

Epidemiology and treatment barriers of patients with erectile dysfunction using an online prescription platform: a cross-sectional study

Severin Rodler ^{1*}, Johannes von Büren ^{2*}, Alexander Buchner ¹, Christian Stief ¹, Katja Elkhanova ², Christian Wülfing ^{3*}, Sven Jungmann^{4*}

¹University of Munich, Department of Urology, Munich, Germany

²Direct Health Services, Munich, Germany

³Asklepios Klinik Altona, Department of Urology, Hamburg, Germany

⁴FoundersLane, Berlin, Germany

* Authors contributed equally

Corresponding Author:

Name	Severin Rodler, M.D.
Email address	severin.rodler@med.uni-muenchen.de
Telephone	0049 89 4400 0

Abstract

Background

Erectile Dysfunction (ED) is a highly common sexual dysfunction of men but often undertreated as patients experience high treatment barriers.

Aim

To characterize patients with ED using an online prescription platforms (OPP) and determine treatment barriers that might prevent patients from seeking care in conventional setting.

Methods

Data from a German OPP was retrospectively analyzed with focus on patients suffering from ED with at least one online prescription of Phosphodiesterase-5 (PDE5) inhibitors between May 2019 and November 2019. In addition, a voluntary questionnaire was used to assess additional social features and prior treatment barriers.

Outcomes

The main outcome measures were the epidemiological data, prescription metadata and follow-up questionnaires.

Results

11,456 male patients received prescriptions via the OPP (Mean age: 49 years (95% CI 46.92 - 47.45)). Patients lived mainly in a rural areas (69%), and frequently sought prescriptions outside the average office times of German urologists (49%). From all patients that responded to a voluntary questionnaire (n=242) the majority were employed full-time (81%), married (50%) and native German (94%). 63.5% had not used PDE5 inhibitors before. From all repeat users, 41% had received them from unreliable sources. Reasons to seek treatment via the OPP were convenience (48%), shame (23%), and discretion (13%).

Clinical Translation

Patients with ED might profit from OPPs that lower treatment barriers as shame and lack of discretion in conventional clinical care settings.

Strengths & Limitations

Causal connections of treatment barriers cannot be concluded from this study and certain patient subgroups might be missed due to the retrospective study design

Conclusion

In this first study to epidemiologically characterize ED patients of an OPP, it was confirmed that inconvenience is a treatment barrier, along with shame and perceived lack of discretion. This is the first evidence that OPPs reduce treatment barriers and ease access for patients to the medical system.

Keywords: Erectile dysfunction, online prescription platform, telemedicine, treatment barrier

Introduction

Erectile dysfunction (ED) is a multidimensional and highly common sexual dysfunction of men [1]. Psychogenic, vasculogenic, neurologic, and endocrinologic changes, among others, are involved in this complex disease [2]. Treatment includes lifestyle interventions, pharmacological treatment with Phosphodiesterase-5 (PDE5) inhibitors, vacuum erection devices, intracavernosal injections, and surgical interventions [3]. As ED is highly associated with metabolic syndrome and cardiovascular disease, incidence rates are high in western countries with 52% among patients between 40 and 70 years old and increasing with age [4]. This high prevalence is confirmed in later studies where researchers noted a prevalence peak of ED at age 50-59 [5]. A desire for therapeutic intervention was expressed in 50% of men in their 60s [6].

Conversely, data on patients treated for ED does not reflect this high prevalence [7]. ED is commonly missed in patient evaluations, either due to a lack of consideration, false patient beliefs, or embarrassment of both clinician and patient [8, 9]. This lack of consideration is aggravated in at-risk populations as studies demonstrate high ED rates but no awareness of the actual disease in this patient group [10]. Further treatment barriers are time and geographical [11] issues that prevent patients from seeking treatment, especially in rural areas.

Direct-to-consumer healthcare platforms have gained interest, especially in highly focused indications with high treatment barriers [12]. In 2006, online consultation was considered effective in the treatment of ED, especially for men who experience high embarrassment [13]. Digital healthcare platforms have also been shown to improve the treatment of urologic patients by overcoming geographical barriers [14] and to provide urgent care for urinary tract infections [15]. At the time of this study, a comprehensive analysis of patients with ED using online prescription platforms (OPP) is lacking.

Objectives

The objective of this study was to describe the characteristics of a population that accesses an OPP for ED, including demographic factors, spatial distribution, and time-related use patterns, along with identifying potential treatment barriers.

Methods

Study design

A cross-sectional study was conducted with anonymized data provided by Direct Health Services, the provider of “www.gospring.de”, a German OPP for men’s health. Additionally, a systematic literature review was conducted. We searched in title and abstract on MEDLINE for synonyms of ED as defined by a MeSH search (i.e.: Dysfunction, Erectile; Male Sexual Impotence; Impotence, Male Sexual; Sexual Impotence, Male; Male Impotence; Impotence, Male; Impotence) combined with either the MeSH synonyms for Telehealth (i.e. Mobile Health; Health, Mobile; mHealth; Telehealth; eHealth; Remote Consultation) or the MeSH synonyms for shame (i.e. shame; embarrassment). The complete set of MeSH terms was searched through <http://www.nlm.nih.gov/mesh/>. The search results were screened by two reviewers working independently and disagreements were resolved through consensus with a third reviewer. This manuscript was prepared according to the RECORD statement, a new extension of the STROBE statement [16]. All research has been carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki) and its later amendments. Informed consent was received by all participants. Prior to initiation of the study the local ethics authority (Ethikkommission der Ludwig-Maximilian-Universität München) revised the project design and waived approval (Reference number: 19-718).

Setting

The service of the OPP is currently available in Germany only. Patient data was collected between May 2019 (service launch date) and November 2019. Between August 2019 and September 2019, a follow-up survey was conducted in this population (P2, Table 1). Participation in the survey was voluntary and a monetary incentive was provided. Questionnaires with at least 90% of questions answered were included.

Participants

Male patients who received prescriptions for ED via the OPP were included in this study. Patients aged 18 years old or older with self-assessed ED were eligible for prescription evaluation. ED was confirmed by physicians prior prescription, including only patients experiencing ED problems regularly [17]. Patients living in cities with more than 100,000 inhabitants were classified as “urban” while all others were considered “rural”[18].

Statistical analysis

A chi-square test was used for statistical analysis, and p-values smaller than 0.05 were regarded as statistically significant. All calculations were conducted by MedCalc 19 (MedCalc, Ostend, Belgium) software.

Results

General patient characteristics

The cohort consisted of 11,456 patients (P1) diagnosed with ED on the OPP between May 2019 and November 2019. Mean age at the time of prescription was 49 years (95% CI 46.92 - 47.45; range 18 - 91, Table 1). Approximately 80% were treated with the active substance sildenafil, and 20% of patients received the active substance tadalafil. Sixty-nine percent reported living in a rural area, whereas 31% lived in urban areas. Approximately half of treatment requests (51%) occurred between 7 a.m. and 5 p.m. during the average working hours of a urologist, whereas 49% occurred between 9 p.m. and 7 a.m. (Figure 1a). The number of prescriptions was independent of the weekday. Twenty-seven percent of prescriptions were written on the weekend and 73% from Monday to Friday. The days with the highest number of treatment requests were Sunday and Monday (Figure 1b).

Analysis was conducted for a subset of 242 patients (P2) that responded to the follow-up survey completely. The P2 group differed significantly in terms of age with an average age of 52 years (95% CI 50.6 - 53.4; range 20 - 78; $p < 0.001$). This age difference also appeared with the subgroup of patients who had previously been treated with PDE5 inhibitors (P3: $n=92$) with a mean age of 52 (95% CI 50.84 – 53.16; range 26 – 78; $p < 0.001$). Other treatment characteristics like active substance used, location, time of day, and day of the week revealed no significant differences between the three groups.

Additional social features of patients

Through a voluntary follow-up survey, further patient characteristics were investigated (Table 2). Mid-range earners were the largest subgroup of those seeking help, represented by 35% with a monthly gross income between 2,001-3,000 euros and 30% between 3,001-5,000 euros. Fifty percent of respondents had a master's or bachelor's degree, 18% had completed vocational training, and 32% had a high school degree as their highest education level. Fifty percent of respondents stated they were married, 26% were in a relationship, and 19% were single. In terms of sexual orientation, 88% of patients identified themselves as heterosexual, 4% as homosexual, and 5% as bisexual. Concerning employment status, 81% of respondents were employed full-time, 4% part-time, and 10% were retired. Regarding ethnicity, 94% considered themselves native German, while 6% identified as immigrants.

Previous usage of Phosphodiesterase-5 (PDE5) inhibitors

Patients who agreed to answer the follow-up survey (n=242) were asked for their previous treatment with PDE5 inhibitors. No previous usage was reported by 63.5% of patients (Figure 2a). Of the patients that had used potency drugs previously (n=92), 41% reported purchasing the medication at a pharmacy, 17% via online sources, 14% via the black market, and 28% via other sources, such as through a friend (Figure 2b).

Rationale for online prescription and source of referral

Patients were asked for their primary motivation to use an OPP in order to identify potential treatment barriers in conventional prescription settings. The question was included in the follow-up survey (P2) with a time lag. Patients (n=152) were allowed to choose multiple options. Forty-eight percent of respondents stated convenience was one of the main reasons for using an OPP, 23% for discretion, and 13% for shame (Figure 3a). Patients were referred to the OPP via TV advertising (40%), Google search engine advertising (29%), online media focusing on ED (19%), friends (1%) and other sources (12%, Figure 3b).

Discussion

In this study of patients with ED using a German OPP for prescription of PDE5 inhibitors, the majority of patients were between 40 and 60 years old, married, and living in a rural area. Convenience, discretion, and shame were major reasons to use this OPP to buy PDE5 inhibitors. For the majority of patients, it was the first prescription of PDE5 inhibitors, while previously treated patients showed considerable use from potentially illegal sources.

The average male in Germany is 43.1 years old [19] with the largest birth group being 55 years old [20]. The incidence of ED increases over time with rates of 28% at age 50 and 64% at age 70 [5]. According to those studies, the ED rate in Germany for 45-year-old patients is reported to be 25.2% [21]. The average age of patients using the OPP was 49 years with 50% of users being between 37 and 56 years old. As we were expecting higher ED rates in the older age groups, the population using the OPP seems to be left-shifted compared with the expected overall prevalence in the respective age groups.

In 2017, 20.9 million or 62% of men above 18 were in relationships, of which 84% were married [22]. In the analyzed cohort, the percentage of people in relationships was 76% higher than the previously mentioned study. Data on sexual orientation in Germany is limited to a few studies, revealing 87% of the German population as heterosexual and around 1% as homosexual [23]. Patients using the OPP presented with a rate of 4% as homosexual, reflecting either a higher engagement of homosexuals with their sexuality or higher rates of homosexual men detected by real-world surveys [24].

The average net income in Germany is 3,132 € [25]—comparable to the study cohort. The distribution across the various income categories confirms this finding and reveals similar percentages in Germany and this study [26]. The employment rate in Germany for men is 79.6% with 6-12% of men working part-time, depending on age [27]. Rates were higher in the study cohort, with a higher percentage in full-time jobs.

Twenty-four percent of males in Germany have a migratory background compared to 6% of OPP users [28]. Patients with migration background might be underrepresented as they are either not attracted by the advertising strategy of the OPP or they have higher treatment barriers than the average population. As this is the first study to characterize a patient cohort using an OPP for ED, it has been revealed that patients were on average younger than expected, were mostly in full-time employment, were less likely to have a migratory background, and were more likely to be in a relationship or married than the overall German population.

ED is commonly associated with high treatment barriers. Embarrassment, either to talk to a doctor or for the doctor to ask, is frequently reported in the literature [1]. Thirteen percent of patients from P2 reported shame and 23% reported discretion as the leading reason to use an OPP, revealing that both aspects related to embarrassment are important. Although many studies focus on shame, the distance to a specialist center is also reported to be a concern [29]. In the study cohort, the majority (69%) was from rural areas, compared to 62% in the overall German population [18]. People in these areas might have less access or have to make greater efforts to reach a specialist.

The analysis of the prescription request times revealed that 49% of prescriptions were written outside the estimated standard office times of a German urologist. Surprisingly, 48% of the study cohort stated convenience as the major reason to use an OPP. Convenience might therefore apply to both geographical and time-related treatment barriers. Interestingly, from a patient perspective, the traditional treatment barriers of shame and discretion are outweighed by convenience. The data suggests that primarily full-time employed, married patients between 40 and 60 use the OPP to get accelerated access to the medical system, and thereby avoid time or distance-related treatment barriers. These findings are highlighted by the fact that for the majority of patients, it is the first prescription of a PDE5 inhibitor.

In the past, treatment barriers have led to high rates of illicit PDE5 inhibitor use as patients bypass the medical system. A Swiss study revealed that the overall prevalence of men using PDE5 inhibitors without prior professional healthcare interaction was 3.0% and that 32.3% of patients buying PDE5 inhibitors bought them without prior professional healthcare interaction [30]. In the OPP group, a large percentage had obtained PDE5 inhibitors either directly from illegal sources or via friends. PDE5 inhibitors from illegal sources put patients at risk of wrong dosing or active ingredient [31]. Additionally, relevant contraindications and conditions where ED is an early warning symptom of other diseases [1] might be overlooked, such as diseases caused by cardiovascular risk factors, like diabetes mellitus, hypertension, dyslipidemia and sleep apnea [32-35]. In this setting, healthcare platforms can grant access for patients confronted by treatment barriers to the medical system and achieve not just an improved quality of life but also treat the underlying disease and treat it effectively. Therefore, OPPs have the potential to reduce illegal substance use and promote the health of men.

OPPs seem to be an important addition to the treatment options of patients. Besides the OPP in this study, health platforms can be applied to other diseases and conditions where specialists are either spatially or temporarily not available [36], where high treatment barriers exist, [37] or where access to medical care has to be facilitated [38]. Quick scalability in predefined indications and thereby access of a large population to specialized care are of great potential, but equivalence in standard of care to in-person visits has still to be demonstrated [12]. OPPs have the potential to provide a high standard of care as treatment algorithms are standardized. High-quality OPPs might focus on structured follow-up to evaluate safety and efficacy of the prescribed drugs besides the initial indication. Through structured follow-up of underlying diseases and prevention, a higher standard than routine outpatient care might be provided. Furthermore, high-risk patients could be referred earlier to a specialist—either in-person or online. Thereby, OPPs can, in selected indications, close an important care gap and add to adherence and pharmacovigilance. As there is limited data on safety and efficacy of such platforms, further research is warranted to assess OPPs prospectively.

This study is limited by the cross-sectional design, as causative connections and developments over time cannot be analyzed. Response to the additional follow-up survey was voluntary and monetarily incented. Despite a high response rate of 35.5% sample bias might apply, as P2 and P3 were significantly older than P1. Nevertheless, important treatment barriers, such as location, time of day and day of the week are equally distributed throughout all groups. As certain parts of the questionnaire include sensitive questions, some patients might have answered inaccurately. The validity of the study is limited by the OPP design and advertising channels, such as TV commercials potentially attracting more elderly people. Therefore,

conclusions about treatment barriers in the overall German population might not be represented and would require further evaluation, especially in underrepresented subgroups.

Conclusion

As the first study to epidemiologically characterize ED patients using an OPP, the majority of patients were found to be full-time employed, married, native German, and living in a rural area. Patients using the OPP reported convenience, shame, and discretion as treatment barriers and searched for solutions to surpass them. OPPs can fill this demand and prevent patients from purchasing PDE5 inhibitors outside the medical system. Through the deployment of interdisciplinary follow-up of associated diseases and the potential to provide an access point to the medical system, OPPs might be beneficial beyond their primary focus. Further research is warranted to verify positive effects on medical care and to determine the safety and efficacy of OPPs prospectively.

Ethics Committee Approval

Prior to initiation of the study the local ethics authority (Ethikkommission der Ludwig-Maximilian-Universität München) revised the project design and waived approval (Reference number: 19-718).

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Table 1: Patient characteristics

Parameter	All prescriptions ED (P1) (n=11456)		Follow-up survey (P2) (n=242)		Previously treated (P3) (n=92)		p value (3 groups)
	%	n	%	x	%	n	
Age							
Median	49		52		52		<0.001
95% CI	46.92 - 47.45		50.6 - 53.4		50.84 - 53.16		
Range	18 - 91		20 - 78		26-78		
Age group	100%	10,680*	100%	237*	100%	84*	<0.001
18-25	6%	685	3%	6	0%	0	
26-30	7%	794	4%	9	4%	3	
31-40	19%	2,045	11%	27	14%	12	
41-50	25%	2,665	26%	62	21%	18	
51-60	30%	3,232	41%	98	44%	37	
61-70	12%	1,259	15%	35	17%	14	
PDE5	100%	9,351*	100%	233*	100%	84*	0.005
Sildenafil	77%	7,154	71%	166	68%	57	
Viagra	3%	285	7%	16	1%	1	
Tadalafil	18%	1,696	20%	47	27%	23	
Cialis	2%	216	2%	4	4%	3	
Location	100%	11,456	100%	242	100%	88	0.09
Rural	69%	7,937	67%	162	59%	52	
Urban	31%	3,519	33%	80	41%	36	
Day time	100%	11,456	100%	242	100%	88	0.216
Office time	51%	5,657	53%	128	57%	50	
Out of office time	49%	5,799	47%	114	43%	38	
Weekday	100%	11,456	100%	242	100%	88	0.84
Monday-Friday	73%	8,318	71%	173	70%	62	
Weekend	27%	3,138	29%	69	30%	26	

*Numbers are lower than the respective population due to changes in the structured questionnaires in the first month of the service

Table 2: Social characteristics

Parameter	Follow-up survey (P2) (n=242)	
	%	n
Income	100%	242
<1000	5%	11
1001-2000	19%	46
2001-3000	35%	84

3001-5000	30%	73
>5000	12%	28
Education	100%	242
University Degree	50%	120
Training	18%	43
School	32%	79
Relationship status	100%	242
Single	19%	47
Relationship	26%	64
Married	50%	120
Other	5%	11
Sexual Orientation	100%	242
Heterosexual	88%	214
Homosexual	4%	10
Bisexual	5%	12
Other	2%	6
Employment status	100%	252*
Full time	81%	203
Part time	3%	8
Unemployed	1%	2
Retired	10%	25
Student	2%	4
Other	3%	10
Migration background	100%	242
German	94%	227
Non German	6%	15

* multiple answers of 242 respondents

Figure 1: Prescription volume by daytime and weekday

a: The average prescription volume (n=11,465) was analyzed by hours. Day time was defined as the time between 8-17 (black), approximating the opening hours of urologists and pharmacies. b: Prescription volumes (n=11,465) were analyzed by weekday. Monday to Friday were defined as weekdays (black), referring to the opening days of urologists in Germany.

Figure 2: Previous prescription and source of potency drugs

a: Patients who agreed to answer the follow-up survey (n=242) were asked for their previous usage of potency drugs. Answer options were limited to either “never” (black) or previous use (white). When patients stated previous use they could choose between “irregular” or “frequent” use. b: All patients who have used potency drugs before (n=92) were selected and asked for the primary source of their prior potency drug prescription.

Figure 3: Rationale and referral for online prescription of PDE5 inhibitors

a: Patients (n=242) were asked where they have heard about the analyzed online prescription platform for the first time. Response options included TV advertising (TV), Google search engine advertisement (Google), online articles about e.g. erectile dysfunction treatment (Online media) and friends as well as other sources. b: Patients (n=152) were asked for their primary reason to use an online prescription platform in order to identify potential treatment barriers in conventional prescription settings.