Original

Phenazopyridine: A drug utilization research in the Costa Rican Social Security

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Abstract

Background: Phenazopiridine is a urinary tract analgesic that has been deemed to be of low intrinsic value; nonetheless it has been used in the Costa Rican social security and has a good record of efficacy and safety within the institution.

Aim: To analyze the use of phenazopiridine in the three different levels of attention in the Costa Rican social security.

Methods: During one month, we obtained electronic pharmacy records from a first, second and third level health center to establish the quantitative characteristics of the prescription of phenazopiridine. For the qualitative analysis a random sample of 30 patients per center was generated; each file was assessed using a pre formulated instrument in order to review those patients' files and obtain the required information.

Results: During the month of January 2011, in three study centers, phenazopiridine was prescribed to 381 patients, mostly females. Prescription varied from 3 to 90 tablets most patients (60.43%) received 10 tablets for their treatment regimen. In 54.55% of the patients' file the diagnosis and prescription was documented. The most frequent daily prescribed dose was 100mg thrice a day equivalent to 300mg per day in half of the patients in the first and second level of attention followed by 100mg twice a day (33.3%). A total of 55.4% of the patients with a diagnosis of urinary tract infection received antibiotic treatment. The duration of treatment varied from 1 to 30 days, being longer in the second and third level of attention.

Conclusion: The use of phenazopiridine is partially adequate, this finding supports the efficacy and safety in the context of attention in the first and second level centers. The diversity in the prescriptional behaviors requires improvement by means of developing actions which would terminally favor the rationality and therefore increase the impact of the benefit offered to the patients.

Keywords: phenazopyridine, urinary tract infection, urinary antiseptics, dysuria, drug utilization, rational drug use.

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Abbreviations: ASSB, Santa Barbara Health Area; CCSS, Costa Rican Social Security; CCD, "Dr. Carlos Duran Cartín" Clinic; DDD, defined daily dosage; HCG, "Dr. Rafael Angel Calderon Guardia" Hospital; UTIs, urinary tract infection; LOM, official list of medications.
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Phenazopyridine is a urinary tract analgesic agent for oral administration. The drug is described as a dye group "azo", whose chemical name is 2,6 diaminopyridine, 3 (phenylazo) Monohydrochloride. In 24 hours, 90% is excreted in the urine, 41% as unchanged drug and 49% as metabolites (most notably paracetamol), which exert a topical analgesic effect on the urinary tract mucosa.[1]

Based on the principles of medicine based on evidence, el analysis of the available scientific information showed the lack of randomized clinical trials with the standard methodology of phase III the lack of systematic reviews with meth-analysis, to sustain the use of phenazopyridine as part of the management of urinary tract infections and other irritative syndromes. Existing information is scarce and of poor quality according to current standards required by scientific publications.[2-9]

Despite this, the drug is included in the Costa Rican Social Security (CCSS) official list of medications (LOM), in presentation of a 100mg tablet. Institutional experience of use of phenazopyridine over 20 years, with a historical profile of safety and effectiveness, and now, the institutional consumption projected about 1830 patients who take this medicine every day, based on the daily defined dosage (DDD) 600 mg / d10 orally, for its main indication as an analgesic for urinary tract infections.[1, 11]

Under the rational use of medications developed with Social Security, the systematic and ongoing use of the drug in clinical practice, which contrasts with the weakness in the scientific information that supports the prescription, forms the basis for the study of drug use, in order to analyze the profile of phenazopyridine use in the context of routine clinical practice in outpatients, at different levels of attention and during a time period of 1 month.

Materials and methods

In order to meet this objective, an applied research design, observational, analytical approach, and approval of the Central Committee of the CCSS Pharmacotherapy for technology assessment in health studies paradigm drug use, according to the model prescription-indication, we proceeded at all times with a strict observation of the ethical principles confidentiality and non-malfeasance.

In analyzing the use of phenazopyridine in the context of clinical practice, as a first step the pharmacy was requested to release the drug during January 2011 in three selected units, one for each level of care: Santa Barbara Health Area (ASSB), Dr. Carlos Durán Clinic (CCD) and Dr. Calderón Guardia Hospital (HCG), with the purpose to prepare a quantative profile of use.

For qualitative analysis of prescription medication on a prescription-indication model, a random selection was made among all cases of drug clearance in each unit, during the period, seeking to have a random sample n = 30/unit. The sample size was defined for a minimum representation of 20% under the assumption of normality for compliance with the central limit theorem.

With emphasis on specific medical consultation that supported the prescription drug, a selective review of the medical records was made, prior to endorsement of the medical departments of the units; in a predesigned form and without identifying individuals, the information on diagnosis, and age, dose, duration and other quantitative variables was registered in an individualized way.

Data was recorded and processed in an Excel ® database for the initial descriptive statistical approach; tables and figures were designed, analytical phase of the results was developed and the comparative analysis was drafted.

Results

In the course of one month, three medical units dispatched 381 of the phenazopyridine prescriptions to patients seen, the vast majority of them, women; the prescription varied in the range of 3 to 90 tablets, although a high percentage of people (60, 43%) were given prescriptions and only 10 tablets sent for treatment (Table 1).

Table 1. Characteristics of prescribing and dispensing of phenazopyridine in three outpatient care centers of the CCSS, January 2011

Variables	III level HCG	II level CCD	I level ASSB	Total
Number Patients	133	147	101	381
Women	102	115	85	302
	76,69 %	78,23 %	84,16 %	79,69 %
Men	31	32	16	79
	23,31%	21,77 %	15,84 %	20,31%
Minimum treatment	5 tablets	10 tablets	3 tablets	10 tablets
Maximum treatment	90 tablets	90 tablets	45 tablets	90 tablets
Prescription	10 tablets	10 tablets	10 tablets	10 tablets
Number of patients with 10 tablets	87	99	49	235
	65,41%	67,35%	48,51%	60,43%
Average of tablets/patient	14,58	15,03	12,07	13,89

Source: dispatch record SIFA pharmacies Santa Bárbara Health Area, Dr. Carlos Durán Clinic and Dr. Rafael Ángel Calderón Guardia Hospital, January 2011

Direct information on the clinical use was available in a considerable amount of medical records requested: 100% was revised in ASSB, 93% in the CCD and 93% in the HCG; but in the latter, only 8 cases (26%) achieved the consultation document that generated the prescription.

Based on the medical indication, it was possible to systematize the annotation of the drug and the dose at 54, 55% of cases. The prescribed daily dose (PDD) was 100 mg TID, equivalent to 300 mg / d, precisely in half of patients; the second prescription scheme was 100 mg BID, in 33, 33%; this profile with both dosages resulted uniform in the units of the first and second level of care. Other schemes prescribed were 200mg TID (5, 56%), 100mg c/6h (5, 56%), 200 mg BID (2, 78%) and 100mg QD (2, 78%).

Phenazopyridine was prescribed to 54,55% of patients with a diagnosis of urinary tract infection (UTI); amongst these, 89% were female patients. It was also prescribed for dysuria in 7,58% and for benign prostatic hypertrophy with prostatism in 7,58% (figure 1). In addition, various causes were recorded as the prescription of the drug to patients with the following conditions and diagnoses (n = 11, 16,67%): asymptomatic bacteriuria, nonspecific urethritis, prostate cancer detection, gastroenteritis, gonorrhea, fever of unknown origin, urinary fixed catheter, transurethral resection of the prostate, kidney transplant, prostatitis and renal cyst. The diagnosis for which the medication was prescribed was not written down by the prescriber in 7,58% of the cases.

Regarding diagnosis in 66 cases, using phenazopyridine was associated with prescribing 89 additional drugs; 89% of patients diagnosed with UTI also received antibiotic prescription. The other four patients also received antibiotic prescription with phenazopyridine, were carriers of asymptomatic bacteriuria, nonspecific urethritis, gonorrhea y prostatitis.
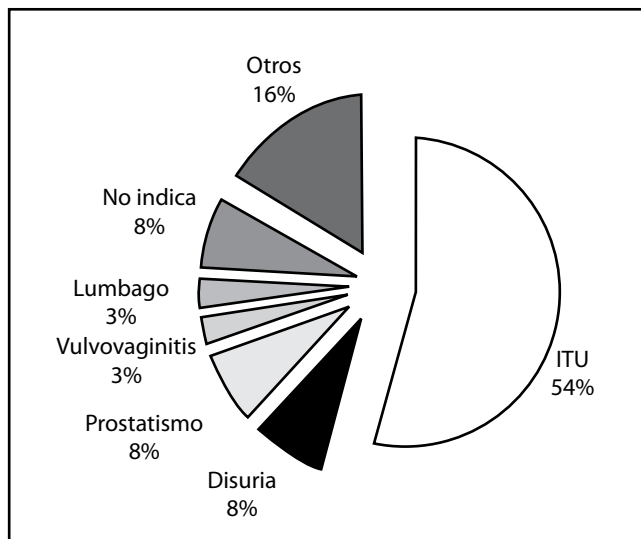
The practice of associating drugs became more evident in the second level of care, with the prescription of 46 drugs to 28 patients (1,6 drugs / patient), the most commonly prescribed concomitant medication was acetaminophen with a 24,24%, followed by nitrofurantoin and trimethoprim-sulfamethoxazole with 18,18%, etc. (Figure 2); an additional prescription of ciprofloxacin, tramadol, metoclopramide or dexamethasone, was recorded to 4 different patients.

The duration of use, according to the number of dispensed tablets, varied between 1 and 30 days. The most prolonged treatment was recorded at the units of second and third level care (90 tablet prescriptions). In formal terms, the treatment duration is recorded in less than half of the cases (48,48%); the most common treatment time was 3 days (43,75%), followed by 5 (28,13 %) and 7 days (21,88%).
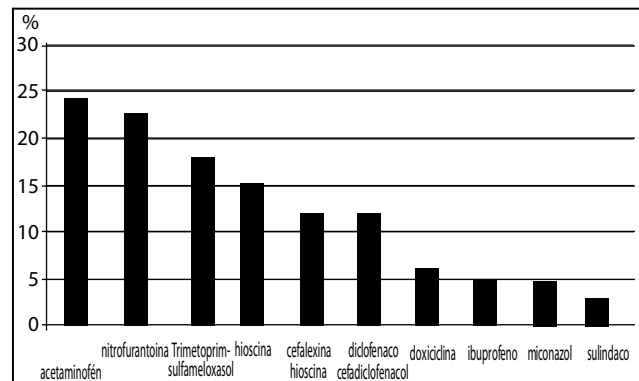
Discussion

This drug utilization study, designed to evaluate the usage profile of phenazopyridine in a pattern of prescription-indication, confirms that the drug is actually used as part of the management of urinary infections, which is attributed to its well known analgesic properties. In addition, as part of this intervention, it is validly associated with causal antibacterial treatment; this therapy jointly showed a strong tendency towards rational use in the first and second level of care.

An important aspect of the findings emerged from this work and based on a habit of prescribing, which also exceeds the pharmaceutical review for release of the medication, is the prescription of a sub-therapeutic dose of phenazopyridine, more than a third of the patients. According to available scientific evidence, it should be remembered that the dose

Figure 1. Relative distribution of the diagnoses for phenazopyridine prescription, CCSS, 2011

Figure 2. Frequency distribution for prescribedy drugs taken with phenazopyridine, outpatients in the CCSS, Januar 2011

for adults is 100 to 200 mg 3 times/day, and for a period of two days, concomitantly with antibacterial treatment.[5, 6,11]

In accordance with the principles of rational drug use, the findings of this study show that most patients use the drug for short period, with the prescription of about 10 tablets per treatment, primarily indicated for the relief in the case of UTI, and with antimicrobials, in the case of UTI. This profile of the drug use is consistent with international recommendations for the clinical use of the drug, as to encourage prescribing for patients with a diagnosis of UTI, for 2 days of treatment, and concomitantly with an antibiotic to resolve the ITU1, [5, 8, 11.]

However, in contrast to the above, it is unfortunate that 11% of patients diagnosed with UTI, were not prescribed an antimicrobial agent. Moreover, it is noteworthy that phenazopyridine is being prescribed to a variety of other diagnoses for which there is no scientific data to support its use in such conditions. The prescription of the drug, in such cases, it turns away from the principles of rational drug use, to nullify the benefit and maximize the inherent risks of the medication, as would be the occurrence of adverse effects. Similarly, the above consideration of the side effects, applies to the interactions derived from the frequent combination with other drugs. (acetaminophen, non-steroidal antiinflammatories, hyoscine).

In the medical files, prescribers documented various diagnoses during consultation, which merited urinary analgesic prescription and lead to dubious rationality questionable practice to alleviate this some degree of urinary mucosal irritation, as a symptom associated in case of gonorrhea, prostatic pathology and vulvovaginitis; however, no valid pharmacotherapeutic information is available to support this practice.

Based on information available from high-quality scientific literature [2-9] and historical experience of institutional use, phenazopyridine is an effective analgesic of urinary mucosa, indicated for prescription for conditions with disuria and burning sensations, frequency and urgency associated with urinary tract infections, but without anti-infective effect; so it is imperative to note that during an ongoing infection, the antimicrobial agent is responsible for the final resolution, so that its prescription should not be omitted.

In conclusion, by analyzing the usage profile of phenazopyridine in the context of clinical practice at the level of general and specialized outpatient medical care, in the different levels of care, for a period of one month, in the paradigm of the principles of rational drug use, the study findings show that the use is partial and reasonably appropriate and, therefore, support the assumption of effectiveness for just over half of the patients, especially in the context of medical care in the first and second level of care, with a historical profile of security. However, the diversity in prescribing habits also highlights the need to improve the use, and it would be appropriate to develop actions to encourage more rational prescription, seeking to maximize the benefit for patients.

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