184 - STUDY OF USE OF HISTAMINE 2 (H2)- RECEPTOR ANTAGONISTS AND PROTON PUMP INHIBITORS

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INTRODUCTION

Histamine H2 receptor antagonists and proton pump inhibitors are highly effective in the treatment of gastric acid hypersecretory disorders such as duodenal ulcer, gastric ulcer and gastroesophageal reflux (BROGDEN et al, 1982). These compounds have also been widely prescribed for the prevention of gastroduodenal injury by steroidal (SAID) and nonsteroidal (NSAID) antiinflammatory drugs and for the prophylaxis of gastroduodenal bleeding caused by stress ulcers. The low incidence of serious adverse drug reactions has contributed to the widespread use of such antagonists and inhibitors for non-ulcer dyspepsia and to their unnecessary prescription for prophylaxis in patients not at risk from stress ulcers. Carmona et al. reported that 40% of the inpatients in three hospitals had prescriptions for H2 antagonists.This indiscriminate use may expose the patients to needless adverse drug reactions (CHOO, GOLDGERG, PLATT, 1994; GONZALO-GARIJO, REVENGA-ARRANZ, ROVIRA-FARRÉ, 1996; TODD et al, 1995) and interactions (BROGDEN et al, 1982; USP DI, 1997), and may have an important economic impact.

The aim of this study was to evaluate the prevalence, patterns and appropriateness of prescriptions for H2 antagonists and omeprazole among hospitalized patients.

METHOD

A cross sectional study was done in three general tertiary care hospitals (one teaching hospital with 400 beds and two private, non-profit facilities with 247 and 320 beds) in the state of São Paulo, Brazil. The pediatric wards and the gynecology/obstetrics departments were excluded. For each hospital all prescriptions of the eligible inpatients on one study day were screened for AH2 and IBP prescriptions. The demographic characteristics (age and gender), the hospital record number and the diagnosis of all patients on ranitidine, cimetidine or omeprazole on the day of the study were recorded. The diagnoses were coded according to ICD - 10th Revision. The point prevalence of prescriptions for H2 antagonists and omeprazole was determined. In addition, the prescribers answered an open question about their reason(s) for prescribing antisecretory drugs. The data of the three hospitals were analyzed all together as their medical staff is partly the same.

The study was approved by the Ethics Committee of the Faculty of Medical Sciences, State University of Campinas. The results were analyzed using the chi-square test or Fisher test as appropriate. A p value 0.05 or less was considered to be significant.

RESULTS

Of the 418 inpatients in the three hospitals on the day of the study, 229 (54.8%) had prescriptions for H2 antagonists or omeprazole. The demographic characteristics and main diagnoses of these 229 patients are shown in Table 1.

TABLE 1. The demographic characteristics and main diagnoses of the 229 patients with prescriptions for H2 antagonists or omeprazole

Categorias	Pacientes		p
	N	%	
Gênero			NS
Masculino	127	55.5	
Feminino	102	44.5	
Idade			p< 0.05
14-29	44	19.2	
30-49	68	29.7	
50-64	51	22.3	
≥65	66	28.8	
Principais diagnósticos			NS
Neoplasias	51	22.5	
Doenças do sistema circulatório	31	13.6	
Lesões, envenenamentos, etc	22	9.7	
Doenças do sistema digestivo	24	10.6	
Sinais e sintomas	15	6.6	
Doenças do sistema Nervoso	14	6.2	
Doenças do sistema respiratório	14	6.2	
outros	56	24.7	
Enfermaria			p< 0.05
Clinica Médica	112	48.9	
Clinica Cirúrgica	97	42.4	
UTI	20	8.7	

The highest percentage of patients on antisecretory drugs occurred in the surgical wards and involved 97 of the among the 137 surgical patients (70.8%). One hundred and twelve of the 247 medical patients (45.3%), and 20 of the 34 ICU patients (58.8%) also had prescriptions for antisecretory drugs. The percentage of antisecretory drug prescriptions among the different wards was significantly different (p< 0.05).

The most commonly prescribed antisecretory drug was ranitidine (200 patients, 87.3%) followed by cimetidine (23 patients, 10,0%) and finally, omeprazole (6 patients, 2,6%). There was no duplication of H2 antagonists or proton pump inhibitors.

Only 15 patients (6.5%) on prescriptions for antisecretory drugs had diagnoses of gastric hypersecretory conditions such as gastritis, reflux esophagitis and duodenal ulcer. In the remaining 214 patients with differing diagnoses, antisecretory drugs were prescribed as prophylaxis against gastrointestinal injury, particularly that caused by NSAID and SAID. Of these 214 patients, 59 (27.6%) had a prescription for one NSAID, 60 (28.0%) had a prescription dor SAID, and 4 (1.9%) had prescriptions for both NSAID and corticosteroids.

The doses and daily dosing for the three antisecretory drugs are summarized in Table 2. The most frequent prescriptions were for oral ranitidine (150 mg twice a day), and intravenous ranitidine (50 mg thrice a day). The distribution of the daily dosing of ranitidine according to age category is shown in Figure 1; there was no dose adjustment for elderly patients. The mean daily dose for oral and intravenous cimetidine was 600 mg and 900 mg, respectively, whereas the corresponding doses for omeprazole were 20 mg and 80 mg, respectively. Again, there was no dose adjustment for the elderly.

TABLE 2: Dose and daily dosing for antisecretory drugs

Medicamento	via	Dose (mg)	Dose diária*				paciente
			1x	2x	3x	4x	n
Ranitidina							
	IV	50	1	16	79	2	98
	IV	150	-	2	2	-	4
	Oral	150	11	59	3	1	74
	Oral	300	19	-	1	-	20
Cimetidina							
	Oral	200	-	-	3	1	4
	IV	300	-	2	9	4	15
	Oral	300	-	1	-	-	1
	Oral	400	2	1	-	-	3
Omeprazol							
	Oral	20	4	-	-	-	4
	IV	40	1	-	-	-	1
	Oral	40	-	1	-	-	1

* Um paciente teve uma prescrição de 50 mg de ranitidina, seis vezes por dia.

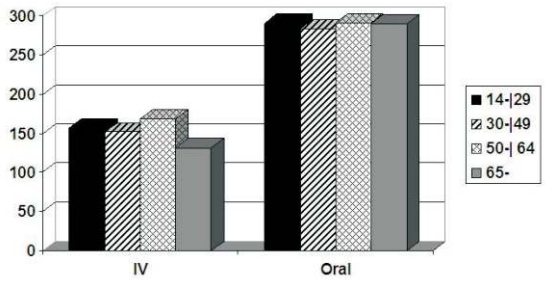

FIGURE 1: Distribution of the mean daily dose of ranitidine according to age interval.

Although the prescribers for only 121 (52.9%) of the patients were interviewed, none of them refused to state the reason for their prescription. Thus, the prescribers for 47,4% of the surgical patients, 51.8% of the medical patients, and 85.0% of the ICU patients were evaluated. Of the 121 replies, 13 were for treatment and 108 were for prophylaxis. The most frequent reasons for prescribing antisecretory drugs, identified according to the ward, included prophylaxis of gastric injury in 34 (28.1%) patients, concomitant use of SAID in 30 (24.8%), concomitant use of NSAID in 19 (15.7%), gastrointestinal diseases in 17 (14.0%), respiratory failure in 12 (9.9%), head trauma in 7 (5.8%), shock in 1 (0.8%) and polytrauma in 1 (0.8%). The prophylaxis of gastric injury included situations like gastric distress caused by macrolides and other antibiotics, psychic stress resulting from hospitalization or prolonged immobility in bed, and recovery from stroke.

TABLE 3. The reasons for antisecretory drug prescriptions according to the ward

	Razão para a prescrição								
	Falência Resp.	AINE	Choque	AIE	TCE	Politrauma	Doença Gástrica	Profilaxia	Total
Enfermaria									
Cirúrgica	0	14	0	8	5	1	5	13	**46**
Clínica Médica	3	5	0	21	1	0	12	16	**58**
UTI	9	0	1	1	1	0	0	5	**17**
Total	12	19	1	30	7	1	17	34	**121**

DISCUSSION

On average, more than half of the patients in the three hospitals received prescriptions for antisecretory drugs, mainly for ranitidine. This percentage was even greater than that reported by Carmona et al. Surgical patients had the highest probability of being prescribed antisecretory drugs.

Patients 65 years old received significantly more prescriptions for antisecretory drugs at the same dose as the non-elderly groups. Ranitidine and cimetidine are partly metabolized in the liver, although most is excreted in the urine without being metabolized. For these reasons the dose of these two drugs needs to be adjusted for hepatic dysfunction, renal impairment, and for an age-related decline in hepatic and renal function (DRAYER et al, 1982; USP DI,1997). Omeprazole is also cleared by hepatic metabolism, and its half-life is prolonged by hepatic dysfunction. Again, the dose for elderly patients must be adjusted (USP DI,1997).

The high prescription frequency of antisecretory drugs along with steroidal antiinflammatory drugs is questionable. Carson et al (1991) studied the risk of gastroduodenal bleeding with corticosteroid therapy in outpatients with asthma and dermatitis and concluded that the incidence of bleeding was very low and that prophylactic antiacids or H2 antagonist therapy should be restricted to high-risk patients, if used at all. The incidence of peptic ulcer has been estimated at 2% in the patients on

steroid therapy. Such a low incidence does not justify the prescription of antisecretory drugs for all patients (SPIRO, 1983).

The toxicity of NSAID to the gastrointestinal tract is well documented, but the incidence of NSAID-induced gastrointestinal complications is relatively low. NSAID produce mucosal injury by local irritative effects and by systemic actions mediated through cyclooxygenase inhibition (SCHEIMAN, 1996). H2 antagonists prevent the duodenal damage by NSAID, and the gastric and duodenal injury can be prevented by omeprazole. Considering the widespread use of NSAID and the low incidence of gastrointestinal complications with these drugs, the cost of the prophylaxis for all patients exposed to NSAID should be prohibitive. This prophylaxis should be restricted to risk populations, such as patients receiving high-doses and/or multiple NSAID therapy, aged patients, especially elderly women, and patients with rheumatoid arthritis, previous ulcer disease, or concomitant corticosteroid therapy (DIJKMANS et al, 1995; FRIES et al, 1991; GRAHAM 1989; HAWKEY 1996; HAWKEY 1998; HAWKEY 1990; ROBINSON et al, 1989; SCHEIMAN 1996; WALLCE 1997).

Although the prescribers claimed their prescriptions were for prophylaxis of stress ulcers, this use frequently did not agree with current guidelines. Thus, the answers given by the prescribers indicated that many times the specific pathophysiology of stress ulcers was inappropriately extended to patients who were not critically ill, and that stress ulcer prophylaxis was prescribed for non-risk clinical conditions, especially when the term stress was used to define psychic stress, and for any kind of epigastric distress. The pathogenesis of stress ulceration in the critically ill involves disruption of the usual mechanisms of gastric mucosal integrity (KLEIMAN, ADAIR, EPHGRAVE, 1988; SMYTHE, ZAROWITZ, 1994; TRYBA, COOK, 1997; WILCOX, SPENNEY,1988). The risk factors for stress ulcer bleeding include respiratory failure (requiring mechanical ventilation for > 24 h), acute renal failure (blood creatinine >3 mg/dl, creatinine clearance <25 ml/min), hepatic failure (blood bilirubin >3 mg/dl, ALT/AST >300%), coagulopathy (elevated PT/PTT >130%, thrombocytopenia <50 x 109/L), shock, extensive burns (25% of total body surface area), polytrauma, severe head trauma, acute pancreatitis, peritonitis, major surgical procedures, severe sepsis, and multiple risk factors (two or more of the above factors) (KLEIMAN, ADAIR, EPHGRAVE, 1988;TRYBA, COOK, 1997; WILCOX, SPENNEY,1988). The relationship between psychological distress and peptic ulcer is still controversial., particularly because risk factors such as Helicobacter pylori were not controlled for LEVENSTEIN et al, 1996). Cost-effectiveness analysis has shown that the cost of prophylaxis is substantial, and may be prohibitive in ICU patients with a low risk of developing stress-related hemorrhage (WADIBIA et al, 1997).

Irrational prescribing is a global problem. Numerous studies in developed and developing countries have shown a pattern that includes polypharmacy, the use of drugs unrelated to the diagnosis or unnecessarily expensive, the inappropriate use of antibiotics and irrational self-medication (HOGERZEIL, 1995).

CONCLUSION

In conclusion, educative interventions such as properly introduced consensus treatment protocols based on wide consultation, with a possibility of feed-back, face-to-face discussions focused on a particular prescribing problem with selected individuals, structured order forms and educational campaigns focused on specific drug problems provide different strategies for promoting the rational use of drugs. Positive results may be anticipated in prescribing practices, with significant reductions in the cost of medication.

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STUDY OF USE OF HISTAMINE 2 (H2)- RECEPTOR ANTAGONISTS AND PROTON PUMP INHIBITORS

ABSTRACT

Histamine 2 (H2)- receptor antagonists and Proton pump inhibitors are highly effective in the treatment of hypersecretory gastrointestinal disorders and are widely prescribed for the prevention of stress ulcer with gastrointestinal bleeding. Objective: To evaluate the prescription patterns and the appropriation of H2 blockers and omeprazole. Methods: A transversal study was conducted in three hospitals(one teaching hospital and two private non profit hospitals). The indications, as well as the type, dose of these drugs were investigated. The prescribers were asked about the reasons for prescribing these medications. Results: Among the 418 patients evaluated 229 (54.8%) received H2 blockers and omeprazole prescriptions. Among these 229 patients, 55.5% were male. The most common diagnoses were: malignancies (21.5%); cardiovascular diseases (11.9%); injury, poisoning and certain other consequences of external causes (9.7%); convalescence following surgery (8.3%); gastrointestinal diseases (7.5%). In 52.9% of the prescriptions the prescribers gave the reason for their prescriptions. The most common justifications were stress ulcer prophylaxis (14%); concomitant use of corticosteroids (13.2%); concomitant use of NSAIDs (8.4%); treatment of gastrointestinal diseases (7.9%). It was also evaluated the mean dose of these drugs for each age stratum. Some of the prophylactic indications did not agree with current guidelines. Educative interventions seem to be necessary to promote rational use of these drugs.

HEADINGS: Histamine H2 blockers, ranitidine, peptic ulcer disease, prophylaxis.

ÉTUDE D'UTILISATION D'ANTAGONISTES DES RÉCEPTEURS HISTAMINE H2 ET INHIBITEURS DE LA POMPE À PRÓTONS

RÉSUMÉ

Bloquants de l'histamine-2 (BH2) inhibiteurs et des inhibiteurs de la pompe à protons (IPP) sont efficaces dans le traitement de l'hypersécrétion gastro-intestinale, largement utilisé dans la prévention de l'ulcère de stress, et a été largement fait usage de drogues à l'hôpital. La contre-étude transversale a déterminé la prévalence de l'usage de l'ulcère dans trois hôpitaux généraux (dont un hôpital d'enseignement et de deux philanthropiques). Nous avons étudié la population de patients hospitalisés présentant un ulcère de prescription en une journée, et a demandé à une justification médicale à la prescription. Sur les 418 patients admis à la journée de l'étude, 54,8% recevaient BH2 ou IBP.Os principaux diagnostics, les patients étudiés étaient malignes (21,5%), cardiovasculaires (11,9%), les intoxications et autres causes externes (9,7%), convelecência après la chirurgie (8,3%), gastro-intestinal (7,5%). Dans 52,87% des prescriptions ont été obtenues les raisons médicales suivantes: la prévention du stress gastrique (14,09%), l'utilisation concomitante de stéroïdes (13,22%), l'utilisation concomitante d'un AINS (8,37%), le traitement des maladies gastro-intestinal (7,9%). Certaines indications prophylactiques constatées ne correspondent pas à ceux trouvés dans la littérature. Interventions éducatives semblent nécessaires pour promouvoir l'usage rationnel des médicaments.

MOTS-CLÉS: bloqueurs des récepteurs H2 de l'histamine, l'ulcère gastro-duodénal, la ranitidine, la prophylaxie.

ESTUDIO DE LA UTILIZACIÓN DE ANTAGONISTAS DE LA HISTAMINA H2 RECEPTORES Y LOS INHIBIDORES DE LA BOMBA DE PROTONES

RESUMEN

Medicamentos bloqueadores de la histamina-2 (BH2) y los inhibidores de los inhibidores de la bomba de protones (IBP) son efectivos en el tratamiento de la hipersecreción gastrointestinales, ampliamente utilizado en la prevención de la úlcera de estrés, y se utiliza ampliamente en el hospital. La cruzada estudio transversal fue determinar la prevalencia de uso de la úlcera en tres hospitales generales (un hospital docente y dos filantrópicas). Se estudió la población de pacientes hospitalizados con úlcera de prescripción en un día, y se le pidió una justificación médica para la prescripción. De los 418 pacientes ingresados

en el día del estudio el 54,8% estaban recibiendo BH2 o IBP.Os principales diagnósticos de los pacientes del estudio fueron los tumores (21,5%), cardiovasculares (11,9%), los envenenamientos y otras causas externas (9,7%), convelecência después de la cirugía (8,3%), digestivo (7,5%). En el 52,87% de las recetas se obtuvieron las siguientes razones médicas: la prevención del estrés gástrico (14,09%), el uso concomitante de esteroides (13,22%), el uso concomitante de AINEs (8,37%), el tratamiento de las enfermedades gastrointestinales (7,9%). Algunas indicaciones profilácticas encontrado no coinciden con los encontrados en la literatura. Las intervenciones educativas parecen necesarias para promover el uso racional de los medicamentos.

PALABRAS CLAVE: bloqueadores de los receptores de la histamina H2, úlcera péptica, ranitidina, profilaxis.

ESTUDO DE UTILIZAÇÃO DE ANTAGONISTAS DE RECEPTORES H2 DA HISTAMINA E DE INIBIDORES DA BOMBA DE PRÓTONS

RESUMO

Os bloqueadores de receptores de histamina-2 (BH2) e inibidores da bomba de prótons (IBP) são efetivos no tratamento da hipersecreção gastrintestinal, amplamente utilizados na prevenção de úlcera de estresse, e se tornaram medicamentos muito utilizados no ambiente hospitalar. O estudo transversal determinou a prevalência de utilização de antiulcerosos em três hospitais gerais (um hospital escola e dois filantrópicos). Estudou-se a população de pacientes internados com prescrição de antiulcerosos em um dia, e foi questionada a justificativa médica para a prescrição. Dos 418 pacientes internados no dia do estudo 54,8% estavam recebendo BH2 ou IBP.Os principais diagnósticos dos pacientes do estudo foram: Neoplasias(21,5%), doenças cardiovasculares (11,9%), envenenamentos e outras causas externas (9,7%), convelecência pós-cirúrgica (8,3%), doenças gastrintestinais (7,5%). Em 52,87% das prescrições foi obtido as seguintes justificativas médicas: profilaxia de estresse gástrico (14,09%), uso concomitante de esteróídes (13,22%), uso concomitante de AINE (8,37%), tratamento de doenças gastrintestinais (7,9 %). Algumas indicações profiláticas encontradas não correspondem às encontradas na literatura. Intervenções educativas parecem necessárias para promover o uso racional destes medicamentos.

DESCRITORES: Bloqueadores dos receptores H2 de histamina, úlcera péptica, ranitidina, profilaxia.

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