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In Vitro Adsorption of Cardiometabolic Drugs by Fiber-Rich Food Materials under Simulated Intestinal Conditions

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Fiber-rich foods are commonly consumed as part of dietary management or self-care by patients receiving long-term cardiometabolic pharmacotherapy. However, their physicochemical interactions with marketed pharmaceutical products under simulated intestinal conditions remain insufficiently characterized. This study evaluated the *in vitro* adsorption behavior of selected orally administered cardiometabolic drugs in artificial intestinal fluid in the presence of basil seeds or wheat bran. Commercially available products containing calcium channel blockers, beta-blockers, statins, or angiotensin II receptor blocker-related drugs were crushed and dispersed in artificial intestinal fluid, followed by the addition of basil seeds or wheat bran. Residual drug concentrations were determined by HPLC, and adsorption profiles were analyzed using pseudo-first-order and pseudo-second-order kinetic models. The reduction in residual drug concentration depended on both the drug and the food material. In the presence of wheat bran, amlodipine and carvedilol showed marked decreases in residual concentration, with residual rates of 32.9% and 16.6%, respectively, after 3 h. Nifedipine and olmesartan medoxomil also showed decreased residual concentrations, whereas bisoprolol, rosuvastatin, atorvastatin, and azilsartan showed only limited changes. The pseudo-second-order model showed better overall agreement with the adsorption profiles of the selected drugs. These findings provide a basis for further biopharmaceutical evaluation of physicochemical interactions between fiber-rich food materials and orally administered cardiometabolic drugs.

Key words food–drug interaction, adsorption, dietary fiber, basil seeds, wheat bran, cardiometabolic drug

INTRODUCTION

Noncommunicable diseases (NCDs), particularly cardiometabolic conditions such as cardiovascular disease, hypertension, diabetes, and dyslipidemia, are major public health problems worldwide.[1)] Their prevention and management require long-term lifestyle modification together with pharmacotherapy. Dietary management, including increased dietary fiber intake, is widely recommended because dietary fiber contributes to the regulation of blood glucose and lipid levels, improves bowel habits, and modulates the gut microbiota.[2–4)] Consequently, patients receiving long-term cardiometabolic pharmacotherapy may also consume fiber-rich foods as part of dietary management or self-care.

Basil seeds (BS) and wheat bran (WB) are fiber-rich food materials with distinct physical and compositional characteristics. After hydration, BS forms a characteristic hydrocolloidal gel-like layer containing polysaccharides such as glucomannan and (1,4)-xylan.[5,6)] In contrast, WB, the outer layer of the wheat grain, contains abundant dietary fiber components, including arabinoxylan, cellulose, and other non-starch polysaccharides.[7–9)] Owing to these contrasting characteristics, BS and WB were selected as fiber-rich food materials with different matrix properties: BS as a hydrated gel-forming material and WB as a bran-derived insoluble fiber-rich material with a more exposed solid surface. Previous studies have reported that BS and WB possess biological properties such as antidiabetic, anti-obesity, and antioxidant effects,[6,10–12)] supporting their potential use as dietary fiber sources.

Food–drug interactions are clinically important because food intake can alter drug bioavailability, gastrointestinal processes, metabolism, or pharmacological effects.[13)] In the context of cardiometabolic pharmacotherapy, a previous animal study reported that simultaneous intake of oat bran and atorvastatin reduced lipid-lowering efficacy and anti-atherosclerotic effects in LDL receptor-deficient mice.[14)] In addition, dietary fibers and related fiber-rich materials have been reported to interact with orally administered drugs through adsorption or binding processes.[15–17)] Collectively, these findings suggest that fiber-rich food materials may reduce the measurable resid-

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ual concentrations of certain drugs in gastrointestinal fluids.

However, evidence regarding interactions between commercially available fiber-rich foods and marketed pharmaceutical products used to treat cardiometabolic diseases under simulated intestinal conditions remains limited. In particular, few studies have investigated whether commercially available fiber-rich food materials reduce the residual concentrations of multiple cardiometabolic drugs in artificial intestinal fluid using marketed pharmaceutical products rather than pure drug substances. Therefore, this study aimed to evaluate the *in vitro* adsorption behavior of selected orally administered cardiometabolic drugs in artificial intestinal fluid in the presence of BS or WB.

MATERIALS AND METHODS

Materials BS and WB, two commercially available fiber-rich food materials, were purchased from Thai Cereal World Co., Ltd. (Bangkok, Thailand) and TOMIZ Co., Ltd. (Tokyo, Japan), respectively. The following orally administered cardiometabolic drugs were selected: calcium channel blockers (amlodipine and nifedipine), beta-blockers (carvedilol and bisoprolol), statins (rosuvastatin and atorvastatin), and angiotensin II receptor blockers or related drugs (azilsartan and olmesartan medoxomil). Commercially available pharmaceutical products were used throughout the study. The product names, dosage forms, strengths, manufacturers, single oral doses, and nominal initial concentrations are summarized in Table S1.

Artificial intestinal fluid was prepared according to the protocol for the second fluid used in the disintegration test described in the Japanese Pharmacopoeia, 18th edition.[18] The physicochemical properties of the tested drugs, including pK_a, logP, and predicted predominant ionic form at pH 6.8, were obtained from DrugBank[19] and are summarized in Table S2.

HPLC Analysis Drug concentrations were determined by HPLC. The HPLC system consisted of an LC-10ATVP pump, CTO-10ASVP column oven, and SPD-10AP UV-Vis detector (Shimadzu Corp., Kyoto, Japan). HPLC conditions were established with reference to the analytical procedures described in the Japanese Pharmacopoeia, 18th edition, with minor modifications where necessary.[18] The analytical conditions for each drug, including the mobile phase and detection wavelength, are summarized in Table S3. As shown in Fig. S1, the calibration curves exhibited good linearity over the tested concentration ranges, with correlation coefficients greater than 0.998 for all drugs.

In Vitro Adsorption Experiments under Simulated Intestinal Conditions The nominal initial concentration of each drug was determined from the corresponding single oral dose and the volume of artificial intestinal fluid used in the experiment. Each pharmaceutical product was crushed, and an amount of powder corresponding to a single oral dose of each drug was added to 500 mL of artificial intestinal fluid to prepare the test solution. When necessary, methanol was added at a final concentration of no more than 2% (v/v) to facilitate dissolution of the active pharmaceutical ingredient.

Subsequently, 1.0 g of BS or WB was added to the test solution, and the mixture was stirred at 100 rpm at 37°C. At 1, 5, 10, 30, 60, 90, 120, 150, and 180 min after the addition of BS or WB, 5-mL aliquots were collected and filtered through a 0.45-μm membrane filter. Residual drug concentrations in the filtrates were then determined by HPLC. The residual rate and amount of drug adsorbed were calculated using Eqs. (1) and (2), respectively:

$$R_d = C_t/C_0 \times 100 \quad (1)$$
$$q = V(C_0 - C_t)/W \quad (2)$$

where R_d is the residual rate (%), q is the amount of drug adsorbed (mg/g), C_0 and C_t are the drug concentrations at the initial and each sampling time point (mg/L), respectively, V is the volume of the solution (L), and W is the weight of BS or WB (g). All data are presented as the mean ± standard error (n = 3). Data were interpreted descriptively, and no inferential statistical testing was performed.

In preliminary control experiments, membrane filtration and stirring without BS or WB did not substantially affect the determined drug concentrations under the present experimental conditions.

Adsorption Kinetic Analysis For drugs that showed substantial decreases in residual concentration, adsorption kinetic analysis was performed using the pseudo-first-order and pseudo-second-order models.[20,21] The adsorption data were fitted to Eqs. (3) and (4), respectively:

$$\ln(q_{e,exp} - q_t) = \ln q_{e,cal} - k_1 t \quad (3)$$
$$t/q_t = 1/(k_2 \times q_{e,cal}^2) + t/q_{e,cal} \quad (4)$$

where $q_{e,exp}$ and $q_{e,cal}$ are the experimentally determined and calculated amounts of drug adsorbed at equilibrium (mg/g), respectively; q_t is the amount of drug adsorbed at time t (mg/g); t is the contact time (h); and k_1 and k_2 are the rate constants of the pseudo-first-order and pseudo-second-order models, respectively. The adsorption amount at 180 min was used as $q_{e,exp}$ for the kinetic analysis.

RESULTS

Residual Drug Concentrations in the Presence of BS and WB The time profiles of residual drug concentrations in artificial intestinal fluid in the presence of BS and WB are shown in Figs. 1 and 2, respectively. After 3 h in the presence of BS, the residual rates of nifedipine, amlodipine, carvedilol, bisoprolol, rosuvastatin, atorvastatin, azilsartan, and olmesartan medoxomil were 84.1%, 74.1%, 77.2%, 89.2%, 91.2%, 89.8%, 90.4%, and 98.1%, respectively. During the experimental period, the residual concentrations of nifedipine, amlodipine, and carvedilol decreased, whereas those of bisoprolol, rosuvastatin, atorvastatin, azilsartan, and olmesartan medoxomil showed relatively small changes.

After 3 h in the presence of WB, the residual rates of nifedipine, amlodipine, carvedilol, bisoprolol, rosuvastatin, atorvastatin, azilsartan, and olmesartan medoxomil were 77.1%, 32.9%, 16.6%, 87.5%, 91.4%, 90.4%, 92.7%, and 57.5%, respectively. During the experimental period, the residual concentrations of amlodipine and carvedilol decreased markedly. Nifedipine and olmesartan medoxomil also showed decreased residual concentrations, whereas bisoprolol, rosuvastatin, atorvastatin, and azilsartan showed only limited changes.

Overall, the extent of residual drug concentration reduction differed between BS and WB. Compared with BS, WB produced greater reductions in the residual concentrations of nifedipine, amlodipine, carvedilol, and olmesartan medoxomil.

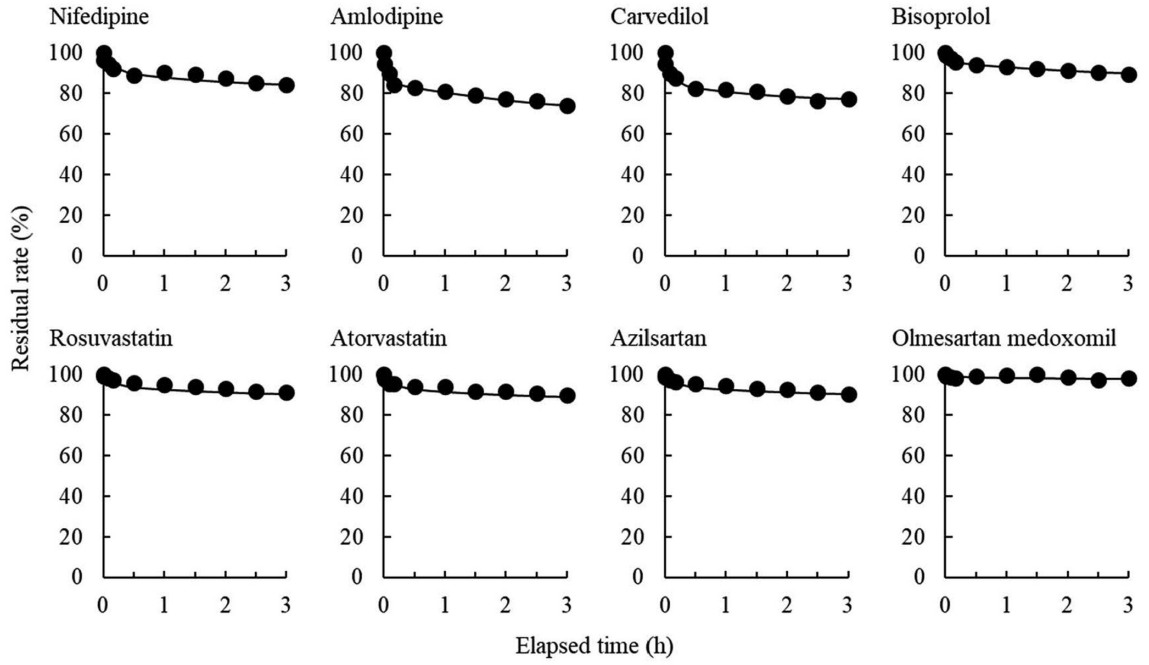

Fig. 1. Residual Drug Concentration Profiles in the Presence of BS

Data are presented as the mean ± standard error (n = 3). BS, basil seeds.

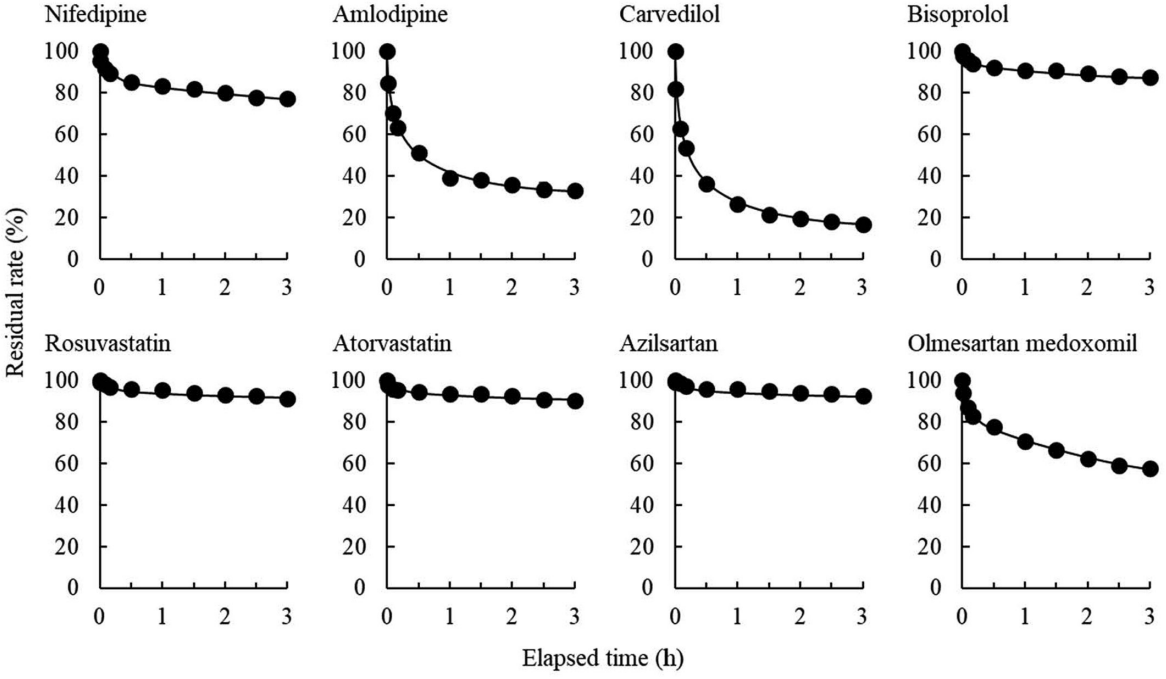

Fig. 2. Residual Drug Concentration Profiles in the Presence of WB

Data are presented as the mean ± standard error (n = 3). WB, wheat bran.

In contrast, the residual concentrations of bisoprolol, rosuvastatin, atorvastatin, and azilsartan changed only slightly in the presence of either BS or WB.

Adsorption Kinetic Analysis of Selected Drugs The time profiles of drug adsorption onto BS and WB are shown in Fig. S2. Among the tested drugs, nifedipine, amlodipine, carvedilol, and olmesartan medoxomil showed substantial adsorption onto at least one of the tested materials. Therefore, these drugs were selected for adsorption kinetic analysis.

The kinetic parameters are summarized in Table 1. For all selected drug–food combinations, the pseudo-second-order model yielded higher coefficients of determination than the pseudo-first-order model. The R^2 values for the pseudo-second-order model ranged from 0.944 to 0.995 for BS and from 0.990 to 0.999 for WB, whereas those for the pseudo-first-order model ranged from 0.112 to 0.823 for BS and from

Table 1. Kinetic Parameters for the Adsorption of Selected Drugs onto BS and WB

Food material	Drug	$q_{e,exp}$ (mg/g)	Pseudo-first-order model			Pseudo-second-order model		
			k_1 (1/h)	$q_{e,cal}$ (mg/g)	R^2	k_2 (g/mg/h)	$q_{e,cal}$	R^2
BS	Nifedipine	1.47	0.65	0.46	0.112	4.65	1.40	0.944
	Amlodipine	0.82	0.91	0.43	0.823	12.12	0.81	0.995
	Carvedilol	1.33	0.70	0.67	0.628	10.88	1.41	0.993
WB	Nifedipine	2.97	1.11	1.95	0.953	2.38	3.07	0.995
	Amlodipine	5.38	1.59	3.18	0.943	1.75	5.58	0.999
	Carvedilol	6.92	2.03	4.67	0.988	1.41	7.15	0.999
	Olmesartan medoxomil	3.30	1.81	3.18	0.869	1.34	3.46	0.990

$q_{e,exp}$ and $q_{e,cal}$ indicate the experimentally determined and calculated amounts of drug adsorbed at equilibrium, respectively. The adsorption amount at 180 min was used as $q_{e,exp}$ for the kinetic analysis. k_1 and k_2 indicate the rate constants of the pseudo-first-order and pseudo-second-order models, respectively. BS, basil seeds; WB, wheat bran.

0.869 to 0.988 for WB. In addition, the $q_{e,cal}$ values obtained from the pseudo-second-order model were generally close to the $q_{e,exp}$ values.

Although the pseudo-first-order model also showed moderate to high R^2 values for several adsorption profiles obtained with WB, the corresponding $q_{e,cal}$ values were less consistent with $q_{e,exp}$ than those obtained using the pseudo-second-order model. Overall, the pseudo-second-order model showed better agreement with the adsorption profiles of the selected drugs under the present experimental conditions.

DISCUSSION

In this study, we evaluated changes in the residual concentrations of orally administered cardiometabolic drugs in artificial intestinal fluid in the presence of BS or WB. The reduction in residual drug concentration depended on both the drug and the food material. Amlodipine and carvedilol showed marked decreases in residual concentration, particularly in the presence of WB, whereas nifedipine and olmesartan medoxomil showed moderate decreases. In contrast, bisoprolol, rosuvastatin, atorvastatin, and azilsartan showed only limited changes in the presence of BS and WB. These findings indicate that fiber-rich food materials can reduce the measurable residual concentrations of selected cardiometabolic drugs under simulated intestinal conditions, although the extent of concentration reduction varies substantially among drug–food combinations.

The observed drug-dependent differences may be partly associated with the ionization state and hydrophobicity of the drugs, together with the surface charge characteristics of BS and WB. The artificial intestinal fluid used in this study had a pH of 6.8.[18] Based on the pH of the artificial intestinal fluid and the acid–base properties of the tested drugs, amlodipine, carvedilol, and bisoprolol are likely to exist mainly as cationic species under the present experimental conditions, whereas rosuvastatin, atorvastatin, and azilsartan are likely to exist mainly as anionic species (Table S2). In addition, the reported pH_{pzc} values of BS and WB are approximately 5.6.[5,22] Because the pH of the artificial intestinal fluid exceeded these pH_{pzc} values, the surfaces of BS and WB were likely negatively charged under the present conditions.

Consequently, electrostatic interactions may partly contribute to the decreases in the residual concentrations of amlodipine and carvedilol. Previous studies have also reported that cationic drugs interact with dietary fibers and related adsorbent materials through ionic interactions.[15–17] However, despite being likely to exist mainly as a cationic species, bisoprolol showed only limited concentration reduction, suggesting that cationic charge alone is insufficient to explain the observed interaction. A previous study reported that carvedilol was more readily adsorbed than bisoprolol onto polystyrene sulfonate resin in artificial intestinal fluid, partly because of differences in hydrophobicity.[23] In the present study, nifedipine also showed reduced residual concentrations despite being largely nonionized under the present pH condition, suggesting that hydrophobicity or partitioning into food-derived matrices may also contribute to the observed concentration reduction. However, these interpretations remain tentative because this study did not directly evaluate the ionization state, hydrophobic partitioning, or molecular-level binding mechanisms of the tested drugs.

The food material also influenced the extent of residual drug concentration reduction. Compared with BS, WB produced greater reductions in the residual concentrations of nifedipine, amlodipine, carvedilol, and olmesartan medoxomil. This difference may be related to the distinct matrix properties of the two food materials. Hydrated BS forms a hydrocolloidal gel-like layer,[5,6] whereas WB is a bran-derived insoluble fiber-rich material with a more exposed solid surface and contains abundant dietary fiber components, including arabinoxylan, cellulose, and other non-starch polysaccharides.[7–9,22] These differences may affect the accessibility of drugs to potential adsorption sites within the food-derived matrices. In particular, olmesartan medoxomil showed a decrease in residual concentration in the presence of WB but not BS. This behavior differed from that of azilsartan, although both were included as angiotensin II receptor blocker-related drugs. Because olmesartan medoxomil is an orally administered prodrug, the present findings should be interpreted as reflecting the behavior of the prodrug in artificial intestinal fluid rather than that of its active metabolite, olmesartan, after absorption.

The adsorption kinetic analysis provided a descriptive characterization of the time-dependent concentration reduction observed for selected drugs. The pseudo-second-order model showed better overall agreement with the adsorption profiles than the pseudo-first-order model, as indicated by higher R^2 values and closer agreement between $q_{e,exp}$ and $q_{e,cal}$. However, better fitting to the pseudo-second-order model should not be interpreted as direct evidence of a specific adsorption mechanism. In adsorption studies, pseudo-second-order fitting can reflect the overall time-dependent profile of sorption processes, but it does not by itself identify the molecular interaction responsible for adsorption. Therefore, the kinetic analysis should be regarded as a descriptive comparison of adsorption behavior rather than mechanistic proof.

The use of commercially available pharmaceutical products is an important feature of this study. Unlike experiments using pure drug substances, this approach provides an *in vitro* setting

in which active pharmaceutical ingredients, formulation excipients, and food-derived materials coexist in artificial intestinal fluid. Therefore, the observed decreases in residual drug concentrations may reflect physicochemical interactions under conditions that incorporate formulation components. However, this design also means that the contribution of excipients could not be distinguished from that of the active pharmaceutical ingredients. From a biopharmaceutical perspective, these findings suggest that interactions between fiber-rich foods and orally administered cardiometabolic drugs warrant further evaluation using more physiologically relevant experimental systems.

This study has several limitations. First, the experiments were conducted in artificial intestinal fluid under static *in vitro* conditions. Therefore, the experimental system did not reproduce the dynamic gastrointestinal environment, including gastric-to-intestinal transition, bile salts, digestive enzymes, intestinal motility, transit time, or continuous removal of dissolved drugs through intestinal absorption. Second, although commercially available pharmaceutical products were used to incorporate formulation components, this design did not allow the effects of formulation excipients to be distinguished from those of the active pharmaceutical ingredients. Third, this study evaluated residual drug concentrations in filtrates but did not directly assess dissolution behavior, intestinal permeability, systemic exposure, or therapeutic outcomes. Finally, only two fiber-rich food materials and eight cardiometabolic drugs were examined. Therefore, the findings should not be generalized to all dietary fiber-containing foods or orally administered drugs.

Further studies using biorelevant media, dissolution–permeation models, and pharmacokinetic approaches are needed to determine whether the *in vitro* concentration reductions observed in this study translate into clinically relevant food–drug interactions. Nevertheless, the present findings provide a basis for further biopharmaceutical evaluation of physicochemical interactions between fiber-rich food materials and orally administered cardiometabolic drugs.

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Conflict of Interest The authors declare no competing interests.

Data Availability The data supporting the findings of this study are included in this article and its Supplementary Materials. Additional data are available from the corresponding author upon reasonable request.

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Ethics Approval Not applicable.

Informed Consent Not applicable.

Supplementary Materials This article contains Supplementary Materials.

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