TOBRAMYCIN AND ALPHA-DORNASE TREATMENT FOR CYSTIC FIBROSIS (CF) IN URUGUAY

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Introduction:

- CF is an inherited disease in which exocrine glands produce abnormally viscous mucus, causing chronic respiratory and digestive dysfunctions. Recurrent infections by Ps. aeruginosa and others are associated with a faster deterioration in lung function and increase morbidity and mortality. Inhaled Tobramycin and mucolytic therapy with Alpha-Dornase have improved lung function and decreased hospitalization days.
- In Uruguay, access to these drugs was restricted because it wasn't covered until December 2007.
- A system of universal coverage, under a policy framework based in the best evidence and supported by a strong monitoring program was implemented. The criteria for treatment with Tobramycin and Alpha-Dornase are shown in table 1.
- A systematic process of evaluation was established since the beginning of the coverage.

Objective: describe the population, evaluate the efficacy of treatment (lung functionality, nutritional assessment) and adherence.

Table 1. INCLUSION CRITERIA FOR TREATMENT

Alpha-Dornase	Tobramycin
Chronic cough with secretions	Chronic colonization or infection with Ps aeruginosa
Diagnosis of CF	Diagnosis of CF
Age > 6 years old	Age > 6 years old
FEV1 < 75% expected	25% < FEV1 < 75% expected
Integral treatment of the disease	Integral treatment of the disease

Methods:

- Cohort study of patients who began treatment with Tobramycin and/or Alpha-Dornase from December 2007 to July 2010.
- Adherence to Tobramycin was measured by an index that relates the number of cycles received/optimal number of cycles, values > 0.8 were considered optimal.
- Changes in forced expiratory volume in 1st second (FEV1) and body mass index (BMI) were assessed at one year of treatment.

Results:

- 34 patients were included (9 Tobramycin, 7 Alpha-Dornase and 18 both). Characteristics of patients are shown in Table 2.
- Indications of Tobramycin treatment were chronic colonization (70%) and chronic infection (19%).
- The efficacy of the treatment is shown in Table 3.

Conclusions:

- A delay in the diagnostic was observed comparing with international literature (acceptable during the first year of life).
- Adherence was good, and lung function improved after one year of treatment and BMI remained stable within acceptable parameters .

Table 2

Characteristics of patients	n (%)
Age at baseline (median, IQ) (years)	18 y (13-23)
Male Gender	21 (61.8)
Montevideo area	21 (61.8)
Private assistance	23 (67.6)
Education according the age	11 (55)
Employment situation	
Active work	8 (57)
Student	4 (29)
Others	2 (14)
Age at diagnostic (years)	2.8
Pancreatic dysfunction	21 (63)
Liver dysfunction	4 (11)
Oxygen dependence	7 (21)
Diabetes	8 (24)

Table 3

Adherence and efficacy of treatment				
			Baseline	12 months
Index of adherence			-	0.81
BMI	(Kg/m2)	(median)	19 (n=23)	20 (n=23)
FEV1	(%)	(median)	43 (n=12)	54 (n=12)
	(lts)	(median)	1.2 (n=12)	1.6 (n=12)*
Hb. SAT O2 (%)		(median)	97 (n=12)	97 (n=12)

* p<0.05