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Pattern of PPIs dispensing and the role of pharmacists in control of inappropriate prescriptions.

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A B S T R A C T:

Even though Proton pump inhibitors (PPIs) are generally considered safe, they still have serious adverse effects in case of inappropriate use. The prescription of PPIs must be based on clear clinical need. This study was aimed to prospects the uncontrolled and inappropriate dispensing of PPIs, as well as the pattern of PPIs prescription. A total of 20932 prescriptions of PPIs were collected from the community and private pharmacies, and the prescribed and non-prescribed dispensing PPIs were evaluated. The results of the study have shown that there is an irrational prescription of PPIs with a huge demand for non-prescribed PPIs. For omeprazole, the percentage of prescribed to non-prescribed was 12% and 88%, respectively. While, Pantoprazole and Esomeprazole were 40% and 60%, and Lansoprazole was 27% and 73%. In summary, PPIs need more control from qualifying pharmacists to avoid the dangers of misuse and drug interaction.

نمط الصرف لمثبطات مضخة البروتون ودور الصيادلة في السيطرة على الوصفات الطبية غير الملائمة

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الكلمات المفتاحية:
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pattern ,
Libya.

المستخلص:

على الرغم من أن مثبطات مضخة البروتون تعد آمنة بشكل عام فإنها ما تزال لها آثار ضارة خطيرة، لذلك يجب أن تستند الوصفة الطبية إلى أعراض سريرية واضحة. استهدفت هذه الدراسة توقُّع خطورة الاستعمال غير المنضبط وغير المناسب لمثبطات مضخة البروتون على النحو الموصوف أو العلاج غير الموصوف. جمع الباحث 20932 وصفة من مثبطات مضخة البروتون من الصيدليات المجتمعية والخاصة، وقام بتقييم مثبطات مضخة البروتون الموصوفة وغير الموصوفة. أظهرت نتائج الدراسة أن هناك وصفات غير منطقية لمثبطات مضخة البروتون مع طلب كبير على مثبطات مضخة البروتون غير الموصوفة. بالنسبة للأوميبرازول كانت النسبة المئوية الموصوفة وغير الموصوفة 12٪ و88٪ على التوالي. بينما كانت بالنسبة لبانتوبرازول وإيزوميبرازول 40٪ و60٪ ولانسوبرازول 27٪ و73٪. باختصار، تحتاج مثبطات مضخة البروتون إلى مزيد من التحكم من الصيادلة المؤهلين لاجتناب خطورة سوء الاستخدام والتفاعل الدوائي.

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INTRODUCTION

Gastric acid secretion is essential to induce the digestive process, as well as act as a defence against food tolerated microbes (Feldman & Peterson, 1993). The stomach produces several hormones including gastrin, somatostatin and ghrelin, the abnormal production of some of these hormones is associated with the development of various gastric diseases (Hunt et al., 1995).

The use of proton pump inhibitors (PPIs) has increased in the last decade, many studies have shown the prescription of PPIs were inappropriate in 40% to 80% of individuals (Ahrens et al., 2012). Even though PPIs are considered safe, they can cause severe adverse effects.

PPIs are considered one of the important drug classes for the treatment of gastritis, ulcer and hyperacidity (Sachs et al., 2006). Treatment with omeprazole has the potential to provide complete symptom relief in patients with dyspeptic symptoms (Talley et al., 1998). Low PPIs dosages seem to be suitable for dyspeptic indication, as 15 mg of lansoprazole was observed to provide a good response within a short period of treatment (Peura et al., 2004).

There is a clear relationship between PPIs and deficiencies of vitamins and minerals such as vitamin B12, vitamin C, calcium, iron, and magnesium. In addition, PPIs can affect the bioavailability and absorption of many vitamins and minerals, which may lead to severe vitamins deficiency (Wedemeyer & Blume, 2014). PPIs decrease the concentration of gastric juices, leading to a diminishing in the bioavailability of vitamin C and its active antioxidant form. The chronic use of PPIs can lead to iron malabsorption and risk of achlorhydria (Radziwill, 2014),

PPIs inhibit the active transport pathways that are mainly responsible for magnesium absorption, and this reduced intestinal magnesium absorption may lead to hypomagnesemia (de Alwis et al., 2022). PPIs have shown an interaction with antiplatelets agents such as clopidogrel, PPIs reduce clopidogrel active metabolite levels and inhibit platelet actions (Wedemeyer & Blume, 2014).

Social and economic pressure are expected to promote additional prescription to non-prescription switches. Moreover, insurance companies, pharmacy benefit management companies, governmental entities, and employers are increasingly expressing the desire and putting more pressure for switching the drug from prescription to non-prescription drugs, over the counter drugs (OTC).

Recently, high profile switches have included drugs in classes previously not eligible, such as omeprazole, and proton pump inhibitor. Switches are forced by many factors such as pharmaceutical sectors, the purpose to extend or make more available of brands names (Cohen, 2003). The decision of making drugs available over the counter affects a large number of

stakeholders, including patients, pharmaceutical firms, physicians, pharmacists, drug regulatory agencies, and private and public health sections. This research is aimed to prognosis the uncontrolled and inappropriate dispensing of PPIs prescription and the role of the pharmacist to restrict and advise patients for correct choices.

MATERIALS AND METHODS

This retrospective study was conducted at AL-Bayda city, Libya. Data were collected from private and community pharmacies. After the permission of pharmacies managers and patients' consent, as well as the Ethics Committee of the Institutional Review Board of our institute, approved the survey. A total of 20932 dispensing prescriptions of PPIs were collected from a database of participant pharmacies over six months. The following prescription information was collected: Date, clinical department, drug generic name, medication route, the total amount of medicine taken, unit price, dosage, gender and age. The data were classified as prescribed and non-prescribed PPIs prescriptions. Data is then calculated as a percentage and analyzed.

RESULTS

Among the 20953 prescriptions of PPIs were collected during the study period from both community and private pharmacies. Our finding shows a high prevalence of uncontrolled dispensing of PPIs, particularly Omeprazole. The following tables and figure shows the data of different PPIs prescriptions.

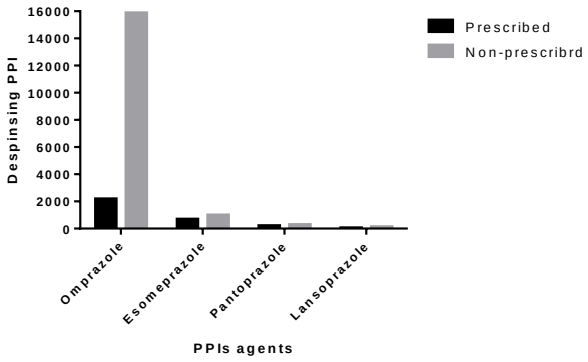

Figure: (1). *Distribution of proton pump inhibitor prescription*

Table 1: Represent the distribution of prescribed to non-prescribed of PPIs.

PPIs agent	Prescribed	Non-prescribed	Total
Omeprazole	2183	15871	18054
Esomeprazole	688	992	1680
Pantoprazole	201	292	493
Lansoprazole	41	121	165
Total	3076	17166	20932

Table 2: The percentage usage of prescribed to non-prescribe PPIs

Type of PPIs agent	Prescribed (%)	Non-prescribed (%)
Omeprazole	12	88
Esomeprazole	41	59
Pantoprazole	40	60
Lansoprazole	27	73

DISCUSSION

PPIs are the most effective drug used in acid suppression that results in fast relief of heartburn and hyperacidity in many patients, the efficacy of PPIs made it permitted to be an OTC drug despite its limitation, drug interaction and appropriate indication.

Due to the high prevalence of heartburn, several non-prescription treatment options are recommended. Patient insistence on taking the PPIs because of low cost and high efficacy.

This study has been showing that the omeprazole was the most common non-prescribed among the PPIs, with 15871 non-prescription, which represents 88%. However, only 12% were dispensing by prescription. This huge difference between prescribed and non-prescribed of PPIs consumption may be included inappropriate dispensing. This finding is in line with novel studies that have been undertaken of the overuse of PPIs a recent review reported that 63% of their use is inappropriate (Veronika et al., 2016). Another review stated that the appropriateness of the hospital prescribing PPIs may be as low as 19% which examined the overuse of PPIs, which support our results (Vakil et al., 2006). The present study has shown that the highly PPIs dispensing brand was omeprazole, Indian origin, this could be due to the low cost of this PPIs brand in comparison with other brands from Europe or North America. Because of the low income of most people and the large difference in price between the two brands, patients preferred to use the Indian brand.

In spite of omeprazole has the greatest potential of drug interaction among the PPIs, it is still the most PPIs used as a prescribed and non-prescribed drug compared to other PPIs. Several factors are involved in a significant increase in taking omeprazole without prescription most likely the cost effect. Inappropriate indication of PPIs without clear clinical need could participate in increasing the non-prescribed of PPIs. Omeprazole and esomeprazole are metabolized by CYP2C19, thereby having a high potential for interaction with other drugs (Hagymasi et al., 2011).

The data has shown that Esomeprazole was the second dispensing PPIs of 1680 prescriptions. Surprisingly, about 60% of Esomeprazole was dispensed as non-prescribing (OTC) although Esomeprazole is not under the OTC category. Also, Pantoprazole and Lansoprazole which the non-prescribed represent 60% and 73%, respectively. This increase in dispensing of these PPIs as OTC drugs is considered alarming for inappropriate prescription patterns of PPIs. The efficacy of PPIs made it permitted to be an OTC drug in spite of its limitation and drug interaction. The uncontrolled non-prescription drug use and inappropriate selection often lead to therapeutic misleading and adverse clinical consequences for patients.

Pharmacists are, therefore, ideally positioned to advise individuals who wish to self-treat their heartburn, primarily by helping them select the most appropriate treatment option. However, it is important to support pharmacists in this role by providing them with appropriate, targeted clinical information to help them assess, guidance, to select the appropriate treatment

Pharmacists should determine whether the

observed symptoms are typical of heartburn, suggestive of complicated GERD or another underlying cause, or are the result of any concomitant medications that the individual may be using. Moreover, pharmacists determine whether any contraindications related to an underlying medical condition are present that may preclude the use of PPIs.

In the case of non-prescription PPI therapy, pharmacists have a responsibility to ensure that the PPIs are being used for the accurate indication in the appropriate individual to avoid any misuse of the drug (Vakil et al., 2006). This study approves that PPIs are commonly prescribed without an appropriate indication, and development of over-prescription.

CONCLUSION

For the product to be switched to OTC status, the manufacturer was required to answer numerous questions about the safety of the ingredients inside the product from raw material to end product. These switched products are considered safe for nonprescription use only because the OTC label helps ensure that you will use them under the exact conditions that help guarantee safety. Although, omeprazole has been approved to switch to an OTC drug with a label warning the patient not to take more than two pills daily and limit the use for 14 days. Pharmacists in both sectors private and community pharmacies need to clarify, identify, educate and help the patients to select appropriate PPIs and the correct dose and period of treatment to restrict and decrease the uncontrolled non-prescribed PPIs. More research should be done to predict the potential of inappropriate prescribing of PPIs and determine the causes behind the lack of obedience to the guidelines of the patient, prescriber, and dispensers.

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