

## **Use Pattern of Oral PDE-5 Inhibitors in Jeddah, Saudi Arabia**

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*Abstract.* This study was designed to investigate the use pattern of oral phosphodiesterase Type 5 inhibitors in Jeddah, SA. All participants (n = 500) above 18 years who sought oral phosphodiesterase type 5 inhibitors from community pharmacies were included in this study. Questionnaires were distributed to a 100 community pharmacies and a computer program was used for data analysis. Of the 500 distributed questionnaires, 337 were received (response rate 67.4%), it was found that 270 (80%) of the respondents had been taking anti-erectile dysfunction drugs without consultation with their doctors and 67 (20%) of respondents had been using their drugs after consultation. The majority of the respondents, 188 (55.7%) had been using phosphodiesterase Type 5 without any medical evidence of Erectile Dysfunction as indicated by themselves, which is statistically significant ( $p \leq 0.005$ ). It was found that 115 (34.1%) of the respondents were not aware of the side effects. The correlation between satisfaction of sexual performance before and after using is ( $\rho = 0.516$ ) and is highly significant ( $p < 0.001$ ). There is an obvious misuse of oral phosphodiesterase type 5 inhibitors in the Jeddah community.

*Keywords:* Erectile dysfunction, Phosphodiesterase Type 5 inhibitors, Misuse, Abuse, Community pharmacy.

### **Introduction**

The prescription of drugs is one of the most important factors in the rising costs of health services in both developed and developing

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countries<sup>[1]</sup>. The lack of proven benefit, and the definite cost and side effects of many prescriptions, have been found in many studies<sup>[2]</sup>. There is a rapidly growing trend in the use of oral anti-erectile dysfunction drugs (AEDD) in Saudi Arabia among individuals without legal prescription or actual need as among people believing in myth. However, there is a lack of information regarding this topic.

Male erectile dysfunction has been defined as the persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual performance. Although Erectile Dysfunction (ED) is a benign disorder, it is related to physical and psychosocial health, and has a significant impact on the quality of life of both sufferers and their partners and families<sup>[2]</sup>. Several modalities are used to treat ED including medications, erectile aids, surgery and counseling. This study focuses on phosphodiesterase Type 5 (PDE-5) inhibitors, which are the first line of treatment for most men with ED. They have revolutionized the treatment of ED since the introduction of sildenafil in 1998<sup>[3,4]</sup>, and experts observed that these medications have significantly affected (both positively and negatively) the sexual culture of people<sup>[3,5-7]</sup>. Three FDA approved PDE-5 inhibitors are currently available: sildenafil (Viagra<sup>®</sup>), tadalafil (Cialis<sup>®</sup>, Snafi<sup>®</sup>) and vardenafil (Levitra<sup>®</sup>). These medications inhibit cyclic guanosine Monophosphate phosphodiesterase 5 (cGMP PDE-5), thereby increasing cGMP levels and tipping the physiological balance in favor of erection<sup>[8]</sup>. However, there are many adverse effects associated with PDE-5 inhibitors therapy, which varies from simple to serious side effects. They may cause visual changes, headache disorders, flu-like symptoms, back pain, skin rashes, myocardial ischemia and death<sup>[9]</sup>. In July 2005, the FDA announced that some patients had lost sight in one eye after using AEDD as Viagra<sup>®</sup>, Tadalafil<sup>®</sup> and Verdenafil<sup>®</sup>. This type of vision loss is called non-arteritic anterior ischemic optic neuropathy (NAION). The FDA have now placed a black label on Viagra<sup>®</sup>, Tadalafil<sup>®</sup> and Verdenafil<sup>®</sup> warning of these side effects<sup>[10]</sup>.

The aim of this study is to investigate the pattern of use of oral PDE-5 inhibitors in the Jeddah community.

## Methods

All participants in this study were men above 18 years of age who sought oral PDE-5 inhibitor products from community pharmacies.

A two-page questionnaire was designed and divided into four sections; the first section was to determine the demographic characteristics of oral AEDD users. The second section was to detect the health state of the respondents. The third section was designed to ascertain the reasons for taking oral AEDD and the respondents' knowledge about these agents. The fourth section was used to determine the satisfaction status before and after using oral AEDD. The front page of the questionnaire was a letter marked with the logo of the Faculty of Pharmacy, King Abdulaziz University, which explained the purpose of the study and contained instructions for how to answer the questions. The questionnaire consisted of 28 checklist questions.

Jeddah, Saudi Arabia was divided into four areas Palestine Street (North and South) and Madinah Road East and West). 100 community pharmacies were randomly selected as follows: twenty-three community pharmacies from the South East side, twenty-three community pharmacies from the South West side, twenty-six community pharmacies from the North West side and twenty-eight community pharmacies from the North East side were selected for distribution. Each pharmacy received five copies of the questionnaire (Total of 500 questionnaires were distributed) and the participating pharmacist distributed them to the participants after taking their consent. Participants electively completed the questionnaire by themselves.

The study was conducted during a two week period from September 15, 2006 to October 1, 2006. A pilot study (20 questionnaires) was conducted one month prior to full distribution to detect any obstacles that may disturb the full distribution and these questionnaires were excluded from the study.

Responses to each question were coded individually and a computer program was designed for statistical evaluation using the Statistical Package for Social Sciences (SPSS) for Windows, Version 13. The analysis included frequency of response for each of the 28 variables. Results were compared using Chi-square test, one-way analysis of variance (ANOVA), Binomial test and "Student's" *t*-test. Correlations among variables were determined by Spearman rank correlation.

## Results

Of the 500 distributed questionnaires, 346 were returned (response rate 69.2%). Nine questionnaires were considered incomplete and thus excluded from the study leaving 337 (67.4%) for analysis. Respondents' demographics and characteristics are shown in Table 1, which shows that the majority of the respondents 193 (57.2%) were between the ages of 30-59 years, while 71 (21%) were between 60 and above, while 69 (20.4%) were between 18-29 years. Of the 337 respondents, it was found that the respondents who consulted medical doctors (80%) were found to be significantly ( $p \leq 0.001$ ) higher than those without medical consultation (20%). This was explained by feeling shy 103 (30.56%), doctors could not help them 17 (5%) and loss of trust 68 (20.17%). Of the 337 respondents, 127 (37.6%) of respondents had been taking their AEDD upon pharmacists' advice, 18 (5.3%) had been using their drugs upon consultation of their general medical doctors and 49 (14.5%) had been using their drugs upon consultation of their specialist, while 58 (17.2%) had been taking their drugs based upon advertisements and 77 (22.8%) had been taking their drugs upon friends' advice.

One hundred eighty-eight respondents (55.78%) indicated that they do not have any ED problems and 134 (39.76%) were with an ED problem. One-hundred ninety-seven (58.45%) of the respondents were taking AEDD because of their fears of sexual intercourse failure and 64 (32.48%) of them were taking more than one tablet per week which is statistically highly significant ( $p < 0.001$ ).

The majority of the respondents, 188 (55.7%) were using AEDD without any medical evidence of ED as indicated by them, which is statistically significant ( $p \leq 0.005$ ). One-hundred seventy-three (51.33%) of the respondents had been taking AEDD for more than one year and 191 (56.7%) of the respondents were using more than one of AEDD, alternatively. Figure 1 shows drugs that were commonly accessible for the respondents in community pharmacies during this study.

One hundred and fifteen (34.1%) of the respondents were not aware of the side effects of AEDD. One hundred and ninety-seven (58.5%) of the respondents indicated that they had advised their friends to use the same AEDD as they were using.

**Table 1. Demographic characteristics (n = 337).**

Variable	Number ( % )
<b>Sex</b>	
Men	337 (100%)
Woman	0 (0%)
<b>Age in years</b>	
18-20	20 (5.9%)
21-29	49 (14.5%)
30-39	56 (16.6%)
40-49	80 (23.7%)
50-59	57 (16.9%)
60-65	36 (10.7%)
66-69	19 (5.6%)
>70	16 (4.7%)
No answer	4 (1.2%)
<b>Education</b>	
Primary School	20 (5.9%)
Intermediate School	48 (14.2%)
High School	113 (33.5%)
University	138 (40.9%)
Non-educated	9 (2.7%)
No answer	9 (2.7%)
<b>Social Status</b>	
Married	289 (85.8%)
Single	34 (10.1%)
Divorced	5 (1.5%)
No answer	9 (2.7%)
<b>Socio-economic</b>	
< 1000 S.R monthly	24 (7.1%)
1000-5000 S.R	129 (38.3%)
5000-10000 S.R	85 (25.2%)
>10000 S.R	43 (12.8%)
No answer	56 (16.6%)

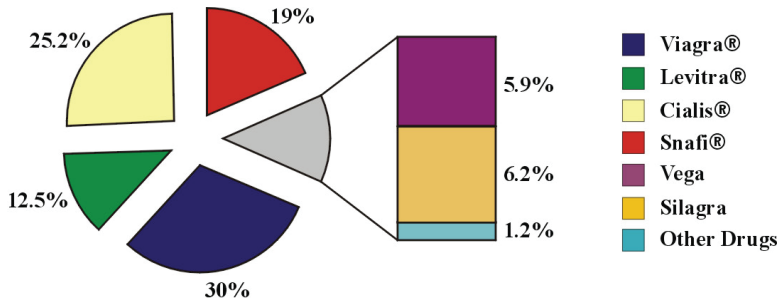


Fig. 1. Different products used by the participants during this study.

The most common co-morbidity diseases are shown in Fig. 2 and drugs that have been used chronically by the respondents are shown in Fig. 3.

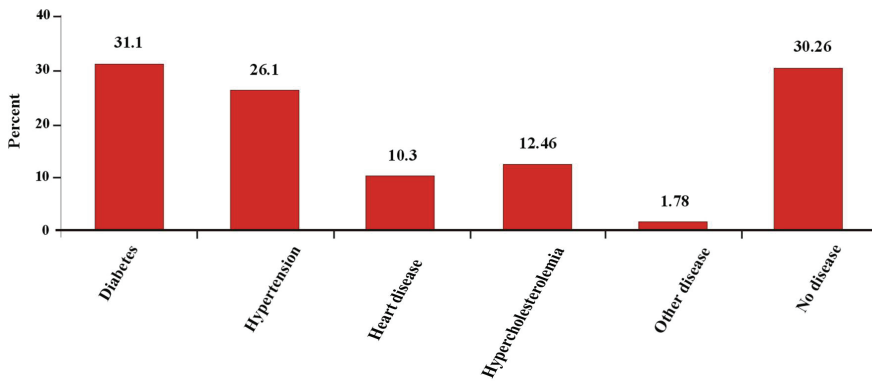


Fig. 2. The most common co-morbid diseases reported by the respondents.

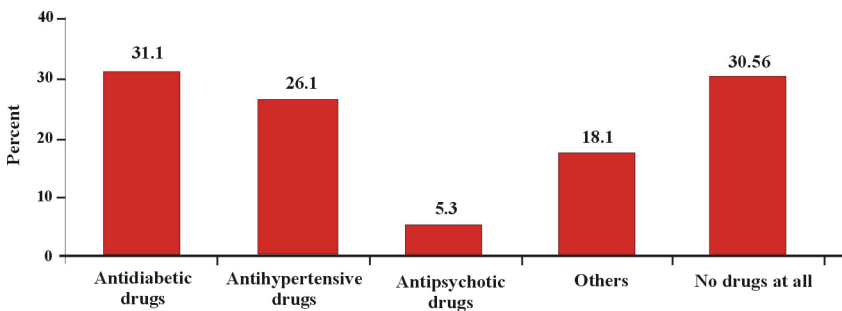
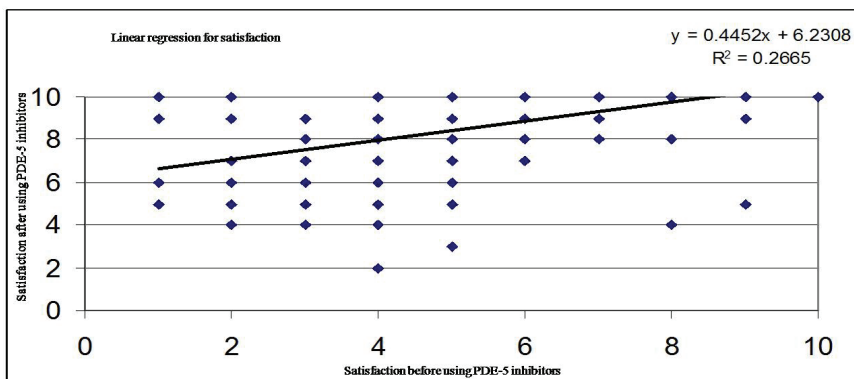


Fig. 3. The most common drugs used chronically by the respondents.

Respondent's satisfaction before and after using AEDD was measured on a one to ten scale, one is the minimum satisfaction and ten is the maximum satisfaction. The mean of satisfaction of sexual performance before using these drugs was 5.07 and the mean of satisfaction of sexual performance after using these drugs was 8.49 that are shown in Table 2 by using the linear regression analysis for satisfaction shown in Fig. 4. It was found that the correlation between satisfaction of sexual performance before using AEDD and after using them is equal to 0.516 and is highly significant ( $p < 0.001$ ).

**Table 2. Satisfaction before and after using (PDE-5) inhibitors products.**

Satisfaction of sexual performance	Mean	N	Std. deviation	Std. error mean	t	p-value	Sig.
Satisfaction of sexual performance before using these drugs	5.07	337	1.69	0.09	40.09	0.000	H. Sig
Satisfaction of sexual performance after using these drugs	8.49	337	1.46	0.08			



**Fig. 4. Linear regression for satisfaction.**

## Discussion

Erectile dysfunction is a worldwide major public health problem, but it is commonly under-diagnosed<sup>[11-13]</sup>. Recent epidemiological studies have shown a high prevalence and incidence of ED worldwide<sup>[14-17]</sup>. There are several factors that have negative feedback effect on normal

sexual performance and many people do not want to admit to poor sexual symptomatology. Discussing the issue of sexuality is very sensitive and personal in Saudi culture and tradition. Many people feel shy in talking about such a topic and others prefer to practice their sexual life even with personal suffering without expressing their problem or seeking medical consultation.

This study may be the first aimed at determining the pattern of use of AEDD in Jeddah, Saudi Arabia and the results may reveal some of the abuse of pharmacy practice in the community pharmacies. In addition, this study sought to identify reasons for the high consumption rate of AEDD and provide recommendations for improving the conventional use of these drugs.

The study paid special attention to the reasons for patients underreporting their ED and the barriers to seeking help from medical doctors. It was found that 103 (30.56%) were embarrassed to discuss their ED problem with their doctors, 68 (20.17%) do not trust their doctors and 17 (5%) thought that their doctors could not help them.

The level of education was not a key factor for AEDD use in this study. It was found that the majority 319 (94.65%) of the respondents were educated and only 9 (2.7%) were not educated. From the educated respondents 138 (40.9%) had university degrees. Commonly, the level of education helps people make the proper decision, however it was found that a significant number of the respondents 262 (77.74%) had their consultation from pharmacists, advertisements, and friends' advice, and only 67 (19.88%) had a medical consultation.

One hundred twenty-seven respondents (37.68%) bought their AEDD upon pharmacist's advice, which reflects the great trust the public has in community pharmacists but unfortunately the community pharmacists have abused this trust. Firstly, they are violating the law of pharmacy practice in Saudi Arabia by dispensing prescription drugs without authorized prescriptions and secondly, they dispense drugs without knowing the exact source of the problem or knowing the other co-administered drugs which may be the cause of ED or interact with the AEDD. In addition they may not consider the health status of users.

The psychological factor of ED is an important one. One hundred and ninety-seven (58.5%) of the respondents in this study, were taking



AEDD because of their fear of impotence, 64 (32.9%) of them were taking two to five tablets per week and 115 (34.1%) of all the respondents do not have any idea of the side effects of these drugs which highlights the hazardous use of these drugs and the low level of health "sex" education in the Jeddah's community.

There are many drugs that can induce ED as shown in (Table 3). In this study, 222 (65.87%) of the respondents were taking many drugs, which may be the cause of their ED problems including (thiazide diuretics, beta-blockers and others)<sup>[18]</sup>.

**Table 3. Medications associated with ED and alternative choices<sup>[13, 18]</sup>.**

Medication associated with ED	Alternative choices
<b>Antihypertensive</b>	
Beta-blockers Thiazide diuretics Hydralazine Methyldopa	ACE inhibitors Angiotensin receptor blockers Calcium channel blockers
<b>Diuretics</b>	
Thiazide diuretics Spironolactone	Furosemide (loop diuretics)
<b>Antidepressants</b>	
Selective serotonin reuptake inhibitors Tricyclic antidepressants Monoamine oxidase inhibitors	Bupropion Mirtazapine
<b>Antipsychotic agents</b>	
Phenothiazines Carbamazepine Risperidone	
<b>Miscellaneous agents found to be associated with ED</b>	
Allopurinol Indomethacin Disulfiram Phenothiazine antihistamines or antiemetics (prochlorperazine) Ketoconazole Niacin	

A major finding in this study is that there are several PDE-5 inhibitor products that are not registered with the Saudi Ministry of Health (MOH), but are available in the market such as Cilagra<sup>®</sup> and Viga<sup>®</sup>, and

are frequently dispensed by the community pharmacists. This reflects and demonstrates the poor control the MOH has on drug sales in the community pharmacies and the clear violation of pharmacy practice law and regulations.

Although all the respondents reported a highly significant satisfaction rate (mean = 8.49) after using their AEDD ( $p < 0.001$ ). The dangerous and the harmful effects that may occur from improper use of these drugs cannot be ignored<sup>[11]</sup>.

The prescription of drugs is one of the most important factors in the rising costs of health services in both developed and developing countries<sup>[1]</sup>. According to the Information Management System (IMS at 2006) database the total Saudi pharmaceutical market is about 5 billion Saudi Riyals per year and AEDD accounts for more than 232 million Saudi Riyals of this market of which 47.5% is solely in the Western Region of Saudi Arabia. This highlights the huge consumption rate of these drugs either prescribed (20%) or non-prescribed (80%).

A major limitation of this study is that participants were asked to fill the questionnaire by themselves and accordingly some questions may not have been clear for some of them, in addition, some answers were missing from the questionnaires.

## Conclusion

Undoubtedly, there is an obvious misuse of oral PDE-5 inhibitors in Jeddah's community. Furthermore, large-scale studies evaluating drug use control systems in accordance with Pharmacy Practice Law and Regulations are highly recommended.

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## تقييم نمط استخدام مثبطات الفوسفو داي استريز النوع الخامس الفموية في مدينة جدة، المملكة العربية السعودية

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المستخلص. إن الهدف من هذه الدراسة هو تحديد نمط استعمال مثبطات الفوسفو داي استريز النوع الخامس الفموية المعالجة لضعف عملية الانتصاب في مدينة جدة، المملكة العربية السعودية. كل الذكور فوق ١٨ سنة الذين دخلوا الصيدليات الخاصة لطلب مثبطات الفوسفو داي استريز النوع الخامس الفموية (عددهم = ٥٠٠) ضموا للدراسة. صمم الاستبيان من صفحتين، وقسم إلى أربعة أقسام، ووزعت على مائة صيدلية مجتمع. جميع الإجابات تم تحليلها باستخدام برنامج إحصائي حاسوبي خاص (إس بي إس إس) النسخة (١٣). من إجمالي عدد الاستبيانات التي وزعت (٥٠٠)، تم استلام ٣٣٧ استبانة، وهو العدد الفعلي للمشاركين (نسبة الاستجابة ٦٧،٤٪)، وجد أن ٢٧٠ مشاركاً (٨٠٪) استخدموا هذه الأدوية بدون استشارة طبية و٦٧ مشارك (٢٠٪) استخدموا هذه الأدوية بناءً على استشارة طبية. غالبية المشاركين ١٨٨ (٥٥،٧٪) استخدموا هذه الأدوية بدون أي دليل طبي يثبت الحاجة إليها، والتي كانت ذات أهمية إحصائية ( $p \leq 0.005$ ). أثبتت الدراسة أن ١١٥ مشاركاً (٣٤،١٪) لا يعلمون شيئاً عن الأعراض الجانبية لهذه الأدوية، وأن الارتباط بين الرضا للأداء الجنسي قبل وبعد استخدام هذه الأدوية كان ٠,٥١٦، والذي كان ذو أهمية إحصائية ( $p < 0.001$ ). مما لا شك فيه، هناك سوء استخدام لمثبطات الفوسفو داي استريز النوع الخامس الفموية في مجتمع جدة.