Improving the Quality of Anti-emetic Therapy

KRISTIN RAMM, SIGNE DE FLON, HROAR PIENE* and CLAES TROPE

Department of Gynaecological Oncology, The Norwegian Radium Hospital, Oslo, Norway
*The Directorate of Health, Oslo, Norway

The outcome of anti-emetic therapy (AT) to women with gynaecological cancer receiving chemotherapy, in total 552 courses, was registered for a 1-year period. A quality improvement (QI) programme was established, based on three standardized AT regimens. Evaluation and documentation of AT effects were performed by the patients themselves, reporting the number of emetic episodes and degree of nausea for 5 days following the chemotherapeutic treatment. The results were visualized in monthly graphic displays. Various factors which might contribute to the achieved improvements are discussed. In conclusion, the continuous QI process seems to be a suitable method in guiding direct patient care.

Key words: Anti-emetic therapy, patient evaluation, quality improvement.

INTRODUCTION

Despite major progress in anti-emetic therapy (AT), nausea and vomiting still remain serious problems for cancer patients receiving chemotherapy. Many active agents are available and recommended as single drugs or in combination regimens, based on results from randomized clinical trials. A new selective serotonin (5-HT3) receptor antagonist, ondansetron, is superior to standard therapy with metoclopramide in the control of acute emesis, with 75% versus 42% complete or major response in patients undergoing cisplatin therapy [1]. For highly emetogenic chemotherapy dexamethasone enhances the efficacy of both ondansetron and metoclopramide [2,3]. However, regarding delayed emesis, no significant difference in response is shown between ondansetron, metoclopramide and placebo, which means that about 50% of the patients, on average, are poorly controlled on the days following chemotherapy [4,5]. In practice, the AT often includes different combinations of drugs used in non-systematic ways as desperate efforts to minimize the emetic problem. Lack of treatment standards results in high costs without documentation of effect. For such reasons, non-optimal AT was considered to be a quality problem in our department. A quality improvement (QI) programme was established in an effort to transfer our knowledge about anti-emetic drugs to clinical use in a way that is beneficial to the individual patient.

MATERIALS AND METHODS

The outcome of AT to women with gynaecological cancer receiving chemotherapy was registered for a 1-year period starting in May 1992. A prospective approach based on criteria of treatment results was used, and the evaluation was performed by the patients them-
TABLE 1. The three standardized anti-emetic therapy regimens

Regimen I

Day 1:
Diazepam 5–10 mg orally 1 hr or i.v. 2 min before start of chemotherapy
Metoclopramide 2 mg/kg b.w. + dexamethasone 20 mg i.v. in 100 ml saline 15 min before start of chemotherapy
Metoclopramide 1 mg/kg b.w. i.v. in 100 ml saline 2 hr after start of chemotherapy and in the evening

Day 2–5
Metoclopramide 10–20 mg orally 3–4 times daily, for at least 3 days. If needed, metoclopramide may be administered 1 mg/kg b.w. i.v. in 100 ml saline, and dexamethasone 20 mg may be repeated on day 2

Regimen II

Day 1:
Diazepam 5–10 mg orally 1 hr or i.v. 2 min before start of chemotherapy
Ondansetron 8 mg i.v. in 100 ml saline 5 min before and 12 hr after start of chemotherapy

Day 2–5:
Ondansetron 8 mg orally b.i.d., for at least 3 days

Regimen III

Day 1:
Diazepam 5–10 mg orally 1 hr or i.v. 2 min before start of chemotherapy
Ondansetron 8 mg + dexamethasone 20 mg i.v. in 100 ml saline 5 min before start of chemotherapy
Ondansetron 8 mg i.v. in 100 ml saline 12 hr after start of chemotherapy. If needed, ondansetron 8 mg can be repeated at the total dose of 32 mg daily

Day 2–5:
Ondansetron 8 mg orally b.i.d., at least for 3 days. If needed, ondansetron 8 mg may be administered i.v. in 100 ml saline, and dexamethasone 20 mg may be repeated on day 2

Instructions of emergency medicine
If emesis: perphenazin or haloperidol 5 mg i.m. max. t.i.d.
If anxiety: diazepam 5–10 mg orally or i.v. every 4–6 hr

b.w., body weight; i.v., intravenously; i.m., intramuscularly; b.i.d., twice a day; t.i.d., three times a day.

selves. Three standardized AT regimens were contrived, each consisting of a basis agent, dosage guidance and instruction on emergency medicine, if needed. They were based on the following drugs: I metoclopramide + dexamethasone, II ondansetron, and III ondansetron + dexamethasone. The regimens were ranked III > II > I according to their assumed effectiveness and costs. For more details, see Table 1. Before each course of chemotherapy each patient was selected to one of the AT regimens by a score of prognostic factors related to age, type of chemotherapy, anxiety and previous emesis problems. If the patient was satisfied with the emetic control obtained, the same regimen was used for the next course of chemotherapy. In the case of non-satisfaction, another, higher ranked regimen was chosen. To obtain more detailed data, the rate of success was evaluated in a systematic way, based on a standardized patient report. This was filled out daily for 5 days by each patient to register the number of emetic episodes (one emetic episode = one vomit or one retch) and the degree of nausea on a four-level scale. Our criterion for successful treatment was defined as "no" or "mild" nausea plus less than two emetic episodes per day. Graphic displays of AT results were sent to the ward staff on a monthly routine basis. The study has been going on as a continuous process, including implementation of improvement efforts on the way.

RESULTS

During the first 6 months of the investigation we registered 147 cases of chemotherapeutic treatment. AT was successful in 77% of all the cases on day 1, but only in 58% on day 2 and 54% on day 3. On day 5 AT was successful in
Anti-emetic therapy

only 66% (Figure 1). Taken as a whole, we did not find any significant differences in success rates between the three anti-emetic regimens, although it gradually became obvious that patients on certain chemotherapy regimens responded best to AT based on ondansetron, which was in accordance with results from clinical trials. Thus, improvement efforts with greater initial use of ondansetron in high emetogenic chemotherapy were carried out systematically, while our evaluation of the results went on simultaneously. For the full study period a total of 552 courses have been registered, and significant AT improvement was shown. AT is now successful in 83% on day 1, 74% on day 2 and 83% on day 5 (Figure 2). The rate of ondansetron used, i.e. regimens II and III, has increased from 41% of all the registered courses in the first study period to 64% in the whole period.

DISCUSSION

As shown in Figures 1 and 2, AT in our department has improved. At the same time the costs that were initially reduced have gradually risen. Improvement efforts, such as greater use of regimens II and III as initial regimens to high emetogenic chemotherapy, contribute to the higher rate of successful treatment. Our study has given good experience in implementing QI as a systematic working method in direct patient care. One important aspect may be the Hawthorne effect, i.e. paying attention to a problem brings improvement by itself. This phenomenon is explained by uncontrolled factors; in this case, a more caring, confident and professional staff in their dealing with AT. Furthermore, the degree of the patients' anticipated emesis and psychological state are important factors that influence the results. We believe that the improvement shown in our study was not due to the changes in medication alone, as the whole concept of introducing the standardized AT plan is considered to give an important secondary effect. Better results are achieved because the department prides itself in these supportive care accomplishments [6].

In fact, our results show slightly better emetic control, especially regarding delayed emesis, than do the randomized trials. Assuming the uncontrolled factors to be constant, this fact indicates the advantage of our AT plan which allows a much less restrictive use of additional medication, and points to the importance of continued use of anti-emetics at home.

The fact that the patients perform the evaluation is of great importance and a well-known principle in quality of life studies. In our QI programme the AT effect is systematically asked for, so if a patient is not satisfied, she is promoted to a more aggressive anti-emetic regimen for the next course. In this way, the effects of our therapeutic activities are documented and give opportunities for planned treatment for each individual patient. Our intention was not to define which anti-emetic drug gives the highest response rate, as this kind of knowledge is available from multiple randomized studies. However, in our study, QI functions as an
instrument to ensure the best use of such knowledge in clinical practice.

The gradual process of QI ensures that the implemented changes in ward procedures are long-lasting, in contrast to urgent initiatives that tend to fall back into old patterns within a short time. It is of great importance that all staff members realize this value of the quality process. A continuous feed back on own activities is a very motivating factor. Consequently, we believe that visualizing the level of emesis control will stimulate even greater AT success in the future.

In fact, the design of this study enabled observation of two separate, though closely related, aspects of AT results. On the one hand, evaluation of effect on a large group of patients formed the basis of systematic changes on a group level. On the other hand, patients' own opinions on satisfaction or dissatisfaction decided the individual choice of the next antiemetic regimen. To which extent the patients' satisfaction is consistent with our findings of successful treatment rates remains, however, unanswered. In other words, we cannot tell how frequent our definition of the criterion for successful treatment is a valid indicator of the patients' satisfaction. Nevertheless, satisfaction is a controversial indicator in health care, and discussions are needed to clarify to which extent health services should be determined by patients' interests. This certainly has economic implications. In this study, improvement of AT was followed by higher costs.

**Conclusion**

QI seems to constitute an effective method in guiding clinical treatment of the patients. The continuous evaluation and the potential for improvement make the QI process a suitable instrument for establishing new standards for permanent routines and procedures. In this study, based on QI principles, the AT has gradually shown better results on a group level. The monitoring of AT itself, however, is on an individual basis.

**REFERENCES**


