Abstract

Objective: The next generation of artificial vision devices (AVDs), currently developed in pre-clinical settings, has the potential to revolutionize the lives of盲 and patients with retinitis pigmentosa (RP) in a manner that they will finally be categorized as visually impaired but no longer as blind. This unprecedented vision improvement will result in a mentionable quality of life gain which poses the question at which costs the next generation AVDs are to be categorized as visual impaired but no longer as blind. This unprecedented vision improvement will result in a mentionable quality of life gain which poses the question at which costs the next generation AVDs are to be categorized as visual impaired but no longer as blind. This unprecedented vision improvement will result in a mentionable quality of life gain which poses the question at which costs the next generation AVDs are to be categorized as visual impaired but no longer as blind. This unprecedented vision improvement will result in a mentionable quality of life gain which poses the question at which costs the next generation AVDs are to be categorized as visual impaired but no longer as blind. This unprecedented vision improvement will result in a mentionable quality of life gain which poses the question at which costs the next generation AVDs are to be categorized as visual impaired but no longer as blind.

Introduction

• After almost half a century of research activities artificial vision systems are moving in the clinical practice. These devices are designed to provide prosthetic vision to the blind by stimulating localized neural populations in one of the retinotopically organized structures of the visual pathways—typically the retina or visual cortex [1].
• According to the World Health Organisation (WHO) blindness affects almost 45 million people worldwide (>300,000 in Germany). The prevalence consistently increases along with population aging [2].
• Retinitis pigmentosa (RP) accounts for ≈4 million patients worldwide [4] and for ≈20,000 patients in Germany [5]. In RP photoreceptor degeneration leads to a progressive reduction of the visual field often declining to legal blindness, in these patients prosthetic vision is so far the only effective treatment strategy [4].

Material and Methods

• A Markov model with yearly cycles consisting of the three health states Blind’, Visual Impaired’ and Death’ was developed in Excel 2010 in order to simulate and to compare the costs and effects of next generation AVDs versus best supportive care.
• As the development of these next generation AVDs is currently in a pre-clinical stage, the actual treatment effect is not yet predictable. Therefore there are five different treatment outcomes: Blind, Visual Impaired, Death, a high-unreliable scenario where personal data were applied in order to simulate the health states‘ utility.
• As the costs for the next generation AVDs are not yet determined (released) different costing scenarios were analyzed (using the cost of the first generation AVDs as estimation basis): the first year cost were set at €35,000, €70,000, €85,000 (mean-case basis), €70,000 and €85,000 whereas the annual follow-up costs were kept constant at €1,000.
• The effect (utility) estimates are based on published health related quality-of-life estimates. According to a recent NOC report the health utility is 0.51 in legally blind (based on 5 publications), and 0.77 for Visual Impaired (based on 8 publications); a health utility of zero was applied for the state ‘Death’.
• Costs were derived from published sources according to German health economic recommendations (Institute for Quality and Efficiency in Healthcare – IQWIG - 2009 [5]).
• Probabilistic sensitivity analyses and deterministic sensitivity analyses were performed in order to investigate the robustness of results.

Results

• The results are provided as incremental cost effectiveness ratio (ICER) that is expressed as the cost per quality-adjusted life year (QALY) gained comparing next generation AVDs versus BSC from a German healthcare payer perspective.

Discussion / Interpretation of Results

• In Germany there is no official WTP threshold set and the Cost-Effectiveness Analysis (CEA) is typically performed by the Federal Ministry of Health. The indications for using CEA in Germany are based on the results of the German consulting company AHEAD, which conducted an analysis for the CEAs of various treatments (e.g. for ARMD therapies and considering the high unmet medical need in blind RP patients) which resulted in costs per QALY gained ranging from €13,505 (4 injections per year) to €87,592 (12 injections per year) as applied in the underlying phase III trials [11].
• However it is currently not clearly predictable which WTP thresholds German authorities might apply for AVDs in RP. However considering these CE ratios for ARMD therapies and considering the high unmet medical need in blind RP patients (there is currently no effective therapy) it is likely that a cost-per-QALY gained threshold of up to €80,000 (50% and the first year AVD costs of €55,000)

Conclusions

• In conclusion the presented early cost-effectiveness evaluation has obtained that next generation AVDs have the potential to be a cost-effective therapy option in patients with RP in Germany.

References