

Objetive

Assess the risk and outcome of chemo-therapies on off-label practices in the pharmacy department of a tertiary hospital.

Results

A total of 6 types off-label drugs were requested and administered to 39 patients for 8 different diseases.

All patients with fotemustine/bevacizumab progressed on treatment.

Complete response in 9 hematologic patients (23%). Treatment related ADRs of any grade were reported in 15(38.5%) patients

- The most common was thrombocytopenia (18%) with fotemustine.
- Discontinuations due to ADRs: bendamustine, doxorubicin liposomal, and fotemustine (1 patient each).

Material and Methods

This study included all patients treated between March 2015 March 2017 with an off-label chemotherapeutic agent prescription.

Data were collected from:

- clinical history of the patients
- pharmacy programs (athos prisma®)

Variables analyzed:

- demographic (age, sex)
- treatment related
- drug involved
- off-label indication
- stage disease
- number of previous treatment lines
- treatment duration
- adverse drug reactions (ADRs)

	OFF-LABEL INDICATION	N.º PATIENTS	STAGE DISEASE	NUMBER OF PREVIOUS TREATMENT LINES	MEDIAN TREATMENT DURATION (CYCLES)
BENDAMUSTINE	NON-HODGKIN'S LYMPHOMAS (NHL) WITHOUT PREVIOUS RITUXIMAB	4	II	0	5
LENALIDOMIDE	DIFFUSE LARGE B-CELL NON-HODGKIN LYMPHOMA	2	IV	3	4
DOXORUBICIN LIPOSOMAL	NHL	5	III	0: 3 PATIENTS 1: 1 PATIENT >3: 1 PATIENT	6
MERCAPTOPYRINE	HISTIOCYTOSIS X	1	III	1	12
FOTEMUSTINE	GLIOBLASTOMA	15	IV	2	5
	OLIGODENDROGLIOMA	1	III	3	8
	ASTROCYTOMA	1	IV	2	1
BEVAZICUMAB	GLIOBLASTOMA	6	IV	2	3
	OLIGODENDROGLIOMA	1	IV	1	3
	ASTROCYTOMA	2	III	1	3
	EPENDYMOMA	1	IV	2	5

Conclusions

In our assessment, off-label therapies not have been effective in most of patients (77%), but safe.

Evaluation of the cost of off-label therapies, in terms of medication risk and effects on the cost of healthcare, will be essential to its widespread clinical utility.

Off-label use may also become the only treatment option, especially in the case of rare tumors.