Therapeutic Education as a Safety Promotion Tool for Patiens on Oral Anticoagulation Therapy

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INTRODUCTION

Our paper focused on clinical risk, looking at the epidemiology of adverse events, the systematic approach, the risk factors and at Reason's model of organizational accidents to assess the efficacy of education in the promotion of the safety of patients on Oral Anticoagulation Therapy (OAT).

Purpose To study the level of patient satisfaction on oral anticoagulation therapy following nursing teaching sessions.

Materials and Methods The teaching program was designed on the basis of the data collected from spontaneous reporting of events correlated to the administration of Oral Anticoagulation Therapy. The survey on these events was made by using a "Spontaneous incident reporting form" (GEN-DS-MD-scheda incident reporting-00), integrated with the incident reporting systems already in place in the healthcare organisation. Patient satisfaction was measured by using a validated questionnaire.
The experimentation of the teaching program involved 9 Units belonging to 5 Hospital Services of the Liguria Local Health Authority.

Results Of the 222 patients attending the teaching sessions, 221 accepted to take part in the survey. Fifty-two percent were women and the average age was 73.8 years (Standard Deviation 10.98) The average period of treatment on oral anticoagulant drugs was about 5 years (61 months). Only the health centre in Voltri did not take part in our survey. The respondents who managed to answer the questionnaire on their own were 163 (73.8%). All the participants rated the teaching program positively (55% said it was good, 45% said it was excellent). The working Group who prepared the information booklet included mainly information that would had a positive impact on the patients' lives.

Conclusions Interestingly, this population mainly included individuals who had been on OAT for more than one year (on average 61 months). Our results showed that participants had understood the usefulness of the information they had received.

Keywords Patient safety, Quality care, Therapeutic education

Introduction

Nowadays, safety failures have reached "epidemic proportions" in the field of healthcare. Although many countries do not systematically gather data on the size of this phenomenon, data gathered in countries like the USA, the United Kingdom and Australia have shown that adverse events have become a priority for healthcare organizations. In its publication (Kohn LT, LT Corrigani JM, Donaldson MS, 1999) the Institute of Medicine (IOM) declared that in the United States errors occur in 3-4% of the total number of hospitalized patients.

Many studies have investigated adverse drug events in the community or outpatient clinic settings: Gandhi (Gandhi TK, Weingart SN, Borus J et al., 2003) showed that the incidence of adverse drug events in 661 outpatients in the range of three months was equal to 17% for unavoidable errors and 3% for avoidable errors, of which more than 50% had severe consequences. The only statistically significant predictive factor for these adverse events was the number of drugs patients took.

A recent American survey found that 93% of OAT patients had experienced an adverse event (Harris Interactive 2005) and other researchers found that many of these adverse events had been caused by avoidable patient errors (Gurwitz JH, Field TS, Harrold LR, Rothschild J, Devellis K, Seger AC, Cadoret C, Fish LS, Garber L, Kelleher M, Bates DW, 2003) ; (Field TS, Mazor KM. Briesacher B, DeBellis KR. Gurwitz JH, 2007)

In order to ensure the efficacy and safety of OAT, patients ought to be aware of the risks and health professionals should know at all times what therapy is being administered.

An adequate test for the International Normalized Ratio (INR) and an in-depth specific clinical examination have shown to be instrumental in optimizing the effectiveness of this treatment. However, many studies have shown that patient's knowledge about the drug is equally important (i.e. its effects, the therapeutic range and possible complications), its interaction with other drugs and foods.

In particular, the amount of knowledge is inversely related to the number of complications. Good results were obtained in patients who played an active role in the management of the therapy and had been effectively instructed by the health professionals on what were the drug interactions, as well as lifestyle and diet changes (Field TS, Mazor KM. Briesacher B, DeBellis KR. Gurwitz JH, 2000; (Tang Eoyl, Lai Csm, Lee Kkc et al, 2003).

Many studies have shown how effective an adequate provision of information on OAT to patients can be for the successful management of the therapy (Newall F, Monagle P, Johnston L., 2005); (Fang MC, Machtinger EL, Wang F, Schillinger D. 2006); (Harris Interactive, 2005); (Claes N, Buntinx F, Vijgen J, Arnout J, Vermylen, Fieuws S, Van Loon H, 2005); (Mazor KM, Baril J, Dugan E, Spencer F, Burgwinkle P, Gurwitz JH, 2007); (Frtschi J, Raddaz- Muller P. Schimid P, Wuillemin WA, 2007).

Some clinical studies conducted in the UK (Heneghan C, Alonso-Coello P, Garcia-Alamino JM, Perera R, Meats E, Glasziou P, 2006), The Netherlands (Cromheecke ME, Levi M, Colly LP, et al., 2000) and in Italy (Cosmi B, Palareti G, Moia M, et al, 2000) even showed how OAT self-management using a portable prothrombin time monitor could be just as effective as administering the therapy in a specialized centre, as long as patients received proper instructions on the characteristics and the possible side-effects of the drug.

However, studies do not always state if patients gain a satisfactory level of knowledge. A study carried out in Germany in 2008 on the level of patients' knowledge on OAT showed that a high percentage of patients – even among those who had been on this therapy for a long time – did not have enough knowledge about the interactions with other drugs and foods (Jank S, Bertesche T, Herzog W, Haefeli WE, 2008). The above-mentioned study did not show a correlation between the patient's level of knowledge and their characteristics, such as their educational titles and age. What emerged though was that it was important to provide instructions at the beginning of the therapy and then periodically check their knowledge with a questionnaire. Results showed that further informative sessions were needed to fill knowledge gaps (Jank S, Bertesche T, Herzog W, Haefeli WE, 2008).

A recent study showed that all patients can benefit from educational programs (Mazor KM, Baril J, Dugan E, Spencer F, Burgwinkle P, Gurwitz JH, 2007). Teaching sessions should not be scheduled only for patients who are starting the treatment, but periodic refresher sessions for patients being treated for months or years can be just as useful, since these individuals often do not have enough knowledge about OAT (Jank S, Bertesche T, Herzog W, Haefeli WE, 2008).

Our study was conducted on the territory of the Local Health Authority n. 3 of Genoa (ASL 3 Genovese), we started by using the data previously collected during the experimentation period of an incident reporting system the above-mentioned organization set up in 2007.

Purpose and Context of the Study

The purpose of our study was to assess the level of patient satisfaction on OAT living in District 8 of the A.S.L. Genovese, in relation to the teaching sessions provided to the patients and the booklet they were given. The assessment was made through the analysis of the questionnaires handed out to patients at the end of the teaching sessions.

The healthcare district 8 has a population of about 102,555 inhabitants and comprises 8 municipalities (Arenzano, Cogoleto, Masone, Rossiglione, Campoligure, Tiglieto, Mele and Genoa). The territory has a densely inhabited stretch of coast. Instead the mountainous communities of Valle Stura and Orba are not so densely inhabited. There is also a fragmented territory with isolated hamlets. The main demographic and geographic data are summarized in Table I.

The various steps:

I. Gathering data on the population included in our study

(numbers, age and frequency of INR Test) and sharing data with the district nursing staff.

2. Preparation of an information booklet to hand out to patients during the educational sessions (Annex I). The booklet, entitled "Your Guide to Oral Anticoagulation Therapy – OAT (La tua guida per la terapia anticoagulante orale - TAO)", was prepared by a working group made up of:

- Nurses of the Social-Healthcare Districts of ASL 3 Genovese;
- General Practitioners of District 8;
- Medical and nursing staff of the Department of Rehabilitation Cardiology at "La Colletta" Hospital of Cogoleto;
- Department of Clinical Pathology ASL 3.

3. Selection of the didactic methodologies tailored on the target and context. (Formal lessons to groups of 10-20 people ending with a free discussion).

4. Preparation of the materials needed for the teaching sessions: slides, invitations, lists of invited patients, attendance sheets.

5. Planning the sessions and giving a personal written invitation to each patient when collecting the blood sample.

6. Carrying out the teaching sessions and evaluation of the attendees' ratings.

The teaching sessions lasted 45-50 minutes and were provided by the nursing staff working in the various centres of the district. Each session included a group of 10-20 people, with a short lesson to explain the contents of the booklet, with the support of a slide presentation, followed by a free discussion with the patients on whatever they deemed important.

Materials and Methods

This was a descriptive and qualitative study, based on the analysis of information gathered through a rating questionnaire handed out to the attendees at the teaching sessions. The need to plan teaching sessions for patients on oral anticoagulant therapy derived not only from the review of the literature, but also from the incident reporting data gathered by the healthcare organization itself highlighting the risks linked to adverse events caused by oral anticoagulant drugs.

In our study, attendees were asked to answer the questionnaire and hand it back at the end of the teaching session. The questionnaires were distributed directly to the attendees by the nurses during the session. This method of administering the questionnaires ensured timeliness and the attendees could immediately and directly provide their impressions. Moreover, respondents could ask questions directly to those who had handed out the questionnaires in case they had any doubts or queries (ASR Regione Emilia Romagna Dossier 88-2003). In some cases, especially with the more elderly people or anyone having particular difficulty, the nurses administered the questionnaire during the interview. Interviewers maintained the same interpersonal attitude with all interviewees while asking the questions, being careful not to comment and/or influence the answers in any way. Once the questionnaires were completed, they were posted into a sealed box to ensure the patient's anonymity.

The locations where the sessions were held and the questionnaires handed out were:

- Campoligure, Masone and Rossiglione for Valle Stura
- Cogoleto
- Voltri for the urban area

A few days before the teaching session, attendees received a personal written invitation from the nursing staff while collecting blood samples for the INR Test.

The tool used for our survey was a structured questionnaire made up of 7 short questions and the respondents had to simply tick the right answer. This was done to help the respondents understand the question and speed up the answering process (ASR Regione Emilia Romagna Dossier 88-2003). The questionnaire was divided into two parts: the first part included administrative items, while the second included the items of our study.

The first part was designed to collect formal data on the teaching session (i.e. the date the session was held, the place, the name of the teacher, the details of the attendee, the age and how long the attendee had been on OAT.

The second part included 7 closed questions of which 6 provided a graded choice and one a fixed choice (YES or NO).

When designing the questionnaire, we took into account three fundamental aspects: the relevance of the survey, the relevance of the questions for the survey and the relevance of the questions for the interviewees. In order to avoid the so-called "response effect", we included a cross-check question (question n. 4) where the answering choices were inverted. This allowed to check that the answers were sincere.

The construction of the questionnaire included a preliminary phase to:

- Analyse the literature on the topic of the survey and the way relevant information was gathered; we reviewed books and journals dealing with the rating of teaching activities.
- Analyse similar experiences; we reviewed questionnaires investigating the satisfaction of people attending teaching sessions/courses.
- Exchange ideas with the Teaching Department of the ASL 3 Genovese and with the nursing staff of District 8, to see whether there were any accessibility issues and gather any opinions and suggestions for the survey.

We did our best to be as clear and as simple as possible when drafting the questions, so that they could be easily understood by all the respondents.

We tested the validity of the questionnaire by distributing it to a group of 11 patients who came to Rossiglione. In this way, we detected and corrected anything that could lead to misinterpretation (by removing redundant, confusing or inappropriate questions and answers, and adding anything that was missing). During this phase, we explained to the

respondents what was the aim of the test and encouraged them to comment on the questions and the answers of the questionnaire, and identify any issues.

The questionnaires were delivered by the abovementioned five centres of District 8 at the end of the teaching sessions. At the end of each teaching session, after briefly explaining the reason for it, the nurses asked the attendees whether they agreed to take part in the survey and if they did, the nurses filled in the first part of the questionnaire.

Then, the questionnaires were handed out to the respondents together with a pen and were they asked not to write their names on them to ensure anonymity.

The data we obtained we included in an Excel file and they were statistically elaborated using STATA SE9 software. Firstly, the data relevant to the entire sample were analysed and then the items of the questionnaire were cross-checked with the age, location and treatment duration variables to draw up the general overview. Subsequently, the data were broken up according to the three categories mentioned above, so that they could be compared to analyse the differences between the various areas of origin.

Results

Of the 222 patients attending the teaching sessions, 221 accepted to take part in the survey. So there was a very high percentage of respondents, in fact only one patient did not return the questionnaire. The respondents were distributed as follows: 33 came from various towns of Valle Stura (Campoligure, Masone and Rossiglione), 86 from Cogoleto and 102 from the urban area of Genoa (the areas of Voltri and Prà).

With regard to the characteristics of the population included in our study, 52% were women and the average age was 73.8 years (ranging between 33 and 94 years). The average period of treatment on oral anticoagulant drugs was about 5 years (61 months). (Table 2 and 3)

The respondents who answered the questionnaire on their own were 163 (73.8%), while 58 questionnaires were filled in with the help of a nurse during the interviews. (Figure 2)

Interestingly, this population mainly included individuals who had been on OAT for years (in average 61 months). In this way, also patients who have been on this therapy for a long time could be interested in attending periodic teaching sessions and benefit from them to update and refresh their knowledge.

Conclusions

The working group who prepared the booklet included information that could have a positive impact on the patient's life. We did not just try to provide patients with theoretical knowledge on the drug (such as the therapeutic indications), but rather to explain its role, how it works and above all what the negative consequences of an overdose or an under-dose would be. One of the main objectives of the entire initiative was to inform patients about the effects of the drug on their organism, its usefulness, but at the same time also its dangerousness. All the information provided had practical implications and could have a positive impact on the patient's life and safety in particular. The answers we obtained showed that participants had understood the usefulness of the information they had received. (Figure 3)

A problem the working group faced when preparing the booklet and the teaching sessions was the unhomogeneity of the population included in our study. This population had an average age of 74 years, with a very wide range between 33 and 94 years. Also the characteristics of the attendees were very diverse (level of education, occupation, etc.). To avoid the risk of having people who would not understand or misunderstand the information that was provided, the working group chose to use a plain and simple language. The main objective was to give a clear message to all patients, including those who had major difficulties in understanding.

The answers to the second question showed that this objective had been satisfactorily achieved. (Figure 4)

Another interesting aspect was that the methodological choice – teaching small groups – did not embarrass patients, on the contrary they benefited from talking to other people who had similar problems.

Discussion

Literature clearly states that many errors occur in healthcare organizations. Although it would not be realistic to eliminate errors completely from healthcare activities, just like in any other human activity, however preventing errors should be a priority for all healthcare organizations. Most of the accidents in complex organizations are the result of the interaction between the technological, human and organizational elements of the system.

According to Reason's model of organizational accidents, it is the system's responsibility to create the conditions that would allow to prevent human errors by providing protection "barriers". There are 2 types of "barriers":

- "Hard" barriers, which are physical: distance of time or space, a switch;
- "Soft" barriers, which are organizational: procedures, protocols, checks.

This model presents two innovative elements: it surpasses the concepts of "blame" and "error" stimulating on the contrary an operational use of the information

drawn from accidents. In addition, it helps to track down the "causes" of the accidents and avoid them. It encourages a holistic approach towards risk, by overcoming the distinction between competences, raising awareness and integrated action of all those involved in managing the event and its many contributing causes, instead of favouring a sectorial approach.

Several studies have shown that the patient's knowledge about the drug (for instance how it works, the therapeutic range and possible complications) and its interaction with other drugs or foods is equally important. In particulare, there was an inverse relationship between the level of knowledge and the onset of complications. Good results were obtained in patients who participated actively in the therapy and had established an efficient communication with the health workers who participated more actively in the therapy and effectively communicated with the health workers on pharmacological interactions, lifestyle and diet changes (Beyth RJ, Quinn L, Lendefeld CS, 2000); (Tang Eoyl, Lai Csm, Lee Kkc et al, 2003).

Many studies have shown how the education of patients on OAT may improve the way the therapy is managed (Newall F, Monagle P, Johnston L, 2005); (Fang MC, Machtinger EL, Wang F, Schillinger D., 2006); (Harris Interactive, 2005); (Claes N, Buntinx F, Vijgen J, Arnout J, Vermylen, Fieuws S, Van Loon H., 2005); (Mazor KM, Baril J, Dugan E, Spencer F, Burgwinkle P, Gurwitz JH, 2007); (Frtschi J, Raddaz- Muller P. Schimid P, Wuillemin WA, 2007). Some clinical studies, conducted in the UK (Heneghan C, Alonso-Coello P, Garcia-Alamino JM, Perera R, Meats E, Glasziou P, 2006), The Netherlands (Cromheecke ME, Levi M, Colly LP, et al, 2000) and in Italy (Cosmi B, Palareti G, Moia M, et al, 2000) have even shown how OAT self-management by using portable prothrombin time monitors was in the worst cases just as effective as when it is managed in a specific centre, but only if patients had been properly instructed on the characteristics of the drug and its possible side-effects.

In the light of what emerged from our study, we reckoned this initiative could be valued positively. The interest in the teaching sessions and the active participation of the attendees, added to the favourable opinions verbally expressed by the participants and was confirmed by the results of the study, demonstrating the positive role a correct educational program can play in the management of a chronic pathology. For this reason we think this type of intervention should not remain as an isolated episode, but should rather be the first of a series of teaching sessions that periodically support patients by providing updates on their therapy or simply just "refresh" the competences they already have.

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Tables

Table 1. Demographic data of District 8

MUNICIPALITY	INHABITANTS	EXTESION KM2	POPULATION DENSITY
Arenzano	11,529	24.6	468.7
Cogoleto	9,539	20.4	467.6
Masone	4,343	29.8	145.7
Campo Ligure	3,492	23.8	146.7
Rossiglione	3634	47.2	146.7
Tiglieto	599	24.5	24.5
Mele	2,714	16.9	160.6
Genoa (Voltri, Prà, Pegli)	66,705	75.9	878.85
TOTAL	**102,555**	**263.1**	**389.79**

Table 2. Age distribution of the respondents

Centre	Mean age	Min age	Max age	Median	Q1	Q3
Campoligure	77.2 (std. dev. 7.8)	63	92	77	72	84
Rossiglione	59 (std. dev. 9)	34	76	64	52	72
Masone	74,6 (std. dev. 9.2)	64	87	74	68	80
Cogoleto	77,9 (std. dev. 9.9)	33	94	79	75	84
Voltri	71,4 (std. dev. 9)	40	87	73	67	78
TOTAL	**73,8 (std. dev. 10.98)**	**33**	**94**	**76**	**69**	**80**

Table 3. Distribution of the respondents' OAT duration (in months)

Centre	Average	Min Value	Max Value	Median	Q1	Q3
Campoligure	76,6 (std. dev. 128)	7	240	36	24	60
Rossiglione	32 (std. dev. 31	1	96	24	8	60
Masone	27 (std. dev. 8)	18	36	24	24	36
Cogoleto	77,2 (std. dev. 74)	1	240	60	24	120
Voltri	49,7 (std. dev. 51)	0	240	36	12	60
TOTALE	**61 (std. dev. 69)**	**0**	**240**	**36**	**14**	**84**

Figures

Figure 1. District 8 of the ASL 3 Genovese

Figure 2

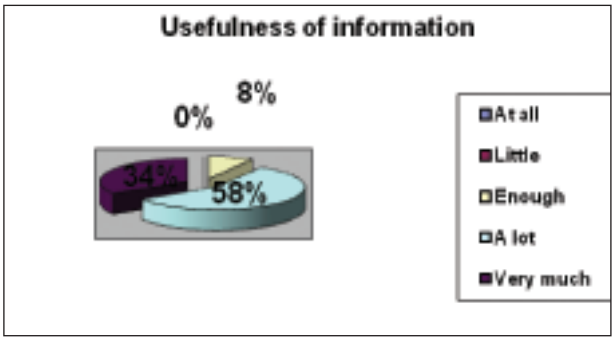
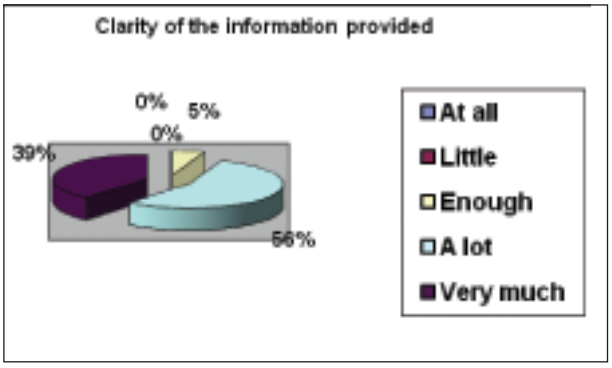


Figure 3



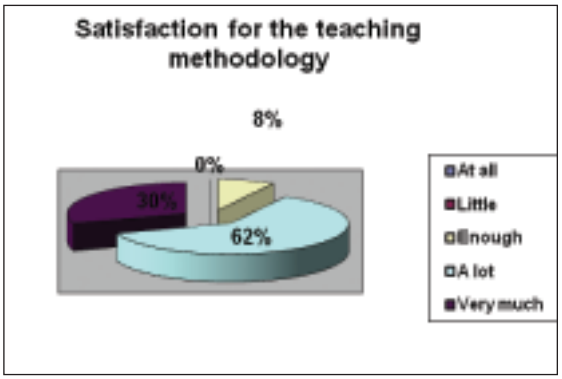


Figure 4