RESEARCH PAPER

Accepted 5 September 2001
Revised 2 July 2001
Received 28 September 2000
Indian J. Pharm. Sci., 2001, 63(6) 491-499

Drug Prescribing Audit of Ranitidine: A Government Hospital Experience

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A drug utilisation evaluation of ranitidine was conducted in a 300-bed government hospital. Baseline audit was done in selected wards of the hospital over 30 days, which identified 228 patients receiving ranitidine. The main reasons for prescribing ranitidine were prophylaxis against non-steroidal antiinflammatory drugs (21%) and pain in the epigastrium (16%). In 20% of the cases, the reason for prescribing ranitidine was unknown. A questionnaire on ranitidine usage was developed and the responses from all the doctors of the hospital were obtained. Guidelines for ranitidine usage in the hospital were framed and officially circulated among doctors in the hospital. Another 30-day audit was carried out in the same wards where baseline audit was performed, during which 145 in-patients were identified to be taking ranitidine. Prophylactic use of non-steroidal antiinflammatory drugs decreased to 13% and only in 10% of the cases reason for prescribing ranitidine was unknown. More than 30% reduction of overall in-patient ranitidine usage was noticed during the study period compared to a similar period from the previous year.The program brought about rational changes in ranitidine prescribing and awareness among doctors regarding cost-effective usage of drugs.

Drug utilisation audits are quality assurance programs to ensure that drugs are used safely and cost effectively[1-4]. The nature of such audits can be quantitative, qualitative or a combination of both. Quantitative audits are concerned with quantifying various facets of drug use within a healthcare system or area or group, where as qualitative audits compare drug use or practice with predetermined standards or criteria. A drug utilisation evaluation program incorporates both quantitative and qualitative review of utilisation and also initiates efforts to improve drug usage that is not consistent with the standards[1-3].

Government Head Quarters Hospital, Ooty (GHQH) is a 300-bed, secondary care, non-teaching government hospital in Tamil Nadu. The hospital has many medical and surgical units and provides free treatment including drugs to the poor patients. GHQH is also a site for clinical pharmacy practice and education. The state government has fixed budgets for each government hospital and primary health centre in the state, specifying the maximum amount that can be spent on drugs and surgicals. The budget for GHQH in the financial year 1997-98 was twenty-three lakh rupees. This budget was exhausted by February 1998 and a crisis of non-availability of essential drugs including antibiotics arose at GHQH during February-March 1998. This situation urged the authors to initiate a drug utilisation audit at GHQH in April 1998.

Common targets for drug audits include those drugs, used in high volume, with high unit cost, highly prone for adverse events and interactions, with narrow therapeutic index, associated with a high rate of inappropriate use in clinical practice and those newly added to the hospital formulary[1-3]. The drugs that were prescribed heavily and those that lead to major expenses in the budget for GHQH during the financial year 1997-98 were identified from the

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A preliminary report of this investigation has appeared as a Letter to the Editor in Indian J. Pharmacol. 2001, 33, 41.

pharmacy records. Antibiotics such as cefotaxime and amoxycillin accounted for most expensive categories, while paracetamol, multivitamins, vitamin B-complex and ranitidine were those that were prescribed heavily.

GHQH did not have facilities for performing culture testing, which forced the clinicians to opt for empiric antibiotic prescribing. The heavy use of multivitamin and vitamin B-complex might be justified after taking into account the fact that many GHQH patients suffer from malnutrition and anaemia. Paracetamol, being the least expensive and relatively safer analgesic-antipyretic, its extensive usage at GHQH was well justified. That leaves ranitidine, which is used widely in most countries for a variety of indications and there existed variations in the approved indications for ranitidine between different settings[5-8]. Inappropriate use of ranitidine has caused unnecessary expenditure to hospital pharmacies in general that has been the subject of many drug utilisation studies[9-16].

Ranitidine was one among the volume leaders in utility at GHQH during 1997-98 and was selected as the target drug for our drug utilisation audit. The prime objective of the program was to ensure rational use of ranitidine at GHQH, through a pharmacy-initiated drug-prescribing audit. The secondary objectives included creating awareness for cost-effective utilisation of drugs in the hospital and to establish beyond dispute the key role of a pharmacist in hospital quality assurance activities on drug utilisation.

MATERIALS AND METHODS

Consent from GHQH authorities was obtained before initiation of the audit. All the healthcare professionals of the hospital were informed about the program through the clinical pharmacy newsletter of the hospital. Baseline data collection was done in selected wards of GHQH over a period of 30 d in June 1998. Wards were selected in consultation with the hospital authorities after considering the nature of admission to various wards and accessibility of data. Wards selected for the audit were the male medical ward, female medical ward, female surgical ward, female special ward, and intensive care unit and intensive care cardiac unit of the hospital.

Inclusion and exclusion criteria:

All in-patients from the six selected wards of the hospital, who received at least one dose of oral or parenteral ranitidine during the study period, were included in this study. Patients were followed up from the time of admission till discharge, death or end of the study period. Patients who were admitted to other wards were excluded from the study. Patients getting transferred from one of the wards included in this study to an outside ward or vice-versa were followed up from their time of admission to the hospital till discharge, death or end of the study period.

A data collection sheet shown in Appendix I was used to gather information on patient demography, reason for admission to the hospital, name of the doctor prescribing ranitidine, reason for prescribing, duration of therapy, reason for stopping and other drugs prescribed along with ranitidine. Data was collected by a single clinical pharmacist through case sheet evaluation as per standard protocol[12,15]. Interpretations were made by the clinical pharmacist wherever there were no proper reasons entered on the case sheet for prescribing ranitidine, such as prophylactic use with non-steroidal antiinflammatory drugs (NSAIDs) and stress ulcer prophylaxis. Opinions of senior surgeons, physicians and the clinical pharmacist in-charge of the particular ward were sought before making such interpretations.

Baseline data collection was followed by a questionnaire phase among the doctors of GHQH. Appendix II shows a model of the questionnaire on ranitidine usage that was designed in consultation with the senior doctors of GHQH and other professional experts. Responses were collected from the doctors by personal visits to their office. A meeting of senior physicians, surgeons, hospital authorities and clinical pharmacists was convened to discuss results of the baseline audit and doctors' responses to the questionnaire. Guidelines for ranitidine usage in GHQH were framed using data from standard medical textbooks and guidelines of other hospitals[5-8]. A copy of this is presented in Appendix III. These guidelines were approved by the hospital authorities and were officially circulated among the GHQH doctors.

Another 30 d audit was done during November-December 1998 to assess the impact of these guidelines on ranitidine prescribing. This audit was carried out in the same wards where baseline data was collected, following the same procedure. Ranitidine prescribing pattern to in-patient and outpatient was obtained separately from the central pharmacy. Qualitative and quantitative analysis

of ranitidine prescribing during baseline phase and post guideline phase was performed and compared.

RESULTS

The baseline phase identified 228 cases on ranitidine therapy out of 497 admissions to the study areas over a 30 d period, where as the final phase identified 145 cases out of 367 admissions over an equivalent time period. Women accounted for nearly two third of the total study subjects in both the phases. During both the phases, patients above 60 y or in 36-40 y group represented one-fifth each of the total study population. Oral dosage forms were prescribed in 82% and 66% of the cases, respectively, during baseline and final phase.

Surgeons and physicians together accounted for 62% of ranitidine prescriptions during baseline phase and 51% during the final phase. All the 23 GHQH doctors were personally met in their office to get their response for the questionnaire. Seventy percent of the doctors were of the opinion that ranitidine is overused in the clinical practice. Majority of the doctors would prescribe ranitidine for patient complaints like epigastric tenderness (65%), pain in the upper abdomen (48%) and heartburn (70%) and for prophylaxis with NSAIDs (70%). But, 60% of doctors felt that prophylactic use of ranitidine with short-term NSAIDs therapy is unnecessary in the absence of evidence for peptic ulcer disease.

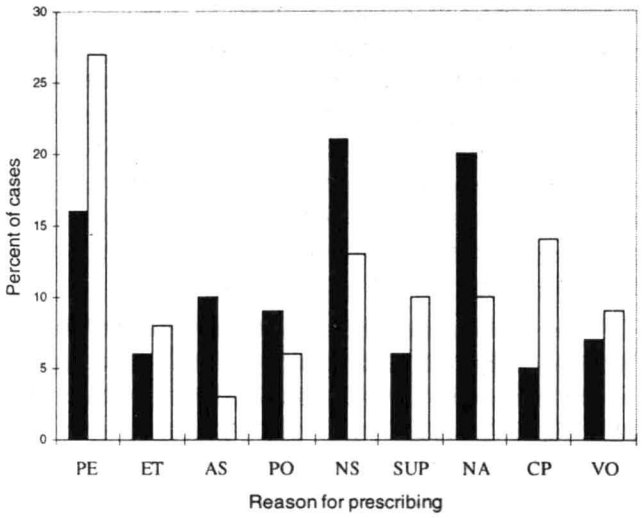

Fig. 1: Reason for prescribing ranitidine

Reasons for prescribing ranitidine during Baseline Phase (■) and Post-Guideline Phase (□).

PE stands for pain in epigastrium; ET for epigastric tenderness; AS for abdomen soft; PO for poisoning; NS for prophylaxis with NSAIDs; SUP for stress ulcer prophylaxis; NA for reason unknown; CP for non-specific chest pain and VO for nausea or vomiting.

Fig. 1 gives a comparison of reasons for prescribing ranitidine between baseline phase and post guideline phase. The main reason for prescribing ranitidine during baseline study was prophylactic use with NSAIDs (21%). The reason for ranitidine usage was not known in 20% of the cases, while pain in epigastrium accounted only for 16% of the prescriptions. In the final phase, pain in epigastrium accounted for 27% of the ranitidine prescriptions. Prophylactic use with NSAIDs came down to 13% during the final phase while prescribing ranitidine for unknown reason decreased to 10%.

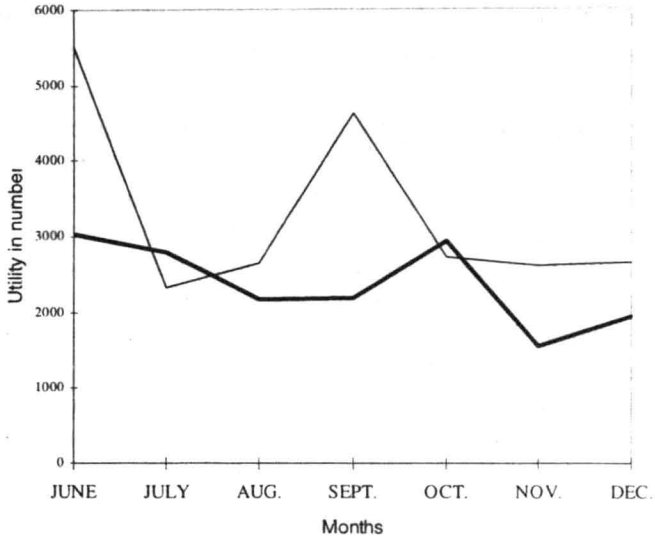

Fig. 2: Comparative in-patient utility of ranitidine tablets

June–December utility of ranitidine on in-patients in 1997 (—) and 1998 (—)

A comparison between the total hospital in-patient ranitidine usage during the study period (June–December 1998) and the corresponding period in 1997 is given in fig. 2. More than 30% reduction in the usage was noticed in the study period compared to 1997. The total hospital consumption of ranitidine tablets (in-patients and outpatients) during the study period recorded a 13% decrease compared to the previous year.

DISCUSSION

The audit has shown that around 37% of the patients getting admitted to GHQH for whatever reason are being prescribed with ranitidine, which is much greater compared

to similar studies[10]. The increased utilisation noticed among women is likely due to the nature of the wards selected for the audit. In 56% of the patients, ranitidine therapy was continued till their discharge from the hospital during baseline and in 45% of the patients during post guideline phase. Surgeons and physicians were found to be the main prescribers of ranitidine during the baseline study, as was the case in other studies reported[12]. Their prescriptions were less during post guideline phase indicating the impact of guidelines.

Personal visits to the clinicians' office ensured 100% response rate to the questionnaire. Wide use of ranitidine with NSAIDs was noticed during baseline study, the reason for which a question on this being included. Questions on patient complaints, clinical conditions and symptoms were included in the questionnaire as the case sheets at GHQH gave these than a final diagnosis such as grade I reflux oesophagitis.

Replacement of NSAIDs with high dose paracetamol for mild to moderate pain or with topical NSAIDs, employing antacids in acute cases of heartburn, risk factors associated with NSAID use, ineffectiveness of ranitidine in preventing NSAID-induced gastric ulcer formation and conditions where prophylactic use of ranitidine is needed with NSAIDs[17-22] were some of the topics discussed during the clinical meeting. Much stress was given to NSAIDs since prophylactic use of ranitidine with NSAIDs was the main reason for prescribing ranitidine during the baseline study. During the final phase, the doctors showed a tendency to initiate ranitidine therapy only after any complaint of gastric irritation by the patient, which gave evidence for the impact of guidelines. Antacid use was encouraged, since they are cheaper and have better results compared to ranitidine for short term or acute use[17]. It was the experience of clinical pharmacists during the post guidelines phase that doctors initiated the patients on ranitidine only after finding that antacid alone was ineffective. For the prophylaxis of stress ulcer and in most cases of poisoning, antacid gel was used alone and found effective.[22]

The indications for ranitidine usage according to the guidelines included duodenal ulcer, gastric ulcer, gastro-oesophageal reflux disorder, stress ulcer prophylaxis, prophylaxis with NSAIDs, pathological hypersecretory conditions and upper GI bleeding. The prophylactic use of ranitidine with NSAIDs was indicated only to those patients with a history of peptic ulcer disease or those on long-term treatment with treated with NSAIDs for arthritis. Labelled and unlabelled indications for ranitidine usage were included in the guidelines after considering the nature of admissions to the hospital and discussion with the doctors.

Unlabelled indications with sufficient literature support only were considered for inclusion. Thus prophylactic ranitidine prescription with short-term oral corticosteroids was omitted even though most doctors in the hospital supported its inclusion in the guidelines. Most doctors felt that the use of ranitidine in nausea and vomiting is not necessary. Upper GI bleeding was included due to the fact that a significant number of corrosive poisoning cases were admitted continuously to this hospital. Use of ranitidine for stress ulcer prophylaxis had the support of standard literature and was hence included in the guidelines.[13, 23]

Qualitative comparison of ranitidine utility was difficult without interpretations, due to poor case sheet documentation by the prescribers. Pain in the epigastrium or chest and epigastric tenderness could be interpreted as gastric ulcer or duodenal ulcer and use of ranitidine in a post surgical patient or an acutely ill patient in intensive care unit could be considered as stress ulcer prophylaxis. Significant decrease in the use of ranitidine for unknown reasons and for prophylaxis with NSAIDs during the post guideline phase is suggestive of impact of the guidelines. Increase in ranitidine utility for epigastric tenderness, stress ulcer prophylaxis and pain in the epigastrium or chest are also positive findings for the effectiveness of guidelines. Though not included in the guidelines, many doctors continue to use ranitidine in nausea and vomiting due to suspected hyperacidity or gastritis. This practice requires further inquiry and discussion.

The total number of prescriptions for ranitidine in the hospital during the study period and the corresponding period in the previous year was obtained from the central pharmacy A reduction in the number of ranitidine prescriptions was recorded even during the baseline phase, compared to the same period in the previous year. This would have been a Hawthorne effect[24], since the health care providers were informed about the program through the clinical pharmacy newsletter. Lowest number of prescriptions was recorded in November 1998, immediately after the framing of guidelines. The total consumption of ranitidine tablets in the hospital decreased from 1,41,038 in (June–December) 1997 to 1,22,993 over the same period in 1998.This brought about a moderate

savings of six thousand rupees to the pharmacy.

The guidelines were not meant to restrict the prescribing pattern of the doctors. Doctors had an initial apprehension towards the program, but once the objectives and benefits were made clear, their co-operation was one hundred percent. One of the major limitations of the programme was poor case sheet documentation. Lack of sufficient diagnostic tools and time due to heavy patient load has contributed to this. The guidelines framed consisted of indications that need confirmation using diagnostic tools, even when the hospital did not have some of these tools. But this was appropriate after considering the scope and purpose of these guidelines. This program has improved the case sheet documentation in GHQH, which resulted in a reduction of ranitidine prescriptions for unknown reasons and an increase in those for pain in the epigastrium and stress ulcer prophylaxis during the post guideline phase. Comparison of prescription patterns between the year of study and the previous year was made without taking into account the difference in the number of patients visited the hospital during the corresponding periods, the reason for admission to the hospital as well as seasonal, prescriber and patient variations. Though there was a constant decrease in ranitidine consumption during the study period, it started to increase once the study period was over. This signifies the need for conducting such quality assurance programmes at periodic intervals so that the impact is sustained.

The drug audit of ranitidine in GHQH brought about awareness on cost effective drug therapy among the healthcare professionals. The program had significant impact on rationalising the ranitidine prescription and promoted cost effective drug therapy. Impact of the program was seen at both in-patient and outpatient departments. The study has proved that clinical pharmacists could participate in quality assurance programmes on drug prescription patterns and influence them even in Indian government hospitals, where the concept of clinical pharmacy itself is naive. Drug utilisation audits should become a part of pharmacy department's routine activities so that safe and cost-effective drug therapy will be ensured.

ACKNOWLEDGMENTS

The authors wholeheartedly acknowledge Frank May, Dave Cosh and Karin Nyfort-Hansen of Repatriation General Hospital, Adelaide, South Australia; Dr. Ruth Ferguson of Otago University, New Zealand and the authorities and staff of GHQH, Ooty for their valuable suggestions, advice and help in carrying out the study.

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