

DRUG UTILIZATION AND PHARMACEUTICAL COSTS OF INTRAVITREAL INJECTED anti VEGFs IN MACULOPATHIES, IN SAN RAFFAELE HOSPITAL ITALY

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OBJECTIVES

Primary

Define annual treatment patterns of patients with maculopathies and describe anti VEGF drug utilization.

Secondary

Assess cost per year of intravitreal anti VEGFs considering the net ex-factory acquisition price for the hospital, stratified by drug indication.
Calculate the average cost per treated patient with maculopathy, stratified by drug indication.
Calculate annual cumulative drug expenditure for antiVEGFs of the Ophthalmology department in San Raffaele Hospital.

METHODS

Study design

Non interventional, descriptive, monocentric secondary data (retrospective) cohort study to understand the use of anti VEGFs in the Ophthalmology Department of San Raffaele Hospital from 2013 to 2015 for the treatment of patients affected by maculopathies (AMD - Age Related Macular Degeneration, DME - Diabetic Macular Edema, MMD - Myopic Macular Degeneration, RVO - Retinal Vein Occlusion).

Patients population

We analyzed all patients of the Ophtalmology Department in San Raffaele Hospital, treated with intravitreal anti VEGFs for: AMD, DME, MMD and RVO during the 2013 – 2015 period.

Study variables

The variables extracted for the study patients' were:

- Age and Gender
- Therapeutic indication of anti VEGF
- AIC and ATC drug code
- Date of the first and last injection
- Dosing
- Number of injections
- Number of total injections per year of treatment (12 months) and, where applicable, for the second eye
- Total drug expenditure

Data sources

- Two data sources were considered:
- The AIFA anti VEGFs monitoring registry
 - The “F flux” reporting system (used for reimbursement of the drug cost between hospital and Local Health Authority)

RESULTS

Patient pool

During the 2013-2015 period 2117 patients started an intravitreal therapy for the diseases of interest in San Raffaele Hospital.
Mean overall follow-up for these patients was 224 days (range 0 -1448).
During the 12 months after therapy starting, 138 patients have changed the therapy.
The 1.979 patients that haven't change it were followed up for 12 months.

Demographic features

The population included in the study was relatively old and mostly feminine, with the exception of DME and RVO, in which males were more represented.

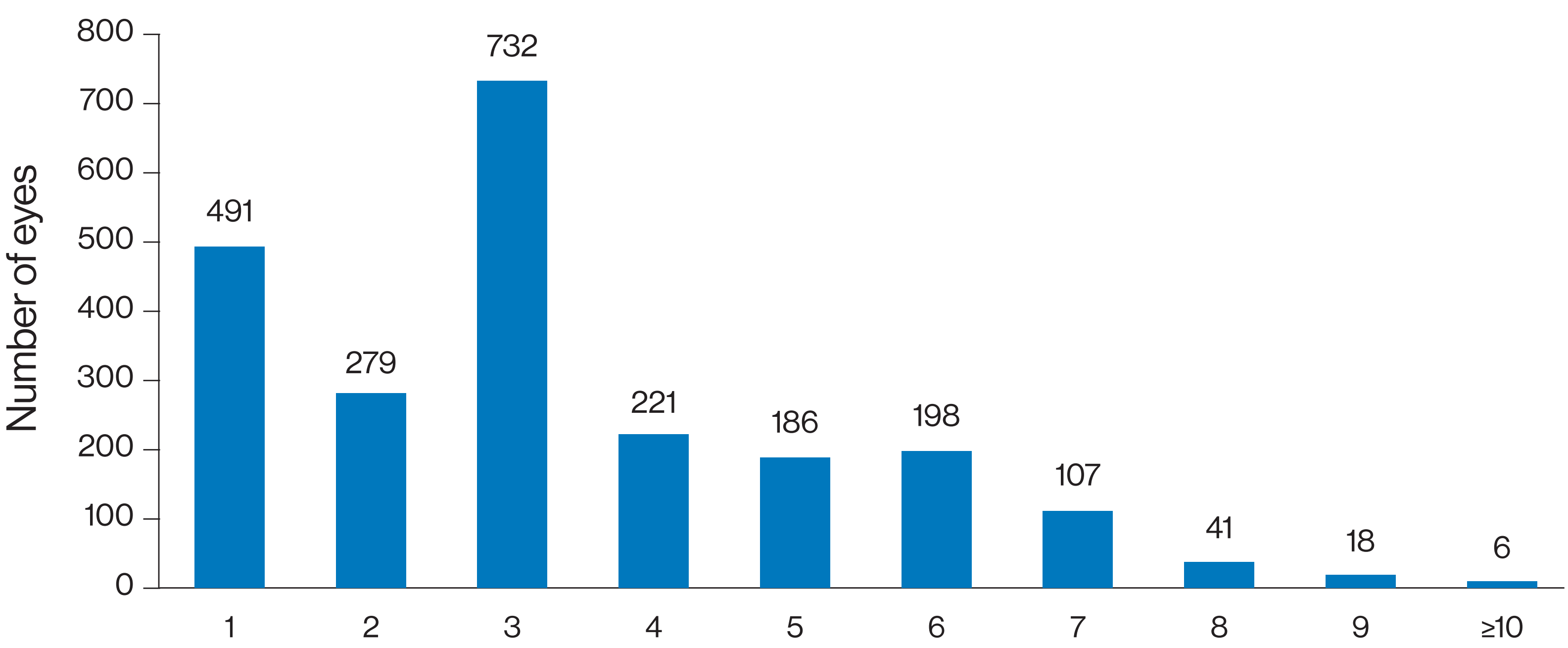
Table 1: Patient population demographic profile

Disease	Number of patients	Age: mean (SD)
AMD	1197	74,9 (± 9,6)
Female	727	75,1 (± 9,9)
Male	470	74,4 (± 9,1)
DME	464	62,6 (± 12,2)
Female	184	63,3 (± 13,1)
Male	280	62,1 (± 11,7)
DMM	140	55,5 (± 14,5)
Female	101	55,4 (±14,5)
Male	39	55,6 (± 14,5)
RVO	178	66,9 (± 14,1)
Female	66	69,7 (± 13,7)
Male	112	65,2 (± 14,1)
Total	1979	69,9 (± 12,9)

Injected drugs used

The anti VEGFs drugs used were aflibercept and ranibizumab.
They were the only approved drugs for the diseases examined , with in label indications for the diseases of interest.
The majority of treated eyes had 3 injections; there were 491 eyes that received 1 injection in 12 months.

Number of injections/eye/12 months



Pharmaceutical expenditure by disease

- More than half of the expenditure for injected anti VEGFs was due to AMD, that had the highest number of treated patients. AMD patients had the highest number of injections and the higher cost/treated eye
- DME had the highest drug expenditure/year/patient, also because of the highest prevalence of patients treated in both eyes
- MMD had the lowest cost/patient. This was because patients with MMD need a lower number of injections/year (in 60% of the cases these patients only had 1 injection in 12 month time).

Whole pharmaceutical expenditure was 5.311.218€/year.

Table 2: Whole expenditure for the 1979 patient/years and number of injections stratified by disease and age

Disease/ Age group	Whole expenditure C	Total number of injections	Number of patients	Mean expenditure/ patient	Mean number of injections/ patient	Number of treated eyes	Mean expenditure/ eye	Mean number of injections/ eye
AMD	3.336.294	4.752	1.197	2.787	3,97	1.306	2.555	3,64
46-55	114.054	160	50	2.281	3,20	53	2.152	3,02
56-65	340.880	478	153	2.228	3,12	166	2.053	2,88
>65	2.881.361	4.114	994	2.899	4,14	1.087	2.651	3,78
DME	1.396.778	1.956	464	3.010	4,22	644	2.169	3,04
≤35	55.760	79	18	3.098	4,39	25	2.230	3,16
36-45	55.251	80	23	2.402	3,48	32	1.727	2,50
46-55	221.489	307	64	3.461	4,80	94	2.356	3,27
56-65	516.939	721	160	3.231	4,51	228	2.267	3,16
>65	547.339	769	199	2.750	3,86	265	2.065	2,90
MMD	184.670	282	140	1.319	2,01	146	1.265	1,93
≤35	16.208	25	11	1.473	2,27	11	1.473	2,27
36-45	28.693	44	26	1.104	1,69	28	1.025	1,57
46-55	35.601	53	36	989	1,47	36	989	1,47
56-65	45.757	70	31	1.476	2,26	34	1.346	2,06
>65	58.411	90	36	1.623	2,50	37	1.579	2,43
RVO	393.476	561	178	2.211	3,15	183	2.150	3,07
≤35	7.923	11	4	1.981	2,75	4	1.981	2,75
36-45	28.181	40	14	2.013	2,86	14	2.013	2,86
46-55	39.636	55	18	2.202	3,06	18	2.202	3,06
56-65	61.599	88	35	1.760	2,51	35	1.760	2,51
>65	256.137	367	107	2.394	3,43	112	2.287	3,28
Total	5.311.218	7.551	1.979	2.684	3,82	2.279	2.331	3,31

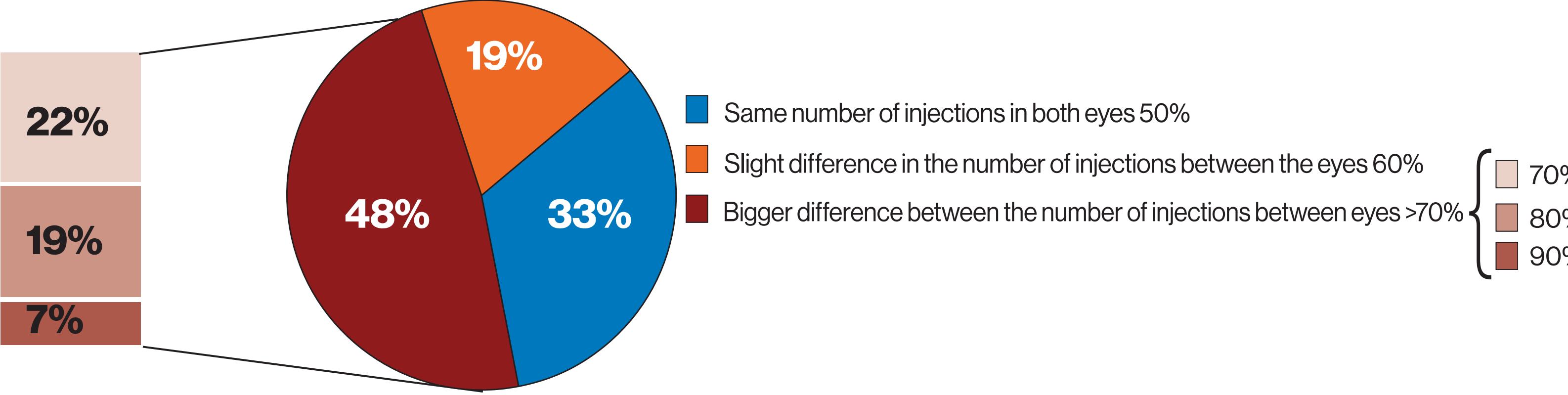
Table 3. The prevalence of patients treated bilaterally splitted by disease, age and sex-gender

Disease	One eye treated		Both eyes treated		Total	
	Number and % of patients	Mean age	Number and % of patients	Mean age	Number of patients (100%)	Mean age
AMD	1.088 (91%)	75	109 (9%)	75	1.197	75
Female	656 (90%)	75	71 (10%)	74	727	75
Male	432 (92%)	74	38 (8%)	76	470	74
DME	284 (61%)	64	180 (39%)	61	464	63
Female	120 (65%)	63	64 (35%)	63	185	63
Male	164 (59%)	64	116 (41%)	60	280	62
MMD	134 (96%)	55	6 (4%)	57	140	55
Female	98 (97%)	55	3 (3%)	54	101	55
Male	36 (91%)	55	3 (9%)	59	39	56
RVO	173 (97%)	67	5 (3%)	77	178	67
Female	66	70	0		66	70
Male	107 (96%)	65	5 (4%)	77	112	65
Total	1.679	71	300 (15%)	66	1.979	70

Number of injections/eye in patients with both eyes treated for AMD

Among the 109 patients with AMD bilaterally treated with anti VEGF, 33% received the same amount of injections in both treated eyes, while almost half of them had a significant difference in the number of injections between the eyes.

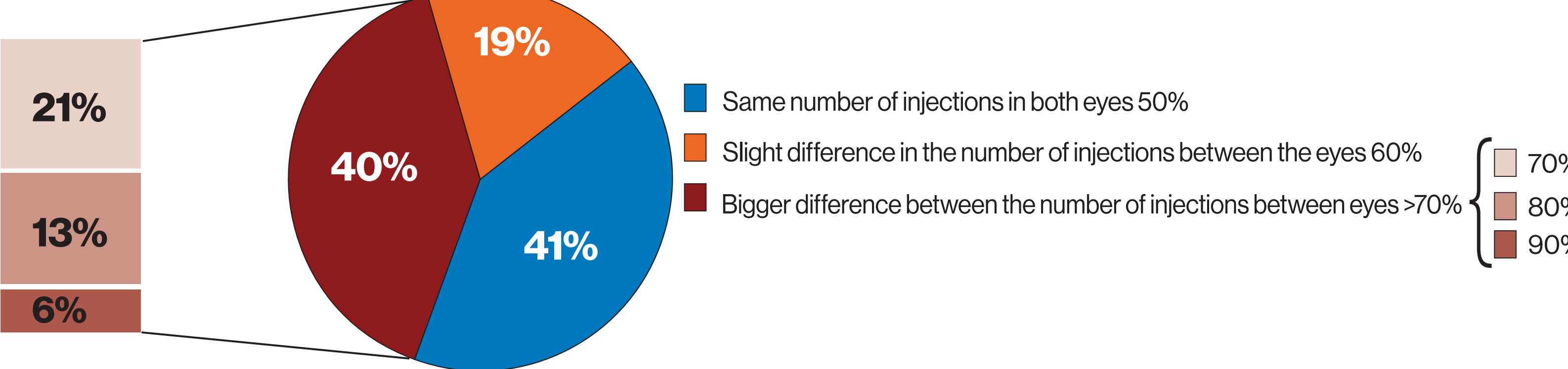
The proportion between the number of injections to the first eye and the total number of injections.



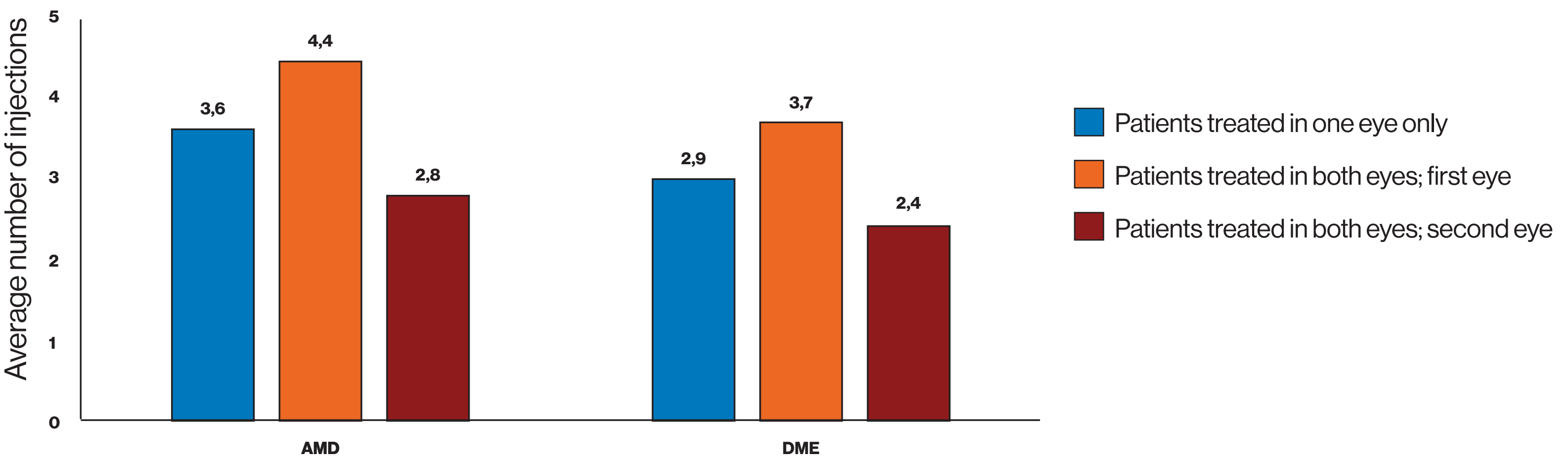
Number of injections/eye in patients with both eyes treated for DME

In the DME patients' population, where both eyes treatment was more frequent, about 40% of the patients received the same number of injections in both eyes; another 40%, receive a higher number of injections in the first treated eye with respect to second. 14% of the patients received only one injection in the second eye, while they had received multiple injections in the first treated eye.

The proportion between the number of injections to the first eye and the total number of injections.



The first injected eye received about 50% more drug injections than the second one



CONCLUSIONS

The anti VEGFs' drug utilization in the 2013-2015 period had arisen to our attention some interesting conclusions.
There was a sub optimal adherence to the treatment when compared to what the drugs' leaflets stated. This may be attributed to the RW setting of the study.
The majority of the drug expenditure was due to AMD, which had the largest pool of patients and was the disease with the highest average number of subministrations/eye.
There was a difference in prevalence between the various diseases in terms of the number of patients treated on both eyes, with DME being the first one with 39% of the patients treated bilaterally.
When patients were treated bilaterally, there was a difference in the number of injections performed in the first and in the second treated eye.