



POP UP: Pediatric Off-label and Polytherapy Use in Palliative care

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Why this study?

- 1) Pediatric palliative care (PPC) patients: a growing population with multiple medical complexities
- 2) The need for many medication to relieve from symptoms and to guarantee the best quality of life (increase the exposition to polypharmacy, off-label drug use «OLDU» and medication burden)
- 3) Polypharmacy and OLDU are associated with both benefits and harms
- 4) Poor data in literature





The aim of the study



To assess the incidence of polypharmacy, of off-label drugs use and of medication burden in our cohort of PPC patients



To estimate the daily cost of the treatment regimens





Study setting and criteria

Type of study	→	Cross-sectional observational study performed between August and October 2021 in the Pediatric Palliative Care Center of Padua, Italy
Population	→	All patients followed at our pediatric palliative care center
Inclusion criteria	→	Age < 23 yo with at least 1 drug treatment prescribed





Definitions

Polypharmacy: the current use of at least five medications (were included as needed and scheduled medications)



Off-label drug use: all medications prescribed in different ways (es. age, indication, route of administration or posology) from those established in the Summary of Product Characteristics (SPC) approved by AIFA (Agenzia Italiana del Farmaco - Italian Medicines Agency)

Medication burden: was defined as polypharmacy and/or more than 2 administration during night





Data collection

Population data: for each patient was collected demographic information from the medical record: age, gender, disease history, main diagnostic category and "do not resuscitate" (DNR) orders.



Medication data: for each patient was collected the number of drugs prescribed, their correspondence to the Anatomical Therapeutic Chemical (ATC) classification, their dosage, frequency and route of administration, their in or off-label use and their ex-factory costs.





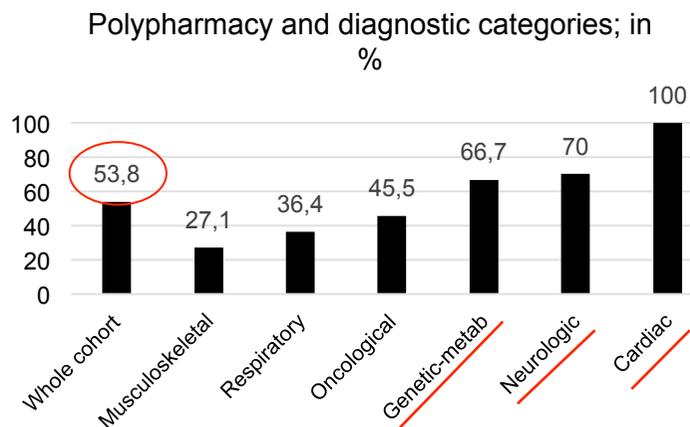
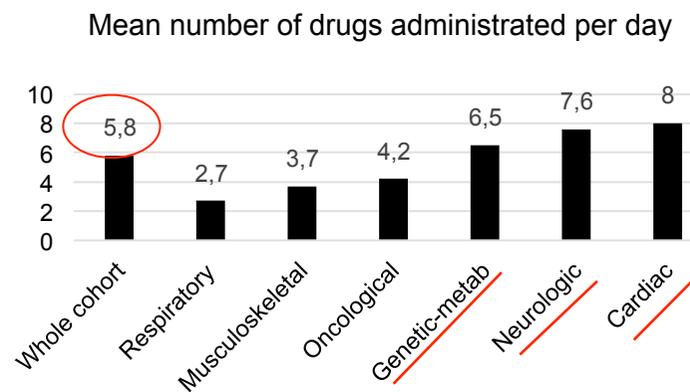
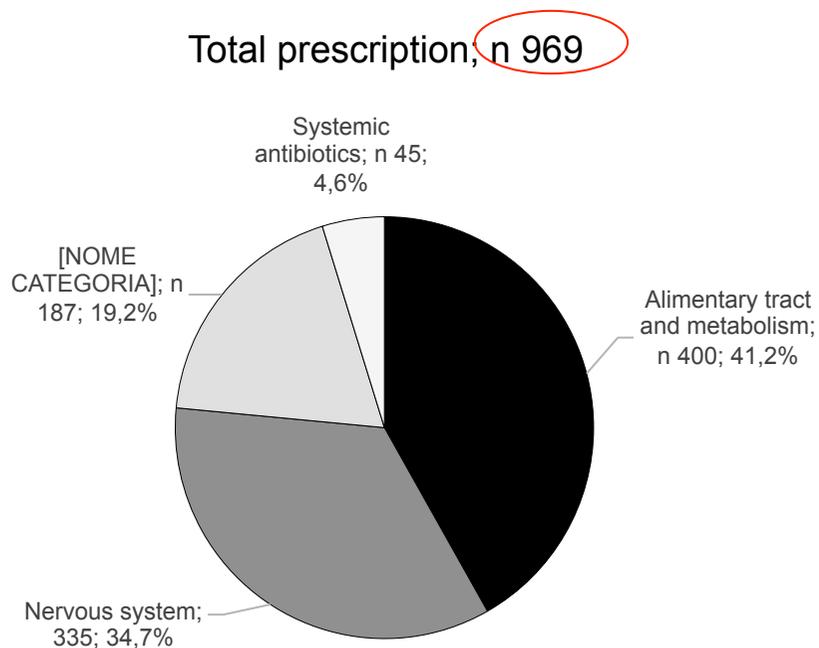
Results: patients' characteristics

Demography	N=169 mean (SD) or n (%)
Male	83 (49%)
Female	86 (51%)
Age (years) median (min-max)	11.2 (±5.9) 12.5 (0.3 - 23)
Infant (0-2 yo)	10 (5.9%)
Preschool (3-5 yo)	33 (19.5%)
School (6-11 yo)	37 (21.9%)
Adolescent (12-17 yo)	66 (39.1%)
Adult (≥18 yo)	23 (13.6%)
Disease history (years) median (min-max)	10.4 (±6.0) 11 (1 -23)
DNR order	42 (25%)
Cardiac	2 (1.2%)
Musculoskeletal	48 (28.4%)
Neurologic	70 (41.4%)
Oncological	11 (6.5%)
Respiratory	11 (6.5%)
Genetic-metabolic	27 (16.0%)
Congenital / Perinatal onset	153 (90.5%)





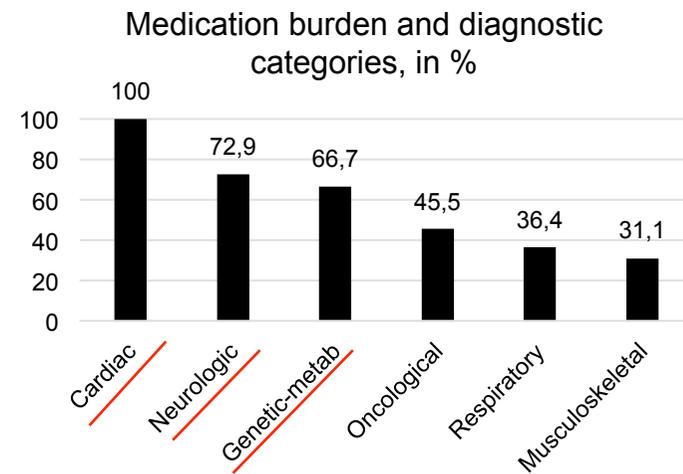
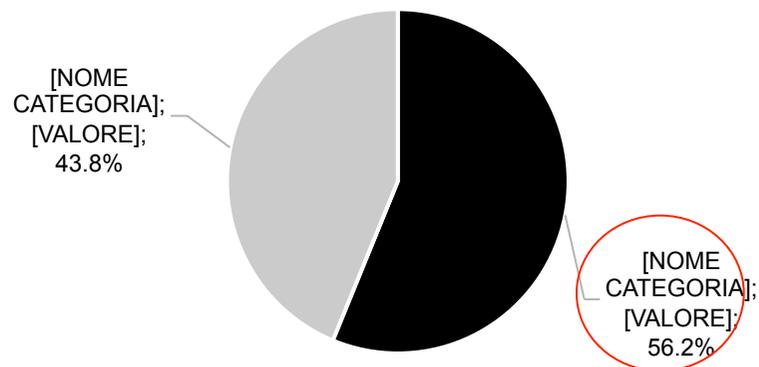
Results: drug categories and polypharmacy





Results: medication burden

Total population; 169

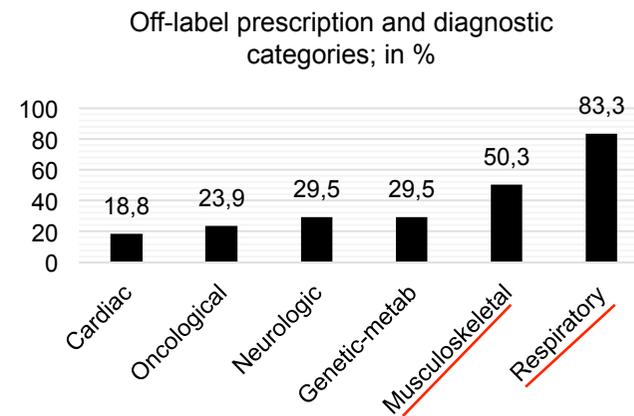
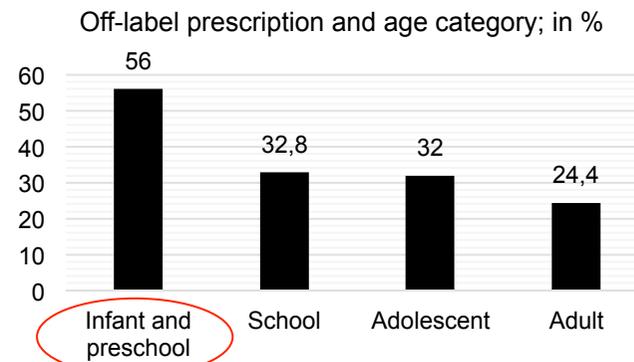
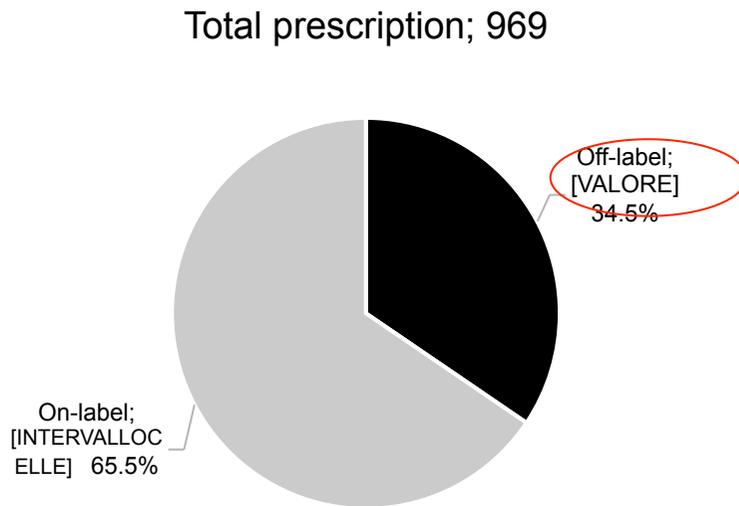


DNR order was more frequent among patients with medication burden than in patients without it (p=0.004)





Results: off-label drugs use

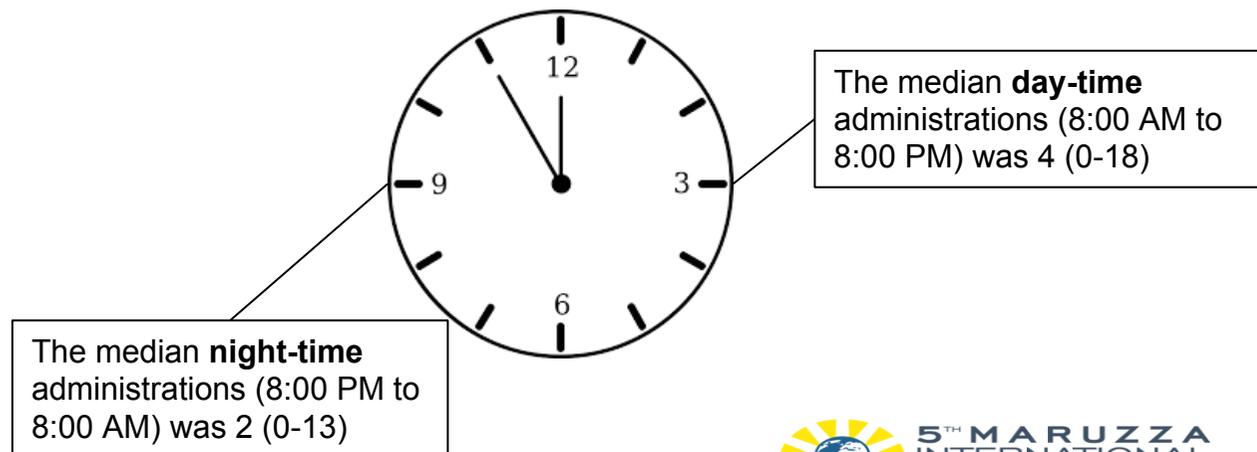




Results: drugs administration

Enteral and oral assumption were the most frequent way of administration.

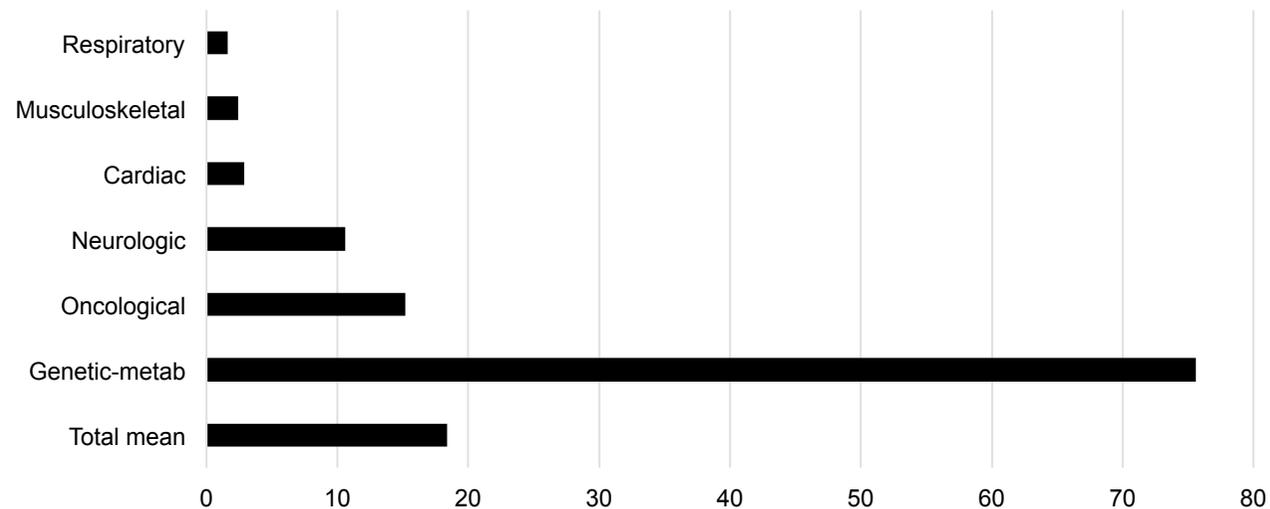
The total median drug administrations per day was 6 (0-28)





Results: pharmaceutical expenditure

Mean daily costs and diagnostic categories; in €



The mean daily cost for each patient was estimated in 18.4 (± 146.2) €





Limitations of the study

- Monocentric study
- The calculation of medication burden
- The exclusion of adverse drug effects (ADEs) or drug interactions from the study





Strengths of the study

- Numerosity
- The distribution of daily drug administration
- The cost analysis





Conclusions

- **Over the half of our population was exposed to polypharmacy and medication burden**
- **Medication burden was significantly more common in DNR patients**
- **Over the third of total prescriptions was off label with a mean daily costs of 18.4 €**





Thank you for your attention!

Grazie per l'attenzione!

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