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Intravenous promethazine vs. diazepam to reduce symptoms of peripheral vertigo in emergency section: a double blind clinical trial

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Abstract

The present research aimed at comparing the effectiveness of promethazine and diazepam in patients suffering from acute peripheral vertigo. This is a double blind clinical trial with a sample of 154 patients visiting the emergency section of Shahid Mohammadi Hospital in Bandar Abbas in 2017-18. The participants were randomly divided into two groups of 77, one treated with intravenous promethazine (50 mg) and the other with intravenous Diazepam (10 mg). The severity of vertigo was measured qualitatively and quantitatively 20 minutes later in both groups. Participants were 46 (29.9%) male and 108 (70.1%) female visiting the emergency section of hospital. The mean score of vertigo severity in Promethazine group was 44.44±17.94 and that of Diazepam group was 2.49±+3.87. The severity scores before and after the treatment in promethazine group were respectively 7.75±1.59 and 2.72±1.93. The mean scores of vertigo severity before and after the treatment in promethazine group was -5.04+2.10 and in the diazepam group it was -3.83+3.09. The intergroup difference was statistically significant (p=.013). The results revealed that intravenous promethazine and diazepam applied 20 minutes after prescription are both effective in controlling the severity of vertigo. Considering the probability of occurrence of extrapyramidal side-effects it can be suggested that the infusion of this medication can be done slowly as it takes longer time. Meanwhile, vital signs should be precisely controlled.

Keywords: Acute peripheral vertigo; promethazine; diazepam; low blood pressure; nausea; vomiting.

Introduction

Real vertigo is to feel off balance and moving [1,2]. Vertigo is among highly prevalent complaints by those visiting the emergency section of hospitals [3]. This disorder would limit people's health to a great extent and if not treated it would lower the quality of life and

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lead to chronic inactivity and loss of appetite [4]. Thus, efficiency is an effective treatment for taking care of these patients and realizing the economic goals of the medication [5]. How to manage vertigo treatment has always been a challenge for researchers and medics. To this aim, different treatments have been suggested. In all cases, the treatment served two purposes, one to decrease the symptoms and the other to mediate the process of emergence. However, as in most cases, the pathological cause of vertigo is unknown, the main purpose of treatment is to cut down on the symptoms of disease [6,7]. Yet, there is no agreed-upon therapeutic protocol in any sources [8]. Standard emergency care services are provided for patients with severe medical symptoms in reference to diagnostic history, examinations and evaluation [9]. Usually, when the causes of central vertigo are rejected, patients undergo a medical treatment procedure of different levels of effectiveness in the emergency section [10]. Drugs consumed to control vertigo are usually effective in 60-80% of cases [11]. Various drugs are used to mitigate the symptoms, including anticholinergic, antihistamine, benzodiazepine, calcium channel blocker and dopamine receptor antagonist [12-15]. Promethazine and diazepam are among the drugs used to treat acute vertigo in emergent cases [16]. Promethazine is a first generation anti-histamine of the phenothiazine group. It acts as an anti-nausea agent which exerts antagonistic effects with dopamine and histamine and muscarinic receptors. Its anti-vertigo effects are through the central anti-muscarinic effect (anti-cholinergic) [17]. However, diazepam belongs to benzodiazepine group. Its mechanism of action on CNS is through inhibiting GABA receptor [18,19]. Not many investigations have been conducted in Iran to treat vertigo. The limited body of research has not addressed the therapeutic effects of these drugs comparatively. Though there are many different guidelines, there is no clear instruction on which drug to choose under certain circumstances. There is no single agreed-upon treatment for peripheral vertigo. Thus, the present research was conducted to compare the effectiveness of intravenous promethazine and diazepam in patients with cute peripheral vertigo.

Materials and methods

Design

The present research is a randomized double blind clinical trial (code: IRCT2017061210330N2) and the ethical code of HUMS.REC.1395.31 authorized in the ethics committee of the deputy of research and technology in Hormozgan University of medical sciences.

Trial registration

The protocol of this study was registered in Iranian Registry of Clinical Trials and the registration code is IRCT2017061210330N2.

Population and sampling

Population of the present research was all patients visiting the emergency section of Shahid Mohammadi Hospital complaining of acute peripheral vertigo in 2017-18. The required sample size was estimated via the formula to compare mean scores with a confidence interval of 95% and test power of 80%. The estimated size was 77 subjects for each group which made a total number of 154 participants. After triage in the emergency section, the patient visitors were examined by an assistant professor of medical emergency. All patients needed to sign an informed letter of consent. Indications and contraindications of drugs were

explained to them. The type of sampling was convenient and included all patients visiting during day and night. After the initial diagnosis, the patients were selected according to the inclusion and exclusion criteria as shown in Table 1. This process went on until the data were satiated for both groups (Table 1).

Research protocol

Patient participants' information was recorded before the treatment to see the extent to which it matched the inclusion and exclusion criteria: age, sex, background diseases such as diabetes, head trauma, cerebral trauma, cerebrovascular disorders, history of consuming anti-vertigo, anti-stress, anti-allergy drugs, sleeping pills, medical allergy, heart disease, hyperlipidemia, high blood pressure, cigarette smoking, alcohol consumption, type and duration of vertigo, vertigo attacks and associated symptoms such as nausea and vomiting, headache, diplopia and blurred vision as well as vital signs, i.e. systolic and diastolic blood pressure, heart rate and respiratory rate per minute. Then a complete neurological, ear, throat and nose examination was done. In case needed, paraclinical measures including lab tests renal function test, biochemistry, electrolyte, brain CT scan [20].

Participants were selected from among those who met the inclusion criteria. After full consent to participate and get to know the research procedures and possible outcomes, male and female patients between 18 and 90 years of age visiting the emergency section complaining of vertigo were examined. Those diagnosed with acute peripheral vertigo were selected randomly to take part in a double blind clinical trial. They were assigned to two groups, A and B. Those meeting the inclusion criteria received either an A or B label from a box handed by a nurse. The former would receive a medical protocol with promethazine and the latter with diazepam. When the patients were randomly assigned to groups, the medications for both were prepared as solved in 100 cc of normal saline in totally similar microsets and were handed to the nurse of the section unaware of the research procedures or medical protocol. Patients' medications in both groups were infused within 20 minutes. First and then after 20 minutes and then once again after 4 hours, a checklist was filled out to check the outcomes by a medical emergency assistant professor who was unaware of the type of treatment. Group A received a treatment with intravenous promethazine (10 mg) made by Caspian Company. The checklist consisted of demographic information, history of disease, severity of vertigo upon admission to emergency section, symptoms upon admission, patient's full examinations, response to treatment, reduction of the severity of symptoms, side effects of treatment and treatment courses [21]. It is noteworthy that 50 mg of promethazine and 10 mg of diazepam are each equal to 1 cc, as used in this study [22].

Measurements

Group A received 50 mg of intravenous promethazine while Group B received 10 mg of intravenous diazepam. Symptoms and severity of vertigo were measured before and after the treatment in four hours via the Visual Analog Scale (VAS) [8, 23, 24]. VAS is a scale to measure the severity of vertigo in which the scoring is based on both qualitative and quantitative criteria of pain measurement rating from 1 to 10. 1 implies the lowest degree of vertigo while 10 means the highest degree [7]. Patients were asked to rate each symptom between 1 and 10 once before the treatment and once again after the

treatment. Then, the severity of vertigo was measured and recorded both qualitatively (very severe, severe, moderate and mild) and quantitatively [1-10]. Then, the vertigo-related tests were administered such as the Hallpike test and cerebellar tests. The patients were examined 30 minutes, 2 hours and 4 hours after the treatment. The criterion for effectiveness of treatment was 50% of rescued qualitative and quantitative symptoms [21]. Patient information as well as the symptoms were recorded in special forms upon admission to emergency section as well as in the course of treatment measurements. Then, the collected data from both groups were cross-compared.

Statistical analysis

The data were analyzed through SPSS19. We reported the descriptive and inferential analysis in this study. The former included mean and standard deviation for age and VAS scores (for quantitative data) and frequency tables and percentage (for qualitative data). The latter included chi-squared test, Fisher exact test, Mann-Whitney U-test, Wilcoxon's test and McNemar Test to compare results before and after intervention. The data are presented as mean ± SD. A value of $P<0.05$ was considered to be significant.

Results and discussion

The present research was conducted on 154 patients in two groups, each with 77 subjects. 29.9% (n=46) of the total number of participants were male and 70.1% (n=108) were female subjects visiting the emergency section of hospital (Table 2). The mean age of the intravenous promethazine group was 44.44±17.94 years and that of the diazepam group was 47.43±15.80 years. The difference between the two was not statistically significant (p=.947). This would prove the homogeneity of the two research groups in terms of age (Table 2). Data analysis also revealed that the two groups did not differ from each other significantly at the outset in terms of age, sex, nausea, vomiting, severe headache, diplopia and blurred vision. With these respects, the two groups were homogenous. To compare the effectiveness of the drug (response to treatment), Fisher exact test was used. The results (p=.442) showed that the two groups did not diverge significantly in terms of the effectiveness of the drug. After treatment, 5 (6.7%) subjects of the promethazine group and 2 (2.8%) of the diazepam group reported having no vertigo (Figure 1). To compare VAS scores in the two groups, ANOVA test was run. The mean severity score was estimated for what the subjects rated between 1 and 10 before and after the treatment. This mean score for the promethazine and diazepam groups was estimated respectively at 7.75±1.59 and 7.66±1.68 before the treatment. The difference between the two was not statistically significant (p=.960).

Table 1. Inclusion and exclusion criteria for screened patients

Exclusion criteria	Inclusion criteria
Lack of informed consent	18-90 years of age
Pregnancy or probability of pregnancy	complaint of peripheral vertigo[1]
Alcohol consumption	
Known allergy to study medications	
Use of antiemetic agents within the past 24 hours	
Evidence of drug-induced vertigo or orthostatic hypotension	
Traumatic brain injury	
Advanced liver disease	
Central origin for vertigo[2]	

1: feeling that either oneself or the surroundings are moving due to changes in the position of head: 2 associated with such neurologic symptoms as headaches, audio/ visual, sensory or motor (diplopia, dysarthria, aphasia, weakness, and sensation abnormalities) and symptoms of cerebellar dysfunction such as dysmetria on finger-to-nose testing and dysdiadochokinesis, loss of balance and difficulty maintaining posture, standing, and walking.

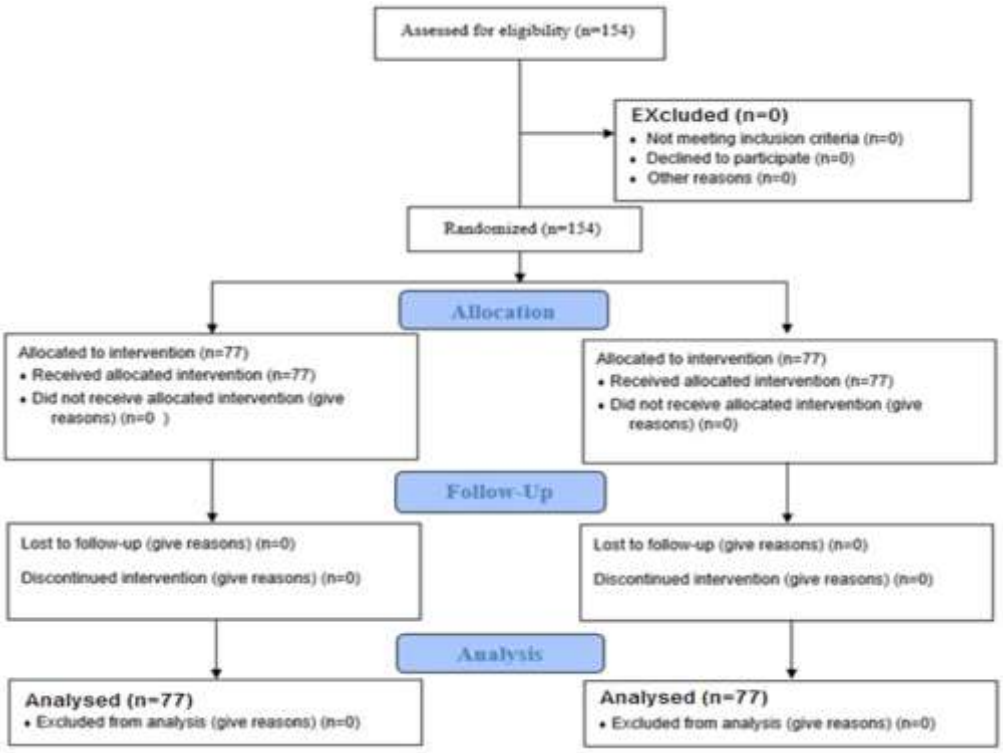
Table 2. Cross-comparison of two research groups in terms of demographic information

Variable	Sub-variable	Research Group		P-value
		Promethazine (n=77)	Diazepam (n=77)	
Age (Mean±SD)		44.44±17.94	47.43±15.80	.947
Sex	male	24 (31.2%)	22 (28.6%)	.725
	female	53 (58.8%)	55 (71.4%)	
Nausea	yes	52 (67.5%)	48 (62.3%)	.499
	no	25 (32.5%)	29 (37.7%)	
vomiting	Yes	37 (48.1%)	36 (46.8%)	.872
	no	40 (51.9%)	41 (53.2%)	
headache	Yes	26 (33.8%)	26 (33.8%)	---
	no	51 (66.2%)	51 (66.2%)	
diplopia	Yes	3 (3.9%)	4 (5.2%)	1.000
	no	74 (96.1%)	73 (94.8%)	
Blurred vision	Yes	7 (9.1%)	6 (7.8%)	.772
	no	70 (90.9%)	71 (92.2%)	

Table 3. Cross-comparison of two research groups in terms of drug effectiveness in severity of vertigo

Vertigo		Research Groups		P-value (Fisher Exact Test)
		Promethazine	Diazepam	
Before treatment	Yes	77 (100%)	77 (100%)	---
	No	0 (0%)	0(0%)	
	Total	77 (100%)	77 (100%)	
After treatment	Yes	70 (93.3%)	70 (97.2%)	.442
	No	5 (6.7%)	2 (2.8%)	
	Total	75 (100%)	72 (100%)	

Consort flow-chart:



This would point to the homogeneity of subjects in two groups before treatment. After the treatment, the mean severity score in promethazine and diazepam groups was respectively 2.72±1.93 and 3.87±2.49. The difference between these two scores was statistically significant (p=.008). The mean severity score before and after treatment in the promethazine group was respectively 7.75±1.59 and 2.72±1.93. The difference between these two was statistically significant. In the diazepam group, the same score was respectively 7.66±1.68 and 3.87±2.49 which similarly showed a statistically significant divergence (p≤.001). The mean severity score before and after treatment in the promethazine group and diazepam was respectively -5.04±2.10 and -3.83±3.09. The difference between the two was statistically significant (p=.013). These can be observed in Table 4. The results summarized in descriptive Table 5 show a reduction in the VAS score through time in both groups. To compare this reduction between the two groups, ANOVA test was run (p≤.001). Comparison of vertigo severity in the two groups based on qualitative ratings (very severe, severe, moderate, mild) showed no significant difference either before or after the treatment. Thus, comparison of the results shows that in both groups, there was a reductive trend of change in severity of vertigo from the pre-intervention stage to the post-intervention. The inter-group variation was statistically significant (p≤.001) (Table 3). Wilcoxon's test was run to compare systolic blood pressure before and after the treatment in the promethazine group and showed a statistically significant difference (p=.002). However, systolic blood pressure did not show any statistically significant difference before and after treatment in the diazepam group (p=.076). The same test was used to compare diastolic blood pressure in each group. In the promethazine group, diastolic blood pressure before and after the treatment was significantly different

(p=.075). No statistically significant difference was observed in diastolic pressure of diazepam group before and after the treatment (p=.155). It is noteworthy that the difference between the two drugs did not show any statistically significant difference before and after the treatment (p≥ .005) (Figure 2). After the treatment was done, patients in the promethazine group showed more reduction in blood pressure. The need for CT scan was compared between the two groups. In the promethazine group, 31 subjects needed CT scan and in the diazepam group, 20 subjects showed the need. The difference between these two was not statistically significant (p=.060).

Vertigo is a common disease that makes people visit the emergency section, and disrupts patients' life-style [8]. Though many medical factors seem to be effective in improving the clinical symptoms, there is a dearth of research to find drugs to cure acute peripheral vertigo with the least side effects [8]. The present randomized, double blind, clinical trial was conducted to compare the effect of intravenous promethazine and diazepam on acute peripheral vertigo. The main results showed that among 154 patients visiting emergency section for acute peripheral vertigo and being treated with intravenous promethazine and diazepam, the former showed better improvement.

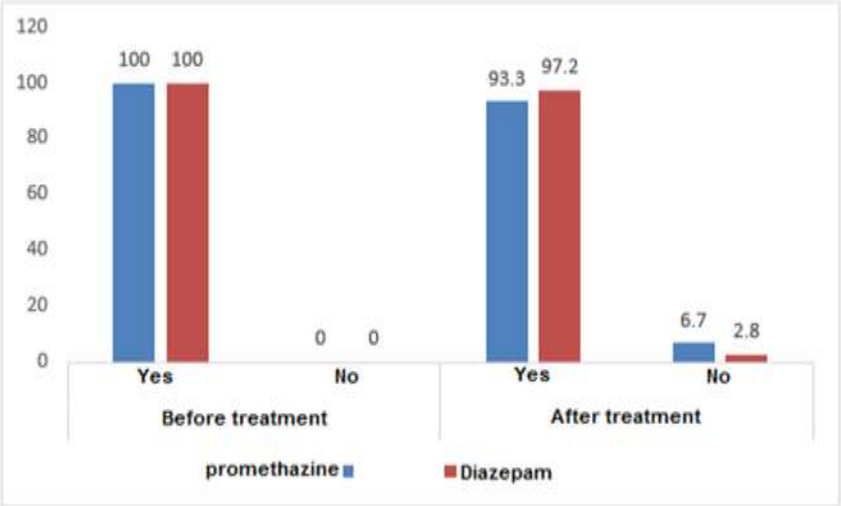


Figure 1. Cross-comparison of two research groups in terms of drug effectiveness in severity of vertigo

Table 4. The trend of change in the severity of vertigo

Vertigo Severity score	Research Groups		Mann-Whitney U-test	P-value
	Promethazine	Diazepam		
	Mean±SD	Mean±SD		
Before treatment	1.59±7.75	1.68±7.66	-.05	.960
After treatment	1.93±2.72	2.49±3.87	-2.667	.008
Before and after (difference)	2.10±5.04	3.09±-3.83	-2.498	.013
Wilcoxon's Test value	-7.544	-6.618		
p-value	<.001	<.001		

Table 5. The trend of qualitative variation in severity of vertigo

Vertigo Severity		Research Groups		Fisher Exact Test p-value
		Promethazine	Diazepam	
Before treatment	**Very severe**	17 (22.1%)	9 (11.7%)	.237
	Severe	44 (57.1%)	51 (66.2%)	
	Moderate	16 (20.8%)	16 (20.8%)	
	Mild	0 (0%)	1 (1.3%)	
	Total	77 (100%)	77 (100%)	
After treatment	**Very severe**	0 (0%)	1 (1.4%)	.213
	Severe	2 (2.9%)	7 (10%)	
	Moderate	25 (35.7%)	25 (35.7%)	
	Mild	43 (61.4%)	37 (52.9%)	
	Total	70 (100%)	70 (100%)	
Increased severity	0	2		
Reduced severity	72	56		
No change	3	14		
Sign Test value	-8.367	-6.959		
P-value	<.001	<.001		

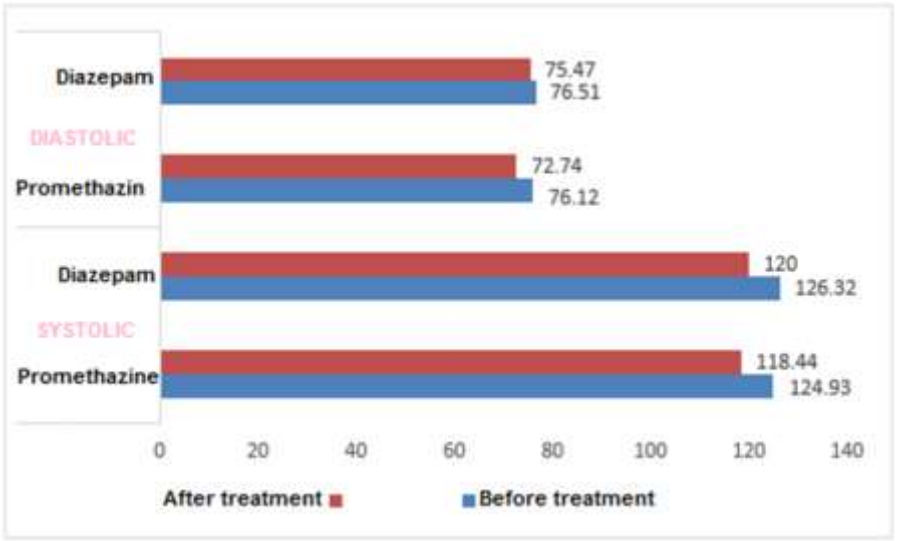


Figure 2. Cross-comparison of two research groups in terms of systolic and diastolic blood pressure

This finding is in line with another randomized clinical trial by Amini et al. explored the effectiveness of intravenous promethazine and lorazepam in treating acute peripheral vertigo. The effect of intravenous promethazine (25 mg) and intravenous lorazepam (2 mg) was checked on 184 visitors of the emergency section of Imam Hossein University affiliated with Shahid Beheshti University. This research showed that the former medicine was more effective in treating acute peripheral vertigo than the latter [21]. The overall findings revealed that promethazine was more effective in treating acute peripheral vertigo than benzodiazepines. In the present study, feeling off balance and movement was reduced more in patients who received promethazine than those who received diazepam. In later evaluation too, clinical symptoms and ability of movement showed to be improved influenced by promethazine.

The research findings by Marill et al. who aimed to compare the effect of intravenous lorazepam and dimenhydrinate on vertigo in the emergency section were consistent with the present study too. The severity of vertigo was reduced more in patients who received dimenhydrinate [8]. Promethazine and dimenhydrinate belong to H1 blocker antihistamine group whereas lorazepam and diazepam belong to the benzodiazepine group. The present findings indicated that promethazine was more effective in treating acute peripheral vertigo.

In some other research, Sutton et al. compared the effect of antihistamine, phenothiazine, anti-cholinergic and sympathomimetic drugs and their combinations in treating vertigo in different modes. They found that such antihistamines as promethazine are more effective in treating acute peripheral vertigo than other treatments [25]. Considering the side effects of corticosteroids and benzodiazepines, antihistamines seem to be more effective in treating vertigo and reducing their associated symptoms. In the present study, VAS score was used to measure the severity of nausea before and after the treatment. The findings revealed the privilege of promethazine in reducing nausea over diazepam. Other related investigations also confirmed the effectiveness of promethazine in reducing nausea and vertigo. Promethazine acts as a phenothiazine derivative or blocker of D2 dopamine receptors in brain and acetylcholine receptors in vestibular system [26,27]. The findings reported by Leila et al. showed that prescribing promethazine (25 mg) is more effective than diazepam in treating nausea and vertigo [28]. Although promethazine had fewer side effects in the present study than diazepam, systolic blood pressure of patients in both groups was lowered after the treatment. Lowered blood pressure yet showed a statistically significant difference in the promethazine group.

Limitations

Among the limitations of the present study, mention can be made of some patients' failure to respond to the questionnaire, qualitative and quantitative criteria of measuring vertigo severity and lack of a control group receiving a placebo. We should add a three-day delay in conducting the research as promethazine made by the target company was out of stock.

Conclusion

The present findings showed that promethazine is more effective in treating vertigo and reducing its symptoms in comparison to benzodiazepines. It is accompanied by fewer side effects too. Moreover, intravenous promethazine and diazepam are effective in 20 minutes of infusion in controlling the severity of vertigo. Yet, the control and improvement of vertigo is more effective with promethazine than diazepam. In the light of the present findings, we can also conclude that to control acute vertigo in patients visiting the emergency section, though no certain side effect was observed in subjects of promethazine group, this drug can probably cause extrapyramidal side effects. Therefore, the infusion should be done slowly and gradually to control vital signs more carefully in longer time.

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Conflicts of interest

The authors declare that they have no competing interest.

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