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THE COMPARATIVE STUDY OF BRANDED DRUGS AND GENERIC DRUGS FOR THE TREATMENT OF HYPERTENSION

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Abstract **-** The comparative study on some data of drug to attain the good efficacy product to the both category of people i.e. economically rich and weaker people for their healthy life is provided. The disease taken for the study of comparison is Hypertension with its treatment. According to that, there are various branded drugs are available in the market by different manufacturers with same drug composition. And from which the pharmacological parameters and products are called 'Branded' and then the next of that i.e. mimicry of brand called 'Generic' which are cheaper but similarly effective.

Keywords - Hypertension, Implicit Association, Antihypertensive

1. INTRODUCTION

Nowadays in an age of globalization, brands are growing ever valuable. The difference of the product differentiation fuels the competition of brands, steering the direction from the simple products competition to the added value of the brands. In the brands competition, customer perceived value is the core of the competing.[1]

High customer expected value means the relevant brand image left in the customer faithfulness and regularity of purchase again showing the status of the brands. There are various price of the products, which gets high as well as low in cost.[1]

Sometime the low cost products give good efficacy over the high cost products and due to that the economically weaker people can buy easily the medicines. Using the method of "**Implicit Association Test"** for analyzing difference of the user experience of two competitive brands and has an insight into the advantages and disadvantage of the competitive brands from four dimension.[1]

There are not only a single drug composition brand for the treatment of hypertension alternatively there are many brands with combination of different drug. The combination of drug depends on the stages of the patients health level or conditions.[1]

Mostly at the initial stage the doctor prefers to patients a single composition branded drugs for treatment. While the health condition changes into increasing of blood pressure of patient physician change the prescription sometime the patient recover the health at initial level on that the single dose of a single drug is sufficient for the maintaining blood pressure.[1]

The Physicians habit of prescription is different for different physician therefore all types of brand are survive in market. [1][2]

1.1 HYPERTENSION

Hypertension is define as bizarre raise in diastolic and systolic pressure. It is a very common disease, mostly start from the middle age. It is not a disease in itself, but is an important risk factor for cardiovascular manometric reading between normotensives and hypertensive is arbitrary. Almost all Hypertension management guideline including NICE, WHO-ISH, EUROPEN society of hypertension define the cut – off level to be 140 mm Hg systolic and 90 mm Hg diastolic.[2]

However the JNC8 have raised the defining level of 150/90 mmHg for individual above 60 years of age. Epidemiological studies have confirmed that higher the pressure (systolic or diastolic or both) greater is the main risk of cardiovascular disease. In most cases are of vital (primary) hypertension i.e. the cause is not known.[2]

Sympathetic and renin angiotensin system (RAS) may or may not be overactive, but they do contribute to the tone of blood vessels and cardiac output in hypertensive, as they do in normotensive. Many antihypertensive drugs interfere with these regulatory system at one level or the other. Antihypertensive drugs by chronically lowering BP, may reset the aerostat to function at a lower level of Blood Pressure.[2]

Blood pressure is elevated when systolic blood pressure exceeds 120 mm Hg and diastolic blood pressure remain below 80 mm Hg. Hypertension occurs when resting systolic blood pressure exceed 130 mmHg or diastolic blood pressure exceeds 80 mmHg. Hypertension result from increased peripheral vascular arteriolar smooth muscle tone, which leads to increase arteriolar resistance and reduce capacitance of the venous system.[3]

In most cases, the reason behind increased vascular tone is not known. Elevated blood pressure is a common disorder, affecting approximately 30% of adult. Although many patient have no symptoms, chronic hypertension can lead to heart disease and stroke, the top two causes of death in the world. Hypertension is also a major risk factor in the expansion of chronic kidney disease and heart failure. Before labeling any individual with hypertension, the blood pressure of the patient should be measured on more than two occasions and he/she should have been resting for at least 5min.[3]

Out –of-office and self –monitoring of BP measurement are recommended to confirm the diagnosis of hypertension and for titration of BP–lowering medication, in conjunction with lifestyle modification strategies. The risk of organ damage is directly related to the extent of elevation of blood pressure. Even mild hypertension increase in proportion to the magnitude of elevation of blood pressure. The chronicity of morbidity and mortality immensely decreases when hypertension is recognize early and is properly medicated and therapy used. The drugs used in the treatment of hypertension.[3]

In recognition of the progressive nature of hypertension, it is classified into four categories. The detection of hypertension is depends on the level of blood pressure and not on symptoms and causes reported by the patients. Hypertension is usually asymptomatic until overt end-organ damage is imminent or has already occurred. The majority of current guideline of the antihypertensive therapy, rather than the category of hypertension.[3]

CLASSIFICATION OF HYPERTENSION

Table No. – 01 : Various classes of Hypertension

Sr. No.	Classes	Systolic (mmHg)	Diastolic (mmHg)
01	Normal	LT 120	LT 80
02	Pre - Hypertension	120 -139	80 – 89
03	Stage 1	140 -159	90 - 99
04	Stage 2	MT 160	MT 100

Essential Hypertension - More than 90% of the individuals with high blood pressure have essential hypertension. Numerous mechanisms have been identified that may contribute to the pathogenesis of this from of hypertension, so identifying the exact underlying abnormality is not possible. Genetic factors gives a vital role in the increasing of essential hypertension.[4]

Secondary Hypertension - Fewer than 10% of patients have secondary hypertension where either a comorbid disease or drug is responsible for elevating blood pressure. In most of these cases, renal dysfunction resulting from sever chronic kidney disease or Reno vascular disease is the most common secondary cause. Certain drugs either directly or indirectly, can cause hypertension or exacerbate hypertension by increasing blood pressure.[4]

Secondary Derived Diseases - Chronic kidney failure, Obstructive sleep apnea-hypopnea syndrome, Hyperparathyroidism , Adrenal paraganglioma, Thyroiditis disease. [4]

Prescribed Drugs - Adrenal steroid, Amphetamine, Decongestant, NSAIDS[4]

Prevalence - Women with 55 plus years of age more prone to hypertension than men. Blood pressure levels increase at an elder age (persistently elevated BP levels) [4]

Risk Factors[4] –

1. High Sodium Intake
2. Low Potassium Intake
3. Alcohol Consumption
4. Obesity And Overweight
5. Lack Of Physical Activity
6. Unhealthy diet

1.2 TREATMENT[2]

ANTIHYPERTENSIVE DRUGS

The drug used in the treatment of Hypertension called as Antihypertensive.

The aim of antihypertension therapy is to prevent morbidity and mortality associated with persistently raised BP by lowering it to the target level, with minimum inconvenience to the patient. Both systolic and diastolic BP predict the likelihood of Target Organ Damage (TOD) and complication. Patient who have already suffered some TOD have greater risk of future organ damage and death at any level of raised BP, than those without TOD.

The JNC7 have also identified compelling indication which may mandate use of specific antihypertension drug even in patients with BP values lower than 140/90 mmHg. Moreover, presence of compelling indication may suggest fixing a lower target BP value to be attained by drug therapy.

Beneficial effects of lowering BP has been established in all patient having BP above 140/90 mmHg and even in the 120 – 139 (systolic) or 80 - 89 mmHg (diastolic) range in those with compelling indication or cardiovascular events to a greater extent than on reducing it up to 90 mmHg.

However, for patient aged 60 years or above it has suggested threshold systolic BP value of 150 mmHg for initiating treatment, as well as to be the treatment goal (< 150 mm Hg). The threshold and goal diastolic BP value of 90 mm Hg is the same as for patient < 60 years age.

Data from several large studies has shown that effective use of antihypertensive drugs reduces occurrence of stroke by 30 - 50% heart failure by 40 – 50 % and Coronary Artery Disease (CAD) by ~15%. If the cause of hypertension can be identified (hormonal, vascular abnormality, tumor, renal disease, drugs) all efforts should be made to remove it. Non – pharmacological measure (life style modification – diet, sodium restriction, aerobic activity or exercise, weight reduction, moderation in alcohol intake, mental relaxation) should be tried first and concurrently with drugs.

When significant cardiovascular and renal damage has already occurred, lowering BP to normotensive level may not be tolerated : edema, CHF, angina, rise in blood urea and syncope may be precipitated. Therefore, BP reduction should be incremental and only to the level supported.

1.3 CLASSIFICATION OF ANTIHYPERTENSIVES[2][3]

1. DIURETICS

1) Thiazide Diuretics
   - Hydrochlorothiazide
   - Chlorthalide
2) High Ceiling Diuretics
   - Furosemide
3) Aldosterone Antagonist
   - Spironolactone
   - Eplerenone

2. RENIN – ANGIOTENSIN SYSTEM INHIBITORS

1) ACE – Inhibitors
   - Captopril
   - Enalapril
   - Ramipril
2) Angiotensin Receptor Blocker (ATRB)
   - Losartan
   - Candesartan
   - Valsartan
3) Direct Renin Inhibitors
   - Aliskiren

3. SYSTOLIC INHIBITORS

1) β – Adrenergic Blocker
   - Propranolol
   - Metoprolol
   - Atenolol
2) α and β Adrenergic Blockers
   - Labetalol
   - Carvedilol
3) α – Adrenergic Blockers
   - Prazosin
   - Doxazosin
4) Central Sympatholytic –
   - Clonidine
   - Methyldopa

4. CALCIUM CHANNEL BLOCKERS

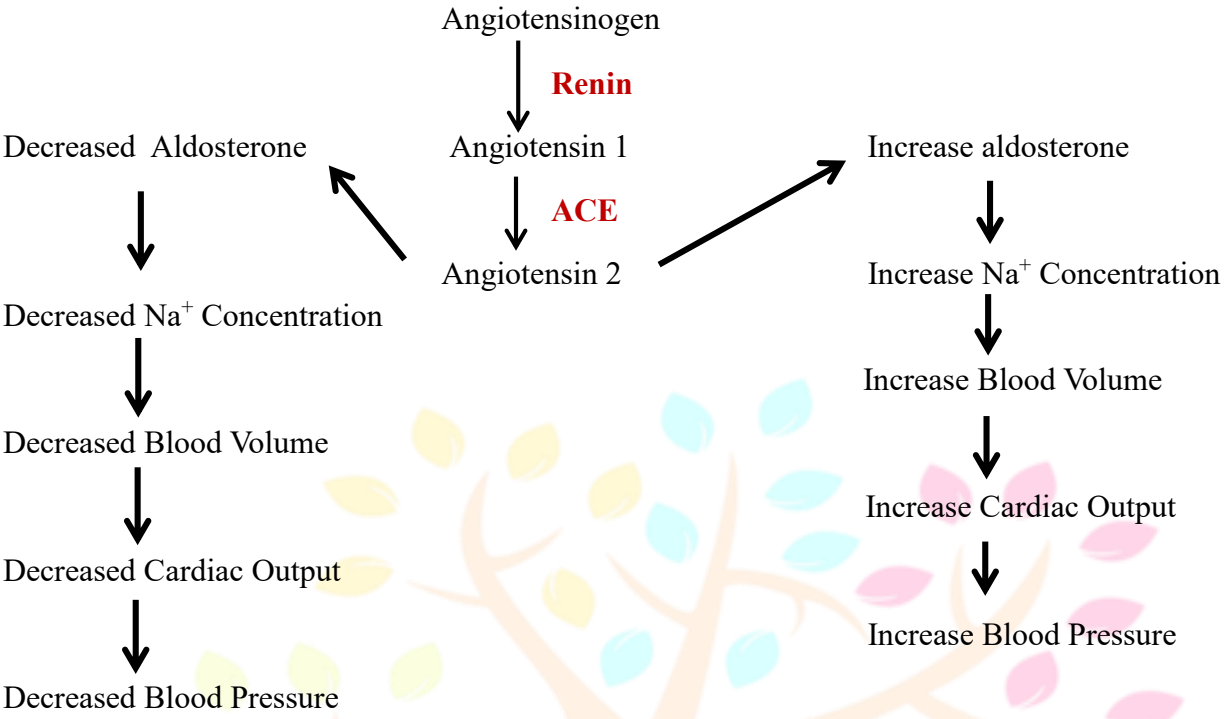
1) Phenyl Alkylamine CCB's
   - Verapamil
2) Benzothiazepine CCB's
   - Diltiazem
3) Dihydropyridines CCB's
   - Nifedipine
   - Amlodipine
   - Nicardipine

5. VASODILATORS

1) Arteriolar Dilators
   - Hydralazine
   - Minoxidil
2) Arteriolar Dilators + Vasodilator
   - Nitroprusside sodium

1.4 MECHANISM OF ACTION OF ANTIHYPERTENSIVES[3][6]

1. ACE INHIBITORS



Adverse Effects –

1. Hypotension – First dose hypotension is prevalent with ACE inhibitor.
2. Persistent dry cough – due to pulmonary kinin accumulation.
3. Hyperkalemia –ACE inhibitor promote potassium retention.
4. Other effects – fatigue, nausea, dizziness, headache.

2. ANGIOTENSIN 2 RECEPTOR BLOCKERS

1. Angiotensinogen convert into angiotensin 1 in the presence of "Renin" in kidney
2. Angiotensin 1 convert into angiotensin 2 by the enzyme ACE (non ACE pathway)
3. Which increases the aldosterone, Na^+ reabsorption, blood volume and finally increase in BP.
4. When the ACE inhibitors are taken they inhibits and inactive the ACE.
5. Due to inactivation of ACE the blood pressure gets normalized.

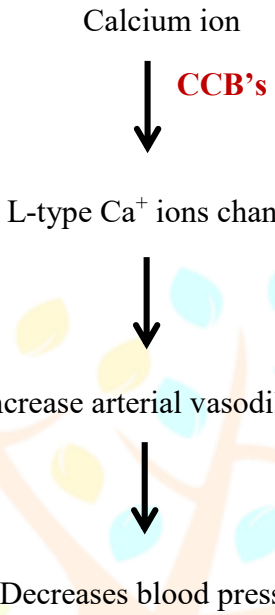
Adverse Effects -

1. Hypotension and Hyperkalemia
2. Renal failure (as with ACE inhibitor)
3. Cough – though less likely than with an ACE inhibitor.

4. As with ACE inhibitors, taking ARBs with NSAIDs increase risk of renal failure .

3. CALCIUM CHANNEL BLOCKERS (CCB's)

Not all calcium channel blockers are used for their antihypertensive effects. CCB's reduces calcium entry into vascular and cardiac cell. This reduces intracellular Ca^+ concentration which causes relaxation on vasodilation in atrial smooth muscle .It also reduce myocardial contractility in the heart .



Adverse Effects –

1. Flushing
2. Headache
3. Ankle swelling and Palpitation
4. Light headedness

4. β - BLOCKERS

Beta blockers acts through a variety of means for hypertension. They act to reduce renin secretion from the kidney and show effect ordinarily mediated by β1 receptors. That β1 receptors are located mainly in the heart, whereas β2 receptor are mainly located in the smooth muscles of blood mainly in the heart, where β2 receptors are mainly located in smooth muscles of blood vessels and in airways.

Adverse Effects –

1. Fatigue
2. Cold extremities
3. Headache and Nausea

5. α - BLOCKERS

α1 receptors are predominantly found in smooth muscle, such as blood vessels or the urinary tract stimulation produces concentration and inhibition causes relaxation α blockers are highly selective for α1 receptor, give rise to vasodilation and a reducing blood pressure .

Adverse Effects -

1. Postural Hypertension
2. Dizziness
3. Faintness

6. α - 2 AGONISTS

As with the α -2 agonists are infrequently used they are usually used when all other conventional options have been depleted , when used they are typically taken alongside a diuretic.

Mechanism of Action

More specifically, α - 2 agonists are classified as centrally acting α - 2 agonists, these receptors are activated in the brain, which once activated in open peripheral blood vessels around the body by reducing blood pressure

Adverse Effects -

1. Sedation
2. Dry nasal mucosa and Dry mouth
3. Rebound Hypertension and Postural Hypertension
4. Headache

7. RENIN INHIBITORS

It works by cleaving angiotensinogen (Hepatic – produced) into angiotensin 1.

↓

ACE then convert Angiotensin - 1 into Angiotensin - 2 and in return Angiotensin - 2 causes increased secretion of aldosterone by increasing the blood pressure.

↓

Renin inhibitors then blocks the effects of Angiotensin - 2 and reduces the blood pressure.

Adverse Effects –

1. Angioedema
2. Hyperkalemia
3. Diarrhea
4. Headache and Dizziness

8. VASODILATORS

Sodium nitroprusside has been used in the case of Hypertensive emergency. It is administered via intravenous route and for this reason, it has a rapid onset of effects. Sodium nitroprusside place nitric oxide for its antihypertensive effect.

Nitric oxide works to reduce TPR and venous return. This reduces both preload and afterload.

Hydralazine is used to treat hypertension, though is more often used to treat high blood pressure, gestational hypertension. Like sodium nitroprusside, it may also use in hypertensive emergency.

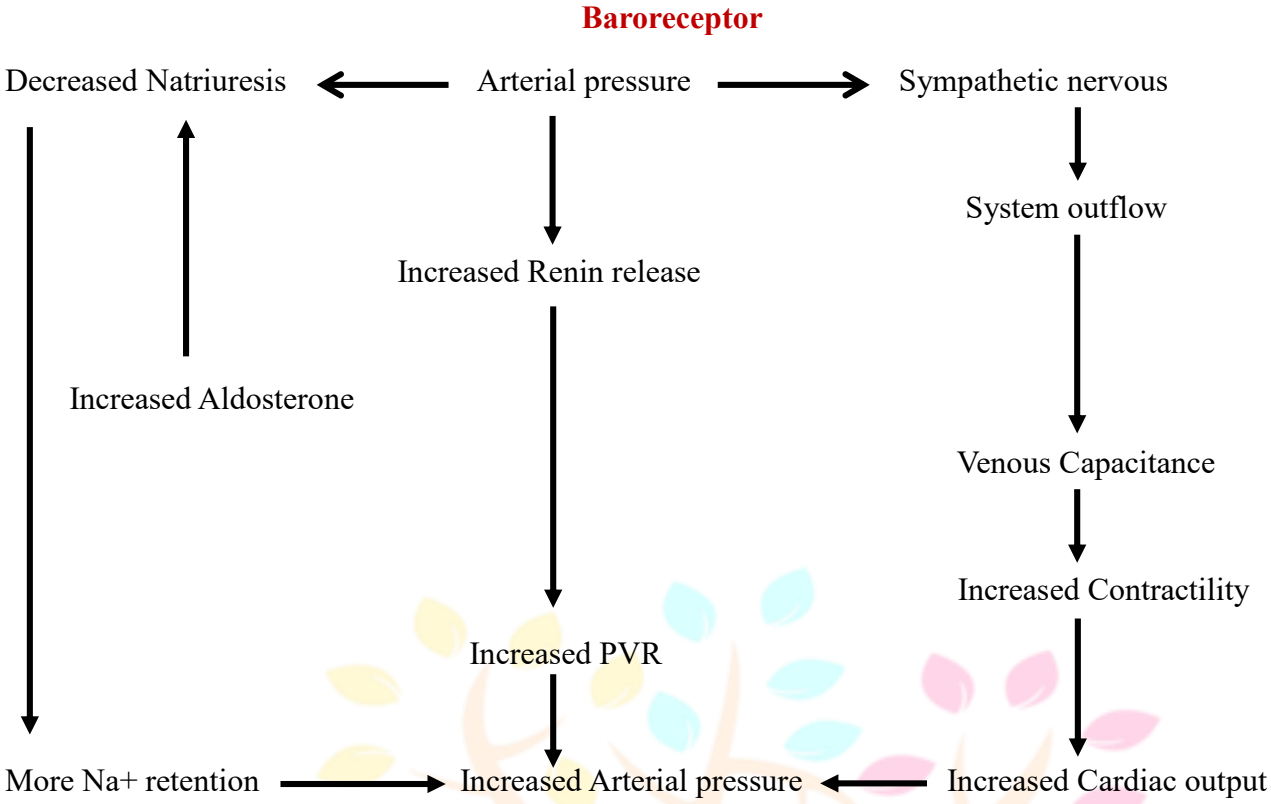
Mechanism of Action -

Vasodilating Drugs

↓

Decreased PVR

↓



Adverse Effects -

1. Headache
2. Tachycardia
3. Palpitation
4. Hypotension
5. Aching and Swollen Joints
6. Flushing

9. DIURETICS

Diuretics are drugs that promote dieresis or water loss. There are many different diuretic classes such as,

1. Loop diuretic act at the thick ascending limb.
2. Thiazide diuretics act at the distal convoluted tubule (DCT).
3. Potassium-sparing diuretics act at cortical collecting duct.
4. Osmotic diuretics act at the proximal tubule.
5. Carbonic anhydrase inhibitors act at the proximal tubule.

Adverse Effects -

- ***Loop Diuretics***
  1. Hypovolemia
  2. Hypokalemia
  3. Metabolic alkalosis
  4. Hyperuricemia

- ***Thiazide***

It is associated with the side effects which are listed for loop diuretic along with Hypercalcemia and Hyponatremia.

1.5 COMPARITIVE SURVEY

Comparison of Brands on Same Data with Respective to Their Cost and Efficacy

Table No. – 02 - Comparative observations of report.

SN	High Cost Brand Drugs	MRP	SN	Low Cost Brand Names	MRP
01	Telvas – 3D	105 Rs.	01	Amlosafe – 3D	73 Rs.
02	Teltrust – H	130 Rs.	02	Telmikind – H	83 Rs.
03	Telma Beta – 25	202 Rs.	03	Telmiprime Beta – 25	97 Rs.
04	Telpres – CT 40/6.25	104 Rs.	04	Telmikind – CT 40/6.25	63 Rs.

It's a comparison between 2 brands on same drug content and Mg content with high cost and low cost. While comparison the brands, it figured out that both brands have the equivalent efficacy. And sometime it depends on patient body nature to accept the drugs.

Both brands are sale frequently and equivalently.

So, it's get helpful for the people who cannot buy the high cost brands drugs. And economically weaker peoples may get good efficacy drugs and therapeutic action.

There is a single drug used brands and also combine drug used brands, depends upon the patient's BP stage.

Depend on that doctor prescribed the drugs to the patient and the brands price also depend on that, what doctor suggested.

METHODOLOGY

1. Generalized Survey (Questioning to the patients)

1. Have you recently started to take medications ?
2. Total how many no.'s of drugs are there in your regular prescription ?
3. How much drug dose is prescribed to take per day ?
4. How many times a day you take the medications ?
5. Do you take your medications as per the guidelines from Doctors or Pharmacists ?
6. Do you feel any kind of ease ever since you started the medications ?
7. Did Doctor had changed your old dose ever since it started ?
8. Did your Doctor have increased your dose because of tolerance ?
9. Did Doctor have reduced the old dose by observing your progress ?
10. Are the medication causing any adverse effect ?
11. If yes, Have you change the dose or stopped the medication because of unwanted effects ?
12. Did you stopped to take the medication whenever you feel better ?
13. Have the medications ever gave you uneasy feeling ?
14. Do you stop taking your medicine if it makes you feel uneasy ?

15. Have you ever tried the different drug with same content of another branding ?
16. If yes, have you compared which drug have good effects or lower side effects ?
17. Did you consult with your physician continuously for your check-up ?
18. Have you seen any progress in your disease by comparing the before and after medication ?
19. Have you ever bought the medicines with effect but with lower cost ?
20. If yes, Which price of drug you refer on the basis of price ?
21. And by comparing the cost which brands gave the better effects as per your point of view ?

2. Self - Observation

1. By observations it is seen that both the having high and low cost gave almost same results.
2. So, people who cannot afford the branded drugs they can purchase low cost brand drugs.
3. There is no difference in efficacy and therapeutic action due to price changes.
4. But the therapeutic action can change if the patient purchase the generic drug instead of branded drug because of low cost but still the final results will be almost same.
5. Mostly the economically weaker people purchases their medications from the Government hospital because of lower cost and that drugs also shows the almost similar or desired effects.
6. Sometime there is huge difference in the private branded drug and the government provided the brands but the designed effect is same and they have proved to show same effects in up to 90% times in most of the recent surveys.
7. There is difference in drugs according to the stage of the patient's Blood Pressure.

CONCLUSION

Based on both the surveys we can conclude that,

Therapeutic response of any formulation confined on its quality parameters. Study results confirm that both the price brand has the equivalent quality and efficacy if both are branded drug. But if one is branded and another one is generic then causes changes in therapeutic action of drug. Because the drug which considered as generic that are mimicry of past formulated drug or presence of any deficiency in that.

Quality of both tablets are related to each other and the pharmacological action of the drug are same. Meet all the standard quality to exert its desired therapeutic response. Finally the study result confirm that if the economically weaker people purchases the low cost product brand then also they will get the desire action of drug.

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