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Extravasation and onco-haematological biological drugs: analysis of reports in the National Italian Pharmacovigilance Network

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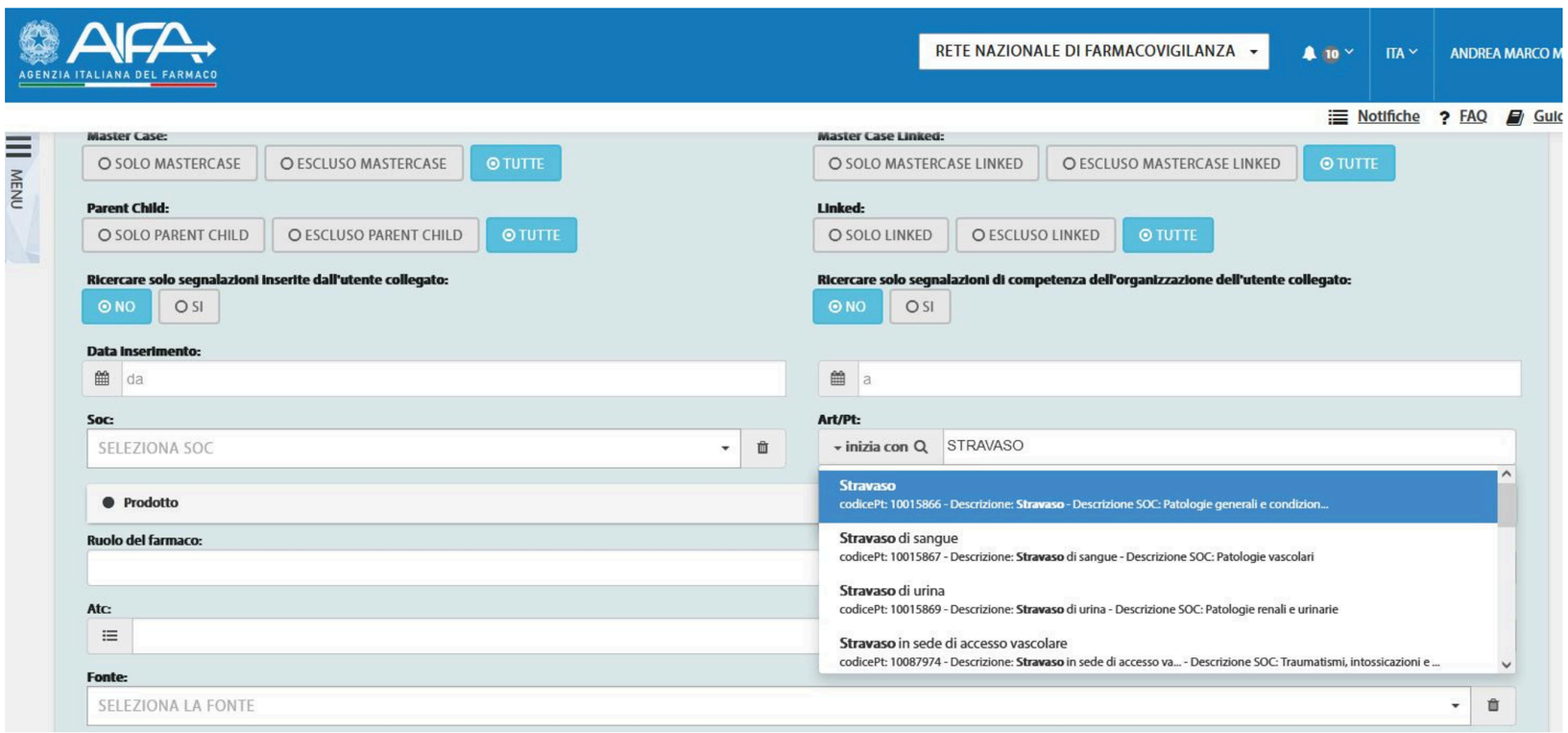
The study aimed to analyze pharmacovigilance data to better understand extravasation as an adverse event in onco-hematological treatments, focusing on new biological drugs.

Extravasation, the unintended leakage of intravenous drugs into surrounding tissues, could cause serious complications, especially with antineoplastic and biological therapies, with an incidence of 0.1% to 6% in chemotherapy patients (1).
Current guidelines often overlook extravasation management for new biological agents, highlighting the need for updated protocols and training. Hospital pharmacists play a key role in assessing risks and providing antidote information, using data sheets, older guidelines, literature, and the National Pharmacovigilance Network (RNF).

Data were extracted from the RNF (Italian National Pharmacovigilance network) from October 2006 to August 2024.

Methods

Reports included data coded with a Lowest Level Term (LLT) linked to "extravasation" and classified as suspected drug-related adverse reactions according to the Anatomical Therapeutic Chemical (ATC) classification 'L- Antineoplastic and Immunomodulating Agents.' Qualitative and quantitative analyses were conducted, focusing on LLTs for each active substance, particularly biological drugs. Biological agents data sheets were reviewed to assess whether they included instructions or recommendations for managing extravasation.



Results

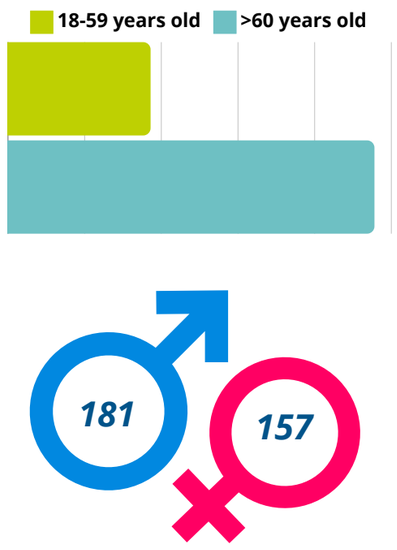
A total of 344 reports were analyzed, including 887 LLTs. The analysis involved 41 active substances, including 12 biological drugs, representing 7% of the total LLTs. There were 23 reports involving biological drugs, accounting for 60 LLTs. Serious LLTs were found in 134 cases, associated with 28 active substances, including 4 biological drugs. Reactions to biological agents included pain, swelling, and irritation.

Extravasation information inside Drug safety sheet :

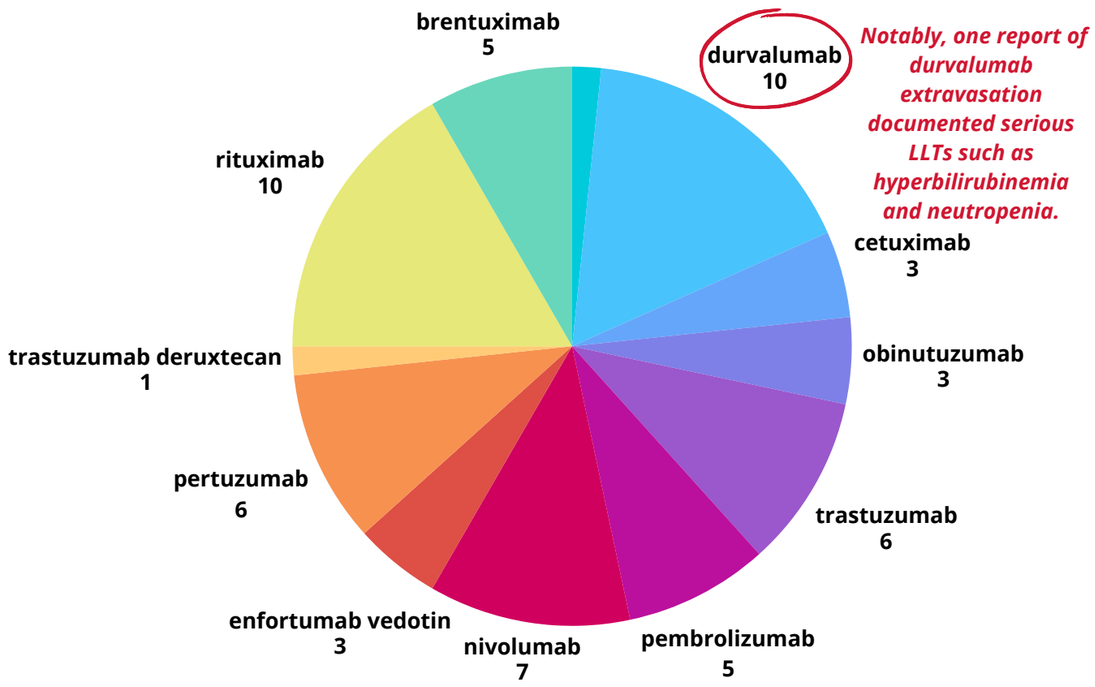
- ✓ Bretuximab Vedotin
- ✗ Avelumab
- ✗ Durvalumab
- ✗ Cetuximab
- ✗ Obinutuzumab
- ✗ Trastuzumab
- ✗ Pembrolizumab
- ✗ Nivolumab
- ✓ Enfortumab vedotin
- ✗ Pertuzumab
- ✗ Trastuzumab deruxtecan
- ✗ Rituximab

The DATA SAFETY SHEETS is the primary source of information for all healthcare professionals.

The absence of references to extravasation creates uncertainty on how to manage the situation and what monitoring procedures to implement.



Pie chart: Number of LLTs obtained for each biological drug in the report analysis



Notably, one report of durvalumab extravasation documented serious LLTs such as hyperbilirubinemia and neutropenia.

		BRENTUXIMAB VEDOTIN	ENFORTUMAB VEDOTIN	AVELUMAB	DURVALUMAB	CETUXIMAB	OBINUTUZUMAB	TRASTUZUMAB	PEMBROLIZUMAB	NIVOLUMAB	PERTUZUMAB	TRASTUZUMAB DERUXTECAN	RITUXIMAB
LLT by similarity	EXTRAVASATION	2	1	1	1	1	2	2	4	3	2	-	4
	PAIN AND DISCOMFORT	-	1	-	1	-	-	2	-	1	2	-	1
	SWELLING AND EDEMA	2	1	-	1	2	1	-	1	3	1	-	2
	IRRITATION, BURNING, INFLAMMATION	1	-	-	1	-	-	1	-	-	-	-	1

Each ADR report can contain multiple LLTs (Lowest Level Terms). LLTs related to extravasation can be associated in the same report with LLTs referring to other symptoms. The table summarizes the LLTs for each suspected biological drug in the reports, grouped by similarity.

In conclusion, extravasation-related adverse events associated with biological drugs are occurring, but may be underreported due to misclassification as general incidents. Notably, only 2 of the 12 biological agents analyzed included specific references to extravasation in their data sheets. Improving the recognition and reporting of extravasation through clearer guidelines may promote patient safety and clinical outcomes.

1) Kreidieh, Firas Y et al. Overview, prevention and management of chemotherapy extravasation. World J Clin Oncol. 2016;7(1):87-97
2) Pérez Fidalgo, J A et al. Management of chemotherapy extravasation: ESMO-EONS Clinical Practice Guidelines. Ann Oncol. 23 Suppl 7 (2012):VIIi167-73