Transición de una década 2010-2020

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Hospital Universitario de León
Sesión 7 enero de 2020
7.30h

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Objetivo de la charla

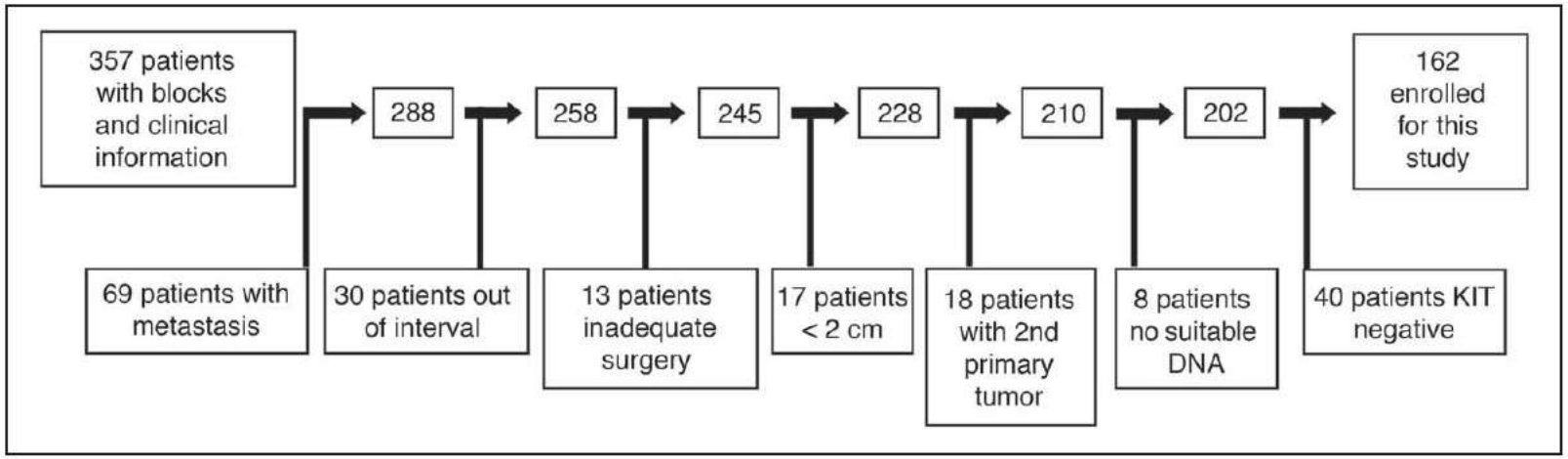
1. **Presentar publicaciones más relevantes**
2. Comentar Ensayos Clínicos
3. Proyectos para la próxima década

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Deletions Affecting Codons 557-558 of the *c-KIT* Gene Indicate a Poor Prognosis in Patients With Completely Resected Gastrointestinal Stromal Tumors: A Study by the Spanish Group for Sarcoma Research (GEIS)

Javier Martín, Andrés Poveda, Antonio Llombart-Bosch, Rafael Ramos, José A. López-Guerrero, Javier García del Muro, Joan Maurel, Silvia Calabuig, Antonio Gutierrez, José L. González de Sande, Javier Martínez, Ana De Juan, Nuria Laínez, Ferrán Losa, Valentín Alija, Pilar Escudero, Antonio Casado, Pilar García, Remei Blanco, and José M. Buesa


357 patients with blocks and clinical information
288
258
245
228
210
202
162 enrolled for this study
69 patients with metastasis
30 patients out of interval
13 patients inadequate surgery
17 patients < 2 cm
18 patients with 2nd primary tumor
8 patients no suitable DNA
40 patients KIT negative

original article

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Prognostic time dependence of deletions affecting codons 557 and/or 558 of KIT gene for relapse-free survival (RFS) in localized GIST: a Spanish Group for Sarcoma Research (GEIS) Study

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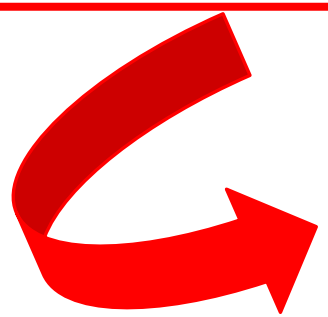
Prognostic factors in localized GIST

- **Mitotic count** and
- **Size** are the most recognized prognostic factors in localized GIST
- Incorporating **tumor location** as an important factor
- Microscopically **free surgical margins**

- Prognostic factors at the **molecular level for localized** GIST



Prognostic factors in localized GIST

- The selection of a final subset of
  - **162 patients** after a clinical and pathological review (paraffin blocks) of 357 cases has been explained previously

Table 2. Univariate analysis of prognostic factors for RFS in the entire follow-up period, the first 4-year interval and beyond the 4 years after surgery

Variable	All intervals, % (range)		Initial period (0–4 years) , % (range)		>4 years, % (range)	
	7-year RFS	*P*	RFS	*P*	RFS	*P*
Sex		0.29		0.47		0.29
Male	67 (55–78))		70 (59–80)		86 (72–100)	
Female	72 (61–82)		75 (65–84)		95 (89–100)	
Age		0.19		0.28		0.43
0–59	62 (50–75)		68 (56–80)		91 (82–100)	
≥60	73 (64–82)		75 (66–84)		91 (82–100)	
Size		<0.001		0.0002		0.029
2–5 cm	83 (75–91)		84 (77–92)		94 (86–100)	
5–10 cm	67 (51–83)		70 (54–85)		95 (87–100)	
>10 cm	41 (24–58)		49 (32–65)		71 (42–100)	
Mitosis		<0.0001		<0.0001		<0.0001
0–5	87 (80–94)		87 (80–94)		100	
6–10	74 (53–96)		74 (53–96)		100	
>10	33 (18–47)		44 (29–58)		51 (20–82)	
Fletcher/NIH		<0.0001		<0.0001		0.0006
Low	95 (89–100)		95 (89–100)		100	
Intermediate	80 (64–96)		80 (64–96)		100	
High	44 (32–57)		52 (40–64)		71 (50–92)	

Table 2. Univariate analysis of prognostic factors for RFS in the entire follow-up period, the first 4-year interval and beyond the 4 years after surgery

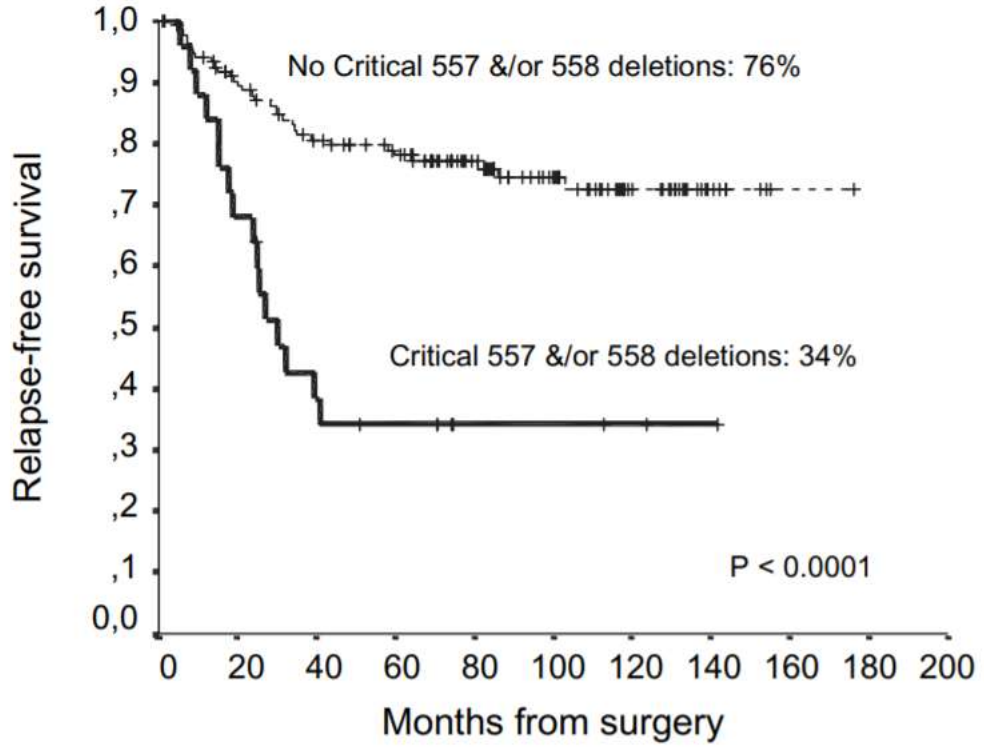
Variable	All intervals, % (range)		Initial period (0–4 years) , % (range)		>4 years, % (range)	
	7-year RFS	*P*	RFS	*P*	RFS	*P*
Localization		0.013		0.0098		0.92
Gastric	76 (67–85)		80 (72–88)		91 (82–100)	
Nongastric	58 (46–71)		61 (48–73)		91 (79–100)	
Mutational status		0.0208		0.0199		0.19
No mutation	79 (69–90)		83 (74–93)		98 (85–100)	
Any mutation	63 (52–73)		66 (56–75)		87 (76–98)	
KIT		0.0025		0.005		0.26
Mutated	60 (49–71)		63 (52–74)		86 (72–100)	
Wild type	79 (69–88)		82 (74–91)		95 (89–100)	
Exon 11 deletion		0.0436		0.0093		0.19
Yes	57 (41–72)		57 (42–72)		100	
No	74 (65–82)		78 (71–86)		89 (80–98)	
Del 557 and/or 558		<0.0001		<0.0001		0.37
Yes	34 (15–53)		34 (15–53)		100	
No	76 (68–83)		80 (73–87)		82 (65–99)	
Exon 11 nondeletion		0.29		0.92		0.0053
Yes	66 (50–83)		73 (58–88)		72 (47–97)	
No	70 (62–78)		72 (64–80)		97 (92–100)	

RFS, relapse-free survival; M-L/AFIP, Miettinen–Lasota/Armed Forces Institute of Pathology; F/NIH, Fletcher/National Institutes of Health.

Table 3. Time-dependent relapses rates (A) and multivariate analysis (B)

B	Relative risk	95% CI	*P*
Entire time period			
M-L/AFIP risk categories			
Intermediate	5.97	2.09–17.06	0.001
High	11.45	4.40–29.76	<0.001
DEL 557 and/or 558	3.05	1.59–5.85	0.001
0- to 4-year time period			
M-L/AFIP risk categories			
Intermediate	4.88	1.66–14.34	0.004
High	8.94	3.39–23.55	<0.001
DEL 557 and/or 558	3.44	1.76–6.73	<0.001

Conclusión



Deletions involving **codons 557–558** within exon 11 of the KIT gene had an **independent prognostic** value for relapse-free survival (RFS)

Long-term effects of continuing adjuvant tamoxifen to 10 years versus stopping at 5 years after diagnosis of oestrogen receptor-positive breast cancer: ATLAS, a randomised trial

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Summary

Background For women with oestrogen receptor (ER)-positive early breast cancer, treatment with tamoxifen for 5 years substantially reduces the breast cancer mortality rate throughout the first 15 years after diagnosis. We aimed to assess the further effects of continuing tamoxifen to 10 years instead of stopping at 5 years.

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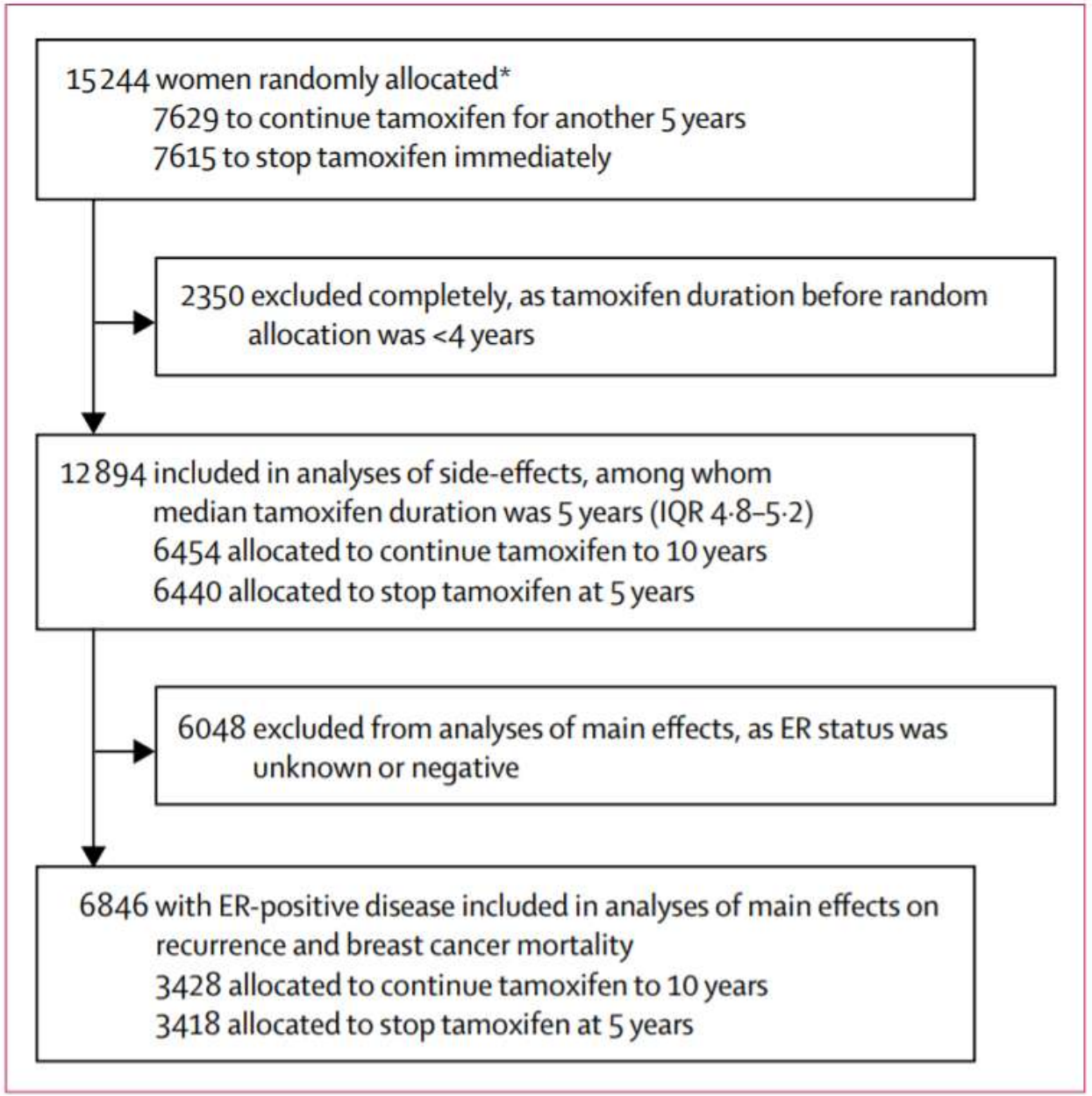
A Sengupta, P Shah, A Sharma, S C Sharma, K K Shenoy, H S Shukla, N K Shukla, S N Shukla, A Singh, K K Singh, A Srivastava, K Subrahmaniyam, P K Sur, H B Tongaonkar, R Vashisht, K V Veerendra Kumar, S Vijaya. *Iran [Peiman Haddad], 247*—K Dehshiri, F Amouzgar-Hashemi, H Madani, S H Mortazavi (deceased), M A Mousavizadeh, J Raafat, B Sadrolhefazi, M Tabatabaeefar. *Ireland [T Finnegan], 1. Israel [Moshe Inbar, previously Noa Ben-Baruch, Adi Shani], 253*—F Barak, N Ben-Zui, R Catane, M Dinerman, E Evron, A Figer, M Gips, H Hayat, E Idelevich, R Isacson, V Kopp, F Kovner, L Marchasin, D Matcejevsky, L Olga, E Perepechi, I G Ron, T Safra, D Sarid, S Shlanger, E Shumeli, E Tepper, N Yaal-Hahoshen (deceased). *Italy [Antonio Nicolucci], (Miriam Valentini), 292*—G Amiconi, F Ascione, S Banducci, G Baratelli, F Battistelli, R Bianchi, S Bravi, A Chiara, B Dall'Omo, A De Matteis, F Di Costanzo, L Di Lullo, B di Nardo, S Ferrari, R Fiore, G Fornari, G Gini, M Giordano, M Giovannini, A Gravina, L Isa, L Laudadio, G Luchena, G Mantovani, M Marcellini, E Mari, P Marpicati, A Martoni, E Massa, A M Molino, A Nuzzo, R Pedersini, E Piana, N L Pinna, M C Pirozzoli, F Recchia, A Riccardi, F S Robbiati, E Rossi, M Sannicoló, G Ucci, M C Valli, C Zamagni. *Japan [Yasuo Ohashi, Tadashi Ikeda, previously Yasuo Nomura], (Emi Yoshida) 137*—S Akashi, K Aogi, E Arita, H Aoyama, A Emi, J Fujisawa, K Fujiwara, T Fukutomi, R Haruta, Y Hata, T Hayashida, T Hojo, Y Hozumi, H Inoue, K Ishida, M Ishida, C Kanbayashi, D Kanke, A Kataoka, A Kato, N Kato, N Katsumata, Y Kawabuchi, H Kawaguchi, M Kitajima, S Kobayashi, M Kodaira, C Koga, S Mitsuyama, M Miyauchi, E Mori, S Murakami, K Nagao, Y Nakamura, S Nishimura, R Nishimura, M Ohba, T Onishi, S Ohno, T Osako, S Osumi, M Sakata, M Sano, T Sato, Y Sato, H Shigematsu, H Takahashi, Y Takahashi, S Takashima, H Takenaka, K Tamae, K Tanaka, T Toge, M Toi, Y Uchida, N Uchiyama, H Yamaguchi, N Yamamoto, H Yamashita, T Yoshiyama. *Latvia [Juris Berzins], 92*—M Bitina, I Gailite, G Keire, T Purkalne, M Ratiani, Z Zvirbule. *Lithuania [Konstantine*

V Alija, D Almenar Cubells, C Alonso, A Alonso Amigo, G Alonso Curbera, E Alonso Redondo, I Alvarez, J Andrade Santiago, R Andrés, S Antolín Novoa, M I Antón, M A Arcusa Lanza, A Arrivi, A Avellà, J P Avellanal Barral, M A Badia i Canto, P Ballesteros Garcia, M d M Barros, R Bastús-Piulats, J N Batista López, E Batiste-Alentorn, J Belón Carrión, M Benavides, R Bernabé Caro, R Blanco Guerrero, U Bohn Sarmiento, M Boleda, C Bosch, J J Bretón Garcia, M A Burillo Cordero, J Buxó i Costa, E Calvo, L Calvo, F Capdevila, F J Carabantes, T Cardona Hernández, E Carrasco, J Casado, A Casas, S Catot Tort, J I Chacón López-Muñiz, M Chaves Conde, L Cirera i Noguera, E Ciruelos, R Colomer, J Cruz, M A De la Cruz, L De La Cruz, H De La Cueva, R Del Moral, M Domènech, F Dominguez Cunchillos, O Donay, J Dorta Delgado, A Duque Amusco, A Escobedo, P España Saz, E Espinosa Arranz, C Esteban Esteban, A Etxeberria, X Fabregat Mayol (deceased), C Falo, E Fernández Bautista, A Fernández Ortega, E Fonseca Sánchez, R M Franquesa Granell, E Gallardo, O Gallego, P Gallurt Moreira, M García, I García Carbonero, M J García López, M García Pérez, A Garrido Saldana, L Garrigós, M Gay, J R Germà Lluch, M Gil, U Giménez, A Gómez Bernal, B González, A González Del Alba, R González Del Val, L M González de Sande, R González Mancha, M M Gordon, C Gravalos Castro, I Guasch i Jordan, M Guillot, J Hornedo, L Iglesias Pérez, M D Isla, M A Izquierdo, E Jiménez Orozco, L Jolis López, I Juez, J M Laín, R Lasso de la Vega, M L Limón, M Llanos, P López, L J López Gómez, J J López López, A Lorenzo Penuel, A M Lozano Barriuso, R Llorente, H Manzano, J Martín Broto, B Martínez, P Martínez del Prado, G Martín García, C Mendiola, F Molina, C Molins, A Montano, J Montesinos, J A Moreno Nogueira, J Múñoz, M Múñoz, V Muñoz Madero, M T Murillo, M Nogué, M Noguer, B Ojeda, S Olmos, J Oramas, L Palomar, P Pastor, R Pérez Carrión, M A Pérez Escutia, J Pérez Olaguer, M d M Pérez Pérez, J Pérez-Regadera Gómez, C Pericay, J Petrement Briones, J M Piera Pibernat, A Plazaola, J Rifà, J A Rivero,

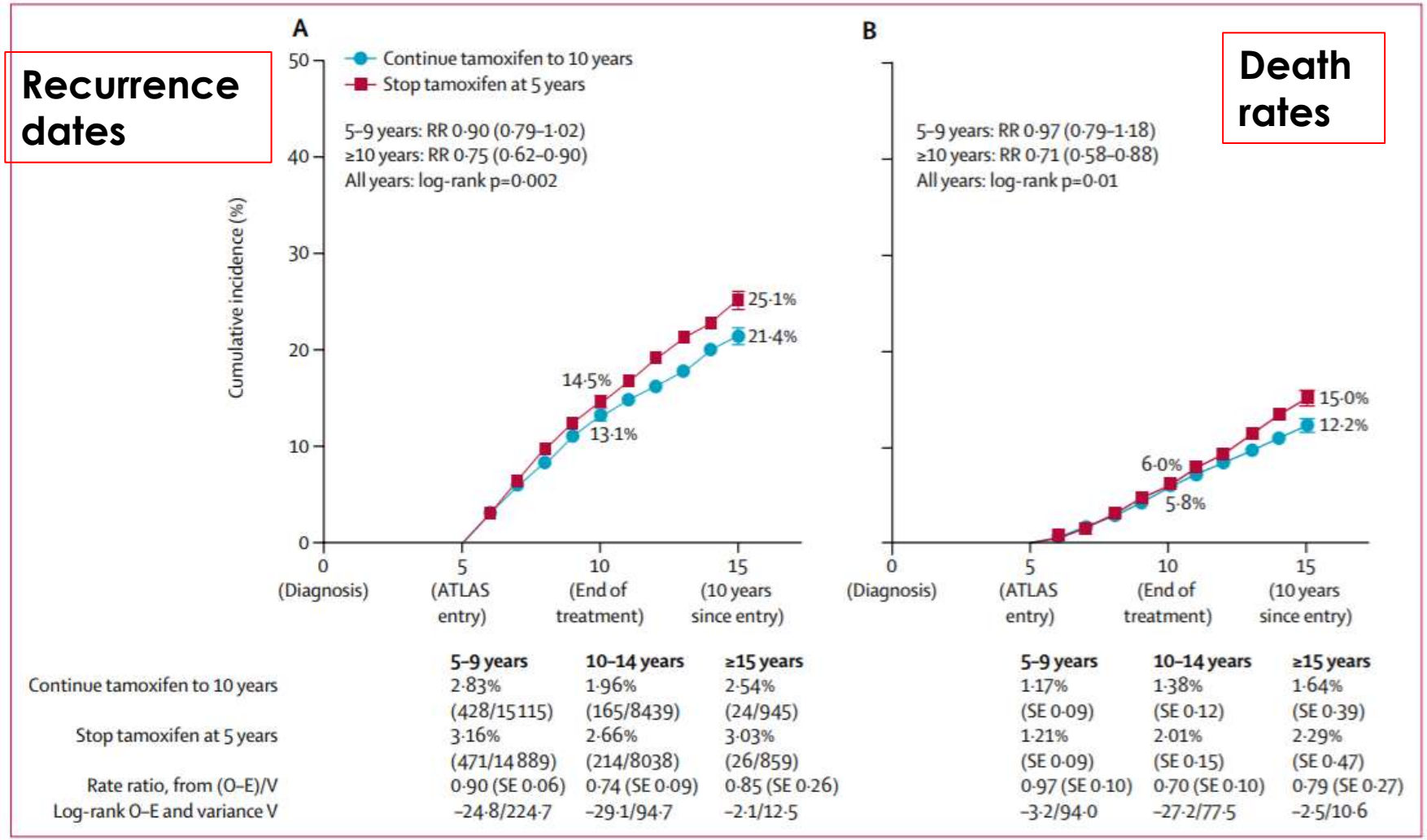
ATLAS recruited patients from 36 countries or regions during 1996–2005.



Recurrence (A) and breast cancer mortality (B) by treatment allocation for 6846 women with ER-positive disease

Recurrence dates

Death rates



	5–9 years	10–14 years	≥15 years	5–9 years	10–14 years	≥15 years
Continue tamoxifen to 10 years	2·83% (428/15115)	1·96% (165/8439)	2·54% (24/945)	1·17% (SE 0·09)	1·38% (SE 0·12)	1·64% (SE 0·39)
Stop tamoxifen at 5 years	3·16% (471/14889)	2·66% (214/8038)	3·03% (26/859)	1·21% (SE 0·09)	2·01% (SE 0·15)	2·29% (SE 0·47)
Rate ratio, from (O–E)/V	0·90 (SE 0·06)	0·74 (SE 0·09)	0·85 (SE 0·26)	0·97 (SE 0·10)	0·70 (SE 0·10)	0·79 (SE 0·27)
Log-rank O–E and variance V	−24·8/224·7	−29·1/94·7	−2·1/12·5	−3·2/94·0	−27·2/77·5	−2·5/10·6

Bars show SE. Recurrence rates are percentage per year (events/patient-years of follow-up). Death rates (overall rate –rate in women without recurrence) are percentage per year (SE). **ATLAS=Adjuvant Tamoxifen: Longer Against Shorter**.

The Oncologist®

Sarcomas

Relevance of Reference Centers in Sarcoma Care and Quality Item Evaluation: Results from the Prospective Registry of the Spanish Group for Research in Sarcoma (GEIS)

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Disclosures of potential conflicts of interest may be found at the end of this article.

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Abstract

Background. Reference centers (RCs) are a key point for improving the survival of patients with soft-tissue sarcomas (STS). The aim of this study was to evaluate selected items in the management of patients with STS, comparing results between RC and local hospitals (LHs).

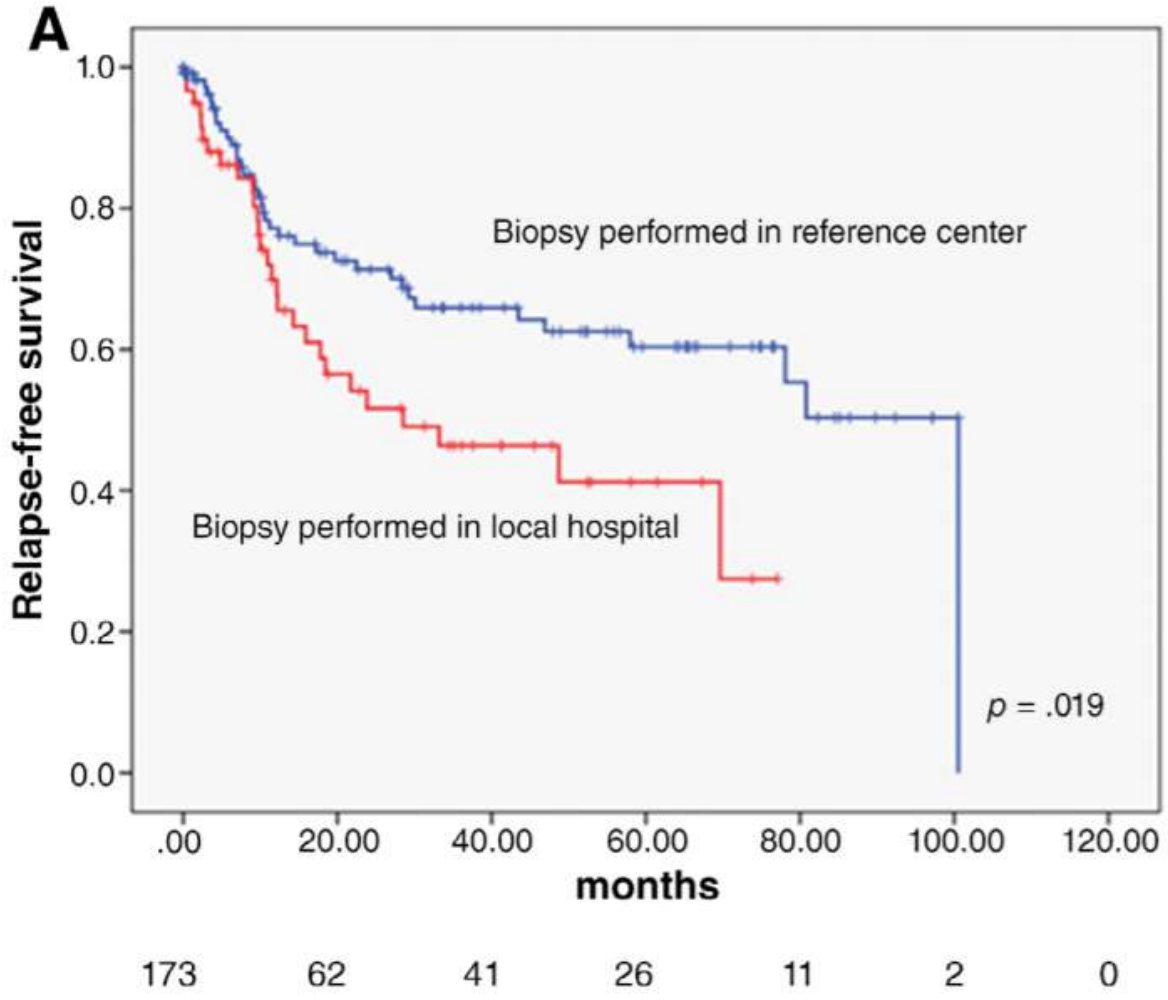
Materials and Methods. Diagnostic and therapeutic data from patients diagnosed between January 2004 and December 2011 were collected. Correlation with outcome was performed.

Results. A total of 622 sarcomas were analyzed, with a median follow-up of 40 months. Imaging of primary tumor preoperatively (yes vs. no) correlated with a higher probability of free surgical margins (77.4% versus 53.7%; $p = .006$). The provenance of the biopsy (RC vs. LH) significantly affected relapse-free survival (RFS; 3-year RFS 66% vs. 46%, respectively; $p = .019$). Likewise, 3-year RFS was significantly worse in cases with infiltrated (55.6%) or unknown (43.4%) microscopic surgical margins compared with free margins (63.6%; $p < .001$). Patients managed by RCs had a better 3-year overall survival compared with those managed by LHs (82% vs. 70.4%, respectively; $p = .003$). Perioperative chemotherapy in high-risk STS, more frequently administered in RCs than in LHs, resulted in significantly better 3-year RFS (66% vs. 44%; $p = .011$). In addition, patients with stage IV disease treated in RCs survived significantly longer compared with those in LHs (30.4 months vs. 18.5 months; $p = .036$).

Conclusion. Our series indicate that selected quality-of-care items were accomplished better by RCs over LHs, all with significant prognostic value in patients with STS. Early referral to an RC should be mandatory if the aim is to improve the survival of patients with STS. ***The Oncologist*** 2019;24:e338–e346

Implications for Practice: This prospective study in patients diagnosed with soft-tissue sarcoma shows the prognostic impact of reference centers in the management of these patients. The magnitude of this impact encompasses all steps of the process, from the initial management (performing diagnostic biopsy) to the advanced disease setting. This is the first prospective evidence showing improvement in outcomes of patients with metastatic disease when they are managed in centers with expertise. This study provides extra data supporting referral of patients with sarcoma to reference centers.

Kaplan-Meier curves for relapse-free survival (RFS) that compare biopsy provenance (reference centers vs. local hospitals) in cases registered by Hospital Son Espases.



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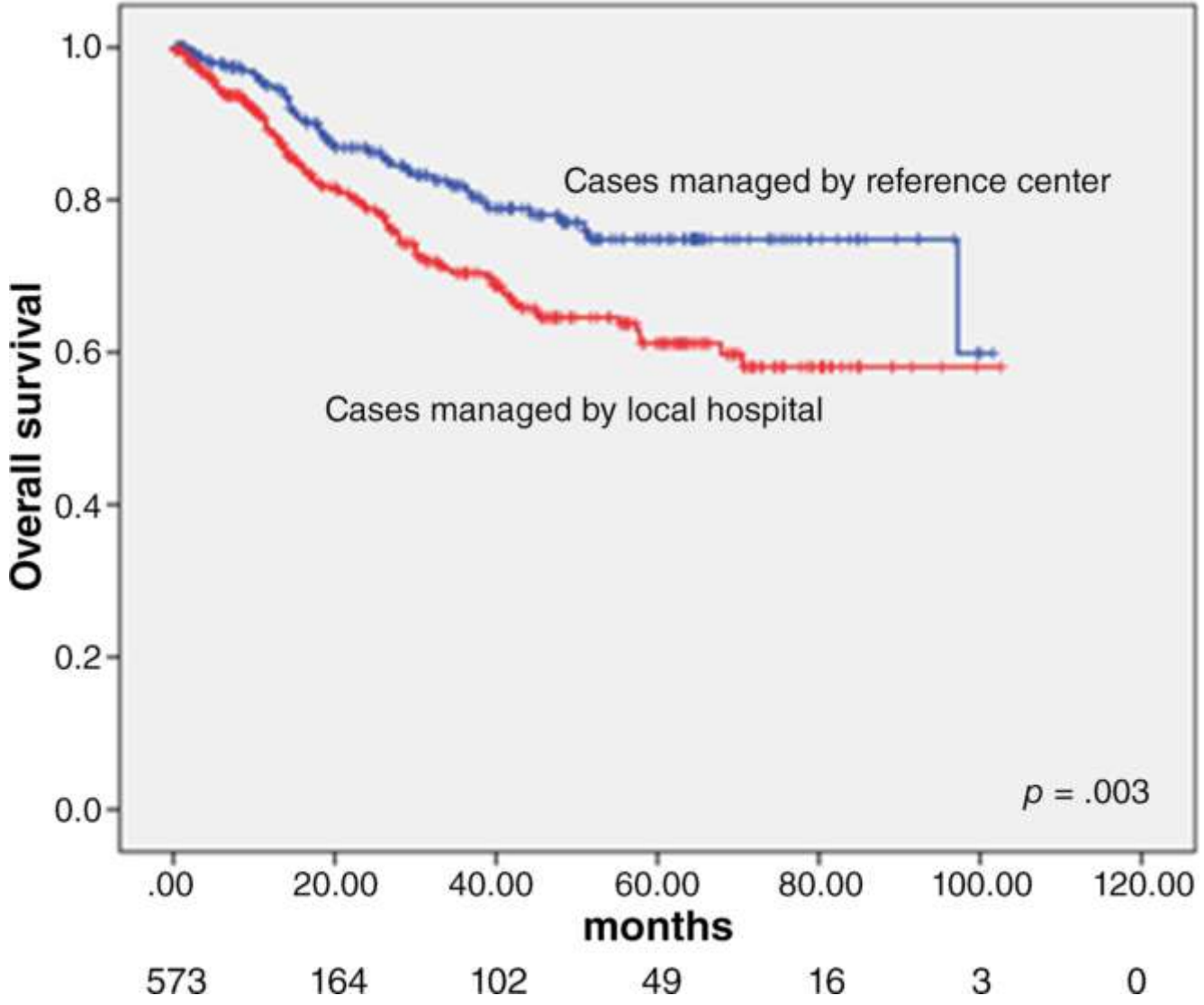
Kaplan-Meier curves for overall survival in relation to center type (reference center vs. local hospital)



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Objetivo de la charla

1. Presentar publicaciones más relevantes
2. **Comentar Estudios y Ensayos Clínicos**
3. Proyectos para la próxima década

European, non-interventional, phase IV NIMES-ROC trial of trabectedin plus pegylated liposomal doxorubicin in patients with platinum-sensitive recurrent ovarian cancer: an interim analysis

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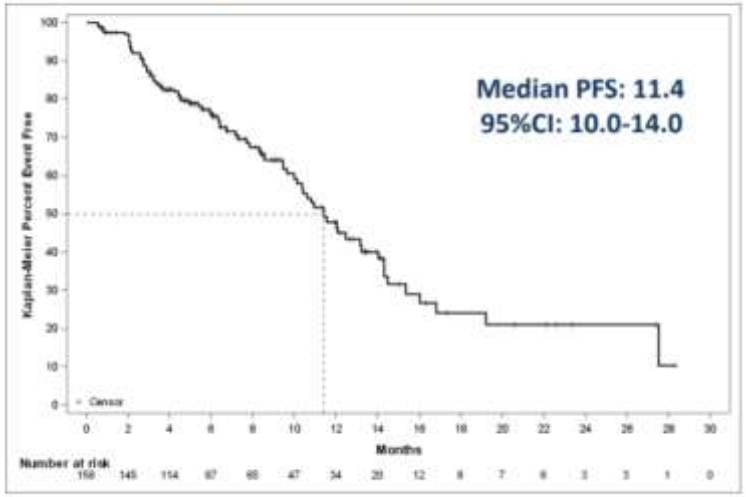
BEST RESPONSE, n (%) *Data not available at cut-off date	Total (n=158)
Complete response (CR)	15 (9.5)
Partial response (PR)	45 (28.5)
Stable disease (SD)	45 (28.5)
Progressive disease (PD)	32 (20.3)
Not evaluable / Missing *	21 (13,3)
Objective response rate (ORR; CR+PR); [95% Confidence interval]	60 (38.0) [30.4-46.0]
Disease control rate (DCR; ORR+SD) [95% Confidence interval]	105 (66.5) [58.5-73.8]

SAFETY, n (%) Most frequent trabectedin related grade 3/5 ADRs	Total (n=158)
Neutropenia	33 (20.9)
Febrile neutropenia	2 (1.3)
Asthenia	7 (4.4)
Anemia	5 (3.2)
Thrombocytopenia	5 (3.2)
Vomiting	3 (1.9)

- ADRs related to trabectedin and PLD were reported in 108 (68.4%) and 104 (65.8%) patients, respectively.
- The safety profile between subgroups was not different from that of the overall population.
- No grade 5 or unexpected treatment related ADRs occurred.

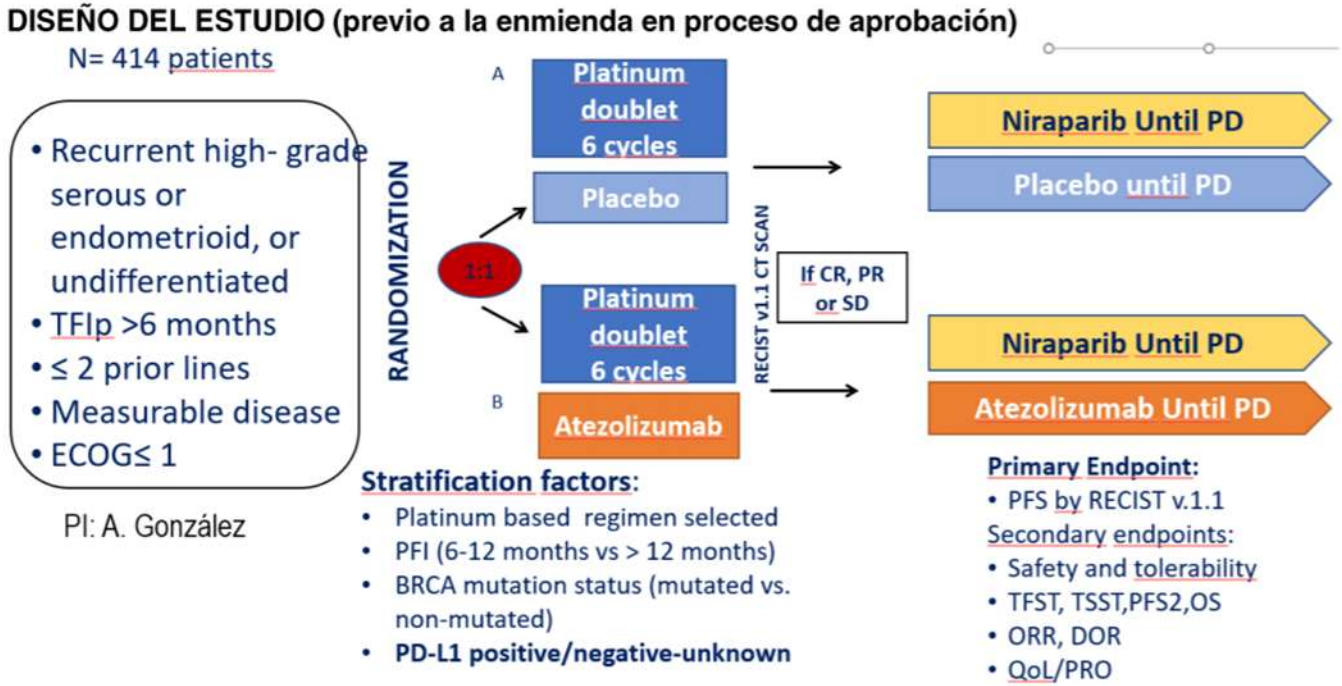
Progression-free survival



ESGO 2019. Athens. Abstract: #A-1025-0007-00099; Poster: P118

Estudio ANITA

- ENGOT-Ov41 / GEICO 69-O / ANITA (**A**tezolizumab and **NI**raparib **T**reatment **A**ssociation in recurrent ovarian cancer and platinum as an option)



Estudio BoRNEO

- Incidence of Somatic and Germline BRCA Mutations in a Spanish Large Clinic-Based Cohort of Patients with non-Mucinous Epithelial Ovarian Cancer with Cross-Laboratory Validation of Somatic Technique (BoRNEO) – A GEICO Study

Estudio GEIS 51

- **PALBOSARC: Ensayo fase II multicéntrico de palbociclib en segunda línea de sarcomas avanzados con sobreexpresión CDK4.**

Estudio GEIS 26

- **Registro de sarcomas raros**: Herramienta de ayuda para evaluar el número de casos de cada subtipo y su orientación terapéutica por el Grupo Español de Investigación en Sarcomas (GEIS).

Estudio GEIS 42

- SSGXXII: Three versus five years of adjuvant imatinib as treatment of patients with operable GIST with a high risk for recurrence: A randomised Ph III study

Objetivo de la charla

1. Presentar publicaciones más relevantes
2. Comentar Ensayos Clínicos
3. **Proyectos para la próxima década**

Publicaciones 2020

REAL-WORLD EVIDENCE OF TRABECTEDIN IN PATIENTS WITH ADVANCED SOFT-TISSUE SARCOMA

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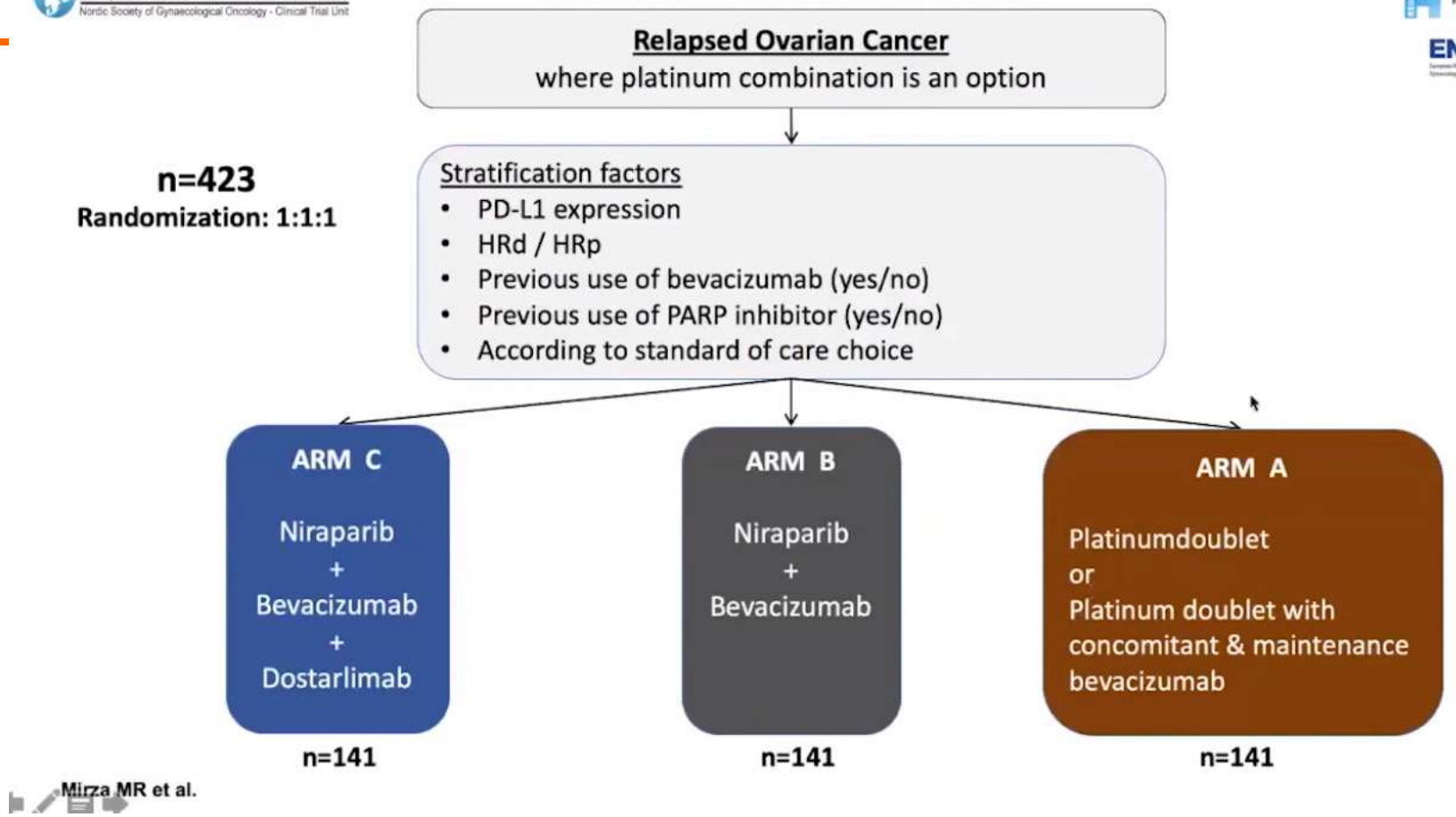
Estudio ENGOT-cx11

- A Randomized, Phase 3, Double-Blind Study of Chemoradiotherapy With or Without **Pembrolizumab** for the Treatment of High-risk, **Locally Advanced Cervical** Cancer (KEYNOTE-A18 / ENGOT-cx11)

ENGOT-OV42 / NSGO-AVATAR



Mirza MR et al.

- Antecedent of cancer and mortality after the first st segment elevation acute myocardial infarction treated with primary coronary angioplasty. A prospective cohort study. **Irene Sillero et al**. **Annals of Oncology (2019)** 30 (suppl_5): v760-v796.
- Relationship between androgen receptor and tumor infiltrating lymphocytes in triple negative breast cancer. L.F. **Sánchez-Cousido et al. Annals of Oncology (2018)** 29 (suppl_8): viii58-viii86.
- Final results of RENO study: randomized phase II of oral vinorelbine or etoposide with cisplatin & chemo-radiation in stage III NSCLC. SLCG 10/02 M. Provencio Pulla. **Diz Taín**. **Annals of Oncology (2018)** 29 (suppl_8): viii488-viii492
- Prospective Observational Study of Pazopanib in Patients with Advanced Renal Cell Carcinoma (PRINCIPAL Study). **Ángel Rodríguez. Oncologist. 2019** Apr;24(4):491-497
- Efficacy and safety of abiraterone acetate plus prednisone vs. cabazitaxel as a subsequent treatment after first-line docetaxel in metastatic castration-resistant prostate cancer: results from a prospective observational study (CAPRO). **Ángel Rodríguez**. **BMC Cancer (2019)** 19:76
- Prognostic role of ***HMG proteins*** in a series of 301 advanced soft tissue sarcoma patients: A Spanish Group for Sarcoma Research Study (GEIS). LM de Sande. CTOS 2019 Annual Meeting. November 13-16. Tokyo, Japan