

Mirvetuximab Soravtansine and its Treatment-Associated Ocular Adverse Effects. A Review of the Current Knowledge

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SUMMARY

Mirvetuximab soravtansine is an antibody–drug conjugate targeting folate receptor alpha (FRα), which is used in the treatment of platinum-resistant ovarian cancer. Its administration is associated with a distinct spectrum of ocular adverse events, representing a clinically relevant limitation of therapy. The most common manifestations include keratopathy, blurred vision, and dry eye symptoms. These effects are generally reversible and manageable upon appropriate ophthalmologic monitoring. This review summarizes the current knowledge regarding the mechanisms, clinical presentation, incidence, prevention, and management of mirvetuximab-associated ocular toxicity.

Key words: mirvetuximab soravtansine, ADC, keratopathy, ocular adverse events, cornea, ovarian cancer

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INTRODUCTION

Ovarian cancer is the eighth most common malignant disease in women worldwide, and at the same time ranks among the most common causes of death within the realm of gynecological tumors [1]. The disease predominantly affects women of more advanced age, the incidence and mortality rate increasing markedly with age and reaching its climax in the post-menopausal period [1,2].

Antibody–drug conjugates (ADC) represent a targeted therapeutic strategy combining the specificity of a monoclonal antibody with the cytotoxic effect of the conjugated pharmaceutical [3]. The monoclonal antibody recognizes the specific antigen on the tumor cell (e.g. folate receptor alpha), binds to the tumor cell, and the complex subsequently enters the cell by means of receptor-mediated endocytosis. A release of the cytotoxic substance takes place within the intracellular environment, which leads to the destruction of the tumor cell [3,4]. The advantage of this procedure is the targeted delivery of the cytotoxic substance combined with relative sparing of the healthy tissues, and this method

of treatment therefore represents a significant advance in targeted oncological therapy [4].

Mirvetuximab soravtansine (Elahere; AbbVie Inc., North Chicago, IL, USA) is the first representative of this group targeted at the folate receptor alpha, which is excessively expressed in a segment of patients with ovarian cancer [5]. This receptor enables selective delivery of the cytotoxic component to the tumor cells, thereby increasing the effectiveness of treatment while maintaining a relatively favorable systemic safety profile [6].

Mirvetuximab soravtansine (MIRV) is generally well tolerated, most of the adverse effects being of a low grade and of a reversible character. The most common adverse effects (Table 1) are ocular complications, in particular blurred vision (approx. 40–43%), keratopathy (29–33%), and dry eye syndrome (27–29%) [7–9]. Ocular adverse events are manifested in approximately 50–60% of patients, while severe ($\geq$ grade 3) adverse effects are relatively rare (approx. 6–11 %) [7,8]. Of non-ocular adverse events, the most common are gastrointestinal complaints, especially nausea (27–41%) and diarrhea (25–39%), also fatigue (35%), peripheral neuropathy (approx. 22%), and hematological abnormali-

ties including anemia (10%) and neutropenia (11%) [8–10]. Overall the treatment has a more favorable systemic safety profile in comparison with conventional chemotherapy; nevertheless specific ocular adverse events constitute a limiting factor of the therapy, and upon the occurrence of ocular adverse events of $\geq$ grade 2 regular ophthalmological monitoring is required [7,8].

The aim of this study is to present an overview of the current knowledge regarding the ocular adverse effects of mirvetuximab soravtansine, focusing on their pathophysiology, clinical picture, incidence, and the possibilities for prevention and treatment.

MATERIAL AND METHOD

This study is a review article founded upon an analysis of the available publications focusing on the safety profile of mirvetuximab, in particular on its ocular toxicity. The source of the data was clinical studies, review articles and the available post-marketing observations.

The literature was accessed in the PubMed database (pubmed.ncbi.nlm.nih.gov) with the aid of the key words “mirvetuximab” in combination with “ocular” or “eye”, without time or language limitations.

RESULTS

Analysis of published studies

As of 1 April 2026 a total of 39 studies corresponding to the entered key words were accessible in the PubMed database. The largest proportion of publications comprised review articles (n = 18; 46.2%), followed by case reports and series of cases (n = 8; 20.5%), then retrospective cohort studies (n = 5; 12.8%). Prospective clinical trials were represented less frequently (n = 3; 7.7%), while other types of studies constituted a smaller part of the cohort (n = 5; 12.8%), specifically

Table 1. The most common adverse reactions of mirvetuximab soravtansin

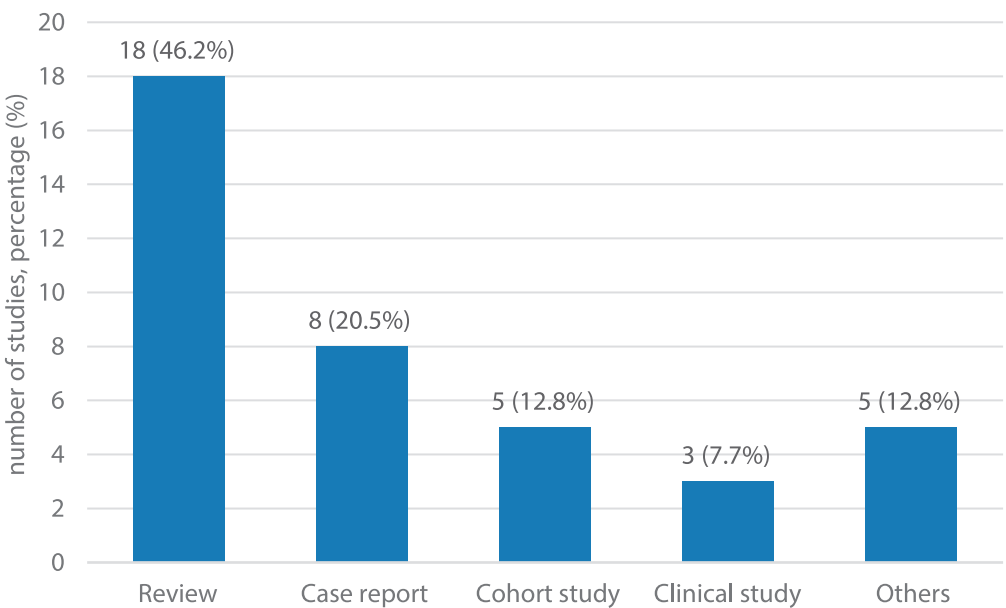
Adverse Reaction	Incidence (%)	Severe ($\geq$ G3) (%)
Blurred vision	40–43	6–8
Keratopathy	29–33	9
Dry Eye	27–29	2–4
Nausea	27–41	$\leq$ 2
Diarrhea	25–39	$\leq$ 1
Fatigue	$\sim$ 35	$\sim$ 5
Peripheral neuropaty	$\sim$ 22	2–4
Anemia	$\sim$ 10	—
Neutropenia	$\sim$ 11	$\sim$ 6

Note: G3 – serious adverse reactions according to the CTCAE (Common Terminology Criteria for Adverse Events) classification

a pharmacovigilance study (Mao et al., 2024) [11], a preclinical experimental study on an animal model (Zhang et al., 2025) [12], a study evaluating the precision of large language models (Marshall et al., 2024) [13], a regulatory summary of approval of a pharmaceutical (Dilawari et al., 2023) [10] and a brief communication (Aschenbrenner, 2023) [14], Graph 1.

Pathophysiology of ocular manifestations in treatment with MIRV

The pathophysiology of the ocular adverse effects of mirvetuximab soravtansine is not yet entirely clarified; nevertheless the non-specific uptake of the conjugate into the cells of the corneal epithelium independently of expression of the folate receptor alpha is considered to be a key mechanism [3,7]. Uptake into the cells is followed by a release of the cytotoxic component DM4, which inhibits the polymerization of microtubules, impairs the cellular cycle and



Graph 1. Representation of individual types of studies

leads to apoptosis of the epithelial cells [15]. This process is clinically manifested in microcystic changes of the corneal epithelium and disorders of vision [7,15]. With reference to the minimal expression of the target antigen in the corneal epithelium, these adverse effects are considered to be a mechanism independent of the target antigen, probably associated with the non-specific uptake of the pharmaceutical by the cells and subsequent intracellular release of the cytotoxic component [3,7]. Similar ocular adverse events have also been described in the case of other antibody–drug conjugates containing microtubular inhibitors, which suggests a common pathophysiological mechanism associated with the used cytotoxic component [3]. In most cases, ocular adverse effects are reversible and depend primarily on the cumulative dose and length of exposure [15].

Clinical picture of ocular affliction

The clinical picture is dominated by affliction of the anterior segment of the eye, primarily the cornea. Patients most frequently state blurred vision, a feeling of a foreign body in the eye, dry eyes and photophobia. In ophthalmological examination it is possible to observe punctate defects of the epithelium, microdeposits in the corneal epithelium and reduction of visual acuity.

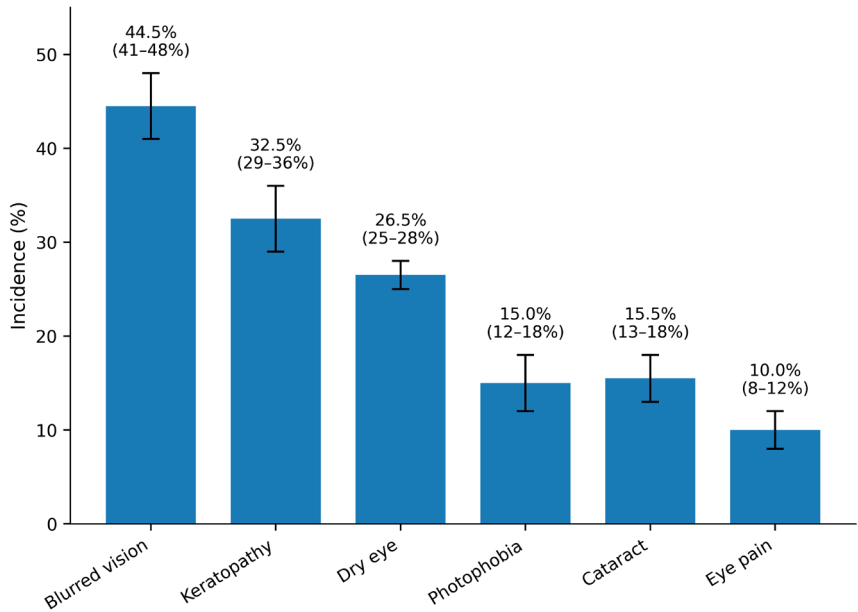
Besides corneal complications, other, less common ocular adverse events have also been described in patients treated with MIRV. These included in particular inflammatory manifestations such as mild anterior uveitis, as well as conjunctivitis, blepharitis, and episodes of chemosis [7,15,16]. As a rule, these manifestations are of a lower grade and of a transitory character, and respond well to local therapy, including corticosteroids and lubricant preparations [16]. By contrast with corneal toxicity,

these complications are not so common and their pathophysiology is not entirely clarified, though it probably concerns a combination of a non-specific toxic effect and local inflammatory reaction [7,15]. Timely diagnosis and adequate treatment of these conditions is important in order to avoid the suspension of oncological therapy.

The overall incidence of ocular adverse events in treatment with MIRV reaches approximately 50–56% of all treated patients [7,8]. The most common manifestations are blurred vision (41%), keratopathy (32%), and dry eye symptoms (27%), as has been described in the MIRASOL study [8]. Less common adverse effects are photophobia (12–18%), cataract (13–18%) and eye pain (8–12%) [7,8,15]. Severe complications of a higher grade are relatively rare (usually < 10%) [8]. Complaints typically appear during the first 4–8 weeks of treatment, and have a tendency to regress upon adjustment of the dose or temporary suspension of therapy [7,8]. The values of adverse effects presented in Table 1 are based on the MIRASOL study, which represents a crucial randomized trial evaluating the safety of MIRV [8]. For the purpose of graphic illustration, a synthesis of the available published data was conducted (including the SORAYA studies and other analyses [8,9,17], in which the minimum and maximum values of the incidence of individual adverse effects were determined. The columns present the mean values of incidence and the error segments illustrate the range between the studies (Graph 2).

Ocular monitoring

An ophthalmological examination is recommended before commencing treatment, and subsequently in the case of ocular adverse events of grade 2 or higher, regularly at least every other cycle of therapy (at an approximate interval of



Graph 2. The most common ocular adverse reactions of MIRV. The columns represent the average incidence of individual adverse reactions, the error bars show the range of values across clinical studies. The data are based on published studies evaluating the safety of treatment, including the SORAYA and MIRASOL studies
MIRV – mirvetuximab soravtansin

six weeks), with more frequent monitoring of symptomatic patients, especially in the first months of treatment [7,8]. The ophthalmological monitoring should include examination of visual acuity and biomicroscopic examination of the anterior segment, focusing on the corneal epithelium and conjunctiva, which may be supplemented with the use of fluorescein staining in order to detect epithelial defects and evaluate the patient's subjective complaints. According to the clinical finding, it is also possible to supplement an examination of the lacrimal film or other specialized methods [7,15].

Management of ocular complications

The management of ocular complications in treatment with MIRV requires a multidisciplinary approach and close cooperation between the oncologist and ophthalmologist [7,15]. The foundation is a preventive regimen, incorporating the regular use of lubricating eye drops without preservative agents, education of the patient, and an ophthalmological examination before the commencement of treatment, followed by monitoring at regular intervals in the case of ocular adverse events of grade 2 or higher [7]. In the case of development of confluent keratopathy or severe visual complaints, an adjustment of the dose, deferral of the next cycle, or temporary suspension of treatment is indicated, depending on the severity of the complaints [7,8]. Local therapy covers above all intensive lubrication, in indicated cases short-term administration of topical corticosteroids, and symptomatic treatment of other manifestations such as dry eye syndrome or inflammatory complications [8,15]. For patients with a persistent defect of the corneal epithelium or more severe form of keratopathy, it is possible also to consider more advanced therapeutic procedures, including the application of an amniotic membrane, which supports healing of the epithelium and regeneration of the ocular surface [18]. The majority of ocular adverse effects are reversible, and upon adequate management do not necessitate the definitive termination of oncological treatment [7,8].

DISCUSSION

Ocular adverse effects of treatment with MIRV represent a specific group of complications which is characteristic of antibody–drug conjugates containing a microtubular cytotoxic component [3,7]. By contrast with classic chemotherapy, this constitutes a relatively well defined profile of adverse effects, the dominant manifestation of which is affliction of the corneal epithelium. Current knowledge indicates that this is a mechanism independent of the target antigen, probably associated with non-specific uptake of the pharmaceutical by cells and intracellular release of the cytotoxic component [3,15]. Similar manifestations have also been described in the case of other ADCs, which supports the hypothesis of a common pathophysiological mechanism linked to the properties of the used cytotoxic component [3,7].

From a clinical perspective, it is of fundamental significance that despite the relatively high incidence of ocular adverse effects, in most cases their course is mild and reversible [7,8]. This fact is reflected also in the relatively

low degree of definitive termination of treatment due to toxicity. In the MIRASOL study, termination of treatment as a consequence of adverse effects was recorded in approximately 9–11% of patients, in which the majority of these cases were associated rather with systemic adverse effects [8]. Ocular adverse effects led to a permanent termination of treatment only in a small proportion of patients (to the order of a few percent), nevertheless, they were relatively more often the reason for temporary suspension or deferral of treatment [7,8]. Adjustment of the dose or deferral of the next cycle due to ocular complications was necessary in approximately 20–30% of patients [7].

A crucial role is therefore played by regular ophthalmological examination, timely identification of changes of the corneal epithelium, and adjustment of dosage according to the severity of the complaints [8,15]. Another significant aspect is interdisciplinary cooperation between oncologists and ophthalmologists, which enables optimization of treatment while maintaining its effectiveness [15]. Patient education and the introduction of preventive measures, especially regular lubrication of the ocular surface, may contribute further to reducing the severity of these complications [15].

A limitation of the available data is its heterogeneity, which is due to the differences in the design of the studies, lack of uniformity of the definitions of ocular adverse effects, and the variability in the ophthalmological evaluation [7,8]. Furthermore, most of the data are taken from clinical studies primarily focusing on oncological results, which may influence the accuracy and detail of the ophthalmological findings. A further limitation is the lack of any long-term data that would enable an evaluation of the long-term impacts of treatment on visual functions.

In future it shall be important to focus on standardizing ophthalmological evaluation, identifying risk factors of the onset of toxicity and optimizing preventive and therapeutic procedures. With the increasing use of ADCs in oncology, it is possible to expect that the issue of ocular adverse effects shall become increasingly significant and will require a systematic and interdisciplinary approach [3,7].

CONCLUSION

The ocular adverse effects of treatment with mirvetuximab soravtansine represent a common but mostly reversible complication of therapy, which are characterized primarily by affliction of the corneal epithelium. Despite their relatively high incidence, as a rule these complaints have a mild course, and to date no case is known where they have led to permanent damage to sight or the need to definitively terminate treatment. A key factor in successful management is timely diagnosis, as well as regular ophthalmological monitoring and adequate adjustment of oncological therapy. Interdisciplinary cooperation and thorough patient education also play a significant role. With the increasing use of antibody–drug conjugates in oncology it is possible to expect that the issue of ocular adverse effects shall become increasingly significant, therefore systematic observation and further research in this field is essential.

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