ORIGINAL ARTICLE

The Prevalence of Amblyopia in Germany

Data From the Prospective, Population-Based Gutenberg Health Study

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SUMMARY

Background: Amblyopia is due to insufficient development of the visual system in early childhood and is a major source of lifelong impairment of visual acuity. Too little is known about the prevalence of amblyopia in Germany and the frequency of its various causes.

Methods: The Gutenberg Health Study of the University of Mainz Faculty of Medicine is an ongoing population-based, prospective, monocentric cohort study with 15 010 participants aged 35 to 74. All participants are examined for the presence of ocular, cardiovascular, neoplastic, metabolic, immunologic, and mental diseases. 3227 participants aged 35 to 44 underwent ophthalmological examination from 2007 to 2012. Amblyopia was defined as impaired visual acuity in the absence of any organic pathology capable of explaining the condition, and in the presence of a known risk factor for amblyopia.

Results: Amblyopia, when defined as a visual acuity less than or equal to 0.63, was present in 182 participants (5.6%, 95% confidence interval [CI] 4.9–6.5%), 120 of whom had a visual acuity less than or equal to 0.5 (3.7%, 95% CI 3.3–5.2%). A narrower definition of amblyopia requiring, in addition, an interocular difference in acuity of at least two lines yielded slightly lower prevalence figures: 5.0% (95% CI 4.2–5.8%) and 3.7% (95% CI 3.1–4.4%), respectively. The causes of amblyopia (visual acuity ≤ 0.63) were anisometropia (different refractive strengths of the two eyes) in 49% of participants, strabismus (a squint) in 23%, both of these factors in 17%, and visual deprivation in 2%. 3 patients (2%) had relative amblyopia due to a traumatic cataract sustained in early childhood. 7% of the participants with amblyopia had binocular amblyopia.

Conclusion: This study yielded a prevalence figure of 5.6% for amblyopia in Germany—a higher figure than in other, comparable population-based studies, which have generally yielded figures of ca. 3% for visual acuity ≤ 0.63 . The distribution of the causes of amblyopia is similar across studies.

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Amblyopia is a condition in which reduced visual acuity is not directly caused by an organic defect (1). Amblyopia can develop when an infant or small child suffers from strabismus. Although both eyes are healthy, different images are formed on each fovea centralis (where vision is sharpest) and on other corresponding locations on the retina; this is in contrast to individuals without strabismus. To prevent double vision the child's brain suppresses the image produced by one eye. Complete visual ability cannot develop in this eye during the sensitive phase of visual development (2).

Approximately half of amblyopia cases (3) are caused by uncorrected higher refractive errors, which are frequently different in each eye: only vague visual outlines are formed on the retina, and the stimulus required for optimal development of visual acuity is absent (4). Deprivation in which the optical axis is displaced by, for example, congenital ptosis (drooping eyelid) or a cataract can also cause amblyopia (5).

Relative amblyopia develops when there are organic defects affecting visual acuity, such as an infantile cataract. The poor visual information provided by the diseased eye is, in addition, suppressed by the child's brain, rendering visual acuity significantly worse than would be expected from organic findings (6). If there is no apparent strabismus or visible organic defect such as ptosis, such amblyopia very often cannot be detected by those around the child. Unilaterally reduced visual acuity has almost no effect on bilateral visual acuity. Even bilaterally reduced visual acuity must be severe in order to be noticeable in the child's day-to-day life.

Treatment for amblyopia must be started early. The older the child and the more advanced visual maturation when treatment begins, the lower the chance of successful treatment (7–9). A large meta-analysis has revealed that treatment begun before the age of seven years yields significantly greater increases in visual acuity—a mean of up to four visual lines—than treatment begun later (a mean of up to two visual lines) (10). Treatment for amblyopia in adulthood is unlikely to be successful (11). Depending on the underlying cause of amblyopia, treatment consists of glasses and/or occlusion therapy (using a patch to cover the better eye). Less common in Germany but confirmed as effective in a Cochrane review is the use of atropine (which

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paralyzes accommodation, leading to worse near vision) in the better eye (12, 13).

Amblyopia remains a lifelong problem if treated too late or left untreated. The risk of bilateral visual impairment is two to three times higher in patients with unilateral amblyopia than in those without amblyopia. In a population-based Dutch study, the cumulative lifetime risk of bilateral visual impairment was 18% in those with unilateral amblyopia and 10% in those without amblyopia (14). In a Finnish study the frequency of loss of sight in the better eye before retirement was 1.75% in those with unilateral amblyopia; the population frequency of blindness was 0.79% (15).

According to large, population-based studies, the prevalence of amblyopia in Australia is approximately 3% among adults (3, 16) and less than 2% in preschool children (17–19). Other studies, conducted in Cameroon for example, report a 10% prevalence of amblyopia in eye clinic patients aged between 5 and 15 years (20). The prevalence of amblyopia among schoolchildren in China is very low, at 1% (21); it is significantly higher (5.5%) among Turkish schoolchildren (22) and lies between these two levels, at 3.1%, in Polish children (23). A selection of population-based studies on the prevalence of amblyopia is provided in Table 1. However, the degree to which different studies on the prevalence of amblyopia can be compared is limited, as participant age in the investigated populations and study quality vary. In addition, the visual criteria used to define amblyopia often differ substantially from each other, as there is no internationally recognized standard.

There are few figures on the frequency of amblyopia in Germany, and there is a lack of epidemiological data from population-based studies. In 1979 a study involving 830 children beginning school found amblyopia in 1.9% of children without strabismus and 44.2% of those with strabismus (24). Another study of 1030 preschool children found manifest strabismus in 3.7% (25) but provided no figures on amblyopia prevalence.

This population-based study aims to obtain more precise figures on the prevalence of amblyopia in Germany and to learn more about the frequency of its causes. This research is based on data from a young population (aged 35 to 44 years).

Methods

Study used as data source

The Gutenberg Health Study (GHS) is a prospective, single-center, population-based cohort study that has been ongoing at Mainz University Medical Center since 2007. Up to 2012, data had been gathered on 15 010 patients aged between 35 and 74 years who had undergone a five-hour basic examination. The population sample was divided into four 10-year age groups, each containing the same number of individuals of each sex and the same number of residents in the city of Mainz and the Mainz–Bingen area. Five-year follow-up is currently ongoing. Further details and findings have been published elsewhere (26–28).

TABLE 1

The prevalence of amblyopia in various studies

	Gutenberg Health Study (GHS)	Blue mountain Eye Study	Visual Impairment Project	Avon Longitudinal Study of Pregnancy and Children (ALSPAC)	Baltimore Pediatric Eye Disease Study	Yaounde Cameroun	Sydney Paediatric Eye Disease Study	Mieroszów Eye Project	Vision Screening Eskişehir	Anyang Childhood Eye Study (ACES)
Prevalence of amblyopia		(3)	(16)	(17)	(18)	(20)	(19)	(23)	(22)	(21)
No. of participants	3227	3647	4730	2029	1.8 (white Americans) 0.8 (African-Americans) 673 (white Americans) 873 (African-Americans)	314	1422	591	709	2893
Age of participants	35 to 44 years	≥49	40 to 95 (mean 59)	≤37 months	30 to 71 months	5 to 15 years (mean 10.5 years)	30 to 72 months	2 months to 12 years	7 to 8 years	Elementary school age (mean 7.1 years)
Year of publication	2015	1998	2000	2001	2009	2011	2012	2012	2013	2014
Country	Germany	Australia	Australia	U.K.	USA	Cameroon	Australia	Poland	Turkey	China

BOX

Definitions of amblyopia used in the Gutenberg Health Study

Unilateral amblyopia

- Best corrected vision in worse eye ≤ 0.63 with a two-line difference* or ≤ 0.5 without such a difference and
- Strabismus or history of strabismus and/or Anisometropia ≥ 1.0 dpt (spherical, cylindrical, affecting the weaker eye) and/or Deprivation or history of deprivation and
- No other ophthalmological abnormalities that explain limited vision

Bilateral amblyopia

- Best corrected vision ≤ 0.63 in both eyes and
- Binocular hyperopia ≥ 4.0 dpt and/or Bilateral astigmatism ≥ 2.0 dpt and/or Bilateral myopia ≥ 6.0 dpt and/or Bilateral deprivation and
- No other ophthalmological abnormalities that explain limited vision

*Two-line difference: difference between the visual acuity of the two eyes of at least two lines of vision

Written informed consent was obtained from all study participants. GHS complies with Good Clinical Practice (GCP), Good Epidemiological Practice (GEP), and the ethical principles of the Declaration of Helsinki. It has been approved by the ethics committee of the Rhineland-Palatinate State Medical Association. It complies with the German Federal Data Protection Act.

The main aims of the ophthalmological section of the GHS are to establish the prevalence and incidence of common ophthalmological diseases, their risk factors, and their genetic bases and to investigate the interdisciplinary settings in which they arise.

Study cohort

Data on one subcohort (youngest age group, aged 35 to 44 years) was evaluated in order to calculate the prevalence of amblyopia.

Definition of amblyopia

There is no generally recognized vision criterion that defines amblyopia. Various boundary values for vision were used in this evaluation to enable comparison with other studies. Details and further criteria used to define amblyopia are listed in the *Box*. "Late relative amblyopia" was taken to be amblyopia in which an organic defect (e.g. traumatic cataract) that had developed in early childhood led to amblyopia.

Ophthalmological examination

All GHS participants were thoroughly examined by an ophthalmologist. Examination included eye position and motility.

Visual acuity and refraction were determined using the Humphrey HARK 599 Autorefractometer Keratometer (Carl Zeiss Meditec AG). This device measures single-optotype visual acuity. Intraocular pressure and central corneal thickness were measured, and retinal images were taken. Static retinal vessel analysis and visual field examinations were performed, and lacrimal fluid was sampled.

Statistics

95% confidence intervals were determined for all amblyopia prevalences. As only the cohort aged 35 to 44 years was used, the sample was not weighted to match the composition of the population of Rhineland-Palatinate or the Federal Republic of Germany.

Results

Of the 15 010 GHS participants, there were 3286 in the youngest age group, of which 3227 (98.2%) underwent ophthalmological examination. Of these, 1671 (51.8%) were women and 1556 were men. 1786 lived in the city of Mainz and 1441 in the Mainz-Bingen area.

Amblyopia was diagnosed in 182 participants on the basis of the vision criterion of 0.63 or less. The prevalence of amblyopia was thus 5.6% (95% confidence interval [95% CI]: 4.9 to 6.5). Female participants accounted for 53.2% of those with amblyopia. 73 participants with amblyopia were aged between 35 and 39 years, 109 between 40 and 44 years. Vision in the amblyopic eye lay between the ability to detect hand movements (vision 0.01) and 0.63, with a median of 0.4. Visual acuity in the amblyopic eye was no better than 0.3 in 49 participants (26.9%). The right eye was affected in 53% of amblyopic individuals and the left eye in 47% (*Table 2*).

Using the two-line difference (difference between the vision of the two eyes at least two lines) as a criterion, the prevalence of amblyopia was 5.0% (95% CI: 4.2 to 5.8). Using the vision criterion of 0.5 or less, there were 120 affected participants, or 3.7% (95% CI: 3.1 to 4.4); the same figure, 3.7% (95% CI: 3.1 to 4.4), was found using the two-line difference as an additional criterion. In almost half of amblyopic participants (48%) anisometropia was the sole cause of amblyopia; in around two-fifths (41%) strabismus caused amblyopia. Details are shown in the *Figure*. Three of

the amblyopic participants had late relative amblyopia. This was caused by a traumatic cataract before school age. Bilateral amblyopia was present in twelve participants. In one case this was caused by bilateral congenital cataract; all other participants had high-grade ametropia.

Discussion

In this study, we present the first population-based figures on the prevalence and causes of amblyopia. Because the GHS is population-based and involves a large cohort, we consider these figures to be a suitable basis for extrapolation to Germany.

Unlike studies conducted in other countries, this research investigated only individuals aged between 35 and 44 years. The incidence and prevalence of eye diseases that affect visual acuity, such as age-related macular degeneration, cataracts, and glaucoma, increase with age—some of these diseases are in fact age-related. If someone suffers from such a disease, it is no longer possible to determine with certainty whether reduced visual acuity is caused by one of these eye diseases or whether the individual may also be suffering from amblyopia. As a result, an absence of abnormal organic findings affecting vision is usually used as a defining criterion of amblyopia in studies on its prevalence. However, this means that the prevalence of amblyopia is underestimated, depending on the age of the investigated cohort. However, in this cohort the prevalence of amblyopia in older participants (aged 40 to 44 years) was higher than in younger participants (aged 35 to 39 years). We attribute this to occlusion therapy, which became established in Germany from the 1960s onwards and which is likely to have been performed in more younger participants than older ones.

When the vision criterion 0.63 was used, the prevalence of amblyopia found was 5.6%. In fact, in both large Australian studies that also calculated the prevalence of amblyopia in adult cohorts, the figure was substantially lower when a criterion of 0.63 or less was used: Attebo et al. (3) found a prevalence of 3.2% among 3654 participants (participant age ≥ 49 years), while Brown et al. (16) found an even lower prevalence of 3.09% among participants aged over 40 years with a mean age of 59 years. The latter working group investigated the prevalence of amblyopia in 4744 participants divided into seven ten-year age groups. Although no correlation was found between age and prevalence of amblyopia, participant numbers varied greatly between age groups, and the group aged over 70 years was small.

With a vision criterion of 0.5, this research found a 3.7% prevalence of amblyopia. Polling et al. used a vision criterion of 0.5 and found a somewhat lower prevalence of amblyopia, 3.1%, in their study of 420 children aged up to 12 years. A possible reason for this may be that examination is more difficult in very small children and preschool children, in whom it is not always possible to interpret findings reliably and therefore to diagnose amblyopia.

TABLE 2

Details of distribution of vision in the investigated cohort

Vision criterion 0.63									
Age group	Total	No. of amblyopic participants	Prevalence	Female	Male	Blind (vision ≤ 0.02)	High-grade visual impairment (vision >0.02 but ≤ 0.05)	Visual impairment (vision >0.05 but ≤ 0.3)	Vision >0.3
35 to 39 years	1472	n = 73	5.0% ^{*1}	36	37	1	3	10	59
40 to 44 years	1755	n = 109	6.2% ^{*2}	61	48	0	5	30	74
Total	3227	n = 182	5.6% ^{*3}	97	85	1	8	40	133
		Percentage		53.3%	46.7%	0.5%	4.4%	22.0%	73.1%
Vision criterion 0.5									
Age group	Total	No. of amblyopic participants	Prevalence	Female	Male	Blind (vision ≤ 0.02)	High-grade visual impairment (vision >0.02 but ≤ 0.05)	Visual impairment (vision >0.05 but ≤ 0.3)	Vision >0.3
35 to 39 years	1472	n = 45	3.1% ^{*4}	20	25	1	3	10	31
40 to 44 years	1755	n = 75	4.3% ^{*5}	38	37	0	5	30	40
Total	3227	n = 120	3.7% ^{*6}	58	62	1	8	40	71
		Percentage		48.3%	51.7%	0.8%	6.7%	33.3%	59.2%

*1 95% confidence interval (95% CI): 3.9 to 6.0; *2 95% CI: 5.1 to 7.4; *3 95% CI: 4.9 to 6.5; *4 95% CI: 2.2 to 4.0; *5 95% CI: 3.7 to 5.0; *6 95% CI: 3.3 to 5.2

Causes of amblyopia, vision criterion 0.63. 95% CI: 95% confidence interval

In addition to bias resulting from different study designs, genetic factors may be another reason for the different prevalences of amblyopia in different countries. This is because there is also a confirmed hereditary influence for strabismus and refractive errors, which often cause amblyopia (29, 30). In fact, there was a lower prevalence of amblyopia (0.8%) among African-American preschool children than among white American or Asian children (both 1.8%) (18, 31).

The most common cause of amblyopia in this study was anisometropia (different ametropia in each eye), accounting for a relative proportion of 48%. The prevalence of amblyopia caused by anisometropia is therefore approximately 2.5%. In other studies, too, anisometropia is the most common cause of amblyopia and, as in this study, responsible for approximately half of amblyopia cases (3, 16, 23). It is precisely this most common form of amblyopia that is often overlooked, as unlike strabismus pure anisometropia is not usually noticeable to those around the child concerned.

Strabismus was found to be the cause of amblyopia in 23% of cases, and strabismus combined with anisometropia in 18%. This means that strabismus was the cause of amblyopia, either in whole or in part, in 41% of cases. Attebo et al. (3) report similar findings, with 46% of their amblyopic study participants having strabismus. In contrast, the frequency of strabismus in the other large Australian study, by Brown et al. (16), was only 4.7%. Brown et al. themselves indicate that some cases of strabismus may have gone undetected.

Unilateral amblyopia, which for many affected individuals initially causes almost no limitation, can later have major consequences if vision in the other eye is also lost, e.g. as a result of injury or age-related diseases later in life. For those affected, this can lead to occupational invalidity and a loss of the abilities to read and drive. It is, in fact, known from various studies that for individuals with amblyopia the risk of loss of vision in the healthy eye is at least two to almost three times as high as in those without amblyopia (14, 15). Accidents are a common cause of this.

There is no obligation in Germany for statutory health insurers to cover ophthalmological check-ups in children. In 2008 the Institute for Quality and Efficiency in Health Care (IQWiG, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen) found no evidence or indication of a benefit of such preschool screening in a preliminary report assessing the benefit of screening for vision disorders in children before the age of six; this report was much discussed and debated by both ophthalmologists and pediatricians (32). In contrast, there are reports from Sweden, where multiple eye examinations are performed before the age of three: at 1.7%, the prevalence of amblyopia in 10-year-olds is substantially lower in Sweden than in Germany (33). In Germany the U7a (age 34 to 36 months) vision test by pediatricians or primary care physicians was introduced in 2008; there is currently no routine vision screening by ophthalmologists for all children in Germany. For many forms of amblyopia, such as amblyopia

KEY MESSAGES

- The Gutenberg Health Study is a large, population-based cohort study conducted at Mainz University Medical Center. It includes 15 010 participants.
- Amblyopia is a major cause of lifelong reduced visual acuity.
- Amblyopia can only be treated successfully in childhood.
- The prevalence of amblyopia in the investigated cohort was 5.6%, substantially higher than previously believed.
- The most common cause of amblyopia is abnormal anisometropia (a difference between the refractive error of the two eyes). Unlike strabismus, this usually remains unnoticed for a long time.

pia resulting from unilateral or bilateral cataract, treatment that does not begin until the age of nearly three years is much too late to achieve beneficial visual acuity.

Limitations

The limitations of this study are that the visual acuity test was performed not “correctly” at a distance of 5 m following manual subjective refraction but using an autorefractometer. In addition, no information was provided on visual reading ability or ability to perform a visual line test. For these examinations of vision, optotypes are close together and are harder to identify, especially for individuals with amblyopia; single-optotype vision (optotypes far apart) is more successful. It is therefore possible that some cases of amblyopia were overlooked in this study. However, both large Australian studies (3, 16) also used single optotypes to measure visual acuity.

Understandably in view of the cohort size of the GHS (15 010 participants) and the high number of examinations performed—not all of which were ophthalmological—less time-consuming examination methods were selected. Even an estimate of only one minute for examination of refraction and vision results in 15 010 minutes, or more than 10 whole days, for examination of the entire GHS cohort. However, it is important not to overestimate the prevalence of amblyopia. All study participants whose measured visual acuity led to suspicion of amblyopia but in whom no amblyogenic factor could be identified with certainty were recorded as nonamblyopic. This was also the case for participants who had been treated for amblyopia in childhood and whose vision was above 0.63. The actual prevalence of amblyopia may therefore be higher than found in this study.

Summary

This data provides the first estimate of the prevalence of amblyopia in Germany. Amblyopia prevalence is substantially higher than in comparable studies conducted in other countries. This data is important not only for ophthalmologists but also for pediatricians and primary care physicians who must detect amblyopia during pediatric screening. It would be worthwhile to

determine whether enough cases of amblyopia are detected and treated within the national pediatric screening program, as early treatment for amblyopia has been shown to be effective (13, 34).

Conflict of interest statement

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The other authors declare that no conflict of interest exists.

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