

Using Real-World Data to Estimate the Social Security Costs of Retinal Diseases: Results from the Observatory on Legal Blindness

Mennini FS^{1,2*}, Trabucco Aurilio M³, Russo S^{1,4}, Migliorini R³, Massimo Piccioni³, and Ricci F⁵

¹Economic Evaluation and HTA (EEHTA) CEIS, Faculty of Economics, University of Rome "Tor Vergata", Via Columbia, 2 – 00133 Rome, Italy

²Institute for Leadership and Management in Health, Kingston University, Kingston Hill Campus, Kingston upon Thames KT2 7 LB, London, UK

³Office of Medical Forensic Coordination, Italian National Social Security Institute (INPS), Via Ciro il Grande, 21 – 00144 Rome, Italy

⁴Department of Statistical Sciences, Sapienza University of Rome, Piazzale Aldo Moro 5, 00185 Rome, Italy

⁵UOSD Retinal Pathology PTV Foundation "Policlinico Tor Vergata", Viale Oxford, 81, 00133, Rome, Italy

Abstract

Background: Several studies estimates that in industrialized country retinal diseases such as macular degeneration (MD) and diabetic retinopathy (DR), have a particularly high prevalence, causes deterioration in quality of life, with significant social and economic consequences.

This study analyses the data of the Observatory on Legal Blindness to estimate, using real-world data, the average number of beneficiaries and the costs related to Supplementary Security Income (SSI) and attendance allowance (AA) for people with specific forms of DR and MD.

Methods: We used data from the National Institute of Social Security (INPS) database regarding disability insurance awards (DIAs) for SSI and the AA for totally blind (TB) and partially sighted (PB) people from 2012 to 2016.

Results: For MD, we estimated yearly averages of 11,600 AA beneficiaries and 9,100 SSI beneficiaries, with mean costs of €53.9 million and €30.1 million, respectively. For DR, we estimated yearly averages of 3,200 AA beneficiaries and 2,500 SSI beneficiaries, with mean costs of €16.7 million and €8.2 million, respectively. Analyses of the DIAs showed a slight increase in the number PB individuals affected by DM and TB individuals affected by RD and DM.

Conclusions: According to this study, MD and DR involve significant economic and social costs due to their chronicity. This is the first study to estimate the welfare costs of these two groups of visual diseases using data from the evaluations provided by the medical commissions and the benefits paid by the INPS.

Keywords: Retinal diseases; Macular degeneration; Diabetic retinopathy; Burden of disease; Real-world data; Social security cost; Social security system; Legal blindness

Abbreviations: MSVI: Moderate to Severe Visual Impairment; AMD: Age-related Macular Degeneration; DR: Diabetic Retinopathy; RVO: Retinal Vein Occlusion; PM: Pathological Myopia; VEGF: Vascular Endothelial Growth Factor; DIAs: Disability Insurance Awards; SSI: Supplementary Security Income; AA: Attendance Allowance; INPS: National Institute for Social Security; TB: Totally Blind; PTB: Pension for the Totally Blind; PPS: Pension for the Partially Sighted; SA: Special Allowance.

Introduction

Visual impairment involves important health problems [1-3] and significant economic and social costs [4]. A recent study 5 estimated that in 2010, approximately 191 million individuals suffered from moderate to severe visual impairment (MSVI), and approximately 32.4 million were blind. Seventy-six percent of individuals with visual impairment and 65% of those who were blind were affected by preventable or treatable diseases. A study conducted in 2016 [4] estimated that in 28 European countries, almost 10 million people aged over 50 years suffer from MSVI, and 1.3 million are blind. The study also estimated that there are approximately 1.3 million individuals with visual impairment and 233,000 blind people in Italy. The associated losses of productivity amount to approximately €2.5 billion and €1.5 billion, respectively. Italy is the European country with the highest number of blind people and the third-highest number of individuals with visual impairment and it has the third-highest costs due to loss of productivity.

Retinal diseases such as age-related macular degeneration (AMD), diabetic retinopathy (DR), retinal vein occlusion (RVO) and pathological myopia (PM) are among the main disorders responsible for partial or total loss of vision. The most recent studies suggest that ophthalmic, such as uncorrected refractive errors and cataracts, [5,6] are the leading causes of eye disorders. However, in industrialized countries, AMD has a particularly high prevalence, especially among the elderly, and is a major cause of MSVI and blindness together with OVD, PM (particularly for people of working age), DR and glaucoma [7,8]. The aetiology of retinal vascular diseases is complex and multifactorial. Many studies have demonstrated that vascular endothelial growth factor (VEGF) plays a central role in the pathogenesis of these diseases [9-12] due to its ability to destabilize the blood-retinal barrier, which causes macular oedema, and to stimulate angiogenesis, which causes the formation of pathological neovessels. Therefore, the use of VEGF inhibitors is the most effective therapeutic option for the treatment of

***Corresponding author:** Francesco Saverio Mennini, Economic Evaluation and HTA (EEHTA) CEIS, Faculty of Economics, University of Rome "Tor Vergata", Via Eleonora Duse 22, Rome 00197, Italy, Tel: +39 333 4991647; E-mail: f.mennini@uniroma2.it

Received January 10, 2019; **Accepted** January 28, 2019; **Published** February 01, 2019

Citation: Mennini FS, Trabucco Aurilio M, Russo S, Migliorini R, Piccioni M, et al. (2019) Using Real-World Data to Estimate the Social Security Costs of Retinal Diseases: Results from the Observatory on Legal Blindness. *Pharmacoeconomics* 4: 120. doi:10.4172/2472-1042.1000120

Copyright: © 2019 Mennini FS, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

vascular retinal diseases for which, until a few years ago, no effective or adequate treatment existed. However, at present, no data are available to permit an accurate evaluation of the individual and collective costs and benefits of these therapies.

This study analyses the data from the Observatory on Legal Blindness with the specific objective to analyses, using real-world data, the disability insurance awards (DIAs) according to the type of benefit granted to people affected by DR and MD and estimate the beneficiaries and the costs incurred for (SSI) and the Attendance Allowance (AA) from the taxpayer perspective from 2012 to 2014. The database of the National Institute for Social Security (INPS) related to legal blindness was used for the analysis.

Data

The Italian Constitution (art. 38) guarantees that citizens with a congenital or acquired disability - even if they do not belong to any group of workers or have insufficient work histories, and if they have low enough incomes - have the right to receive support by means of economic and non-economic benefits. These benefits are funded by tax payers and paid by the INPS [13,14]. There are different kinds of legal disability: legally disabled, legally blind and deaf. This study specifically considers the legally blind. In accordance with the provisions of law no. 138, dated 3rd April 2001, visual impairment comprises total blindness, defined as complete vision loss in both eyes, even with spectacle correction, and partial blindness, defined as visual acuity of no more than 20/400 in both eyes with correction (visual impairment of 20/400).

Totally blind

The totally blind (TB) are eligible for specific types of SSI and the AA: pension for the totally blind (PTB) and the AA. PTB is granted to TB Italian citizens residing in national territory who are older than 18 years, have economic needs, and do not exceed specific income limits (for the year 2017, the threshold was € 16,532.10). PTB is paid 13 months at time. The AA is granted independently from the economic circumstances and age of the recipient and is compatible with employment. The AA is paid 12 months at time.

Partially sighted

The pension for the partially sighted (PPS) is granted to partially sighted individuals with a visual acuity of no better than 20/400 in

both eyes due to congenital or acquired disability and not caused by war wounds or accidents at work. It is granted to partially sighted individuals of any age with Italian citizenship and residing in national territory who have an income below a specific threshold (in 2017 it was €16,532.10) [14]. The PPS is paid 13 months at time. The special allowance (SA) for partially sighted people (20/400) is granted to those with the disability independent of economic need, age and admission to any treatment clinic.

Data description: total costs of legal blindness

The Statistics Observatory of INPS [15,16] collects all the data of the beneficiaries and aggregates them by type of SSI, AA, age, sex, geographical area and amount. Costs reported are in current price. The PTB and SA amounts remained steady from 2012 to 2016 (Supplementary Figure 1A), while the PPS increased by 5.3%, and the AA decreased by 4.3%. Over the examined period, the highest number of SSI and AA recipients were partially sighted, with an average of 70,440 for the SA and 58,807 for the PPS; the TB accounted for 54,525 AA recipients and 39,880 PTB recipients, on average. Additionally, we considered the point prevalence per 100,000 populations, calculated as the relationship between the number of SSI and AA benefits paid as of 1st January of each year and the resident population on that day (Supplementary Figure 1B). In comparison with previously reported absolute values, the PTB and the SA were less stable, with decreases of 2.4% and 2%, respectively. The PTB showed less of an increase than previously recorded, equal to 3.1%, while the AA had a greater decrease of 6.3%. Likewise, the number of benefits granted to the partially sighted had higher average yearly values, equal to 116.9 out of 100,000 for the SA and 96.9 out of every 100,000 individuals for the PPS. The AA and the PTB on average accounted for 91.0 and 66.2 per 100,000 residents in Italy, respectively. Figure 1 reports the cost analysis of the SSI and AA benefits being examined. The costs of all benefits but the PTB increased from 2012 to 2016. In particular, the SA rose by 6.9%, and the AA rose by 4.1%. The AA had the highest costs: €2.8 billion in total over the examined period and a yearly average cost of €564 million; the PPS had a total cost of €934 million and an average yearly cost of €187 million; the SA had a total expense of €844 million and an average yearly expense of €169 million; the PCA had a total cost of €687 million and an average cost of €137 million. The AA had the highest average and total costs considering that, for example, the average monthly AA pay-out was four times higher than that of the SA.

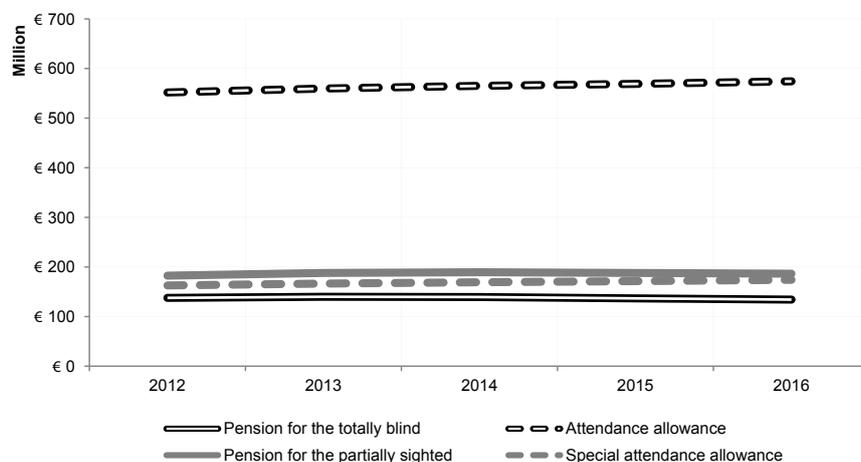


Figure 1: Total costs of supplemental security income and attendance allowance for the totally blind and partially sighted from 2012 to 2016.

Disability insurance awards for diabetic retinopathy and macular degeneration

The INPS data concerning the DIA for each year and the total number of SSI and AA benefits paid [13] and distributed [12] from 2012 to 2014 were used to estimate the number of SSI and AA beneficiaries with the selected ophthalmic diseases. The INPS database used by the Medico-Legal Coordination provides information regarding whether an applicant was registered as TB or partially sighted during the 2012-2014 period. Ocular diseases are indicated with a disease code specified by the International Classification of Diseases – 9th revision – Clinical Modification (ICD9–CM): (362.0) Diabetic retinopathy, (362.01) Simple diabetic retinopathy, (362.02) Proliferative diabetic retinopathy, (362.5) Macular degeneration and posterior pole degeneration of the retina, (362.51) Nonexudative age-related macular degeneration of the retina, (362.50) Unspecified (age-related) macular degeneration of the retina, (362.52) Exudative age-related macular degeneration of the retina, (362.53) Cystoid macular degeneration of the retina. It should be noted that the number of evaluations related to the four-digit ICD9-CM codes (362.0 and 362.5) does not include the evaluations related to the five-digit codes. Therefore, the values related to the less-specific codes are not the sum of all the values of the more-specific codes. The reported data only indicate the code that was added by the medical commission. Regarding the applications for legal blindness, we considered the evaluations issued by the health commission on the TB, partially sighted and sighted in terms of both absolute values and the percentage of the total evaluations accounted for by the specific visual disease (Figure 2 and Supplementary Figure 2). Between 2012 and 2014, 4,319 evaluations were performed for MD (an average of 1,440 per year), and 1,294 were performed for disorders related to diabetic retinopathies (an average of 431 evaluations per year). For both types of disorders, most of the evaluations were for visually impaired people. Specifically, an average of 64.2% of the evaluations concerned DM-related diseases, while 21.9% and 12.9% concerned to the partially sighted and the TB, respectively. Between 2012 and 2014, 2,812 registrations were issued for partially sighted individual (937 on average), 952 for sighted individuals (317 on average) and 555 for TB individuals (185 on average) affected by MD. Although over the three considered years, all types of evaluations increased in absolute value (+10.5% total evaluations from 2012 to 2014), among the total evaluations, only the number of evaluations of the sighted increased (by 11.9%, compared with -2.4% for the TB and -2.9% for the partially sighted). Regarding the considered retinopathies, 52.6% of those evaluated were partially sighted: 680 evaluations were performed, with an average of 227 evaluations per year; 32.5% were sighted: 422 evaluations were performed, with an average of 141 evaluations per year; and 14.9% were TB, with a total of 192 evaluations performed and an average of 64 evaluations performed yearly. Over the considered period, the total number of evaluations grew in absolute value by 22.4%; in particular, TB evaluations showed a 27.8% increase. Evaluations related to the partially sighted were the only ones that decreased in number; they showed a 10.8% decrease.

Methods

As there is no income limit associated with the AA and SA, each registration corresponds to an economic benefit. The estimated numbers of beneficiaries and those with MD and DR who were examined for AA and SA were based on the hypothesis of an exact correspondence between the relative weight of the diseases considered by the DIA and the number of beneficiaries receiving the AA and SA for the legally blind. This can be expressed by the following formula:

$$\frac{\text{Approved totally blind}_{i,t}}{\text{Approved totally blind}_i} = \frac{\text{Beneficiaries Attend. Allow}_{i,t}}{\text{Beneficiaries Attend. Allow}_i} \quad (1)$$

which becomes:

$$\text{Beneficiaries Attend. Allow}_{i,t} = \text{Beneficiaries Attend. Allow}_i \times \frac{\text{Approved totally blind}_{i,t}}{\text{Approved totally blind}_i} \quad (2)$$

Beneficiaries Attend. Allow_{i,t} represents the average number of individuals benefitting from the AA for disease *i* (in this case, MD or DR) in year *t*. Beneficiaries Attend. Allow_i represents the average number of AA beneficiaries for all diseases in year *t* (calculated as the average of the AA being paid on 1st January of year *t* and the AA being paid on 1st January of the year *t*+1). Approved totally blind_{i,t} represents the number of DIAs for TB individuals during year *t*. The same procedure was applied to estimate the number of SA beneficiaries affected by MD or DR. Unlike the AA and SA, the PTB and the PPS are SSI paid to legally blind individuals in economic need who fall below a specific income threshold, as provided by the law. The Medico-Legal Coordination database of the INPS reports the results of applicant visits by disease. The data exclusively concern health information, and it is not possible to establish whether the claimant registered as TB or partially sighted has any specific economic needs. Therefore, indirect estimates based on the pension beneficiaries were made using the commission's positive evaluations in favour of individuals affected by the ocular diseases of interest and the relationship between the PTB or PPS beneficiaries and the beneficiaries of the AA or SA for the legally blind. These values are known and can be expressed by the following formula:

$$\text{Benef. pens. tot. blind}_{i,t} = \text{Benef. Attend. Allow}_{i,t} \times \frac{\text{Benef. pens. tot. blind}_i}{\text{Benef. Attend. Allow}_i} \quad (3)$$

Benef. pens. tot. blind_{i,t} represents the average number of PTB beneficiaries with disease *i* (MD or DR) in year *t*. Benef. Attend. Allow_{i,t} represents the previously estimated average number of AA beneficiaries with disease *i* in year *t*; Benef. pens. tot. blind_i corresponds to the total number of PTB beneficiaries in year *t* (calculated as the mean of the PTB beneficiaries on 1st January in year *t* and the PPS beneficiaries on 1st January of year *t*+1), and the *Benef. Attend. Allow_i* represents the average number of AA beneficiaries in year *t* (calculated as the average of the number of AA beneficiaries on 1st January of year *t* and the number of AA beneficiaries on 1st January of year *t*+1). The same procedure was used to estimate the number of PPS beneficiaries affected by MD or DR.

Results

Average number of beneficiaries and total costs

For the two groups of diseases, an average of approximately 14,800 beneficiaries were estimated; of these, 31% were TB (approximately 4,600 beneficiaries), and the remaining (approximately 10,200 beneficiaries) were partially sighted. Regarding the allowances, over the considered period, approximately 11,600 beneficiaries on average had MD; of these, 71% (approximately 8,200 beneficiaries) benefited from the SA. DR accounted for 3,200 beneficiaries; of these, 63% received the AA (approximately 2,000 beneficiaries). Overall, for both groups, the estimates were higher for SA than for AA, especially among the beneficiaries with MD. The same was true for the pensions, for which the number partially sighted beneficiaries was higher than the number of beneficiaries of the PTB. Pension beneficiaries with MD account for an average of approximately 9,100 individuals per year; of these, 73% (approximately 6,700 beneficiaries) received the PPS. An estimated 2,500 pension beneficiaries had DR; of these, 66% (approximately 1,600

beneficiaries) received the PPS. In terms of the costs, specifically those related to MD, an estimated €161.6 million (yearly average of €53.9 million) was spent over the three investigated years; this included €103.5 million (approximately 64%) for the AA and €54.1 million for the SA (approximately 36%). In contrast with the results of the analysis of the benefits paid, the AA had the highest costs. This is because, for example, the average AA payment is more than four times higher than the average SA payment. The same situation applied to DR. A total of approximately €50 million in benefits was paid between 2012 and 2014 (yearly average of €16.7); of this, €36 million was paid out as AA (72%) and €14 million as SA (28%). The pension costs for MD over the three-year study period amounted to €90.4 million (€30.1 million per year on average), including €25.6 million for the PTB (approximately 28%) and €64.9 million for the PPS (72%). Between 2012 and 2014, the costs for DR were €24.6 million (yearly average of €8.2 million), including €8.9 million for the PTB (36%) and €15.7 million for the PPS (approximately 64%). Contrary to what was previously highlighted for AA and SA, the relative percentage distribution among beneficiaries and costs of these pensions were basically unchanged as the average costs of the PPS and the PTB according to beneficiary category are basically the same.

Beneficiaries and costs per year

As previously noted, for both groups of diseases, the SA is the benefit with the highest number of beneficiaries, although it had a limited increase compared to the AA (Supplementary Figure 3A and B). Specifically, the number of AA beneficiaries with MD increased by 20% in 2014 compared to 2012, from approximately 3,100 beneficiaries to 3,700. The SA increased by only 8%, from approximately 7,700 beneficiaries in 2012 to 8,300 in 2014. For DR, the number of AA benefits increased by 42%, from approximately 937 beneficiaries in 2012 to 1,330 in 2014, while the number of SA beneficiaries decreased by 10%, from 1,982 to 1,788 individuals. The estimated data for pension beneficiaries indicate a similar trend. For MD, the number of PTB beneficiaries increased by 22%, from 2,200 beneficiaries in 2012 to 2,700 in 2014. The PPS had a less significant increase of 11%, from 6,200 beneficiaries at the beginning of the analysis to 6,900 at the end. For DR, the PTB had the most significant increase (approximately 45%), from 668 to 968 beneficiaries. Conversely, the SA showed a 7% decrease, from 1,600 beneficiaries in 2012 to 1,500 individuals in 2014. Figure 3

reports the costs of the two types of allowances. As previously reported, the AA had the highest costs for both disease groups. The trends in costs over time for the two disease groups were similar the trends in beneficiaries. In fact, for MD, the AA increased most significantly, by approximately 25%, with costs of €30.8 million in 2012 and €38.5 million in 2014. Conversely, the SA increased by 12%, with costs of €17.8 million in 2012 and €20 million in 2014. Likewise, for DR, the AA soared by 48% over three years, from €9.2 million to €13.7 million. In contrast, in line with the changes in beneficiaries, the SA costs decreased by approximately 7%, from €4.6 million in 2012 to €4.3 million in 2014. The pension costs (Supplementary Figure 3C and 3D) showed a trend similar to the trends in the beneficiaries of these SSI. For MD, the PTB increased by 24%, with costs of €7.6 million in 2012 and €9.4 million in 2014. The PPS had a smaller increase of approximately 12%, from €19.8 million in 2012 to €22.3 million in 2014. For DR, the PTB increased by 46%, and the cost increased from €2.3 million in 2012 to €3.4 million in 2014. Conversely, the PPS decreased by 7%, from €5.1 million in 2012 to €4.8 million in 2014. Finally, we considered the total costs for all types of SSI and AA, broken down by disease (Supplementary Figure 3D). As previously noted, the MD costs were significantly higher; they were three and a half times greater than the costs for DR. Analysing the data from a time perspective, both groups increased the cost estimated for the MD in 2012 by 19% and by approximately 23% for the DR. A comparison of the data for the different years showed that for MD, the greatest increase was between 2012 and 2013. The first year showed an increase of 13%, while from 2013 to 2014, only a 5% increase was observed. For DR, this trend was even more evident. From 2012 to 2013, there was an increase of 27%, while in the following period, from 2013 to 2014, there was a 3% decrease in costs. The analyses indicated that the increases occurred because from the first to the second year, the costs of all the benefits increased. Specifically, for the legally blind affected by DR, the costs of the AA and the PTB increased by approximately 39%. In contrast, during the following period, both groups of diseases showed a smaller increase in the benefits for total blindness (AA and PTB), while the costs of the benefits for partial blindness (SA and PPS) decreased, especially in the DR group.

Beneficiaries and costs by disease group

This section analyses the data for the total costs of the selected diseases. Figure 4 reports the expenses for MD-related diseases from 2012 to 2014. Macular degeneration and posterior pole degeneration of

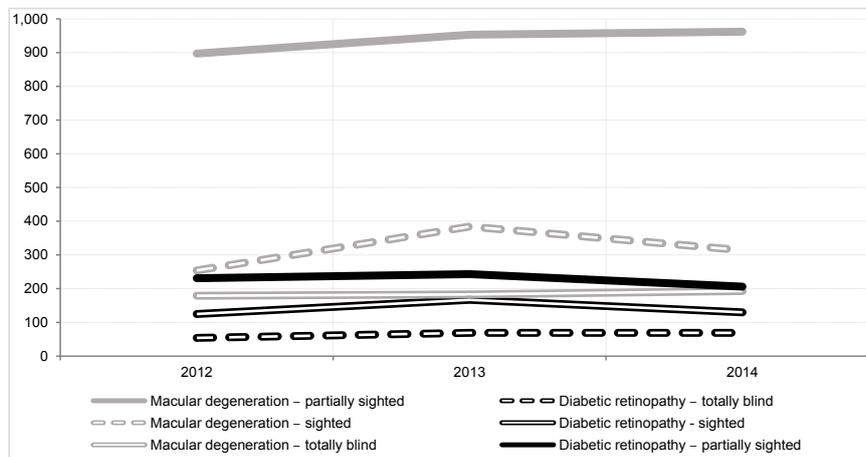


Figure 2: Evaluations of the blind, partially sighted and sighted. Absolute values.

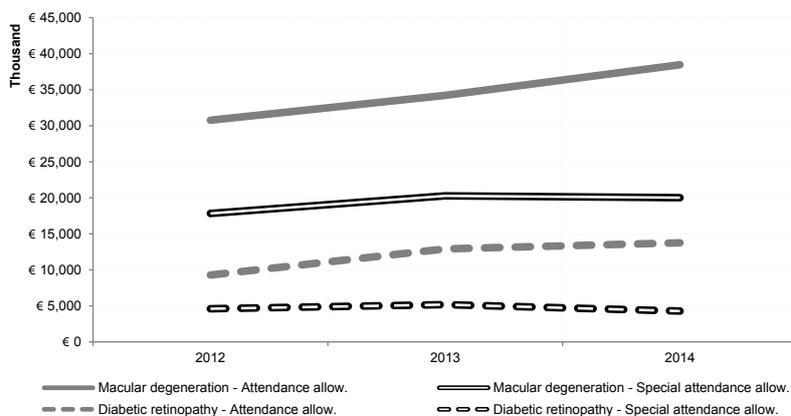


Figure 3: Costs of attendance allowance between 2012 and 2014 by disease group.

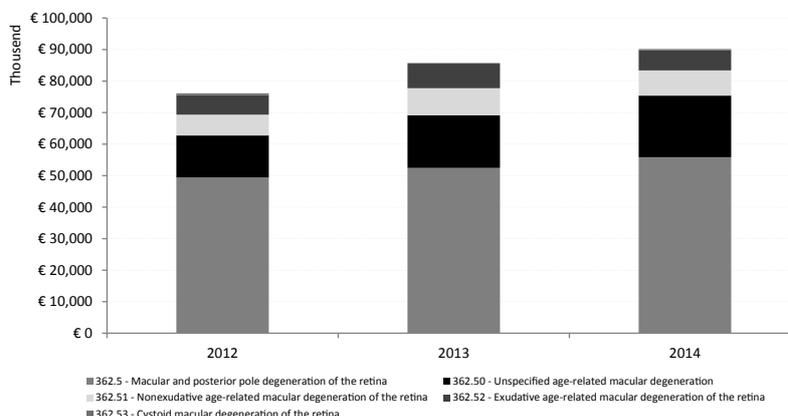


Figure 4: Total costs between 2012 and 2014 by type of macular degeneration.

the retina (ICD9-CM 362.5) had the highest costs as it was associated with a less-specific identification number than the other MD-related diseases. However, it should be noted that the costs of this nosological identification number do not include the costs of the more-specific identification numbers. Overall, €157.7 million were spent on this disease over the three-year study period, with a yearly average expense of €52.6 million and an increase of 13% between 2012 and 2014. Unspecified (age-related) macular degeneration of the retina (ICD9-CM 362.50) had a total cost of approximately €49.6 million and a yearly average cost of €16.5 million; it showed the greatest increase among MD-related diseases (46.5%). Nonexudative AMD of the retina (ICD9-CM 362.51) had a total cost of €23.2 million, with a yearly average of €7.7 million and an increase of 20.8%. Exudative AMD of the retina (ICD9-CM 362.52) had a cost of €20.3 million over the considered period, with a yearly average of €6.8 million and an increase of 2.2%. Finally, cystoid macular degeneration of the retina (ICD9-CM 362.53) had a cost of €1.1 million, with a yearly average of approximately €371,000 and a decrease of 16.7% over the study period. Diabetic retinopathy (ICD9-CM 362.0) had the highest costs (Supplementary Figure 4): €47.1 million over the three-year study period, with an average of €15.7 million per year and an increase of 35.9% between 2012 and 2014. Proliferative diabetic retinopathy (ICD9-CM 362.02) had a total cost of €25.7 million, a yearly average of €8.6 million and an increase of 12.6%. Finally, simple diabetic retinopathy (ICD9-CM 362.01) had a

total cost of €1.7 million, a yearly average of approximately €572,000 and a decrease of 56.5%.

Discussion

The main focus of our study was to estimate the average number of beneficiaries and the costs related to SSI and AA for people with specific forms of DR and MD, using real-world data. This is the first study to estimate the welfare costs of these two groups of visual diseases using real-world data from the evaluations provided by the medical commissions and the SSI and AA benefits paid by the INPS. First, we examined the global situation of the legally blind in terms of the average SSI and AA benefits paid yearly and related costs. Between 2012 and 2016, approximately 223,000 beneficiaries received SSI and AA for legal blindness; the total cost of these benefits was €5.2 billion, corresponding to an average cost of €1 billion a year and a yearly increase of 3.3%. Most of the benefits are provided for partial blindness with a yearly average of 70,400 beneficiaries for SA and 58,800 for PPS. In terms of total costs, the AA has the greatest expenditure, with a yearly average of €564 million, followed by the PPS with €187 million, the SA with €168.8 million and the PPB with €137 million. For MD, approximately 11,600 beneficiaries were estimated on average each year, with a total cost of approximately €161.6 million and a yearly average of €53.9 million. The SA had the highest number of beneficiaries, with a yearly average of 8,200, followed by the PPS,

with 6,700 beneficiaries. Regarding DR, there were an average of 3,200 beneficiaries yearly, with a total expense of €50 million and a yearly average of €16.6 million. Specifically, there were approximately 2,000 beneficiaries of the SA and 1,600 beneficiaries of the PPS. Regarding costs, the AA and the PPS had the highest values in both disease groups, with yearly averages of €34.5 million and €21.6 million, respectively, for MD and €12.0 million and €5.2 million, respectively, for DR. These results show that Retinal Vascular diseases account for the 12% of the total beneficiaries of the disability insurance with a visual impairment. Notice that all citizens, of any age, also foreigners with residence permit, can get the Attendance Allowance, just thanks to the impairment, regardless economic conditions. This means that the total beneficiaries of AA and SA represent a significant part of the total blind population. However, this study has some limitation. First, SSI and AA for MD and DR were estimated without considering the different survival probabilities for the groups of diseases classified by INPS. This could be a cause of discrepancies between the percentage of DIA distribution for each disease group and the amounts of SSI and AA paid. To estimate the beneficiaries of the PTB and the PPS it has not been possible to consider the differences between the proportion of pension beneficiaries with total legal blindness and the proportion of those beneficiaries affected by MD and DR. Second, it is not possible to estimate if the increase in the number of beneficiaries and in the related cost is due to an increase in awareness of such allowances, even if these benefits have been introduced since 1948 [14-19].

Conclusion

In conclusion MD and DR are highly disabling diseases that involve significant economic and social costs due to their chronicity. Although some of the analysed welfare costs have decreased in the recent years, they consume substantial amounts of economic resources that may increase in the future due to population ageing. To limit the consequences of this scenario, more appropriate treatments, faster access to innovative treatments and more efficient management model are necessary; Italy is the European Union member country with the longest delays in access to treatments, and improving this situation would reduce the costs incurred by the social security system, reduction in terms of loss of productivity and improve the effectiveness of therapeutic actions, accompanied by an increase in quality of life.

Declarations

Ethics approval and consent to participate

Not applicable

Consent for publication

Not applicable

Availability of data and materials

The datasets analysed during the first part of the study are available in the National Institute of Social Security (INPS) repository: <https://www.inps.it/webidentity/banchedatistatistiche/vig9/index01.jsp?CMDNAME=NAV63>; <https://www.inps.it/webidentity/banchedatistatistiche/liq5/index.jsp>.

The data that support the findings of the second part study are available from National Institute of Social Security (INPS) but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of National Institute of Social Security (INPS).

Competing interests

The authors declare that they have no competing interests

Funding

This research was supported by Novartis Farma S.p.A.

Novartis Farma S.p.A. provided a financial support to the Observatory on Legal Blindness of the Research Centre "Economic Evaluation and HTA (EEHTA) – CEIS, Faculty of Economics, University of Rome Tor Vergata". Novartis Farma S.p.A. had no role in the analysis, interpretation or preparation of the manuscript.

Authors' contributions

SR, FSM designed the study, collected data and performed data analysis.

SR, FSM, FR, RM, MTA interpreted the findings, and drafted and revised the manuscript. All authors read and approved the final manuscript.

Acknowledgement

Not applicable

References

1. Haegele JA, Kirk TN, Zhu X (2018) Self-efficacy and physical activity among adults with visual impairments. *Disabil Health J* 11: 324-329.
2. Wrzesińska M, Urzędowicz B, Nawarycz T, Motylewski S, Pawlicki L, et al. (2017) The prevalence of abdominal obesity among pupils with visual impairment in Poland. *Disabil Health J* 10: 559-564.
3. Williams G, Aggio D, Stubbs B, Pardhan S, Gardner B, et al. (2018) Physical activity levels in children with sensory problems: Cross-sectional analyses from the Millennium Cohort Study. *Disabil Health J* 11: 58-61.
4. Chakravarthy U, Biundo E, Saka RO, Fasser C, Bourne R, et al. (2017) The economic impact of blindness in Europe. *Ophthalmic Epidemiol* 24: 239-247.
5. Bourne RR, Stevens GA, White RA, Smith JL, Flaxman SR, et al. (2013) Causes of vision loss worldwide, 1990-2010: a systematic analysis. *Lancet Glob Health* 1: e339-e349.
6. Pascolini D, Mariotti SP (2012) Global estimates of visual impairment: 2010. *Br J Ophthalmol* 96: 614-618.
7. <https://medlineplus.gov/magazine/issues/summer08/articles/summer08pg14-15.html>
8. Ho M, Liu DT, Lam DS, Jonas JB (2016) Retinal vein occlusions, from basics to the latest treatment. *Retina* 36: 432-448.
9. Bhagat N, Grigorian RA, Tutela A, Zarbin MA (2009) Diabetic macular edema: pathogenesis and treatment. *Surv Ophthalmol* 54: 1-32.
10. Augustin AJ, Kirchhof J (2009) Inflammation and the pathogenesis of age-related macular degeneration. *Expert Opin Ther Targets* 13: 641-651.
11. Brand CS (2012) Management of retinal vascular diseases: a patient-centric approach. *Eye* 26: S1-S16.
12. Freund KB, Korobelnik JF, Devenyi R, Framme C, Galic J, et al. (2015) Treat-and-extend regimens with anti-vegf agents in retinal diseases: a literature review and consensus recommendations. *Retina* 35: 1489-1506.
13. National Institute of Social Security (2017) Civil disability.
14. National Institute for the Social Security (INPS) (2017) Benefits to the legally blind.
15. National Institute for the Social Security (INPS) (2017) Benefits to the legally blind. Observatory on current pensions.
16. National Institute for the Social Security (INPS) (2017) Benefits to the legally disabled. Observatory on pensions paid.
17. Holz FG, Tadayoni R, Beatty S, Berger AR, Cereda MG, et al. (2016) Determinants of visual acuity outcomes in eyes with neovascular AMD treated with anti-VEGF agents: an instrumental variable analysis of the AURA study. *Eye* 30: 1063-1071.
18. Menchini U, Bandello F, De Angelis V, Ricci F, Bonavia L, et al. (2015) Ranibizumab for Visual Impairment due to Diabetic Macular Edema: Real-World Evidence in the Italian Population (PRIDE Study). *J Ophthalmol* 2015: 1-10.
19. Russo P, Mennini FS, Siviero PD, Rasi G (2010) Time to market and patient access to new oncology products in Italy: a multistep pathway from European context to regional health care providers. *Ann Oncol* 21: 2081-2087.