LEVEL OF COMPLIANCE AMONG DIABETIC AND HYPERTENSIVE PATIENTS AND AFFECTING FACTORS IN AL-MADINA, KINGDOM OF SAUDI ARABIA.

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Abstract

Introduction:- Chronic disease, such as diabetes mellitus and hypertension, is a condition that requires compliance to health care provider's recommendations to be under control. When a chronic disease is inadequately managed, the condition may worsen.

Objectives:- To determine the level of compliance among diabetic and hypertensive patients and the factors affecting their compliance.

Methods:- A cross sectional analytic study was conducted and included diabetic and hypertensive patients participated in the campaign (Your Health is Your Life VI) held in Al-Medina. Data collected by administering a questionnaire and measuring glycosylated hemoglobin and blood pressure for all participants.

Results:- Among 104 participants included in this study the level of compliance was 47.1% to regular follow-up, 53.8% to medications, 66.3% to doctor's advice on diet and 62.5% on exercise. Urban participants have a higher percentage in compliance to regular follow-up and medications compared to rural. The age above 41 years associated with better compliance to advice on diet. Participants with both diabetes and hypertension and those managed by pills have better compliance to other medications. An excellent patient-doctor relationship, feeling satisfied after each visit and good information about health state associate with good compliance to regular follow-up and doctor's advice on diet and exercise. The forgetfulness was the cause of non-compliance in more than half of participants.

Conclusion:- The compliance was good among almost half of the participants and it was significantly associated with good patient-doctor relationship. The most affecting factors was related to the presence of co-morbidities and type of prescribed medications.

Introduction:-
Diabetes mellitus and hypertension are chronic diseases that required compliance to management and regular follow up to control the disease and prevent complications. World health organization defined compliance as "the extent to which a person's taking medication behavior, following a diet and/or executing life style changes, corresponds with agreed recommendations from health care providers"(1).
Hypertension and diabetes mellitus are common diseases worldwide (2). Hypertension is defined as persistent elevation of systolic blood pressure (SBP) ≥ 140 mm Hg and/or diastolic blood pressure (DBP) ≥ 90 mm Hg based on at least two readings on separate occasions in adults who are not on antihypertensive medications (3). Chronically, this elevation is associated with a higher risk of renal, cardiac, and brain damage, as well as with other diseases (4). Worldwide, it is estimated to cause 7.5 million deaths, about 12.8% of the total of all deaths (5). A study on about 17,230 of Saudi population showed that the prevalence of hypertension in Kingdom of Saudi Arabia is about 26.1% (6). The prevalence of hypertension is projected in year 2025 to increase by 24% in developed countries and 80% in developing countries (7).

Diabetes mellitus (DM) is a chronic progressive metabolic disorder characterized by hyperglycemia mainly due to absolute (Type 1 DM) or relative (Type 2 DM) deficiency of insulin hormone. DM virtually affects every system of the body mainly due to metabolic disturbances caused by hyperglycemia, especially if diabetes control over a period of time proves to be suboptimal (8).

Diabetes is associated with complications such as cardiovascular diseases, nephropathy, retinopathy and neuropathy, which can lead to chronic morbidities and mortality (9,10). Saudi Arabia has the second highest rate of diabetes in the Middle East and is seventh highest in the world, according to the World Health Organization. Prevalence of diabetes in Saudi Arabia among adults (20-79 years) at 2014 is 20.5% (11).

When a chronic illness is inadequately managed, the condition may worsen (12). Non-compliant patients are those whose health-seeking or maintenance behaviors lack congruence with the recommendations prescribed by a healthcare provider (13). Patient non-compliance is a serious healthcare concern that poses a great challenge to the successful delivery of healthcare. This is widespread and has been reported from all over the world (14).

Factors most often cited as contributing significantly to compliance are the nature of the patient-provider interaction, specific psychological and social characteristics of the patient, and the amount and type of support given the patient in his or her environment (15). Other many factors can affect general compliance as: misunderstanding of prescribed instructions, frequent changes to drug regimens, multiple health care providers prescribing medications, limited faith in the medications, forgetfulness, physical difficulties limiting access to or use of medication, limited education about the illness or the need for medication, few symptoms, chronic illness, a complicated regimen, polypharmacy (use of multiple medications for the treatment of a patient's medical conditions), cost of drugs, and real or perceived adverse drug reactions (16).

This topic in spite of its importance, is not well understood in our country.

**Objectives:**
1. To determine the level of compliance among diabetic and hypertensive patients.
2. To determine the factors affecting their compliance.

**Methodology:**

**Study design and participants:**
Cross-sectional analytical study was conducted and included 104 participants previously diagnosed with diabetes mellitus and/or hypertension during the event of “Your Health is Your Life Fourth Campaign” in the period from 8/6/2015 till 14/6/2015 for seven days, which was organized by Taibah Medical Club, Madinah, Saudi Arabia. It was conducted at the main place of the campaign "Al-Rashid Mega Mall, Madina" as well as through scheduled visits to some governmental agencies such as Al Madinah branch of Ministry of Education, Al Madinah branch of Ministerial agency of civil affairs, Al Madinah branch of directorate general of passports and Al Madinah branch of ministry of labor.

The study was designed to assess the level of compliance among patients with hypertension and/or diabetes mellitus and affecting factors. The participants were selected based on inclusion and exclusion criteria which include people who were previously diagnosed with hypertension and/or diabetes mellitus in a health clinic by a physician at least 6 months ago and on prescribed medications. Age of participants should be 18 years or more. The study excluded participants who have recently diagnosed with hypertension and/or diabetes mellitus for less than 6 months, gestational diabetes or less than 18 years old.
Data collection:-
A self-administered questionnaire form "papers" has been developed to assess the level of compliance and affecting factors. The questionnaire was translated into Arabic and was pretested. It included sections on socio-demographic data (age, gender, occupation, marital status, level of education, income level and residency) and data about patients' chronic diseases and the prescribed medications. Also, it was containing questions to assess their level of compliance regarding to regular follow up, adherence to treatments and following doctor's advices on diet and exercise as well as patient-doctor relationship.

The patient was considered to be compliant to regular follow up if had not missed more than one appointment in the last one year. Medications non-compliance was defined as missing two or more doses of medications over a period of 7 days prior to the date of study. Compliance to doctor's advices on diet and exercise determined by asking the patient if he following the doctor's advice on it.

The questionnaire is sub-structured with the measurements of blood pressure and glycosylated hemoglobin (HA1C) for all participants. Blood pressure and glycosylated hemoglobin was measured to determine the level of control. Control of hypertension was defined as systolic blood pressure <140 mmHg and diastolic blood pressure <90 mmHg. Participating diabetic patients were divided into two groups: patients with HbA1c of 7% or more and those with less than 7%. This classification was based on the American Diabetes Association (ADA) guidelines. Blood pressure was measured using both mercury sphygmomanometer and Welch Allyn electronic sphygmomanometer with appropriate cuff sizes and at least 2 measurements after 5 minutes rest. Glycosylated hemoglobin was measured by using kits of A1cNow from Bayer.

Data analysis:-
Data were analysed by using Statistical Package for Social Science Software (SPSS) version 18. Association between the level of compliance (to regular follow up, medications and doctor's advice on diet and exercise) and independent variables related to patients, diseases, medications characteristics and patient-doctor relationship were determined by using Chi-square and Fisher's exact tests. Statistical significance was set at P value <0.05.

Ethical consideration:-
The study had an approval from research and human ethics committee in Taibah University. The participants were informed about the objectives of the study and confidentiality of the data. Verbal consent was obtained from all the subjects and they participated voluntarily in the study.

Results:-
A total number of 104 participants included in this study, thirty four of them had both diabetes mellitus and hypertension (32.69%), fifty of them had diabetes mellitus only(48.08%), and twenty of them had hypertension only (19.23%).

Regarding regularity of follow up 41.3% of participants (n=43) had not missed any appointment in the last one year, while 5.8% (n=6) had missed an appointment once, 31.7% (n=33) twice, and 21.2 % (n=22) more than twice. The reason for missed appointment was no time among 26%, 9.6% forgetfulness, 9.6% no need for attend (neglecting), 7.7% difficulty in transport and financial problems and 4.8% due to travel.

According to medication compliance 32.69% (n=34) had not missed their medications in the last one week, 21.15% (n=22) had missed their medications once and 46.15% (n=48) twice and more.

The forgetfulness was the cause of non-compliance in more than half of participants. Theparticipants also reported other causes such as multiple-medications (14.3%), change time of sleeping (14.3), limited faith in the medications (8.2%) and lack of symptoms (6.1%).

66.3% of participantes (n=69) said that they are following doctor's advice on diet and 62.5% (n=65) on exercise.

There were statistically significant differences (p<0.05) in compliance to regular follow up and medications between participants regarding to residency. The urban participants had a higher percentage in compliance to regular follow
up (51.60%) comparing to rural participants (15.40%). The compliance to medications among urban participants was (58.20%) while (23.10%) among rural participants.

**Table 1**: Socio-demographic Data of the participants.

| Variable             | Percentage (no) |
|----------------------|-----------------|
| **Age:**             |                 |
| 18-30                | 15.40%(16)      |
| 31-40                | 21.20%(22)      |
| 41-50                | 31.70%(33)      |
| More than 50         | 31.70%(33)      |
| **Gender:**          |                 |
| Male                 | 53.80%(56)      |
| Female               | 46.20%(48)      |
| **Occupation:**      |                 |
| Student              | 7.70%(8)        |
| Unemployed           | 44.20%(46)      |
| Administrative       | 23.10%(24)      |
| Teacher              | 11.50%(12)      |
| Military             | 10.60%(11)      |
| Engineer             | 1.90%(2)        |
| Doctor               | 1.00%(1)        |
| **Educational Level:** |               |
| Illiterate           | 10.60%(11)      |
| Primary              | 10.60%(11)      |
| Intermediate School  | 15.40%(16)      |
| High School          | 31.70%(33)      |
| Higher Education     | 31.70%(33)      |
| **Residence:**       |                 |
| Urban                | 98.08%(102)     |
| Rural                | 1.92%(2)        |

There was statistically significant difference (p<0.05) in compliance to doctor's advice on diet regarding to age. Patients between 41 and 50 years old had highest percentage in compliance to doctor's advice on diet (78.80%) followed by those above 50 years old (75.80%) then those between 18 and 30 years (50.00%) and lastly participants between 31 and 40 (45.50%). Other socio-demographic factors discussed in our study showed no statistically significant differences.

The compliance to medications was better among those had both diabetes mellitus and hypertension (64.70%) followed by those had diabetes mellitus only (58.00%) and lastly those had hypertension only (25.00%). Among the hypertensive participants with good compliance to regular follow up and medications 77.3% and 81.5%, respectively, had controlled blood pressure (<140/90 mmHg). Among the diabetic participants with good compliance to regular follow up and medications (40.5%) and (37.3%) respectively, achieved the target level of glycemic control (HA1C <7%).

Table 2, 3, 4 & 5 show that there were statistically significant differences between participants in compliance to regular follow up and doctor's advice on diet and exercise regarding patient doctor relationship. Participants who said that the doctor versed about their health state and give them enough information about it had a higher percentage in compliance to regular follow up (54.90%) (52.30%) respectively as well as in compliance to doctor's advices on diet (74.4%) (81%) and exercise (67.10%) (68.60%) respectively. Participants with excellent relationship with their doctor and feel satisfied after each visit had better compliance to regular follow up (62.50%) (60.30%) respectively, and to doctor's advices on diet (79.7%) (81%) and exercise (71.9%) (79.4%) respectively. When doctor answer about all patients' questions regarding their health state and disease they complying more to his advices on diet (72.7%) and exercise (67%). The compliance to medications shows no significant association with patient doctor relationship.
Table 6 shows that there was statically significant association between type of diabetic medications and patient’s compliance to medications. Patients on pills only had higher percentage in compliance (84.8%) in comparing to those with insulin (48.7%) or both insulin and pills (33.3%). Other characters of prescribed medications show no significant association with compliance.

**Table 2:** Association between level of compliance to regular follow up and patient doctor relationship.

|                          | Compliance | Non-compliance | P value |
|--------------------------|------------|----------------|--------|
| Do you think your doctor is versed about your health state? |            |                | *0.002 |
| • Yes                    | 54.90%(45) | 45.10%(37)     |        |
| • No                     | 18.20%(4)  | 81.80%(18)     |        |
| How is your relationship with your doctor?               |            |                | *<0.001|
| • Excellent              | 62.50%(40) | 37.50%(24)     |        |
| • Medium                 | 21.90%(7)  | 78.10%(25)     |        |
| • Bad                    | 25.00%(2)  | 75.00%(6)      |        |
| Do you feel satisfied after each visit?                   |            |                | *0.004 |
| • Always                 | 60.30%(38) | 39.70%(25)     |        |
| • Sometimes              | 28.60%(8)  | 71.40%(20)     |        |
| • Never                  | 23.10%(3)  | 76.90%(10)     |        |
| Does your doctor give you enough information about your health state? |            |                | *0.02  |
| • Yes                    | 52.30%(45) | 47.70%(41)     |        |
| • No                     | 22.20%(4)  | 77.80%(14)     |        |
| Does your doctor answer you about all your question about your health and diseases? | | | 0.054 |
| • Yes                    | 51.10%(45) | 84.90%(43)     |        |
| • No                     | 25.00%(4)  | 75.00%(12)     |        |

**Table 3:** Association between level of compliance to medications and patient doctor relationship.

|                          | Compliance | Non-compliance | P value |
|--------------------------|------------|----------------|--------|
| Do you think your doctor is versed about your health state? |            |                | 0.684  |
| • Yes                    | 54.90%(45) | 45.10%(37)     |        |
| • No                     | 50.00%(11) | 50.00%(11)     |        |
| How is your relationship with your doctor?               |            |                | 0.583  |
| • Excellent              | 57.80(37)  | 42.20%(27)     |        |
| • Medium                 | 46.90%(15) | 53.10%(17)     |        |
| • Bad                    | 50.00%(4)  | 50.00%(4)      |        |
| Do you feel satisfied after each visit?                   |            |                | 0.374  |
| • Always                 | 58.7%(37)  | 41.30%(26)     |        |
| • Sometimes              | 42.90%(12) | 57.10%(16)     |        |
| • Never                  | 53.80%(7)  | 46.20%(6)      |        |
| Does your doctor educate you very well about your diseases |            |                | 0.719  |
| • Yes                    | 54.70%(47) | 45.30%(39)     |        |
| • No                     | 50.00%(9)  | 50.00%(9)      |        |
| Does your doctor answer you about all your question about your health and diseases? | | | 0.834 |
| • Yes                    | 53.40%(47) | 46.60%(41)     |        |
| • No                     | 56.20%(9)  | 43.80(7)       |        |
Table 4: Association between level of compliance to doctor's advices on diet and patient doctor relationship.

|                                | Compliance | Non-compliance | P value |
|--------------------------------|------------|----------------|---------|
| Do you think your doctor is versed about your health state? |            |                |         |
| Yes                            | 74.40%(61) | 25.60%(21)     | *.001   |
| No                             | 36.40%(8)  | 63.60%(14)     |         |
| How is your relationship with your doctor?                      |            |                |         |
| Excellent                      | 79.70%(51) | 20.30%(13)     | *.001   |
| Medium                         | 50.00%(16) | 50.00%(16)     |         |
| Bad                            | 25.00%(2)  | 75%(6)         |         |
| Do you feel satisfied after each visit?                        |            |                |         |
| Always                        | 81.00%(51) | 19.00%(12)     | <.001   |
| Sometimes                     | 50.00%(14) | 50.00%(14)     |         |
| Never                         | 30.80%(4)  | 69.20%(9)      |         |
| Does your doctor educate you very well about your diseases      |            |                |         |
| Yes                           | 74.40%(64) | 25.060%(22)    | *.01    |
| No                            | 27.80%(5)  | 72.20%(13)     |         |
| Does your doctor answer you about all your question about your health and diseases? |            |                |         |
| Yes                           | 72.70%(64) | 27.30%(24)     | *.001   |
| No                            | 31.20%(5)  | 68.80%(11)     |         |

Table 5: Association between level of compliance to doctor's advices on exercise and patient doctor relationship.

|                                | Compliance | Non-compliance | P value |
|--------------------------------|------------|----------------|---------|
| Do you think your doctor is versed about your health state? |            |                |         |
| Yes                            | 67.10%(55) | 32.90%(27)     | *.063   |
| No                             | 45.50%(10) | 54.50%(12)     |         |
| How is your relationship with your doctor?                      |            |                |         |
| Excellent                      | 71.90%(46) | 28.10%(18)     | *.009   |
| Medium                         | 40.60%(13) | 59.40%(19)     |         |
| Bad                            | 75.00%(6)  | 25.00%(2)      |         |
| Do you feel satisfied after each visit?                        |            |                |         |
| Always                        | 79.40%(50) | 20.60%(13)     | <.001   |
| Sometimes                     | 35.70%(10) | 64.30%(18)     |         |
| Never                         | 38.50%(5)  | 61.50%(8)      |         |
| Does your doctor educate you very well about your diseases      |            |                |         |
| Yes                           | 68.60%(59) | 31.40%(27)     | *.005   |
| No                            | 33.30%(6)  | 66.70%(12)     |         |
| Does your doctor answer you about all your question about your health and diseases? |            |                |         |
| Yes                           | 67.00%(59) | 33.00%(29)     | *.025   |
| No                            | 37.50%(6)  | 62.50%(10)     |         |
Table 6: Association between level of compliance to medications and characters of prescribed medications.

|                      | Compliance     | Non-compliance | P value |
|----------------------|----------------|----------------|---------|
| **Type of medications** (Diabetic patients) |                |                |         |
| • Insulin            | 48.70%(19)     | 51.30%(20)     | *0.001  |
| • Pills              | 84.80%(28)     | 15.20%(5)      |         |
| • Both insulin & pills | 33.3%(4)      | 66.70%(8)      |         |
| **Numbers of medications** |            |                |         |
| • One                | 52.40%(22)     | 47.60%(20)     |         |
| • Two                | 48.40%(15)     | 51.60%(16)     | 0.41    |
| • Three              | 62.50%(10)     | 37.50%(6)      |         |
| • Four               | 58.30%(7)      | 41.70%(5)      |         |
| • Five               | 100%(2)        | 0%(0)          |         |
| • Six                | 0%(0)          | 100%(1)        |         |
| **Frequency of taking medications** |            |                |         |
| • Once               | 47.40%(9)      | 52.60%(10)     |         |
| • Twice              | 52.80%(28)     | 47.20%(25)     | .864    |
| • Three times        | 59.30%(16)     | 40.70%(11)     |         |
| • Four times         | 60.0%(3)       | 40.00%(2)      |         |

**Discussion:**
There is strong evidence that many patients with chronic disease including diabetes mellitus and hypertension have difficulty in compliance to their recommended regimens. This results in suboptimal management and control of the disease. Poor compliance is the primary reason for suboptimal clinical benefit. It causes medical and psychosocial complications of disease, reduces patients' quality of life, and wastes health care resources (1).

For that we focused in this problem and we study the compliance with regular follow up, medications and doctor's advices on diet and exercise.

Compliance with regular follow up was very higher in our study than the earlier findings in Al Hasa district of Saudi Arabia (17) that included diabetic patients. Our results showed that 41.3% of participants had not missed any appointment in the last one year, while 5.8% had missed an appointment once, 31.7% twice and 21.2% more than twice. However, in Al Hasa was found to be 7.9% had not missed an appointment in the last one year, while 49.4% had missed an appointment once or twice, and 41% more than twice. In other study conducted in primary health center in Saudi Arabia the non-compliance to regular follow up was 25% which is lower than our finding (52.9%).

The non-compliance with medication in our study was 46.15% of participants which was higher than the results of study conducted in Uganda (28.9%). However, our finding was lower than earlier findings in Palestine (19), Hong Kong (20), Mexico (21), Al Hasa district(17) and India(22)where it was found to be 57.9%, 59%, 61%, 57.5% and 76.3% respectively.

Regarding doctor's advices on diet 66.3% of participants in our study was complying which is approximately similar to Al Hasa study (64.66%), lower than results of study conducted in Alexandria (23), Egypt, which was 94.3% and higher than that in PHC in Saudi Arabia which was 40%. However, in Alexandria study compliance was divided into two categories (92.1% sometimes compliance with diet and 2.2% always compliance). Compliance to doctor's advice on exercise in our results was 62.5% while in Alexandria only 2.8%, in Al Hasa 45.33% and in other study held at India was 37.03%. (24)

There was a statistically significant difference in the compliance to regular follow up and medications regarding residency among the diabetic and hypertensive participants in our study. The compliance to regular follow up in the urban population was significantly higher than the rural population (51.60 vs 15.40). And also the compliance to medications in the urban population was significantly higher than rural population (58.20% vs 23.10%). In contrast, study done in the Al Hasa have shown that rural participants have better compliance than urban participants (39.85 vs 28.96). We suggest that the lower level of compliance among rural people related to low socio-economic status and educational level and difficulty in access to health services.
There was a statistically significant difference in compliance to doctor's advices on diet regarding to age in our study. Patients above 41 years old have highest percentage in compliance to doctor's advice on diet (78.80%). In contrast, studies done in Abha have shown that young patients less than 40 years old have highest percentage in compliance to doctor's advice on diet. (25)

Our study shows higher rates of non-compliance to medication among patients who managed by both insulin and pills (66.70%) followed by those managed by insulin only (51.30%) and the least rate of non-compliance to medication among patients who managed by pills (15.20%).

The high non-compliance rate among patient taking insulin agrees with other studies that conducted in AL-Hasa district and Scotland which found to be 20.96%, 29% respectively. That maybe because taking pills is much easier and comfortable than insulin injections or multiple medications.

There was statistically significant difference between the participants in the level of compliance to medication regarding to the presence of the disease in our study. The patients who have both diabetes and hypertension have a higher percentage in compliance to medications (64.70%). The results of current study agree with a study conducted in USA in 2008 that reported the presence of comorbidities were associated with higher compliance to medications.

Patient doctor relationship found to be significantly associated with good compliance to regular follow up and doctor's advices on diet and exercise. Participants said that the doctor versed about their health state, give them enough information about it, have excellent relationship with their doctor and feel satisfied after each visit show better compliance. This is agreed with Alexandria study regarding to diet only. While other categories of compliance showed no statically significant difference. Also, that study conduct in Al Hasa district considers patient doctor relationship as an important factor affects the compliance.

Our study showing that patients not compliance to regular follow up and medication more likely to be poorly controlled (HA1c more than 7%). This is proved by a study published in 2014 at AlQasim, Saudi Arabia (26) as there was statically significant difference in compliance to regular follow up and medication regarding to glycemic control.

**Conclusion:-**
The compliance was good among almost half of the participants. The most affecting factors was related to the presence of co-morbidities and type of prescribed medications. In addition, there was significant association between compliance and patient-doctor relationship. So, more effort should be provided to enhance the patient-doctor relationship to improve level of compliance among chronic patients.

**Acknowledgment:-**
We would like to express our gratitude and appreciation to all those who gave us the possibility to complete this study. We are very grateful to Taibah Medical Club for arrangement of this campaign and providing us with the kits of HbA1c and sphygmomanometer. We also would like to acknowledge with much appreciation all TMC members for their crucial role in helping us in the collection of data. In addition, we are very grateful to the supervisor of our research Dr. Suliman Amer for his great efforts and encouragement.

**Competing interests:-**
Authors have declared that no competing interests exist.

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