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PALIVIZUMAB OFF LABEL USE IN TERTIARY REFERRAL HOSPITAL

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BACKGROUND

- ✓ The indication of palivizumab is the prevention of serious lower respiratory tract disease requiring hospitalisation caused by respiratory syncytial virus (RSV) in children at high risk for RSV disease,
- ✓ but medication assessment in different conditions to the authorised ones is a fairly common situation in our environment, thus the hospital maintain a multidisciplinary pharmacy committee which evaluates this medication for personalised authorization.

PURPOSES

The purpose of this study is to evaluate the palivizumab off label use in a third level hospital during 2016 and 2017.

MATERIAL AND METHODS

Observational retrospective study of patients receiving palivizumab off label use (2016-2017). The analysed variables are; base pathology, gestational age, hospitalisation number, costs and evidence degree according to "US Agency for Healthcare Research and Quality" scale.

RESULTS

- ✓ 18 children, of which the 22,2% repeated prophylaxis the second year, were treated with palivizumab with an average age of 24,76 (5-63 months), 44,4% girls. Palivizumab use "off label" represented the 8,7 % of total patients treated with palivizumab (230 patients).

DISEASE	Cystic fibrosis	Congenital myopathy	Respiratory disorders (recurrent pneumonia, pulmonary hypoplasia and respiratory infections secondary to kidney dysplasia, esophageal atresia, interstitial lung disease).
	33,3%	33,3%	5,5%

- ✓ According to the evidence level, in children with cystic fibrosis presents grade I-b, in myopathy prophylaxis the grade is II (cohorts) and for esophageal atresia, pulmonary malformations and serious respiratory diseases the grade is IV (expert opinion).
- ✓ 33,3% of patients had a gestational age under 37 weeks. 11,1% of hospitalisations by RSV infection required oxygen therapy (a patient after having received prophylaxis in previous years and another hospitalization by VRS in 2016 that was not repeated after the palivizumab treatment in 2017)(7,7 hospitalization days).

DOSAGE	COST/PATIENT/YEAR	ESTIMATED ECONOMIC IMPACT	TOTAL OF PALIVIZUMAB COST
15 mg/kg monthly during the 4-5 months of the risk season.	6.255, 75-7.807, 5€ (VAT included).	112.603, 5€-140.535€	16, 8% and 21%

CONCLUSIONS

- ✓ Given the existing low degree evidence and this study results there are no clear advantages of this medication in patients with cystic fibrosis and neuromuscular problems.
- ✓ Consequently and given the high cost that palivizumab use implies, it would be necessary establish protocols that define use condition and identification of patients that may benefit better the treatment.