FONDO NACIONAL DE RECURSOS
Medicina Altamente Especializada

Adjuvant Treatment with Trastuzumab in Patients with Breast Cancer in Uruguay

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Fondo Nacional de Recursos
Uruguay

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NATIONAL RESOURCES FUND.

Uruguay

*** National Agency for Highly Specialized Medical Procedures**

*** Created by law in 1980**

- ***Guarantees universal* access to highly specialized medicine (HSM).**

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NATIONAL RESOURCES FUND.

Uruguay

*** Budget**

- *** U$S 150,000,000 /year**
  (6% of health expenditure)
- * **U$S 24,000,000 / year** on medicines in 2010
- * **U$S 30,000,000** expected for 2011

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INTRODUCTION

- Breast cancer, in Uruguay
  - the most frequent in women (1800 cases/year)
  - Leading cause of death in women (600 death/year)
  - 15% - 25% express HER2 growth factor
- Trastuzumab
  - Recombinant humanized antibody
  - Targeted against HER2 receptor
  - Fase III RCT had shown benefit associated to chemotherapy
    - At 3 years: DFS 85.7 - 87.1%
      OS 92.4 – 94.3%
    - Adverse events: 7 – 24%
    - Stopped treatment: 8.5 – 28% Cardiac: 4 – 19%

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INTRODUCTION

- 2006, coverage started at the NRF, with progressive broadening of inclusion criteria.
- 12 month protocol was implemented
- Inclusion criteria
  - Breast cancer confirmed by histopathology
  - Primary tumor with invasive component ≥ 1 cm.
  - Primary tumor expressing HER2/neu.
  - Age ≤ 70 y
  - Performance status (Karnofsky scale value > 70%)
  - Adequate clinical status than predict tolerance to chemotherapy protocol treatment.
  - Time since the end of chemotherapy < 3 months

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OBJECTIVE

- **To assess**
  - the effectiveness and
  - tolerance

  of Trastuzumab associated with chemotherapy in patients with HER2-positive breast cancer.

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Methods

- Cohort study of patients treated with adjuvant Trastuzuamb between October 2006 and March 2009.
- End-points
  - disease-free survival and overall survival (Kaplan-Meier method),
  - adverse effects.
- Data
  - Monthly information was required during 12 month treatment,
  - Mortality from Health Ministery and Social Security Service
  - Phone interview was made for long-term follow-up.

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Results

- 215 patients requested treatment.
- 171 (79.5%) approved.
- Median of follow-up: 31.9 months.
- 12 (7%) patients lost of follow-up for disease progression evaluation.
- 20 patients died and 36 patients progressed.

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Results

- At 3 years, disease-free survival rate was 75.6%.

Group	Disease-free Survival Rate			
	3 months	12 months	24 months	36 months
Negative axilar nodes N= 31	100%	100%	90,3	
Positive axilar nodes N=127	98,4%	91,2%	79,1	72,7%
Total N=158	**98,7% N=156**	**93 % N=146**	**81,5% N=90**	**75,6% N=36**

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Results

- At 3 years, survival rate was 85.9%.

Group	Survival rate			
	3 months	**12 months**	**24 months**	**36 months**
Negative axilar nodes N= 33	100%	100%	100%	
Positive axilar nodes N=137	98,5%	96,4%	89,7%	82,5%
Total N=170	**98,8%** **N=168**	**97,1 %** **N=165**	**91,7%** **N=118**	**85,9%** **N=45**

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Results

- **Adverse effects**: 37 (22.2%) patients
  - Cardiovascular in 15 (8.8%).
- **Stop of treatment**: 15 (7.8%) patients,
  - 12 (7%) for cardiac adverse effects
    9 definitively, 3 temporarily.

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Conclusions

- Disease-free survival and overall survival were lower than internationally reported.
- Adverse effects were frequent and similar to reported.
- Monitoring of adverse cardiac effects should be carefully done.