

THIRD-GENERATION HOSPITAL-EXCLUSIVE CEPHALOSPORINS: DIFFERENT SAFETY PROFILES?

Betânia Abreu Faria¹, Alexandre Carvalho¹, João Paulo Fernandes², Márcia Silva², Sara Barroso¹

¹HOSPITAL DE BRAGA, UNIDADE DE FARMACOVIGILÂNCIA DE BRAGA, BRAGA, PORTUGAL

²INFARMED – AUTORIDADE NACIONAL DO MEDICAMENTO E PRODUTOS DE SAÚDE- I.P., DIREÇÃO DE GESTÃO DO RISCO DE MEDICAMENTOS, LISBOA, PORTUGAL.

Background and importance

Third-generation cephalosporins are clinically relevant due to their broad spectrum of activity against Gram-negative, Gram-positive, and Pseudomonas aeruginosa bacteria. Monitoring the safety profile of these medicinal products in a real-world setting is of paramount importance, aiming to protect both individual and collective health. As far as we are aware, no study with the aim of comparing the safety profiles of these medicinal products has been conducted in the Portuguese context

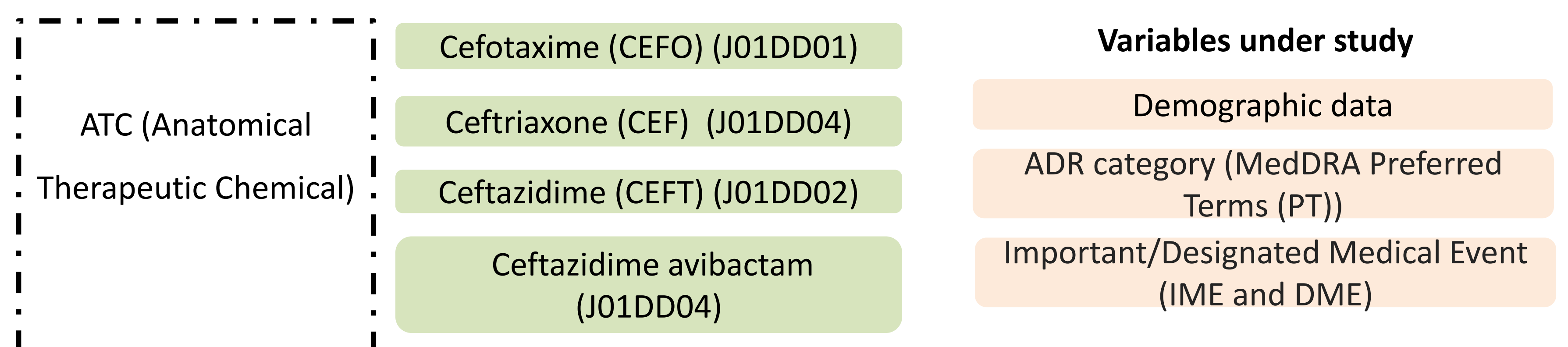
Aim and objectives

Assess the reports of suspected adverse drug reactions (ADRs) received by the Portuguese National Pharmacovigilance System concerning third-generation hospital-exclusive cephalosporins, with the aim of comparing the safety profile of these medicinal products

Material and Methods

- ✓ Retrospective study
- ✓ Used data from Portal RAM between January 1, 2013, and March 31, 2023

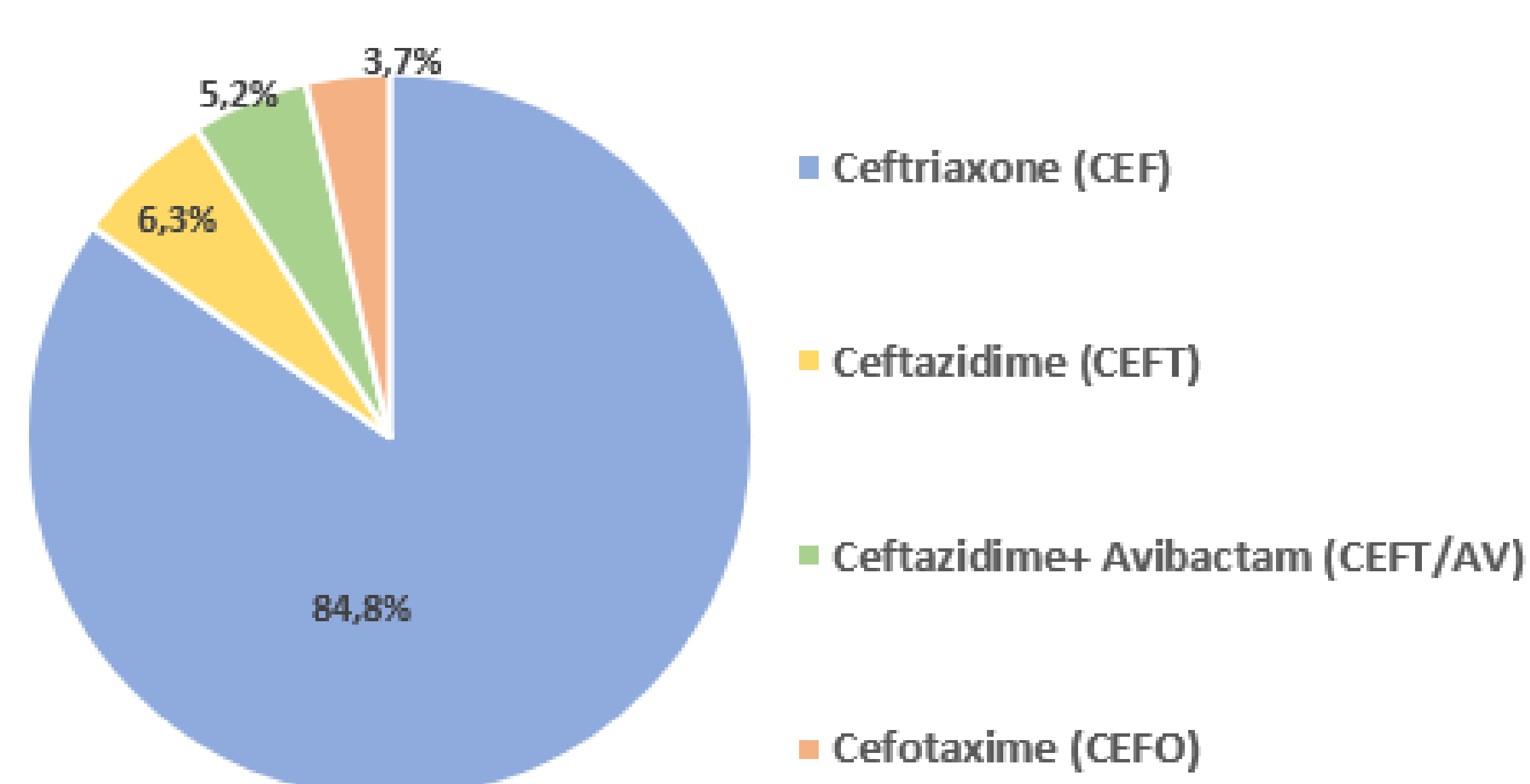
Individual Case Safety Reports (ICSRs)
(selected if they identified only one third-generation hospital-exclusive cephalosporin as the suspect drug)



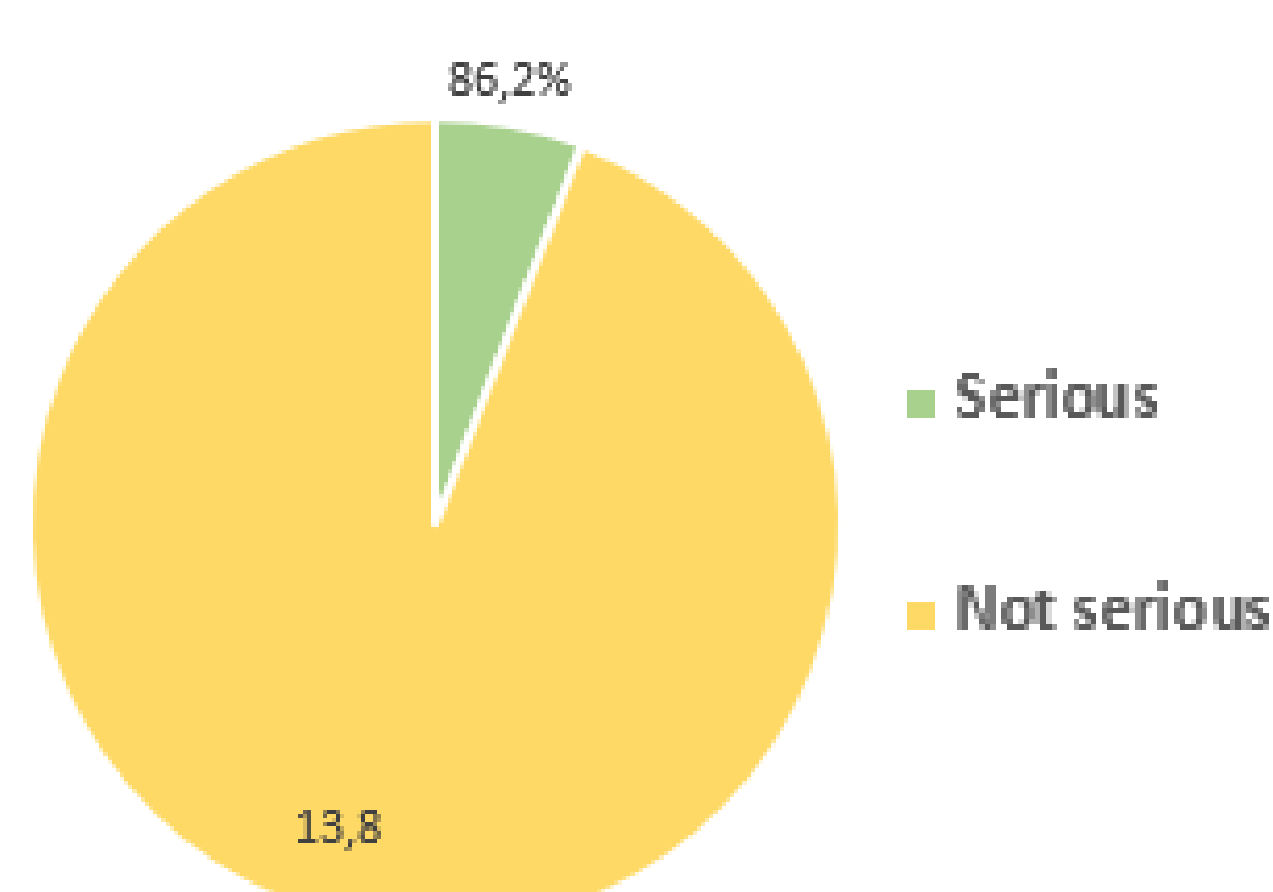
Results

The search returned 269 ICSRs of interest, with the majority related to CEF (84.8%). (**Graphic 1**) Most ICSRs were classified as severe (CEFO:80.0%; CEF:88.2%; CEFT:82.4%; CEFT/AV:64.3%). (**Graphic 2**) For all the cephalosporins under study, there was a predominance of male patients, with a median age over 50 years, except for CEFO (15.0±10.0). Regarding the number of ICSRs containing IME terms, CEFT/AV had the highest percentage at 64.3%, while 25.4% of CEF ICSRs contained a DME term. The highest percentage of ICSRs with PT terms related to off-label use and lack of efficacy belonged to CEFT, with 11.8% and 23.5%, respectively. In all cephalosporins, the majority of ICSRs evolved towards recovery. (**Table 1**)

Graphic 1: Distribution of ICSR by suspected drug



Graphic 2: ICSR distribution by gravity



	CEFO	CEFT	CEF	CEFT/AV
Masculin (%)	80,0	47,1	51,3	71,4
Median Age	15,0 ± 10,0	62,0 ± 43,0	53,0 ± 50,0	68,0 ± 9,5
ICSR serious (%)	80	82,4	88,2	64,3
Evolution (Cure) (%)	70	47,1	57,9	42,9
SOC most notified and %	Skin and subcutaneous tissue disorders (50,0%)	General disorders and administration site conditions (52,9%)	Skin and subcutaneous tissue disorders (44,7%)	Skin and subcutaneous tissue disorders (35,7%)
ICSR with IME (%)	30,0	35,3	61,4	35,7
ICSR with DME (%)	0,0	17,6	25,4	7,1
Lack of effectiveness (%)	10,0	23,5	8,3	21,4
Off- Label use (%)	0,00	11,80	6,10	0,00

Table 1: Caracterization of ICSRs under study

Conclusion and Relevance

Our results appear to indicate that there are no significant differences in the safety profile of these medicinal products. However, further studies are needed. The implementation of active pharmacovigilance protocols at the hospital level may contribute to a safer and more rational use of these drugs, minimizing the impact of ADRs on Public Health, both in terms of economic burden on healthcare systems and morbidity and mortality for citizens.

