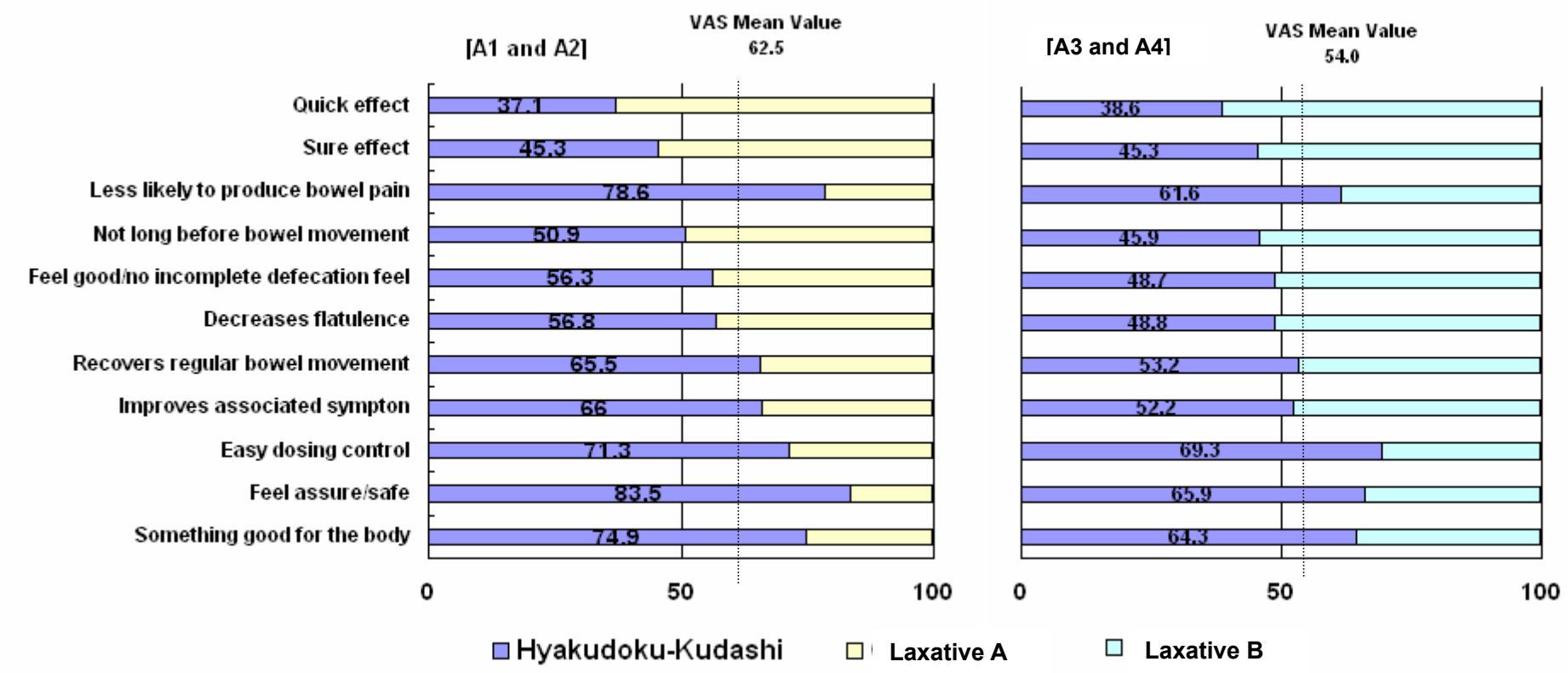

Fig 3. Evaluation of Satisfaction Factors in "Dosing Comparison" Test Groups

4. Influence of Hyakudoku-Kudashi on blood lipid

When rate of change before and after dosing was considered in “lipid measurement” test groups (Fig.4), total cholesterol (TC) of “continuous dosing” group of Hyakudoku-Kudashi was -3.4% (p=0.001) and LDL was -5.6% (p=0.005), both were significantly different from the “control” group.

As for the amount of change before and after dosing, it decreased from 227.1±13.7mg/dL before dosing to 219.4±12.3mg/dL (p=0.001) in 4 weeks of after dosing in TL, and 142.9±16.4mg/dL to 135.0±13.8mg/dL (p = 0.003) in LDL, both were found to be significantly different before and after dosing. Moreover, declining trend was observed in triglyceride (TG).

Fig. 4. Rate of change of blood lipid in "Lipit Measurement" Test Group

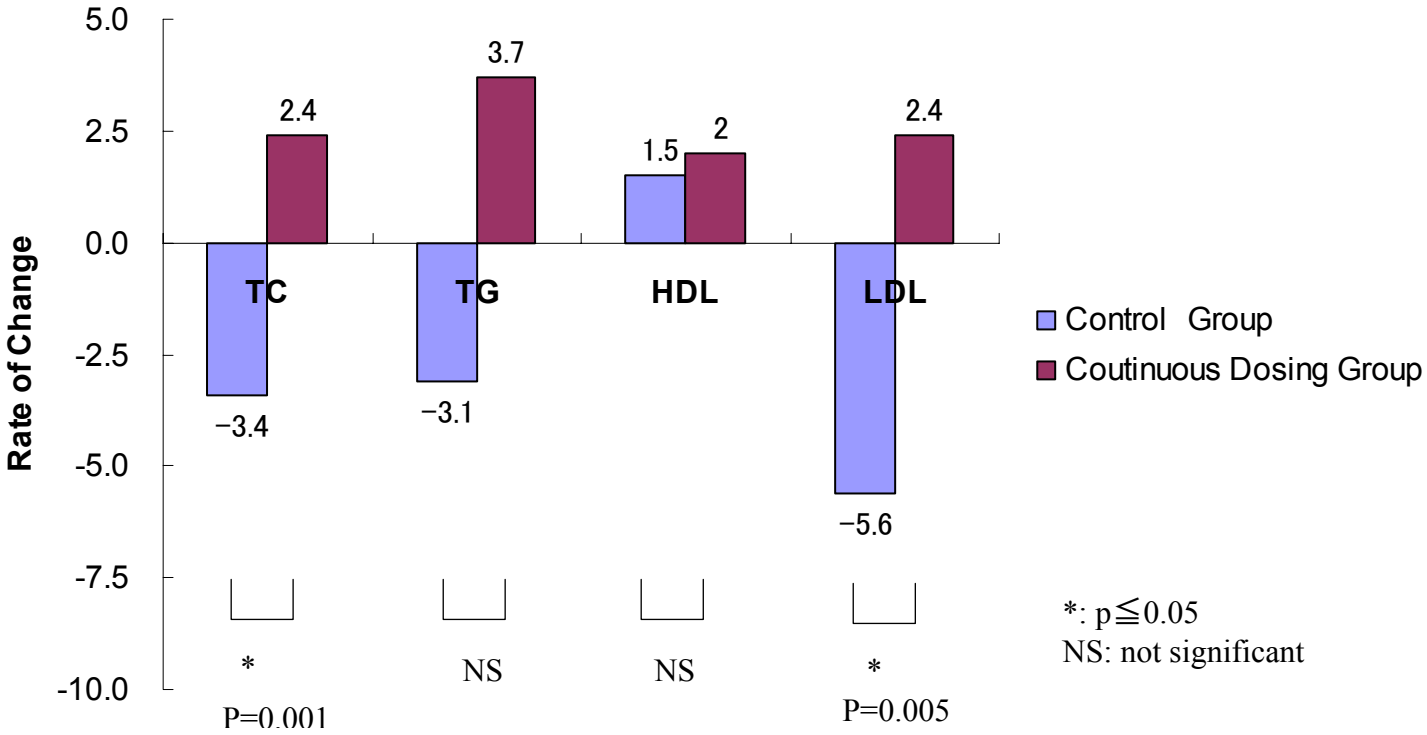

Table 4. Change of Lipid in "Lipid Measurement" Test Group

		n	Before Dosing (Week O)	After Dosing (Week 4)	Before/After Dosing (p value)	Rate of Change Before/After (%)	VS Control Group (p value)
Total Cholesterol (TC)	Continuous Dosing Group	16	227.1±13.7	219.4±12.3	0.001*	-3.4	0.001*
	Control Group	7	228.4±15.5	234.0±15.7	0.143	2.4	
Triglyceride (TG)	Continuous Dosing Group	16	110.6±59.8	107.3±66.0	0.476	-3.1	0.302
	Control Group	7	124.0±41.7	128.6±34.8	0.621	3.7	
HDL	Continuous Dosing Group	16	62.1±13.8	63.0±14.4	0.350	1.5	0.714
	Control Group	7	64.6±10.3	65.9±8.2	0.639	2.0	
LDL	Continuous Dosing Group	16	142.9±16.4	135.0±13.8	0.003*	-5.6	0.005*
	Control Group	7	139.1±14.1	142.4±15.6	0.182	2.4	

Mean Unit:
mg/dL

*: $p \leqq 0.05$

IV. Discussion

However the monitors were limited to women, occupation of 105 monitors were 24 housewives (22.9%) and 10 students (9.5%). The rest 71 (67.6%) of them, about 70 % were working women who worked every day, particularly as part-time workers. It is easy to imagine that they might suffer stress from their jobs. In addition, their timings of defecation are tend to become irregular due to household duties, care of family members or work-related matters[9]. Physiological alternation caused by menstruation, even though it was not researched in this study, are thought to be one of the important affecters[10]. These life circumstance and physiological alternation cause various symptoms of constipation and that leads to reduce QOL, which, however, many people seem to handle it with self-care, as most of the symptoms are not much serious as seeing the doctor. So, this study was conducted for the purpose to comprehend characteristic effects of OTC laxatives used for self-care, by evaluating users' satisfaction with them through questionnaires.

According to the VAS evaluation of the questionnaires, significant difference was observed between Hyakudoku-Kudashi and Laxative A in "after-dosing" satisfaction, and Hyakudoku-Kudashi obtained higher satisfaction than Laxative A and Laxative B in "compared satisfaction".

JCRSS volunteer panels who cooperated in this study live in Kansai district, where is out of sales area of Hyakudoku-Kudashi, and most of the monitors took it for the first time. Despite this, it was confirmed that Hyakudoku-Kudashi received high evaluation, which included that from the monitors who had already took Laxative A or Laxative B.

When VAS mean value of Hyakudoku-Kudashi in "dosing comparison" test groups and VAS evaluation of it in "lipid measurement" test groups were compared, they were 61.8±19.1% and 72.2±15.6% respectively and there was significant difference ($p=0.047$) between them (No data is presented). This difference must have been occurred because "continuous dosing" group were requested to took the sample drugs continuously as much as possible, while "dosing comparison" group took them at the discretion of the monitors. It is considered that Hyakudoku-Kudashi provides higher satisfaction when dosing continuously than used on an as-needed basis.

When satisfactory factors were reviewed, Hyakudoku-Kudashi was praised high satisfaction more than VAS mean value with the issues of 3) being less likely to produce abdominal pain, 9) being easy to control dosage, 10) providing a sense of assurance and safety, and 11) having something good for the body. Since these issues are necessary requirements for continuous dose of the medicine in order to control daily constipation symptoms, this characteristic of Hyakudoku-Kudashi was considered to be "less concerns" for continuous dose and to make "continuous dose" possible.

As Laxative A and Laxative B obtained high satisfaction with the issues 1) having quicker effect, 2) having sure effect, and 4) being not long before bowel movement, it was though that they were valued because they provided a sense of direct effect to bowel to promote the movement. In other words, Laxative A and Laxative B might have the characteristics that provide satisfactions to the patients with using OTC laxatives on "as-needed basis", who wants to counteracts their constipation by defecating quickly, for some reasons including that they would like to defecate in advance, to be relieved from a feel of constipating, or they might expect to suffer from constipation before special activities. On the other hand, Hyakudoku-Kudashi obtained high satisfaction with the issues 3) being less likely to produce abdominal pain and 7) recovering the regular bowel movement, and this drug was thought to be supported due to its work of promoting relatively natural bowel movement without abdominal pain. In addition, Hyakudoku-Kudashi is considered to be used for avoiding constipation in advance, by taking it the day before the predetermined event, for example, a travel or a ceremony.

As patients with obstinate constipation were excluded from the study, the participants were thought to be relatively less varied groups in symptoms of constipation. However, continuities and usage of the drugs in "dosing comparison" groups were varied individually. For self-care, no instructions were expected from doctors or chemists, and there exists no guidelines to control the symptoms. OTC laxative seem to be taken without being understood their characteristics.

While some patients use OTC laxatives such as Laxative A and Laxative B on as-needed basis in order to counteract the constipation, there exits patients who take the medicine to resolve the constipation "gently" with "controlling "dosage depending on the condition of the day.

Hyakudoku-Kudashi was confirmed to be the OTC laxative that can provide high satisfaction to these patients.

In considering of the influence to blood lipid in “lipid measurement” test group, Hyakudoku-Kudashi suggested an advantage of improving TC, LDL and TG. The ingredients of Hyakudoku-Kudashi includes powdered rhubarb, powdered aloe, powdered pharbitidis semen, eijitsu (rosa multiflora) extract, sankirai extract, powdered licorice, and its pharmacologic effects of Japanese and Chinese medicine are expected to help reduce blood lipid by regulating enteral environment and improving metabolism in the liver. Improving effect of Hyakudoku-Kudashi on blood lipid is thought to further enhance satisfactions with the issues such as 8) improving the symptoms that accompany constipation, 10) providing a sense of assurance and safety, or 11) having something good for the body.

Conclusion

In this study, satisfactions with OTC laxatives were compared using questionnaire. As a characteristic of Hyakudoku-Kudashi, it is confirmed that this is the satisfactory medicine for the patients who have not took it before and will switch from Laxative A or Laxative B. Characteristic differences were observed in the satisfactory factors such as 3) being less likely to produce abdominal pain, 9) being easy to control dosage, 10) providing a sense of assurance and safety and 11) having something good for the body. From the result, it is confirmed that Hyakudoku-Kudashi can be taken continuously with ease, and have characteristic effect that provides high satisfaction in accordance with the daily symptoms.

Moreover, from the result of the parallel study, in which influence on blood lipid was researched, it was suggested that continuous dose of Hyakudoku-Kudashi might provide positive improvement effect on blood lipid.

Reference

(Omitted)