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Original article

Results of the treatment of patients with exudative AMD during the COVID-19 pandemic

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ABSTRACT

Background and objective: The SARS-CoV-2 pandemic has caused chaos in all health systems on the planet. It has been difficult to cope with COVID 19, but also to maintain the activity in other specialties. In ophthalmology, the scientific societies recommended providing urgent care, including the intravitreal treatment of patients with active neovascular age-related macular degeneration (AMD), since a delay in treatment implies a potential loss of visual acuity (VA).

The main objective of this study was to measure the impact of the coronavirus lockdown on the activity and visual results in patients with neovascular AMD in Area 3 of Madrid.

Material and method: A retrospective observational study was conducted of all patients with neovascular AMD who attended a consultation and/or received intravitreal treatment in the 3 months before the lockdown.

Results: In the 3 months before the lockdown, 144 patients with neovascular AMD were treated, of whom only 51 attended a consultation during the lockdown and, at 6 months after it, only 117 patients had resumed their follow-up. Mean VA before the lockdown was 58.0 ± 23.7 letters and was statistically significantly reduced to 53.0 ± 27.1 letters at 6 months after the lockdown. We also observed a significant decrease in the number of visits during the lockdown, despite the security measures implemented.

Conclusions: Our study shows that patients with neovascular AMD have had a statistically significant decrease in VA due to the lockdown. A VA of almost 58 letters was reduced to 53 at 6 months after the lockdown. The percentage of patients who lost 15 or more letters doubled. We observed a 63.3% loss of temporary follow-up during the lockdown and a 14.58% loss of permanent follow-up at 6 months after the lockdown.

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Resultados del tratamiento de los pacientes con DMAE exudativa durante la pandemia por COVID-19

RESUMEN

Antecedentes y objetivo: La pandemia SARS-CoV-2 ha supuesto un caos organizativo para todos los sistemas sanitarios del planeta. No solo ha sido complicado hacer frente a la COVID-19, sino también ajustar la actividad asistencial en otras especialidades. En oftalmología las recomendaciones de las sociedades científicas eran dar asistencia urgente y dentro de esta se contemplaba el tratamiento intravitréo de los pacientes con degeneración macular asociada a la edad neovascular (DMAEn) activa, puesto que el retraso en el tratamiento supone una Pérdida potencialmente irreversible de agudeza visual (AV).

El objetivo primario del presente estudio es medir el impacto en la actividad y los resultados visuales del confinamiento por coronavirus en los pacientes con DMAEn en el área 3 de la Comunidad de Madrid.

Material y método: Se plantea un estudio observacional retrospectivo de todos los pacientes con DMAEn que habían acudido a consulta y/o recibido tratamiento intravitréo los 3 meses previos al inicio del confinamiento.

Resultados: Los 3 meses previos al confinamiento se atendieron a 144 pacientes con DMAEn de los cuales solo 51 acudieron durante el confinamiento y a los 6 meses tras el confinamiento solo 117 pacientes han retomado su seguimiento. La AV media antes del confinamiento era de 58 ± 23,7 letras y se redujo de forma estadísticamente significativa a 53 ± 27,1 letras a los 6 meses tras el confinamiento. También observamos una disminución significativa del número de visitas durante el confinamiento a pesar de las medidas de seguridad implementadas.

Conclusiones: Nuestro estudio demuestra que los pacientes con DMAEn presentan una disminución estadísticamente significativa de la AV durante el confinamiento. De una AV de casi 58 letras, se redujo a 53 a los 6 meses del confinamiento. El porcentaje de pacientes que perdieron 15 o más letras se duplicó. Observamos un 63,3% de pérdida de seguimiento temporal durante el confinamiento y un 14,6% de pérdida de seguimiento permanente a los 6 meses tras el confinamiento.

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Introduction

Coronavirus disease (COVID-19) is a new, highly contagious and potentially fatal infectious disease that appeared in China in December 2019 and spread globally as a pandemic in the following months. Spain, along with Italy, has been one of the European countries with the highest incidence of the disease, to the extent that on 14 March 2020 the Spanish government declared a state of alarm and ordered a national lockdown in order to contain the spread of the new coronavirus disease (COVID-19).

The healthcare systems of all countries were under a huge healthcare burden, not only because they have had to deal with a new and unknown disease but also because it has affected activity in other medical and surgical specialties. In the field of ophthalmology, the pandemic has had a major impact, being one of the specialties in which activity has fallen the most. This is due to the high load of ophthalmology consultations and the high risk of infection among professionals and patients.

One of the diseases in which we have detected the highest incidence of care problems after lockdown has been neovascular age-related macular degeneration (AMD), as patients belong to the group with the highest risk of death from COVID-19 due to their advanced age, and on the other hand, they may have a potentially irreversible loss of vision if they do not receive treatment.

AMD is the leading cause of blindness among people over 50 years of age in developed countries. Loss of visual function is highly associated with impaired quality of life and a high social burden. AMD is currently treated with intravitreal injections (IVI) of anti-angiogenic drugs, vascular endothelial growth factor inhibitors. These drugs, which are expensive, must be administered in the form of IVI in the operating theatre or in a clean room. Aggregate evidence indicates that visual acuity (VA) declines rapidly if no treatment is provided, with loss of a line after 3 months or even after 3 weeks. The efficacy of anti-angiogenic treatment is time-dependent, with better results the earlier the disease is detected and the earlier the treatment is started, and also depends on the degree of compliance with the schedule of check-ups and number of IVI during the maintenance period.

The monitoring and treatment of AMD in Area 3 of the Community of Madrid is carried out in the AMD monographic clinic of the Príncipe de Asturias Hospital by 2 ophthalmology specialists, with the activity data as well as the results of
the treatment of all patients being collected in computerised form.

The AMD consultation was created in 2011 and follows a protocolised procedure. New patients are admitted directly from the emergency department and follow a loading regimen with 3 injections of vascular endothelial growth factor inhibitor and subsequent re-evaluation. The maintenance regimen was initially “Pro re Nata” with monthly reviews,7 but from 2018 we started in “naïve” patients with a “Treat and Extend” regimen8,9 with 2-week increments up to a maximum of 3 months and trying to do a single act when possible. IVI is administered in a positive pressure room with a 9-chair preparation area. Typically 35–45 patients are seen in 5 groups of 7–9 patients 2 days a week. Bilateral cases were injected with a one-week interval between the two eyes.

During the state of alert for the management of the health crisis situation caused by COVID-19, a number of changes to the procedure were made to increase the safety of nAMD patients, and some of these changes were subsequently maintained and integrated into the procedure for the management of nAMD patients.

On the one hand, the number of IVI appointment groups was increased and the number of patients included in each group was reduced to 4, in order to avoid crowding in the preparation room and to maintain the 2m safety distance. Simultaneous bilateral injection was started for all candidate patients who agreed to it.10–12 In addition, on 14 March 2020 the Techniques Room in which the IVI is administered was closed and moved to the operating theatre of the peripheral specialties which had been closed to the public for a week and during the lockdown period was only open one day a week for IVI administration.

By recommendation of the Ministry of Health and following the protocols established by the various ophthalmological societies, from 14 March, telephone consultations were started with all patients with nAMD who had an appointment for consultation or injection.23 They were asked about AMD-related symptoms (metamorphopsia, decreased VA, etc.) and also about general symptoms related to coronavirus infection (fever, cough, dyspnoea, etc.). Treatment was prioritised for those patients with symptoms of active AMD, with functional single eyes or bilateral nAMD13,14 involvement and the risk of irreversible vision loss and the risk of COVID-19 infection were explained to them.25 All patients who, after the telephone interview, were considered to require evaluation, and those attending for emergency care, were reviewed in the consultation room.

Once care activity resumed as normal, the number of patients per consultation was reduced in proportion to the number of slots in the waiting room, as dictated by the Ministry of Health. The hospital’s technical room was reopened, but the appointment groups of four patients per group and simultaneous bilateral injections were maintained. As for the treatment regimen, from the beginning of the lockdown we changed the regimen according to the recommendations of the Spanish Retina and Vitreous Society to a fixed regimen of multiple injections with the longest interval of inactivity that the patient had maintained.13,15,16 Over the months, as the situation improved, we switched to a “Treat and Extend” regimen with multiple injections and a single act whenever possible, in order to reduce the number of patient visits to the hospital.

The coronavirus pandemic has generated an unpredictable and chaotic health situation in Spain, which has affected the different communities and even the different health areas within each province unevenly. Moreover, it is progressing in a disparate manner over time and across the territory, which forces us to review the mechanisms we are implementing in order to be able to continue healthcare activity safely in diseases other than COVID-19.

Therefore, in order to assess the effect of the pandemic on healthcare, it is important to refer to a precise time and location. It is also important to try to quantify the effect of the security measures implemented in the performance of our procedures, both in terms of healthcare activity and health outcomes as well as in terms of the quality perceived by our patients. In this way, we will be able to decide which measures are useful and which are not, and in which pathology the reduction of healthcare activity and the lockdown of the population will have the greatest impact on health.

Methods

A retrospective observational study of all consecutive patients with AMD in our centre who had attended the AMD consultation and/or had been treated with antiangiogenic drugs for AMD in the 3 months prior to lockdown was proposed.

The primary objective of the present study is to measure the impact on the activity and visual outcomes of patients with exudative AMD in our area, when adopting the safety measures implemented during lockdown and in the immediate aftermath.

Patients from the AMD consultation who had attended for consultation and/or treatment in the 3 months prior to the start of lockdown (14 March 2020) were included. All patients gave written consent to participate in the study, which was conducted according to the ethical standards described in the Declaration of Helsinki for biomedical research, and the protocol was approved by the Medical Research Ethics Committee (CEIm) of the Príncipe de Asturias Hospital, Alcalá de Henares.

The activity in the consultation and injection room before, after and during lockdown were studied. The number of face-to-face consultations and of injections were recorded as well as the change in mean VA in 3 time periods; in the 6 months before lockdown, during the period of lockdown and in the 6 months after lockdown.

Patient absenteeism in the consultation and in the injection room during lockdown and whether it was related to any other patient characteristics, age, gender, VA, etc. were also measured.

A survey (Appendix A) was conducted among a sample of patients who came to the clinic after the pandemic to determine users’ perceived security and their assessment of the measures implemented to increase security.

The statistical analysis was performed using Statview SE+ Graphics (Abacus Concept Inc., Berkeley, CA, USA) and a Macintosh Power Book 1400 cs/117 personal computer (Apple Computer Inc., Cupertino, CA, USA). A parametric descriptive analysis was performed, obtaining the mean and standard
deviation of the continuous quantitative variables and the percentage of the qualitative variables. For comparisons, the unpaired 2-tailed Student’s t-test was used, with p-values <0.05 being considered significant. Comparisons of proportions and/or frequency distributions were analysed using the chi-square test (or Fischer’s exact test when appropriate).

**Results**

Between 1 December 2019 and 13 March 2020, 144 patients with AMD, of which 54.86% were female, attended the AMD consultation and/or IVI. Most of the patients were unilaterally affected (83.33%) and only 24 patients were bilaterally affected (out of a total of 168 AMD eyes seen and/or treated in the 3 months prior to lockdown). Of the 120 patients with unilateral involvement, 39 (32.50%) had functional single eyes as the contralateral eye has vision equal to or less than 35 letters for any cause. The demographic characteristics of the patients are shown in [Table 1](#).

The mean VA before lockdown was 57.99 ± 23.68 letters and diminished in a statistically significant manner to 53.03 ± 27.14 letters at 6 months after lockdown. This correlates with a clinically and statistically significant decrease in the number of visits during lockdown ([Table 2](#)), which has not recovered and remains almost halved (1.42 ± 1.47 injections and 1.91 ± 0.88 visits) in the 6 months after lockdown.

Regarding VA changes, 10 eyes have had no VA change data in the previous 6 months, 7 because they started the disease immediately before lockdown and 3 because they stopped treatment without the VA control visit; of these, 2 resumed visits and/or treatment when the situation normalised and one has not yet returned to consultation.

The mean change in VA in the 6 months before lockdown was 1.08 ± 11.86 letters lost, while in the 6 months after lockdown it was 4 ± 15.43 letters lost, with no statistically significant difference between the two (p = 0.1).

A statistically significant difference was also observed when comparing the percentage of eyes gaining letters, maintaining vision and losing letters during the 6 months before lockdown and the 6 months after (p = 0.004). While in the 6 months prior to lockdown 60.50% of eyes (95 eyes) remain stable (changes equal to or less than 5 letters), 17.83% of eyes gain more than 5 letters and 21.67% of eyes lose more than 5 letters ([Fig. 1](#)). In the 6 months after lockdown the percentage of eyes maintaining vision was significantly lower (48.15%), although no significant difference was found in the percentage of eyes gaining more than 5 letters (18.51%) or in the percentage of eyes losing more than 5 letters (33.34%), although the latter is higher. The percentage of eyes losing 15 or more letters doubled from 8.29% before the pandemic to 17.04% after the pandemic; however, due to the low number of eyes in the group, the percentage does not reach statistical significance ([Table 3](#)).

Ninety-three patients (64.58%) did not attend for AMD and/or injections during the period of lockdown, 5 because they passed away during lockdown, all of them due to COVID-19. There is one more patient who came for a check-up during this period who died of COVID-19 after lockdown. After the end of the lockdown, 17 patients did not return to the AMD clinic or to injections and 71 resumed their treatment and check-ups as normal ([Fig. 2](#)).

No significant differences were found in the baseline characteristics of the patients attending for consultation and/or treatment; neither in the age or sex of the patient nor in the duration of the disease, previous VA, nor in the activity of the lesion prior to the start of the lockdown, nor in whether they were single functional eyes or disease with bilateral involvement. We did find differences in the mean number of injections received in the 6 months after lockdown, which was higher in patients who maintained follow-up.

A small sample of 35 patients who attended the hospital’s consulting room and/or technical room after the first wave of the coronavirus pandemic was subjected to a brief quality survey, which can be found in Appendix B anexo 1. The results are as follows: the majority of patients consider that there is no risk of becoming infected with coronavirus either in the consulting room (25/35) or in the Technical Room (26/35). The majority of patients (33/35) consider that the measures taken so far to improve safety and prevent infection are useful, and only 6 patients suggest additional measures, of which 4 were general measures such as increasing distance and improving

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**Table 1 – Demographic characteristics of patients.**

| Total patients (N = 144 patients) |   |
|----------------------------------|---|
| **Age**                          | 79.06 ± 7.58 years |
| **Sex**                          | 54.86%♀ |
| **Ethnicity**                    | 100% Caucasian |
| **Laterality**                   | 83.33% unilaterial |
| **Tobacco use**                  | 13 ex-smokers |
| **Type of neovascular membrane** | 54.11% type 1 |
| **Date of onset of the disease** | 64 patients between 2018 and 2020 |

**Table 2 – VA data, visits and number of injections.**

| N = 168 eyes | Before lockdown | In lockdown | After lockdown |
|--------------|-----------------|-------------|---------------|
| Average VA   | 57.99 ± 23.68   | 3.03 ± 0.56 | 1.42 ± 1.47   |
| Nr. injections | 2.35 ± 3.02 | 0.33 ± 0.56 | 0.27 ± 0.87   |
| Nr. visits   | 2.72 ± 0.87     | 0.27 ± 0.53 | 1.91 ± 0.88   |

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Table 3 – Patient characteristics according to whether or not they attend for consultation and/or injections during lockdown.

|                              | 51 go for consultation and/or injections | 88 do not attend consultations and injections | p   |
|------------------------------|------------------------------------------|--------------------------------------------|-----|
| Age                         | 78.21 ± 8.25 years                       | 79.84 ± 7.17 years                        | 0.8 |
| Sex                         | 48.3%♂                                   | 42.3%♂                                      | 0.5 |
| Functional single eye       | 25.41%                                   | 21.6%                                      | 0.7 |
| Bilateral disease           | 21.56%                                   | 17.04%                                     | 0.6 |
| Disease onset in 2018–2020  | 47.05%                                   | 50%                                        | 0.7 |
| VA ≥70 letters              | 21.56%                                   | 38.82%                                     | 0.2 |
| VA ≥65 letters              | 60.78%                                   | 54.11%                                     | 0.7 |
| Active at last pre-lockdown review | 60.86%                                     | 50%                                        | 0.5 |
| Average change in VA in the 6 months post-lockdown | −3.25 ± 14.05 letters                   | −4.51 ± 16.37 letters                      | 0.6 |
| Nr. visits in 6 months post-lockdown | 1.85 ± 0.87                             | 1.95 ± 0.89                               | 0.5 |
| Nr. injections in 6 months post-lockdown | 2.10 ± 1.42                             | 0.95 ± 1.31                               | 0.0001 |

Discussion

The coronavirus pandemic is having a major impact on the normal activity of our healthcare system. To cope with the chaos of the initial phase of the disease, a series of containment measures aimed at reducing the transmission of the virus were adopted by consensus of experts, guidelines of the
Medical Societies and the Ministry of Health and the various regional ministries, which had a strong impact on the healthcare of non-COVID pathology, mainly chronic patients.

AMD patients are a population requiring chronic and regular care and treatment. In addition, they are particularly susceptible and at high risk of mortality from COVID-19 as the average age in our population is around 80, and accordingly many are in nursing homes and generally have more comorbidity and other associated diseases.

Some studies have reported that ophthalmology has been one of the specialties with the greatest decrease in activity during the pandemic. And they evaluate the decrease in the number of consultations, IVI and surgical interventions in retina in other countries such as the USA or Italy, among others.

We now have the data to determine not only the extent to which activity has been reduced, but also how these measures have affected the vision outcomes of our patients.

The average age of the patients in the AMD clinic is 79 years, 55% are female and most of them have type 1 neovascular membranes. Approximately half of the patients started treatment in the previous 2 years and the other half are chronic patients with more than 3 years of follow-up, in general, they are patients in the maintenance phase. The number of visits in the 6 months prior to lockdown was 2.50 and the mean number of injections was 2.35. This was reduced during the period of lockdown to an average of 0.27 visits and 0.33 injections despite the fact that we contacted all patients who had appointments for consultation and injection during this period and informed them of the safety measures to reduce the risk of contagion and discussed with them the personal risk of non-recoverable vision loss depending on the situation of the eye as well as previous treatment needs, type of lesion, etc. Telephone contact with older patients is hindered by their hearing impairment and they are also often reluctant to make decisions in unconventional situations, so many changed their minds after consulting with younger relatives.

It is possible that written information or information in local public media explaining the hospital situation, safety measures and outsourcing of IVI to an out-of-hospital centre with a low risk of contagion, would be more effective.

This drop in activity during lockdown was not fully recovered in the 6 months after lockdown, when the mean number of visits was 1.91 and the mean number of injections was 1.42, partly because it overlapped with the summer months when many of the patients did not attend because they were away from their usual residence. This is supported by the fact that patients who maintained follow-up and treatment during the pandemic had a significantly higher mean IVI in the 6 months after lockdown than those who did not maintain follow-up.

The limitations of this study are its retrospective nature and being restricted to one health area within the Community of Madrid. However, this is not so negative as it allows us to refer the changes to the specific measures taken in that area.

The main conclusion of the present study is that the mean VA before lockdown was almost 58 letters and was reduced to 53 letters at 6 months after lockdown. There was a 63.30% temporary loss of tracking during lockdown and 14.58% permanent loss of tracking at 6 months after lockdown.

Conflict of interest

The authors have no commercial interest in any aspect of this study, there is no private funding for this study.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.joftale.2021.02.012.

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