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Use of phosphodiesterase type 5 inhibitors in assistive living and home care settings

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ABSTRACT

The purpose of this descriptive study was to assess frequency of phosphodiesterase type (PDE-5) inhibitor use (sildenafil, tadalafil, ardenafil) in community settings.
Methods: A retrospective record review was conducted to determine PDE-5 inhibitor use in older males (mean age 79.2) residing in three assisted living communities (n = 126), or living in private homes with home care services (n = 109).
Results: Two participants from assisted living had PDE-5 inhibitors listed on medication profiles, while no participants from the home care setting had any listed.
Implications: Many factors may have contributed to the absence of PDE-5 inhibitors in records, including comorbidities precluding use; fear of side effects; reluctance to report use; and lack of erectile dysfunction diagnosis to name a few. It is unknown whether sexual function, or the need for PDE-5 inhibitors was ever assessed by providers. Future research is warranted given the aging population and the benefits of holistic assessments.
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1. Introduction

Erectile dysfunction (ED) is the inability to achieve or maintain a penile erection for satisfactory sexual performance (Sivalingam, Hashim, & Schwaibold, 2006). This common sexual dysfunction is diagnosed in approximately 40% of men aged 70–75 in the USA (Sanford, 2013). With the ever aging population, projections indicate that by 2025, 322 million men worldwide will experience ED (McMahon, 2014). Overall quality of life is affected by all aspects of sexual satisfaction throughout the life span (Kazer, 2013). ED is frustrating, embarrassing, and causes distress for individuals (Brody & Weiss, 2015), but there are effective treatment regimens. The literature supports the treatment of ED, in part, with the use of phosphodiesterase-5 (PDE-5) inhibitors. In spite of the availability of this class of drugs, the majority of treatment recipients are under the age of 70 (Brody & Weiss, 2015; Peate, 2012), suggesting the possibility that older males may not be offered, or may refuse this treatment option.

The purpose of this descriptive study was to assess the frequency of PDE-5 inhibitor use (sildenafil, tadalafil and vardenafil) among older males living in assisted living communities, or receiving home care services in private homes.

2. Background

Several physiological functions must occur in order for a male to experience an erection, including dilation of penile vasculature, relaxation of smooth muscle and increased intracavernosal blood flow (McMahon, 2014). Any pathological condition affecting endothelial function can cause ED, including diabetes mellitus (DM), cardiovascular (CV) disease, hypertension (HTN) and obesity (McMahon). The function of the endothelium is to regulate homeostasis by alternating between vasodilation and vasoconstriction of the blood vessels when necessary. When adequately functioning, the endothelial lining and cells therein maintain adequate vascular tone. However, continuous and prolonged stress on the endothelial lining contribute to disease formation, commonly seen in older adults where many years of endothelial stress and damage result in such co-morbidities as HTN, DM, CV disease, obesity and ED (Vita & Keaney, 2012).

The process of diagnosing ED can be problematic, partly due to the sensitivity and perceived stigma of the subject. With increasing awareness of ED, accurate and specific questionnaires have been developed over the last 5 years to assess patients for ED, and thus to assist them to achieve sexual satisfaction. One example is the International Index of Erectile Function (15 items) which has two abbreviated versions: the Erectile Function Domain (6 items) and the Sexual Health Inventory for Males (5 items) both of which are the primary instruments used among men with ED, while the Premature Ejaculatory Profile (4 items) is used for patients with premature ejaculation (Giuliano, 2013). Another comprehensive instrument is the Male Health Sexual Questionnaire (25 items) that includes topics such as erection, desire for sex, ejaculation and sexual satisfaction (Cappelleri & Rosen, 2007).

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Although these instruments are readily available, their use has not yet become a routine part of clinical assessments either in primary care, or in the urology specialty area (Cappelleri & Rosen, 2007).

Challenges to ED diagnosis also include necessary in-depth physical and psychosocial assessments, requiring that patients must be extremely descriptive and provide specific information so that best treatment options are selected. Additionally, patients diagnosed with ED require further screening for potential CV disease, which can be sometimes be under-diagnosed in this situation (Tamas & Kempler, 2014). After a thorough history is obtained, a physical examination focused on secondary sexual characteristics follows, and is used to rule out various possible causes of ED (Glina, Cohen, & Vieira, 2014). For example, assessment of patient's height, weight, blood pressure, and waist circumference are performed, results of which may indicate risk factors for CV disease or DM. Fasting blood sugars may be drawn, as well as lipid panels to rule out DM and hyperlipidemia respectively. Other blood tests may be performed including testosterone, prolactin, and/or prostate levels, all of which can interfere with the ability to maintain an erection (Steggall, 2012). Additionally, one-third of ED cases are psychological in origin, requiring assessments and screenings for depression, stress and debilitating anxiety (Waren, 2009).

2.1. Pharmacological treatment: Phosphodiesterase type 5 inhibitors

PDE-5 inhibitors are the drugs of choice for ED treatment. Sildenafil (Viagra), vardenafil (Levitra) and tadalafil (Cialis) act by the same mechanism that is, relaxing smooth muscles and thus, increasing blood flow (Steggall, 2012). Sildenafil and vardenafil are ordered on an "as needed" basis, whereas tadalafil can be taken as a regular scheduled daily dose (Steggall). Patients should be advised that these medications should be taken in conjunction with some form of sexual stimulation to improve the probability of an erection and an enhanced sexual experience. Medication dosage is patient specific and typically begins low and may titrate upward. Sildenafil is prescribed 30 minutes prior to sexual activity, vardenafil, 1–2 hours prior, and tadalafil is prescribed with no regard to sexual activity (Seftel, Kim, Goldfischer, Baygani, & Burns, 2014).

Although PDE-5's are within the same drug classification, they are very different drugs with varied onsets of action, and therefore, different optimal times to ingest prior to sexual activity. All PDE-5's are rapidly absorbed from the gastrointestinal tract. Food, particularly fatty food, is known to slow down the absorption of sildenafil, but has no effect on tadalafil. When taken with food the rate and extent of sildenafil absorption is reduced by approximately 30%, while the rate of absorption of vardenafil is reduced by 20% (Seftel et al., 2014). Prescribers must be familiar with the patient and each medication to optimize drug action, and consequently, the patient's sexual experience.

Sildenafil (Viagra), commonly referred to as the "little blue pill", acts as a selective inhibitor of cyclic GMP (cGmp)-specific PDE-5, which results in smooth muscle relaxation, vasodilation, increased blood flow to the penis and an enhanced erection. The vasodilation action affects the arteries and veins and can cause side effects such as headache, facial flushing and significant hypotension. For that reason, it is contraindicated in patients who take long-acting nitrates or who are using short-acting nitrates for coronary artery disease due to the already increased vasodilation (Bruzziches, Francomano, Gareri, Lenzi, & Aversa, 2013). The initial dose in the elder population is 25 mg 30 minutes pre coitus, and the action lasts up to 6 hours (Steggall, 2012).

Vardenafil (Levitra) has the same mechanism of action as sildenafil. It is recommended 20–60 minutes prior to coitus. While it acts more rapidly than sildenafil or tadalafil, side effects are similar to those of sildenafil and include headache, hypotension and flushing due to the vasodilation (Bruzziches et al., 2013).

Tadalafil (Cialis), a potent highly selective PDE-5 enhances relaxation of trabecular smooth muscle of men with ED, with a rapid response lasting up to 24 hours. It allows patients to maintain erections, increased penetration ability and sexual satisfaction without having to remember to take a pill pre-coitally; rather the pill is taken daily (Corona et al., 2011). This PDE-5 is reserved for patients who have regular sexual activity (2–3 times a week) and has similar side effects to sildenafil and vardenafil (Corona et al., 2011).

2.2. Review of literature

Increasing age does not necessarily indicate decreasing sexuality. In fact, findings from a 2007 study (Lindau et al., 2007) on sexuality among older adults (n = 1455) suggested that 54% of people between the ages of 75–85 years in this study remained sexually active at least two to three times per month while 23% reported having sex once a week or more. Of this population, 31% reported engaging in oral sex, and 52% reported masturbating regularly. A total of 41% of respondents in this age group reported sex as "not important at all", whereas 59% felt it was "very important" (Lindau et al., 2007).

Despite the sexual needs of older adults, and the availability of PDE-5 drugs, they are prescribed more often in younger males than in older adults (Brody & Weiss, 2015). Evidence suggests that PDE-5 inhibitors have a lower response rate in the elderly population when compared to younger patients due to patients not taking the PDE-5 inhibitor (Gareri, Castagna, Francomano, Cerminara, & DeFazio, 2014). In this study related causes of ED were identified such as neurogenic, hormonal, psychological, physiological, iatrogenic and arterial. Pharmacological and non-pharmacological treatments for ED were evaluated in the treatment of ED. The use of PDE-5 inhibitors were found to be most effective for ED, however a response rate was achieved in older adult males as compared to younger adult males (Gareri et al., 2014).

Although remarkable progress has been made in ED treatment, many elderly males refuse to seek medical attention and believe ED is an irreversible condition and a part of the aging process (Zhang et al., 2014). A study conducted between 2007 and 2008 identified and diagnosed 4507 patients, between the ages of 20–80 with ED for the purpose of describing current medical treatment for erectile dysfunction and whether aging males (over the age of 60) found it beneficial to receive medical treatment for ED. A total of 4241 completed the study, 3837 were treated with a PDE-5 inhibitor. After receiving treatment for ED with PDE-5 inhibitors, scores on their International Index Function-Erectile Function, Erection Hardness Scale and IIEF ("How satisfied have you been with your overall sex life?" improved significantly in the older adults, supporting that it is never too late to treat ED.

Given the dearth of literature examining community-dwelling older adults who are being treated with PDE-5 inhibitors for ED, the current descriptive study was conducted. As more data are gathered about older men and potential ED treatment regimens, providers will be better able to meet their holistic needs surrounding sexuality as they age.

3. Methods

Internal review board approval was obtained from the researchers' university and from the home care agency, while the director of nursing for the three assisted living facilities granted permission for researchers to perform retrospective record reviews of all male patients living therein. Patient confidentiality and anonymity were maintained, no patient names were documented in findings, and data were reported in the aggregate without any identifiers used. A convenience sample was used, and inclusion criteria were: all males over the age of 65 residing in any of three assisted living facilities, or receiving home care services from one visiting nursing agency in CT.

Researchers gathered data from the previous 12 months by reviewing all medication records for the presence of PDE-5 inhibitors for all patients meeting inclusion criteria. Records were examined alphabetically based on lists of current residents/patients, and presence of PDE-5 inhibitor drugs on the medication profile was documented.

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