97953

Validation of a standard set of patient-centered outcomes for lung cancer in Spain

Vicente Escudero[1], Antonio Calles[2], Roberto Collado[1], Belén Marzal[1], Marilena Appierto[3], Marta Comellas[3], Luis Lizán[3,4], Jorge Suarez[5], Carmen Garrido[5], Aurora Ortiz[5], Carlos Polanco[5]

[1]Hospital Pharmacy, Hospital General Universitario Gregorio Marañón, Madrid, Spain; [2]Medical Oncology, Hospital General Universitario Gregorio Marañón, Madrid, Spain; [3]Outcomes'10, Castellón de la plana, Spain; [4]Medicine Department, Universitat Jaume I, Castellón de la plana, Spain; [5]Bristol-Myers Squibb, Madrid, Spain.

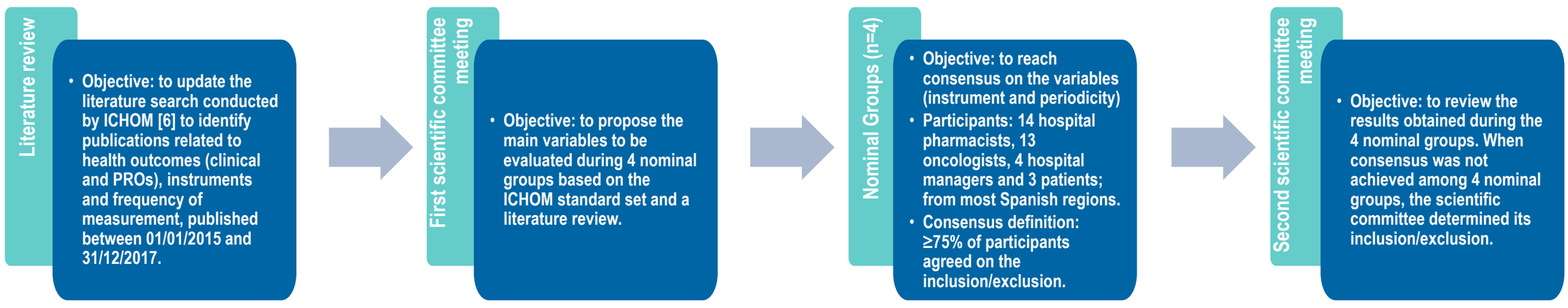
Introduction

- Lung cancer (LC) is one of the most frequently diagnosed cancers worldwide [1]. In Spain, 28,645 new cases are diagnosed each year, representing the leading cause of cancer-related mortality [2]. The disease and its treatment may affect several aspects of patients' lives [3–5]. Nevertheless, while survival outcomes are frequently assessed, patient-centered outcomes are rarely collected during patient follow-up.
- Filling this gap, the International Consortium for Health Outcomes Measurement (ICHOM) developed a standard set of variables aimed at following-up of newly diagnosed LC patients [6]. To implement this standard set, different aspects need to be considered: 1) selected variables should be routinely collected in clinical practice or, at least, doctors and patients should be familiarized with them; 2) the technology needed to measure the selected variables should be available; 3) instruments to collect the variables should be available and validated in the language of the country; 4) the target population to which the standard set may apply, should be defined according to each country clinical needs.
- Since clinical practice might vary across countries, the main objective of this project was **to validate and adapt this set of variables to the Spanish setting.**

Methods

- A scientific committee, consisting of an oncologist specialized in LC, three hospital pharmacists and two patient representatives, led and coordinated the project.

Phases of the project



Results

Condition scope and treatment covered

- In line with the ICHOM standard set for LC, the target population of the standard set defined within the present project framework included all Spanish patients with newly diagnosed LC, regardless of the disease stage, type or therapeutic option.

Spanish standard set of patient-centered outcomes in LC

- Table 1 and Table 2 show selected case-mix and outcomes variables.

Table 1. Spanish standard set of patient-centered outcomes in LC. Case-mix variables

Patient profile	Variable	Supporting information	Measurement instrument	Timing	Data sources
Demographic factors					
All patients	Age		Date of birth	Baseline (before treatment begins)	Clinical
	Gender		Male/Female		Clinical
	Family support	Degree of family support and degree of patient dependence	Yes/No		Patient-reported
	Educational level	Level of schooling completed	(0) Without studies; (1) primary school level; (2) secondary school level; (3) higher education		Patient-reported
Baseline clinical factors					
All patients	Unintentional weight loss		Yes/No/I don´t know	Baseline (before treatment begins)	Patient-reported
	Smoking status	Smoking status at diagnosis	Never-smoker (<100 cigarettes in lifetime), ex-smoker (stopped >1 year before diagnosis), current smoker		Patient-reported
	Performance status		ECOG scale		Clinical
	Patient-reported health status		Tracked via generic questionnaire EQ-5D-5L and lung cancer specific questionnaire LCSS		Patient-reported
	Comorbidities		Charlson index		Clinical
	Pulmonary function	FEV_1	NA		Clinical
Baseline tumor factors					
All patients	Clinical stage		TNM staging system	Baseline (before treatment begins)	Clinical
	Pathological stage		TNM staging system		Clinical
	Histology		NA		Clinical
	EGFR mutation; ALK translocation; ROS-1 determination; PD-L1 expression*		Yes/No/undetermined		Clinical
Treatment factors					
All patients	Treatment intent		(1) curative; (2) palliative	Baseline (before treatment begins)	Oncologist-reported
	Completed treatment		(1) Yes, with dose reduction; (2) No, due to toxicity; (3) No, due to patient´s will; (4) No, due to patient´s death	At treatment ending	Oncologist-reported

NA: not applicable; ECOG: Eastern Cooperative Oncology Group; EQ-5D-5L: EuroQol; LCSS: Lung Cancer Symptoms Scale; FEV_1: forced expiratory volume; TNM: Tumor, Nodes, Metastasis; EGFR: Epidermal growth Factor Receptor; ALK: Anaplastic Lymphoma Kinase; ROS-1: ROS proto-oncogene 1 receptor tyrosine kinase; PD-L1: Programmed Death-ligand; *List of Biomarkers annually valuated and updated .

Table 2. Spanish standard set of patient-centered outcomes in LC. Outcomes variables

Patient profile	Variable	Supporting information	Measurement instrument	Timing	Data sources
Degree of health					
All patients	Performance status		ECOG scale	During follow-up visits	Clinical
	Patient-reported health status	Global health status, physical and emotional function	Tracked via generic questionnaire EQ-5D-5L and lung cancer specific questionnaire LCSS	At 3, 6 and 12 months. Later, tracked annually for life*	Patient-reported
		Fatigue, vitality, pain, cough, difficulty breathing, hemoptysis and loss of appetite	Tracked via lung cancer specific questionnaire LCSS		
Survival					
All patients	Overall survival		Date of death	NA	Administrative data (death registry)
	Cause of death	Tumor/ treatment related or not	NA		Clinical
Quality of death					
All patients	Place of death		NA	Date of birth	Administrative data (death registry)
	Aggressive intervention and palliative care	Earle criteria: (1) patient receives chemotherapy or other antineoplastic therapy in last 14 days of life; (2) patient initiates a new therapeutic scheme in the last month of life; (3) patient goes to emergency room more than once in the last month of life or Intensive Care Unit admitted; (4) patient dies at an oncology unit instead of receiving palliative care; (5) patient does not receive palliative care before passing away; (6) patient die while was receiving palliative care in the last 72 hours before hospital admission		30 days before death	Clinical
	Existence or doctor´s knowledge about the living will of patients		Yes/No	NA	Oncologist-reported
Acute complications of treatment					
Patient receiving surgical resection	Major surgical complications	(1) Secondary complication related to surgical care; (2) Urgent re-admission after the next 7 days post-discharge, for a cause related to surgical treatment; (3) Death after surgery (in the next 30 days)		NA	Clinical
Patient with systemic therapy or/and radiotherapy	Major systemic therapy or/and radiotherapy complications	Presence of grade ≥3	CTCAE	NA	Clinical
			PRO- CTCAE	NA	Patient reported
Others					
All patients	Time from diagnosis		Date of hospital admission or non-hospital consultation when data of the histological or cytological confirmation is unknown	At diagnosis	Clinical
	Time from diagnosis to treatment		NA	When treatment begins	Clinical
	Patient productivity loss	Sick leave or disability	Yes/No	NA	Patient reported

NA: not applicable; ECOG: Eastern Cooperative Oncology Group; EQ-5D-5L: EuroQol; LCSS: Lung Cancer Symptoms Scale; *when treatment is changed, patient-reported health status will be evaluated at 3, 6 and 12 months; CTCAE: Common Terminology Criteria for Adverse events; PRO-CTCAE: Patient-Reported Outcomes version of the CTCAE

Conclusions

- **Variables included in the present Standard set are the most relevant for the follow-up of patients with lung cancer in the Spanish setting. They can be routinely collected in clinical practice and both the technology and the instruments needed to measure them are available in Spain.**
- **Validation and adaptation of ICHOM standard set to the Spanish setting may facilitate its implementation in clinical practice, paving the way to standardize lung cancer variables collection.**

References

1.Bray et al. Cancer J Clin. 2018;68:394–424.; **2.** Sociedad Española de Oncología Médica. Las cifras del cáncer en España 2018. **3.** Gralla et al. Thorac Oncol.; 2014;9:1243–8. **4.** Walker et al. Psychooncology. 2017;26:755–62. **5.** Migliorino et al. J Cancer Res Clin Oncol.; 2017;143:783–91. **6.** Mak et al. Eur Respir J 2016; 48: 852–860

Acknowledgments

- Bristol-Myers Squibb (Princeton, NJ) and ONO Pharmaceutical Company Ltd. (Osaka, Japan)
- This study was supported by Bristol-Myers Squibb
- All authors contributed to and approved the presentation; writing and editorial assistance was provided by M. Comellas PhD, of Agency Outcomes'10 funded by Bristol-Myers Squibb

Aurora.OrtizNunez@bms.com