

# Cabazitaxel for treatment of refractory germ-cell cancer - A German Testicular Cancer Study Group case series

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## Background

- GCT are a unique curable malignancy model
- At relapse HD-chemo and TIP are established curative salvage options
- GOP as most effective regimen for r/rGCT (ORR 50%)
- Outcomes remain poor for r/r GCT patients with a median OS of a few months only
- New treatment options urgently needed
- Cabazitaxel is active in resistant GCT models *in vitro*

GCT, germ cell tumour; GOP, gemcitabine, oxaliplatin, paclitaxel; r/r, relapsed/refractory; TIP, paclitaxel, ifosfamide, cisplatin

## Objectives

- To assess efficacy and toxicity of cabazitaxel in r/rGCT
- Endpoints:** 12-week PFS rate, Median PFS/OS, ORR, DCR, tumour marker responses, toxicity

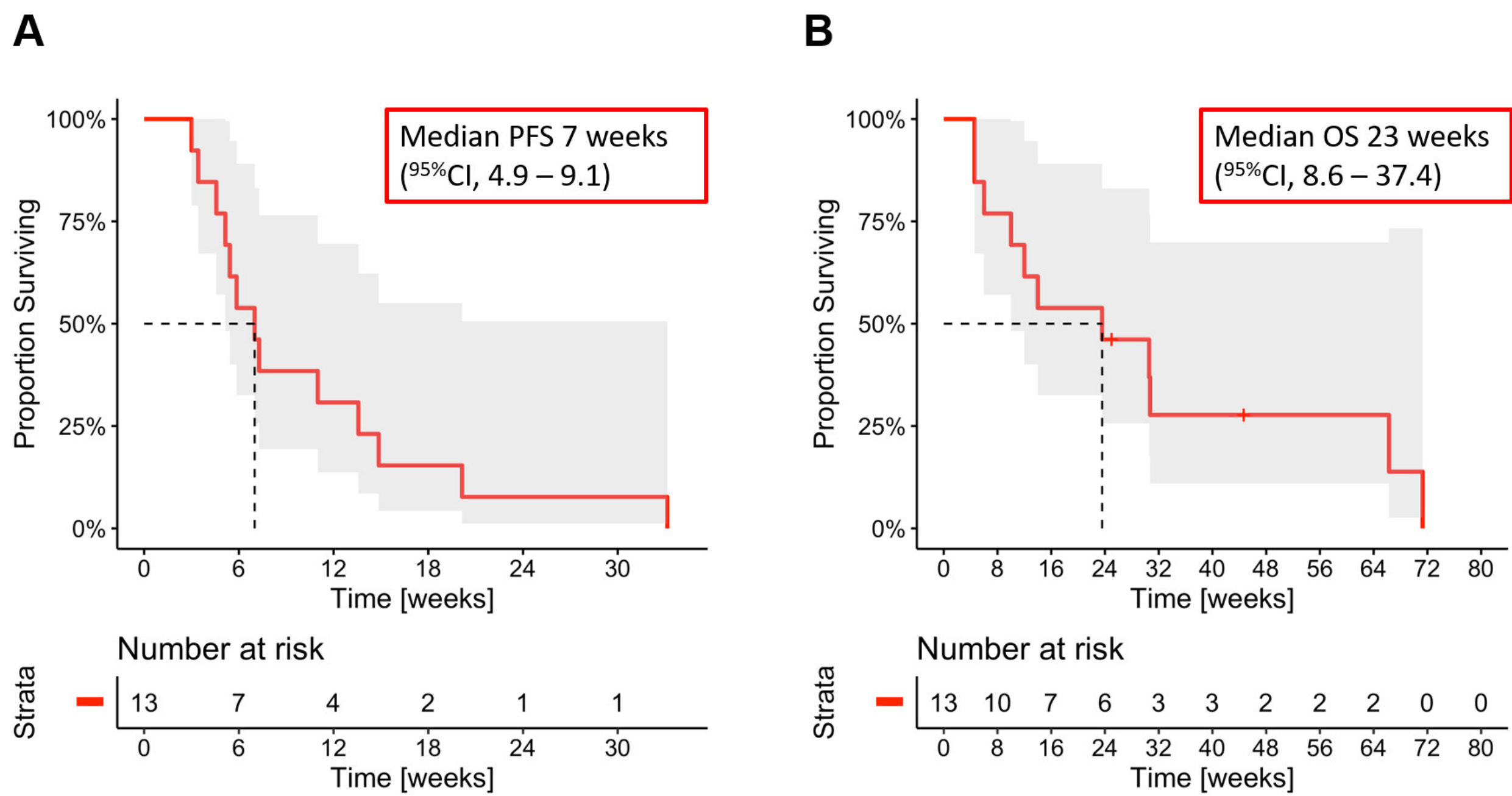
## Patients and Methods

- German Testicular Cancer Study Group registry study on palliative systemic treatment for r/r GCT
- 13 patients treated with cabazitaxel off-label at 9 different GTCSG-affiliated centres
- Treatment between 2014 and 2019
- Retrospective data collection and central analysis
- Descriptive statistics (SPSS v.23) and survival estimation (R, surviminer package)

## Results

Characteristic	N/total population (%)
Characteristics at primary diagnosis	
Gender	
Male	12/13 (92.3)
Female	1/13 (7.7)
Primary tumour site	
Gonadal	9/13 (69.2)
Retroperitoneum	2/13 (15.4)
Mediastinum	1/13 (7.7)
Primary histology	
Non-seminoma/Mixed	13/13 (100)
Clinical characteristics at baseline before Cabazitaxel	
Median age, years (IQR)	33 (15)
Median tumour marker levels at baseline (range)	
AFP [kU/L]	25.8 (0.8 - 35,114)
βHCG [IU/L]	6.0 (0.2 – 93,269)
LDH [IU/L]	269.5 (150 - 590)
Sites of metastasis at baseline	
Lymph nodes, retroperitoneum	8/13 (61.5)
Lymph nodes, mediastinal	3/13 (23.1)
Lungs	9/13 (69.2)
Liver	4/13 (30.8)
Brain	5/13 (38.5)
Bones	2/13 (15.4)
LBB	9/13 (69.2)
Other	4/12 (33.3)
Prior lines of treatment	
2	1/13 (7.7)
3	2/13 (15.4)
4	3/13 (23.1)
≥5	6/13 (46.2)
Prior high-dose chemotherapy	13/13 (100%)
Prior G/O/P doublet or triplet chemotherapy	13/13 (100%)
Prior paclitaxel-based chemotherapy	12/12 (100)
ECOG, Eastern central cooperative group performance status; GO, gemcitabine oxaliplatin; GOP, gemcitabine, oxaliplatin, paclitaxel; IQR, interquartile range; LBB, liver, bone and/or brain metastases	

Measure	Frequency, N (% of total study population)
Non-haematological grade 3-5 AEs	
Bowel perforation (SUSAR)	2 (15.4)
Fatigue	1 (7.7)
Asthenia	1 (7.7)
Grade 3-4 haematologic toxicity	7 (53.9)
Grade 3-4 neurotoxicity	0 (0)
Dose reductions	2 (15.4)
Prophylactic G-CSF application	6 (46.2)
Primary	3 (23.1)
Secondary	3 (23.1)
AE, adverse event; G-CSF, granulocyte colony stimulating factor	



- 12-week PFS rate 31%
- Marker-positive PR 15% (2/13) | DCR 39% (5/13)

Measure	Outcome
Number of cycles, median (range)	2 (1-7)
Best radiographic response, N (%)	
CR	0 (0)
PR	2 (15.4)
SD	3 (23.1)
PD	7 (53.9)
Unknown (early death due °V toxicity)	1 (7.7)
OR [CR+PR], N (%)	2 (15.4)
DC [CR+PR+SD], N (%)	5 (38.5)
Best tumour marker response, N (%)	
None [normal markers]	1 (7.7)
Decrease <50%	3 (23.1)
Decrease ≥50%	3 (23.1)
Increase	5 (38.5)
Unknown (early death due to early death)	1 (7.7)
DC, disease control (CR+PR+SD); PR, partial remission; SD, stable disease; PD, progression disease; OR, objective responses; OS, overall survival; PFS, progression-free survival	

## Conclusion

- Limited and only transient activity of cabazitaxel after failure of established standard treatment options
- Higher activity than molecularly targeted agents
- Two phase II studies currently ongoing in Norway and France (NCT02115165, NCT02478502)





# Offenlegung Interessenskonflikte

## 1. Anstellungsverhältnis oder Führungsposition

Kein/e

## 2. Beratungs- bzw. Gutachtertätigkeit

Keine

## 3. Besitz von Geschäftsanteilen, Aktien oder Fonds

Kein

## 4. Patent, Urheberrecht, Verkaufslizenz

Kein

## 5. Honorare

Keine

## 6. Finanzierung wissenschaftlicher Untersuchungen

Roche

## 7. Andere finanzielle Beziehungen

Keine

## 8. Immaterielle Interessenkonflikte

Keine

