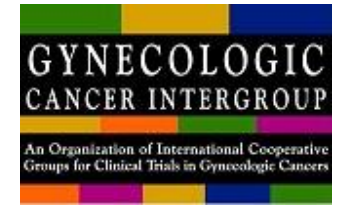




# Medical Therapies in Ovarian Cancer The Arabic Perspectives



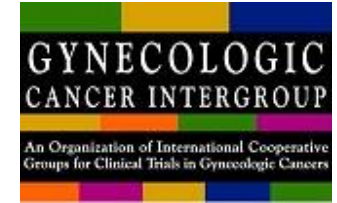
**Mezghani Bassem -Tunisia**

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- **Tunisian Health System:** Social Welfare with a Public insurance for all citizens including Indigent persons.  
(± Additional private insurance)
- Choice: Public Hospital/Private Clinics (Indigents → Public H)
- **National Drug Administration**
  - ✓ **Registration for definitive Approval:** one or several diseases / uses
  - ✓ **Case by case Approval:** Drugs with no current Registration → Approval with restrictions to a person, in a specific use and limited duration
- **National Research Ethics Committee:** Approval for drugs use in Clinical Trials ( & **National Drug Administration**)



# Medical Therapies in Ovarian Cancer The Arabic Perspectives

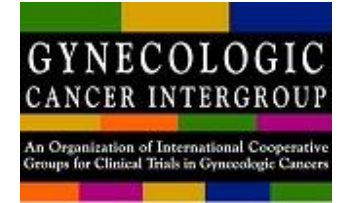


**Mezghani Bassem -Tunisia**

- Salah Azaiz Cancer Institute Tunis –Tunisia
  - Annually: ≈80 newly diagnosed; ≈140 received Pacli-Carbo CT (All)
  - Pharmacy:
    - ▶ Drugs with Registration and Approval: “Efficient” System (!! Drugs availability in the [National Central Pharmacy](#) – Number of Providers; Imported/local Made)
    - ▶ Drugs with no current Registration or with Registration but no Approval for the planned use →
      - 1) Practitioners: Specific applications to the [National Drug Administration](#) for a case by case Approval: **If accepted**
      - 2) Pharmacy: Drug is bought from the [National Central Pharmacy](#)
      - 3) Drug administration
      - 4) [Social Welfare](#) reimbursement (Indigent persons: Hospital)
    - ▶ Drugs – Clinical Trials



# Medical Therapies in Ovarian Cancer The Arabic Perspectives

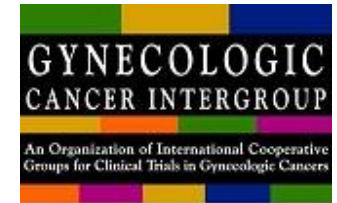


**Mezghani Bassem -Tunisia**



Drug	Approval - disease	Approval -use	Procurement	Availability	Hospital Pharmacy
Paclitaxel	Ovarian Cancer	<ul style="list-style-type: none"> <li>First line adjuvant</li> <li>Metastatic disease</li> </ul>	<ul style="list-style-type: none"> <li>Local</li> <li>Imported</li> </ul>		Out of stock Events: <b>Rare</b> → Short delay++ → No protocols amendments
Carboplatin	<ul style="list-style-type: none"> <li>Ovarian Cancer</li> <li>Others</li> </ul>	All	Imported		
Gemcitabine	Others <del>Ovarian Cancer</del>	<del>X</del>	Imported		
Docetaxel	Others <del>Ovarian Cancer</del>	<del>X</del>	<ul style="list-style-type: none"> <li>Local</li> <li>Imported</li> </ul>		



# Medical Therapies in Ovarian Cancer The Arabic Perspectives

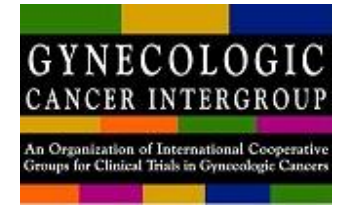


**Mezghani Bassem -Tunisia**

Drug	Approval - disease	Approval -use	Procurement	Availability
Cisplatin	<ul style="list-style-type: none"> <li>• Ovarian Cancer</li> <li>• Others</li> </ul>	All	Imported	
Doxorubicin	<ul style="list-style-type: none"> <li>• Ovarian Cancer</li> <li>• Others</li> </ul>	All	Imported	
Topotecan	×	×	×	×
Pegylated Liposomal Doxorubicin	×	×	×	×
Albumin-Bound Paclitaxel	×	×	×	×
Trabectedin	×	×	×	×



# Medical Therapies in Ovarian Cancer The Arabic Perspectives

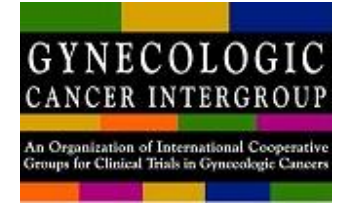


**Mezghani Bassem -Tunisia**

Drug	Approval - disease	Approval -use	Procurement	Availability
Bevacizumab	<ul style="list-style-type: none"> <li>Others</li> <li>Ovarian <del>Cancer</del></li> </ul>		Imported	
Pazopanib	<ul style="list-style-type: none"> <li>Others</li> <li>Ovarian <del>Cancer</del></li> </ul>		Imported	
Olaparib	<del>X</del>	<del>X</del>	<del>X</del>	<del>X</del>
Niraparib	<del>X</del>	<del>X</del>	<del>X</del>	<del>X</del>
Rucaparib	<del>X</del>	<del>X</del>	<del>X</del>	<del>X</del>
Erlotinib	<del>X</del>	<del>X</del>	<del>X</del>	<del>X</del>
Pemetrexed	<ul style="list-style-type: none"> <li>Others</li> <li>Ovarian <del>Cancer</del></li> </ul>		Imported	










# Medical Therapies in Ovarian Cancer The Arabic Perspectives



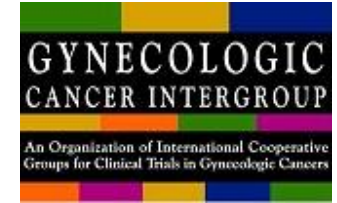
**Mezghani Bassem -Tunisia**

## Rare Ovarian Tumors

Regimen / Drug	Approval	Procurement	Availability
<b>Bleomycin</b> Etoposide Cisplatin	Choriocarcinoma Embryonal Carcinoma	Imported	 
Vincristin <b>Actinomycin</b> Cyclophosphamide	<ul style="list-style-type: none"> <li>• Ovarian Cancer</li> <li>• Others</li> </ul>	Imported	 
Ifosfamide	<ul style="list-style-type: none"> <li>• Ovarian Cancer</li> <li>• Others</li> </ul>	Imported	
Fluorouracil <b>Oxaliplatin</b>	<ul style="list-style-type: none"> <li>• Others</li> <li>• Ovarian Cancer for FU</li> </ul>	Imported	 



# Medical Therapies in Ovarian Cancer The Arabic Perspectives



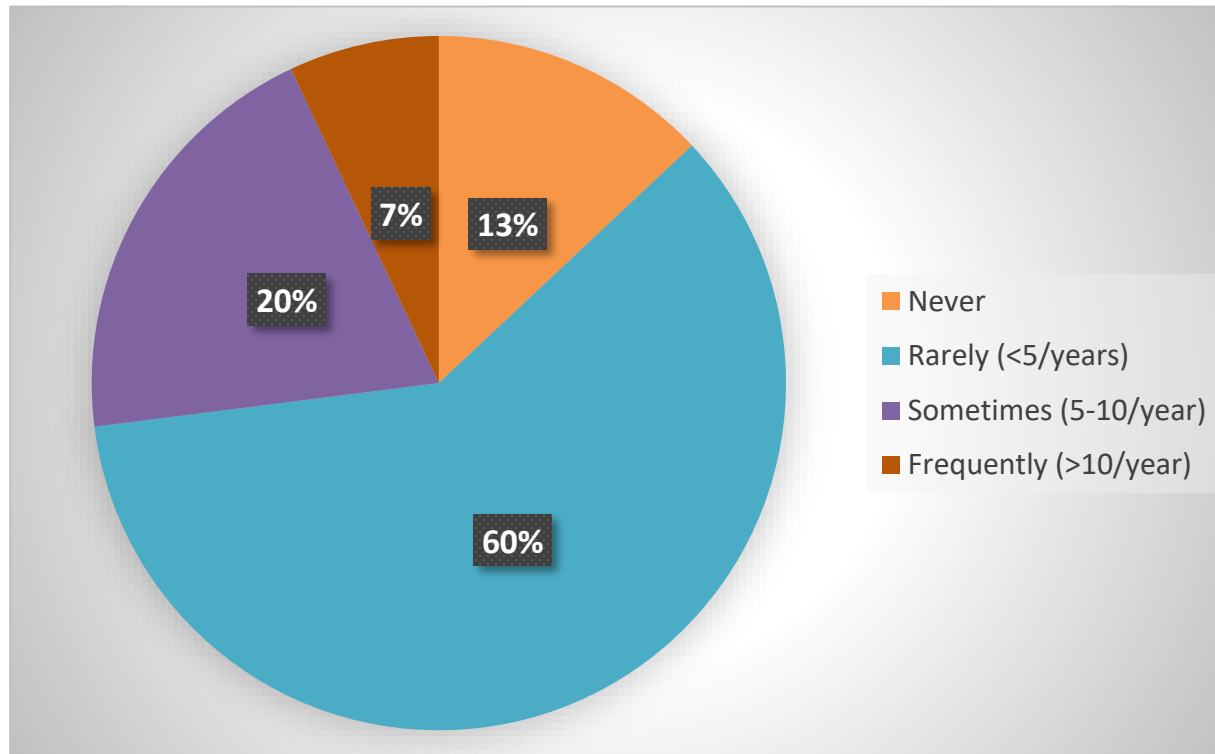
**Mezghani Bassem -Tunisia**

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## Survey

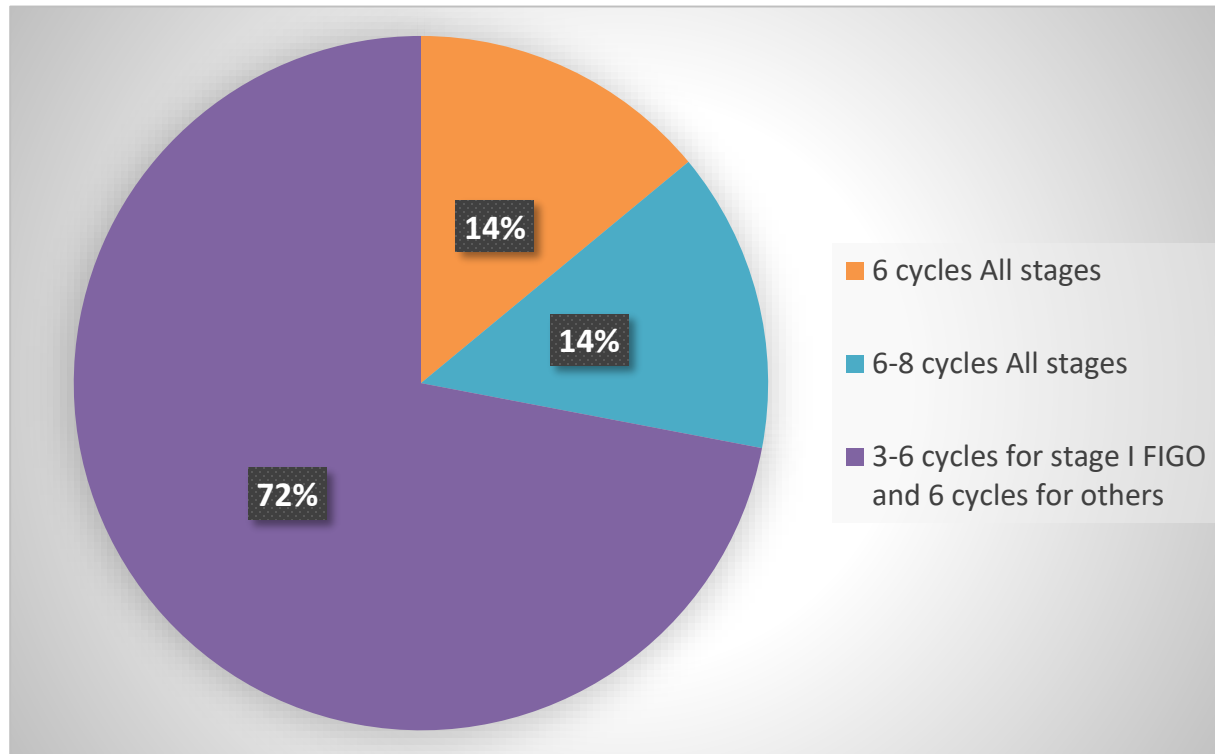
- January 2018
- Medical Oncologists: Hospital / Private Clinics
- 15 Questions
  - Drugs availability
  - Complying with Updated Guidelines and Standard of Care
  - Use of Unregistered Drugs
  - Use of regimens inspired by the design of Current Clinical Trials

- 1) Availability of Paclitaxel and Carboplatin : Frequency of out of Stock events that led at least to to an administration delay or require a protocol amendment

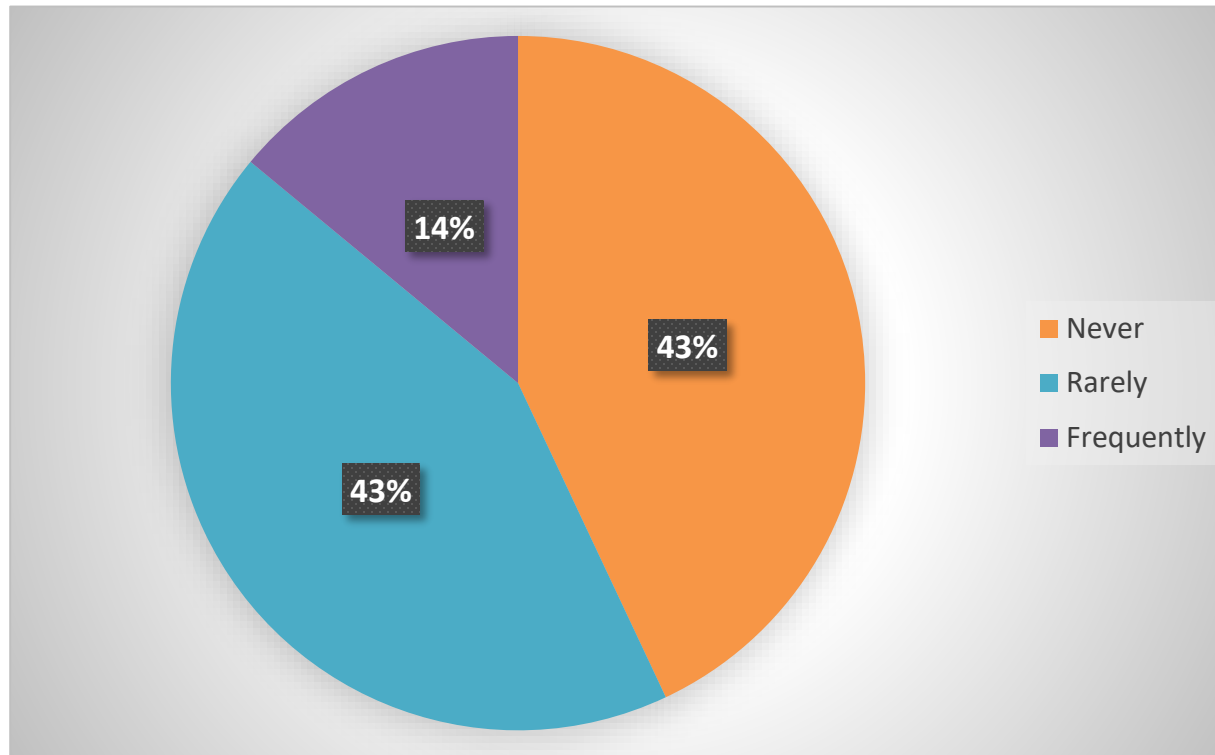




2) 3 weekly Paclitaxel and Carboplatin Regimen in an adjuvant use : Number of cycles?

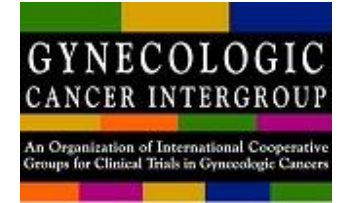


3) Dose-dense Paclitaxel + 3 weekly Carboplatin regimen in an adjuvant use  
(GOG262, ICON 8 Design)



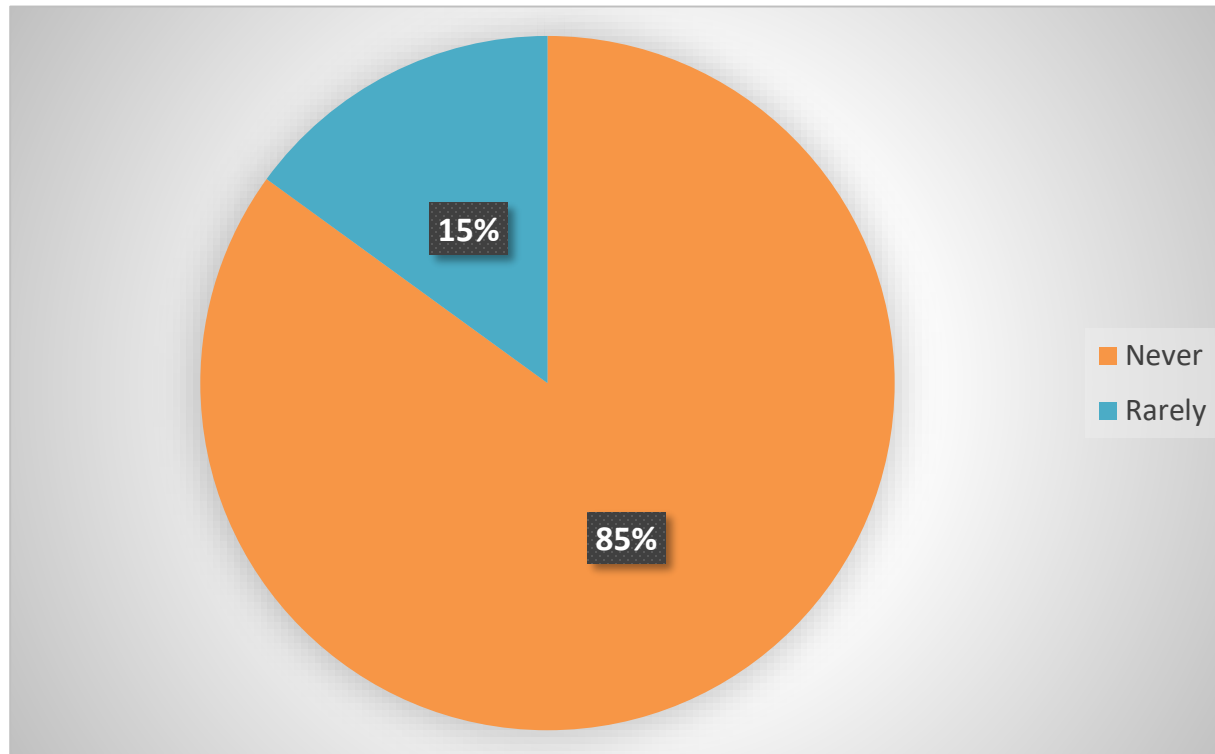


# Medical Therapies in Ovarian Cancer The Arabic Perspectives



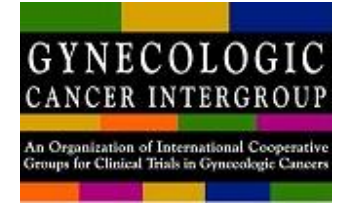
**Mezghani Bassem -Tunisia**

4) Dose-dense Paclitaxel + weekly Carboplatin AUC 2 regimen in an adjuvant use  
(MITO 7, ICON 8 Design)



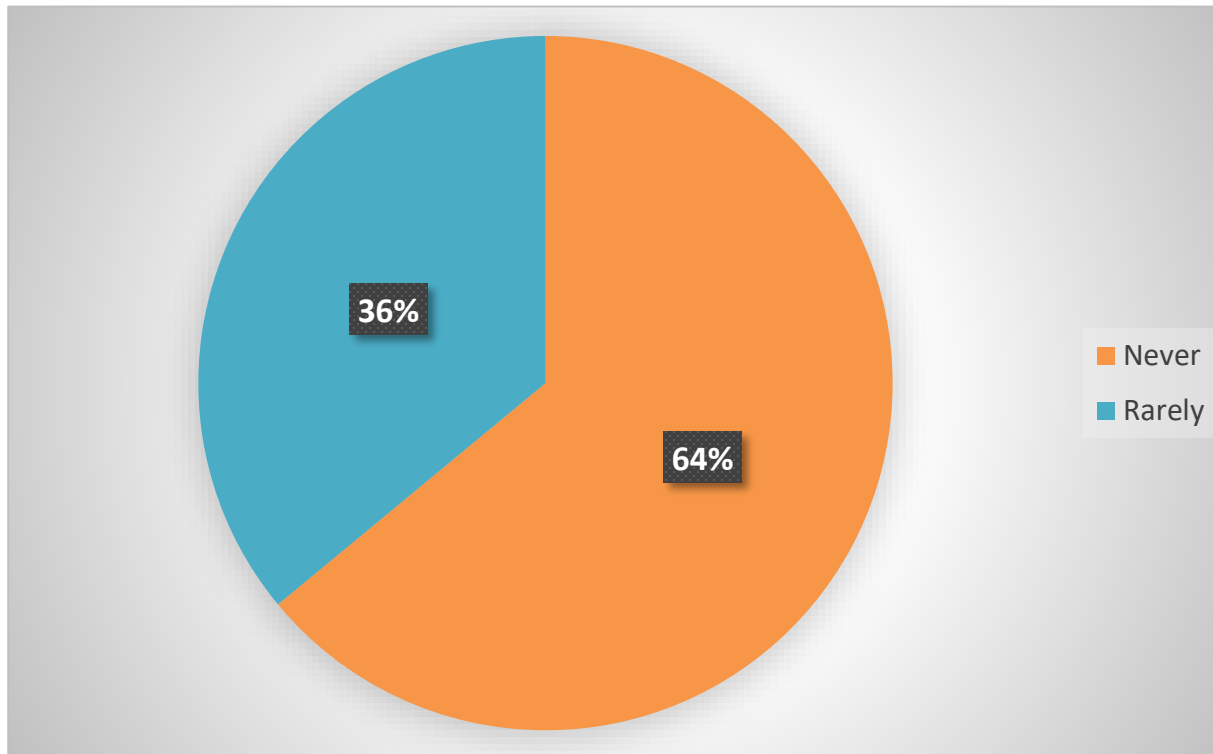


# Medical Therapies in Ovarian Cancer The Arabic Perspectives



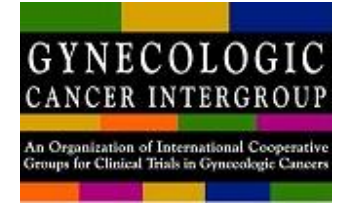
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5) 3 weekly Carboplatin regimen in an adjuvant use in Stage I FIGO if chemotherapy is appropriate



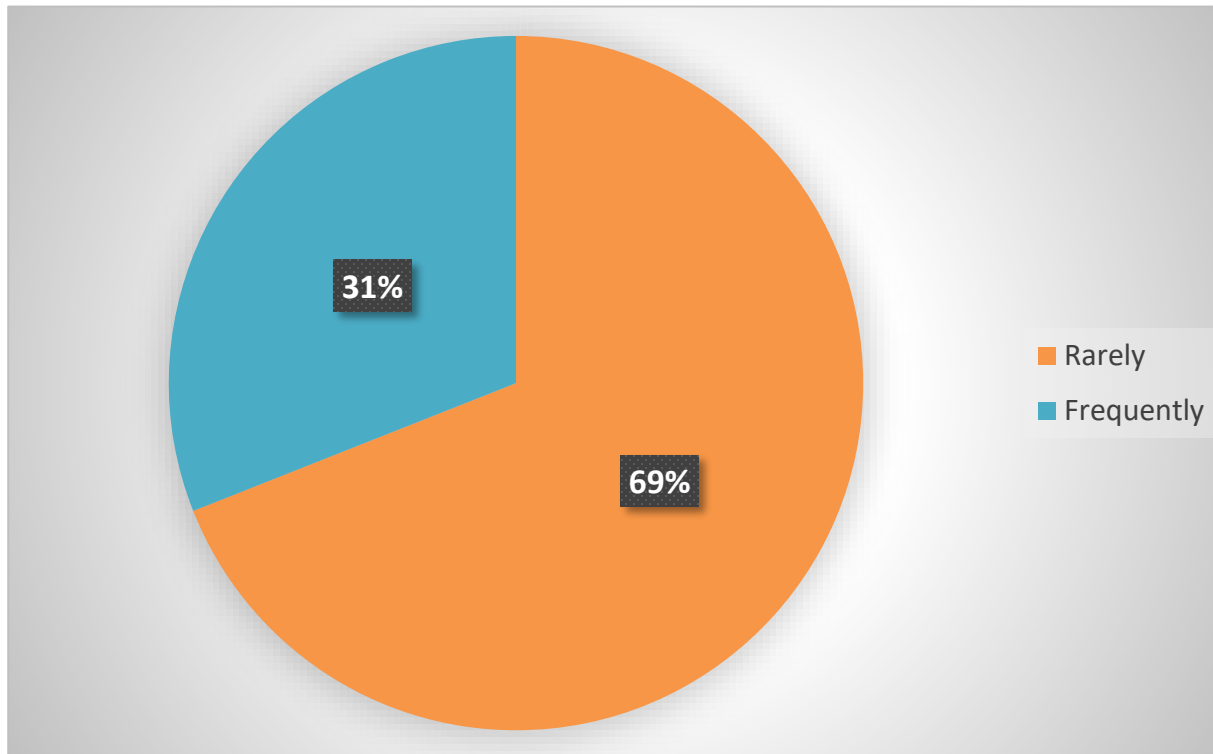


# Medical Therapies in Ovarian Cancer The Arabic Perspectives



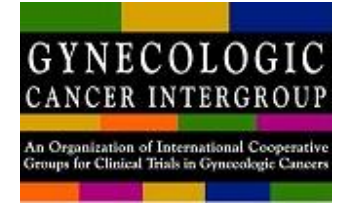
**Mezghani Bassem -Tunisia**

6) 3 weekly Carboplatin regimen in an adjuvant use in Eldery >70 Stage III/IV FIGO



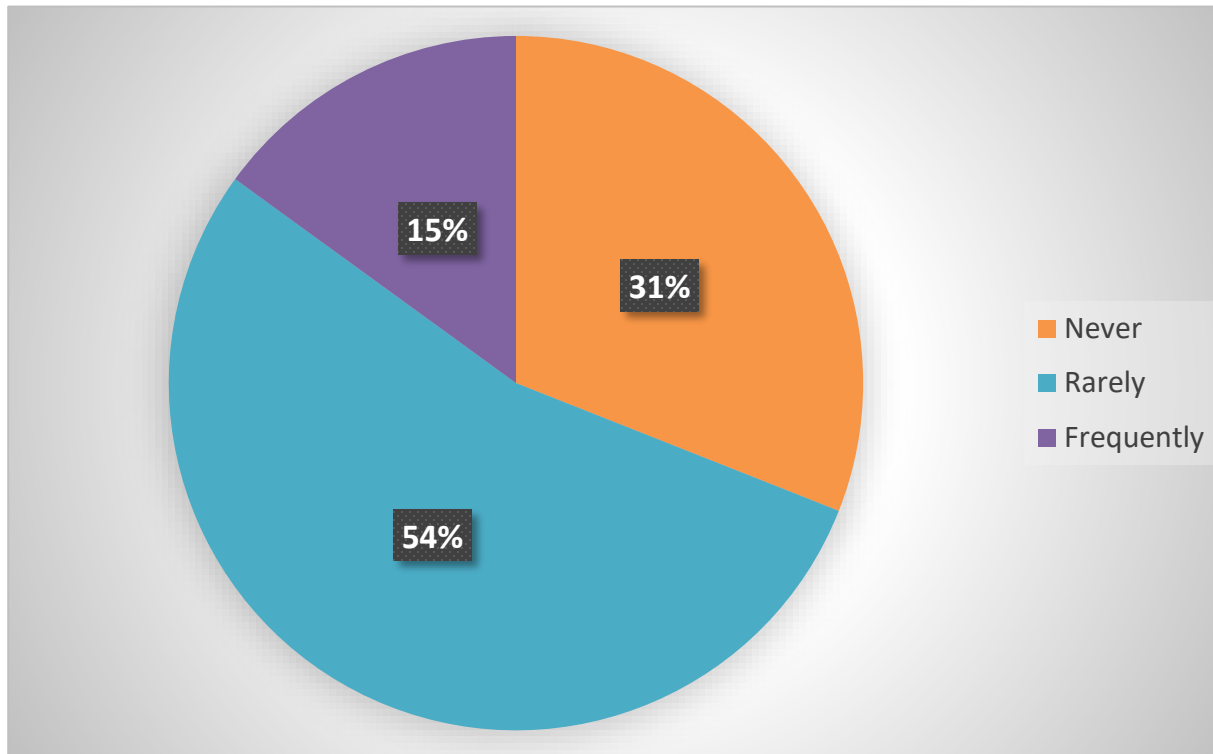


# Medical Therapies in Ovarian Cancer The Arabic Perspectives

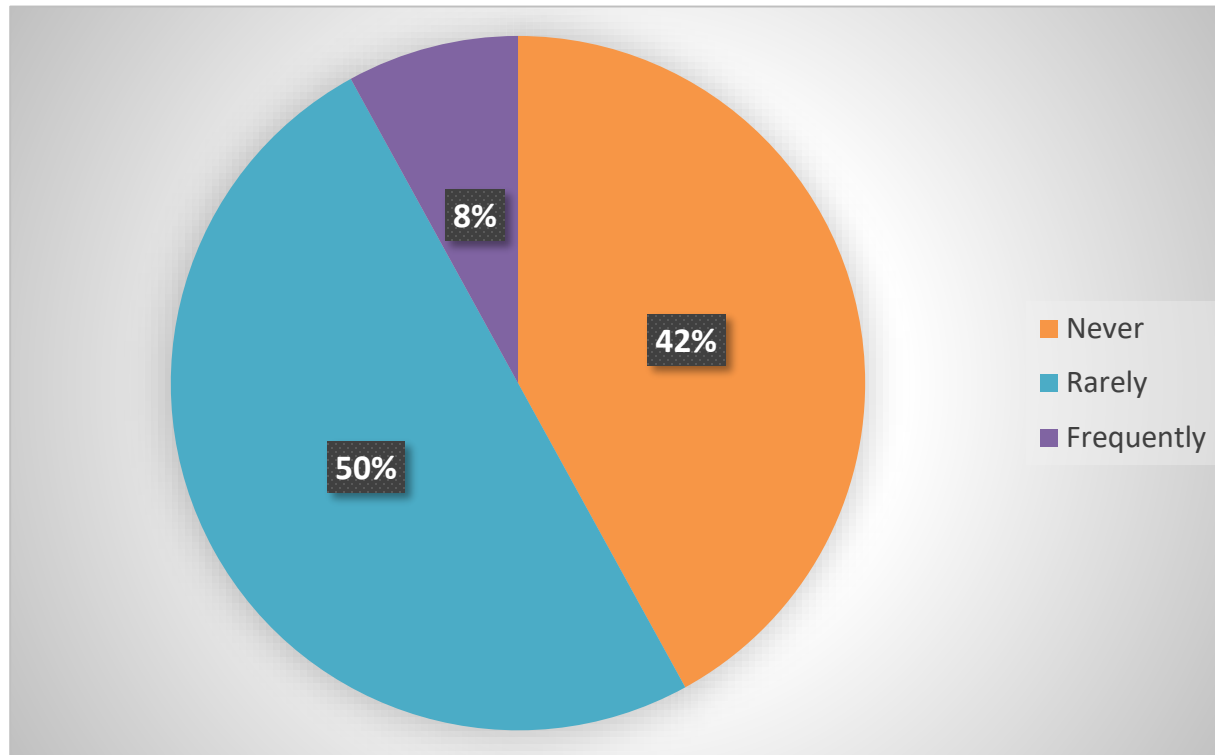


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7) Weekly Paclitaxel 60mg/m<sup>2</sup> + Carboplatin AUC 2 regimen in an adjuvant use in Eldery >70 Stage III/IV FIGO (EWOC 1 Design)

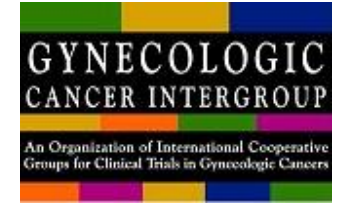


8) Bevacizumab + Paclitaxel-Carboplatin regimen in an adjuvant use in case of Residual disease or Stage IV FIGO (ICON 7 Design)



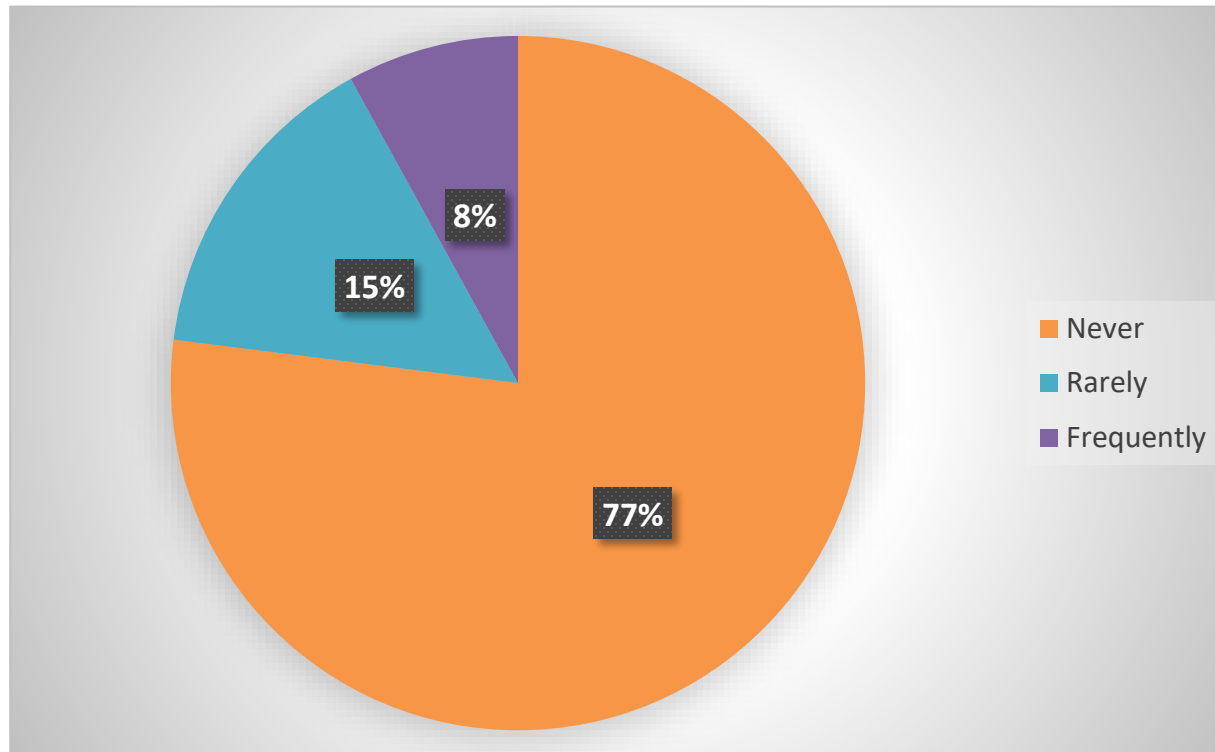


# Medical Therapies in Ovarian Cancer The Arabic Perspectives



**Mezghani Bassem -Tunisia**

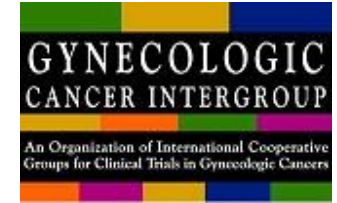
9) Maintenance Therapy with weekly Paclitaxel regimen following adjuvant chemotherapy





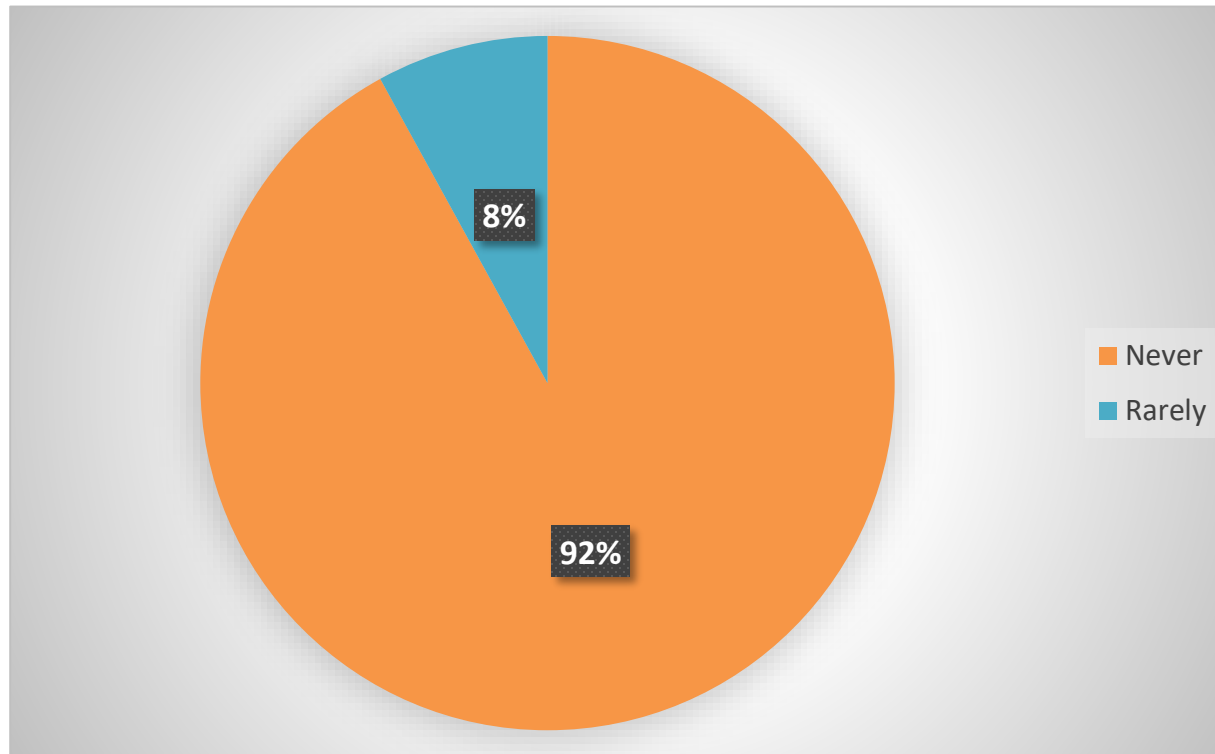


# Medical Therapies in Ovarian Cancer The Arabic Perspectives



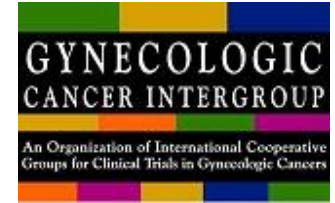
**Mezghani Bassem -Tunisia**

10) Maintenance Therapy with 4 weekly Paclitaxel regimen following adjuvant chemotherapy



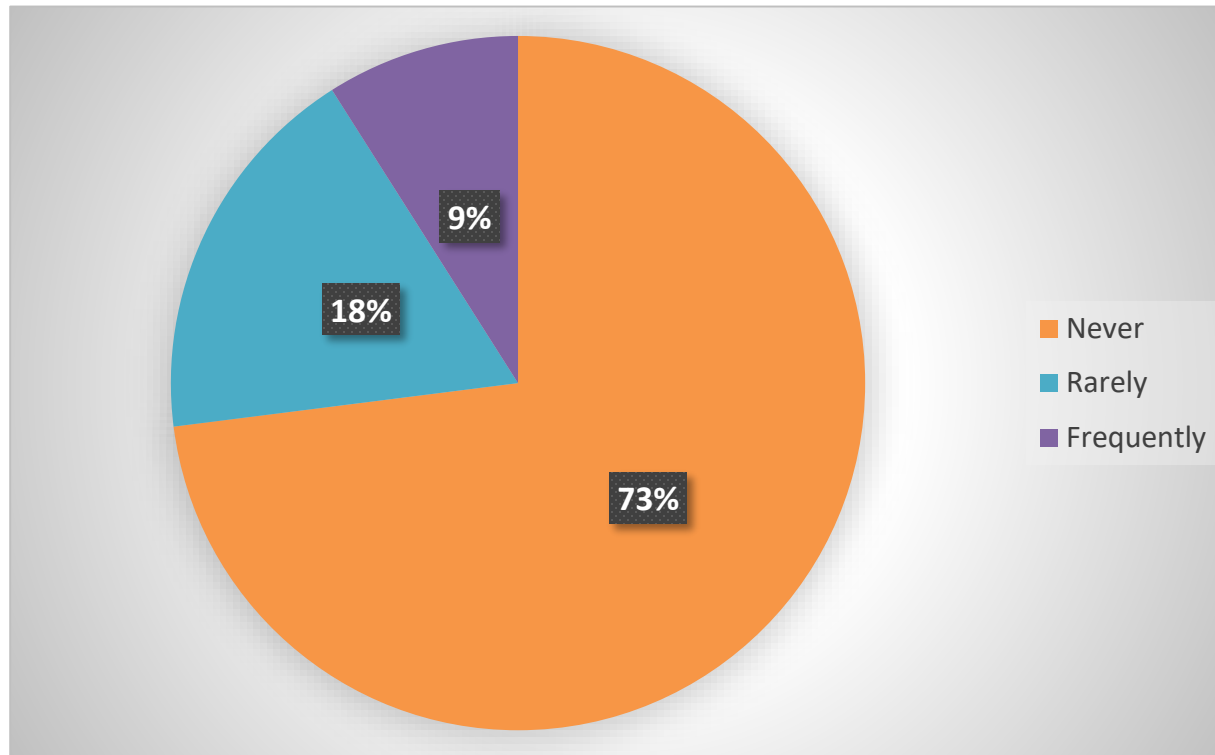


# Medical Therapies in Ovarian Cancer The Arabic Perspectives



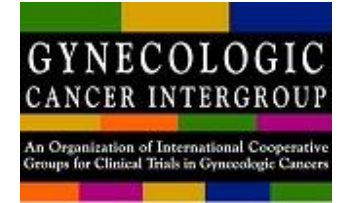
**Mezghani Bassem -Tunisia**

11) Maintenance Therapy with Bevacizumab following adjuvant chemotherapy + Bevacizumab



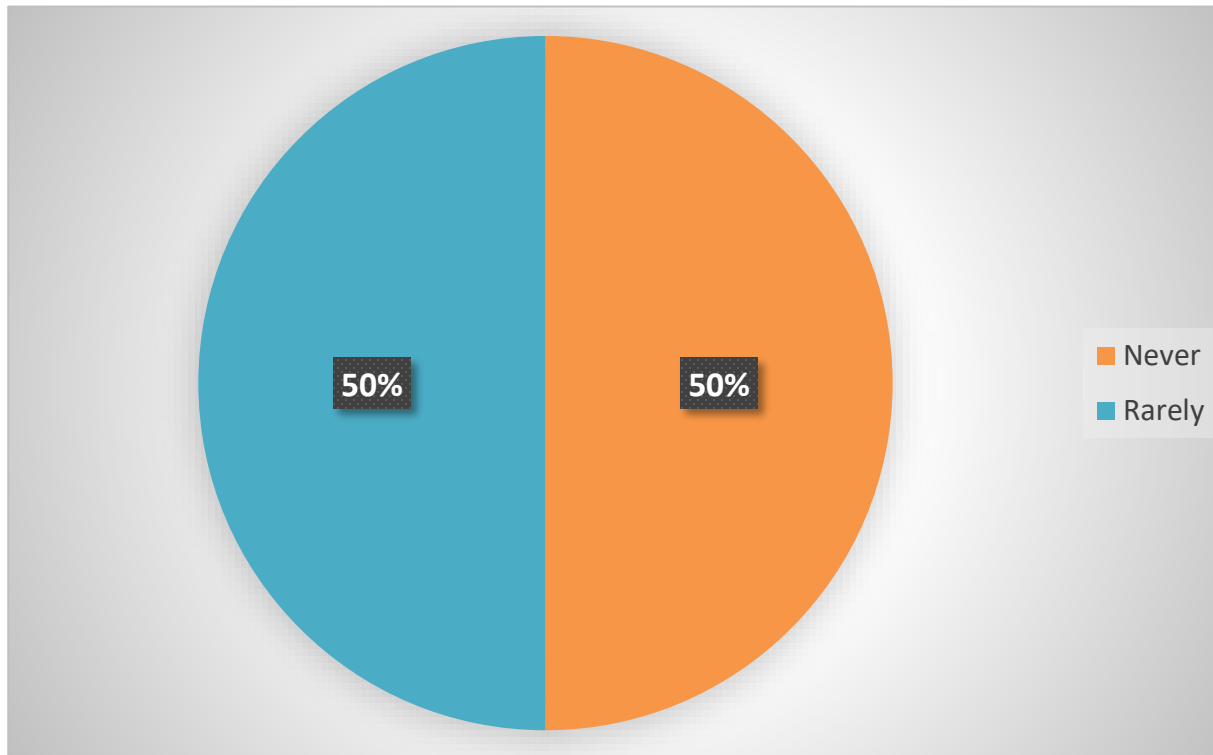


# Medical Therapies in Ovarian Cancer The Arabic Perspectives

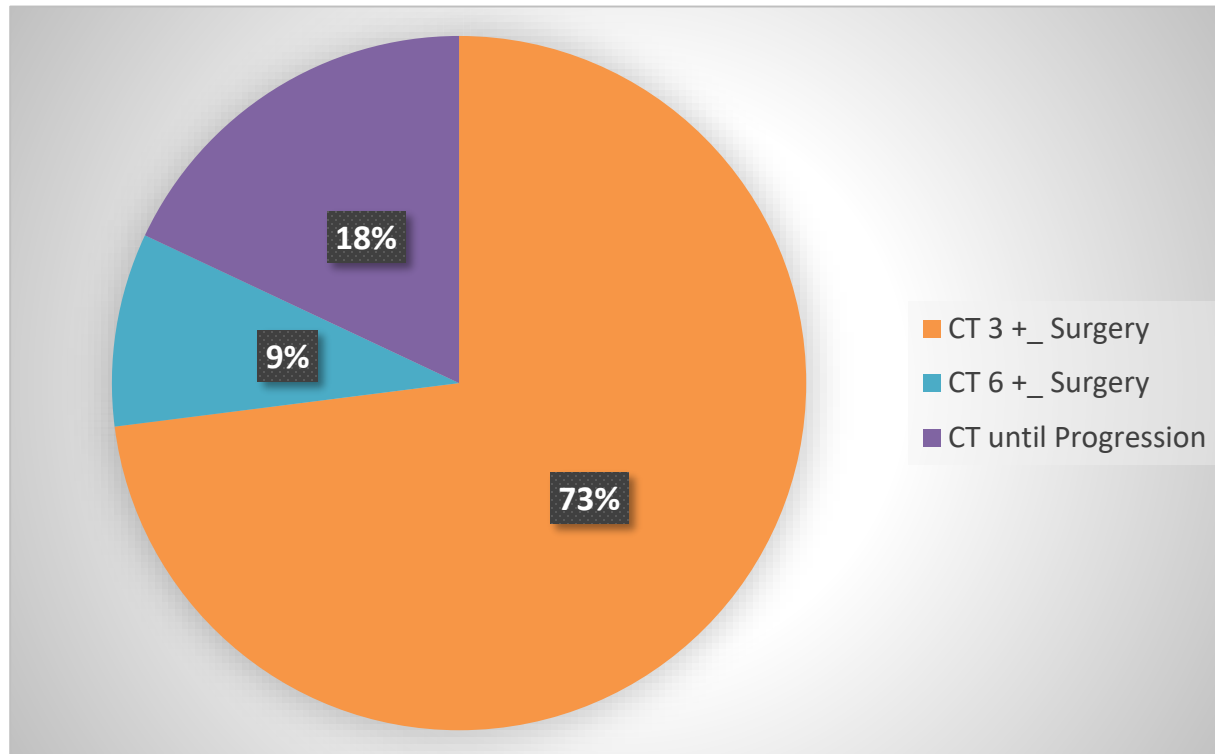


**Mezghani Bassem -Tunisia**

12) Bevacizumab Addition to Chemotherapy in patients with Platinum Resistant Ovarian Cancer (AURELIA Design)

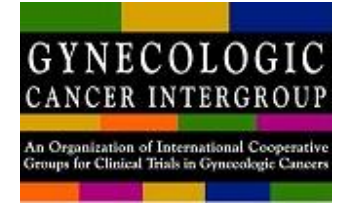


### 13) Platinum Sensitive Recurrences: Therapeutic protocols?



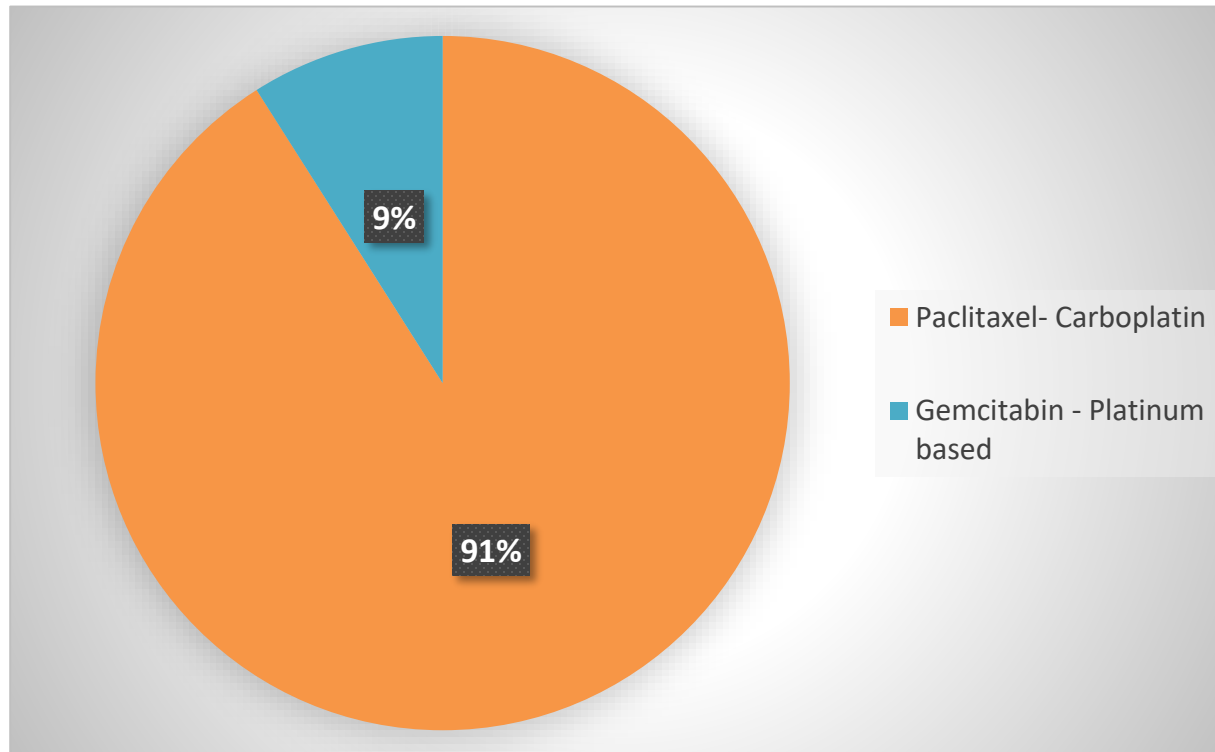


# Medical Therapies in Ovarian Cancer The Arabic Perspectives



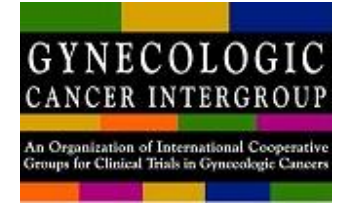
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## 14) Platinum Sensitive Recurrences: Chemotherapy Regimens?



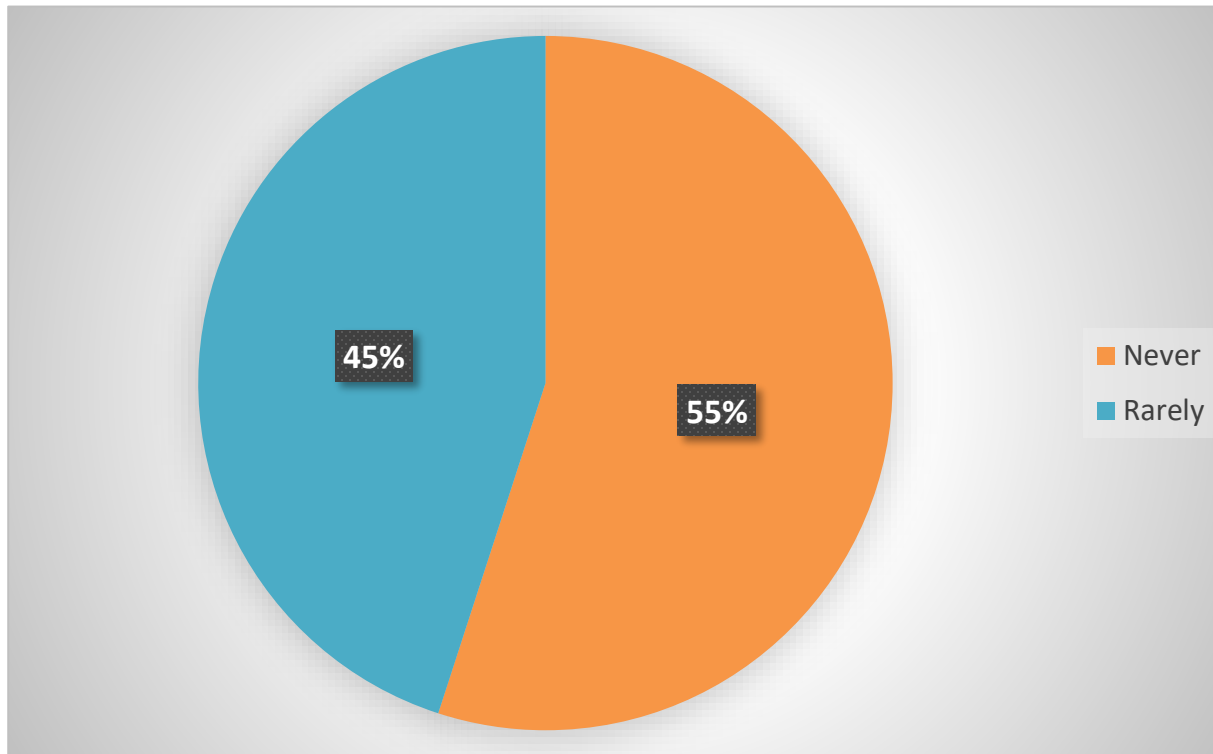


# Medical Therapies in Ovarian Cancer The Arabic Perspectives



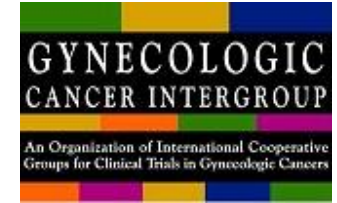
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15) Platinum Sensitive Recurrences: Bevacizumab use + Chemotherapy?





# Medical Therapies in Ovarian Cancer The Arabic Perspectives



Mezghani Bassem -Tunisia

## Conclusion

- Daily Practice
  - ✓ All patients  $\supset$  Indigents receive conventional CT adequately (Rare delays  $\leftarrow$  Rare Out of Stock events)
  - ✓ Limited access to innovative drugs  Limited Financial resources (Tunisian Health System)
- National Drug Administration  Registration/Specific Approval
- Clinical Trials National Research Ethics Committee & National Drug Administration  Approval for drugs use in Clinical Trials