UNIVERSITY OF TORINO – DEPARTMENT OF ONCOLOGY

Dare voce al paziente: i "patient-reported outcomes" in oncologia mammaria.

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Background

- Information available about symptomatic toxicities of anti-cancer treatments is based on reports made by clinicians, not on direct reporting by patients. [1]
- Therefore, some side effects could be under-reported. [2,3]
- Scientific interest in the integration of patient-reported outcomes into drug safety evaluation is growing. [4]

[1] Basch E. J Natl Cancer Inst 103: 1808-10, 2011.
[2] Petersen MA. Eur J Cancer 42: 1159-66, 2006.
[3] Fromme EK. J Clin Oncol 22: 3485-90, 2004.
[4] Basch E. Annu Rev Med 65: 307-17, 2014.

Patient versus clinician symptom reporting using the National Cancer Institute Common Terminology Criteria for Adverse Events: results of a questionnaire-based study

Ethan Basch, Alexia Iasonos, Tiffani McDonough, Allison Barz, Ann Culkin, Mark G Kris, Howard I Scher, Deborah Schrag

Summary

Background The Common Terminology Criteria for Adverse Events (CTCAE) are used as standard practice in trials of cancer treatments by clinicians to elicit and report toxic effects. Alternatively, patients could report this information directly as patient-reported outcomes, but the accuracy of these reports compared with clinician reports remains unclear. We aimed to compare the reporting of symptom severity reported by patients and clinicians.

Methods Between March and May, 2005, a questionnaire with 11 common CTCAE symptoms was given to consecutive outpatients and their clinicians (physicians and nurses) in lung and genitourinary cancer clinics in the Memorial Sloan-Kettering Cancer Center, New York, NY, USA. Patients completed a version that used language adapted from the CTCAE for patient self-reporting. The results from the questionnaire were compared with clinician reporting of the same symptoms.

Lancet Oncol 2006; 7: 903–09

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See Reflection and Reaction page 883

Department of Epidemiology and Biostatistics (E Basch MD, A Iasonos PhD, T McDonough BA, A Barz BA, D Schrag MD), Department of

Basch E et al, Lancet Oncol 2006; 7:903-909

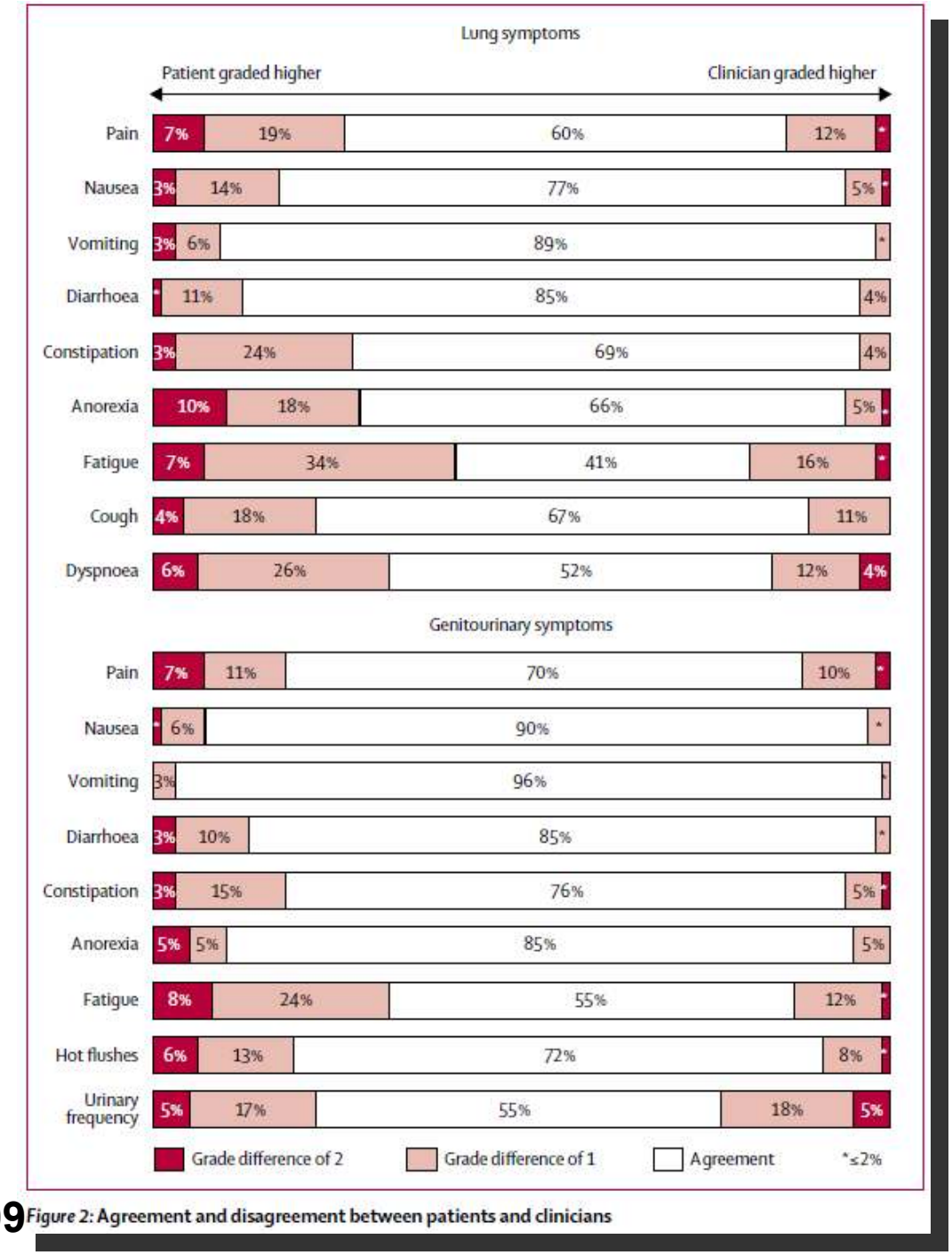

Figure 2: Agreement and disagreement between patients and clinicians

Basch E et al, Lancet Oncol 2006; 7:903-909

- *For most symptoms, **agreement between patient and clinician was high**, and most discrepancies were within a grade difference of one point.*
- *Agreement was higher for symptoms that could be observable directly, such as vomiting and diarrhoea, than for **more subjective symptoms**, such as fatigue and dyspnoea*

Basch E et al, Lancet Oncol 2006; 7:903-909

original article

Annals of Oncology 20: 1929–1935, 2009
doi:10.1093/annonc/mdp287
Published online 17 July 2009

Clinician versus nurse symptom reporting using the National Cancer Institute—Common Terminology Criteria for Adverse Events during chemotherapy: results of a comparison based on patient's self-reported questionnaire

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Background: Monitoring adverse events during chemotherapy by clinicians is a standard practice but clinicians may report fewer side-effects or lower symptom severity than patients. Our aim was to compare symptoms self-reported by patients with symptoms registered by clinicians and nurses, to assess validity of a nurse reporting.

Methods: From April to August 2007, a double-blind questionnaire with 13 common items graduated according to the National Cancer Institute's Common Terminology Criteria for Adverse Events was completed by clinicians and nurses for outpatients undergoing chemotherapy at our Medical Oncology Day Hospital Unit. Patients completed a modified questionnaire with simplified terms. They were requested to specify seriousness of symptoms with a subjective scale varying from 1 to 4. Every patient–nurse–clinician questionnaire was registered for the statistical analysis. Agreement was evaluated by Cohen's kappa coefficient.

Results: Eighty-five paired questionnaires were completed. Patients, nurses and clinicians agreed on most

Table 1. Form of patient self-reported questionnaire

Name ————

Date of submission ——— Date of collection ————

Dear Mr/Mrs, you are kindly requested to complete this dairy of side-effects from chemotherapy. This form will be collected from nurses before next chemotherapic infusion.

Fatigue	From day —/—/—	To day —/—/—	Mild/moderate/severe/intolerable
Respiratory distress	From day —/—/—	To day —/—/—	Mild/moderate/severe/intolerable
Fever	From day —/—/—	To day —/—/—	Maximum of fever (°C) ——
Conjunctivitis	From day —/—/—	To day —/—/—	Mild/moderate/severe/intolerable
Mucositis	From day —/—/—	To day —/—/—	Mild/moderate/severe/intolerable
Nausea	From day —/—/—	To day —/—/—	Mild/moderate/severe/intolerable
Vomiting	From day —/—/—	To day —/—/—	How many times each day?
Diarrhoea	From day —/—/—	To day —/—/—	How many times each day?
Stipsis	From day —/—/—	To day —/—/—	Mild/moderate/severe/intolerable
Muscular pain	From day —/—/—	To day —/—/—	Mild/moderate/severe/intolerable
Tingling of hands/feet	From day —/—/—	To day —/—/—	Mild/moderate/severe/intolerable
Skin alterations	From day —/—/—	To day —/—/—	Mild/moderate/severe/intolerable
Pain	From day —/—/—	To day —/—/—	Mild/moderate/severe/intolerable

Cirillo M et al, Ann Oncol 2009;20(12):1929-35.

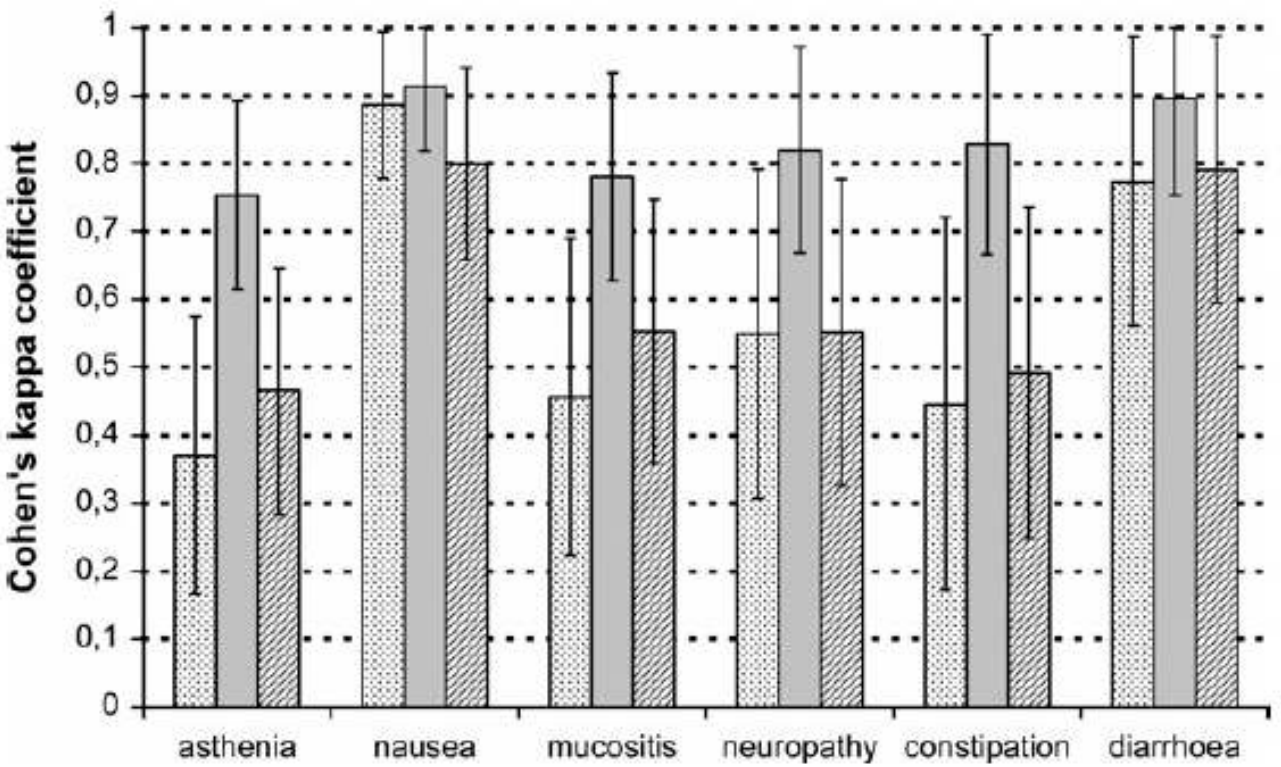

Figure 1. Cohen's kappa coefficient of agreement for the six most common adverse events between patient and physician (dotted columns), patient and nurse (grey columns) and physician and nurse (dashed columns). Columns are kappas; bars are 95% confidence intervals.

Cirillo M et al, Ann Oncol 2009;20(12):1929-35.

- *Patients, nurses and clinicians agreed on most symptoms and toxicity grade.*
- *Agreements between **patients and nurses** were stronger than those between patients and physicians for the six most common symptoms.*
- *The nurse staff could be successfully employed in collecting toxicity data because of a greater ability to elicit information from patients than the medical staff.*

Cirillo M et al, Ann Oncol 2009;20(12):1929-35.

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ORIGINAL REPORT

Symptomatic Toxicities Experienced During Anticancer Treatment: Agreement Between Patient and Physician Reporting in Three Randomized Trials

Massimo Di Maio, Ciro Gallo, Natasha B. Leighl, Maria Carmela Piccirillo, Gennaro Daniele, Francesco Nuzzo, Cesare Gridelli, Vittorio Gebbia, Fortunato Ciardiello, Sabino De Placido, Anna Ceribelli, Adolfo G. Favaretto, Andrea de Matteis, Ronald Feld, Charles Butts, Jane Bryce, Simona Signoriello, Alessandro Morabito, Gaetano Rocco, and Francesco Perrone

Listen to the podcast by Dr Snyder at www.jco.org/podcasts

Di Maio M et al, J Clin Oncol 2015 Mar 10;33(8):910-5.

Aim of the study

- To describe patients' and physicians' reporting of 6 symptomatic toxicities occurred during anti-cancer treatment, based on data prospectively collected in randomized trials, in order to evaluate:
  - the **agreement** between patients and physicians
  - the rate of possible **under-reporting** by physicians

Di Maio M et al, J Clin Oncol 2015 Mar 10;33(8):910-5.

Patients

Patients enrolled in 3 multicenter, randomized trials (coordinated by the Clinical Trials Unit, NCI Naples)

Trial	Enrolment years	Setting	Treatments
ELDA [1] (NCT00331097)	2003 – 2011	Early breast cancer, pts 65 – 79 yrs	• CMF • Docetaxel
GECO [2] (NCT00385606)	2003 – 2005	Advanced NSCLC, pts < 70 yrs	Cisplatin/Gemcitabine +/- Rofecoxib
TORCH [3] (NCT00349219)	2006 – 2009	Advanced NSCLC, pts < 70 yrs (Italy), no age limit (Canada)	• Cisplatin/Gemcitabine • Erlotinib

[1] Perrone F. Ann Oncol 26(4):675-82, 2015.
[2] Gridelli C. Lancet Oncol 8: 500-12, 2007.
[3] Gridelli C. J Clin Oncol 30: 3002-11, 2012.

Di Maio M et al, J Clin Oncol 2015 Mar 10;33(8):910-5.

Methods (1)

Trial	Adverse events reporting	QoL questionnaires
ELDA (NCT00331097)	NCI-CTC v2.0	EORTC QLQ C30 + BR23
GECO (NCT00385606)	NCI-CTC v2.0	EORTC QLQ C30 + LC13
TORCH (NCT00349219)	CTCAE v3.0	EORTC QLQ C30 + LC13

- **Adverse events** prospectively collected by physicians → any grade during each cycle
- **Quality of life (QoL)** questionnaires filled in by patients at the end of each treatment cycle → any severity during last week

Di Maio M et al, J Clin Oncol 2015 Mar 10;33(8):910-5.

Methods (2)

- Analysis was limited to the first 3 cycles.
- Rates of **6 toxicities** reported by patients and physicians were described:
  - Anorexia
  - Nausea
  - Vomiting
  - Constipation
  - Diarrhea
  - Hair loss
- **Agreement** between patients' and physicians' evaluation was assessed by Cohen's ?.
- **Relative under-reporting** was calculated (toxicity reported by patients but not by physicians).

Di Maio M et al, J Clin Oncol 2015 Mar 10;33(8):910-5.

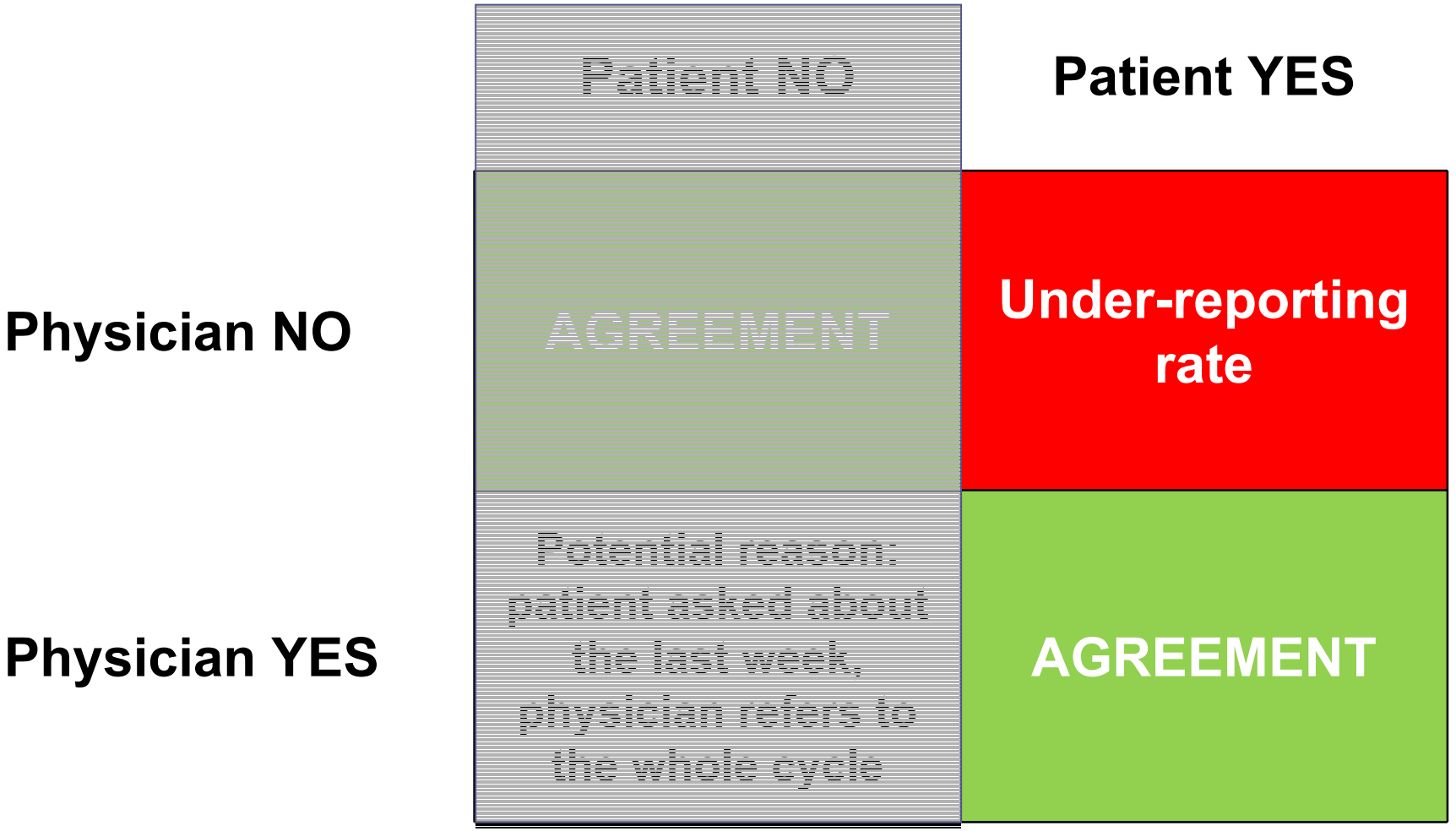
Agreement of patients' and physicians' reporting

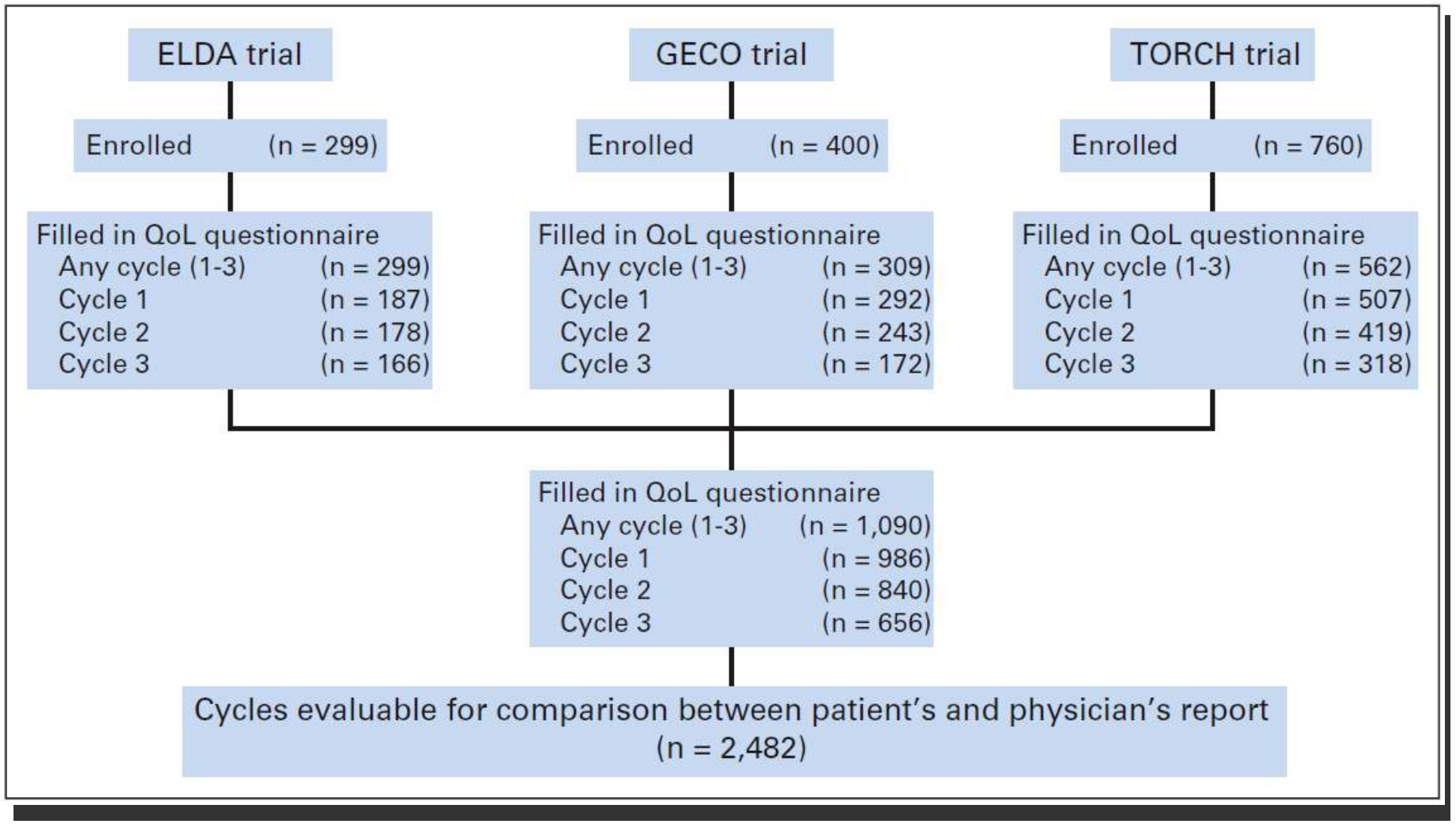
	Patient NO	Patient YES
Physician NO	AGREEMENT	NO AGREEMENT
Physician YES	NO AGREEMENT	AGREEMENT

Agreement of patients' and physicians' reporting

	Patient NO	Patient YES
Physician NO	AGREEMENT	NO AGREEMENT
Physician YES	Potential reason: patient asked about the last week, physician refers to the whole cycle	AGREEMENT

Under-reporting by physicians





Di Maio M et al, J Clin Oncol 2015 Mar 10;33(8):910-5.

Patients' characteristics (n=1090)

Age	Median (range)	64	(29 – 81)
Gender	Males	618	(56.7%)
	Females	472	(43.3%)
ECOG performance status	0	642	(58.9%)
	1	448	(41.1%)
Country	Italy	957	(87.8%)
	Canada	133	(12.2%)
Type of disease	Early breast cancer	219	(20.1%)
	Advanced NSCLC	871	(79.9%)
Treatment	Cisplatin + gemcitabine	469	(43.0%)
	Cis + gem + rofecoxib	116	(10.6%)
	Erlotinib	286	(26.2%)
	CMF	116	(10.6%)
	Docetaxel	103	(9.4%)

Di Maio M et al, J Clin Oncol 2015 Mar 10;33(8):910-5.

Agreement

Association between patient reporting (any severity) and physician reporting (any grade) – 1090 patients

	Anorexia	Nausea	Vomiting	Constipation	Diarrhea	Hair loss
Toxicity reported by:						
Patient: NO Physician: NO	35.1%	30.8%	64.2%	46.1%	59.1%	47.8%
Patient: NO Physician: YES	2.6%	9.2%	9.8%	2.9%	5.2%	1.4%
Patient: YES Physician: NO	46.3%	9.8%	12.3%	35.3%	18.1%	33.1%
Patient: YES Physician: YES	16.0%	2.9%	13.7%	15.6%	17.6%	17.7%
Cohen's κ*	0.153	0.342	0.407	0.244	0.447	0.316

* κ>0.75: excellent agreement; κ=0.40-0.75: fair to good agreement; κ<0.40: poor agreement.
(Fleiss JL . New York: John Wiley 1981)

Di Maio M et al, J Clin Oncol 2015 Mar 10;33(8):910-5.

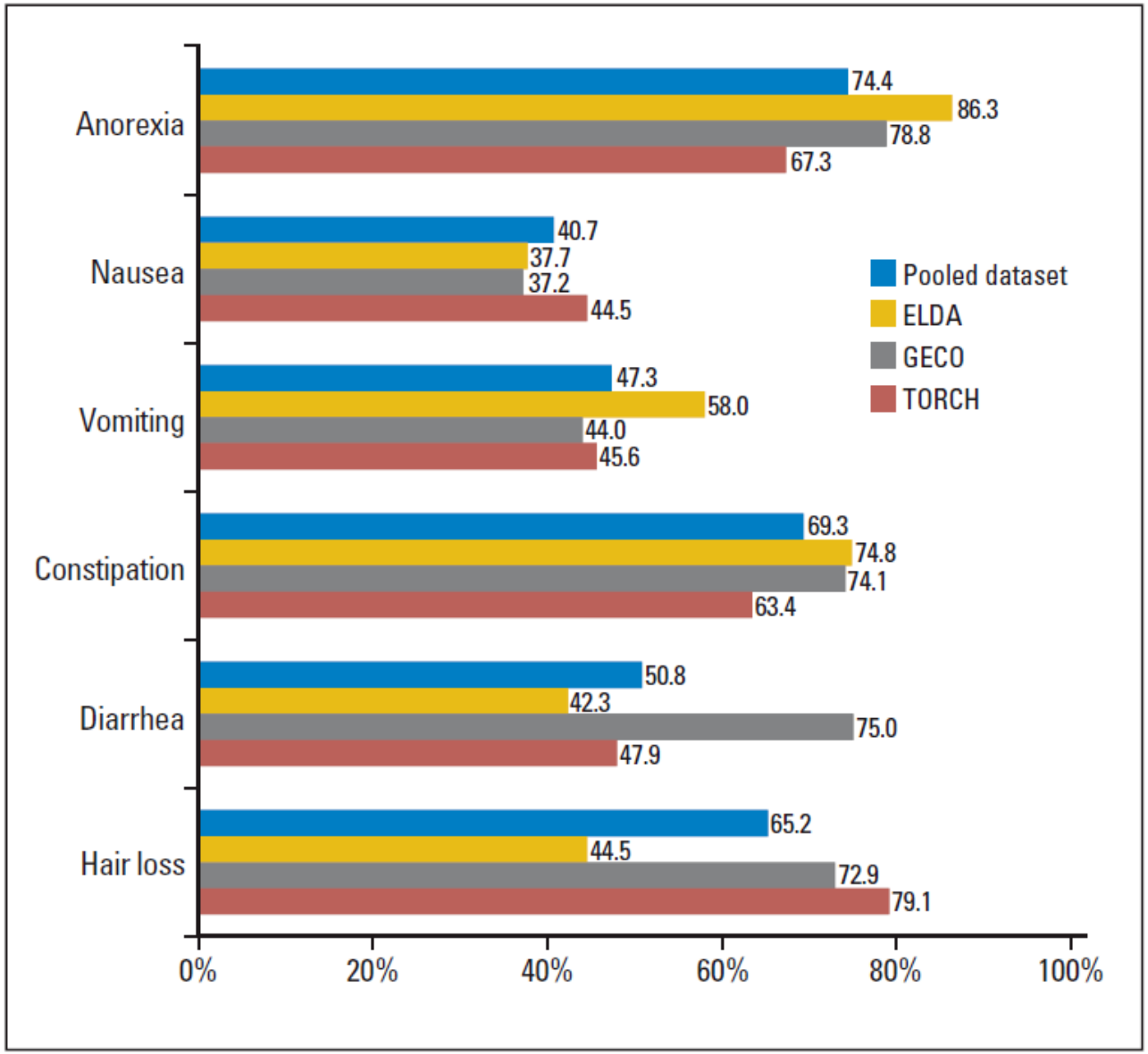
Under-reporting

Association between patient reporting (any severity) and physician reporting (any grade) – 1090 patients

		Anorexia	Nausea	Vomiting	Constipation	Diarrhea	Hair loss
Toxicity reported by:							
Patient: Physician:	NO NO	35.1%	30.8%	64.2%	46.1%	59.1%	47.8%
Patient: Physician:	NO YES	2.6%	9.2%	9.8%	2.9%	5.2%	1.4%
Patient: Physician:	**YES NO**	46.3%	9.8%	12.3%	35.3%	18.1%	33.1%
Patient: Physician:	**YES YES**	16.0%	2.9%	13.7%	15.6%	17.6%	17.7%
Under-reporting by physicians		**74.4%**	**40.7%**	**47.3%**	**69.3%**	**50.8%**	**65.2%**

Di Maio M et al, J Clin Oncol 2015 Mar 10;33(8):910-5.

Under-reporting: any severity



Di Maio M et al, J Clin Oncol 2015 Mar 10;33(8):910-5.

Under-reporting: "very much" toxicity

Appendix Table 6. Proportion of patients with under-reporting* by physician of toxicity ("very much" toxicity reported by patient) in the pooled dataset and scattered by trial.

Toxicity	Pooled dataset	ELDA	GECO	TORCH
Anorexia	38 / 76 (50.0%)	21 / 26 (80.8%)	5 / 7 (71.4%)	12 / 43 (27.9%)
Nausea	16 / 62 (25.8%)	4 / 23 (17.4%)	4 / 9 (44.4%)	8 / 30 (26.7%)
Vomiting	3 / 23 (13.0%)	0 / 6 (0%)	2 / 5 (40.0%)	1 / 12 (8.3%)
Constipation	34 / 77 (44.2%)	11 / 21 (52.4%)	9 / 16 (56.2%)	14 / 40 (35.0%)
Diarrhea	7 / 29 (24.1%)	4 / 11 (36.4%)	0 / 0 (n.a.)	3 / 18 (16.7%)
Hair loss	44 / 103 (42.7%)	17 / 55 (30.9%)	15 / 25 (60.0%)	12 / 23 (52.2%)

**Under-reporting is calculated as the proportion of patients with toxicity (very much) reported by patient but not reported at all by physician.*

Di Maio M et al, J Clin Oncol 2015 Mar 10;33(8):910-5.

Results (summary)

- **Agreement was low**
  - Toxicity rates reported by physicians were always lower than those reported by patients

- **Under-reporting by physicians was high**
  - ranging from **40.7% to 74.4%** of patients reporting **"any severity" toxicity**
  - ranging from **13.0%** to **50.0%** examining only cycles when patients reported **"very much" toxicity**

Di Maio M et al, J Clin Oncol 2015 Mar 10;33(8):910-5.

Conclusions

- Subjective toxicities are at high risk of **under-reporting** by physicians, even when prospectively collected within randomized trials and even if perceived as “very much” by the patient.
- Our findings strongly support **the incorporation of patient-reported information** into reporting of adverse events in clinical trials.

Di Maio M et al, J Clin Oncol 2015 Mar 10;33(8):910-5.

Potential causes of under-reporting

- Information about toxicity correctly acquired but not reported
- Defect in communication between patient and physician

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		Risk of sub-optimal treatment
Information about toxicity correctly acquired but not reported		
Pre-existing symptoms	Physicians could decide not to report those symptoms already present before treatment start, if considered unrelated to treatment but related to previous treatments or to disease itself.	+/-

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Symptoms attributed to the disease itself	Even if the symptoms were not present before treatment start, physicians could decide not to report those symptoms if considered related to disease itself.	+/-

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Symptoms attributed to the disease itself	Even if the symptoms were not present before treatment start, physicians could decide not to report those symptoms if considered related to disease itself.	+/-
Mild symptoms / Symptoms not needing intervention	Physicians could pay less attention in reporting mild symptoms or those symptoms that do not need treatment modification (interruption, delay, dose reduction) or supportive treatments.	+/-

		Risk of sub-optimal treatment
Information about toxicity correctly acquired but not reported		
Pre-existing symptoms	Physicians could decide not to report those symptoms already present before treatment start, if considered unrelated to treatment but related to previous treatments or to disease itself.	+/-
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Mild symptoms / Symptoms not needing intervention	Physicians could pay less attention in reporting mild symptoms or those symptoms that do not need treatment modification (interruption, delay, dose reduction) or supportive treatments.	+/-
Toxicities correctly reported in patient's file, but not in CRF.	Physicians could correctly report the occurrence of toxicity in patient's clinical file, but not in study case report form.	-

Potential causes of under-reporting

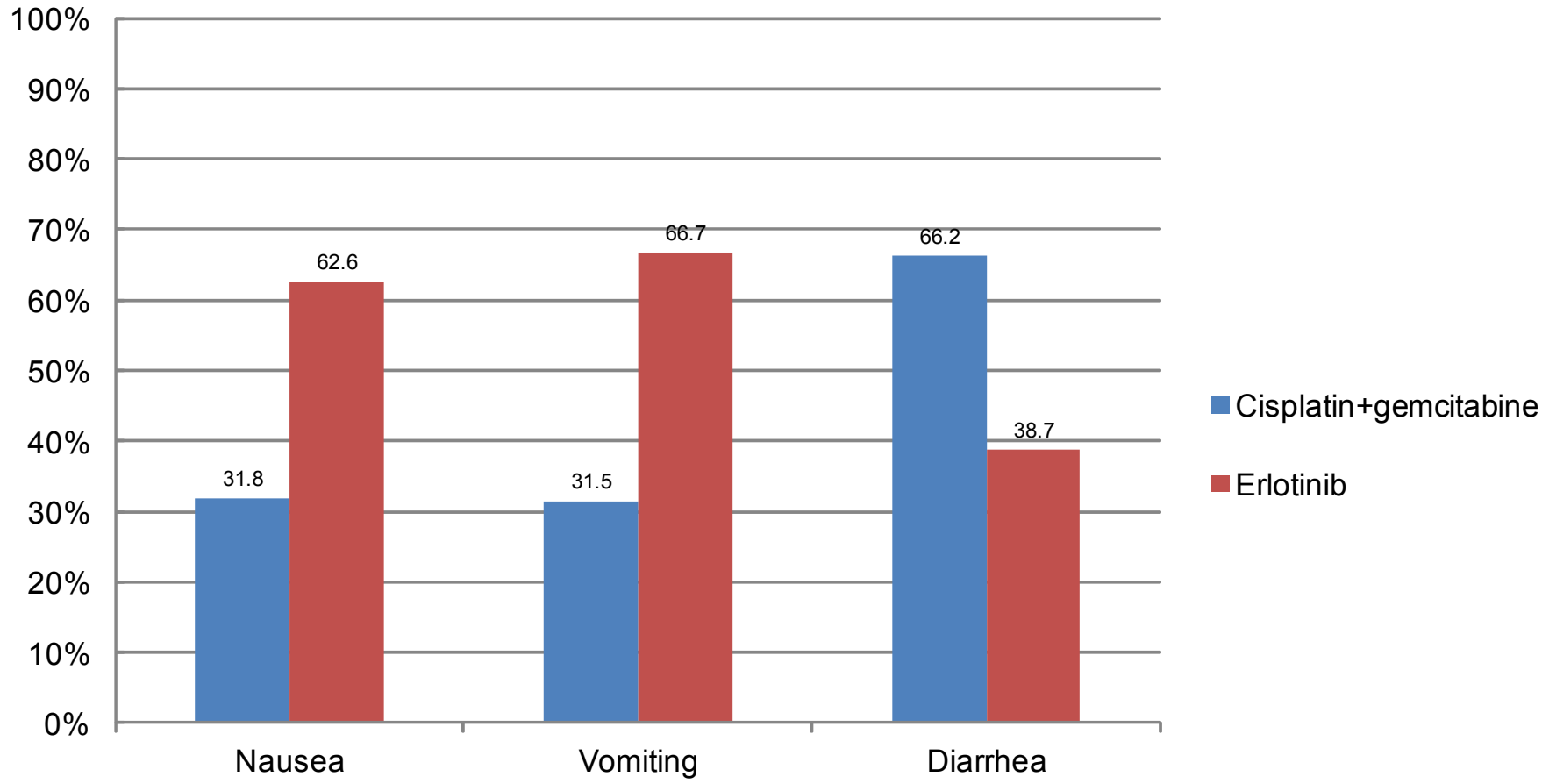
- Information about toxicity correctly acquired but not reported

- **Defect in communication between patient and physician**

		Risk of sub-optimal treatment
Defect in communication between patient and physician		
Side effects largely expected	Physicians could be less likely to report a toxicity that is largely expected (and “routinely” managed) with the specific drug.	+/-

		Risk of sub-optimal treatment
Defect in communication between patient and physician		
Side effects largely expected	Physicians could be less likely to report a toxicity that is largely expected (and “routinely” managed) with the specific drug.	+/-
Unusual side effects	Physicians could be less likely to ask patients about the occurrence of a toxicity that is not commonly expected with the specific drug.	+

Under-reporting of nausea, vomiting and diarrhea in the TORCH trial



Di Maio M et al, J Clin Oncol 2015 Mar 10;33(8):910-5.

		Risk of sub-optimal treatment
Defect in communication between patient and physician		
Side effects largely expected	Physicians could be less likely to report a toxicity that is largely expected (and "routinely" managed) with the specific drug.	+/-
Unusual side effects	Physicians could be less likely to ask patients about the occurrence of a toxicity that is not commonly expected with the specific drug.	+
Toxicity not referred by patients	If not part of a systematic assessment, toxicity will be reported only if specifically asked by the physician, or spontaneously reported by the patient.	++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Measurement of Outcomes
Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)
Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)
The purpose of the PRO-CTCAE project is to develop an electronic-based system for patient self-reporting of symptom adverse events (AEs) listed in the CTCAE in an effort to improve the accuracy and precision of grading of this class of AEs. The accurate reporting of AEs that occur to patients on clinical trials is a federal requirement that facilitates evaluation of new therapies.
Dr. Ethan Basch at Memorial Sloan-Kettering Cancer Center was awarded a contract to develop and test the PRO-CTCAE system. In the first project year beginning in October 2008, Dr. Basch and his co-investigators initiated development of an electronic patient-reported system for monitoring and reporting symptomatic AEs that patients may experience during treatment. In the second project year, Dr. Basch and his co-investigators will conduct studies to evaluate the validity, reliability, feasibility, and clinical utility of the new PRO-CTCAE, and they will create supporting training and educational materials.
Support and oversight for this contract is provided by representatives from NCI's Division of Cancer Control and Population Sciences, Division of Cancer Prevention, Community Oncology and Prevention Trials Research Group, Division of Cancer Treatment and Diagnosis, and the Center for Bioinformatics. The NCI is working collaboratively with the Food and Drug Administration (FDA) to develop the PRO-CTCAE and to assure that the PRO-CTCAE will be compliant with the Medical Dictionary for Regulatory Activities (MedDRA).
For additional information, visit the NCI Wiki page or send an email to NCIPROCTCAEInquiries@mail.nih.gov.
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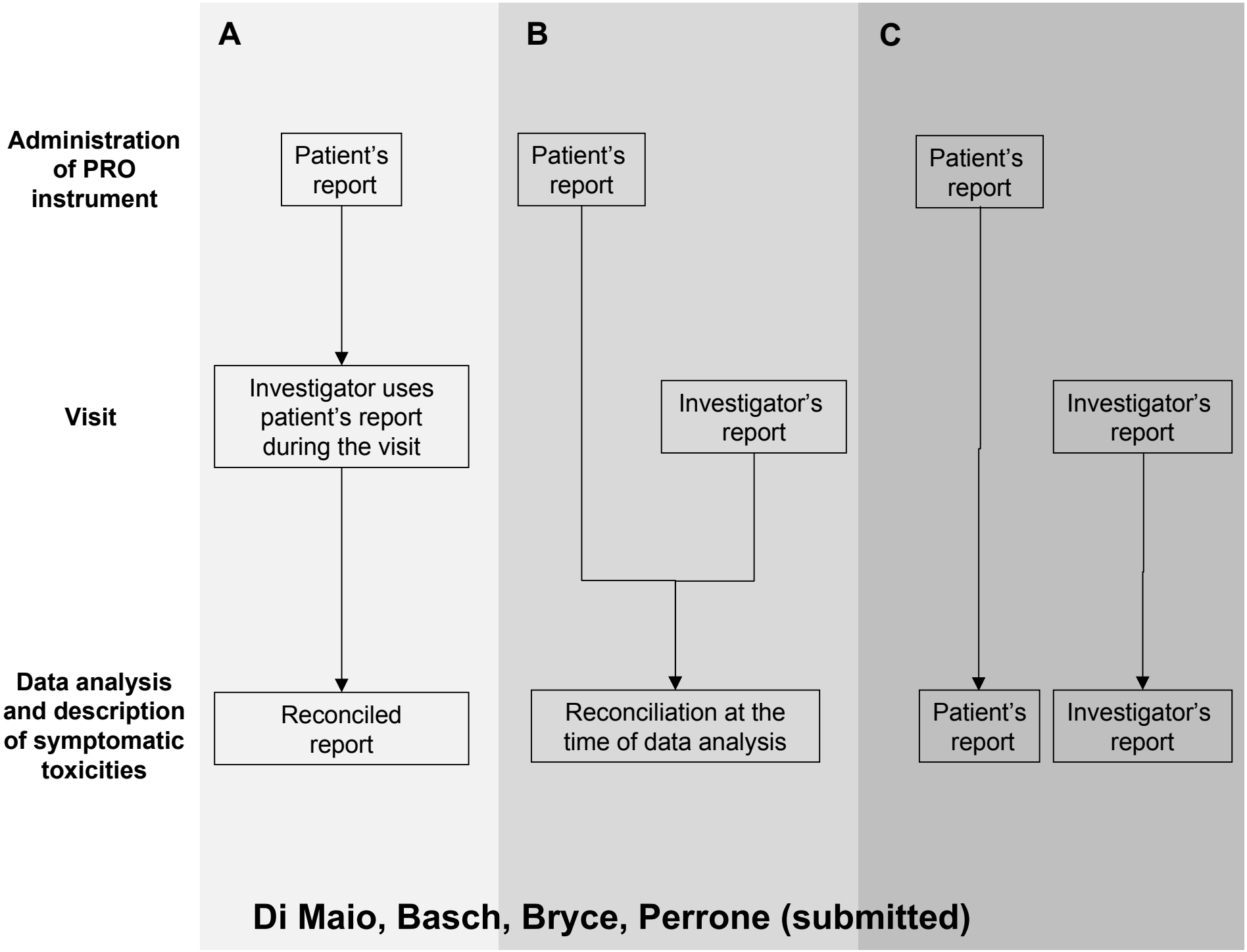
Research

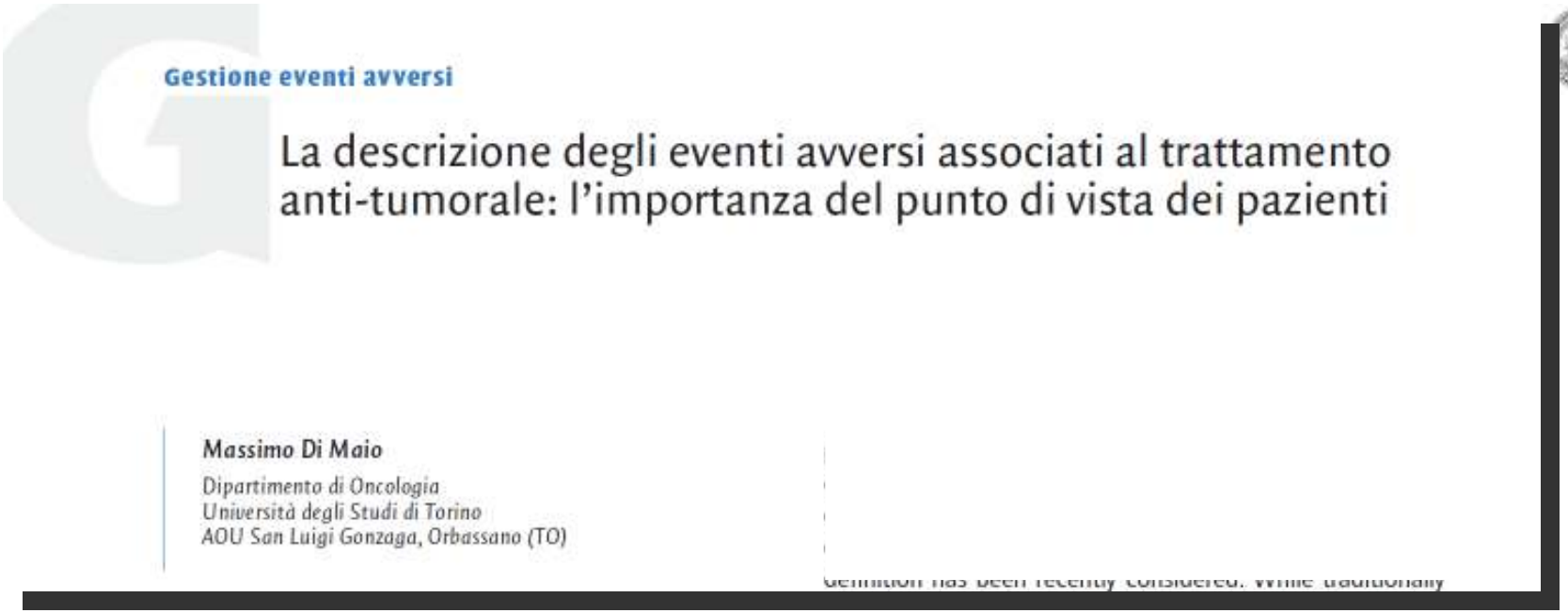
Original Investigation

Validity and Reliability of the US National Cancer Institute's Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)

Amylou C. Dueck, PhD; Tito R. Mendoza, PhD; Sandra A. Mitchell, PhD, CRNP, AOCN; Bryce B. Reeve, PhD; Kathleen M. Castro, RN, MS, AOCN; Lauren J. Rogak, MA; Thomas M. Atkinson, PhD; Antonia V. Bennett, PhD; Andrea M. Denicoff, MS, RN, ANP; Ann M. O'Mara, PhD, RN, FAAN; Yuelin Li, PhD; Steven B. Clauser, PhD, MPA; Donna M. Bryant, MSN, ANP-BC, OCN, CCRC; James D. Bearden III, MD, FACP; Theresa A. Gillis, MD; Jay K. Harness, MD; Robert D. Siegel, MD, FACP; Diane B. Paul, AAS; Charles S. Cleeland, PhD; Deborah Schrag, MD, MPH; Jeff A. Sloan, PhD; Amy P. Abernethy, MD, PhD; Deborah W. Bruner, RN, PhD, FAAN; Lori M. Minasian, MD, FACP; Ethan Basch, MD, MSc; for the National Cancer Institute PRO-CTCAE Study Group

Dueck et al, JAMA Oncol. 2015 Aug 13. [Epub ahead of print]


A
B
C
Administration of PRO instrument
Visit
Data analysis and description of symptomatic toxicities
Patient's report
Patient's report
Patient's report
Investigator uses patient's report during the visit
Investigator's report
Investigator's report
Reconciled report
Reconciliation at the time of data analysis
Patient's report
Investigator's report
Di Maio, Basch, Bryce, Perrone (submitted)



Gestione eventi avversi

La descrizione degli eventi avversi associati al trattamento anti-tumorale: l'importanza del punto di vista dei pazienti

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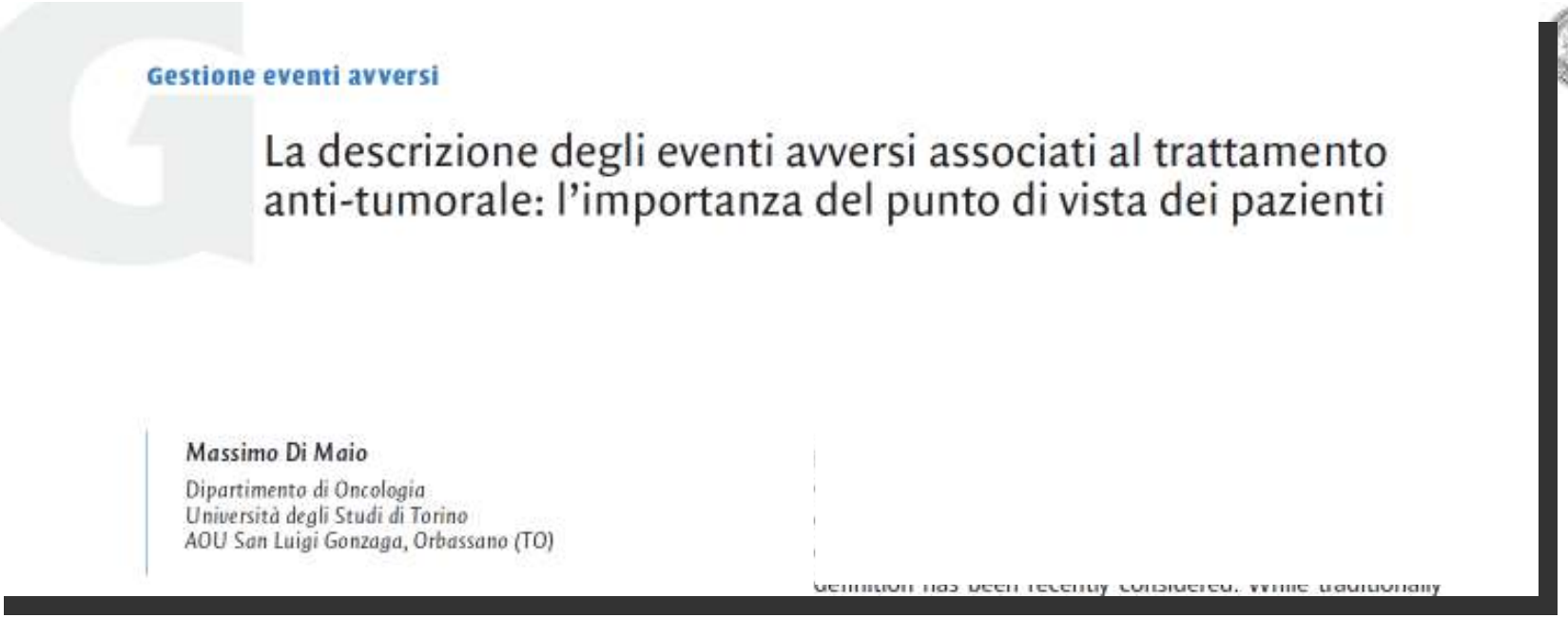
AOU San Luigi Gonzaga, Orbassano (TO)

definition has been recently considered. While traditionally

Così come l'impiego dei CTCAE è stato storicamente fondamentale per consentire l'adozione di un "linguaggio comune" nella descrizione della tossicità dei trattamenti da parte dei medici, lo sviluppo dei PRO-CTCAE è una tappa importante per integrare la prospettiva dei pazienti in tale descrizione.

Di Maio M, CASCO (in press)



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La descrizione degli eventi avversi associati al trattamento anti-tumorale: l'importanza del punto di vista dei pazienti

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AOU San Luigi Gonzaga, Orbassano (TO)

I medici hanno la competenza per interpretare i sintomi del paziente alla luce del contesto generale della malattia e del trattamento, ma il valore aggiunto dell'impiego di uno strumento che "dà voce" direttamente ai pazienti è che questi ultimi possono comunicare direttamente la loro esperienza soggettiva. •

Di Maio M, CASCO (in press)

Ipotesi di studio prospettico

- E’ ormai dimostrato che l’*under-reporting* della tossicità comporta una descrizione sub-ottimale del reale profilo di effetti collaterali associati alla somministrazione dei trattamenti anti-tumorali.

- Non è invece chiaro se una rilevazione sistematica delle tossicità riportate dai pazienti, mediante somministrazione di questionari dedicati possa anche **migliorare la gestione stessa dei pazienti**, contribuendo ad ottimizzare il trattamento delle tossicità e, di conseguenza, la qualità di vita dei pazienti.

Obiettivo

Valutare **l'impatto di una rilevazione sistematica delle tossicità da parte del personale infermieristico** (quale figura intermedia fra medico e paziente e sicuramente più vicina alla valutazione dell'ultimo), nei pazienti oncologici sottoposti a trattamenti anti-tumorali, mediante **somministrazione di questionari dedicati e successiva discussione dei risultati in aggiunta alla normale visita**, sulla gestione delle tossicità e sulla qualità di vita dei pazienti oncologici.

- Confronto tra 2 gruppi di pazienti:
  - il gruppo di controllo sarà sottoposto alle normali visite con lo specialista oncologo.
  - I pazienti assegnati al gruppo sperimentale, prima della normale visita con lo specialista oncologo, compileranno, con la guida del personale infermieristico e con l'ausilio di strumenti elettronici interattivi (tablets), la scheda di rilevazione sistematica delle tossicità riportate nel periodo trascorso dalla precedente visita. Sarà quindi cura del personale infermieristico discutere il risultato del questionario con il medico, nel corso della visita.

- I pazienti assegnati ad entrambi i gruppi, in occasione di ciascuna visita, compileranno un questionario validato per la valutazione della qualità di vita (EORTC), che consentirà di confrontare le risposte nei 2 gruppi.
- Obiettivo primario dello studio è il confronto tra i 2 gruppi durante il trattamento, allo scopo di verificare l'ipotesi che la rilevazione sistematica delle tossicità si associ ad un miglioramento della qualità di vita.

- Determinazione della numerosità campionaria: metodo dell'*effect size*
- La variabile considerata come indice sul quale viene dimensionato lo studio è la "qualità di vita globale" (EORTC QLQ 29 e 30)
- Il valore di δ prescelto è pari a 0.50, vale a dire un effetto di dimensioni medie.
- Con errore alfa bilaterale pari a 0.05 e potenza del 90% è necessario inserire nello studio 172 pazienti.

UNIVERSITY OF TORINO – DEPARTMENT OF ONCOLOGY

Dare voce al paziente: i "patient-reported outcomes" in oncologia mammaria.

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