BEACON (BEAVRS case collection initiative) study outline form

Full Title: The use of "autologous or allogenic plugs" in vitrectomy for the surgical management optic disc pit maculopathy
Acronym: OPTIMA (autologous or allogenic plugs in vitrectomy for the surgical management optic disc pit maculopathy)

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What you are studying: Anatomical and functional results of vitrectomy combined with different ancillary techniques involving the creation of a plug for the optic disc pit with autologous (e.g. internal limiting membrane (ILM) flap, sclera, neurosensory retina, platelet-rich plasma) or allogenic tissues (e.g. human amniotic membrane)

What is your primary research question: Is vitrectomy and autologous/allogenic tissue plugging an effective surgical option for the treatment of optic disc pit maculopathy?

Background and importance: A wide variety of surgical approaches have been proposed for the treatment of optic pit maculopathy with varying success rates. In particular, pars plana vitrectomy has been combined with different ancillary techniques, including ILM peeling, endolaser and use of various autologous or allogenic tissues as a plug over or in the optic disc pit. So far, no conclusive evidence is available regarding the comparison of these techniques in terms of anatomical and functional results.

Case definition:
Inclusion criteria:

- Patients undergoing a plugging technique for the primary or secondary management of optic disc pit maculopathy.

To note: the last surgery performed (index surgery) has to be the one in which a plugging material was used. Please, include both successful and failed cases.

Exclusion criteria:

- patient lost to follow-up before 1 year
- high myopia (>-6 dioptres or axial length >26mm)
- late age-related macular degeneration
- diabetic retinopathy worse than background or presence of diabetic maculopathy
- uncontrolled intraocular inflammation
- glaucoma with significant optic disc damage or other optic nerve diseases

Likely incidence:
Prospective/Retrospective data collection?: Retrospective data collection.

If Retrospective:
Eligible study period: January 2017 – December 2021
Target completion for end of data collection: ≥ 40 cases by the end of December 2022

Primary outcome measure: anatomical success (resolution of intra- and sub-retinal fluid)

Secondary Outcome measures: postoperative visual acuity, distribution of intra-retinal and/or sub-retinal fluid

Pre-planned analysis outline: Descriptive statistics will be used to calculate demographic data. Mann-Whitney U test will be used to assess nonparametric continuous data and chi-square test for categorical data. T-test and Wilcoxon rank-sum test will be performed for comparative tests. P values ≤ 0.05 will be considered statistically significant.

Data collection form(s): see Excel file attached

Images required: OCT over the macular area allowing the calculation of central foveal height, central macular thickness (1-mm diameter centred on the foveal centre) and macular oedema extent, OCT over the disc. The images will be anonymised by study number.

Commented [HRJ1]: Any reason not to extend further back? One of mine is from 2016, for example.