

A COMPARATIVE STUDY OF DATA COLLECTION METHODS IN THE PROCESS OF NURSING: DETECTION OF CHEMOTHERAPY SIDE EFFECTS USING A SELF-REPORTING QUESTIONNAIRE

Marco Di Muzio¹, Alessandra Marinucci², Anna De Benedictis² and Daniela Tartaglini²

¹Department of Public Health and Infectious Diseases, Sapienza University of Rome, Rome, Italy;

²University Campus Bio-Medico, Rome, Italy

SUMMARY – Toxicity of chemotherapy is a factor that most negatively affects the quality of life of cancer patients. Monitoring of side effects and adverse effects may be subject to errors due to various factors such as the lack of privacy during data collection, shame on the part of the patient to talk about some issues, lack of recognition of symptoms and/or unawareness of side effects of treatments, and/or inappropriate reference model of data collection. In order to assist caregivers in proper data collection, a 'self-reporting questionnaire' was designed. The questionnaire was developed using validated scales such as the Common Terminology Criteria for Adverse Event, Edmonton Symptom Assessment Scale and Douleur Neuropathique en 4 Questions. The survey involved the population of patients scheduled for chemotherapy in Day Hospital at the Campus Bio-Medico University Hospital, Rome, between June and July 2015. During the period of observation, 367 patients were admitted to Day Hospital, 57.5% of women and 38.4% of men, average age 64 years, for a total of 622 accesses; of these, only 173 were interviewed by the nursing staff in relation to side effects and toxicity. During the trial, 381 patients were involved, of which 60.1% of women ($p=0.8$) and 38.3% of men ($p=0.9$), average age 63 years ($p=0.9$), for a total of 611 accesses and 498 self-reporting questionnaires administered. At the end of the trial period, in order to evaluate usability, an evaluation questionnaire was given to medical personnel, including five doctors and six nurses, to consider possible amendments to the instrument and its perceived effectiveness. Comparative analysis of data collected during the observation period and the trial showed how the use of the self-reporting questionnaire allowed for detection of side effects of chemotherapy earlier and in a more detailed way than relying only on medical examination and unstructured interview by nursing staff. It also enabled reaching a larger number of users. In conclusion, the use of self-reporting systems, together with the work and clinical judgment of the expert, can contribute to improvement in the patient quality of life, corroborating nurse interviews through a precise and systematic data collection process that reduces the amount of interpretation of symptoms by the patient and the caregiver, while providing them with precise instructions on what to report and how to report it. The significant and rapid spread of computers, tablets and smartphones allows for speculating on further use and implementation of this system through its computerized application.

Key words: Nursing process; Data collection; Neoplasms – drug therapy; Antineoplastic drugs – adverse effects; Surveys and questionnaires; Self-assessment

Introduction

Toxicity of chemotherapy is a factor that most negatively affects the quality of life of cancer patients. Cytotoxic effects¹⁻³ become evident as undesirable clinical

Correspondence to: *Alessandra Marinucci, MD*, University Campus Bio-Medico, Via Alvaro del Portillo 200, 00128, Rome, Italy.
E-mail: a.marinucci@unicampus.it

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symptoms that occur after administration of most anti-cancer therapies, due to the low therapeutic index of chemotherapy drugs⁴⁻⁶. The problem associated with this therapy is poor cellular selectivity; moreover, toxic effects often overlap with therapeutic effects as healthy cells are also damaged by the treatment. These symptoms usually disappear once the treatment ends, but their underestimation, lack of timely treatment, or perpetration of exposure to chemotherapeutic agents may lead to irreversible damage to the patient or to the need to suspend a therapeutically effective treatment, thus causing death.

In managing side effects, it is essential to know the probability of toxic response^{1,3,7} to chemotherapy and to properly assess the signs and symptoms in the patient before and during treatment, to avoid errors in therapeutic decisions. Cancer patients may indeed show one or more symptoms related to the disease and/or to therapies that influence their daily life, independently of the stage and spread of the disease; often in addition, some symptoms are not immediately recognized or are underestimated by the oncologist⁸.

Monitoring of side effects and adverse events may, however, also be subject to errors and/or omissions due to various factors including the lack of privacy during data collection, shame on the side of the patient to talk about some issues, the lack of recognition of symptomatology and/or unawareness of the treatment side effects, or inappropriate reference model of data collection^{9,10}.

To this purpose, validated scales¹¹ have been established to provide support in detection and treatment of symptoms, with the aim to improve the quality of life of patients and their families and guarantee continuous care through early integration of simultaneous care first and palliative care afterwards.

In the literature, there are no articles on validation of a 'self-reporting questionnaire' in terms of detection of toxicity and side effects associated with chemotherapy. However, field studies use this technique for collecting monitoring data in home care and outpatient environments through the application of the Common Terminology Criteria for Adverse Event (CTCAE)^{12,13}. Studies suggest CTCAE as a valid source of information in addition to clinical data for detection of chemotherapy toxicity^{14,15}.

In this regard, this project aimed to create a self-reporting questionnaire in order to improve data col-

lection related to chemotherapy side effects, improve reception of the patient, and minimize prescription errors due to:

- absence of dedicated reception areas;
- lack of privacy;
- uneasiness;
- non-recognition of symptoms;
- patient inability to describe or quantify symptoms;
- unawareness of side effects of treatments; and
- inadequate reference model of data collection.

Subjects and Methods

In order to assess usefulness and effectiveness of the self-reporting questionnaire administered to cancer patients, a one-month period of observation was carried out on the data collection method utilized by the medical and nursing staff at the Oncology Day Hospital, Campus Bio-Medico di Roma. It was followed by a comparable period of experimentation of the self-reporting questionnaire.

The self-reporting questionnaire (available on request) has been developed using validated scales such as the CTCAE^{12,13}, the Edmonton Symptom Assessment Scale (ESAS)^{16,17}, and Douleur Neuropathique en 4 Questions (DN4)^{18,19}.

In developing the questionnaire, symptoms were considered that are more easily recognizable and quantifiable by the patient, and the manifestation of which precludes administration of chemotherapy.

At the end of the trial period, an evaluation questionnaire was given to physicians and nurses in the Oncology Day Hospital to assess the usability of the self-reporting questionnaire.

The evaluation questionnaire on practicality and usability of the self-reporting questionnaire by health workers has been designed on the basis of previous internal reports performed at the Hospital Campus Bio-Medico of Rome by the Group of Improvement JCI (Joint Commission International) Clinical Risk Management, as well as the usability requirements expressed in the Development of a Model of Integrated Patient Folder project of the Ministry of Health²⁰.

Eight questions were identified with 5 possible answers on a Likert scale, from excellent to inadequate, in addition to the years of service in the oncology area, particularly at the Day Hospital, and 3 open questions.

Sample

The self-reporting questionnaire was administered to all patients scheduled for chemotherapy in Day Hospital at the Campus Bio-Medico of Rome, with approval from the Hospital Health Management. A total of 498 questionnaires were administered.

During the period of observation, 367 patients were admitted to Day Hospital, 57.5% of women and 38.4% of men, average age 64 years. For 4.1% of them, it was not possible to determine their sexual category because of incomplete master data. Total number of accesses was 622; of these, 173 were interviewed by the nursing staff concerning side effects and toxicity.

During the trial, 381 patients were involved, 60.1% of women ($p=0.8$) and 38.3% of men ($p=0.9$), average age 63 years ($p=0.9$), while for 1.6% it was not possible to determine sexual category. Total number of admissions was 611.

The following therapies were administered during the two study periods: alkylating agents 2.2% *vs.* 3.5%,

$p=0.8$, 13% *vs.* 10.4% antimetabolites $p=0.7$, antimetabolic 9.4% *vs.* 10.7%, $p=0.94$, cytotoxic antibiotics 0.5% *vs.* 0% $p=0.47$, targeted therapies 30.4% *vs.* 33.3% $p=0.77$, hormones and hormone antagonists 6.9% *vs.* 5.6% $p=0.93$, various agents 4.7% *vs.* 4.2% $p=0.86$, and polychemotherapies 32.9% *vs.* 32.3% $p=0.95$.

The two samples did not show statistically significant differences and were found to be consistent with the existing clinical and epidemiological national studies⁴.

The medical staff of the Department of Oncology Day Hospital, Campus Bio-Medico University Hospital, Rome, which filled-out the evaluation questionnaire consisted of 5 medical specialists, including 2 specialists and 3 interns; as for the nursing staff, the questionnaire was administered to 6 nurses working in the oncology area in June, totaling 11 questionnaires to assess the usability of the tool.

The two populations were compared by standard statistical measurements of the mean, standard deviation and percentage. The values of p were calculated by the χ^2 -test for discontinuous variables and Student's T test for continuous variables. The values of $p < 0.05$ were considered statistically significant.

The study was approved by the Ethics Committee of the Campus Bio-Medico University Hospital, Rome, Italy.

Table 1. Toxicity revelation

	Observational group: interview	Experimental group: self-reporting questionnaire
Total admission	622	611
Interview/questionnaire	173	498
Reported toxicity	61	2738
Mean toxicity by patient	0.1	4.5

Results

The research results proved to be consistent with those reported from scientific studies in the field. Comparative analysis of data collected during the observation period and the trial revealed that the use of

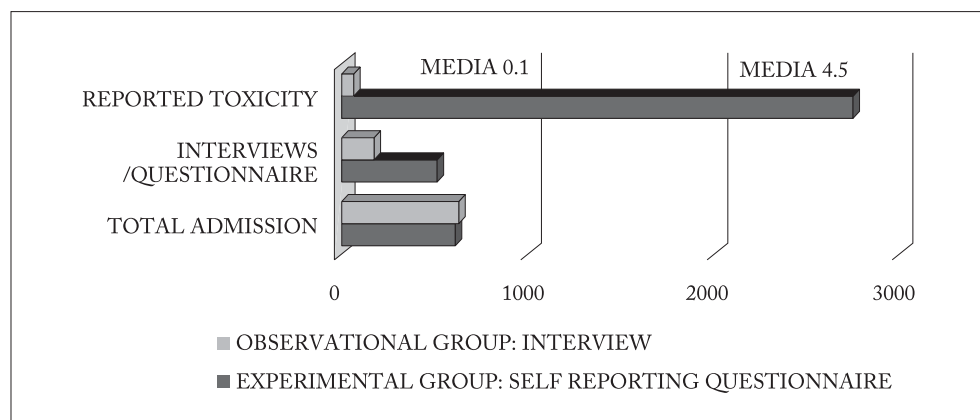


Fig. 1. Toxicity revelation.

Table 2. *Chemotherapy toxicity and side effects*

	Toxicity and side effects	Observational group (%)	Experimental group (%)	p
Common Terminology Criteria for Adverse Event (CTCAE)	Hyperthermia	2.3	3.6	0.9
	Skin reaction	2.3	18.7	0.0004
	Mucositis	0	16.5	0.0001
	Gastric toxicity	1.2	6	0.14
	Bowel toxicity	7	33.7	0.0000
Edmonton Symptom Assessment Scale (ESAS)	Pain	4	41.4	0.0000
	Tiredness	5.8	74.1	0.0000
	Nausea	2.3	28.9	0.0000
	Depression	0	31.7	0.0000
	Anxiety	0	41.6	0.0000
	Drowsiness	0	51.4	0.0000
	Lack of appetite	0	33.1	0.0000
	Wellbeing	0.6	40.2	0.0000
Douleur neuropathique en 4 questions (DN4)	Shortness of breath	0	24.9	0.0000
	Burn	0	9.8	0.0039
	Cold	0	6.2	0.0339
	Electric shock	0.6	11.4	0.0035
	Numbness	2.9	25.9	0.0000
	Painful cold	0	5.6	0.0486
	Electric shock	0	10	0.0035
	Itching	0.6	11.6	0.0031
	Pain evoked by light touching	0	8.6	0.0181
Others	5.8	23.1	0.0010	

the self-reporting questionnaire allowed for detection of chemotherapy side effects earlier and in a more detailed way than relying only on medical examination and unstructured interviewing by nursing staff. It also enabled reaching a larger number of users (Table 1, Fig. 1).

Careful analysis of the types of toxicity observed in the nursing interviews and questionnaires showed how the adverse event monitoring by clinicians during chemotherapy often did not take into account the subjective and emotional components, as well as the implication these symptoms may have in daily life; comparison of the symptoms self-reported by patients with those recorded by nurses revealed that patients and nurses agreed on the incidence of the most common and/or objectifiable symptoms such as hyperthermia and gastric toxicity, but they did not agree on less widespread toxicities that go unrecognized by the population as potential effects of chemotherapy, as well as

on psychosomatic states. These conditions often are not considered really compromising by attending physicians from a prescriptive point of view, but prove to be highly invalidating²¹⁻²³ from the point of view of patients. In particular, highly significant results are achieved concerning the presence of alteration of bowel function, pain, anxiety and depression, malaise, fatigue and abnormal sleep-rest pattern^{8,24}, as such toxicities, very frequently suggested by patients, tend to be underestimated and undervalued by operators²⁵⁻²⁹ (Table 2, Fig. 2).

Discussion and Conclusions

The use of self-reporting systems, together with the work and clinical judgment of the expert, can contribute to improvement in the quality of life of cancer patients. It also helps the nurse in conducting patient interview through precise and systematic data collec-

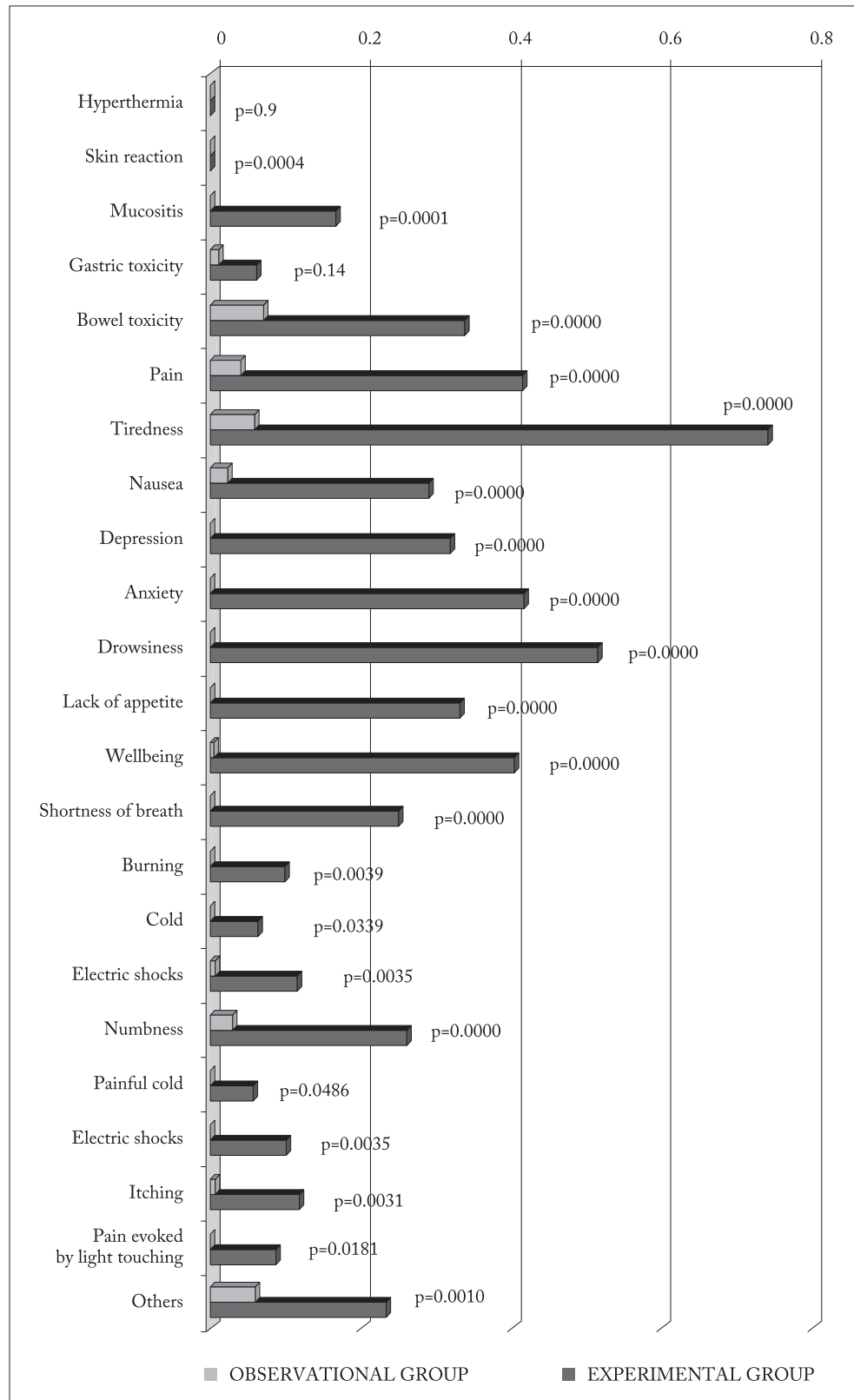


Fig. 2. Chemotherapy toxicity and side effects.

Table 3. Folders filling correctly

	Observational group	Experimental group	p
Folders filling correctly	27.8%	82%	0.0000

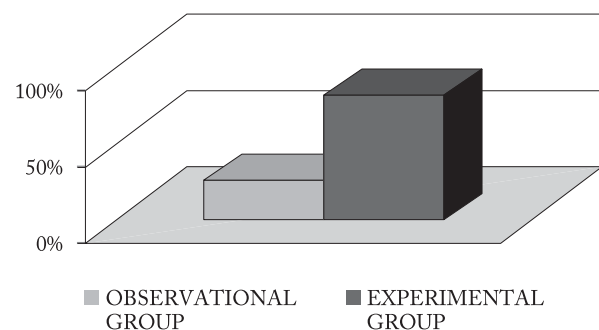


Fig. 3. Folders filling correctly.

tion. This in turn reduces the interpretative amount of symptoms by patients and caregivers, while providing them with precise instructions on what to report and how to report it.

The method of self-administration also guarantees more privacy and freedom to reveal symptoms that are deemed embarrassing. The use of a standardized form allows for reporting real and relevant data into computerized medical records, thus guaranteeing storage of information towards greater continuity of care.

The tool also shows good versatility of use; its use as a checklist during the active interview by physicians and nurses can be anticipated, in addition to the self-administration mode, whereas privacy conditions are guaranteed.

The significant and rapid availability of computers, tablets and smartphones, which in recent years has involved not only young people but also people of all ages and social classes, also allows to envision further use and implementation of this system through its computerized application, as already happens internationally³⁰. Specifically, one might think to fill-in an online questionnaire in order to allow regular monitoring of patient symptoms, their performance status and their needs, as well as to obtain information on the patient health in real-time, thus improving efficiency and quality of care, communication and help requests³¹.

The use of telemedicine systems in oncology is expected to be on an equal footing with those already

widespread in Italy for the care of patients with chronic degenerative diseases. The use of such technologies would improve clinical care³² by reporting symptoms with consistent time savings through standardized methods and addressing useful links for clinical treatment, such as summary reports in the patient computerized medical record and immediate e-mail alerts to healthcare personnel whenever patients report acute needs³³.

Ultimately, the importance of maintaining an effective physician/nurse-patient relationship cannot be underemphasized in order to avoid depersonalization of the helping relationship that the exclusive use of computerized methods may entail.

Acknowledgment

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Sažetak

USPOREDBENO ISTRAŽIVANJE METODA PRIKUPLJANJA PODATAKA
U PROCESU SESTRINSKE NJEGE: OTKRIVANJE NUSPOJAVA KEMOTERAPIJE
POMOĆU UPITNIKA ZA SAMOPROCJENU*M. Di Muzio, A. Marinucci, A. De Benedictis i D. Tartaglino*

Toksičnost kemoterapije je čimbenik koji ima najteži učinak na kvalitetu života u bolesnika s karcinomom. Praćenje nuspojava i štetnih učinaka može biti podložno greškama zbog raznih čimbenika kao što je nedostatna zaštita povjerljivosti tijekom prikupljanja podataka, nevoljkosti bolesnika da govori o nekim problemima, neprepoznavanje simptoma i/ili nepoznavanje nuspojava liječenja i/ili neodgovarajući referentni model prikupljanja podataka. Zato smo izradili upitnik za samoprocjenu kako bismo pomogli u ispravnom prikupljanju podataka onima koji pružaju skrb ovim bolesnicima. Upitnik je izrađen uz pomoć provjerenih ljestvica kao što su *Common Terminology Criteria for Adverse Event*, *Edmonton Symptom Assessment Scale* i *Douleur Neuropathique en 4 Questions*. Istraživanje je obuhvatilo bolesnike naručene za kemoterapiju u Dnevnoj bolnici Sveučilišne bolnice Campus Bio-Medico u Rimu u lipnju i srpnju 2015. godine. U tom razdoblju u Dnevnu bolnicu je primljeno 367 bolesnika, 57,5% žena i 38,4% muškaraca prosječne dobi od 64 godine, za ukupno 622 pristupa. Od svih tih bolesnika sestrinsko osoblje je samo njih 173 ispitalo o nuspojavama i toksičnosti. Za vrijeme istraživanja bio je uključen 381 bolesnik, od toga 60,1% žena ($p=0,8$) i 38,3% muškaraca ($p=0,9$) prosječne dobi od 63 godine ($p=0,9$), za ukupno 611 pristupa i 498 izdanih upitnika za samoprocjenu. Kako bismo procijenili primjenjivost ovoga upitnika, na kraju istraživanja upitnik za njegovu procjenu je podijeljen medicinskom osoblju uključujući pet liječnika i šest medicinskih sestara kako bi razmotrili moguće potrebne dopune ovoga instrumenta te njegovu učinkovitost. Usporedbena analiza podataka prikupljenih tijekom istraživanja pokazala je da je primjena upitnika za samoprocjenu omogućila otkrivanje nuspojava kemoterapije ranije i detaljnije nego kad se to oslanjalo samo na medicinski pregled i nestrukturirani razgovor sestrinskog osoblja s bolesnicima. Uz to, ovom metodom je obuhvaćen veći broj korisnika. U zaključku, primjena sustava za samoprocjenu zajedno sa stručnim radom i kliničkom prosudbom može doprinijeti poboljšanju bolesnikove kvalitete života, pružiti potporu razgovoru sestrinskog osoblja s bolesnikom kroz proces preciznog i sustavnog prikupljanja podataka, čime se znatno smanjuje tumačenje simptoma od strane bolesnika i osoba koje ih njeguju, ali im pruža točne upute o čemu trebaju izvijestiti i kako. Zahvaljujući značajnom i brzom širenju računala, tableta i 'pametnih telefona' može se promišljati o daljnjoj primjeni ovoga sustava kroz njegovu računalnu aplikaciju.

Ključne riječi: *Sestrinska njega, postupci; Podaci, prikupljanje; Tumori – farmakoterapija; Antitumorski lijekovi – štetna djelovanja; Ankete i upitnici; Samoprocjena*