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Retinal detachment: a prognostic factor analysis

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Retinal detachment: a prognostic factor analysis

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Dr. Manuel Alberto de Almeida e Sousa Falcão

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Retinal detachment: a prognostic factor analysis

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RETINAL DETACHMENT: A PROGNOSTIC FACTOR ANALYSIS

Prognostic factors in retinal detachment

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Abstract

Purpose: To evaluate prognostic factors for retinal detachment.

Methods: The patient's medical records were reviewed and preoperative and intraoperative data analysed to ascertain an association with the outcomes: VA ≤0,52 logMAR, VA ≤0,3 logMAR, VA ≤0,52 logMAR in eyes with macula-off and redetachment.

Results: The difference in final visual acuity between the population of macula-on and macula off was statistically significant (t-test: p <0,001). Mean postoperative VA was 0,41 ± 0,51 logMAR (n= 39; Snellen: 20/51) and 0,62 ± 0,59 logMAR (n=109; Snellen: 20/83), respectively. Macula-off was a factor of poor prognosis (final VA worse than 0,3 logMAR). Mean time to surgery was 4 days. The time to surgery did not affect final VA < 0,52 logMAR (p=0,694).

Conclusions: The state of the macula only influenced the prognosis in a negative way when the final VA considered was 0,3 logMAR. These situations can be managed as urgent procedures without the need of emergency interventions. In our series, time to surgery and pre-operative visual acuity were not prognostic factors.

Keywords: retinal detachment, prognostic factors, macula

Introduction

Retinal detachment occurs when the sensory retina and the retinal pigment epithelium separate (1,2,3).

Three types of retinal detachment have been described: Rhegmatogenous, tractional and exsudative. Only the first type will be considered in this paper.

The most common type (2,3,4), rhegmatogenous retinal detachment (RRD), is due to a retinal tear or break that may be instigated by trauma or posterior vitreous detachment (1). This break allows the accumulation of liquefied vitreous between the sensory retina and the retinal pigment epithelium. Posterior vitreous detachment is characteristic of the elderly, but there are other risk factors that can lead to this condition such as myopia, aphakia, focal retinal atrophy, trauma (1,4), family history and retinal detachment in the fellow eye (3).

Affected individuals may be asymptomatic. However, most people have symptoms: photopsia, floaters, visual field loss, diminished visual acuity (VA) or blurred vision (1,4). The diagnosis can be confirmed by ophthalmoscopy (3).

If the tear is not repaired, the progressive accumulation of fluid between layers will have degenerative effects and eventually lead to blindness (3).

A study undertaken in Portugal in 2010 estimated an incidence of 19 cases per 100000 inhabitants (2).

There are many treatment options. If there is just a tear in the retina, laser or cryotherapy may prevent the progression of fluid in the subretinal space preventing a complete retinal detachment. Nonetheless, if the retinal detachment is established, the first line treatment is surgical. Up to now the

preferred surgical technique lacks consensus (5) but several options are available, being retinopexy, scleral buckling and vitrectomy with internal tamponade the most frequently used surgical approaches (3).

Up to now, the definition of prognostic factors still raises substantial discussion. Several definitions have been put forward, among which the most consensual ones are macula on/off (2,6,7,8,11), number of days until surgery (2,5,8,9,12,13), pre-operatory visual acuity (6,9) and age (9,10). Notwithstanding the results are yet to be widely accepted, particularly with regards to the number of days between the retinal detachment and surgery.

This paper aims to analyse the prognostic factors in our population in the total number of retinal detachments and in patients with macula-off retinal detachments.

Methods

During a 29-month period, from January 2008 until May 2010, all patients with a retinal detachment who were admitted to Hospital de São João from the emergency department or referred by ophthalmologists, were enrolled in this study.

Data was collected retrospectively from the medical records. Initially, all patients were included (n=265). Subsequently, those with retinal redetachment or retinal detachment other than rhegmatogenous were excluded.

The following variables were analysed: age, sex, type of retinal detachment, affected eye, date of diagnosis, number of days from the appearance of the first symptoms until diagnosis, number of days until surgery, pre-operative visual

acuity (logMAR), myopia, phakia, simultaneous phacoemulsification with intra-ocular lens implantation, number of quadrants involved, number of tears, location of the tears, presence of a giant tear, macula on/off, pre-operative proliferative vitreoretinopathy (PrePVR), vitreous haemorrhage, surgical technique (vitrectomy, scleral buckling or combined vitrectomy and scleral buckling), vitreous substitute, primary surgeon, pneumopexy used (cryotherapy or laser), final visual acuity at least 5 months after surgery (logMAR), and redetachment rate.

A literature review of the studies focusing on prognostic factors of retinal detachment has been conducted in the MEDLINE database up to March 2014. Studies have been identified by using combinations of key words and through MeSH-based electronic searches. The reference lists of the relevant studies were thoroughly searched for additional studies.

Statistical analysis was performed using SPSS version 22 (SPSS inc, Chicago, Illinois, USA). Descriptive statistics were obtained for all variables. Univariate analysis was performed to assess the association between the explanatory variables and the final outcome, using Mann-Whitney U test and Chi-square test. Logistic regression models were developed to identify factors that might influence the prognosis. Four outcomes were analysed: post-operative VA of 0,52 logMAR or better, postoperative VA of 0,3 logMAR or better, redetachment during follow-up, and postoperative VA of 0,52 logMAR or better in the macula-off population. The level of statistical significance was set at $p<0,10$.

Results

The study included 245 eyes (Table I). The mean age of all patients was 60±14 years (mean ± standard deviation) and there were 150 men (61,2%). A total of 156 eyes were phakic (63,7%), 70 were pseudophakic (28,6%) and 7 were aphakic (2,9%). The macula was detached in 164 patients (66,9%), pre-operative proliferative vitreoretinopathy was present in 12 patients (4,9%) (missing data: 17 (6,9%)) and vitreous haemorrhage in 18 patients (7,3%) (missing data: 15 (6,1%)).

The mean time since the appearance of symptoms to diagnosis and to surgery was 19,08 ± 87,62 and 4,42 ± 4,47 days respectively. In the subpopulation with macula-on, the mean time to surgery was 4,67 ± 7,10 days while in those with macula-off it was 4,32 ± 2,64 days since diagnosis.

The most common procedure performed was vitrectomy in 185 patients (75,5%) (missing data: 3 (1,2%)). As for the others, 51 (20,8%) had vitrectomy + scleral buckle and 6 (2,4%) performed scleral buckling. A vitreous substitute was used in 236 patients (96,3%) (missing data: 9 (3,7%)): gas tamponade (70,6%) and silicone oil tamponade (25,7%).

Simultaneous cataract surgery and intra-ocular lens implantation was performed in 121 patients (49,4%) (missing data: 2 (0,8%)). Retinopexy was performed by cryotherapy in 10 patients (4,1%) and laser in 228 patients (93,1%). In 2.8% of cases, there was no information regarding retinopexy procedures.

Pre-operative VA was documented in 188 patients (1,35 ± 0,88 logMAR). Post-operative VA was recorded in 148 patients. The information regarding pre-operative macular status was missing in 9 of these patients. Mean postoperative VA was 0,58 ± 0,59 logMAR (20/76). In the macula-on population,

the mean postoperative VA was 0,41 ± 0,51 logMAR (n= 39; Snellen: 20/51). Considering the macula-off population, mean postoperative visual acuity was 0,62 ± 0,59 logMAR (n=109; Snellen: 20/83). This difference in visual acuity was statistically significant (t-test: p <0,001).

Visual acuity was then dichotomized using two different outcomes: 0,3 logMAR (Snellen: 20/40) and 0,52 logMAR (Snellen: 20/66). From the 148 patients, 85 (57,4%) had a visual acuity worse than 0,3 logMAR, whereas 47 (31,8%) had a visual acuity worse than 0,52 logMAR. 145 patients were considered when comparing the patients final VA and macular status. Among those patients with a final VA worse than 0,52 logMAR, 7 were macula-on eyes (17,9% of the total macula on eyes) and 38 were macula-off eyes (35,8% of macula-off eyes). As for those with a final VA worse than 0,3 logMAR, 16 (41%) were macula-on and 66 (62,3%) were macula-off eyes.

A univariate analysis to identify the factors that could be associated with a final visual acuity better than 0,52 logMAR was initially performed. The following factors were selected to perform a logistic regression: preoperative VA, number of retinal tears, giant retinal tear, macula on/off, type of vitreous substitute and cryotherapy (the variables with p>0,2 were excluded). The logistic regression analysis revealed that multiple retinal tears (p=0,083) and gas tamponade (p=0,025) correlated statistically with the outcome (Table II). The involvement of the macula was not associated with the end result (p=0,807).

To evaluate the independent predictors of poor outcome for a final visual acuity worse than 0,3 logMAR (Table III), the risk factors selected after the univariate analysis were: gender, time to surgery, number of quadrants involved, giant

retinal tear, macula on/off, surgical technique and type of vitreous substitute (the variables with p>0,2 were excluded). Two significant associations with final visual acuity were established with the logistic regression analysis: macula off (p=0,060) and use of silicone oil tamponade (p=0,054). In this case, time to surgery did not show an association with the outcome (p=0,694).

A univariate analysis was performed to select the variables for the logistic regression model in the subpopulation with macula-off, comparing those with a final VA better or worse than 0,52 logMAR. Time to surgery, number of retinal tears, vitreous haemorrhage and cryotherapy entered the logistic regression model (the variables with p>0,2 were excluded). Table IV shows that the presence of a vitreous haemorrhage (p=0,082), the use of silicone oil tamponade (p=0,054) and cryotherapy (p=0,071) are statistically significant predictors of a final visual acuity worse than 0,52 logMAR.

Retinal redetachment occurred in 44 patients (18%). In this case, the variables selected for the logistic regression model by the univariate analysis were: gender, presence of PrePVR, surgical technique and cryotherapy (the variables with p>0,2 were excluded). With regards to this outcome (Table V), performing indentation plus vitrectomy (p=0,064), as well as female gender (p=0,024), were associated with the outcome (no redetachment).There was some evidence of association between redetachment and the presence of PrePVR (p=0,1).

Discussion

Multiple surgical techniques can be used to approach retinal detachment. It is therefore very difficult to try and evaluate factors associated with a better prognosis, as several confounding variables may be present.

Nonetheless, in this series, our aim was to ascertain the prognostic factors of rhegmatogenous retinal detachment. Two visual outcomes were defined: 0,3 logMAR, usually considered driving vision, and 0,52 logMAR – reading vision.

This series demonstrated that there are two factors associated with better prognosis in order to have a VA 0,52 logMAR or better. These are: multiple tears (ORs (95% (CI): 0,145 (0,016 – 1,288)) and use of gas tamponade (ORs (95% (CI): 0,241 (0,070 – 1,834)). On the other hand, the use of silicone oil tamponade was linked with bad prognosis if the outcome was 0,3 logMAR (ORs (95% (CI): 2,780 (0,938 – 7,856)). Time to surgery was not associated with either of these outcomes.

Our series revealed that the type of vitreous substitute used (gas or silicone oil) can be an important prognostic factor. Silicone oil was a factor of poor prognosis for two of the outcomes analysed: final VA 0,3 and final VA 0,52 in the macula-off population. We must take into consideration that silicone oil is generally used when surgeons feel that there is a higher risk of redetachment and when a poorer prognosis is already expected. Therefore, it is likely that it is not the silicone oil that is a factor of poorer prognosis but rather that it is the tamponade that is used in patients that has a predisposition for a poorer prognosis. It is possible that silicone oil is a confounding variable. Nonetheless,

with this retrospective analysis, we were not able to determine which isolated variables led to the decision of using silicone oil as the internal tamponade.

In our series, we found an association between multiple tears and having a final visual acuity better than 0.52 logMAR. However, when we raised the threshold for good prognosis to the level of 0.3 logMAR, the number of retinal tears was not associated with the final prognosis. Caution must be taken in interpreting these results. Visual acuity is not related with the peripheral retina and therefore, theoretically speaking, the number of tears should not interfere with visual acuity. Further studies that focus on the number of retinal tears may help to explain these results.

Our findings showed that, although there was no association between visual acuity and macula using the cut-off of 0,52 logMAR (p=0,807), if we used the cut-off 0,3 logMAR, the association could be made (p=0,060). The reason is that many patients with macula-off retinal detachments can achieve visual acuities better than the cut-off we defined; as such, the probability of having at least reading vision after a retinal detachment is the same in people that present an attached or detached macula and it is greater than 50% in both studied populations. However, the patients that presented a macula-on retinal detachment had a better final visual acuity (0,41 ± 0,51 logMAR) compared with those with macula-off (0,62 ± 0,59 logMAR) (odds ratios (ORs) (95% confidence interval (CI): 2,286 (0,965 – 5,414)). These findings are consistent with other reports that have been published (7,11). Salicone (7) reported that 78% of patients with macula-off had final visual acuity worse than 0,3 logMAR compared with 28% in the macula-on group. We demonstrated that the probability of having a final visual acuity better than 0.3 logMAR was greater in

the patients with macula on, showing that an attached macula is an important prognostic factor for better final visual acuities. However, in our series, pre-operative visual acuity was not associated with final visual acuity. We expect patients with a macula-on retinal detachment to have a better visual acuity at diagnosis and these two variables could have similar significance. However, there are patients with bullous retinal detachments with hidden macula-on detachments. This is probably why the status of the macula is a better prognostic factor than pre-operative visual acuity.

When analysing the macula off population and using the endpoint of 0,52 logMAR, we found three risk factors associated with poor prognosis: vitreous haemorrhage on diagnosis (ORs (95 %CI): 9,206 (0,752 – 112,742)), the use of silicone oil tamponade (ORs (95% (CI): 3,561 (0,980 – 12,940)) and cryotherapy (ORs (95% (CI): 5,908 (0,856 – 40,761)). However, since vitreous haemorrhage was present in 4 patients only and cryotherapy was performed in 8 patients, these variables presented very wide confidence intervals, and therefore their results must be carefully interpreted.

Focusing on the group of patients with macula-off, many authors have discussed the role of the time to surgery. This series showed that there is no association between the number of days until surgery (p=0,694) and the final outcome (using the endpoint: final visual acuity 0,3 logMAR). Other authors have reported the same findings (7-9, 12-13). However, the number of days in which this hypothesis can be verified is still under discussion. Thelen (13) reported that the surgery could be postponed for 3 days without compromising the prognosis, while Ross (8) reported a 7-day period, Hassan (9) a 10 day period and Doyle (13) a 30 day period. Our series showed that a 4-day wait

from diagnosis to surgery probably does not interfere with final visual acuity. These findings have clinical relevance as the decision to have surgery can be postponed for a short period of time until the best conditions for surgery can be optimized. Surgery for retinal detachment can be considered an urgent, but not an emergent, condition.

We must emphasize that 242 of our patients had surgery within 2 weeks from the initial symptoms. We cannot infer results for patients that have had retinal detachments for more than two weeks.

With resgards to redetachment rates, Foster (14) reported a 12% incidence of retinal detachment. In our series, 18% of cases redetached. Performing scleral buckling along with a vitrectomy was associated with better prognosis (ORs (95 %CI): 0,064 (0,003 – 1,487)), as well as female gender (ORs (95 %CI): 0,372 (0,158 – 0,876)). These results differ from those of Kinori (15) who reported equal redetachment rates for cases treated solely with vitrectomy and for cases treated with vitrectomy and scleral buckle. Our series show that there may still be a role for a combined procedure in selected patients. Finding a protective effect in the female patients has not previously been reported. Although genetic markers have recently been associated with proliferative vitreoretinopathy (16)**,** gender has not been classically associated. We may hypothesise that these differences can be related to unknown hormonal factors that must be confirmed and investigated by further studies.

Preoperatory proliferative vitreoretinopathy showed some degree of association with retinal redetachment (p=0,1; ORs (95% (CI): 3,083 (0,806 – 11,799)).

Nevertheless, only 12 patients (4,9%) presented with this condition rendering the variable a poor estimate.

Our study has limitations. The major weakness is the retrospective nature of the study that used clinical records of regular clinical practice that lacks important data, making statistical analysis challenging. As far as visual acuity is concerned, this variable was not evaluated at the same post-operative stage. The range varies from five to 24 months. It has been suggested that visual acuity continues to improve for a period of up to 5 years (17), and this may limit the extrapolation of the results.

Conversely, we have a large number of patients, which allows us to draw some conclusions.

The majority of macula-on and macula-off patients present a visual acuity better than 0.52 logMAR. Nevertheless, having a macula-on increases the probability of having a visual acuity better than 0.3 logMAR. Furthermore, those patients with macula off can obtain reading vision in the majority of cases and surgery can be postponed for some days without compromising the results. Lastly. there might still be a role for combined vitrectomy and scleral buckling for retinal detachments for the prevention of redetachment.

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Table I

Characteristics of the sample

Variables		Missing data n (%)
Socio-demographic characteristics		
Age (years)		0
Mean (SD)	60±14	
Gender, n (%)		0
Male	150 (61,2%)	
Female	95 (38,8%)	
Time to diagnosis (days) (mean ± SD)	19,08 ± 87,62	74 (30,2%)
Time to surgery since diagnosis (days) (mean ± SD)	4,42 ± 4,47	2 (0,8%)
Preoperative VA logMAR (mean ± SD)	1,35 ± 0,88	57 (23,3%)
Refractive error, n (%)		85 (34,7%)
Myopia < -6D	125 (51%)	
Myopia > -6D	35 (14,3%)	
Lens status, n (%)		12 (4,9%)
Phakic	156 (63,7%)	
Pseudophakic	70 (28,6%)	
Aphakic	7 (2,7%)	

RRD extent, n (%)		17 (6,9%)
1 quadrant	48 (19,6%)	
2 quadrant	101 (41,2%)	
3 or 4 quadrant	79 (32,2%)	
Retinal tears, n (%)		30 (12,2%)
None	24 (9,8%)	
One	110 (44,9%)	
Multiple	81 (33,1%)	
Giant retinal tear, n (%)		26 (10,6%)
Yes	18 (7,3%)	
No	201 (82%)	
Macula, n (%)		9 (3,7%)
On	72 (29,4%)	
Off	164 (66,9%)	

Abbreviations: VA – visual acuitity; D – diopters; RRD – Rhegmatogenous retinal detachment; SD – standard deviation

Table II

Results of the logistic regression analysis for final visual acuity lower than 0,52 logMAR.

Risk Factors	p value	Odds ratio	95% CI
Preoperative VA	0,154	1,873	0,791-4,433
Retinal tears			
None		1.0 (referent)	
One	0,422	0,427	0,053-3,408
Multiple	0,083	0,145	0,016-1,288
Giant tear	0,231	2,878	0,510-16,228
Macula on/off	0,807	1,230	0,233-6,494
Gas Tamponade	0,025	0,241	0,070-0,834
Cryotherapy	0,095	5,077	0,755-34,160

Abbreviations: VA – visual acuity; CI – confidence intervals

Table III

Results of the logistic regression analysis for final visual acuity lower than 0,3 logMAR.

Risk Factors	p value	Odds ratio	95% CI
Gender, Female	0,398	1,409	0,637 – 3,121
Time to surgery	0,694	1,034	0,874-1,225
RDD extent			
1 quadrant		1.0 (referent)	
2 quadrant	0,435	1,438	0,578– 3,578
3 or 4 quadrant	0,204	1,990	0,965- 5,760
Macula on/off	0,060	2,286	0,965- 5,414
Giant tear	0,130	3,137	0,714-13,790
Scleral buckle + vitrectomy	0,312	1,601	0,634-3,991
Silicone oil Tamponade	0,054	2,780	0,983-7,856

Abbreviations: RDD - Rhegmatogenous retinal detachment; CI – confidence intervals

Table IV

Results of the logistic regression analysis for final visual acuity < 0,52 logMAR in the macula-off population.

Risk Factors	p value	Odds ratio	95% CI
Time to diagnosis	0,761	1,004	0,977 – 1,033
Vitreous haemorrhage	0,082	9,206	0,752 – 112,742
Silicone oil Tamponade	0,054	3,561	0,980 – 12,940
Cryotherapy	0,071	5,908	0,856 – 40,761
Retinal tears			
None		1.0 (referent)	
One	0,722	0,727	0,126-4,193
Multiple	0,117	0,218	0,031-1,465

Abbreviations: CI – confidence intervals

Table V

Results of the logistic regression analysis for retinal redetachment

Risk Factors	p value	Odds ratio	95% CI
Gender, Female	0,024	0,372	0,158 – 0,876
PrePVR	0,100	3,083	0,806 – 11,799
Surgical technique			
Indentation		1.0 (referent)	
Vitrectomy	0,242	0,170	0,009 – 3,311
Scleral buckle + vitrectomy	0,087	0,064	0,003 – 1,487
Vitreous substitute	0,981	0,996	0,728 – 1,363
Cryotherapy	0,282	2,268	0,511 – 10,074

Abbreviations: CI – confidence intervals; PrePVR - preoperatory proliferative vitreoretinopathy

Anexos

CONTENT TYPE

Original articles. Previously unpublished manuscripts, directed to ophthalmologists and visual science specialists describing clinical investigations, clinical observations, relevant clinical laboratory investigations. An original article should consist of around 16-18 double-spaced, typewritten pages, corresponding to 6-8 printed pages. The text of articles must be divided into sections with the headings Introduction, Methods, Results and Discussion

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- **Meeting presentation**. If the paper was presented at a meeting, state its name, place and date on which it was read;
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f) Structured abstract, which must not exceed 250 words and which must be structured and divided in the sections Purpose, Methods, Results, and Conclusions. It must be acceptable for use without revision.
g) Below the abstract, identify 3 to 6 keywords in alphabetical order under which you believe the article should be indexed.
h) If you are submitting a manuscripts which has been previously rejected please inform the Journal and the Reviewers of the previous review comments, how and where the manuscript has been improved according to the reviewers' comments.

MANUSCRIPT TEXT

Starting on a **new page**, type manuscript using Arial font size 12, as this creates less problems when building your PDF, and save it as Word document (.doc). Use double spacing and do not justify the right margin. Use only standard abbreviations and avoid abbreviations in the title. The full term for which an abbreviation stands for should preceed its first use in the text. The average published manuscript in European Journal of Ophthalmology, including references, is up to 6 pages in length. This corresponds to between 16 and 20 double-spaced typewritten pages. Type your manuscript as a single Word file, divided in the following sections:
Introduction: should be pertinent to the study but not an in-depth review of the literature.
Materials and methods: should be clearly defined so that the study may be duplicated by other investigators.
Results: should be as concise as possible.

Discussion: offers an explanation of the results of the study and should limit itself to the subject matter of the paper.

Cite figures consecutively in the text and number them in the order in which they are presented. Figures must be submitted as separate files and not embedded in the word document.

CANCER CLASSIFICATION SCHEME

The European Journal of Ophthalmology encourages Authors to use the classification scheme proposed by the American Joint Commission on Cancer. Please use these when describing patients with ophthalmic malignancies (see AJCC Cancer Staging Manual, 7th Edition, Springer New Yok)

ACKNOWLEDGEMENTS

Acknowledge statistical consultation and assistance or writing assistance (when provided by a person different from the author) in an acknowledgement at the end of the article before the references Indicate the name, degree and affiliation of the individual. For all others assisting in the preparation of a manuscript acknowledgements cannot be done, however valuable their service.

REFERENCES

1. If you use automated reference numbering software or bibliography software, **turn it off before submitting the manuscript.**
2. References should follow the text and begin **on a separate page**.
3. They must be double-spaced and numbered consecutively in order of appearance in the text, using the automated numbering tool of Word.
4. Identify references in text, tables, and legends in Arabic numerals in parentheses, i.e. (7).
5. If there are 6 or fewer authors, all authors should be listed. If there are more than 6 authors, list the first three and then "et al"
6. References used within tables should appear as footnotes in the table legend. **These references should not be repeated in the main reference list unless they are also cited within the text.**
7. List only references pertinent to the manuscript, which you have read and that the reader can retrieve in a literature research.
8. Journals' names should be abbreviated according to Index Medicus/Medline. If there is any doubt about abbreviation of a journal name, it should be spelled out completely.
9. All references must be verified by the Author(s) against the original documents.
10. Personal communications, unpublished data, abstracts, oral or poster presentations should be limited and incorporated in parentheses within the text without a reference number.
11. Any references to studies (including books or articles) that have been accepted for publication, but not yet published, should indicate where they will be published and have the term "in press" in the reference in place of volume and page numbers. These must be updated prior to publication, if possible.
12. Delete digits when in the same range: 534-7 or 1007-11 (NOT 534-537; 1007-1011)
13. Do not add a discussion or comment to a reference. If applicable indicate it as Eur J Ophthalmol. 2007;17:534-7, Comment in: Eur J Ophthalmol. 2009;19:327; author reply 327.
14. Suffixes such as Jr, Sr, and III follow authors initials

The inclusion references available onlline only should be limited: if also available in print, then it is preferred to include the print citation. The online reference should be listed with complete information including title and authors, adding the URL address and date of access, which should always be confirmed with every revision submission.

Reference formatting examples:

Standard journal article*: (List all Authors when six or less; when seven or more, list only first three and add et al.) Gass JD, Harbin TS Jr, Del Piero EJ. Exudative stellate neuroretinopathy and Coats' Syndrome in patients with progressive hemifacial atrophy.* ***Eur J***

Ophthalmol. 1991;1:2-10*.*
Book: *Harrington DO, Drake MV. The visual field. Text and atlas of clinical perimetry, 6th ed.* ***St Louis: CV Mosby, 1990; 156.***

FIGURE LEGENDS
Starting **on a new page**, type legends for figures double-spaced, with Arabic numerals corresponding to the figures. All figures must have a legend. When symbols, arrows, numbers, or letters are used to identify parts of the figures, identify and explain each one clearly in the legend. Any figure that has been published elsewhere should have an acknowledgment to the original source; a copy of the release to publish the figure, signed by the copyright holder, must also be submitted.

TABLES
As a general rule, tables should not unnecessarily offer duplicate information given in the text. Starting on a new page, type each table on a separate sheet, using double spacing. Tables should be created in a Word document using the table tools.**Do not format tables as columns** or tabs and do not submit tables as figures. Tables should be numbered consecutively in Roman numerals by order of citation in the text. Each table must include title, appropriate column heads and explanatory legends, including definitions of any abbreviation used. References used within tables should appear as footnotes in the table legend. These references should not be repeated in the main reference list unless they are also cited within the text.

SUMMARY STATEMENT
On a separate file please supply a summary statement (90/100 words) describing the purpose, the methodological outline and the main outcomes of your submission. The objective of this is to provide the reader with a brief, quick and focused summary of your work in the perspective of other data. This is different from a version of the Abstract and is not a cover letter.
(**An example**: This pilot study, the first of its type, was conducted to determine the features of five different types of metals on computed tomographic (CT) scan. Pre-measured spherical pieces of iron, copper, lead, aluminum and silver were inserted into animal eyes. All five metal types measured on CT were larger than actual size. Iron was enlarged by a factor of 2.29; silver, 1.77; copper, 1.26; and aluminum, 1.17. Features including central core, ring density and artifacts varied for each type of metal, giving each one a characteristic appearance.)

FIGURES AND ILLUSTRATIONS
Cite figures consecutively in the text, and number them in the order in which they are discussed. Figures must be submitted as individual files, choosing "figure" in the pull down menu in the “Attach file” step during the submission. Below it there is the "Description" box; where you should enter the figure number. Do not enter legends here, just the figure number. Please name figure files as fig. 1, fig. 2 etc. Always ensure that the file extension is present to ensure quick and easy format identification.

Clinical photographs (including those generated electronically from machines such as MRIs, fluorescein angiography, visual fields, etc.) must be masked to prevent identification of the patient. Clinical photographs that permit identification of an individual (those exposing anything more than just the eyes) must be accompanied by a signed statement by the patient or guardian granting permission for publication of the pictures for educational purposes.

Do not embed figures in the Word document .

If figures are not submitted in a high enough resolution for publishing, they will be returned to the author.

Digital art should be created/scanned, saved and submitted as either a TIFF (tagged image file format) or an EPS (encapsulated postscript) file. Do not submit figures as PPT files (Powerpoint files). Electronic photographs and scanned images must have a resolution of at least **300 dpi** . Line art must have a resolution of at least **1200 dpi**. Any figure containing text should be saved **only** as TIFF file. Color images must be created/scanned and saved and submitted as CMYK files. The physical dimensions of any artwork must fit within the dimensions of the pages within the Journal. (i.e., width no more than 10 cm)

No text should appear on the face of a figure. Lettering, arrows, and other symbols should be large enough to remain legible after reduction to a figure with a base of 10 cm. All symbols or letters that appear on the figures should be defined in the legend. Composites are recommended for figures in more parts (e.g., Fig 1A, 1B, 1C, 1D, 1E), labeled using typed text in a corner of the each image. Composite are encouraged for multipanel figures. Arial font should be used for any lettering or text on a figure. If possible use the same font type and size in all artworks (we recommend Arial 12).

The Author should use colour figures only when necessary. **If a manuscript has been submitted, reviewed and accepted with colour figures, then it MUST be published with colour figures**. The publisher charges authors directly for colour figures included in their manuscript. Colour figure charge is Euro 500,00 for the first page plus Euro 80,00 for each additional page. Authors will receive a colour charge form from the publisher together with the typeset proofs, to be returned completed with the corrected proofs.

A CA c/
para parecer DC
12.2.2014

AUTORIZADO
CONSELHO DE ADMINISTRAÇÃO ® REUNIÃO DE 13 FEV 2014
Presidente do Conselho de Administração
(Prof. Doutor António Ferreira)
Directora Clínica | Enfermeira Directora | Vogal Executivo | Vogal Executivo
(Dra. Margarida Tavares) | (Enfermeira Eurídice Portela) | (Dr. João Oliveira) | (Dr. Amaro Ferreira)

Exmo. Senhor

Presidente do Conselho de Administração do

Centro Hospitalar de S. João – EPE

Assunto: Pedido de autorização para realização de estudo/projecto de investigação

Nome do Investigador Principal: Mafalda Seabra

Título do projecto de investigação: Factores de prognóstico do descolamento da retina

Pretendendo realizar no Serviço de Oftalmologia do Centro Hospitalar de S. João – EPE o estudo/projecto de investigação em epígrafe, solicito a V. Exa., na qualidade de Investigador/Promotor, autorização para a sua efectivação.

Para o efeito, anexa toda a documentação referida no dossier da Comissão de Ética do Centro Hospitalar de S. João respeitante ao estudo/projecto de investigação, à qual endereçou pedido de apreciação e parecer.

Com os melhores cumprimentos.

Porto, 13 / Maio / 2013

O Investigador

Mafalda Seabra

7. SEGURO

a. *Este estudo/projecto de investigação prevê intervenção clínica que implique a existência de um seguro para os participantes?*

SIM ☐ (Se sim, junte, por favor, cópia da Apólice de Seguro respectiva)

NÃO ☒

NÃO APLICÁVEL ☐

8. TERMO DE RESPONSABILIDADE

Eu, Mafalda Maria Laracho de Seabra, abaixo-assinado, na qualidade de Investigador Principal, declaro por minha honra que as informações prestadas neste questionário são verdadeiras. Mais declaro que, durante o estudo, serão respeitadas as recomendações constantes da Declaração de Helsínquia (com as emendas de Tóquio 1975, Veneza 1983, Hong-Kong 1989, Somerset West 1996 e Edimburgo 2000) e da Organização Mundial da Saúde, no que se refere à experimentação que envolve seres humanos. Aceito, também, a recomendação da CES de que o recrutamento para este estudo se fará junto de doentes que não tenham participado em outro estudo no decurso do actual internamento ou da mesma consulta.

Porto, 16 / Maio / 2013

24/05/13

A Comissão de Ética para a Saúde tendo aprovado o parecer do Relator, aguarda que o Investigador/Promotor esclareça as questões nele enunciadas para que possa emitir parecer definitivo.

Prof. Doutor Filipe Almeida
Presidente da Comissão de Ética

Mafalda Seabra

O Investigador Principal

PARECER DA COMISSÃO DE ÉTICA PARA A SAÚDE DO CENTRO HOSPITALAR DE S. JOÃO

emitido na reunião plenária da CES de / /

Considerando que foram prestados os esclarecimentos pedidos pelo investigador

A Comissão de Ética para a Saúde APROVA por unanimidade o parecer do Relator, pelo que nada tem a opor à realização deste projecto de investigação.

Prof. Doutor Filipe Almeida
Presidente da Comissão de Ética

2014.01.28

SÃO JOÃO
HOSPITAL

COMISSÃO DE ÉTICA PARA A SAÚDE – CENTRO HOSPITALAR SÃO JOÃO

PARECER

Título da Investigação: "Fatores de prognóstico do descolamento da retina"

Investigador: Mafalda Maria Laracho de Seabra

Orientador: Dr. Manuel Falcão

Elo de ligação: Dr. Manuel Falcão

Serviço onde se realizará a Investigação: Serviço de Oftalmologia; foi enviada a esta CES uma Declaração de Concordância com a realização do presente trabalho de Investigação, pelo Sr. Diretor do Serviço, Prof. Doutor Falcão Reis

Promotor: N.A.

Pertinência do estudo:

O descolamento da retina é uma urgência oftalmológica que pode conduzir à cegueira total.
Com este estudo pretende-se:

- Averiguar os fatores de prognóstico do descolamento da retina;
- Avaliar a taxa de recidiva.

Conceção do estudo:

Trata-se de um estudo retrospetivo. A amostra será constituída pelos doentes que foram submetidos a intervenção cirúrgica no Centro Hospitalar São João, por descolamento da retina, entre Janeiro de 2012 e Junho de 2012 e que cumpriram 6 meses de *follow-up*.

Será recolhida informação acerca do sexo, idade, estado do cristalino, tipo de cirurgia efetuada, duração do descolamento da retina, nº e quais os quadrantes envolvidos.

Benefício/Risco: N.A., dada a natureza deste estudo

Respeito pela liberdade e autonomia do sujeito: N.A. a obtenção de Consentimento Informado, dada a natureza deste estudo

Confidencialidade dos dados: A confidencialidade será garantida através dum sistema de numeração automática, à qual apenas os investigadores terão acesso

Financiamento: N.A.

Indemnização por danos: N.A.

Propriedade dos dados: Equipa de investigação; está prevista a publicação dos resultados deste estudo numa revista da especialidade.

CV do investigador: A investigadora é aluna do Mestrado Integrado em Medicina na FMUP

SÃO JOÃO
HOSPITAL

COMISSÃO DE ÉTICA PARA A SAÚDE – CENTRO HOSPITALAR SÃO JOÃO

PARECER

Conclusão: Este trabalho cumpre todos os requisitos éticos que permitem a esta CES a emissão de um parecer favorável à sua implementação.

Porto, 28 de janeiro de 2014

A relatora,

Raquel Ribeiro

Comissão de Ética

De: Mafalda [mafseabra@hotmail.com]
Enviado: quinta-feira, 27 de Fevereiro de 2014 12:21
Para: comissao.etica@hsjoao.min-saude.pt
Assunto: RE: Alteração ao Protocolo

Bom dia.
O meu orientador acho relevante avaliar um periodo maior, no contexto da tese de mestrado
Assim sendo, peço que o periodo seja alterado para: Janeiro de 2008 a Dezembro de 2010.

Peço desculpa pela alteração adicional.
Obrigada,
Mafalda Seabra

From: mafseabra@hotmail.com
To: comissao.etica@hsjoao.min-saude.pt
Subject: Alteração ao Protocolo
Date: Mon, 24 Feb 2014 21:21:48 +0000

Envio este email para pedir a alteração das datas sobre o qual se debruça o estudo "Factores de Prognóstico do Descolamento da Retina" aprovado pela Comissão de Ética do Centro Hospitalar de São João no dia 13 de Fevereiro de 2014.
No protocolo enviado estava o periodo de Janeiro de 2012 a Junho de 2012 e passaria a ser de Janeiro de 2008 a Dezembro de 2008.

Obrigada,
Mafalda Seabra

Aprovado

2014.02.28

Prof. Doutor Filipe Almeida
Presidente da Comissão de Ética