Toxicity profile and discordance between patients/physicians regarding niraparib maintenance in recurrent ovarian cancer (ROC) patients: lessons from the NiQoLe real-life study – GINECO study.

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Authors: Joly F.[1], Kalbacher E.[2], Garbay-Decoopman D.[3], Ouldbey Y.[4], Follana P.[5], Dawood H.[6], Legouffe E.[7], Brachet P-E.[8], Spaeth D.[9], Combe P.[10], Hardy-Bessard A-C.[11], Selle F.[12], Grenier J.[13], Lebreton C.[14], Derbel Miled O.[15], Lancry-Lecomte L.[16], Fournel P.[17], Fernandez Diez Y.[18], Quesada S.[19], Kurtz J-E.[20]

1 HoMe@baclesse.unicancer.fr Department of Medical Oncology, Baclesse Cancer Centrer, Caen, France, 2 Department of Oncology, CHRU Besancon - Hopital Jean Minjoz, Besançon, France, 3 Clinique Tivoli-Ducos, Bordeaux, France, 4 DepartmenLéon Bérard Cancer Center, Lyon, France, 5 Medical Oncology, Centre Anticancer Antoine Lacassagne, Nice, France, 6 Medical Oncology Department, CHR Orléans, Orléans, France, 7 Oncology Department, Oncogard - Polyclinique KenVal - Institut de Cancérologie du Gard - Nimes, France, 8 Department of Medical Oncology, Baclesse Cancer Center, Caen, France, 9 Medical Oncology, Centre d'Oncologie de Gentilly, Nancy, France, 10 Department of Medical Oncology, Oncology, Pôle Santé Léonard de Vinci, Chambray-lès-Tours, France, 11 Department of Medical Oncology, Centre Armoricain d'Oncologie, Plérin, France, 12 Department of Medical Oncology, Groupe Hospitalier Diaconesses Croix Saint-Simon, Paris, France, 13 ICAP Avignon Provence, Avignon, France, 14 Department of Medical Oncology, Institut Bergonié, Bordeaux, France, 15 Department of Medical Oncology, Centre Léon-Bérard, Lyon, France, 16 Medical Oncology Department, GHM - Groupe Hospitalier Mutualiste de Grenoble, Grenoble, France, 17 Department of Medical Oncology, Nord University Hospital, Saint-Etienne, France, 18 Medical Oncology Department, Centre Alexis Vautrin, Vandoeuvre-lès-Nancy, France, 19 Medical Oncology Department, Montpellier Cancer Institute (ICM), Montpellier, France, 20 Medical Oncology, Institut of Cancer Strasbourg (ICANS), Strasbourg, France

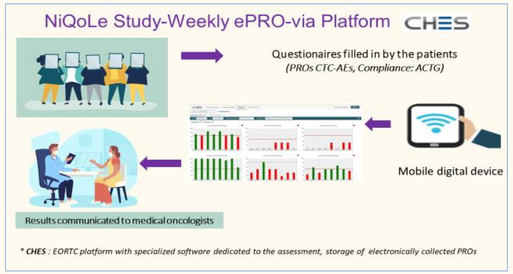
INTRODUCTION & STUDY DESIGN

➔ Niraparib (NI) maintenance is a standard of care in platinum-sensitive ROC. Based on pivotal randomized trials, toxicity profile appears manageable through adapted initial drug dosing.

➔ However, **real world data** on **tolerance** and **feasibility** for unselected patients (pts) (including those > 70 years old) are missing.

➔ Furthermore, while adverse events (AEs) have been extensively described by physicians (CTC-AEs) in clinical trials, pts reported outcomes (PROs) have been overlooked to date. As such, **PROs (PRO-CTC-AEs)** were integrated within the design of the NiQoLe study

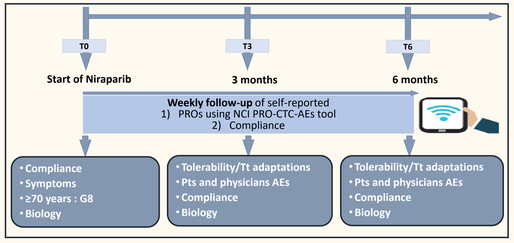
Main inclusion criterion : ROC after platinum-based chemotherapy
Tools : Pts reported symptomatic AEs with CHES* remoted device



Primary endpoint: Real-world data on NI dose modifications induced by physicians' reported AEs at 3 months

Secondary endpoints: To evaluate regular PROs AEs: correlation between symptomatic CTC-AEs (reported by physicians) and PROs-CTC-AEs (reported by pts)

Follow-Up of Niraparib Maintenance in real world



RESULTS

PATIENTS' CHARACTERISTICS

	N=139
Median age in years [range]	70 [44-88]
G8<14 (pts > 70 yrs)*	20 (36%)
Performance status ECOG 0 - 1	137 (98%)
FIGO stage III/IV**	118 (85%)
Histology serous high grade	127 (91%)
Endometrioid grade 2/3	6 (4%)
Undifferentiated	5 (3%)
Other	2 (1%)
BRCA mutations	7 (5%)
Median Hb (G/L) [range]	118 [93-143]
Weight < 77 (kg) and/or platelets > 175 (G/L)	106 (76%)
Surgery	**N=139**
At least one surgery	131 (94%)
Residual disease (after the last surgery)	80 (58%)
Previous medical treatments	**N=139**
Median of previous platinum CT lines	1 [1-5]
Previous bevacizumab	99 (71%)
Previous olaparib	5 (4%)
Response to last Platinum	**N=139**
CR	48 (35%)
PR	78 (56%)
Stable disease	13 (9%)
Median delay (days) between platinum and NI [range]	49 [15-109]

* n=55 (20 missing data), ** n=126

DOSE ADAPTATIONS

Initial dose (mg)	n=139
100	1 (1%)
200	111 (80%)
300	27 (19%)
Treatment exposure	**N=139**
Median duration (months)	6 [0.2-21]
Treatments ≥ 6 months	63 (45%)
Dose adaptation (3 first months)	**N=139**
At least 1 adaptation	84 (60%)
At least 1 adaptation for AE	66 (45%)
At least one reduction for AE	17(12%)
At least one interruption for AE	53(38%)
Discontinuation for AE	11(8%)
Median delay of the 1rst adaptation	36 days [8-58]
Main AEs inducing adaptation	
Thrombocytopenia	46 (70%)
Anemia	6 (9%)

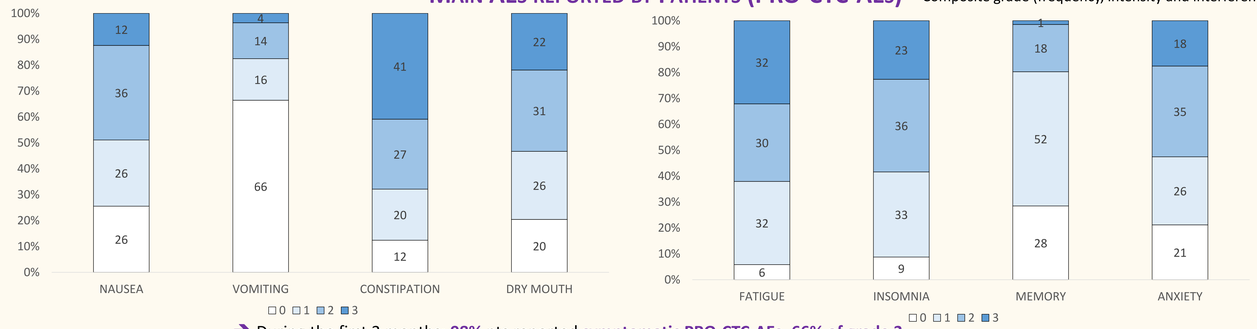
COMPLIANCE AND EFFICACY

➔ High rate of compliance : **69%**

➔ 3 and 6 months progression rate: 19 and 45%, respectively

MAIN AES REPORTED BY PATIENTS (PRO-CTC-AES)

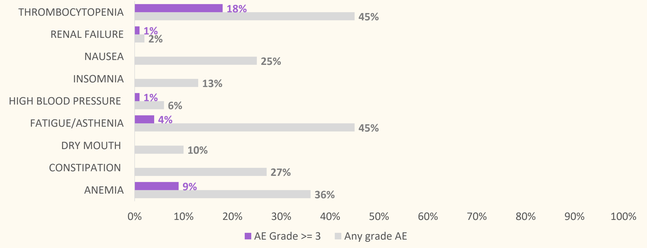
Composite grade (frequency, intensity and interference)



➔ During the first 3 months: **98%** pts reported **symptomatic PRO-CTC-AEs, 66% of grade 3**

➔ **59% of the physicians** regularly **acceded the PROs reports and 31%** of them found it was **useful** for the **pts follow-up**

MAIN AES REPORTED BY PHYSICIANS (CTC-AES)



AEs G ≥ 3 during the first 3 months: **Total =29%, Related to Niraparib=24%**

DISCREPANCY BETWEEN PTS AND PHYSICIANS MOST IMPORTANT SYMPTOMATIC PRO-CTCAES AND CTC-AES

Main symptomatic AEs	Patients (%)		Physicians (%)	
	All	Severe*	All	Severe**
Fatigue	93	32	43	2
Nausea	73	12	26	0
Constipation	86	40	26	2
Dry mouth	78	22	9	0
Insomnia	90	22	12	0

*Grade 3 according to PRO-CTC-AEs (including severe and very severe), ** Grade 3 and 4 according to CTC-AEs

CONCLUSION

- The NiQoLe study included a population of patients with poor prognosis including : **a high proportion of elderly patients, limited platinum response and mainly BRCA^{wt} patients.**
- However, patients had **a high level of treatment compliance** and **remote self-reported PROs-CTC-AEs.**
- Despite initial individual dosing, NI maintenance required **frequent dose-adaptations during the first 3 months** of treatment.
- There was a **strong discrepancy** between symptomatic AEs regularly captured by pts and those reported by physicians.

➔ **The next generation of clinical trials should integrate pts' perspective** (PRO-CTC-AEs in addition to CTC-AEs) **to better assess side effects and manage treatment course**

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Poster discussion *presented at ASCO Annual Meeting, On June 2-6, 2023 in Chicago*

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