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## Research Article

# Assessing Adherence to Annual Dilated Eye Exam Recommendations in Patients with Diabetes and Erectile Dysfunction

### Abstract

**Aims:** This prospective, observational, pilot study assessed adherence rates of annual dilated fundus examinations (DFEs) among patients with diabetes mellitus (DM) and erectile dysfunction (ED) in a university-based practice and identified predictors associated with DFE adherence.

**Methods:** A total of 56 men who had been diagnosed with ED and type I or type II DM were enrolled in the study and given a 24-question survey assessing their knowledge of DFE recommendations and ocular history. Patients were classified as adherent (n=39) or non-adherent (n=17) to the annual DFE. The differences in demographics, baseline characteristics, and survey responses between the adherent and non-adherent groups were analyzed using Fisher's exact test for the comparison of proportions and Student's t-test for the comparison of means.

**Results:** The adherent group was more likely than the non-adherent group to be seeing an eye doctor (p=0.03). The most common cited reasons for not seeing an ophthalmologist were "Too busy" (n=5) and "Unable to pay the co-pay" (n=4).

**Conclusions:** Patients with ED and DM showed a greater adherence to annual DFE recommendations than those in the reported non-ED population. Minimizing the cost barrier and educating about diabetes complications may increase adherence in obtaining a DFE.

## Abbreviations

ED: Erectile Dysfunction; DM: Diabetes Mellitus; DFE: Dilated Fundus Exam; DR: Diabetic Retinopathy; BMI: Body Mass Index; HbA1c: Hemoglobin A1C; TJU: Thomas Jefferson University;

## Introduction

Erectile dysfunction (ED) is a highly prevalent disorder that affects more than 18 million men in the U.S [1]. An estimated 18.4% of men aged 20 years and older suffer from ED, which is diagnosed as the frequent inability to achieve and maintain an erection firm enough for sexual intercourse [1,2]. During sexual arousal, blood enters the penis through the cavernosal artery; compression of the plexus of subtunical vessels traps blood in the penis, increasing pressure within the lacunar space, making the penis erect [3]. While ED may be linked to hormonal or psychological causes, vascular insufficiency is a common etiology. Men with ED are 2.6 times more likely to have diabetes mellitus (DM), and an estimated 78% of men with DM have some degree of ED [4-6].

Diabetic retinopathy (DR) also occurs as a result of microvascular pathology [7]. High blood glucose levels cause thickening of capillary basement membranes, pericyte dropout, retinal hemorrhages, microvascular infarcts, ischemia, and retinal edema [8]. An estimated 40% of patients with DM have DR [9]. There is significant overlap among risk factors for both ED and DR, such as age, smoking,

hypertension, hyperlipidemia, obesity, poor glucose control, and an African-American race or Hispanic ethnicity [10].

Despite the risk of retinopathy and guidelines by the American Diabetes Association and the National Eye Institute for annual dilated fundus exams (DFE), 50% to 65% of people with diabetes do not adhere to these recommendations [11,12]. Additionally, only 30% of men with ED seek professional help, resulting in both ED and DR remaining untreated in a large portion of the population [13]. Targeting patients with ED and DM who are seeking treatment in a urology practice may be an effective, focused strategy for improving their access to eye care, increasing adherence to annual DFE recommendations, and improving visual outcomes. This pilot study aimed to 1) assess adherence rates of annual DFE among patients with DM and ED in a university-based practice and 2) identify predictors associated with adherence to annual DFEs in patients with DM and ED.

## Materials and Methods

### Subjects

Thomas Jefferson University (TJU) Institutional Review Board reviewed and approved this study. Patients were identified from TJU Hospital's Department of Urology Sexual Dysfunction Program in Philadelphia, Pennsylvania, USA. Men 18 years of age or older, diagnosed with ED and type I or type II DM were eligible for the study. Other inclusion criteria included fluency in spoken English

and the ability to engage in informed consent decision making. Exclusion criteria included patients diagnosed with hormonal ED or psychological ED and patients who had undergone radical prostatectomy. A total of 56 patients were enrolled in the study. Patients were classified according to their adherence to following annual DFE recommendations, resulting in 39 patients in the “Adherent” group, and 17 patients in the “Non-adherent” group.

## Study design

This was a prospective, observational study. Patients were identified using ICD-9 billing codes for ED and DM in the TJU electronic medical records system. Consent was obtained by Wills Eye Hospital research staff during patients’ routine follow-up appointments in the urology clinic. Surveys, consent forms, and self-addressed return envelopes were mailed to patients who met eligibility criteria. These patients were called and notified that a survey was being sent. This 24-question survey assessed patients’ ocular history as well as their knowledge of DFE recommendations. Additional demographic information and body mass index (BMI), co-morbidities, hemoglobin A1C (HbA1c), metabolic panel, lipid panel, smoking history, and blood pressure results were obtained from patients’ electronic records. Patients were compensated with a \$5 gift card for their participation in the study.

## Primary outcome

The primary outcome of this study was to determine patients’ self-reported adherence to an annual DFE. Secondary outcomes included patients’ awareness of current eye exam recommendations, patients’ ability to recall their primary care physician’s (PCP) eye exam recommendations, current barriers to obtaining eye exams, and coexisting ocular conditions in patients with ED and DM.

## Statistical analysis

To investigate the difference between the adherent and non-adherent groups, demographics, baseline characteristics, and the survey responses were compared by Fisher’s exact test for the comparison of proportions and by Student’s t-test for the comparison of means. Statistical analysis was performed by using SAS v9.4 (SAS Institute, Inc, Cary, NC).

## Results

A total of 56 patients were enrolled between November 14, 2012 and January 30, 2014. Demographic information was similar among both groups as shown in [Table 1](#). There were no significant differences in ethnicity, smoking history, drug use, marital status, employment status, insurance status, primary insurance, or highest degree of education received between the groups. However, those who received a graduate degree were more likely to be adherent than those who did not receive a graduate degree. Social alcohol use was reported by 100% of patients responding in the non-adherent group compared to 48.7% in the adherent group ( $p=0.02$ ).

The baseline characteristics are shown in [Table 2](#). Baseline characteristics among the two groups were comparable, with no statistically significant difference in age, BMI, HbA1c, systolic pressure, diastolic pressure, BUN, creatinine, total cholesterol, HDL

cholesterol, LDL cholesterol or triglyceride level. The mean BMI for both groups were classified as “obese” (defined as  $BMI>30$ ) and was 30.2 for the adherent group and 34.4 for the non-adherent group ( $p=0.07$ ). The mean HbA1c level was 8.3, and only 26% of patients had an  $HbA1c < 7.0\%$ . HbA1c was lower (albeit not statistically significant) on average in the adherent group by 1.6%, a 17% reduction (7.8% vs 9.4%).

A significant percentage of patients in the adherent group, 74.4%, reported that they were seeing an eye doctor at the time, compared to 41.2% of patients in the non-adherent group ( $p=0.03$ ). Although ophthalmologists were the primary eye care providers for 84.9% of patients in the adherent group compared to 62.5% of those in the non-adherent group, this was not a significant difference. Similarly, 66.7% of adherent patients could recall being told by their PCP to get an eye exam, compared to 58.8% of the non-adherent patients ([Table 3](#)). Finally, in the adherent group, 92.1% of subjects, and in the non-adherent group, 88.2% of subjects accurately knew how often they were supposed to receive eye exams.

A history of any eye disease or eye surgery was more common in the adherent group compared to the non-adherent group (59.0% vs. 23.5%,  $p=0.02$ ). A diagnosed pathology was more common in the adherent group compared to the non-adherent group. A significantly higher portion of patients from the adherent group reported a history of DR, compared to the non-adherent group (38.9% vs. 6.3%,  $p=0.02$ ). There were no statistically significant differences between the adherent and non-adherent group for a history of eye surgery in the previous year ( $p=0.25$ ), any previous history of eye surgery ( $p=0.11$ ), cataract surgery ( $p=0.41$ ), and a history of glaucoma ( $p=0.40$ ). A diagnosis of macular degeneration was noted by 3 patients in the adherent group and none in the non-adherent group. Both groups of patients reported 10 or more years of DM in  $\geq 50\%$  (50% adherent vs. 52.9% non-adherent;  $p=0.95$ ).

Among non-adherent patients, the most common cited reasons for not seeing an ophthalmologist were “Too busy” ( $n=5$ ), “Unable to pay the co-pay” ( $n=4$ ), “No changes to vision” ( $n=3$ ), and “Don’t have insurance” ( $n=3$ ) ([Table 3](#)).

## Discussion

In this pilot study, patients with ED and DM showed a greater adherence to annual DFE recommendations than those in the reported non-ED population—70% vs. an estimated range of 35% to 50% [[11,12](#)]. The high adherence rate may reflect patients’ awareness of DM complications, specifically DR and ED. An estimated 40% of all patients with DM have a diagnosis of DR, a similar finding to the adherent group with ED in this study [[14](#)]. The more symptomatic patients are, the more likely they are to follow-up with monitoring their disease [[11](#)]. Despite increased adherence to exams, only 30% of patients were in good glycemic control indicated by an  $HbA1c < 7.0\%$ . This is important because blood-sugar control is essential to slowing the progression of retinopathy [[15,16](#)]. Patients with a graduate level education were also more likely to be adherent. It is possible that those with a graduate level of education have increased awareness of the importance of ocular exams, which led to their greater adherence.

**Table 1:** Demographic Information.

|                         |  | Group          |                    | P value |
|-------------------------|--|----------------|--------------------|---------|
|                         |  | Adherent n (%) | Non-adherent n (%) |         |
| Ethnicity               | African American                             | 17 (43.6)      | 11 (64.7)          | 0.36    |
|                         | Caucasian                                    | 19 (48.7)      | 5 (29.4)           |         |
|                         | Latino/Hispanic                              | 3 (7.7)        | 1 (5.9)            |         |
| Alcohol History         | Abuse  | 1 (4.76)       | 0 (0)              | 0.024   |
|                         | Hx Abuse                                     | 1 (4.76)       | 0 (0.0)            |         |
|                         | No use                                       | 9 (42.9)       | 0 (0.0)            |         |
|                         | Social Use                                   | 10 (47.6)      | 10 (100.0)         |         |
| Current Smoker          | Currently Smokes                             | 9 (23.1)       | 2 (11.8)           | 0.68    |
|                         | Hx of Smoking                                | 11 (28.2)      | 5 (29.4)           |         |
|                         | No History                                   | 19 (48.7)      | 10 (58.8)          |         |
| Drug Use                | Current Use                                  | 1 (5.0)        | 0 (0.0)            | 1.00    |
|                         | Hx of Use                                    | 1 (5.0)        | 1 (9.1)            |         |
|                         | Normal                                       | 22 (84.6)      | 8 (72.7)           |         |
| Marital Status          | Single                                       | 8 (20.5)       | 5 (29.4)           | 0.21    |
|                         | Married                                      | 23 (59.0)      | 9 (52.9)           |         |
|                         | Divorced                                     | 6 (15.4)       | 1 (5.9)            |         |
|                         | Widowed                                      | 2 (5.13)       | 0 (0.0)            |         |
|                         | Other  | 0 (0.0)        | 2 (11.8)           |         |
| Employment Status       | Unemployed                                   | 3 (7.7)        | 3 (17.7)           | 0.79    |
|                         | Part-time                                    | 3 (7.7)        | 1 (5.9)            |         |
|                         | Full-time                                    | 16 (41.0)      | 8 (47.1)           |         |
|                         | Retired                                      | 13 (33.3)      | 4 (23.5)           |         |
|                         | Other  | 4 (10.3)       | 1 (5.9)            |         |
| Insurance Status        | No Insurance                                 | 0 (0.0)        | 1 (5.9)            | 0.65    |
|                         | Medicare Private Insurance                   | 1 (2.6)        | 0 (0.0)            |         |
|                         | Medicaid                                     | 2 (5.1)        | 0 (0.0)            |         |
|                         | Medicare                                     | 13 (33.3)      | 4 (23.5)           |         |
|                         | Medicare Medicaid                            | 2 (5.1)        | 1 (5.9)            |         |
|                         | Private Insurance Medicaid                   | 1 (2.6)        | 0 (0.0)            |         |
|                         | Private Insurance Medicare                   | 2 (5.1)        | 0 (0.0)            |         |
|                         | Private Insurance                            | 18 (46.2)      | 11 (64.7)          |         |
| Primary Insurance       | No Insurance                                 | 0 (0.0)        | 1 (5.9)            | 0.44    |
|                         | Medicaid                                     | 2 (5.1)        | 0 (0.0)            |         |
|                         | Medicare                                     | 15 (38.5)      | 5 (29.4)           |         |
|                         | Private Insurance                            | 22 (56.4)      | 11 (64.7)          |         |
| Highest Degree Received | Did not graduate high school                 | 1 (2.6)        | 3 (17.7)           | 0.12    |
|                         | High School or GED                           | 18 (47.5)      | 6 (35.3)           |         |
|                         | Undergraduate Degree or BA/BS                | 9 (23.7)       | 6 (35.3)           |         |
|                         | Graduate Degree (Masters, PhD, MD, JD, etc.) | 10 (26.3)      | 2 (11.8)           |         |

In this study, 66.7% of adherent patients, and 58.9% of non-adherent patients were able to recall being informed by their PCP to get an eye exam, consistent with previous reports. Interestingly, of the 22 patients who answered “No” or “Don’t remember”, 100% believed that they should get an exam at least once every 12 months. Past research has concluded that a recommendation from a PCP was the most significant predictor for receiving an eye exam [17]. This stresses the importance of DM education by primary care physicians. While many patients were aware that they should be getting annual eye exams, many of them did not. In the non-adherent group 88.2% of the subjects were aware that they should be getting an eye exam “every year”, “at least once a year,” or “every six months.” However, awareness that they should be receiving an annual eye exam did not translate to patients actually receiving an eye

exam. The primary barriers reported for not adhering to the annual DFE recommendations were that they were “Too busy” and “Unable to afford the co-pay.” Previous studies have reported that cost is a barrier to obtaining a DFE [18,19]. Minimizing the cost barrier may provide an avenue to increase adherence in obtaining a DFE.

There are limitations to this study. Patients were targeted men from a university urology practice and were seeking treatment. The patients enrolled in this study represent a highly motivated population seeking treatment in a university hospital setting and may adhere more strongly to physician recommendations. The sample size is small, especially in the non-adherent group and surveying more patients would strengthen the results and conclusion. In addition, an estimated 30% of ED patients seek treatment in any setting. For

**Table 2:** Baseline Characteristics.

|                    | Group                 |              |                   |                           |              |                   | P value |
|--------------------|-----------------------|--------------|-------------------|---------------------------|--------------|-------------------|---------|
|                    | Adherent Group n = 39 |              |                   | Non-adherent Group n = 17 |              |                   |         |
|                    | N                     | Mean (STD)   | Median (min, Max) | n                         | Mean (STD)   | Median (min, Max) |         |
| Age                | 39                    | 57.9 (12.3)  | 59 (28-80)        | 16                        | 60.5 (9.6)   | 59.5 (43-81)      | 0.46    |
| BMI                | 35                    | 31.1 (5.6)   | 30.2 (24.7 ,44.5) | 17                        | 34.4 (7.1)   | 35 (21 ,45.8)     | 0.07    |
| Systolic Pressure  | 37                    | 131.4 (15.4) | 131 (80 ,161)     | 17                        | 139 (21)     | 132 (118 ,201)    | 0.14    |
| Diastolic Pressure | 37                    | 77.9 (9.4)   | 78 (54 ,102)      | 17                        | 77.3 (10)    | 80 (56 ,96)       | 0.82    |
| HbA1c              | 23                    | 7.8 (1.6)    | 7.8 (5.3, 10.9)   | 11                        | 9.4 (3.2)    | 9 (5.6, 16.3)     | 0.15    |
| BUN                | 28                    | 17 (4.6)     | 16.5 (10 ,33)     | 15                        | 18.9 (14.8)  | 14 (9 ,68)        | 0.63    |
| Creatine           | 29                    | 1.4 (1.9)    | 1.1 (0.6 ,11)     | 15                        | 1.2 (0.7)    | 1 (0.7 ,3.6)      | 0.61    |
| Total Cholesterol  | 26                    | 156.2 (39.7) | 147.5 (85 ,251)   | 11                        | 164.9 (42)   | 155 (111 ,241)    | 0.55    |
| HDL Cholesterol    | 26                    | 46.7 (16.4)  | 42.5 (21 ,100)    | 11                        | 45.6 (11.6)  | 46 (26 ,66)       | 0.85    |
| LDL Cholesterol    | 25                    | 83 (33.5)    | 81 (18 ,180)      | 9                         | 90.3 (30.3)  | 86 (61 ,165)      | 0.57    |
| Triglyceride       | 26                    | 135.9 (70.2) | 125 (49 ,334)     | 11                        | 139.4 (84.8) | 119 (45 ,302)     | 0.90    |

If there was value "Don't know" or "Can't Remember" for any variables, it was treated as missing value.

**Table 3:** Survey Responses.

|  |                             | Group          |                    | P value |
|--|-----------------------------|----------------|--------------------|---------|
|  |                             | Adherent n (%) | Non-Adherent n (%) |         |
| Prescription Glasses                               | No                          | 11 (28.2)      | 4 (23.5)           | 1.00    |
|  | Yes                         | 28 (71.8)      | 13 (76.5)          |         |
| Currently Seeing An Eye Doctor                     | No                          | 10 (25.6)      | 10 (58.8)          | 0.03    |
|  | Yes                         | 29 (74.4)      | 7 (41.2)           |         |
| Last Time Pupils Were Dilated                      | Past 12 Months              | 39 (100.0)     | 0 (0.0)            | N/A     |
|  | Between 1 and 2 Years Ago   | 0 (0.0)        | 11 (68.8)          |         |
|  | 2 or More Years Ago         | 0 (0.0)        | 4 (25.0)           |         |
|  | Never                       | 0 (0.0)        | 1 (6.3)            |         |
| Ophthalmologist or Optometrist                     | Ophthalmologist Optometrist | 1 (3.0)        | 1 (6.3)            | 0.18    |
|  | Ophthalmologist             | 28 (84.9)      | 10 (62.5)          |         |
|  | Optometrist                 | 4 (12.1)       | 5 (31.3)           |         |
| Told By PCP To Get An Eye Exam                     | No                          | 12 (33.3)      | 7 (41.2)           | 0.76    |
|  | Yes                         | 24 (66.7)      | 10 (58.8)          |         |
| How Long Have You Had Diabetes                     | Less Than 1 Year            | 1 (2.6)        | 0 (0.0)            | 0.95    |
|  | 1 To 5 Years                | 5 (13.2)       | 3 (17.7)           |         |
|  | 5 Years To 10 Years         | 13 (34.2)      | 5 (29.4)           |         |
|  | More Than 10 Years          | 19 (50.0)      | 9 (52.9)           |         |
| How Often Should You Get Examined By An Eye Doctor | Every 6 Months              | 6 (15.8)       | 4 (23.5)           | 0.17    |
|  | Every Year                  | 3 (7.9)        | 0 (0.0)            |         |
|  | At Least Once Per Year      | 26 (68.4)      | 11 (64.7)          |         |
|  | Every Two Years             | 0 (0.0)        | 2 (11.8)           |         |
|  | Every Five Years            | 1 (2.6)        | 0 (0.0)            |         |
|  | Don't Know                  | 2 (5.3)        | 0 (0.0)            |         |
| Eye Surgery Within Last Year                       | No                          | 30 (79.0)      | 16 (94.1)          | 0.25    |
|  | Yes                         | 8 (21.1)       | 1 (5.9)            |         |
| Eye Surgery Ever                                   | No                          | 25 (65.8)      | 15 (88.2)          | 0.11    |
|  | Yes                         | 13 (34.2)      | 2 (11.8)           |         |
| Glaucoma   | No                          | 27 (81.8)      | 15 (93.8)          | 0.40    |
|  | Yes                         | 6 (18.2)       | 1 (6.3)            |         |
| Diabetic Retinopathy                               | No                          | 22 (61.1)      | 15 (93.8)          | 0.02    |
|  | Yes                         | 14 (38.9)      | 1 (6.3)            |         |
| Macular Degeneration                               | No                          | 29 (90.6)      | 16 (100.0)         | 0.54    |
|  | Yes                         | 3 (9.4)        | 0 (0.0)            |         |
| Corneal Ulcer                                      | No                          | 33 (97.1)      | 17 (100.0)         | 1.00    |
|  | Yes                         | 1 (2.9)        | 0 (0.0)            |         |
| Eye Cancer/Melanoma                                | No                          | 36 (100.0)     | 15 (100.0)         | 1.00    |
|  | Yes                         | 0 (0.0)        | 0 (0.0)            |         |



|   |  |           |           |      |
|---|--|-----------|-----------|------|
| Cataract Surgery  | No   | 32 (82.1) | 16 (94.1) | 0.41 |
|   | Yes  | 7 (18.0)  | 1 (5.9)   |      |
| Reason For Not Having An Eye Exam In Past Year <sup>a</sup> | Don't Think An Eye Exam Is Needed Every Year |           | 2         |      |
|   | Had An Unpleasant Experience In An Eye Exam  |           | 1         |      |
|   | No Changes To Vision                         |           | 3         |      |
|   | Too Busy                                     |           | 5         |      |
|   | Unable to Pay the Co-pay                     |           | 4         |      |
|   | Don't Have Insurance                         |           | 3         |      |
|   | Don't Have Transportation                    |           | 2         |      |

<sup>a</sup> Respondents could chose more than one option.

more generalizable studies, patients with ED and DM should be recruited and enrolled from a variety of settings and not just those seeking treatment. In addition, this study uses self-reported data from patients and is subject to recall bias.

Subspecialty clinics treating symptomatic DM patients with diseases such as ED may be particularly effective sites for DR screening. These patients are already seeking eye care at a higher rate, primarily due to their symptoms and higher level of awareness about diabetes complications. The hurdles for overcoming remaining barriers may therefore be relatively easier to achieve. Convenient, low cost telemedicine strategies, such as cell phone and hand-held cameras to take fundus photographs of the retina, are now being implemented nationally and internationally.

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