

BC Cancer Protocol Summary for Treatment of Relapsed/Progressing Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma Using Topotecan

Protocol Code

GOOVTOP

Tumour Group

Gynecologic Oncology

Contact Physician

Dr. Paul Hoskins

PREFACE:

- In platinum sensitive disease: patients should be considered for doublet therapy consisting of CARBOplatin plus either a taxane or gemcitabine or DOXOrubicin pegylated liposomal (e.g., GOOVCA^{TR}, GOOVCA^D, GOOVCA^G, GOOVPL^{DC})
- In platinum resistant disease (i.e., cancer progresses within six months of completing a platinum-containing treatment protocol): patients will ideally receive single agent CARBOplatin, as it is the least toxic and most convenient choice of the equally efficacious agents available (i.e., GOOVCA^{RB})
- In platinum refractory disease (i.e., cancer progresses while being treated with a platinum) choose between available agents based upon toxicity profile and convenience of dosing regimen. Options include: GOOVTOP, GOOLDOX, GOOVGEM, GOOVETO, GOOVVIN, GOOVTAX3, GOOVDOC.
- Patients who will not benefit from further therapy after second or subsequent rounds of chemotherapy can be identified by the following formula: “day 1 of treatment N to day of progression on treatment N+1 is less than or equal to 6 months.” They should be offered symptomatic management or investigational protocols.

ELIGIBILITY:

- Platinum refractory ovarian, primary peritoneal or Fallopian tube carcinoma
- Platinum resistant ovarian, primary peritoneal or Fallopian tube carcinoma in cases where patient-specific concerns dissuade the clinician from selecting single-agent CARBOplatin
- Platinum sensitive ovarian, primary peritoneal or Fallopian tube carcinoma in cases where actual or potential toxicity precludes the use of CARBOplatin or CISplatin alone or in combination with a taxane or gemcitabine.
- Adequate hematologic, liver and cardiac function
- PS ECOG 3 or better

EXCLUSIONS:

- creatinine clearance less than 40 mL/min. See DOSE MODIFICATIONS for reduced starting dose in patients with renal dysfunction

TESTS:

- Baseline: CBC & diff (including platelets), creatinine, tumor marker (at physician’s discretion), imaging for tumour assessment (at physician’s discretion)
- Before each cycle on day 1: CBC & diff (including platelets), tumor markers (at physician’s discretion)
- Days 8 and 15 first cycle only (except if dose modification made): CBC & diff (including platelets) to determine nadir levels
- In future cycles, if clinically indicated: creatinine

PREMEDICATIONS:

- Antiemetic protocol for chemotherapy with low to low-moderate emetogenicity (see [SCNAUSEA](#))

TREATMENT:

Drug	Starting Dose	BC Cancer Administration Guideline
topotecan	1.25 mg/m ² /day x 5 days (days 1-5)*	IV in 50 mL NS over 30 minutes

Repeat 5-day treatment every 21 days [until disease progression \(usual treatment 9 cycles\)](#).

* In heavily pre-treated patients, suggested starting dose is 1 mg/m²/day x 5 days

DOSE MODIFICATIONS:

1. Hematological:

(a) on treatment day:

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose
greater than or equal to 1.0	and	greater than or equal to 100	treat as per nadir
less than 1.0	and/or	less than 100	delay until recovery

(b) at nadir:

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose
less than or equal to 0.5	and/or	less than or equal to 75	↓ by 0.25 mg/m ² /day

(c) Febrile neutropenia: decrease dose by 0.25 mg/m²/day. In the case of a second occurrence, use filgrastim (G-CSF) and maintain the same dose level, or discontinue topotecan treatment.

2. **Any Grade 3 or 4 toxicity (except nausea):** decrease dose by 0.25 mg/m²/day

3. Renal Dysfunction:

Creatinine Clearance (mL/min)	Topotecan Dose
greater than or equal to 40	100%
20-39	50%
less than or equal to 20	not recommended

$$\text{CrCl in mL/min} = \frac{1.04 \times (\text{weight in kg})(140 - \text{age in years})}{\text{SCr in micromol/L}}$$

PRECAUTIONS:

1. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.

Call Dr. Paul Hoskins or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.