Relationship between age and erectile dysfunction diagnosis or treatment using real-world observational data in the United States

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SUMMARY

Aims—With self-reporting of erectile dysfunction (ED) in population-based surveys, men with ED may not represent men who are bothered sufficiently to seek an ED diagnosis and treatment. We used real-world observational data to assess: 1) the prevalence of ED diagnosis or treatment by age subgroups; and 2) the relationship of age with ED diagnosis or treatment after controlling for ED-related comorbidities in the United States.

Methods—This cross-sectional study used de-identified claims data (MarketScan® databases; primary analysis). Sensitivity analysis was conducted using electronic health records (Humedica® database). Inclusion criteria were men aged 18 years with a 360-day continuous enrollment before the index date. We assessed the prevalence of ED diagnosis or phosphodiesterase type 5 inhibitor (PDE5I) prescription by age and the risk for ED diagnosis or treatment by age after controlling for comorbidities (hypertension, other cardiovascular disease, diabetes mellitus, depression, and benign prostatic hyperplasia).

Results—Of 19,833,939 men meeting inclusion criteria in the primary analysis, only 1,108,842 (5.6%) had an ED diagnosis or PDE5I prescription (mean [SD] age: 55.2 [11.2] years). Prevalence of ED diagnosis or treatment increased from age 18–29 years (0.4%) to 60–69 years (11.5%), then decreased in the 7th (11.0%), 8th (4.6%), and 9th (0.9%) decades. Men with ED diagnosis or treatment had a higher prevalence of any comorbidity (63.1% vs 29.3% for men without ED) and

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of each comorbid condition. In multivariate analyses, age was an independent risk factor for ED diagnosis or treatment. Sensitivity analysis provided consistent results.

Conclusions—In a real-world setting in the United States, the prevalence of ED diagnosis or PDE5I treatment is generally low, increases with age, decreases in very old men, and is associated with increased prevalence of comorbidities. Age is an independent risk factor for ED diagnosis or treatment after controlling for comorbidities.

Keywords

erectile dysfunction; phosphodiesterase type 5 inhibitors; age groups; comorbidity; real-world claims data; electronic health records; observational study

INTRODUCTION

Erectile dysfunction (ED) is defined as the inability to achieve or maintain an erection sufficient for satisfactory sexual performance [1]. Based on the results of population survey epidemiologic studies in the United States (US) published in the last decade, ED is a common condition and is associated with increasing age [2–5]. The overall prevalence of ED has been estimated at 18% [4] to 47% [2] in the US, with rates dependent on the age of the men in the sample and the method used to identify ED. Data from the US National Health and Nutrition Examination Survey indicate that the prevalence of ED increased from 8.2% in men aged 40–49 years to 77.5% in those aged 75 years [4]. In addition to increasing age, ED is associated with comorbidity and lifestyle factors, such as diabetes mellitus, obesity, smoking, cardiovascular disease, stroke, hypertension, and lower urinary tract symptoms [3, 4, 6–11].

Population-based epidemiologic surveys collect ED information by questioning a sample of men and then generalize the results to a larger population, thereby providing valuable subject-reported data. However, because of the self-reporting method used in population-based epidemiologic studies, men with ED in these studies may not represent those who are bothered sufficiently by their ED to seek a diagnosis or treatment. In contrast, real-world observational data collected in large health insurance claims databases and electronic health record (EHR) databases provide clinically meaningful information on ED from men who actually sought a diagnosis or treatment for their ED. Consequently, real-world data on ED can provide additional insights and complement population survey epidemiologic data.

Several studies have previously assessed the prevalence of underlying comorbidities in men with ED using data from US health insurance claims databases[12–15] and from a United Kingdom general practice EHR database.[16] US health insurance claims databases have also been used to characterize ED treatment in a large population of men [17] and to determine the impact of ED treatment on adherence to long-term medications for comorbidities [18]. No study has used claims or EHR data to assess the relationship of age with ED diagnosis or treatment in a real-world setting. Using real-world observational data in the United States, this study assessed the relationship of age with ED diagnosis or treatment after controlling for ED-related comorbidities.

Methods

Data source

This cross-sectional non-interventional observational study was based on an analysis of de-identified insurance claims data from 07/01/2009 to 06/30/2014 in the Truven Health MarketScan® Research Databases (primary analysis). The MarketScan databases contain medical and prescription drug claims for individuals in the United States who have employer-sponsored health insurance, including Medicare supplemental coverage. The data are pooled from large employers, managed care organizations, hospitals, and public organizations. Research using MarketScan databases has been widely published in peer-reviewed journals [19, 20].

To assess the robustness of the study findings, a sensitivity analysis was conducted using the Humedica® EHR database. Humedica aggregates EHR data directly from providers, integrating multiple EHRs from across the continuum of care, both inpatient and ambulatory. This database captures a comprehensive clinical picture that includes medications, laboratory results, vital signs, physician notes, diagnoses, procedures, demographics, hospitalizations, and outpatient visits. Once aggregated, Humedica normalizes, validates, and de-identifies these data. The sensitivity analysis used the same methodology as the primary analysis and included data from 1/1/2007–12/31/2014 (ie, all available data at the time the study was conducted).

Study subjects

Included in this analysis were men aged 18 years with 360 days of continuous enrollment before the index date. There were no exclusion criteria. Men with ED were defined as those with an ED diagnosis (organic and/or psychogenic origin; ICD-9-CM codes 607.84 or 302.72) or with a PDE5I prescription (eg, avanafil, sildenafil, tadalafil, or vardenafil). The data do not include men with a claim for other ED treatments (eg, penile injection, implant), which represent only a small percentage of ED treatments.

Study period

The study period included the pre-index period and index date. The pre-index period was the 12 months (360 days) immediately before the index date, which allows assessment of baseline characteristics and comorbid conditions. For men with ED, the index date was the date of first claim of an ED diagnosis or the date of first prescription of a PDE5I. For men without ED, the index date was the end of enrollment. No outcomes were assessed after the index date.

Assessments

The variables examined in men with ED and those without ED included age at the index date, ED-related comorbid conditions, including essential hypertension (ICD9 401, 4010, 4011, and 4019), other cardiovascular diseases (stroke [ICD9 430–438], myocardial infarction and angina [ICD9 410–413], coronary heart disease [ICD9 414.0], and congestive heart failure [ICD9 428]), diabetes mellitus (ICD9 2500–2509, 7751), depression (ICD9 3004, 311, 2962, 29620–29626, 2963, 29630–29636), and benign prostatic hypertrophy

(ICD9 600, 596.0, 788.20, and 788.21), geographic region, health plan indicator, health plan type, coverage indicator, capitated service-claim indicator, and index year and month.

Data analysis

Univariate analysis using descriptive statistics was conducted to assess the prevalence of ED identified by diagnosis or PDE5I prescription in the overall population and in age-by-decade subgroups (ie, 18–29, 30–39, 40–49, 50–59, 60–69, 70–79, 80–89, and   90 years). The prevalence rates of ED-related comorbid conditions were compared between men with ED diagnosis or treatment and men without ED diagnosis or treatment. To assess the potential impact of ED-related comorbid conditions, the prevalence of ED diagnosis or treatment in age-by-decade subgroups was further evaluated among men with each comorbid condition. In addition, multivariate logistic regression analysis was conducted to assess the relationship between ED diagnosis or treatment and age after adjusting for ED-related comorbidities and baseline variables (geographic region, health plan, plan type, capitated vs non-capitated plan) and the year and month of the index date. Backward stepwise multivariate binary logistic regression analysis was conducted to assess which baseline variables significantly differentiated between men with ED and men without ED. All statistical tests were 2-sided with an α-level of 5% with no adjustments for multiple comparisons.

RESULTS

Of the 19,833,939 men in the MarketScan claims database (primary analysis) who met the inclusion criteria, only 1,108,842 (5.6%) had an ED diagnosis or a PDE5I prescription (mean age: 55.2 years). For the Humedica EHR database, of the 5,292,370 men included in the study, 364,723 (6.9%) had an ED diagnosis or a PDE5I prescription (mean age: 58.1 years). Age data for the men with and without an ED diagnosis or PDE5I treatment at baseline in the claims and EHR databases are reported in Table 1. Based on claims data, the prevalence of ED diagnosis or treatment increased with each decade of age until 60–69 years (11.5%), and then decreased during age 70–79 years (11.0%), decreased further during age 80–89 years (4.6%), and even further during age   90 years (0.9%; Figure 1A). The prevalence of ED diagnosis or treatment by age had a similar trend in the EHR database (Figure 1B).

In the claims database, men with an ED diagnosis or treatment had a higher prevalence of any comorbid condition (63.1%) compared with men without an ED diagnosis or treatment (29.3%), including hypertension, other cardiovascular disease, diabetes mellitus, depression, and benign prostatic hyperplasia (Figure 2A). Similar prevalence rates for any comorbidity and each comorbidity in men with and those without ED diagnosis or treatment were observed in the EHR database (Figure 2B). In both the claims and the EHR database, analyses of men with each comorbid condition showed a similar relationship between age and the prevalence of ED diagnosis or treatment (Figure 3A and 3B) as that in the overall population.

The results of multivariate analyses demonstrated an association between age and ED diagnosis or treatment after controlling for comorbid conditions, baseline characteristics, and the year and month of the index date. For the analysis based on the MarketScan claims

database, relative to men aged 18–29 years, the odds of having an ED diagnosis or treatment increased more than five-fold in men aged 30–39 years and in those aged 80–89 years, more than 15-fold in men aged 40–49 years, and more than 20-fold in men aged 50–59 years, 60–69 years, and 70–79 years (all *P*<0.0001; Table 2). In contrast, men aged 90 years had a significantly lower odds of having an ED diagnosis or treatment relative to men aged 18–29 years (*P*<0.0001). Multivariate analysis based on the Humedica EHR database indicated results that were consistent with those from the MarketScan claims database (Table 2).

After controlling for age, baseline characteristics, and the year and month of the index date, the odds of an ED diagnosis or treatment was significantly increased in men with hypertension, diabetes mellitus, depression, or benign prostatic hyperplasia, whereas cardiovascular disease other than hypertension was significantly associated with a lower odds of an ED diagnosis or treatment (*P*<0.0001; Table 3). These results were consistent in the MarketScan claims database and the Humedica EHR database.

Discussion

In the real-world setting represented by two distinct databases, US health insurance claims data and EHR data, analyses indicated that the prevalence of ED diagnosis or treatment is generally low and that there is a significant association between age and ED diagnosis or treatment. The prevalence of ED diagnosis or treatment increased with age, whereas very old age was associated with a decrease in ED diagnosis or treatment. The decrease in ED diagnosis or treatment in very old age may reflect the absence of a sexual partner, lack of interest in sexual activity, insufficient bother by the condition to seek medical care, the impact of other concomitant conditions, or a decreased likelihood that medical practitioners ask very old men about the presence of ED.

Men with an ED diagnosis or treatment had a higher prevalence of comorbid conditions than men without an ED diagnosis or treatment. In addition, the relationship between age and ED diagnosis or treatment also was demonstrated within each comorbidity subgroup. In multivariate analyses, age (each decade after age 29 years and before age 90 years) and certain comorbidities were independently associated with an increased odds of ED diagnosis or treatment. Hypertension, diabetes, depression, and benign prostatic hypertrophy were significant risk factors for ED diagnosis or treatment after controlling for age and other baseline variables. In contrast, other cardiovascular diseases (eg, stroke, myocardial infarction and angina, coronary heart disease, and congestive heart failure) were significantly associated with lower odds of ED diagnosis or treatment, possibly because the severity of these cardiovascular conditions makes sexual activity inadvisable or relatively less important.

The results of the current study were generally consistent with previously published results of real-world observational data. Previous studies have assessed the prevalence of underlying comorbidities in men with ED using data from US health insurance claims databases [12–15] and in men from a UK general practice EHR database [16]. The age distribution of the men was not reported in the UK study, but the reported age distribution of men with ED in the US studies (5%–7% aged 35 years; 16%–17% aged 36–45 years; 34%–36% aged 46–

55 years; 34%–36% aged 56–65 years; 5%–7% aged 66–75 years; and 2% aged 76 years) [12–15] was broadly similar to that of the current study. In men with ED, the prevalence of hypertension (35.9% [12], 41.2% [15], and 41.6% [13]) was similar to that in the current study (45.0%) and the prevalence of diabetes mellitus (16.5% [12], 20.0% [14], and 20.2% [13]) was similar to that in the current study (19.9%). However, the prevalence of depression (9.1% [12] and 11.1% [13]) was somewhat higher than that in the current study (7.0%). Consistent with the present results, the prevalence of comorbid conditions was significantly higher in men with ED than in men without ED [12, 14–16]. Multivariate analysis estimated that the risk of diabetes, hypertension, and depression were increased, overall and across age groups [14–16].

The results of the current study differ from those of US population survey epidemiologic studies of ED prevalence published in the last decade. This is not unexpected because the current study assessed ED diagnosis or treatment, whereas previous population-based epidemiologic studies assessed ED symptoms. Age-specific prevalence rates of ED estimated from the US National Health and Nutrition Examination Survey are higher than those in the current study of claims-based ED diagnosis or treatment: 8.2% versus 5.7% in the current study (40–49 years); 23.9% versus 10.0% (50–59 years); 43.7% versus 11.5% (60–69 years); 60.2% (70–74 years) versus 11.0% (70–79 years); and 77.6% (75 years) versus 4.6% (80–89 y) and 0.9% (90 y) [4]. Similarly, results of a cross-sectional, population-based, nationally representative probability survey in the general community setting estimated higher ED prevalence rates of approximately 10% (40–49 y), 15% (50–59 y), 30% (60–69), and >50% (70 y) [3]. As was the case in the current study, multivariate analysis of the data from this probability survey estimated that hypertension and diabetes were significant risk factors for ED after controlling for age and other characteristics [3]. Concordance between real-world observational data and population survey epidemiological data has been variable in recent studies of other healthcare topics, including diabetes prevalence [21, 22], myocardial infarction prevalence [23], in vitro fertilization usage rates [24], mental health visit frequency [25], asthma medication possession [26], and clinical diagnosis, medication use, and healthcare utilization [27]. Several factors may account for the differences in outcomes, including recall and non-response bias [28], coding errors, and self-reported symptoms versus EHR or claims-based diagnosis or treatment.

The association of ED diagnosis or treatment with hypertension and diabetes in the current study supports the importance of ED as a harbinger of cardiovascular disease. The link between ED and cardiovascular disease has been extensively reviewed by the Princeton Consensus Conferences [29, 30]. Future real-world observational studies with a specific focus on myocardial infarction and stroke and the severity of ED seem warranted.

Strengths of the present study are the use of two large different databases, with both databases pooling data from diverse points of care. The MarketScan databases include data from large employers, managed care organizations, hospitals, and public organizations, thereby providing greater generalizability than data from single-payer databases. The Humedica EHR database contains multiple EHRs from across the continuum of care, both inpatient and ambulatory. However, the MarketScan databases include only employer-sponsored insurance data, so study findings may not be generalizable to men with other

insurance types, men without health insurance, or men who seek ED treatment outside of legitimate medical channels. Furthermore, elderly men in the MarketScan databases are restricted to those with Medicare supplemental insurance. Similarly, the findings generated from the Humedica EHR database may not apply to hospitals not included in the database. Because the current study is cross-sectional, it is not possible to infer any causal relationship between age and ED diagnosis or treatment. Lastly, some men may have had an ED diagnosis or PDE5I prescription before the index date and may have been misclassified as men without ED.

Conclusions

In the real-world setting in the United States, the prevalence of ED diagnosis or treatment is generally low, increases with age, decreases in very old men, and is associated with an increased prevalence of comorbidities. Age is an independent risk factor for ED diagnosis or treatment after controlling for comorbidities. Future studies may be warranted to evaluate whether barriers exist to the diagnosis or treatment of ED in the real-world setting.

Acknowledgments

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What's known

Population-based epidemiologic surveys collect information on ED by questioning a sample of men and then generalize the results to a larger population, thereby providing valuable subject-reported data. However, because of the self-reporting method used in population-based epidemiologic studies, men with ED participating in the surveys may not represent those who are bothered sufficiently by their ED to seek a diagnosis or treatment.

What's new

Based on real-world observational data in the United States, the prevalence of ED diagnosis or treatment is low, increases with age, decreases in very old men, and is associated with increased comorbidities. Age is an independent predictor of ED diagnosis or treatment after controlling for comorbidities.
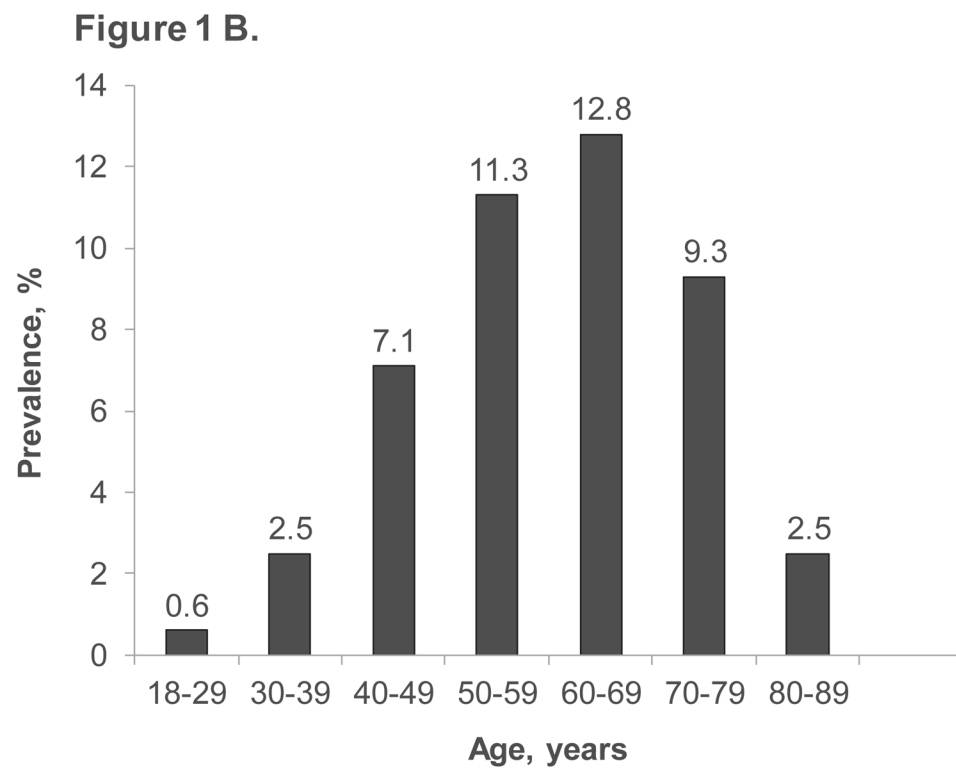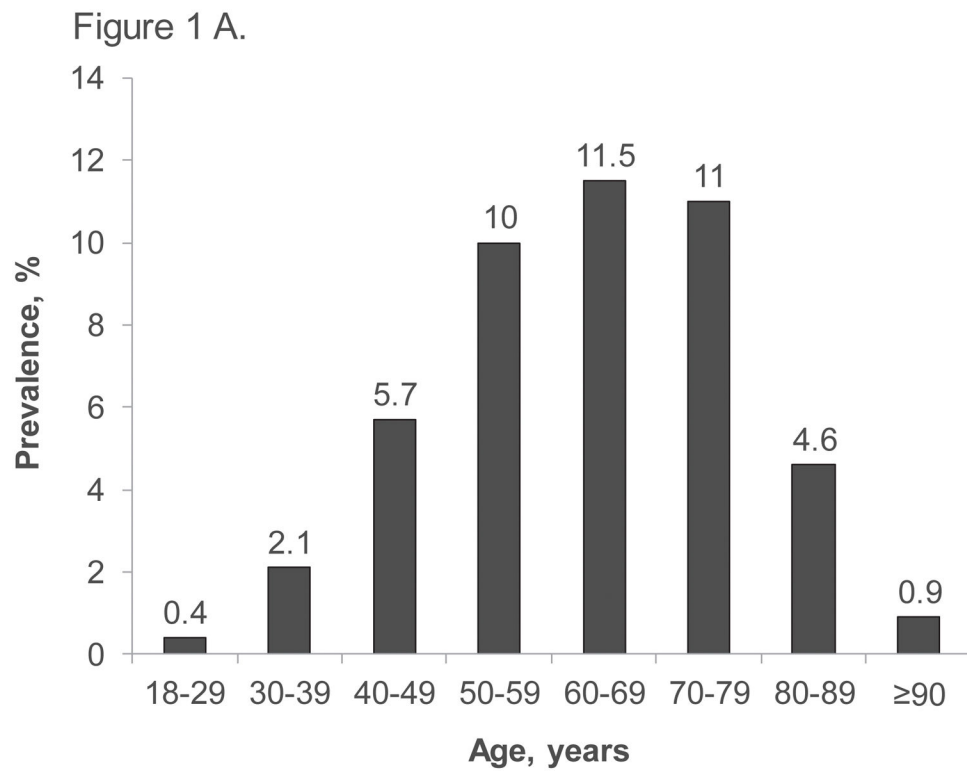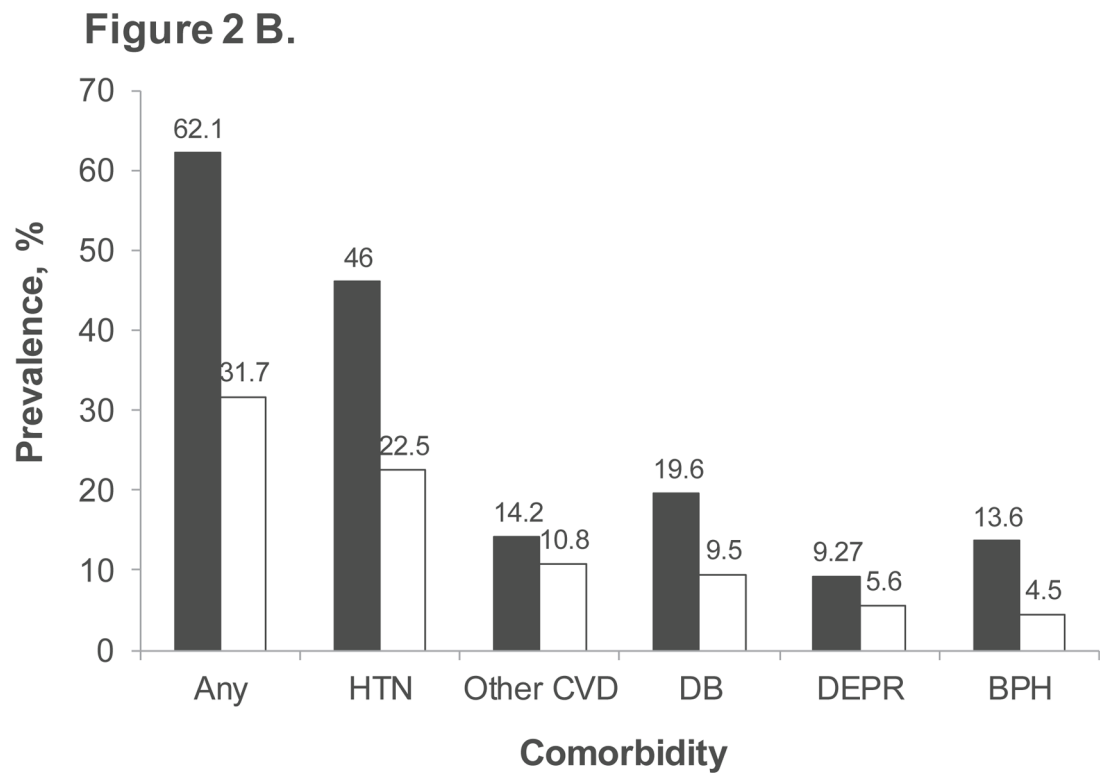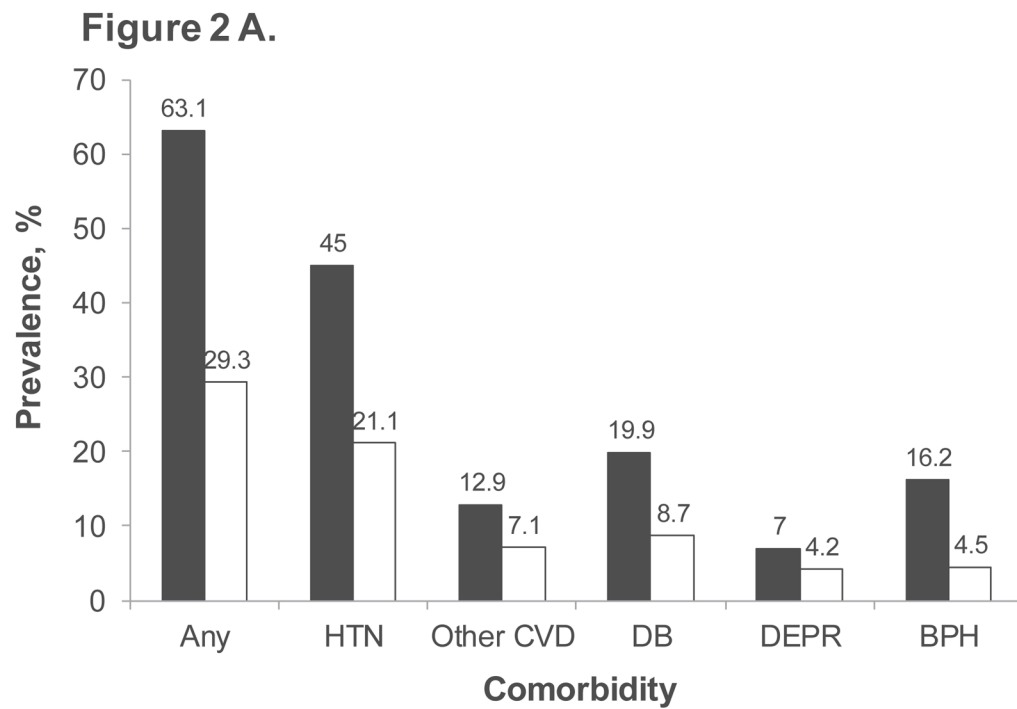
Figure 1 A.

Figure 1 B.

Figure 1.

Prevalence of ED diagnosis or treatment by age in MarketScan claims database (A) and Humedica EHR database (B)

Figure 2 A.

Figure 2 B.

Figure 2.
Prevalence of comorbid conditions in men with and without ED diagnosis or treatment in MarketScan claims database (A) and Humedica EHR database (B)
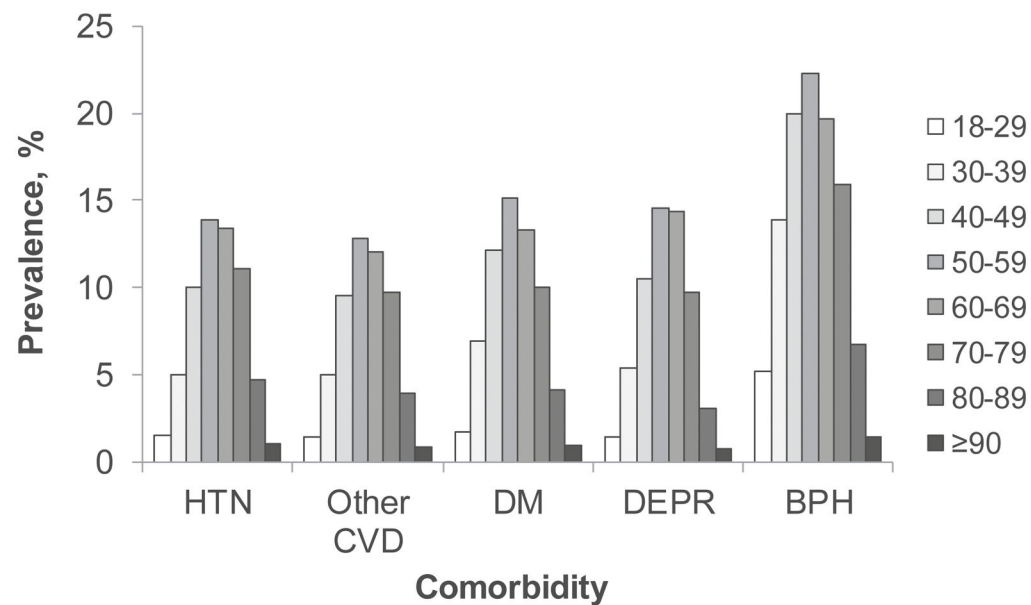
BPH=benign prostatic hyperplasia; CVD=cardiovascular disease; DEPR=depression; DM=diabetes mellitus; ED=erectile dysfunction; HTN=hypertension; Other CVD included stroke, myocardial infarction and angina, coronary heartdisease. and congestive heart failure.

Figure 3 A.

Figure 3 B.

Figure 3.
Prevalence of ED diagnosis or treatment by age and comorbidity in MarketScan claims database (A) and Humedica EHR database (B)
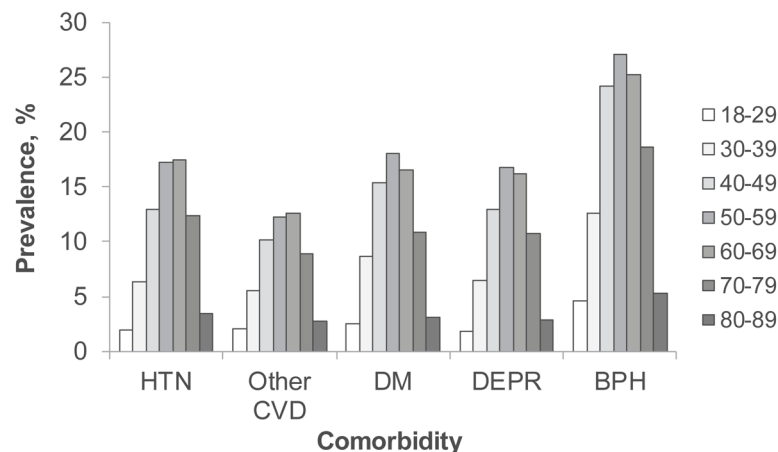BPH=benign prostatic hyperplasia; CVD=cardiovascular disease; DEPR=depression; DM=diabetes mellitus; ED=erectile dysfunction; HTN=hypertension; Other CVD included stroke, myocardial infarction and angina, coronary heartdisease. and congestive heart failure.

Table 1

Age of men with and without ED diagnosis or PDE5I prescription in MarketScan claims database and Humedica EHR database

	With ED Diagnosis or Treatment	Without ED Diagnosis or Treatment
MarketScan Claims Database		
Number of men (% of total)		
Total	1,108,842 (100)	18,725,097 (100)
ED diagnosis only	404,575 (36.5)	–
PDE5I prescription only	464,039 (41.8)	–
ED diagnosis and PDE5I prescription	240,228 (21.7)	–
Mean (SD) age, years	55.2 (11.2)	43.7 (16.5)
Range	18–100	18–120
Age group, years, n (% of total)		
18–29	19,180 (1.7)	4,563,501 (24.4)
30–39	73,731 (6.6)	3,454,937 (18.5)
40–49	223,153 (20.1)	3,723,583 (19.9)
50–59	399,669 (36.0)	3,609,524 (19.3)
60–69	289,919 (26.1)	2,221,472 (11.9)
70–79	83,290 (7.5)	671,891 (3.6)
80–89	19,127 (1.7)	396,345 (2.1)
90	773 (0.1)	83,844 (0.4)
Humedica EHR Database		
Number of men (% of total)		
Total	364,723 (100)	4,927,647
ED diagnosis only	107,529 (29.5)	–
PDE5I prescription only	100,031 (27.4)	–
ED diagnosis and PDE5I prescription	157,163 (43.1)	–
Mean (SD) age, years	58.1 (11.9)	49.9 (19.0)
Range	18–84	18–84
Age group, years, n (% of subgroup)		
18–29	5,212 (1.4)	919,114 (18.7)
30–39	18,591 (5.1)	718,919 (14.6)
40–49	59,392 (16.3)	782,266 (15.9)
50–59	111,653 (30.6)	880,516 (17.9)
60–69	106,105 (29.1)	719,791 (14.6)
70–79	54,226 (14.9)	527,542 (10.7)
80–89	9,544 (2.6)	379,499 (7.7)

ED=erectile dysfunction; EHR=electronic health records; PDE5I=phosphodiesterase type 5 inhibitor.

Table 2

Multivariate analysis of the relationship between age and ED diagnosis or treatment in MarketScan claims database and Humedica EHR database

Age, y	Regression Coefficient (SE)	Odds Ratio*(95% CI)
MarketScan Claims Database		
18–29		1
30–39	1.628(0.008)	5.095[†](5.012–5.181)
40–49	2.732(0.00792)	15.357[†](15.120–15.597)
50–59	3.327(0.008)	27.865[†](27.440–28.297)
60–69	3.062(0.008)	21.376[†](21.043–21.715)
70–79	3.227(0.009)	25.211[†](24.752–25.678)
80–89	1.755(0.012)	5.785[†](5.651–5.922)
90	−0.311(0.0381)	0.733[†](0.680–0.790)
Humedica EHR Database		
18–29		1
30–39	1.612(0.017)	5.012[†](4.845–5.185)
40–49	2.603(0.016)	13.51[†](13.09–13.94)
50–59	3.051(0.016)	21.14[†](20.50–21.80)
60–69	3.107(0.016)	22.36[†](21.68–23.07)
70–79	2.436(0.016)	11.43[†](11.07–11.81)
80–89	1.132(0.019)	3.103[†](2.987–3.223)

Multivariate logistic regression analysis adjusted for comorbidities, baseline variables, and year and month of index date.

[*] Estimated odds of ED diagnosis or treatment relative to age 18–29 years (odds ratio=1).

[†] 2-sided $P<0.0001$.

ED=erectile dysfunction; EHR=electronic health records.

<div align="center">**Table 3**</div>

Multivariate analysis of the relationship between each comorbidity and ED diagnosis or treatment in MarketScan claims database and Humedica EHR database

	Regression Coefficient (SE)	Odds Ratio[*] (95% CI)
MarketScan Claims Database		
Hypertension	0.6324 (0.00271)	1.882[†] (1.872–1.892)
Other cardiovascular disease[‡]	−0.4873 (0.004)	0.614[†] (0.610–0.619)
Diabetes mellitus	0.2839 (0.00333)	1.328[†] (1.320–1.337)
Depression	0.3202 (0.00488)	1.377[†] (1.364–1.391)
Benign prostatic hyperplasia	0.8991 (0.00379)	2.457[†] (2.439–2.476)
Humedica EHR Database		
Hypertension	1.084 (0.005)	2.956[†] (2.928–2.985)
Other cardiovascular disease[‡]	−0.403 (0.007)	0.669[†] (0.660–0.677)
Diabetes mellitus	0.331 (0.006)	1.393[†] (1.376–1.410)
Depression	0.442 (0.008)	1.555[†] (1.532–1.579)
Benign prostatic hyperplasia	1.110 (0.007)	3.033[†] (2.990–3.076)

Multivariate logistic regression analysis adjusted for age, baseline variables, and year and month of index date.

[*] Estimated odds of ED diagnosis or treatment relative to men without the comorbidity (odds ratio=1).

[†] 2-sided $P<0.0001$.

[‡] Other cardiovascular disease included stroke, myocardial infarction and angina, coronary heart disease, and congestive heart failure.

ED=erectile dysfunction; EHR=electronic health records.