Published in final edited form as:

J Sex Med. 2011 November ; 8(11): 3051–3057. doi:10.1111/j.1743-6109.2011.02423.x.

Correlates of PDE5i Use Among Subjects with Erectile Dysfunction in Two Population-Based Surveys

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Abstract

Introduction—Erectile dysfunction is thought to affect some 150 million men worldwide, but many men with ED symptoms do not seek treatment. Existing surveys suggest that men with severe ED and who report support from their partners are more likely to receive treatment than were others. Less is known, however, concerning the influence of sociomedical factors such as income and body composition on receipt of treatment.

Aim—To determine the importance of socioeconomic status, comorbidities and body composition on receipt of treatment for ED symptoms.

Methods—We used data on 638 men enrolled in the Boston Area Community Health (BACH) survey reporting ED symptoms and/or treatment for ED as evidenced by phosphodiesterase type 5 inhibitor (PDE5i) use. Logistic regression was employed to assess the relative strength of association between receipt of treatment and socioeconomic factors, BMI, and medical factors. A replication of these results was then provided via a parallel model using the 2004 follow-up of the Men's Attitudes to Life Events and Sexuality (MALES).

Main outcome measure—In BACH, ED was deemed present if a subject scored 16 points or fewer on the five-item International Index of Erectile Function (IIEF-5) or reported PDE5i use. In MALES, presence of ED was indicated by use of a validated single question querying ED severity.

Results—Controlling for age, body composition and other factors, increased household income, availability of a sexual partner and provider diagnosis of high blood pressure were positively associated with treatment seeking via the use of PDE5i therapy in BACH. Results on data available in MALES produced similar results for household income and partner availability.

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Conflict of Interest: The MALES project was sponsored by the Bayer Pharma AG. Funding for the BACH Survey was provided by NIH NIDDK Award Number U01DK056842. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIDDK or the NIH. Additional funding for these analyses was provided to New England Research Institutes by Bayer Healthcare, Bayer Pharma AG. Raymond C. Rosen reports that he serves as a consultant and research advisor to Bayer Pharmaceuticals, Boehringer Ingelheim, Eli Lilly, Palatin Technologies, GSK, and Johnson and Johnson. He has no stock or ownership to report. All other authors report no conflicts of interest.

Conclusion—These data provide evidence that financial disadvantage may present a barrier to treatment of ED, an increasingly important sentinel marker of the cardiovascular and overall health among aging men.

Introduction

Erectile dysfunction is thought to affect some 150 million men worldwide (1,2) and nearly one in five men in the United States (3). Though small early studies produced promising evidence suggesting the possibility of its spontaneous remission (4,5), and more recent population-based analyses confirm that many subjects' ED symptoms lessen in severity with time (6), the majority of ED sufferers nevertheless see their symptoms persist or even progress.

Aging, physical inactivity, elevated BMI, and comorbid conditions including diabetes and cardiovascular disease are strong predictors of ED and its progression (3,6,7), and emerging evidence suggests that fitness and weight management contribute to the maintenance of erectile functioning (8-11). Absent fully effective lifestyle interventions, however, pharmacologic therapies have made important and successful contributions to the clinical management of ED. In particular, the introduction of phosphodiesterase type 5 inhibitors (PDE5i) has provided a novel and largely successful pharmacologic intervention in the treatment of ED symptoms given even omnipresent medical comorbidities such as cardiovascular disease and diabetes (12,13).

Though these therapies are now in use by an estimated 25-30 million men (14), the majority of ED sufferers do not seek or maintain treatment via PDE5i. In a previous analysis of data from the multinational Men's Attitudes to Life Events and Sexuality (MALES) Study, members of our group considered treatment seeking via PDE5i therapy as a function of men's attitudes and concerns surrounding the presence and severity of ED symptoms (15). In general, men who described their symptoms as severe, who perceived support for treatment seeking from their sex partners and medical professionals, and who believed PDE5i therapy was safe, were more likely to seek treatment than were others. These findings, and notably the influence of the partner in treatment seeking, are largely in agreement with those obtained from other studies and populations (11,16-19).

Less is known, however, concerning the influence of socioeconomic status, comorbidities, and other patient-specific factors described above, on treatment seeking in the presence of potential covariates such as body composition. To address these questions, we developed a multivariate model of the use of PDE5i therapy in ED using data from the Boston Area Community Health survey, a large population-based epidemiologic study of randomly selected men living in and around Boston, MA, USA (20). To test the resistance of the resultant model to variation across survey designs, we then replicated the construction of a portion of this model using contemporary data obtained from the United States subcohort of MALES 2004 subjects (REF MALES 2004).

Methods

The Boston Area Community Health Survey

BACH is a cross-sectional study of health and urologic symptoms in randomly selected, community-dwelling persons aged 30-79 y. The design of the BACH Survey has been previously described (20). A multistage, stratified cluster sampling design was used to recruit approximately equal numbers of persons in pre-specified groups defined according to age (30 to 39, 40 to 49, 50 to 59, 60 to 79), race and ethnicity (black, Hispanic, white) and gender. This analysis used baseline data collected from men between April 2002 and June

2005 during a two-hour, in-person interview conducted by a trained, bilingual interviewer after acquisition of written informed consent. BACH study procedures were approved by the Institutional Review Board of the New England Research Institutes.

The Men's Attitudes to Life Events and Sexuality survey

The MALES studies are two-phase multinational assessments of ED and its correlates, conducted in the USA, Brazil, Mexico, and five European nations (Germany, France, Spain, Italy, UK). Design details have previously been published (15,17). In brief, MALES obtained detailed information on ED and treatment seeking behavior among 2912 men, of whom 1841 were re-contacted in 2004. Of the men who reported some level of ED at any time in the past, 919 who had participated in the original MALES multinational study agreed to participate in the MALES 2004 study and were sent a 65-item questionnaire. A total of 808 of these men contributed questionnaires.

ED status and receipt of treatment

Among BACH subjects, self-reported ED severity was obtained using the five-item International Index of Erectile Function (IIEF-5) a self-administered, validated questionnaire (21). This score ranges from 5 to 25, with lower scores indicating poorer erectile function. Severity of ED was categorized as severe ED (score 5-7), moderate ED (8-11), mild to moderate ED (12-16), mild ED (17-21), and no ED (22-25). In this analysis, the presence of ED as indicated by IIEF-5 was defined using a cutoff score of 16 or fewer points (combining the mild to moderate, moderate, and severe ED categories). In addition, BACH participants were asked to gather all medications used in the past four weeks for label recording by the interviewer, and participants were queried as to whether they were taking drugs for specific indications, including ED. The definitive *absence* of ED was therefore indicated by a subject's having *both* an IIEF score of at least 17 *and* no evidence of the use of PDE5is or other prescription ED medications during the past month (n=2 men who used papaverine or prostaglandin were excluded from analyses). Models of predictors of PDE5i use included men whose collected medication information showed they were users of PDE5i, and/or who had IIEF-5 scores <17.

In MALES, subjects gave a single-question assessment of the severity of their ED symptoms, for which subjects are asked to report the level of their ED as one of "none," "minimal," "moderate," or "severe/complete". The single ED question measure has been clinically validated against an independent clinical determination of erectile function (22). All subjects enrolled in MALES 2004 exhibited at least minimal ED symptoms.

Covariate Data

In BACH, racial/ethnic groups were defined using self-identification according to the federal Office of Management and Budget categories and were considered in order to measure health disparities (23). A socioeconomic status (SES) variable was constructed as a function of standardized income and education variables for the Northeastern U.S. and reclassified into low, middle and high (24). Household income was self-reported, and further categorized. Depressive symptoms were considered present among participants with at least five of eight symptoms on the abridged Center for Epidemiologic Studies Depression Scale (25).

The assessment of comorbidities was based on the query, "Have you ever been told by a health care provider that you have or had...?" Cardiovascular disease was taken to be indicated by the presence of one or more of the following: coronary artery bypass surgery or angioplasty, heart attack, angina, cardiac pacing, congestive heart failure, transient ischemic attack, stroke, carotid artery surgery, intermittent claudication, surgery or angioplasty for

arterial disease of the leg, pulmonary embolism, aortic aneurysm, heart-rhythm disturbance, deep vein thrombosis, Reynaud's disease or peripheral vascular disease. Body mass index (BMI) was calculated from interviewer-measured weight and height. Self-reported health status was measured using the Medical Outcomes Study 12-item Short Form Survey (SF-12) (26); participants reporting 'fair' or 'poor' health (combined) were compared to those rating their health 'good' or 'very good' or 'excellent' (combined).. The availability of a sex partner was self-reported.

In MALES, subjects' age and income were ascertained by self report. Major comorbidities (heart disease, high blood pressure, high cholesterol, diabetes, and depression) were indicated by of a subject's self-report of a physician diagnosis and/or of his currently being treated for the relevant condition. Partner availability was indicated by a subject's reporting that he "currently ha[s] a sexual partner."

Analytic Samples

A total of N=638 BACH subjects met the selection criteria described above for models of PDE-5i use. To enhance comparability of the BACH and MALES samples, MALES 2004 subjects were restricted to the 353 residing in the U.S. Among these subjects, N=341 of these men had complete data on their ED status as described above.

Statistical Analysis

The primary analysis was directed toward examining associations between covariates and PDE5i therapy use in BACH. Due to the sampling design, these analyses were weighted in inverse proportion to the probability of a subject's being selected for inclusion in the study. Analyses were conducted using SUDAAN version 10.0 (RTI International, Research Triangle Park, NC). Missing data were replaced by plausible values using multiple imputation (27); less than 1% of data were missing for most variables. Medication variables were not imputed. A multivariate logistic regression model was used to identify significant predictors of PDE-5i use via odds ratios (ORs) and 95% confidence intervals (CIs). Except for BMI (included for its importance and available only in BACH), covariates for models were initially chosen based on mutual availability in both the BACH and MALES datasets. Covariates included in the final model were selected on the basis of a backwards stepwise procedure with an inclusion criterion of $p < 0.15$, with age included as a baseline factor regardless of significance.

In a second analysis, this approach was repeated for the data available on the MALES 2004 subcohort. In MALES, the statistical significance of individual predictor factor was obtained using likelihood ratios from nested models, with computations restricted to nonmissing records to preserve degrees of freedom for testing. Analyses of MALES data were performed in Stata version 11.0 (StataCorp LP, College Station, TX).

Results

Descriptive Results and Unadjusted Associations

Descriptive results for the BACH cohort are presented in Table 1. In considering medical in comparison to sociodemographic variables, we observed that differences between users and non-users were generally stronger for sociodemographics. Those using PDE5i tended to have substantially greater income, years of education and likelihood of having private health insurance compared to subjects with ED but who did not use PDE5i. Those using PDE5i therapy were, in addition, much more likely to have a current sex partner (91.7%) compared with nonusers with ED (71.9%), and exhibited somewhat greater likelihood of hypertension, diabetes, or cardiovascular disease than their counterparts with ED who did not use PDE5i.

Descriptive results for the MALES 2004 cohort are presented in Table 2. Those subjects stating they had used PDE5i were again more likely to have a sexual partner, and there was limited evidence of association between PDE5i use and high blood pressure. In MALES 2004, those subjects from 50-59 years of age were most likely to report having used PDE5is for ED symptoms.

Multivariate Analyses

A logistic regression model for receipt of treatment among subjects with ED is presented for the BACH cohort in Table 3. Here, controlling for the influence of body composition (BMI) and other factors that remained significant in a parsimonious model obtained by the backwards stepwise procedure (see Methods), increased household income was strongly associated with an increased likelihood of PDE5i use, with an odds ratio (OR) of 3.88 vis-à-vis moderate income, as is the availability of a partner (OR = 3.61 as compared to subjects reporting no sex partner), and high blood pressure (OR = 2.49 as compared to subjects reporting no history of elevated blood pressure). Having a normal BMI compared to an obese BMI was also substantially associated with PDE5 use (OR=3.41). Though age group was nonsignificant in predicting PDE5i use after control for the effect of other covariates, the 50-59 age bracket was again the most likely to report use of PDE5i. We constructed an alternative model that used either the combination of income and education, or the SES score (see methods); in each case results were similar, in that the lower levels of income or SES were associated with lesser uses of SES.

A parallel model predicting PDE5i use in MALES is reported in Table 4. Here again the 50-59 age group is the most likely to report PDE5i use, as are the two highest income brackets, with those subjects reporting income in excess of \$30,000 per year approximately four times as likely to report PDE5i use as compared to those subjects reporting less than \$15,000 income per year. As in unadjusted results (Table 2), the availability of a sexual partner is highly predictive of PDE5i use.

Discussion

Analyses from the BACH survey reported above provide evidence that self-reported household income as well as high blood pressure are predictive of PDE5 use among subjects with ED even when controlling for age, other comorbidities, body composition as expressed by BMI, and other factors. This result was consistent when multiple SES factors (e.g. income, education, insurance status) were considered in unadjusted analyses, when SES was considered as a score combining income and education information (24), or when attention was restricted to income alone. BACH results also indicate that availability of a sexual partner and hypertension were associated of PDE5i use. By contrast, other comorbidities such as diabetes and cardiovascular disease considered broadly (see methods) appeared to have no strong association with PDE5i use.

Despite providing access only to a subset of the subject-level variables described here for the BACH Survey, the MALES 2004 study provides results that are quite similar to those observed in BACH. Of the health history variables considered in Table 2, for instance, only high blood pressure exhibits any trend toward association with PDE5i use, and this remains the case in multivariate models (Table 4).

These results are largely consistent with those reported in earlier studies of treatment seeking for erectile dysfunction, which have indicated that partner availability and support are dominant indicators of the likelihood to seek treatment for ED symptoms (18,19). We would speculate that perceived need to address erectile dysfunction as a concern needing to be addressed is enhanced among men who are currently active with a sexual partner.

The role of comorbidity in the treatment of ED and associated conditions is potentially more complex. It is now generally believed that ED is an indicator of endothelial dysfunction, and is a sentinel condition presaging incident cardiovascular events and (potentially) premature mortality (28-31). It seems likely that the patterns of lifestyle interventions, and potentially pharmacologic treatment, in ED and cardiovascular disease may undergo some level of convergence (32). Though severity of ED is positively associated with treatment seeking, it is not clear that comorbid conditions play a similar role. In their analysis of data from the CNSMHI, Shabsigh and colleagues provided limited evidence that hypertension is negatively associated with treatment seeking for ED (16). In moderate contrast, the analyses we report here suggest that among men with ED, those with a diagnosis of high blood pressure are more likely to have been treated for ED via PDE5 inhibition. It seems likely that this inconsistency is due to the fact that 'high blood pressure' is rather broadly defined in population-based surveys such as BACH and MALES.

Some limitations of this analysis should be acknowledged. Given the small number of BACH subjects with evidence of ED in the analytic sample, only simpler models of treatment usage are possible. In particular, use of other medications and polypharmacy are not considered. The design of the MALES database, meanwhile, is focused on attitudes of men and their partners, deemphasizing epidemiologic data such as body composition. The confirmatory analyses reported in Tables 2 and 4 are limited by these exclusions.

These limitations are counterbalanced by numerous strengths. BACH is among the largest population-based studies of urologic health ever conducted, and its diverse sampling frame is unmatched for examining the influence of SES and comorbidity on ED and other conditions. Meanwhile, the parallel findings from two studies of differing design provides support for our analytic results.

The strong association between SES and treatment seeking observed here provides evidence that financial disadvantage may present a barrier to treatment of ED, an increasingly important marker of the health of an aging male population. Future efforts to treat ED and leverage its role as an indicator of cardiovascular risks, whether in the form of lifestyle interventions or pharmacologic therapies, should acknowledge these potential barriers so as not to exacerbate disparities in CVD prevalence and severity.

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Table 1

Assessment of unadjusted associations among users of PDE5is, and non-users with erectile dysfunction (ED)* with age, income and other factors, Boston Area Community Health Survey, 2002-2005, N=638.

Variable	PDE5i users (n=44)	Untreated ED (n=594)	p value [†]
Age, y, Mean (SE)	53.3 (2.4)	56.2 (1.0)	0.26
Median	52.3	57.7	
Education, y, Mean (SE)	17.2 (0.5)	12.7 (0.4)	<0.001
Median	17.2	11.7	
IIEF-5 score, Mean (SE)	13.9 (1.3)	11.7 (0.2)	0.11
IIEF-5 16	61.8	100.0	<0.001
Annual income (%)			
<\$30,000	23.3	58.4	0.01
\$30,000 to \$69,999	25.2	30.6	
\$70,000	51.6	11.0	
No sex partner (%)	8.3	28.1	0.01
Low libido (%)	24.2	44.6	0.08
Poor/fair self-reported health (%)	24.2	30.3	0.59
Race/ethnicity (%)			0.14
Black	17.8	31.6	
Hispanic	8.4	16.8	
White	73.8	51.6	
Health insurance (%)			<0.01
Private	87.9	50.6	
Public	7.8	35.6	
None	4.3	13.9	
Body mass index categories (%)			0.18
<25.0	31.1	22.2	
25.0-29.9	49.6	42.3	
30.0+	19.2	35.4	
Cardiovascular disease (%)	44.5	38.8	0.59
Hypertension (%)	55.5	42.5	0.30
Diabetes (%)	28.2	19.0	0.44
Depressive symptoms (%)	16.1	23.8	0.47

* PDE-5 users were men who used any phosphodiesterase inhibitors in the past 4 weeks, while untreated ED was defined as an IIEF-5 score of 16 and no evidence of ED drug treatment (PDE-5s, papaverine or prostaglandin)

[†] P value from the chi-square test of heterogeneity or Wald F test (for continuous variables); all estimates were weighted by the inverse of the probability of being sampled. Percents shown are column percents.

Table 2

Assessment of unadjusted association of PDE5i use with to age, income and other factors. MALES 2004 United States subcohort; N=341.

Variable	PDE5 Inhibitor Use ^a (N = 98)	No PDE5i Use ^a (N = 243)	p-value ^b
Age, y			< 0.001
20-49	7 (7)	35 (14)	
50-59	37 (38)	47 (19)	
60-69	37 (38)	83 (34)	
70-75	16 (17)	78 (32)	
Current Annual Income			0.03
< \$15,000	7 (7)	39 (16)	
\$15,000 - \$30,000	37 (38)	63 (26)	
\$30,000 - \$50,000	37 (38)	63 (26)	
> \$50,000	16 (17)	76 (32)	
Sex partner available	86 (88)	169 (70)	0.001
Heart Disease	30 (36)	90 (40)	0.42
High Blood Pressure	63 (68)	133 (58)	0.07
High Cholesterol	51 (57)	136 (59)	0.76
Diabetes	27 (32)	78 (35)	0.53
Depression	23 (28)	64 (29)	0.80

^a Column proportions computed with respect to nonmissing records

^b Chi-square significance test of no association between covariates and PDE5i use

Table 3

Logistic regression model estimating associations with PDE5 use among PDE5 users and non-users who report erectile dysfunction (IIEF-5 <17) in Boston Area Community Health Survey, 2002-2005, N=638.

Variables	Odds ratio	95% CI	Overall p value for variable
Age, y			0.31
<50	1.00 (ref)		
50-59	2.26	(0.55, 9.25)	
60-69	0.95	(0.33, 2.76)	
70-79	0.52	(0.17, 1.55)	
Annual Household Income			0.01
<\$30K	0.46	(0.10, 2.10)	
\$30K-\$69.9K	1.00 (ref.)		
>\$70K	3.88	(1.33, 11.32)	
Sex partner available	3.61	(0.74, 17.58)	0.11
High blood pressure	2.49	(0.73, 8.43)	0.14
Body mass index, kg/m²			0.06
<25.0	3.41	(1.17, 9.95)	
25.0-29.9	2.55	(0.77, 8.38)	
30.0+	1.00 (ref.)		

Table 4

Logistic regression analysis of PDE5 use; MALES 2004 U.S. subcohort, N=341.

Variable	Odds Ratio	95% CI	p-value ^a
Age group, y			<0.001
20-49	0.22	(0.08, 0.57)	
50-59	1.00 (ref)		
60-69	0.40	(0.21, 0.77)	
70-75	0.18	(0.08, 0.40)	
Annual Household Income			0.04
< \$15,000	1.00 (ref)		
\$15,000 - \$30,000	2.7	(0.87, 8.41)	
\$30,000 - \$50,000	4.0	(1.31, 12.35)	
> \$50, 000	3.9	(1.30, 11.44)	
Sex partner available	2.82	(1.39, 5.75)	0.003
High blood pressure	1.74	(0.98, 3.08)	0.06