Original Article

Evaluation on the Effects of *Tamarindus Indica* L. Fruit on Body Weight and Several Cardiometabolic Risk Factors in Obese and Overweight Adult Patients: A Randomized Controlled Clinical Trial

Sedigheh Asgary, Rasool Soltani[1], Najmeh Barzegar[2], Nizal Sarrafzadegan[3]

Hypertension Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran, [1]Department of Clinical Pharmacy and Pharmacy Practice, Faculty of Pharmacy and Pharmaceutical Sciences, Isfahan University of Medical Sciences, Isfahan, Iran, [2]Student Research Committee, Faculty of Pharmacy and Pharmaceutical Sciences, Isfahan University of Medical Sciences, Isfahan, Iran, [3]Isfahan Cardiovascular Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran

Address for correspondence:
Dr. Rasool Soltani, Department of Clinical Pharmacy and Pharmacy Practice, Faculty of Pharmacy and Pharmaceutical Sciences, Isfahan University of Medical Sciences, Hezar-Jerib Avenue, Isfahan, Iran.
E-mail: soltani@pharm.mui.ac.ir

Abstract

Background: Animal studies have shown the anti-obesity effects of *Tamarindus indica* L. (tamarind) fruit pulp. This study aimed to evaluate the weight-reducing effects of *T. indica* L. fruit as well as its blood pressure- and lipid-lowering effects in a clinical trial. **Methods:** In a randomized controlled clinical trial, obese and overweight patients were randomly and equally assigned to tamarind and control groups. Both groups were instructed proper diet and maintaining physical activity for 6 weeks. Furthermore, the participants of tamarind group were instructed to consume 10 grams of tamarind fruit pulp twice daily with meals for the same period. Body mass index (BMI), waist circumference, systolic blood pressure (SBP) and diastolic blood pressure (DBP), fasting serum levels of glucose (fasting plasma glucose, FPG), total cholesterol, triglycerides (TG), low-density lipoprotein cholesterol (LDL-C), and high-density lipoprotein cholesterol (HDL-C) were determined and recorded for all patients pre- and post-intervention. **Results:** Twenty patients in each group completed the study. Tamarind significantly reduced BMI, WC, LDL-C, SBP, and DBP compared to baseline. However, none of these effects were statistically significant compared to control group. **Conclusions:** Consumption of tamarind fruit pulp with daily dose of 20 g has no significant effects on body weight, waist circumference, serum lipid profile, blood glucose, and blood pressure.

Keywords: *Clinical trial, obesity, overweight, serum lipid profile, Tamarindus indica L*

Introduction

Obesity is one of the most common metabolic disorders characterized by the accumulation of fat tissue in the body.[1] In Iran, according to the first national study, almost half of those 15- to 65-year-old are overweight or obese. Furthermore, the prevalence of overweight and abdominal obesity is higher in women compared with men.[2] Although obesity is one of the most important public health challenges, it is one of the preventable causes of death around the world.[3]

The presence of obesity and overweight is associated with significant risk of many diseases including diabetes mellitus, hypertension, hyperlipidemia, and cardiovascular disorders.[4] Furthermore, it has been shown that overall mortality parallels increased adiposity.[5,6]

Strategies for weight loss usually include a combination of lifestyle changes (e.g., limiting caloric intake, increasing physical activity, and behavioral modification) and pharmacotherapy as well as bariatric surgery for severe or resistant cases.[3] Most of drugs used for treatment of obesity (e.g., lorcaserin, phentermine, phendimetrazine, and diethylpropion) are not available in Iran. Furthermore, they have the potential for abuse, have been approved only for short-term use (less than 12 weeks),[3] and have serious side effects and special cautions and contraindications for use.[3,7-9]

Nowadays, herbal medicine is in widespread use because of the belief that it is safe. Many studies have shown the significant effects of various plants or herbal products in decreasing body weight and body mass index (BMI).[10]

Tamarindus indica L. (*T. indica*; tamarind) is a tropical tree grown in Southeast Asia with the leaves, flowers, fruits, and seeds being used for making salads, stews, soups and curries in several countries. The leaves and fruit pulp exhibit anti-oxidant activity and blood glucose-reducing properties.[11]

How to cite this article: Asgary S, Soltani R, Barzegar N, Sarrafzadegan N. Evaluation on the effects of *Tamarindus indica* L. fruit on body weight and several cardiometabolic risk factors in obese and overweight adult patients: A randomized controlled clinical trial. Int J Prev Med 2020;11:24.

Access this article online

Website: www.ijpvmjournal.net/www.ijpvm.ir

DOI: 10.4103/ijpvm.IJPVM_558_18

Quick Response Code:

Two animal studies have shown the anti-obesity and anti-hyperlipidemic effects of tamarind fruit.[12,13] However, in the only human study about this effect found in our search, using 15 mg/kg of dried pulp of *T. indica* fruits had no significant effect on body weight and systolic blood pressure, while it significantly decreased total cholesterol and LDL-cholesterol levels as well as diastolic blood pressure.[14] However, the main aim of this study was evaluation of lipid-lowering effects of the plant and the study population was not obese patients. Therefore, the present study aimed to evaluate the weight-reducing effects of *T. indica* L. fruit as the primary outcome as well as its blood pressure- and lipid-lowering effects as secondary outcomes in a clinical trial.

Methods

Plant material and standardization

Tamarind fruits were purchased from the market and confirmed by department of pharmacognosy in faculty of Pharmacy, Isfahan University of Medical Sciences. Standardization was performed by determining the polyphenolic compounds content of pulps using Folin-Ciocalteu method.[15] For this, 100 g of fruit pulps was dried in the shade and powdered by electric grinder (Moulinex, France). Then 65 g of obtained powder was extracted with 260 ml of 70% ethanol (Estalk, Iran) by maceration for three times and, after passing through the filter paper, concentrated under vacuum using rotary evaporator (Heidolph, Germany). Finally, the obtained concentrate was freeze-dried using freeze dryer (Christ, Germany). After creating the calibration curve with plot of absorbance (765 nm) versus gallic acid concentration (R^2 = 0.992) using Folin-Ciocalteu method, the polyphenolic content of the obtained dry powder was determined by measuring the absorbance (Spectrophotometer, Perkin-Elmer, USA) using the following equation:[15,16]

$$C = C_1 \times V/m$$

where C is the content of total phenolic compounds in mg/g, C_1 is the concentration of gallic acid obtained from the calibration curve in mg/ml, V is the volume of the extract in ml, and m is the weight of the extract in g.

Study type and patient selection

This was a randomized controlled clinical trial conducted in Isfahan Cardiovascular Research Center affiliated to Isfahan University of Medical Sciences from December 2015 to June 2016. The study was registered in Iranian Registry of Clinical Trials (IRCT) with the registration code of IRCT201608259662N11. The sample size was calculated by the following equation:

$$n = 2SD^2 (Z_{\alpha/2} + Z_{\beta})/d^2$$

where SD is standard deviation of the main variable in the study (body weight), $Z_{\alpha/2}$ is 1.96 at type 1 error of 5%, Z_{β} is 0.84 at type 2 error of 20%, and d is effect size (the difference between mean values from the previous studies). Using the results of a previous study, SD and d were determined to be 2.4 and 2, respectively.[17] Therefore, sample size of 22 was calculated for each study group.

Patients were selected from those referring to obesity clinic of Cardiovascular Research Center. The inclusion criteria were: (1) Age >18 years; (2) being either overweight or mildly to moderately obese based on BMI (25 to 39.9 kg/m^2). (3) Non-smoker; (4) not using alcohol and/or other substances of abuse; (5) Not having type 1 diabetes mellitus, cardiovascular disease (heart failure, angina pectoris, arrhythmias, and history of myocardial infarction), liver impairment (ALT or AST serum levels more than three times the upper limit of normal) or renal impairment (serum creatinine more than 1.2 mg/dl); (5) not taking any drug or supplement affecting body weight including sulfonylureas, antipsychotics, antidepressants, sodium valproate, orlistat, phentermine, topiramate, and metformin) within the last 2 months; (6) not using drugs or supplements affecting serum lipid profile including statins, fibrates, estrogens, progestins, β-blockers, α_1-blockers (e.g., prazosin), glucocorticoids, isotretinoin, cyclosporine, tacrolimus, sirolimus, thiazide and loop diuretics, and fish oil (omega-3 fatty acids) within the last 2 months; (7) not having severe hypertension (systolic blood pressure >180 mm Hg or diastolic blood pressure >100 mm Hg); (8) No change in the dose of antihypertensive drug (if used) within the last month; (9) being non-pregnant and non-lactating (women).

Irregular use of tamarind pulp, incompliance for instructed diet and physical activity, and allergic reaction to the pulp were considered as the exclusion criteria.

Study design and interventions

Informed consent was obtained from all participants and the study protocol was approved by the ethical committee of Isfahan University of Medical Sciences. Patients who met the inclusion criteria were randomly and equally assigned to tamarind and control groups. Randomization was done by sequential simple random assignment using a pre-designed table that determined group assignment based on the order of patients' enrollment. Before intervention, demographic features (age and sex), body weight, height, body mass index (BMI), waist circumference (measured midway between the lowest ribs and the iliac crest), systolic blood pressure (SBP) and diastolic blood pressure (DBP) were recorded for each patient. Also, by obtaining 5 mL of blood sample and its centrifugation for 5 minutes (2000 rpm; Kubota, Japan), fasting serum levels of glucose (fasting plasma glucose, FPG), total cholesterol, triglycerides (TG), low-density lipoprotein cholesterol (LDL-C), and high-density lipoprotein cholesterol (HDL-C) were measured for all patients using ELISA kits (Pars Azmoon, Iran). Both groups were instructed to use proper diet (including reduction of daily consumption of fat and

cholesterol; not using high-fat dairy products, red meat, and sweet products (e.g., pastries and cookies); and increasing intake of fruits and vegetables) and maintaining physical activity (walking briskly at least 30 minutes a day for at least 5 days a week) for 6 weeks. Furthermore, the participants of tamarind group were instructed to consume 10 grams of tamarind fruit pulp (already prepared in 10-g packs) twice daily with meals for the same period. The patients' compliance for diet, physical activity, and tamarind consumption was monitored regularly by telephone contact as well as counting their tamarind packs (for tamarind group) at the end of use. The obtained data were included in statistical analysis if the patient used more than 80% of his/her packs. At the end of intervention, all variables were measured again and compared between the groups.

Statistical analysis

Normal distribution of obtained data was assessed by Kolmogorov-Smirnov test. Chi-square test was done to compare gender distribution between the groups. Paired-Samples *t*-test was used for comparison of baseline and final values within each group. Analysis of covariance (ANCOVA) was used for comparing values between tamarind and control groups with statistical control of baseline values. $P < 0.05$ was considered statistically significant.

Results

Standardization of plant material

The total phenolic content of the fruit pulp was found to be 45.7 mg/g of dry extract.

Clinical study

Over the study period, of 55 patients who met the inclusion criteria, 44 patients were willing to participate. They were randomly and equally divided into two groups with two patients from each group being excluded due to no tendency for continuation of the study. Therefore, 20 patients in each group completed the study [Figure 1] with 60% (n = 12) and 50% (n = 10) of patients being male in tamarind and control groups, respectively. The mean (±SD) age of patients in tamarind and control groups was 34.65 (±12.8) and 30.50 (±8.6), respectively ($P = 0.238$).

Table 1 shows the effects of interventions on evaluated parameters in each group. As shown, tamarind significantly reduced BMI, WC, LDL-C, SBP, and DBP compared to baseline. However, none of these effects was statistically significant compared to control group.

No adverse effect was reported from patients of tamarind group during the study.

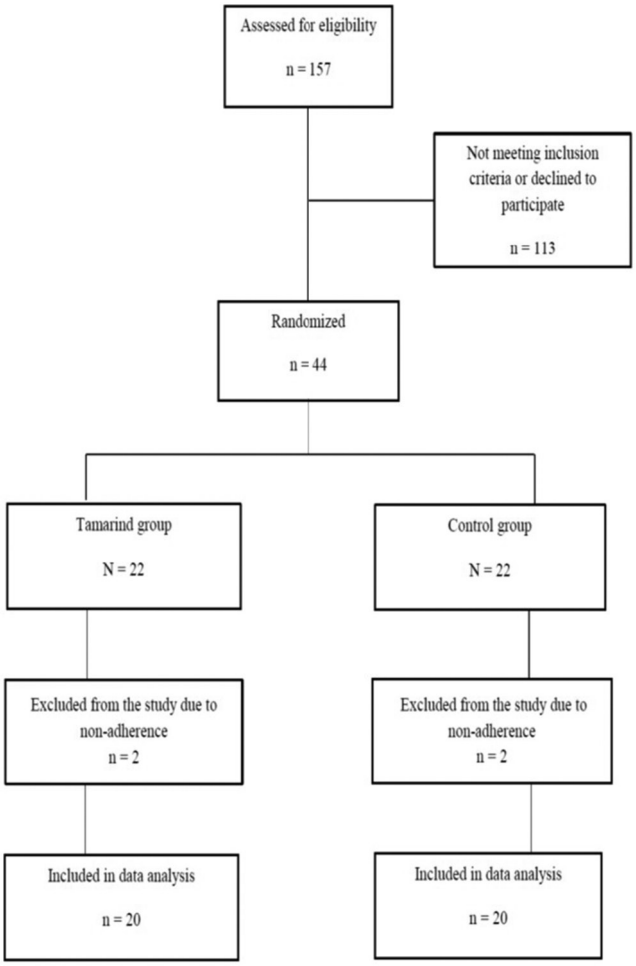

Figure 1: Flowchart of Patients allocation and participation in the study

Discussion

In the present study, tamarind fruit pulp did not show significant weight loss effect. At the best of our knowledge, this is the first clinical study of *T. indica* on overweight and obese patients. Based on our results, although tamarind significantly reduced BMI and WC compared to baseline values, these effects were not significant compared to control group. Similarly, in the only human study about this effect, dried pulp of *T. indica*, at a dose of 15 mg/kg body weight, had no significant effect on body weight.[14] However, considering substantial reducing effect on BMI compared to baseline in our work, it would be possible that use of higher doses with longer duration has significant weight loss effect. In contrast to these two human studies, the animal study of Azman *et al*. with duration of 10 weeks showed significant anti-obesity effect of tamarind aqueous extract in a dose-dependent manner as shown by a substantial reduction in adipose tissue weight.[12] Reduction of fatty acid synthase (FAS) activity, induced by tamarind flavonoids including quercetin and avicularin, was suggested as a possible mechanism of this effect.[12] In addition, another animal study showed weight-reducing effect of the ethanolic extract of *T. indica* fruit pulp in obese rats.[13] Variations in study cases (human vs. animal), the type of plant material (raw fruit pulp vs. fruit extract), and durations of interventions could be responsible for these different results.

Table 1: The effects of interventions on evaluated parameters after 6 weeks in each group. The values are presented as mean (SD)

Parameter (Unit)	Tamarind (*n*=20)	Control (*n*=20)	*P*[a]
BMI (kg/m^2)			
Baseline	29.54 (3.16)	29.76 (3.52)	
End	28.91 (3.43)	29.09 (3.53)	0.923
Change	-2.24 (1.61)	-2.29 (1.27)	
*P**	<0.001	<0.001	
WC (cm)			
Baseline	100.80 (10.27)	96.65 (10.35)	
End	98.00 (10.18)	94.60 (10.44)	0.224
Change	-2.79 (1.62)	-2.13 (1.74)	
P	<0.001	<0.001	
Total cholesterol (mg/dL)			
Baseline	173.10 (39.00)	165.65 (32.99)	
End	168.30 (38.68)	155.80 (32.86)	0.568
Change	-1.13 (19.54)	-4.70 (9.67)	
P	0.516	0.125	
LDL-C (mg/dL)			
Baseline	108.05 (30.47)	104.40 (25.72)	
End	101.75 (30.93)	100.55 (23.60)	0.348
Change	-6.03 (10.81)	-3.06 (8.87)	
P	0.019	0.115	
TG (mg/dL)			
Baseline	100.90 (50.77)	107.95 (35.73)	
End	107.80 (51.93)	102.30 (34.08)	0.198
Change	15.65 (57.19)	-2.10 (20.03)	
P	0.372	0.430	
HDL-C (mg/dL)			
Baseline	48.90 (11.09)	42.75 (7.90)	
End	49.30 (9.47)	42.00 (6.90)	0.369
Change	2.16 (10.74)	-0.96 (10.96)	
P	0.748	0.427	
FPG (mg/dL)			
Baseline	92.85 (10.53)	87.40 (7.51)	
End	94.40 (10.81)	88.80 (8.18)	0.935
Change	1.94 (8.00)	1.75 (6.45)	
P	0.340	0.277	
SBP (mm Hg)			
Baseline	113.25 (13.40)	107.50 (8.66)	
End	107.50 (11.64)	103.25 (9.36)	0.672
Change	-4.74 (6.88)	-3.86 (6.05)	
P	0.004	0.070	
DBP (mm Hg)			
Baseline	89.50 (12.76)	85.75 (10.67)	
End	86.00 (11.19)	84.00 (9.95)	0.436
Change	-3.56 (6.81)	-1.48 (9.60)	
P	0.023	0.340	

BMI, body mass index; WC, waist circumference; LDL, low-density lipoprotein; TG, triglycerides; HDL, high-density lipoprotein; FPG, fasting plasma glucose; SBP, systolic blood pressure; DBP, diastolic blood pressure. *Paired-Samples *t*-test (within-group comparison); [a]ANCOVA test (between-group comparison)

In our study, tamarind did not exert significant lipid-lowering and hypoglycemic effects. Conversely, in an animal model study performed for 10 weeks, the crude extract of *T. indica* fruit decreased the serum levels of total cholesterol (50%), non-HDL cholesterol (73%) and TG (60%), and increased serum HDL cholesterol level.[18] These effects were attributed to epicatechin content of tamarind.[17,19] Also, the two above-mentioned animal studies confirmed similar hypolipidemic effects of tamarind in addition to its weight loss activity.[12,13] Therefore, it seems that use of higher doses or fruit extract for longer durations could have positive effects on serum lipid profile.

Despite no significant effect of tamarind fruit on FPG in our research, an animal study showed dose-dependent hypoglycemic effect of tamarind seed extract in streptozotocin-induced diabetic rats compared to control diabetics.[20] However, no significant changes in blood glucose levels were observed in normal rats. This is consistent to our result, since our patients were not diabetic. As the mechanism of hypoglycemic effect was restoring pancreatic beta cells and repairing streptozotocin-induced damages and subsequent increase of serum insulin,[20] it seems that tamarind has potential therapeutic effects in type 1 diabetes mellitus. However, extra-pancreatic effects including insulin sensitization in target organs and inhibition of insulinase activity in both liver and kidney have also been suggested.[21]

The main limitations of the present study were short duration of intervention, not using the extract of the pulps, no control of calorie use by patients, and absence of placebo.

Conclusions

Consumption of tamarind fruit pulp with daily dose of 20 g has no significant effects on body weight, waist circumference, serum lipid profile, blood glucose, and blood pressure. More studies with higher doses and longer durations are required to evaluate these effects.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Source of support

The Vice-Chancellery for Research and Technology at the Isfahan University of Medical Sciences.

Acknowledgments

This study was financially supported by the Vice-Chancellery for Research and Technology at the

Isfahan University of Medical Sciences. The authors would like to acknowledge Mrs Keshvari and the staff of Laboratory Department of the Isfahan Cardiovascular Research Institute for their assistance.

Registration number

IRCT201608259662N11 (Iranian Registry of Clinical Trials [IRCT] with URL: www.irct.ir).

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

Received: 15 Dec 18 **Accepted:** 14 Oct 19
Published: 17 Feb 20

References

1. Flegal KM, Carroll MD, Kit BK, Ogden CL. Prevalence of obesity and trends in the distribution of body mass index among US adults, 1999-2010. JAMA 2012;307:491-7.
2. Janghorbani M, Amini M, Willet WC, Mehdi Gouya M, Delavari A, Alikhani S, *et al*. First nationwide survey of prevalence of overweight, underweight, and abdominal obesity in Iranian adults. Am J Clin Nutr 2007;15:2797-808.
3. Chen JT, Sheehan AH, Yanovski JA, Kalis KA. Obesity. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM. editors. Pharmacotherapy, A Pathophysiologic Approach. New York, USA: McGraw-Hill; 2011. p. 2567-84.
4. Guh DP, Zhang W, Bansback N, Amarsi Z, Birmingham CL, Anis AH. The incidence of comorbidities related to obesity and overweight: A systematic review and meta-analysis. BMC Public Health 2009;9:88.
5. Janssen I, Bacon E. Effect of current and midlife obesity status on mortality risk in the elderly. Obesity 2008;16:2504-9.
6. Reis JP, Macera CA, Araneta MR, Lindsay SP, Marshall SJ, Wingard DL. Comparison of overall obesity and body fat distribution in predicting risk of mortality. Obesity 2009;17:1232-9.
7. McClendon KS, Riche DM, Uwaifo GI. Orlistat: Current status in clinical therapeutics. Expert Opin Drug Saf 2009;8:727-44.
8. Smith SR, Weissman NJ, Anderson CM, Anderson CM, Sanchez M, Chuang E. Multicenter, placebo-controlled trial of lorcaserin for weight management. N Engl J Med 2010;363:245-56.
9. Hendricks EJ. Off-label drugs for weight management. Diabetes Metab Syndr Obes 2017;10:223-34.
10. Hasani-Ranjbar S, Jouyandeh Z, Abdollahi M. A systematic review of anti-obesity medicinal plants – An update. J Diabetes Metab Disord 2013;12:28.
11. Kuru P. *Tamarindus indica* and its health related effects. Asian Pac J Trop Biomed 2014;4:676-81.
12. Azman KF, Amom Z, Azlan A, Esa NM, Ali RM, Shah ZM, *et al*. Antiobesity effect of *Tamarindus indica* L. pulp aqueous extract in high-fat diet-induced obese rats. J Nat Med 2012;66:333-42.
13. Jindal V, Dhingra D, Sharma S, Parle M, Harna RK. Hypolipidemic and weight reducing activity of the ethanolic extract of Tamarindus indica fruit pulp in cafeteria diet- and sulpiride-induced obese rats. J Pharmacol Pharmacother 2011;2:80-4.
14. Iftekhar AS, Rayhan I, Quadir MA, Akhteruzzaman S, Hasnat A. Effect of *Tamarindus indica* fruits on blood pressure and lipid-profile in human model: An *in vivo* approach. Pak J Pharm Sci 2006;19:125-9.
15. Singleton VL, Orthofer R, Lamuela-Raventós RM. Analysis of total phenols and other oxidation substrates and antioxidants by means of folin-ciocalteu reagent. Methods Enzymol 1998;299:152-78.
16. Siddiqui N, Latif A, Rauf A, Rehman S, Mahmood Z. Phytochemical screening and spectrophotometric estimation of total phenolic content in Unani herbal drug Asl-us-soos (*Glycyrrhiza glabra* L.). Int J Adv Pharm Med Bioallied Sci 2015;3:46-9.
17. Jung EY, Cho MK, Hong YH, Kim JH, Park Y, Chang UJ, *et al*. Yeast hydrolysate can reduce body weight and abdominal fat accumulation in obese adults. Nutrition 2014;30:25-32.
18. Chan PT, Fong WP, Cheung YL, Huang Y, Ho WK, Chen ZY. Jasmine green tea epicatechins are hypolipidemic in hamsters (*Mesocricetus auratus*) fed a high fat diet. J Nutr 1999;129:1094-101.
19. Martinello F, Soares SM, Franco JJ, Santos AC, Sugohara A, Garcia SB, *et al*. Hypolipemic and antioxidant activities from *Tamarindus indica* L. pulp fruit extract in hypercholesterolemic hamsters. Food Chem Toxicol 2006;44:810-8.
20. Mahmoudzadeh-Sagheb H, HeidarI Z, Shahraki M, Moudi B. A stereological study of effects of aqueous extract of *Tamarindus indica* seeds on pancreatic islets in streptozotocin-induced diabetic rats. Pak J Pharm Sci 2010;23:427-34.
21. Maiti R, Das UK, Ghosh D. Attenuation of hyperglycemia and hyperlipidemia in streptozotocin-induced diabetic rats by aqueous extract of seed of *Tamarindus indica*. Biol Pharm Bull 2005;28:1172-6.