ORIGINAL RESEARCH—ED PHARMACOTHERAPY

A Feasibility Study Comparing Pharmacist and Physician Recommendations for Sildenafil Treatment

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ABSTRACT

Introduction. In Europe , pharmacists may be an important first point of contact for men with erectile dysfunction (ED) asking for advice and treatment.

Aim. To determine if European community pharmacists could appropriately recommend suitability for supply of sildenafil 50 mg for the treatment of ED.

Methods. For this cross-sectional, observational study, the current Summary of Product Characteristics was adapted to create a study drug information sheet for use in a pharmacy setting in which, for certain patients, supply is not suitable and referral to a physician is recommended. After training and with use of a guidance questionnaire, pharmacists assessed the suitability of supply of sildenafil 50 mg for men presenting to their pharmacy. Men with self-reported ED who were not currently using a phosphodiesterase type 5 inhibitor were recruited. Within 7 days of the pharmacist-patient interaction, a physician with experience in the management of ED telephoned the subject to assess suitability. If there was discordance between the pharmacist and physician recommendations, the case was independently reassessed by a physician specialist in sexual medicine.

Main Outcome Measures. The primary end point was the concordance rate (with 95% confidence intervals) between pharmacist and physician recommendations. Rates were weighted by country sample sizes.

Results. Concordance (95% confidence interval) was 0.70 (0.66–0.74) between pharmacist and physician recommendation, indicating agreement in 70% of cases, and was 0.90 (0.86–0.94) between pharmacist and physician specialist in sexual medicine. Furthermore, if the cases in which the pharmacist did not put subjects at risk (i.e., gave an acceptable recommendation) are assessed, the success rate is 83.5% (79.6–87.4%) and 92.8% (90.1–95.5%), respectively.

Conclusion. Pharmacists were accurate in providing suitable treatment recommendation, generally not recommending sildenafil for men without ED and recommending physician assessment when there was any question about cardiovascular health, other comorbidity, or co-medication. **Symonds T, Dean JD, Carr A, Carlsson M, Marfatia A, and Schnetzler G. A feasibility study comparing pharmacist and physician recommendations for sildenafil treatment. J Sex Med 2011;8:1463–1471.**

Key Words. Erectile Dysfunction; Nonprescription Drugs; Pharmacist; Sildenafil; Treatment Guidance; Phosphodiesterase Type 5 Inhibitors

Introduction

In Europe, the public recognizes community pharmacies as a "vital, integral part of the health services" that are conveniently accessible and ". . . where sound, objective advice on health issues can be obtained, from a knowledgeable health professional, in an informal environment in which they feel relaxed, without the need to make an appointment." [1] A corresponding role for pharmacists as providers of patient-focused and medicine-focused care is now common [2]. Thus,

community pharmacists are an important first point of contact with a healthcare professional for people seeking advice and guidance on treatment. These services are increasingly used and studied in various countries in Europe, either in the context of improving patient adherence to prescription treatment, additional medication review for potential drug–drug interactions, or supply of nonprescription medicines [3–7]. Benefits of specific education, training programs, and ongoing support on pharmacists' confidence in determining patient suitability for medicine supply and in providing patient counseling have been demonstrated for emergency hormonal contraception [8], simvastatin [9], and nicotine replacement therapy [10].

Community pharmacists may also be an important first point of contact with a healthcare professional for men with erectile dysfunction (ED). Recently, an observational study compared men with vs. without a prescription for a phosphodiesterase type 5 inhibitor (PDE5i: sildenafil, tadalafil, or vardenafil) who asked for ED treatment at one of more than 500 pharmacies in Spain [11]. There were no statistically significant differences between the two groups of men in ED severity, the proportion without ED, or the duration of symptoms before first consultation with a healthcare professional (mean of 26 months in each group). In the nonprescription group, the pharmacy visit was the first discussion about ED for 60%, 50% of those who had previously discussed ED had done so with a pharmacist in the first instance, and 85% asked for a PDE5i. Some recommendations exist for ED management in community pharmacies [12], and a small patient group direction initiative is ongoing in the United Kingdom [13].

Aim

The aim of this study was to determine if community pharmacists across several European Union (EU) countries, given support by tailored training documents and a Pharmacy Guidance Questionnaire (PGQ [14], available upon request), could make an appropriate recommendation for supply of sildenafil 50 mg to treat ED.

Methods

A study drug information sheet was adapted from the current Summary of Product Characteristics [15], with additional restrictions, for use in the pharmacy setting. The PGQ was based on the study drug information sheet. The PGQ was initially developed and studied in the United Kingdom. However, to identify whether this assessment at a community pharmacy is also practical in other EU countries, the study was expanded to Germany, Spain, and the Czech Republic, which were chosen to represent different languages, cultures, and daily practice.

Participants

Eligible pharmacists were in full-time practice in community pharmacies in cities in the United Kingdom (n = 18), Germany (n = 11), Spain (n = 15), and the Czech Republic (n = 9).

Eligible primary care physicians had experience in the management of ED and performed telephone consultations in the United Kingdom (n = 5), Germany (n = 3), Spain (n = 3), and the Czech Republic (n = 2).

Eligible men were 18 years or older and had self-reported ED or erection problems likely to constitute ED, defined as a positive response to the question "Do you have difficulty getting or keeping an erection that is satisfactory for sexual intercourse?" Those currently using a PDE5i were excluded. The study was advertised using local media advertisements (Germany, the United Kingdom, and the Czech Republic) or in the pharmacy (Spain and the United Kingdom), depending on legal and regulatory limitations. Interested subjects rang a call center, where they received additional information about the study and were screened for eligibility.

Study Design

This was a cross-sectional, observational study; no medication was dispensed. Subjects visited a participating pharmacy and completed the patient-screening questionnaire of the PGQ and, to confirm ED status, the Sexual Health Inventory for Men (SHIM), a validated five-item questionnaire developed from the International Index of Erectile Function as a diagnostic tool for ED [16]. Using the guidance from the PGQ and the study drug information sheet, pharmacists assessed suitability for sildenafil 50 mg use—suitability was not communicated to the men. Within 7 days of the pharmacist assessment, a study physician telephoned the subject to perform an independent clinical assessment (using the clinical questions typical to his or her practice) and judge suitability. If there was discordance between the recommendations of the pharmacist and physician, a physician who was a specialist in sexual medicine reassessed the case using all available information from the PGQ, the SHIM, and the physician's and