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BEVACIZUMAB BIOSIMILAR USE IN OPHTHALMOLOGY

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INTRODUCTION

Bevacizumab is an anti-VEGF antibody currently used in ophthalmology as an off-label treatment for age-related macular degeneration, diabetic macular oedema, and oedema secondary to retinal vein occlusion. Despite is off-label use, various studies had shown similar results between bevacizumab and other anti-VEGF treatments. With the availability of a biosimilar with same presentation and excipients a switch program was implemented.

AIM AND OBJECTIVES

Compare the effectiveness of Bevacizumab Avastin® versus Biosimilar MVASI® in Ophthalmology Department.

METHODS

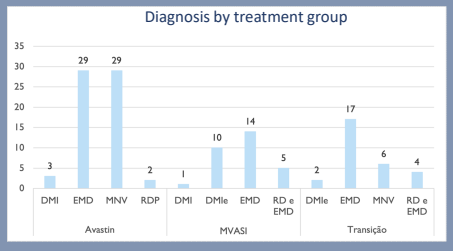
A retrospective observational study analyzed 122 patients (65 were male and 57 female) who underwent the first intravitreal administration (IVI) between January 2020 and March 2021. Data from best corrected visual acuity (BCVA) and central subfield thickness (CST) were collected. Exclusion criteria were the absence of registration of Optical Coherence Tomography (OCT) and BCVA or failure to comply to 3 loading dose injectins. The patients were divided into 3 groups: group 1, 63 patients (3IVI of Avastin), group 2, 30 patients (3 IVI of biosimilar), and group 3, 29 patients (3 IVI, transitioning from Avastin® to the biosimilar, either with 1 or 2 Avastin® administrations. Manova test was used to determine statistically significant differences among the groups, taking into account the values of BCVA and CST, patient's age, and the number of days between the last registration prior to the first IVI and the first posterior to the third IVI, without any corrections for differences between groups. T-tests were used to obtain graphic representations of the results.

RESULTS

The analyzed sample had a mean of ages of 71.56 years. After three IVI, in group 1, there was 82% of improvement for CST; in group 2 there was 92% and for group 3 there was 84%. MANOVA test was performed showing no statistical significance in BCVA and OCT central thickness difference between three groups [Wilk's Lambda (p=0.238)] neither between MVASI group with the Avastin® group [Hotelling T-square Test (p=0.114, equal covariance)].

	Avastin ®			Mvasi®			Transition		
	Average	IC95%	n	Average	IC95%	n	Average	IC95%	n
Age	73,65	[71,36;75,94]	63	63,8	[63,73;71,87]	30	73,24	[68,93;77,55]	29
Evaluation Days	117	[110,7;123]	63	121	[112,3;129,4]	30	128	[120,7;136]	29
AVD	3,73	[3,06;4,4]	43	3,39	[2,52;4,25]	22	3,34	[2,29;4,25]	16
AVD	3,59	[2,92;4,27]	43	4,46	[3,5;5,1]	22	3,59	[2,41;5,41]	16
Δ AVD	-0,14	[-0,78;0,5]	43	1,07	[0,26;1,88]	22	0,25	[-0,32;1,88]	16
ECC	3,73	[345;403]	63	348	[309;391]	28	404	[355;460]	28
ECC	305	[281;330]	63	315	[281;352]	29	336	[295;382]	29
Δ ECC	81,80%	[0,748;0,894]	63	91,90%	[0,83;1,017]	27	83,60%	[0,761;0,919]	28

Table 1. Clinical data evaluated
AVD: Snellen visual acuity, on the decimal scale; ECC: sub-centre field thickness, in µm



Figur1 1. Diagnosis by treatment group
DMI – Age-related macular degeneration; DMIe - Age-related macular degeneration with choroidal neovascularization; MNV – Neovascular Membrane; EMD – Diabetic Macular Edema; RD – Diabetic Retinophaty; RDP – Prolifeative Diabetic Retinopathy

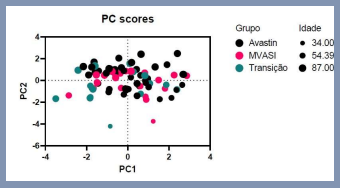


Figure 2. Analysis of the main componentes: age, number of days between assessments, initial ADL, final ADL, initial ECC and final ECC

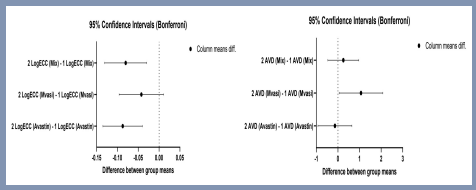


Figure 3. T Tests for paired differences

CONCLUSION

We found no difference, for the analyzed sample, in outcomes and adverse effect between Avastin® and biosimilar MVASI, which supports the switching program from Avastin® to MVASI® in Ophthalmology in simultaneous with oncology, ensuring a significant cost reduction.