EVALUATION OF DRUG PRESCRIBED IN PREGNANT WOMEN AND ITS COMPARISON WITH THE CATEGORIES OF THE FOOD AND DRUG ADMINISTRATION (FDA) IN KABUL, AFGHANISTAN 2021: A DESCRIPTIVE, CROSS-SECTIONAL STUDY

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SUMMARY

INTRODUCTION: Pregnancy is one of the natural periods in women's lives, during which the body undergoes physiological changes. These changes also affect the effects of the drug. Taking the drug during pregnancy requires caution, and the life of the fetus and mother is endangered by taking it arbitrarily and without consulting a doctor.

OBJECTIVES AND METHODS: The purpose of this study is to compare the amount of medication prescribed during pregnancy and compare it with the categories of the Food and Drug Administration (FDA).This research is descriptive and information has been obtained from the copies to fill in the questionnaires. In this study, 34 health centers in Kabul city have been used during 4 months of 2021, which has evaluated a total of 612 pregnant women.

RESULTS: In this study, the drug prescriptions of 612 pregnant women were evaluated, of which about 2107 drugs were prescribed to the participants during four months. Among the prescribed drugs, most of the drugs were related to drugs affecting the digestive system (32.90%), vitamins-minerals (28.10%), antibiotics (19.90%), analgesics (10.80%), and drugs affecting the cardiovascular system (8.10%). Most drugs prescribed in category A (60.90%), category B (57.4%), category C (16.5%), category D (9.2%) and category X (0.00%). About 612 pregnant women participated in the study.

DISCUSSION AND CONCLUSION: Prescribing the drug to pregnant women is of particular importance, which can be prevented by informing the public about the arbitrary use of the drug in pregnant women. Co-administration of several drugs can lead to more side effects in pregnant women.

Keywords: Pregnancy, FDA categories and Kabul, Afghanistan.

1. INTRODUCTION

Pregnancy is one of the most important periods in a woman's life. The use of drugs at this time is of particular importance, because there is a possibility of teratogenic effects due to the use of inappropriate drugs. The physiology of the pregnant mother affects the kinetics and dynamics of the drug, some drugs have the ability to cross the placenta and cause teratogenic effects. The importance of taking the drugs in pregnancy occurred after the Thalidomide incident in (1960) and di ethylstilbestrol. The dangerous effects of drug use on pregnant women have led the Food and Drug Administration to regulate drug use during pregnancy. [17]

Pregnancy is one of the natural periods in the life of women, during which changes occur in the body of pregnant women. These changes cause changes in the pharmacology of drugs. During pregnancy, the pH of the stomach increases, but the movements of the stomach decrease, which affects the rate of drug absorption through the intestines, also, with increasing plasma volume in the mother, it also leads to a change in the volume of drug distribution. On the other hand, by increasing the levels of progesterone and estradiol, it affects the metabolism of some drugs. By increasing the glomerular filtration rate (GFR), it also leads to increased renal blood flow, which in turn has a medicinal effect on Excretion. [7]

During this period, the body also needs some supplements to be able to perform its normal activities. For example, the use of iron and folic acid supplements during pregnancy can help prevent events such as maternal anemia, puerperal sepsis, low birth weight and preterm birth. [19]

The US Food and Drug Administration (FDA) has divided all drugs used during pregnancy into five classes, taking into account animal and human studies, to use a clinical guideline for prescribing the drug to pregnant women. [17]

Group A: In this group of drugs, sufficient studies have been performed on pregnant women and the results of the studies indicate that no risk is observed in the fetus during the first trimester of pregnancy. This group of drugs is called drugs allowed during pregnancy.

Group B: In this group of drugs, studies in pregnant animals have shown that the drug does not pose a risk to the fetus, but not enough studies have been performed in pregnant women on the risk to the fetus in the first trimester of pregnancy.

Group C: In this group of drugs, studies in pregnant animals have shown that the drug has side effects on the fetus, but not enough studies have been performed on

humans. The drug may be prescribed if the benefits of taking the drug outweigh the harms of the drug to pregnant women.

Group D: In this group of drugs, studies and their results indicate a risk to the human fetus. Doctors will prescribe the medicine when the use of the drug is unavoidable for pregnant women and the possible risks are accepted.

Group X: This group of drugs has been shown to cause disorders, injuries and abnormalities in the fetus. Due to the harm to the fetus and the high risk of taking the drug, the use of these drugs during pregnancy is prohibited and they are called contraindicated drugs during pregnancy. [1], [16]

Unfortunately, the arbitrary use of drugs (self-medication practice) during pregnancy leads to dangerous effects on the mother and fetus. In a study conducted by Kidanemariam and Solomon on 617 pregnant women, the rate of self-medication practice was about (26.6%). [11],

According to research in Mainland, China, about (11.7%) of pregnant women have used at least one drug during pregnancy. Injectable solutions, vitamins, minerals, progesterone and antibiotics are the most commonly used drugs during pregnancy in pregnant women. (65.5%) of pregnant women use the drug only in the first trimester and about (12.4%) of pregnant women use the drug in all trimesters of pregnancy. According to the results of this study, Blood and Blood Forming organs, about (49.3%) and Alimentary tract and metabolism about (48.1%) were prescribed to pregnant women, which is the highest rate of drug in this study. About (6.2%) of cardiovascular drugs have also been prescribed. [10]

In another study conducted in Saudi Arabia, 760 pregnant women, about 500 pregnant women (65.8%) were university students, about (340) pregnant women (44.7%) were between 30 and 40 years old, and about (620) pregnant women (81.8%) were housewives. Medications prescribed to these pregnant women include non-steroidal anti-inflammatory drugs (NSAIDs) (1.3%), Paracetamol (13.2%), antibiotics (2.6%), Antihistaminic (1.3%), antiemetic drugs (2.6%) and vitamins (13.2%) have been prescribed to pregnant women. [14]

In a study conducted in India on pregnant women, antibiotics (26.10%), antacids (2%), antiemetic and vomiting drugs (0.57%), antiulcer (23.06%), analgesics (18.51%), Vitamins and minerals (14.92%), Minerals and folic acid (6.24%), Group A drugs (16.58%), Group B drugs (56.73%), Group C drugs (16.64%), Group D drugs (8.78%)) And group X drugs (1.24%) have been prescribed to pregnant women. The highest age range in women included in this study is between 21 to 25 years (52.04%). Also in this study, the amount of drug prescribed in each prescription for pregnant women has been evaluated, such as prescriptions with one drug (2.91%), two drugs (22.33%), three drugs (26.94%), four drugs (16.01%), five drugs (9.46%) and more than five drugs (22.33%) were prescribed for pregnant women. The average prescription was 4.66 per prescription, but World Health Organization (WHO) standards accepted an average of 2 prescriptions for pregnant women. There is also a percentage of the drug

prescribed with its generic name (38%), as the standard accepted by the World Health Organization (100%). [4]
Also in a study conducted in Turkey on pregnant women, chemotherapy drugs (17.6%), analgesics (10.7%) and drugs affecting the cardiovascular system (9%) were prescribed to pregnant women. [13]
A study was performed on (200) pregnant women in Hamadan, Iran. The most prescribed drugs during all three trimesters belonged to group B, which (48.8%), (65.6%) and (66.7%), respectively. It is prescribed for pregnant women. Also, the most prescribed drugs, in the first trimester of pregnancy, are drugs affecting the digestive system (44.2%), in the second trimester, antibiotics (53.1%) and in the third trimester analgesics and drugs affecting the digestive system (42.4%) and (42.5%) was prescribed to pregnant women respectively. (44%) of pregnant women in Iran use at least one drug during pregnancy. The most commonly prescribed drugs for pregnant women are drugs that affect the digestive system, analgesics and antibiotics. [2]
In another study in Canada on (18575) pregnant women, the highest age of pregnant women was in the range of 25 to 29 years and about (39.20%) of pregnant women experienced their first pregnancy. The highest prescribed of group C drugs (15.8%) was observed in the first trimester and the highest rate of group D drugs (3.7%) was observed in the first trimester. [18]
In a study conducted in Pakistan, (3769) pregnant women, according to the statistics of this study, the most prescribed drugs for pregnant women, vitamins and minerals (79.4%), analgesics (6.2%), antacids (1.2%), Antihistamines (0.6%), antihypertensive drugs and vomiting (1.5%). [6]
Drug use during pregnancy also varies in other countries, such as Italy (70%) [9], Hungary (70%) [5], USA (64%) [12], Denmark (42%) [15], France (93%) [3] and Norway (57%) [8] Women use the drug during pregnancy. Consumption of group D drugs also varies in different countries, such as in the United States (4.8%), France (95%), Italy (2%) and Canada (7.3%), women during pregnancy use this group of drugs have done. Group X drugs have also been reported in the United States (4.6%), France (1.6%) and Italy (1%). The most prescribed drugs in Italy are antibiotics, analgesics and drugs affecting the digestive system. The most prescribed drugs in the United States and China are antibiotics, but in France, the most prescribed drugs are drugs that affect the system. Digestion has been observed.

2. OBJECTIVES AND METHODS

The main purpose of this study is to examine the rate of drug use during pregnancy in Kabul, during the 4 months of 2021 and compare it with the categories of the Food and Drug Administration (FDA). In this study, the required information was collected from prescriptions of patients (pregnant women) by filling out a questionnaire.

2.1 Design study

This research is a descriptive cross-sectional study. In this research, the required information was obtained from 34 health centers in Kabul city during 4 months (April 15 to August 15) by filling out questionnaires. The questionnaire was divided into 4

sections (demographic information, health information, information about pregnancy and information about drug use).

2.2 Analysis

In this study, data was collected from (612) pregnant women, the data entry process was done through Excel program and after completing the data entry, it was analyzed by Excel programs and IBM SPSS statistics. 26 done. To provide graphs and charts from Excel and IBM SPSS statistics. 26 have been used.

2.3 Ethical considerations

All ethical issues are done during this research and after the completion of the study and the confidentiality of the participants' data is guaranteed.

3. Results

3.1 Assessments of general demographic information

3.1.1 Age: In this study, (612) pregnant women participated, of which (194) pregnant women were in the age range of 20 to 30 years, (247) pregnant women were between 31 to 40 years old and (171) pregnant women were between 41 to 50 years old. The maximum number of participants in this study is between 31 and 40 years old. Table (1) provides information on the age of pregnant women:

Table (1): Age information

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	20 - 30	194	31.7	31.7	31.7
	31-40	247	40.4	40.4	72.1
	41-50	171	27.9	27.9	100.0
	Total	612	100.0	100.0	

3.1.2 Education level: Among the (612) pregnant women participating in this study, (117) pregnant women are illiterate, (161) pregnant women have primary education, (140) pregnant women have secondary education, (120) pregnant women are students and 74 pregnant women are graduates. Most of the participants in the study were illiterate and the least number of participants were university graduates. Table (2) provides information on the educational level of the participants:

Table (2): Education level information

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Illiterate	117	19.1	19.1	19.1
	Primary	161	26.3	26.3	45.4
	Secondary	140	22.9	22.9	68.3
	University	120	19.6	19.6	87.9
	Postgraduate	74	12.1	12.1	100.0
	Total	612	100.0	100.0	

3.1.3 Occupation: Out of (612) participants, (333) pregnant women are housewives, (42) pregnant women are students, (88) pregnant women are Health related career employee and (149) pregnant women perform other duties. Among these, the highest

number of participants was housewives and the lowest number of participants was students. The details of the participants' duties are listed in Table (3).

Table (3): Occupation information					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Housewife	333	54.4	54.4	54.4
	student	42	6.9	6.9	61.3
	Health related career employee	88	14.4	14.4	75.7
	Other employee	149	24.3	24.3	100.0
	Total	612	100.0	100.0	

3.2 Assessments of pregnancy information

3.2.1 Trimester: Of the (612) pregnant women participating in the study, (223) were pregnant in the first trimester, (197) were pregnant in the second trimester, and (192) were pregnant in the third trimester. Most participants were in the first trimester. Table (4) presents the details of the participants related to the trimester:

Table (4): Trimester information					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	First trimester	223	36.4	36.4	36.4
	Second trimester	197	32.2	32.2	68.6
	third trimester	192	31.4	31.4	100.0
	Total	612	100.0	100.0	

3.2.2 Parity: Among the (612) pregnant women participating in the study, (128) pregnant women were having their first pregnancy, (409) pregnant women had 1 - 3 previous children, and (75) pregnant women had more than 3 children. Table (5) lists the parity characteristics of pregnant women:

Table (5): Parity information					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	First time	128	20.9	20.9	20.9
	1 - 3 previous children	409	66.8	66.8	87.7
	More than 3 previous children	75	12.3	12.3	100.0
	Total	612	100.0	100.0	

3.2.3 PAC (Previous Abnormal Children): Out of (612) pregnant women participating in the study, 35 pregnant women had experienced PAC, but (577) pregnant women did not have PAC experience. Table (6) lists the PAC specifications:

Table (6): PAC information					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Yes	35	5.7	5.7	5.7
	No	577	94.3	94.3	100.0
	Total	612	100.0	100.0	

3.3 Assessments of Medicines prescription information

3.3.1 Health Services: Out of (612) pregnant women, (454) pregnant women referred to private health centers and (158) pregnant women referred to government health centers in Kabul. Details of services for referring to health centers are listed in Table (7):

Table (7): Health services information

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Private	454	74.2	74.2	74.2
	Government	158	25.8	25.8	100.0
	Total	612	100.0	100.0	

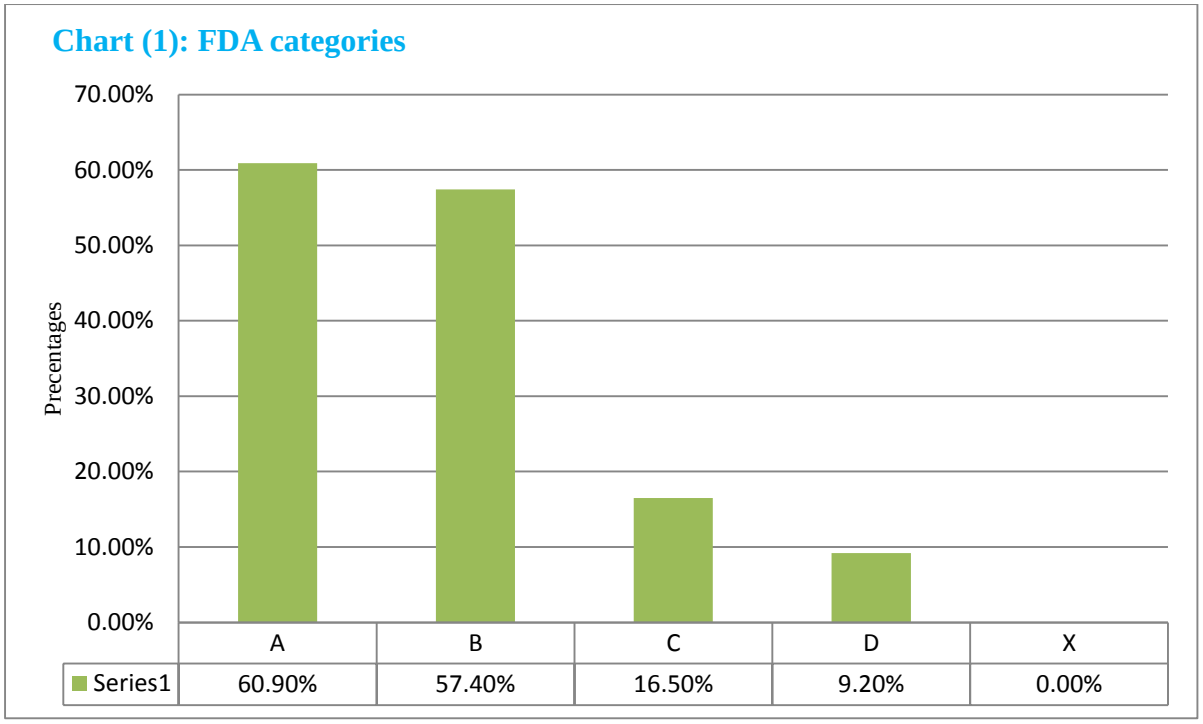
3.3.2 Generic name prescription: Also in this study, (612) prescriptions of pregnant women were evaluated. The number of drugs prescribed in the prescriptions was also specified as generic.

Of the (128) prescriptions, no generic drugs were prescribed. In (82) prescriptions, use one generic name, in (158) prescriptions use 2 drugs called generic, in (106) prescriptions, use only 3 generic names, in (67) prescriptions, use 4 generic names and still in (35) and (36) prescriptions, respectively, five and more than Five drugs called generic have been prescribed. Table (8) lists the specifications of the number of prescribed drugs called generic:

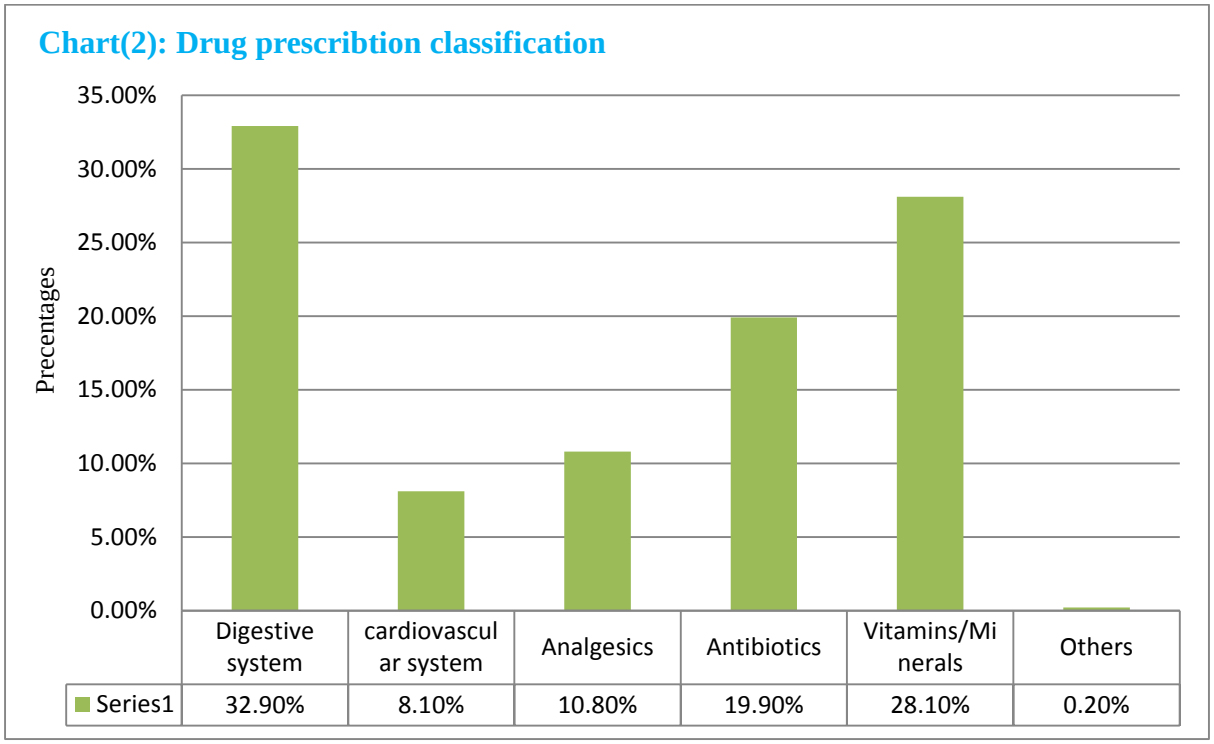
Table (8): Drug prescribed in generic name information

	Quantity	Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Zero	128	20.9	20.9	20.9
	One	82	13.4	13.4	34.3
	Two	158	25.8	25.8	60.1
	Three	106	17.3	17.3	77.5
	Four	67	10.9	10.9	88.4
	Five	35	5.7	5.7	94.1
	More than five	36	5.9	5.9	100.0
	Total	612	100.0	100.0	

Also in this study, (60.90%) of the prescribed drugs were in group A, (57.40%) in group B, (16.50%) in group C, (9.20%) in group D and (0.00%) in group X. Most of the prescribed drugs are in category A and the least prescribed drugs are in group X. Chart (1) of FDA drug categories in this study is presented:



In this study, drugs prescribed in different body systems have also been evaluated. The most prescribed drugs were in the digestive system (32.90%), cardiovascular system (8.10%), analgesics (10.80%), antibiotics (19.90%), vitamins-minerals (28.10%) and others, prescribed drugs (0.20 %) have been prescribed to pregnant women in Kabul, Afghanistan.



4. DISCUSSION

According to this study, a total of about (2107) drugs have been prescribed to (612) pregnant women during four months in Kabul health centers. The average of medication for pregnant women in this study was (3.44), which is lower than the average dose of medication prescribed in India (4.66) and higher than the standard of the World Health Organization (2.00).

In this study, the highest age of participants was in the range of (31 to 40 years), in a similar study in Saudi Arabia, the highest number of participants was in the range of 30 to 40 years (44.7%). In a similar study in India, most participants were between 21 and 25 years old (52.04%).

In this study, most participants had a primary education level, but in a similar study in Saudi Arabia, the most participants (65.8%), were students. Afghanistan is a developing country that, due to poor economic, cultural and security conditions, has prevented women from continuing their education.

In this study, most of the participants were housewives. In a similar study in Saudi (81.8%), the participants were housewives. In this study, most participants had the experience of giving birth to a baby, but in a similar study in Canada (39.20%) of the participants had the experience of giving birth to a baby. Afghanistan is a traditional country and intermittent births are often not considered important.

In this study, (5.7%) of the participants had a history of birth defects, in a similar study in Saudi Arabia (6.6%) of the participants in the study had a history of birth defects. The majority of participants in this study were referred to private health centers, because health services in public health centers are not appropriate and effective. Lack of health and medical supplies, large number of patients, low number of health workers and lack of government budget have caused the quality of public health centers to decline.

In this study, (128) unnamed generic prescriptions were prescribed. In a similar study in India, (38%) of generic drugs were prescribed to pregnant women, but the standard scale of the World Health Organization is (100%). Lack of public awareness of generic prescriptions and the market of pharmaceutical and commercial markets has led some doctors in Kabul (Afghanistan) to prescribe brand names in prescriptions.

In this study, the most prescribed drugs were in category A, so that in a similar study, Iran and India were the most prescribed drugs in category B. Category D drugs have also been prescribed in Kabul, this amount (9.20%) was lower than France, (95%), but was higher in countries such as India, the United States, Italy and Canada. The main reason is the lack of knowledge and experience of the doctor when prescribing the drug in Kabul, Afghanistan.

The most prescribed drug in this study is the drug affecting the digestive system. In similar studies in countries such as India and Iran, the most prescribed drug is the drug affecting the digestive system. The rate of antibiotics prescribed in this study was lower than in India and higher than in Saudi Arabia, but lower than the WHO standard

(30%). Vitamins and minerals in this study are the second group prescribed to pregnant women in terms of digestive drugs, which is lower than Pakistan (79.4%) and higher than Arab and Indian countries, (13.2). %) and (14.92%) respectively.

5. CONCLUSION

Irrational use of drugs in different countries is considered a major problem. This problem leads to dangerous effects on consumer body. Taking medication during pregnancy is of particular importance and requires expert advice. Arbitrary use of the drug without consulting a specialist can lead to dangerous effects on the mother and baby. In this study, group D drugs were also prescribed to pregnant women, which can have dangerous effects on pregnant women. Also, the number of drugs prescribed for pregnant women is more than the standards of the WHO, and not prescribing a drug called generic can affect the irrational use of the drug.

Research Limitations

- Outbreak of coronavirus in the country
- Patients' lack of interest in participating in research
- Lack of accurate statistics on drug use in pregnancy the country
- Arbitrary use of the drug in pregnant women without consulting a doctor or a Pharmacist.

Future study direction: The statistics obtained from this research can be used in the future and used to improve prescribing in health centers.

Contributions: In this research, the members of the research committee of Cheragh Institute of Higher Medical Education have taken an active part in all parts of the research equally.

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Conflict interest: None

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